Collaborative Drug Therapy Agreement: Ambulatory Clinic Pharmacists

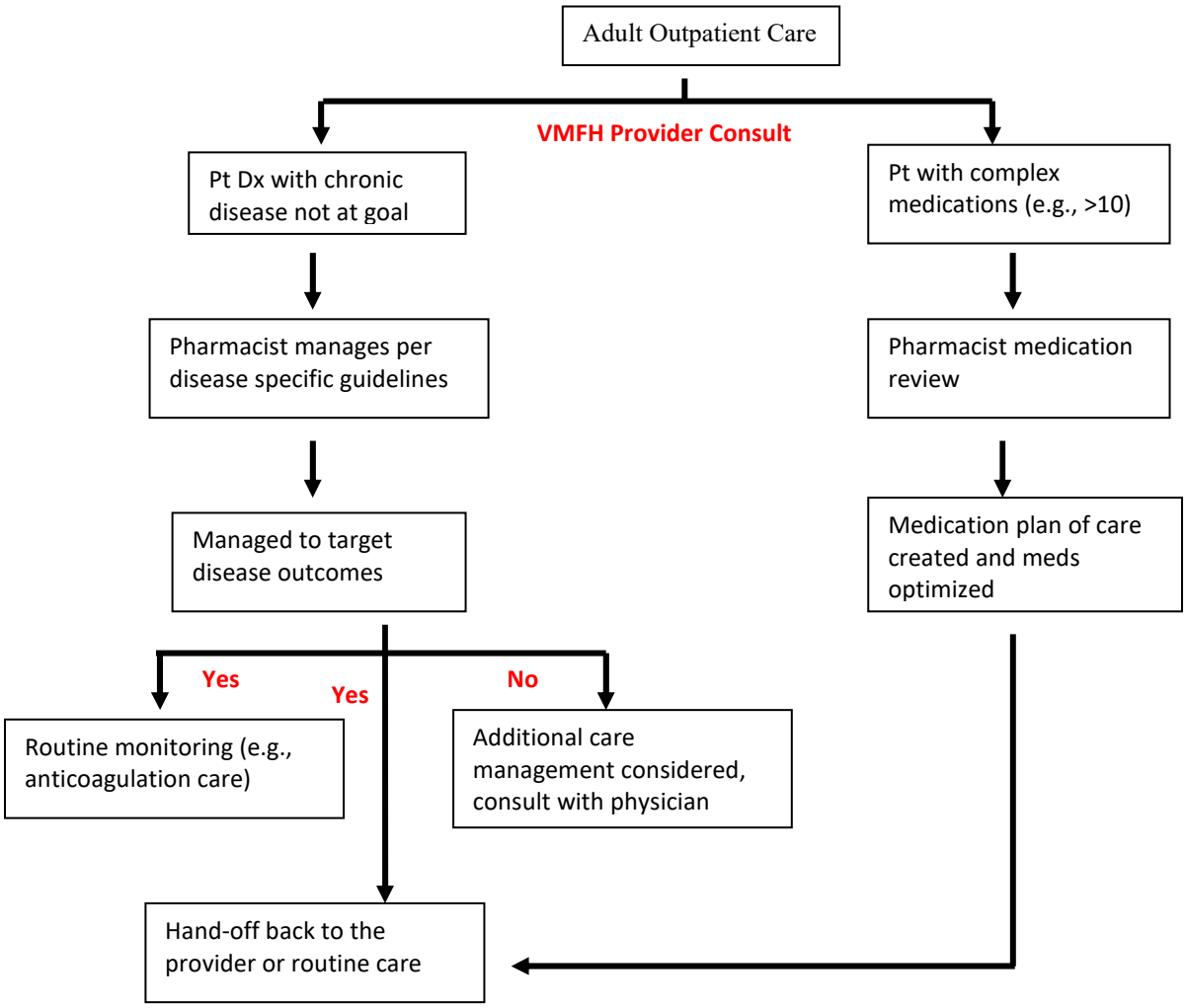
Issued: ***April 2023***	**Review date:** ***April 2025***
Title	Collaborative Drug Therapy Agreement- Ambulatory Clinic Pharmacists
Rationale	Provide medication management services to patients within Virginia Mason Franciscan Health (VMFH). These services include, but are not limited to: • Comprehensive medication review to identify opportunities to optimize, initiate, discontinue, and modify prescribed therapy (e.g. drug, frequency, dose), ordering laboratory tests and other activities required to manage medication use. • Provide disease specific drug therapy management for established VMFH patients that are referred to the pharmacist to achieve therapeutic endpoints (e.g., anemia, anticoagulation, diabetes, hypertension) and other diseases based on VMFH approved pathways or established best practice guidelines • Assess, and identify previously undocumented disease based on objective criteria set forth by guidelines that can be determined solely by laboratory and clinical criteria (e.g., elevated HbA1c, elevated blood pressure, BMI, etc.) Physical exam is limited to assessments within pharmacist's scope of training.
Organization	Virginia Mason Franciscan Health, Pharmacy Department
Patient Criteria for Inclusion - Scope	• Patient selection for medication management services is based on identified need from a consulting provider (refer to algorithm for example - Appendix A) or by screening processes used to identify existing care gaps and opportunities to improve patient health outcomes. • Referrals may originate from any physician/advanced practitioner at VMFH or a pharmacist/care manager nurse/flow manager with documented written approval from the responsible provider.
Authorized Persons	Credentialed and privileged clinic pharmacists practicing under a Virginia Mason Franciscan Health approved collaborative therapy agreement

Responsibilities	**The pharmacist provider is responsible for the following:** • Ensure the patient has appropriately documented reason for referral from consulting provider with clear goals for medication review and/or clinical objective(s). • Perform appropriate clinical evaluations to monitor treatment (e.g., limited physical assessment). • Order appropriate follow-up clinical and laboratory testing. • Complete medication review and develops care plan • Prescribe, discontinue and/or adjust medications according to established VMFH guidelines, national best practice guidelines or the manufacturer FDA approved recommendations. • Arrange for appropriate follow-up • Refer patients back to referring provider or other health care professional (nutritionist, RN care manager, etc.) as indicated by severity of condition and/or scope of practice. • Document the complete care plan in the electronic medical record for provider review **The referring physician is responsible for the following:** • Document referral to pharmacist provider in the electronic medical record. • Reason for consult (e.g., medication profile review, lipid therapy management) will be included along with the desired outcome when applicable (e.g., blood pressure goal < 140/90). • Be available for consultation with the pharmacist when an issue beyond the scope of the agreement arises or when the presence of critical lab values or vitals suggests further evaluation and/or intervention. • The consulting department will coordinate with pharmacy leadership to review and revise internal best practice standards and guidelines to incorporate new evidence-based practices as available.
Training	• Upon hiring, a pharmacist will be added to the CDTA. Initial training is completed side-by-side a current credentialed and privileged provider authorized to use this agreement. • Initial supervision will include review of the standard visit practices and review of the trainee's clinical documentation. • All pharmacists must complete training and be credentialed and privileged as providers before they can see patients as part of this agreement. Provisional status to practice under the direct supervision of an approved pharmacist is permitted (e.g., residents). • Departmental skills map will be updated after pharmacist provider has completed training and has been privileged to provide care • Upon termination of employment, all privileges associated with the Virginia Mason CDTA will be discontinued immediately.
Quality Assurance	Ongoing quality assurance includes, but is not limited to: • Annual pharmacist peer reviews: one by pharmacist peer and one by non-pharmacist provider peer. • Just in time training and peer-to-peer feedback. • Annual review of clinical quality metrics as determined with the organization leadership (e.g., time in therapeutic range, achievement of department quality goals). The consulting departments will coordinate with pharmacy leadership to review and revise internal best practice guidelines to incorporate new evidence-based practices as available.

Evidence Source	Add any applicable regulations here. E.g., This protocol is written in accordance with the laws (RCW 18.64.011) and regulations (WAC 246-863-100) of the State of Washington. This protocol is also aligned with the guidance document from the Washington State Pharmacy Quality Assurance Commission published in December 2018.		
Reviewed by	**Laura Hanson, Pharm D**	Date	*7/28/23*
Title	Ambulatory Pharmacy Manager		
Approved By	**Medical Executive Committee**	Date	**Reviewed May 2023**

APPENDIX A

Collaborative Drug Therapy Agreement: Consult Algorithm Example



Pharmacy Anticoagulation Service Protocol

Authorization for Use of Protocol
Pharmacists on staff at Peninsula Community Health Services (PCHS) are given prescriptive authority to manage anticoagulation therapy. Any physician, nurse practitioner, or physician assistant on staff who has prescribing privileges may elect this service. All established patients of the PCHS clinics with a diagnosis of thrombosis or those at risk of thrombosis are eligible for enrollment in the service. Pharmacy anticoagulation services will commence after the "Medication Management Agreement for Anticoagulation Therapy" has been reviewed and signed by the patient.

Training & Continuing Education
Pharmacists utilizing anticoagulation prescriptive authority protocol will complete a training program approved by the Director of Pharmacy Services and the P&T committee. Pharmacists will demonstrate competence with INR Point of Care machine technique annually. Proof of training will be maintained in the Pharmacist's credentialing file.

Clinical Guidelines
Guidelines for the prescribing of warfarin to provide anticoagulation are based on the most recent ACCP guidelines. The guidelines are not intended to replace clinical judgment and, at times, it will be necessary to deviate from the below/attached guidelines due to specific patient characteristics/scenarios.

Clinical Evaluation& Management
The anticoagulation target INR and goal range will be determined by the referring medical provider in collaboration with the clinical pharmacist using the current ACCP guidelines, unless otherwise specified. The duration of therapy will be determined by the referring provider and will generally follow the current ACCP guidelines unless otherwise specified by the physician.

The patient will be interviewed regarding the following items:

- Compliance with (and confirmation of) recommended dose
- Number of doses missed during the past 5-7 days
- Medications started or discontinued since last visit
- Over-the-counter medications started or discontinued since last visit
- Herbal products started or discontinued since last visit
- Diet changes since last visit
- Change in exercise routine
- Recent acute illnesses
- Recent use of alcohol
- Peripheral edema
- Recent bruising or bleeding problems
    - Minor bleeds (blood in urine, stool, bleeding gums, repeated nosebleeds, etc
        - The patient will be instructed to hold doses until bleeding resolves. Questionable cases will be referred to provider
    - Major bleeds
        - The patient will be referred to the provider for emergency management.

The pharmacist will be responsible for patient assessment, ordering and/or performing PT/INR testing with point-of-care coagulation monitor, ordering venous PT/INR from outside lab services, ordering CBC with differential, coordinating care with home health agencies, medication initiation/adjustment and documenting patient care through chart notes in the electronic medical record and scheduling patient follow-up appointments.

Dosage adjustments will follow the current ACCP guidelines.

Maintenance follow-ups will be patient-dependent using the following recommendations unless otherwise specified:

Recent Dosage Change:	Follow-up lab in 1-14 days
Dosage change less than 2 weeks ago:	Follow-up lab in 2-3 weeks
Dosage change more than 2 weeks ago:	Follow-up lab in 3-4 weeks
Unstable or unreliable patient:	Follow-up lab in 1-14 days

The onsite medical provider will be consulted immediately for any findings of concern, or in response to an elevated INR which requires an action to reverse the effects of warfarin.

Prior to an invasive medical procedure or dental procedure, the pharmacist will consult the physician/dentist performing the procedure and the referring provider to coordinate patient care and anticoagulation management using the current ACCP guidelines

All patients on warfarin will be managed at clinic sites unless they meet the criteria for home INR monitoring as set by PCHS P&T Committee

Home INR Monitoring:

- Patient selection
    - Must be on warfarin for greater than 3 months prior to consideration of home INR monitoring
    - Must be reliable with follow up and communication
    - Must have reasonably stable INR prior to home monitoring
- Pharmacist/provider will enroll patient in home INR monitoring if patient/pharmacist/provider feel it is a good fit
- Patient will test INR every 1-2 weeks
    - Test are uploaded to vendor's software and electronically into the EHR
        - If patient fails to adhere to testing schedule, may reconsider whether pt is a good candidate for home monitoring
        - Vendor will call results to pharmacist for INR levels below 1.4 or above 4.4
    - Pharmacist will follow up with patient by phone for interview, dose adjustment and follow up
- Telephone encounters will be documented in EHR similar to lab-drawn INRs.
- Patients will be seen in clinic for face to face follow up and education at least once every 3 months.

Documentation
The pharmacist will document all patient care interventions and prescribing activity in the electronic medical record per PCHS policy and standards of care, readily available for review by the referring provider. Any new prescriptions resulting from the pharmacist's clinical judgement will be issued in the pharmacist's name, as per WAC 246-863-100.

The following information will be documented by the pharmacist with each patient encounter:

- date of service
- target INR
- current warfarin dose
- relevant laboratory data including PT/INR, CBC with diff
- next clinic appointment
- oral or written communications with the patient
- any reported hemorrhagic or thrombotic events
- any changes in medication regimens or medical status
- any potentially significant dietary or activity changes

Patient education on initial visit will include the following:

- Drug interaction screening with patient's current drug regimen.
- Herb interaction screening with herbals the patient may be taking.
- Dietary considerations.
- Importance of maintaining anticoagulation.
- Signs of hypercoagulation.
- Importance of compliance and follow-up monitoring.
- Written information about herbal interactions, OTC interactions, dietary Vitamin K content, and warfarin information will be given to the patient.
- Importance of medical alert identification.

Follow up education will be conducted on subsequent visits as follows:

- The patient will be questioned about signs of bruising and/or bleeding.
- The patient will be offered repeat education to reinforce previous education.
- Questions will be answered regarding anticoagulation therapy.
- Importance of compliance and follow-up will be reinforced.
- Screening for new or discontinued drugs, OTC products, and herbal supplements

Quality Assurance
Pharmacy staff will periodically peer review anticoagulation management encounters as a quality assurance measure. Results will be reported to the Quality Director and the Quality Management Council.

Any adverse drug reactions or adverse outcomes associated with pharmacist medication management encounters will be recorded and reported to the P&T and/or the Peer Review Committee(s).

Time in therapeutic range will be calculated for all patients enrolled in the service and reported to the Quality Management Council, P&T and/or the Peer Review Committee(s) as requested.

Patient Recall

A weekly, automated report will be generated and sent to the pharmacy department listing the patients who cancelled or did not attend a scheduled appointment. The pharmacy department will conduct recalls for patients using the following procedure:

- Two calls will be made on 2 separate days to reschedule the patient
- If the patient cannot be contacted after the second phone call, a letter will be sent to the patient
- The above procedure will be performed weekly for two consecutive weeks
    - 4 total phone calls and 2 no show letters
    - During the phone call and letter attempts, the quantity of warfarin prescribed will be reduced
    - If the patient has not scheduled an appointment after the above procedure, a warning letter will be sent to the patient by the pharmacist (signed by PCHS Pharmacy Department)
    - Notification in the EHR will be made to the supervising provider
- After a warning letter has been sent to the patient, the patient will be scheduled to see a physician to discuss risks and benefits of anticoagulation therapy
    - If the patient does not attend the appointment scheduled with the physician, anticoagulation services will be discontinued and a letter of discharge will be sent to the patient
- If the patient does not make any contact to schedule a physician appointment within 2 weeks, anticoagulation services will be discontinued and a letter of discharge will be sent via certified mail to the patient and signed by the supervising physician.

Chief Medical Officer's signature: _____ Effective date:_____

References

1. Ansell J, Hirsh J, Hylek E, et al. Pharmacology and management of the vitamin K antagonists. CHEST. 2008;133:160-198S.
2. Douketis J, Berger P, Dunn A, et al. The perioperative management of antithrombotic therapy. CHEST. 2008;133:299-339S.
3. Horton JD, Bushwick BM. Warfarin therapy: evolving strategies in anticoagulation. Am Fam Physician. 1999;3:635-46.
4. Ebell MH. Evidence-based adjustment of warfarin (Coumadin®) doses. Am Fam Physician. 2005;71:1979-82.
5. Jack E. Ansell, Lynn B. Oertel, and Ann K. Wittkowsky. I Managing Oral Anticoagulation Therapy: Clinical and Operational Guidelines 2nd ed. St. Louis, MO: Wolter Kluwer Health, 2005

Virginia Mason Franciscan Health™

AUTHORIZATION STATEMENT FOR COLLABORATIVE THERAPY AGREEMENT FOR PHARMACY DOSING PROCEDURE

Authorization:

As a member of the Medical Staff of Virginia Mason Franciscan Health (VMFH) and a licensed healthcare provider authorized to prescribe legend and controlled substances in my practice, **I, David Carlson,** grant authority to **the authorized pharmacist listed below** employed by VMFH Pharmaceutical Services headquartered in Tacoma, Washington to dose medications managed by active VMFH physicians as specified in the **Pharmacy Dosing Procedure Policy.** This authority is in accordance with law (RCW 18.64.011) and regulation (WAC 246-945-350) of the State of Washington.

Organization:

Virginia Mason Franciscan Health, Department of Pharmacy, which includes Virginia Mason Medical Center in Seattle, WA; St Joseph Medical Center in Tacoma, WA; **St Francis Hospital in Federal Way, WA;** St Clare Hospital in Lakewood, WA; St. Anthony Hospital in Gig Harbor, WA**; St Elizabeth Hospital in Enumclaw, WA; St Anne Hospital in Burien, WA**: St Michael Medical Center in Silverdale, WA.

Authorized Activity:

To dose selected medications as specified in the accompanying policy and for patients treated at VMFH facilities. Specific formulary medications covered by this authority are referenced in the policy. Medications will be prescribed according to guidelines. Corresponding appropriate laboratory values will be ordered as needed to dose and monitor medications outlined in the policy. In exercising this authority, the authorized pharmacist is to use appropriate clinical judgment considering among other factors: usual dosing parameters of the medication ordered, patient age, sex, weight, height, allergy, renal and hepatic clearance, potential drug-drug interactions, and individual pharmacokinetics. Pharmacists will document all prescribing decisions in the patient's medical record. Pharmacists are responsible for maintaining appropriate communication with physicians and patients.

Scope of Authority:

CDTA is enacted for inpatients meeting policy, protocol and guideline criteria.

Training and Competency:

Authorized pharmacists may initiate, modify, and discontinue medications for inpatients.

This authority is enacted when an unmet patient need is identified. Examples include but are not limited to missing antidotes and /or supportive medications. This authority is enacted when a prescriber submits an order for a medication via a medication order or pharmacy consult. Pharmacists will adjust medications and order appropriate labs based on published medical literature, policies, protocols and guidance documents. Authorized pharmacists will provide ongoing medication management for patients whose orders were modified under hospital approved protocols including but not limited to below list. Pharmacy to dose and monitor medications with or without defined protocols; if there are any questions about the therapy, or the goals of therapy, the pharmacist will contact the providers.

VMFH

- Pharmacy Dosing Procedure Policy

VMMC

- Renal and Weight-Based Dosing
- Intravenous to Oral Conversion
- Parenteral Nutrition
- Therapeutic Interchange
- Crushed Medications Conversion

Legacy CHI

- Antiemetic Dosing Guidelines
- Nephrology and Renal Dose Adjustment Guidelines
- Pain Management Guidelines
- Pharmacokinetic Dosing Guideline (Renal / Obesity / Geriatric)
- Parenteral Nutrition (Adult) Guidelines
- Vancomycin Dosing Guidelines
- Warfarin Dosing Guidelines

Quality Assurance:

Ongoing training and competency assessment involves periodic review and assessment of protocol compliance. This agreement shall be in effect for a period of two years from the date of approval unless rescinded by the Pharmacy Quality Assurance Commission or authorizing parties.

Signatures:

AUTHORIZED PHARMACIST NAME	CREDENTIAL	LICENSE NUMBER	DATE

AUTHORIZING PRESCRIBER NAME	CREDENTIAL	LICENSE NUMBER	DATE
David Carlson, DO	Doctor of Osteopathy	OP60758010	

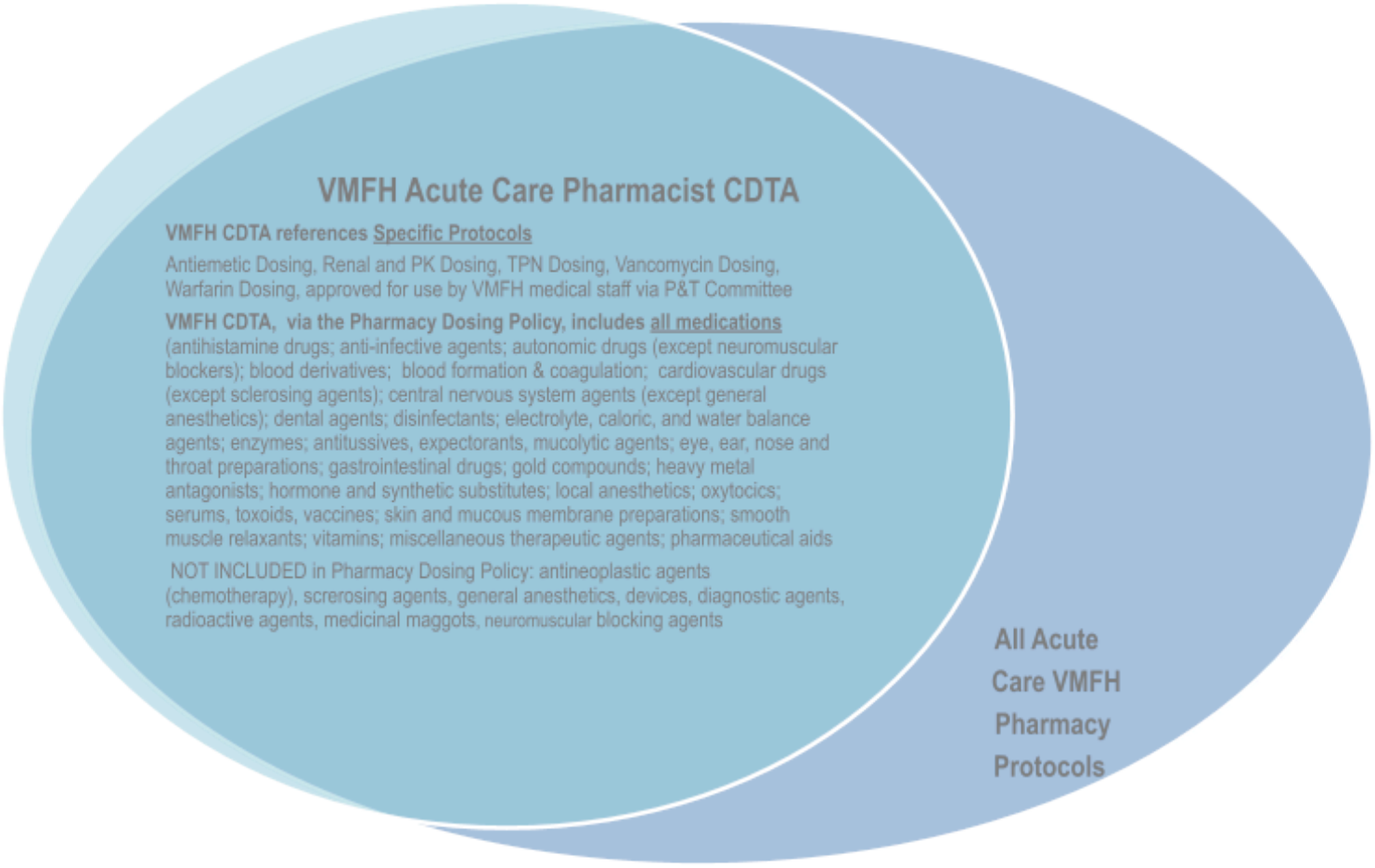
VMFH Pharmacists sign an agreement with a medical provider, that outlines the VMFH Pharmacy Dosing CDTA's authority: as the prescriber, the pharmacist will dose, monitor, adjust, +/- discontinue therapy when consulted for a medication that is outlined in policy

Pharmacist Dosing Policy outlines broad authority for pharmacist to "dose the medication and order appropriate labs, based on published medical literature, VMFH Protocols and Dosing Guidelines, evidence-based dosing guidelines, and the patient's individual clinical parameters" as well as scopes in the medications covered and not covered under authority

Medication order as appears in the EHR indicates the pharmacist as the ordering provider, and the attending or specialist as the authorizing provider, and therefore the pharmacist is issuing a prescription in their own name and credentials

Medication orders are signed "per protocol" by the ordering provider (the pharmacist)

Medication orders are not authenticated and or cosigned by the authorizing provider



WAC 246.945.350 Collaborative drug therapy agreements

1. A pharmacist exercising prescriptive authority in their practice must have a valid CDTA on file with the commission and their practice location.
2. A CDTA must include:
   a. A statement identifying the practitioner authorized to prescribe and the name of each pharmacist who is party to the agreement;
      i. The practitioner authorized to prescribe must be in active practice; and
      ii. The authority granted must be within the scope of the practitioners' current practice.
   b. A statement of the type of prescriptive authority decisions which the pharmacist is authorized to make, which includes:
      i. A statement of the types of diseases, drugs, or drug categories involved, and the type of prescriptive authority activity (e.g., modification or initiation of drug therapy) authorized in each case.
      ii. (ii) A general statement of the training required, procedures, decision criteria, or plan the pharmacist is to follow when making therapeutic decisions, particularly when modification or initiation of drug therapy is involved.

c. A statement of the activities the pharmacist is to follow in the course of exercising prescriptive authority, including:
    i. Documentation of decisions made; and
    ii. A plan for communication or feedback to the authorizing practitioner concerning specific decisions made.
3. A CDTA is only valid for two years from the date of signing.
4. Any modification of the written guideline or protocol shall be treated as a new CDTA.

Hormonal Contraception
Collaborative Therapy Agreement Protocol

As a licensed health care provider authorized to prescribe medications in the State of Washington, I authorize the listed licensed pharmacists at Kelley-Ross Pharmacy to prescribe and administer hormonal contraceptives and/or emergency contraceptives according to the following protocol. The protocol provides written guidelines for initiating drug therapy in accordance with the law (RCW 18.64.001) and regulations (WAC 246-863-100) of the State of Washington.

Purpose: This agreement will enable pharmacists to provide patients with timely access to hormonal contraceptives and/or emergency contraceptive pills and to ensure patient receives adequate information to successfully comply to therapy.

Patients: These guidelines are developed to provide emergency and hormonal contraception to people 18 years and older with the ability to become pregnant.

National Guidelines: This protocol is developed from the U.S. Medical Eligibility Criteria for Contraceptive Use (US MEC) developed by the Centers for Disease Control (CDC). Pharmacists prescribing or administering hormonal contraceptives under this protocol will follow these guidelines as standards of care.

Procedures:

1. Emergency Contraception:
    a. Assessment: When the patient(s) request emergency contraception, the pharmacist will assess the need for treatment and/or ongoing contraceptive care. The pharmacist will determine the following:
        i. The date of the patient's last menstrual period to rule out established pregnancy
        ii. That the elapsed time since unprotected intercourse is less than 72 hours or 120 hours.
        iii. Whether the patient has been a victim of sexual assault
        iv. The age of the patient
    b. Treatment: The pharmacist will prescribe one of the following medications approved for emergency contraception
        i. Within 72 hours of unprotected intercourse:
            1. Plan B One-Step (levonorgestrel) 1.5mg – take 1 tablet by mouth as soon as possible within 72 hours after unprotected intercourse.
            2. Yuzpe method: combined hormonal contraceptives using ethinyl estradiol 100 mcg and levonorgestrel 0.5 mg (or equivalent). Take first dose by mouth within 72 hours after unprotected intercourse. Repeat second dose 12 hours after.
        ii. Within 120 hours (5 days) of unprotected intercourse
            1. ELLA (ulipristal acetate) 30mg – take 1 tablet by mouth as soon as possible, within 120 hours (5 days) after unprotected intercourse or known suspected contraceptive failure
        iii. Prophylactic provision: The pharmacist may also prescribe and dispense a course of ECPs to a patient in advance of the need for emergency contraception.
            1. The pharmacist will counsel the patient on available options for regular contraceptive methods and/or offer contraceptive services.

c. Referral
    i. If ECP services are not available at the pharmacy
    ii. If established pregnancy cannot be ruled out or if the elapsed time since unprotected intercourse is greater than 120 hours.
    iii. If there is a concern that the patient may have contracted a sexually transmitted disease through unprotected sex, the pharmacists may utilize the existing STI CDTA for screening and treatment.
    iv. If the patient indicates that she has been sexually assaulted, the pharmacist will initiate appropriate referral while providing emergency contraception.
    v. While ECPs can be used repeatedly without serious health risks, patients who request ECPs repeatedly will be offered regular contraceptive method.

2. Hormonal Contraception:
    a. Assessment: When the patient(s) request hormonal contraception, the pharmacist will:
        i. Screen and assess appropriateness of hormonal contraception using Hormonal Contraception Patient Screening Form (Appendix A)
        ii. When appropriate, order and assess pregnancy laboratory test.
        iii. Measure and record patient's seated blood pressure if combined hormonal contraceptives are requested or recommended.
        iv. Counseling:
            1. Assess current knowledge of potential benefits and potential risks of hormonal contraception
            2. Provide education about hormonal contraception medications, different routes, use in therapy
            3. Review effectiveness of family planning methods (Appendix B)
            4. Educate that hormonal contraception does not protect against sexually transmitted infections
    b. Treatment: When prescribing hormonal contraception for eligible patients, the pharmacist will:
        i. Prescribe hormonal contraception based on patient preferred method and medical eligibility based on US MEC Criteria for Contraceptive Use (Appendix C) and Characteristics of Hormonal Contraceptives (Appendix D)
        ii. Counsel on contraceptive use, administration, side effects, and expectations
        iii. Discuss importance of adherence, potential barriers, how to handle missed doses and develop adherence plan
    c. Referral: When complicated patients are encountered, such as those who are pregnant or those who have a condition that represents an unacceptable health risk if the contraceptive is used (US MEC 3, US MEC 4), the pharmacist will refer the patient to their PCP. If the patient does not have a PCP, a referral will be made to another appropriate health care provider.

Documentation and Quality Assurance: Each prescription authorized by the pharmacist will be documented in a patient profile as required by law.

On an annual basis, the authorizing prescriber and the pharmacist will perform a quality assurance review of the prescribing decisions according to mutually acceptable criteria. The prescriber and pharmacist will also maintain a relationship such that the pharmacist may call and make inquiries of the prescriber as appropriate.

Training: The pharmacists who participate in the protocol will complete ACPE training covering the procedures listed above, in addition to US MEC guidelines and clinical supplement.

Laboratory samples will be obtained per package insert or manufacturer's instructions. If the device or test requires venous blood, any pharmacist doing venipuncture must obtain a Medical Assistant-Phlebotomist Certification through the Washington State Department of Health.

Terms: This Agreement shall remain in effect for two years unless rescinded earlier in writing by either party. Any changes in the Agreement must be agreed upon in writing by the participants.

Hormonal Contraception
Collaborative Therapy Agreement Protocol

As a licensed health care provider authorized to prescribe medications in the State of Washington, I authorize the listed licensed pharmacists at Kelley-Ross Pharmacy to prescribe and administer hormonal contraceptives and/or emergency contraceptives according to the following protocol. The protocol provides written guidelines for initiating drug therapy in accordance with the law (RCW 18.64.001) and regulations (WAC 246-863-100) of the State of Washington.

Physician:	License Number	Date
Pharmacist:	License Number	Date

Appendix A:

CONTRACEPTION: Self-Screening Patient Intake Form

(CONFIDENTIAL-Protected Health Information)

Date _____/_____/_____ Date of Birth _____/_____/_____ Age_____
Legal Name_____ Name _____
Sex Assigned at Birth (circle) M / F Gender Identification (circle) M / F / Other____
Pronouns (circle) She/Her/Hers, He/Him/His, They/Them/Their, Ze/Hir/Hirs, Other_____
Street Address _____
Phone ( ) _____ Email Address _____
Healthcare Provider Name _____ Phone ( ) _____ Fax ( ) _____
Do you have health insurance? Yes / No Insurance Provider Name _____
Any allergies to medications? Yes / No If yes, please list _____
Any allergies to foods (ex. soy, lactose)? Yes / No If yes, please list _____

Background Information:

1.	Have you previously had a contraceptive prescribed to you by a pharmacist? If yes, when was the last time a pharmacist prescribed a contraceptive to you?	□ Yes □ No ___/___/___
2.	What was the date of your last reproductive or sexual health clinical visit with a non-pharmacist?	___/___/___

Contraception History:

3.	Have you ever been told by a healthcare professional not to take hormones? -If yes, what was the reason? _____	□ Yes □ No
4.	Have you ever taken birth control pills, or used a birth control patch, ring, or shot/injection?	□ Yes □ No
5.	Did you ever experience a bad reaction to using hormonal birth control? - If yes, what kind of reaction occurred? _____	□ Yes □ No
6.	Are you currently using any method of birth control including pills, patch, ring or shot/injection? - If yes, which one do you use? _____	□ Yes □ No
7.	Do you have a preferred method of birth control that you would like to use? - If yes, please check one: □ Oral pill □ Skin patch □ Vaginal ring □ Injection □ Other (IUD, implant)	□ Yes □ No

Pregnancy Screen:

8.	Did you have a baby less than 6 months ago, are you fully or nearly-fully breast feeding, AND have you had no menstrual period since the delivery?	□ Yes □ No
9.	Have you had a baby in the last 4 weeks?	□ Yes □ No
10.	Did you have a miscarriage or abortion in the last 7 days?	□ Yes □ No
11.	Did your last menstrual period start within the past 7 days?	□ Yes □ No
12.	Have you abstained from sexual intercourse since your last menstrual period or delivery?	□ Yes □ No
13.	Have you been using a reliable contraceptive method consistently and correctly?	□ Yes □ No

Medical Health & History:

14.	What was the first day of your last menstrual period?	___/___/___
15.	Have you had a recent change in vaginal bleeding that worries you?	□ Yes □ No
16.	Have you given birth within the past 21 days? If yes, how long ago? _____	□ Yes □ No
17.	Are you currently breastfeeding?	□ Yes □ No
18.	Do you smoke cigarettes?	□ Yes □ No
19.	Do you have diabetes?	□ Yes □ No
20.	Do you get migraine headaches? If yes, have you ever had the kind of headaches that start with warning signs or symptoms, such as flashes of light, blind spots, or tingling in your hand or face that comes and goes completely away before the headache starts?	□ Yes □ No □ Yes □ No □ N/A
21.	Are you being treated for inflammatory bowel disease?	□ Yes □ No
22	Do you have high blood pressure, hypertension, or high cholesterol? (Please indicate yes, even if it is controlled by medication)	□ Yes □ No
23.	Have you ever had a heart attack or stroke, or been told you had any heart disease?	□ Yes □ No

CONTRACEPTION: Self-Screening Patient Intake Form

(CONFIDENTIAL-Protected Health Information)

24.	Have you ever had a blood clot?	□ Yes □ No
25.	Have you ever been told by a healthcare professional that you are at risk of developing a blood clot?	□ Yes □ No
26.	Have you had recent major surgery or are you planning to have surgery in the next 4 weeks?	□ Yes □ No
27	Will you be immobile for a long period? (e.g. flying on a long airplane trip, etc.)	□ Yes □ No
28.	Have you had bariatric surgery or stomach reduction surgery?	□ Yes □ No
29.	Do you have or have you ever had breast cancer?	□ Yes □ No
30.	Have you had an organ transplant?	□ Yes □ No
31.	Do you have or have you ever had hepatitis, liver disease, liver cancer, or gall bladder disease, or do you have jaundice (yellow skin or eyes)?	□ Yes □ No
32.	Do you have lupus, rheumatoid arthritis, or any blood disorders?	□ Yes □ No
33.	Do you take medication for seizures, tuberculosis (TB), fungal infections, or human immunodeficiency virus (HIV)? - If yes, list them here: _____	□ Yes □ No
34.	Do you have any other medical problems or take any medications, including herbs or supplements? - If yes, list them here: _____ _____ _____	□ Yes □ No

Patient Signature_____Date_____

CONTRACEPTION: Standardized Assessment and Treatment Care Pathway

Algorithm A: Oral, Vaginal and Transdermal Contraception with Combined Hormonal Contraceptives (CHC) and Progestin Only Pills (POP). RPH must utilize Summary US MEC (v. 2020) & Full US MEC (v. 2016) to make determinations below. In Full US MEC, Appendix D contains classifications for CHCs and Appendix C contains classifications for POPs.

1) Background Information – Review Patient Intake Form Questions #1-2. Each patient must complete a new Patient Intake Form a minimum of every twelve months.

-Never prescribed contraception by RPH **-or-**
-Previously prescribed contraception by RPH **-and-**
had clinical visit with a healthcare provider, other than a pharmacist, for reproductive or sexual health in past 3 years

-Previously prescribed contraception by RPH **-and-**
has not had clinical visit with a healthcare provider, other than a pharmacist, for reproductive or sexual health in past 3 years

No Exclusion Criteria

Any Exclusion Criteria → Refer

2) Pregnancy Screen- Review Patient Intake Form #8-13

- If YES to AT LEAST ONE and is free of pregnancy symptoms

- If NO to ALL of these questions, pregnancy can NOT be ruled out

Patient is not pregnant

Patient is possibly pregnant → Refer

3) Medical and Medication History - Review Patient Intake Form #14-34 (and med list in pharmacy record). Evaluate medical health & history utilizing the US MEC. Evaluate medications utilizing the US MEC and any current references for drug-drug interactions with contraceptives.

- If ALL boxes are labeled 1 or 2 (green) on the US MEC for the type of contraception that RPH plans to prescribe (e.g., CHC, POP)

-If ANY boxes are labeled 3 or 4 (pink/red) on the US MEC or a significant drug-drug or drug-disease interaction exists for the type of contraception that RPH plans to prescribe (e.g., CHC, POP)

No Contraindicated Condition(s) or Medication(s)

Any Contraindicated Condition(s) or Medication(s) → Refer

4) Blood Pressure Screen:
Assess the patient's self-reported blood pressure or document the pharmacist's measurement of the patient's current blood pressure. Note: RPH may choose to take a second reading if initial report or measurement is ≥ 140/90

CHC + BP < 140/90 **-or-**
POP + Any BP

CHC + BP ≥ 140/90 → Refer or consider POP or DMPA

5) Evaluate patient contraception history, preference, and current therapy for selection of treatment.

Not currently on birth control

Currently on birth control

6a) Choose Contraception

- ***Initiate*** contraception based on patient preferences, adherence, and history for new therapy

6b) Choose Contraception

- ***Continue*** current form of pills, ring or patch, if no change is necessary **-or-**
- ***Alter*** therapy based on patient concerns, such as side effects patient may be experiencing; or refer, if appropriate

- ***Prescribe and dispense*** up to 12 months of desired contraception product. This must be done as soon as practicable after the pharmacist issues the prescription and must include any relevant educational materials.
  ORS 743A.066 requires prescription drug benefit programs to reimburse for 3 months for the first dispensing and 12 months for subsequent dispensing of the same contraceptive.

7) Provide Counseling

- Address any unexplained vaginal bleeding that worries patient (Patient Intake Form #15) – Refer for further evaluation
- Address any high blood pressure - Refer for further evaluation
- Discuss the management and expectations of side effects (bleeding irregularities, etc.)
- Discuss initiation strategy for initial treatment/change in treatment (as applicable). For quick start - instruct patient they can begin contraceptive today; use backup method for 7 days
- Discuss adherence and opportunities for follow-up visits
- Encourage routine health screenings and STI prevention

8) Discuss and provide visit summary to patient and advise the patient to consult with a primary care practitioner or women's health care practitioner per ORS 689.689(2)(b)(D).

CONTRACEPTION: Standardized Assessment and Treatment Care Pathway

Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use

This summary sheet only contains a subset of the recommendations from the USMEC. It is color coded in the left column to match the corresponding question of the Contraception Patient Intake Form
For complete guidance, see: Summary US MEC (v. 2020) & Full US MEC (v. 2016)
Note: Most contraceptive methods do not protect against sexually transmitted diseases (STDs). Consistent and correct use of the male latex condom reduces the risk of STDs and HIV

Key:

1	No restriction (method can be used)
2	Advantages generally outweigh theoretical or proven risks
3	Theoretical or proven risks usually outweigh the advantages
4	Unacceptable health risk (method not to be used)

Corresponding to the Contraception Patient Intake Form:

Condition	Sub-condition	Combined pill, patch (CHC)		Progestin-only Pill (POP)		DMPA (Inj)		Other Contraception Options Indicated for Patient
		Initiating	Continuing	Initiating	Continuing	Initiating	Continuing	
a. Age		Menarche to <40=1		Menarche to <18=1		Menarche to <18=2		Yes
		≥40=2		18-45=1		18-45=1		Yes
				>45=1		>45=2		Yes
b. Smoking	a) Age < 35	2		1		1		Yes
	b) Age ≥ 35, < 15 cigarettes/day	3		1		1		Yes
	c) Age ≥ 35, ≥15 cigarettes/day	4		1		1		Yes
c. Pregnancy	(Not Eligible for contraception)	NA*		NA*		NA		NA*
d. Vaginal Bleeding	Unexplained or worrisome vaginal bleeding	2		2		3		Yes
e. Postpartum (see also Breastfeeding)	a) < 21 days	4		1		1		Yes
	b) 21 days to 42 days:							
	(i) with other risk factors for VTE	3*		1		1		Yes
	(ii) without other risk factors for VTE	2		1		1		Yes
	c) > 42 days	1		1		1		Yes
f. Breastfeeding (see also Postpartum)	a) < 1 month postpartum	3/4*		2*		2*		Yes
	b) 30 days to 42 days							
	(i) with other risk factors for VTE	3*		2*		2*		Yes
	(ii) without other risk factors for VTE	2*		1*		1*		Yes
	c)> 42 days postpartum	2*		1*		1*		Yes
g. Diabetes mellitus (DM)	a) History of gestational DM only	1		1		1		Yes
	b) Non-vascular disease							
	(i) non-insulin dependent	2		2		2		Yes
	(ii) insulin dependent‡	2		2		2		Yes
	c) Nephropathy/ retinopathy/ neuropathy‡	3/4*		2		3		Yes
	d) Other vascular disease or diabetes of >20 years' duration‡	3/4*		2		3		Yes
h. Headaches	a) Non-migrainous	1*		1		1		Yes
	b) Migraine:							
	i) without aura (includes menstrual migraines)	2*		1		1		Yes
	iii) with aura	4*		1		1		Yes
i. Inflammatory Bowel Disease	a) Mild; no risk factors	2		2		2		
	b) IBD with increased risk for VTE	3						
j. Hypertension	a) Adequately controlled hypertension	3*		1*		2*		Yes
	b) Elevated blood pressure levels (properly taken measurements):							
	(i) systolic 140-159 or diastolic 90-99	3*		1*		2*		Yes
	(ii) systolic ≥160 or diastolic ≥100‡	4*		2*		3*		Yes
	c) Vascular disease	4*		2*		3*		Yes
k. History of high blood pressure during pregnancy		2		1		1		Yes
l. Peripartum cardiomyopathy‡	a) Normal or mildly impaired cardiac function:							
	(i) < 6 months	4		1		1		Yes
	(ii) ≥ 6 months	3		1		1		Yes
	b) Moderately or severely impaired cardiac function	4		2		2		Yes
m. Multiple risk factors for arterial CVD	(such as older age, smoking, diabetes, hypertension, low HDL, high LDL, or high triglyceride levels)	3/4*		2*		3*		Yes
n. Ischemic heart disease‡	Current and history of	4		2	3	3		Yes
o. Valvular heart disease	a) Uncomplicated	2		1		1		Yes
	b) Complicated‡	4		1		1		Yes
p. Stroke‡	History of cerebrovascular accident	4		2	3	3		Yes
q. Known Thrombogenic mutations‡		4*		2*		2*		Yes

I = initiation of contraceptive method; C = continuation of contraceptive method; NA = Not applicable
* Please see the complete guidance for a clarification to this classification: Full US MEC (v. 2016)
‡ Condition that exposes a woman to increased risk as a result of unintended pregnancy.

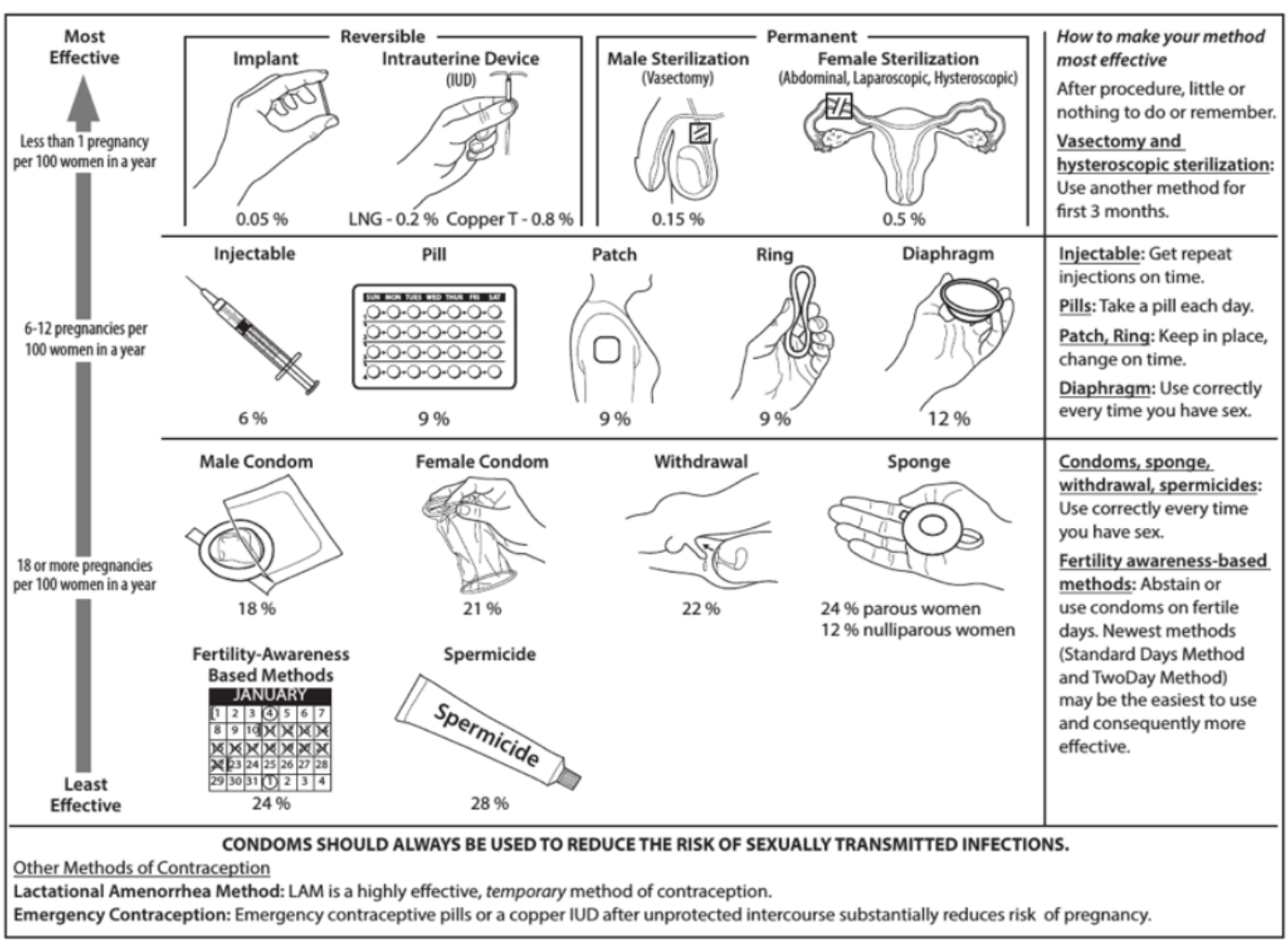
CONTINUES NEXT PAGE →

CONTRACEPTION: Standardized Assessment and Treatment Care Pathway

Condition	Sub-condition	Combined pill, patch (CHC)		Progestin-only Pill (POP)		DMPA (Inj)		Other Contraception Options Indicated for Patient
		Initiating	Continuing	Initiating	Continuing	Initiating	Continuing	
r. Deep venous thrombosis (DVT) & Pulmonary embolism (PE)	a) History of DVT/PE, not on anticoag therapy							
	i) higher risk for recurrent DVT/PE	4		2		2		Yes
	ii) lower risk for recurrent DVT/PE	3		2		2		Yes
	b) Acute DVT/PE	4		2		2		Yes
	c) DVT/PE and established on anticoagulant therapy for at least 3 months							
	i) higher risk for recurrent DVT/PE	4*		2		2		Yes
	ii) lower risk for recurrent DVT/PE	3*		2		2		Yes
	d) Family history (first-degree relatives)	2		1		1		Yes
	e) Major surgery							
	(i) with prolonged immobilization	4		2		2		Yes
	(ii) without prolonged immobilization	2		1		1		Yes
	f) Minor surgery without immobilization	1		1		1		Yes
s. Superficial venous disorders	a) Varicose veins	1		1		1		
	b) Superficial venous thrombosis (acute or history)	3*		1		1		
ll. Multiple Sclerosis	a) With prolonged immobility	3		1		2		Yes
	b)Without prolonged immobility	1		1		2		Yes
t. History of bariatric surgery‡	a) Restrictive procedures	1		1		1		Yes
	b) Malabsorptive procedures	COCs: 3	P/R: 1	3		1		Yes
u. Breast Disease & Breast Cancer	a) Undiagnosed mass	2*		2*		2*		Yes
	b) Benign breast disease	1		1		1		Yes
	c) Family history of cancer	1		1		1		Yes
	d) Breast cancer:‡							
	i) current	4		4		4		Yes
	ii) past/no evidence current disease x 5yr	3		3		3		Yes
v. Solid Organ Transplant	a) Complicated – graft failure, rejection, etc.	4		2		2		Yes
	b) Uncomplicated	2*		2		2		Yes
w. Viral hepatitis	a) Acute or flare	3/4*	2 C	1		1		Yes
	b) Carrier/Chronic	1	1	1		1		Yes
x. Cirrhosis	a) Mild (compensated)	1		1		1		Yes
	b) Severe‡ (decompensated)	4		3		3		Yes
y. Liver tumors	a) Benign:							
	i) Focal nodular hyperplasia	2		2		2		Yes
	ii) Hepatocellular adenoma‡	4		3		3		Yes
	b) Malignant‡ (hepatoma)	4		3		3		Yes
z. Gallbladder disease	a) Symptomatic:							
	(i) treated by cholecystectomy	2		2		2		Yes
	(ii) medically treated	3		2		2		Yes
	(iii) current	3		2		2		Yes
	b) Asymptomatic	2		2		2		Yes
aa. History of Cholestasis	a) Pregnancy-related	2		1		1		Yes
	b) Past COC-related	3		2		2		Yes
bb. Systemic lupus erythematosus‡	a) Positive (or unknown) antiphospholipid antibodies	4*		3*		3*	3*	Yes
	b) Severe thrombocytopenia	2*		2*		3*	2*	Yes
	c) Immunosuppressive treatment	2*		2*		2*	2*	Yes
	d) None of the above	2*		2*		2*	2*	Yes
cc. Rheumatoid arthritis	a) On immunosuppressive therapy	2		1		2*		Yes
	(i) Long-term corticosteroid therapy					3		Yes
	b) Not on immunosuppressive therapy	2		1		2		Yes
dd. Blood Conditions & Anemias	a) Thalassemia	1		1		1		Yes
	b) Sickle Cell Disease‡	2		1		1		Yes
	c) Iron-deficiency anemia	1		1		1		Yes
ee. Epilepsy‡	(see also Drug Interactions)	1*		1*		1*		Yes
ff. Tuberculosis‡ (see also Drug Interactions)	a) Non-pelvic	1*		1*		1*		Yes
	b) Pelvic	1*		1*		1*		Yes
gg. HIV	a) High risk for HIV	1		1		1*		Yes
	b) HIV infection	1*		1*		1*		Yes
	(i) On ARV therapy	If on treatment, see Drug Interactions						Yes
hh. Antiretroviral therapy (All other ARVs are a 1 or 2)	a) Fosamprenavir (FPV)	3		2		2		Yes
	(i) Fosamprenavir + Ritonavir (FPV/r)	2		2		1		Yes
ii. Anticonvulsant therapy	a) Certain anticonvulsants (phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine)	3*		3*		1*		Yes
	b) Lamotrigine	3*		1		1		Yes
jj. Antimicrobial therapy	a) Broad spectrum antibiotics	1		1		1		Yes
	b) Antifungals	1		1		1		Yes
	c) Antiparasitics	1		1		1		Yes
	d) Rifampin or rifabutin therapy	3*		3*		1*		Yes
kk. Supplements	a) St. John's Wort	2		2		1		Yes

I = initiation of contraceptive method; C = continuation of contraceptive method; NA = Not applicable
* Please see the complete guidance for a clarification to this classification: Full US MEC (v. 2016)
‡ Condition that exposes a woman to increased risk as a result of unintended pregnancy.

Appendix B: Effectiveness of Family Planning Methods



CONDOMS SHOULD ALWAYS BE USED TO REDUCE THE RISK OF SEXUALLY TRANSMITTED INFECTIONS.

Other Methods of Contraception

Lactational Amenorrhea Method: LAM is a highly effective, *temporary* method of contraception.

Emergency Contraception: Emergency contraceptive pills or a copper IUD after unprotected intercourse substantially reduces risk of pregnancy.

Appendix C: Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use

Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use

Centers for Disease Control and Prevention
National Center for Chronic Disease Prevention and Health Promotion

Condition	Sub-Condition	Cu-IUD I	Cu-IUD C	LNG-IUD I	LNG-IUD C	Implant I	Implant C	DMPA I	DMPA C	POP I	POP C	CHC I	CHC C
Age		Menarche to <20 yrs:**2**		Menarche to <20 yrs:**2**		Menarche to <18 yrs:**1**		Menarche to <18 yrs:**2**		Menarche to <18 yrs:**1**		Menarche to <40 yrs:**1**	
		≥20 yrs:**1**		≥20 yrs:**1**		18-45 yrs:**1**		18-45 yrs:**1**		18-45 yrs:**1**		≥40 yrs:**2**	
						>45 yrs:**1**		>45 yrs:**2**		>45 yrs:**1**			
Anatomical abnormalities	a) Distorted uterine cavity	**4**		**4**									
	b) Other abnormalities	**2**		**2**									
Anemias	a) Thalassemia	**2**		**1**		**1**		**1**		**1**		**1**	
	b) Sickle cell disease‡	**2**		**1**		**1**		**1**		**1**		**2**	
	c) Iron-deficiency anemia	**2**		**1**		**1**		**1**		**1**		**1**	
Benign ovarian tumors	(*including cysts*)	**1**		**1**		**1**		**1**		**1**		**1**	
Breast disease	a) Undiagnosed mass	**1**		**2**		**2***		**2***		**2***		**2***	
	b) Benign breast disease	**1**		**1**		**1**		**1**		**1**		**1**	
	c) Family history of cancer	**1**		**1**		**1**		**1**		**1**		**1**	
	d) Breast cancer‡												
	i) Current	**1**		**4**		**4**		**4**		**4**		**4**	
	ii) Past and no evidence of current disease for 5 years	**1**		**3**		**3**		**3**		**3**		**3**	
Breastfeeding	a) <21 days postpartum					**2***		**2***		**2***		**4***	
	b) 21 to <30 days postpartum												
	i) With other risk factors for VTE					**2***		**2***		**2***		**3***	
	ii) Without other risk factors for VTE					**2***		**2***		**2***		**3***	
	c) 30-42 days postpartum												
	i) With other risk factors for VTE					**1***		**1***		**1***		**3***	
	ii) Without other risk factors for VTE					**1***		**1***		**1***		**2***	
	d) >42 days postpartum					**1***		**1***		**1***		**2***	
Cervical cancer	Awaiting treatment	**4**	**2**	**4**	**2**	**2**		**2**		**1**		**2**	
Cervical ectropion		**1**		**1**		**1**		**1**		**1**		**1**	
Cervical intraepithelial neoplasia		**1**		**2**		**2**		**2**		**1**		**2**	
Cirrhosis	a) Mild (*compensated*)	**1**		**1**		**1**		**1**		**1**		**1**	
	b) Severe‡ (*decompensated*)	**1**		**3**		**3**		**3**		**3**		**4**	
Cystic fibrosis‡		**1***		**1***		**1***		**2***		**1***		**1***	
Deep venous thrombosis (DVT)/Pulmonary embolism (PE)	a) History of DVT/PE, not receiving anticoagulant therapy												
	i) Higher risk for recurrent DVT/PE	**1**		**2**		**2**		**2**		**2**		**4**	
	ii) Lower risk for recurrent DVT/PE	**1**		**2**		**2**		**2**		**2**		**3**	
	b) Acute DVT/PE	**2**		**2**		**2**		**2**		**2**		**4**	
	c) DVT/PE and established anticoagulant therapy for at least 3 months												
	i) Higher risk for recurrent DVT/PE	**2**		**2**		**2**		**2**		**2**		**4***	
	ii) Lower risk for recurrent DVT/PE	**2**		**2**		**2**		**2**		**2**		**3***	
	d) Family history (*first-degree relatives*)	**1**		**1**		**1**		**1**		**1**		**2**	
	e) Major surgery												
	i) With prolonged immobilization	**1**		**2**		**2**		**2**		**2**		**4**	
	ii) Without prolonged immobilization	**1**		**1**		**1**		**1**		**1**		**2**	
	f) Minor surgery without immobilization	**1**		**1**		**1**		**1**		**1**		**1**	
Depressive disorders		**1***		**1***		**1***		**1***		**1***		**1***	

Condition	Sub-Condition	Cu-IUD I	Cu-IUD C	LNG-IUD I	LNG-IUD C	Implant I	Implant C	DMPA I	DMPA C	POP I	POP C	CHC I	CHC C
Diabetes	a) History of gestational disease	**1**		**1**		**1**		**1**		**1**		**1**	
	b) Nonvascular disease												
	i) Non-insulin dependent	**1**		**2**		**2**		**2**		**2**		**2**	
	ii) Insulin dependent	**1**		**2**		**2**		**2**		**2**		**2**	
	c) Nephropathy/retinopathy/neuropathy‡	**1**		**2**		**2**		**3**		**2**		**3/4***	
	d) Other vascular disease or diabetes of >20 years' duration‡	**1**		**2**		**2**		**3**		**2**		**3/4***	
Dysmenorrhea	Severe	**2**		**1**		**1**		**1**		**1**		**1**	
Endometrial cancer‡		**4**	**2**	**4**	**2**	**1**		**1**		**1**		**1**	
Endometrial hyperplasia		**1**		**1**		**1**		**1**		**1**		**1**	
Endometriosis		**2**		**1**		**1**		**1**		**1**		**1**	
Epilepsy‡	(*see also Drug Interactions*)	**1**		**1**		**1***		**1***		**1***		**1***	
Gallbladder disease	a) Symptomatic												
	i) Treated by cholecystectomy	**1**		**2**		**2**		**2**		**2**		**2**	
	ii) Medically treated	**1**		**2**		**2**		**2**		**2**		**3**	
	iii) Current	**1**		**2**		**2**		**2**		**2**		**3**	
	b) Asymptomatic	**1**		**2**		**2**		**2**		**2**		**2**	
Gestational trophoblastic disease‡	a) Suspected GTD (immediate postevacuation)												
	i) Uterine size first trimester	**1***		**1***		**1***		**1***		**1***		**1***	
	ii) Uterine size second trimester	**2***		**2***		**1***		**1***		**1***		**1***	
	b) Confirmed GTD												
	i) Undetectable/non-pregnant ß-hCG levels	**1***	**1***	**1***	**1***	**1***		**1***		**1***		**1***	
	ii) Decreasing ß-hCG levels	**2***	**1***	**2***	**1***	**1***		**1***		**1***		**1***	
	iii) Persistently elevated ß-hCG levels or malignant disease, with no evidence or suspicion of intrauterine disease	**2***	**1***	**2***	**1***	**1***		**1***		**1***		**1***	
	iv) Persistently elevated ß-hCG levels or malignant disease, with evidence or suspicion of intrauterine disease	**4***	**2***	**4***	**2***	**1***		**1***		**1***		**1***	
Headaches	a) Nonmigraine (mild or severe)	**1**		**1**		**1**		**1**		**1**		**1***	
	b) Migraine												
	i) Without aura (includes menstrual migraine)	**1**		**1**		**1**		**1**		**1**		**2***	
	ii) With aura	**1**		**1**		**1**		**1**		**1**		**4***	
History of bariatric surgery‡	a) Restrictive procedures	**1**		**1**		**1**		**1**		**1**		**1**	
	b) Malabsorptive procedures	**1**		**1**		**1**		**1**		**3**		COCs: **3** P/R: **1**	
History of cholestasis	a) Pregnancy related	**1**		**1**		**1**		**1**		**1**		**2**	
	b) Past COC related	**1**		**2**		**2**		**2**		**2**		**3**	
History of high blood pressure during pregnancy		**1**		**1**		**1**		**1**		**1**		**2**	
History of Pelvic surgery		**1**		**1**		**1**		**1**		**1**		**1**	
HIV	a) High risk for HIV	**1***	**1***	**1***	**1***	**1**		**1**		**1**		**1**	
	b) HIV infection					**1***		**1***		**1***		**1***	
	i) Clinically well receiving ARV therapy	**1**	**1**	**1**	**1**	If on treatment, see Drug Interactions							
	ii) Not clinically well or not receiving ARV therapy†	**2**	**1**	**2**	**1**	If on treatment, see Drug Interactions							

Key:

1 No restriction (method can be used)	**3** Theoretical or proven risks usually outweigh the advantages
2 Advantages generally outweigh theoretical or proven risks	**4** Unacceptable health risk (method not to be used)

Abbreviations: ARV = antiretroviral; C=continuation of contraceptive method; CHC=combined hormonal contraception (pill, patch, and, ring); COC=combined oral contraceptive; Cu-IUD=copper-containing intrauterine device; DMPA = depot medroxyprogesterone acetate; I=initiation of contraceptive method; LNG-IUD=levonorgestrel-releasing intrauterine device; NA=not applicable; POP=progestin-only pill; P/R=patch/ring; SSRI=selective serotonin reuptake inhibitor; ‡ Condition that exposes a woman to increased risk as a result of pregnancy. *Please see the complete guidance for a clarification to this classification: https://www.cdc.gov/reproductivehealth/contraception/contraception_guidance.htm.

Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use

Centers for Disease Control and Prevention
National Center for Chronic Disease Prevention and Health Promotion

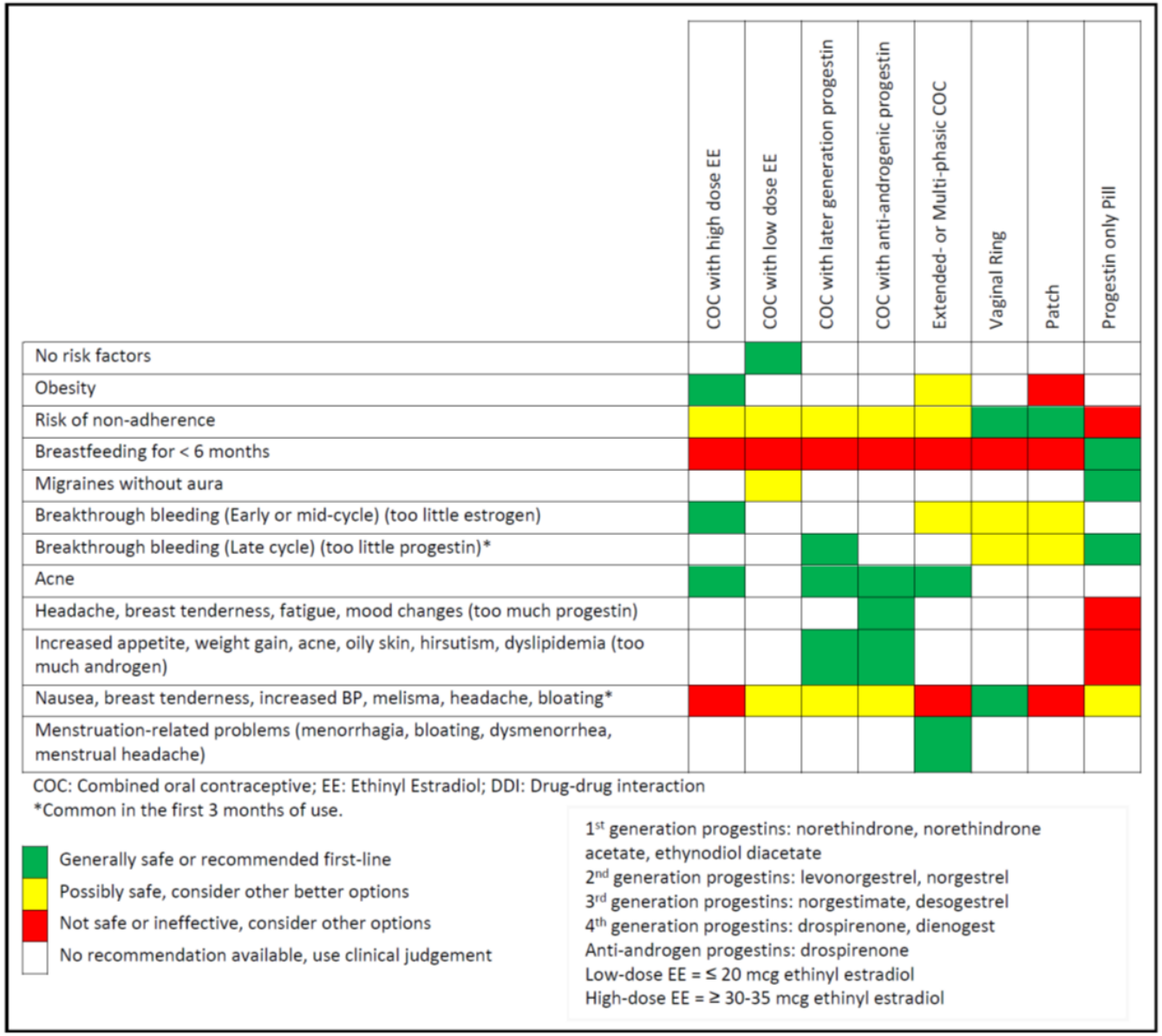
Condition	Sub-Condition	Cu-IUD		LNG-IUD		Implant		DMPA		POP		CHC	
		I	C	I	C	I	C	I	C	I	C	I	C
Hypertension	a) Adequately controlled hypertension	1*		1*		1*		2*		1*		3*	
	b) Elevated blood pressure levels (*properly taken measurements*)												
	i) Systolic 140-159 or diastolic 90-99	1*		1*		1*		2*		1*		3*	
	ii) Systolic ≥160 or diastolic ≥100‡	1*		2*		2*		3*		2*		4*	
	c) Vascular disease	1*		2*		2*		3*		2*		4*	
Inflammatory bowel disease	(*Ulcerative colitis, Crohn's disease*)	1		1		1		2		2		2/3*	
Ischemic heart disease‡	Current and history of	1		2	3	2	3	3		2	3	4	
Known thrombogenic mutations‡		1*		2*		2*		2*		2*		4*	
Liver tumors	a) Benign												
	i) Focal nodular hyperplasia	1		2		2		2		2		2	
	ii) Hepatocellular adenoma‡	1		3		3		3		3		4	
	b) Malignant‡ (hepatoma)	1		3		3		3		3		4	
Malaria		1		1		1		1		1		1	
Multiple risk factors for atherosclerotic cardiovascular disease	(e.g., older age, smoking, diabetes, hypertension, low HDL, high LDL, or high triglyceride levels)	1		2		2*		3*		2*		3/4*	
Multiple sclerosis	a) With prolonged immobility	1		1		1		2		1		3	
	b) Without prolonged immobility	1		1		1		2		1		1	
Obesity	a) Body mass index (BMI) ≥30 kg/m²	1		1		1		1		1		2	
	b) Menarche to <18 years and BMI ≥ 30 kg/m²	1		1		1		2		1		2	
Ovarian cancer‡		1		1		1		1		1		1	
Parity	a) Nulliparous	2		2		1		1		1		1	
	b) Parous	1		1		1		1		1		1	
Past ectopic pregnancy		1		1		1		1		2		1	
Pelvic inflammatory disease	a) Past												
	i) With subsequent pregnancy	1	1	1	1	1		1		1		1	
	ii) Without subsequent pregnancy	2	2	2	2	1		1		1		1	
	b) Current	4	2*	4	2*	1		1		1		1	
Peripartum cardiomyopathy‡	a) Normal or mildly impaired cardiac function												
	i) <6 months	2		2		1		1		1		4	
	ii) ≥6 months	2		2		1		1		1		3	
	b) Moderately or severely impaired cardiac function	2		2		2		2		2		4	
Postabortion	a) First trimester	1*		1*		1*		1*		1*		1*	
	b) Second trimester	2*		2*		1*		1*		1*		1*	
	c) Immediate postseptic abortion	4		4		1*		1*		1*		1*	
Postpartum (*nonbreastfeeding women*)	a) <21 days					1		1		1		4	
	b) 21 days to 42 days												
	i) With other risk factors for VTE					1		1		1		3*	
	ii) Without other risk factors for VTE					1		1		1		2	
	c) >42 days					1		1		1		1	
Postpartum (*in breastfeeding or nonbreastfeeding women, including cesarean delivery*)	a) <10 minutes after delivery of the placenta												
	i) Breastfeeding	1*		2*									
	ii) Nonbreastfeeding	1*		1*									
	b) 10 minutes after delivery of the placenta to <4 weeks	2*		2*									
	c) ≥4 weeks	1*		1*									
	d) Postpartum sepsis	4		4									

Condition	Sub-Condition	Cu-IUD		LNG-IUD		Implant		DMPA		POP		CHC	
		I	C	I	C	I	C	I	C	I	C	I	C
Pregnancy		4*		4*		NA*		NA*		NA*		NA*	
Rheumatoid arthritis	a) On immunosuppressive therapy	2	1	2	1	1		2/3*		1		2	
	b) Not on immunosuppressive therapy	1		1		1		2		1		2	
Schistosomiasis	a) Uncomplicated	1		1		1		1		1		1	
	b) Fibrosis of the liver‡	1		1		1		1		1		1	
Sexually transmitted diseases (STDs)	a) Current purulent cervicitis or chlamydial infection or gonococcal infection	4	2*	4	2*	1		1		1		1	
	b) Vaginitis (*including trichomonas vaginalis and bacterial vaginosis*)	2	2	2	2	1		1		1		1	
	c) Other factors relating to STDs	2*	2	2*	2	1		1		1		1	
Smoking	a) Age <35	1		1		1		1		1		2	
	b) Age ≥35, <15 cigarettes/day	1		1		1		1		1		3	
	c) Age ≥35, ≥15 cigarettes/day	1		1		1		1		1		4	
Solid organ transplantation‡	a) Complicated	3	2	3	2	2		2		2		4	
	b) Uncomplicated	2		2		2		2		2		2*	
Stroke‡	History of cerebrovascular accident	1		2		2	3	3		2	3	4	
Superficial venous disorders	a) Varicose veins	1		1		1		1		1		1	
	b) Superficial venous thrombosis (acute or history)	1		1		1		1		1		3*	
Systemic lupus erythematosus‡	a) Positive (or unknown) antiphospholipid antibodies	1*	1*	3*		3*		3*	3*	3*		4*	
	b) Severe thrombocytopenia	3*	2*	2*		2*		3*	2*	2*		2*	
	c) Immunosuppressive therapy	2*	1*	2*		2*		2*	2*	2*		2*	
	d) None of the above	1*	1*	2*		2*		2*	2*	2*		2*	
Thyroid disorders	Simple goiter/ hyperthyroid/hypothyroid	1		1		1		1		1		1	
Tuberculosis‡ (*see also Drug Interactions*)	a) Nonpelvic	1	1	1	1	1*		1*		1*		1*	
	b) Pelvic	4	3	4	3	1*		1*		1*		1*	
Unexplained vaginal bleeding	(suspicious for serious condition) before evaluation	4*	2*	4*	2*	3*		3*		2*		2*	
Uterine fibroids		2		2		1		1		1		1	
Valvular heart disease	a) Uncomplicated	1		1		1		1		1		2	
	b) Complicated‡	1		1		1		1		1		4	
Vaginal bleeding patterns	a) Irregular pattern without heavy bleeding	1		1	1	2		2		2		1	
	b) Heavy or prolonged bleeding	2*		1*	2*	2*		2*		2*		1*	
Viral hepatitis	a) Acute or flare	1		1		1		1		1		3/4*	2
	b) Carrier/Chronic	1		1		1		1		1		1	1
Drug Interactions													
Antiretrovirals used for prevention (PrEP) or treatment of HIV	Fosamprenavir (FPV) All other ARVs are 1 or 2 for all methods.	1/2*	1*	1/2*	1*	2*		2*		2*		3*	
Anticonvulsant therapy	a) Certain anticonvulsants (phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine)	1		1		2*		1*		3*		3*	
	b) Lamotrigine	1		1		1		1		1		3*	
Antimicrobial therapy	a) Broad spectrum antibiotics	1		1		1		1		1		1	
	b) Antifungals	1		1		1		1		1		1	
	c) Antiparasitics	1		1		1		1		1		1	
	d) Rifampin or rifabutin therapy	1		1		2*		1*		3*		3*	
SSRIs		1		1		1		1		1		1	
St. John's wort		1		1		2		1		2		2	

Updated in 2020. This summary sheet only contains a subset of the recommendations from the U.S. MEC. For complete guidance, see: https://www.cdc.gov/reproductivehealth/contraception/contraception_guidance.htm. Most contraceptive methods do not protect against sexually transmitted diseases (STDs). Consistent and correct use of the male latex condomreduces the risk of STDs and HIV.

CS314239-A

Appendix D: Characteristics of Hormonal Contraceptives



Pharmacist Collaborative Drug Therapy Agreement (CDTA)

Agreement Expires: _____

Authorizing Prescriber Statement

I, Robert Lutz, MD, licensed in the State of Washington, do hereby authorize, the Pharmacists listed below, licensed in the State of Washington, to initiate or adjust medications as outlined in the specific clinical pharmacy protocols below in section VI and in accordance with the laws (RCW 18.64.011) and regulations (WAC 246-945-350) of the State of Washington.

This authorization will be in effect for two years, unless rescinded earlier in writing to the Washington State Pharmacy Quality Assurance Commission by either party. Any significant changes in the protocol must be agreed upon by the participants and submitted to the Commission.

Pharmacists included in this agreement:

Name	Signature	License #	Date
Pharmacy Name Address Phone: | Fax:			
Pharmacy Name Address Phone: | Fax:			

Robert Lutz, MD, MPH

Physician Signature: _____
License: MD00043817 Date: ____ / ____ / _____

Pharmacist Collaborative Drug Therapy Agreement (CDTA)

I. **Purpose:** To increase access to high quality care rendered by community pharmacists and to leverage a pharmacists' training to positively impact population health for a variety of minor ailments, vaccine needs, travel needs, and chronic disease management.

II. **Policy:** This CDTA will be in effect for two (2) years unless rescinded earlier in writing. The parties must agree to any significant changes to this agreement. The CDTA has been developed in accordance with federal and state rules and regulations and with respect to current practice guidelines.

III. **Qualifications of the Protocol Physician:** The Protocol Physician must be an authorized prescriber and in good standing in the state where the service(s) will be performed. The Protocol Physician must be authorized to supervise or delegate to the Pharmacist according to the applicable code, rules, and regulations of the State of Washington, including laws (RCW 18.64.011) and regulations (WAC 246-945-350). The Protocol Physician must be licensed in the State of Washington in the practice of medicine.

IV. **Qualifications of Pharmacists**: To be qualified to provide the services outlined in Section VII of this protocol, the Pharmacist must:
   a. Be a current associate and have signed page 1 of this protocol. Future Pharmacists may sign an addendum to page 1 that is signed by both the qualified Pharmacist and Protocol Physician.
   b. Maintain all applicable federal or state licensure and competency requirements.
   c. Maintain continuing education (CE) credits as required for state licensure.
   d. Complete training courses specific to the service(s) as required by the state and approved by the pharmacy.
   e. Complete certification of immunization training and maintain a current Cardiopulmonary Resuscitation and/or Basic Cardiac Life Support Certification for Healthcare Provider card.
   f. Maintain a copy of this protocol in a readily retrievable manner.
   g. Maintain knowledge of the associated guidelines and resources available for the service(s) they are providing.

V. **Scope of Supervision**: Reports of prescribing activities performed by the Pharmacists under this Agreement shall be compiled and sent to the Protocol Physician quarterly. The Protocol Physician may periodically review the activities of the Pharmacists providing the clinical pharmacy services outlined below in section VII and provide feedback as deemed appropriate. A detailed report with the following information must be made available to the Protocol Physician upon request, including, but not limited to patient name, date of birth, prescription name, date of service, and Pharmacist's name. As guidelines change or new medications are introduced, additional medications may be prescribed with documented approval from the Protocol Physician.

VI. **Risk and Liability:** The Protocol Physician is not liable for care provided by the Pharmacist(s) under this Agreement.

VII. **Authorized Clinical Pharmacy Services:**
   a. Vaccines & Preventative Health
      i. Vaccines
      ii. Travel Medicine

iii. Tobacco Cessation
iv. Naloxone
v. Opioid Use Disorder Management

b. Monitoring of Drug Therapy, Refills, OTCs, and Supplies
   i. Pharmacist Assessment & Monitoring of Drug Therapy
   ii. Emergency & Adherence Fills
   iii. Over-the-Counter Therapy
   iv. General Supplies
c. Test-to-Treat
   i. COVID-19
   ii. Influenza
   iii. Streptococcal Pharyngitis
d. Chronic Disease Management
   i. Asthma and COPD Management
   ii. Cholesterol Management
   iii. Diabetes Management
   iv. Hypertension Management
e. Minor Ailments
   i. Bee Stings
   ii. Human, Canine, & Feline Bites
   iii. Burns
   iv. Acute Uncomplicated UTI
   v. Vaginal Yeast Infection
f. Sexual Health
   i. Hormonal Contraceptives
   ii. PrEP & PEP
   iii. Uncomplicated STI Management

VIII. Criteria to Perform Clinical Pharmacy Services: Qualified Pharmacists may provide the clinical pharmacy services as outlined in Section VII if patient eligibility is confirmed using the approved algorithms, resources, and/or state specific criteria. Patient evaluation shall include a review of medical and social history as well as consideration of contraindications and precautions identified through screening and assessment, The qualified Pharmacist will evaluate, manage, and prescribe in accordance with approved algorithms. The authority to prescribe may not be delegated. If a patient has a primary care practitioner, the provider shall be notified of the service(s) in a timely manner as appropriate. This includes when new medication(s) is prescribed, but not necessarily for supplies (i.e., pen needles) that accompany a prescription or for immunizations that are reported to the state registry.

IX. Documentation and Record Retention: Appropriate consent forms will be utilized to record necessary information as required by state law. The encounters will be documented electronically in an electronic health record and/or pharmacy dispensing software and stored in accordance with federal and state law.

X. Emergency Procedures for Adverse Reactions:

a. For adverse reactions, pharmacies will have an emergency kit containing:
   i. A blood pressure cuff(s), sphygmomanometer, and stethoscope OR an automated cuff and monitoring system
   ii. A CPR mask or mouth shield

iii. Epinephrine: May have aqueous 1:1000 (1 mg/mL) dilution in ampules, vials of solution, or prefilled syringes or may use epinephrine autoinjectors (i.e., EpiPen).
    1. If using aqueous epinephrine, emergency kit must contain 1cc tuberculin syringes with needle length and gauge appropriate for IM injection
    2. If autoinjectors are stocked, as least 2 should be available of each strength (0.15 mg and 0.3 mg prefilled autoinjectors)

b. Recommendations from the Centers for Disease Control and Prevention (CDC) "Preventing and Managing Adverse Reactions" guidance and Up-To-Date is outlined below in case of an emergency or adverse event.

<table>
<tr><td>Diagnosis is made clinically</td><td>The most common signs and symptoms are cutaneous (i.e., sudden onset of generalized urticaria, angioedema, flushing, pruritus); however, 10-20% of patients have no skin findings.

DANGER signs: rapid progression of symptoms, respiratory distress (wheezing, dyspnea, increased work of breathing, persistent cough, cyanosis), vomiting, abdominal pain, hypotension, dysrhythmia, chest pain, and collapse</td></tr>
<tr><td>Acute management</td><td>The 1st and most important treatment of anaphylaxis is epinephrine. There are NO absolute contraindications to epinephrine in the setting of anaphylaxis.

Dosing:

<table>
<tr><th>< 10 kg</th><th>10-25 kg</th><th>25-50 kg</th><th>> 50 kg</th></tr>
<tr><td>0.1 mg autoinjector or 0.15 mg autoinjector (alternative)</td><td>0.15 mg autoinjector (preferred)</td><td>0.3 mg autoinjector (preferred)</td><td>0.3 mg autoinjector (alternative)</td></tr>
<tr><td>Draw up 0.01 mg/kg of epinephrine 1 mg/mL (preferred)</td><td>Draw up 0.15 mg (0.15 mL of epinephrine 1 mg/mL (alternative)</td><td>Draw up 0.3 mg (0.3 mL of epinephrine 1 mg/mL (alternative)</td><td>Draw up 0.5 mg (0.5 mL of epinephrine 1 mg/mL (preferred)</td></tr>
</table>

Administration:
Inject epinephrine in the mid-outer thigh. May repeat in 5–15 minute intervals or sooner if indicated.</td></tr>
<tr><td>Additional emergency management steps</td><td>Call Emergency Medical Services.

Place patient in recumbent position, if tolerated, and elevate lower extremities.

Continue to monitor blood pressure and pulse.</td></tr>
</table>

c. Serious adverse drug reactions shall be recorded in the patient's record and reported

to the patient's primary care practitioner and the Protocol Physician in a timely manner as appropriate.

d. Adverse Events related to vaccines will be reported to the Vaccine Adverse Event Reporting System (VAERS) at https//vaers.hhs.gov/. Click here for a complete list of required and recommended vaccine-related reportable events.

XI. Emergency Procedures for Acute Distress:

a. Signs and symptoms of acute distress:
    i. Difficulty breathing or shortness of breath
    ii. Pain or pressure in the chest or abdomen
    iii. Severe or persistent vomiting
    iv. Dehydration (e.g. dizziness, anuria)
    v. Altered mental status
    vi. Acute onset of:
        1. Numbness or weakness in the face, arm, or leg, especially on one side of the body
        2. Confusion, trouble speaking, or difficulty understanding speech
        3. Trouble seeing in one or both eyes
        4. Trouble walking, dizziness, loss of balance, or lack of coordination

b. Procedures for acute distress management
    i. Evaluate the severity of the patient's symptoms and assess the patient's medical status.
    ii. Call 911.
    iii. Follow-up with the patient to provide ongoing support and to reinforce appropriate action.

Vaccines

Services Authorized to Perform and Products Authorized to Prescribe:

Qualified Pharmacists may initiate, modify, continue, and/or administer any vaccine that is approved or authorized by the Food and Drug Administration (FDA) and in accordance with the **Advisory Committee on Immunization Practices (ACIP)** recommendations and federal and state regulations. Yellow Fever vaccines may only be provided at a pharmacy maintaining status as a Certified Yellow Fever Vaccination Center by Pharmacists with a **Centers for Disease Control and Prevention (CDC)** Yellow Fever Certificate.

When a patient requests, or there is indication of need for vaccine(s) for patients ≥ 6 months old, the Pharmacist will assess their vaccine history, medical history, and pertinent risk factors. The Pharmacist will integrate patient-specific information with **ACIP** and **CDC** recommendations to determine appropriate treatment and/or referral to primary care practitioner for further assessment.

The Pharmacist will defer vaccination or refer the patient to a primary care practitioner as appropriate if they have relevant allergies, have had serious reactions to prior vaccination, or have other vaccine-specific contraindications and precautions as identified by the manufacturer.

In addition to vaccine(s), patients will be provided with the most current vaccine information statement (VIS) or other federally approved patient information sheets for the vaccines(s) administered. Patients will also be informed about the indication, potential adverse reactions and how to follow up with primary care practitioner or seek additional medical assistance.

Each prescription provided will be documented in a patient profile as required by law and will be reported as required to the state immunization registry.

Vaccines to be initiated, modified, continued, administered, and/or recommended include, but are not limited to:

- COVID-19 vaccines
- Cholera
- DT
- DTaP
- Hep A
- Hep B
- Hep A/B
- Hib
- HPV
- Influenza (seasonal or variant)
- Japanese Encephalitis
- Meningococcal
- MMR
- PCV
- PPSV
- Polio – IPV
- Rabies
- RSV
- Td
- Tdap
- Typhoid
- Varicella
- Yellow Fever*
- Zoster
- Any future FDA and/or ACIP approved or authorized vaccines

*Yellow Fever vaccines may only be provided at a pharmacy maintaining status as a Certified Yellow Fever Vaccination Center by Pharmacists with a CDC Yellow Fever Certificate.

Travel Medicine and Vaccines

Services Authorized to Perform and Products Authorized to Prescribe:

Qualified Pharmacists may initiate, modify, continue, and/or administer any medicine or vaccine to support healthy travel that is approved by the Food and Drug Administration (FDA) and in accordance with the **Advisory Committee on Immunization Practices (ACIP)**, **World Health Organization (WHO)**, and **Centers for Disease Control and Prevention (CDC) Yellow Book** recommendations, and federal and state regulations, including but not limited to malaria prophylaxis, Traveler's diarrhea, motion sickness, acute mountain sickness, nausea, and vaccines.

When a patient requests, or there is indication of need for travel medicine, the Pharmacist will assess their vaccine history, medical history, travel itinerary and pertinent risk factors. The Pharmacist will integrate patient-specific information with **ACIP, WHO,** and **CDC** recommendations to determine appropriate treatment and/or referral to primary care practitioner for further assessment as appropriate if they have relevant allergies or have other vaccine/medication specific contraindications/precautions as identified by the manufacturer.

In addition to travel medicine, patients will be provided with information on the indication, potential adverse reactions and how to follow up with primary care practitioner or seek additional medical assistance.

Each prescription provided will be documented in a patient profile as required by law and if the patient has a primary care practitioner, that provider will be notified of the service. The pharmacy team will transfer the prescription to be filled at a different pharmacy if requested by the patient.

Medications to be initiated, modified, continued, administered, and/or recommended include:

Malaria Prophylaxis
- Atovaquone-proguanil (Malarone®)
- Doxycycline
- Mefloquine
- Hydroxychloroquine
- Chloroquine
- Primaquine

Traveler's Diarrhea or yeast infection
- Azithromycin
- Ciprofloxacin
- Levofloxacin
- Rifaximin
- Fluconazole
- Miconazole (topical)

Vaccines
- Refer to the Vaccines protocol for vaccine needs assessment prior to travel

Motion Sickness
- Scopolamine
- Promethazine
- Meclizine

Acute Mountain Sickness
- Acetazolamide

Nausea
- Ondansetron

Medication Refills
- Refer to the Emergency & Adherence Fills protocol for routine medications with refill needs prior to travel

Tobacco Cessation

Services Authorized to Perform and Products Authorized to Prescribe:

Qualified Pharmacists may initiate, modify, or continue any medication for tobacco cessation that is approved or authorized by the Food and Drug Administration (FDA) and in accordance with the **World Health Organization (WHO)** recommendations and federal and state regulations.

When a patient requests, or there is indication of need for tobacco cessation counseling, the Pharmacist will assess the necessity of tobacco cessation pharmacotherapy. A patient history will be taken including tobacco use and previous quit attempts. The Pharmacist will integrate patient-specific information and disease-state knowledge with **WHO** recommendations to determine appropriate treatment and/or referral to a primary care practitioner for further assessment.

The Pharmacist will refer the patient to a primary care practitioner if pharmacologic smoking cessation options may not be appropriate for the patient or if the following conditions are present: age <13 years, or if the patient has had a cardiovascular event in the past 2 weeks.

In addition to medication(s), patients will be provided with information on the proper use of the medication for tobacco cessation aid, potential adverse reactions and how to follow up with primary care practitioner or seek additional medical assistance.

Each prescription provided will be documented in a patient profile as required by law, and if the patient has a primary care practitioner, that provider will be notified of the service. The pharmacy team will transfer the prescription to be filled at a different pharmacy if requested by the patient.

Medications to be initiated, modified, continued, and/or recommended include:

Non-nicotine products

- Varenicline
- Bupropion

Nicotine replacement products

- Nicotine patches
- Nicotine gum
- Nicotine lozenges
- Nicotine inhaler
- Nicotine solution (nasal)

Naloxone

Services Authorized to Perform and Products Authorized to Prescribe:

Qualified Pharmacists may initiate, modify, or continue any medication for opioid harm reduction and overdose prevention that is approved by the Food and Drug Administration (FDA) and in accordance with the **American Society of Addiction Medicine (ASAM)** guidelines, the **Substance Abuse and Mental Health Services Administration (SAMHSA)** recommendations, and federal and state regulations.

When a patient requests, or there is indication of need for naloxone, the Pharmacist will assess their opioid history and pertinent risk factors. The Pharmacist will integrate patient-specific information with **ASAM** and **SAMHSA** recommendations to determine appropriate treatment and/or referral to primary care practitioner for further assessment. If an individual requests naloxone but does not have a history of opioid use, the Pharmacist will use clinical judgement to determine appropriateness of the request and will prescribe where applicable.

The Pharmacist will refer the patient to a primary care practitioner as appropriate if they need a higher level of care or are appropriate to consider opioid dose de-escalation.

In addition to a naloxone prescription, patients will be provided with information on the indication, directions for providing potentially life-saving care, activating emergency response, and potential adverse reactions.

Each prescription provided will be documented in a patient profile as required by law, and if the patient has a primary care practitioner, that provider will be notified of the service. The pharmacy team will transfer the prescription to be filled at a different pharmacy if requested by the patient.

Medications to be initiated, modified, continued, and/or recommended include:

- Naloxone

Opioid Use Disorder Management

Services Authorized to Perform and Products Authorized to Prescribe:

Qualified Pharmacists may initiate, modify, or continue **buprenorphine** that is approved by the Food and Drug Administration (FDA), in accordance with the **American Society of Addiction Medicine (ASAM)** guidelines, the **Substance Abuse and Mental Health Services Administration (SAMHSA)** recommendations, and federal and state regulations on the management of opioid use disorder. For this protocol, qualified pharmacists also include pharmacists who have active, registered DEA numbers and have completed 8 hours of a training program that is in compliance with the DEA and Medication Access and Training Expansion (MATE) act.

When a patient requests or there is indication of need for buprenorphine initiation and/or maintenance, the Pharmacist will assess patient's opioid history and pertinent risk factors. The Pharmacist will integrate patient-specific information with **ASAM** and **SAMHSA** recommendations to determine appropriate treatment and/or referral to primary care practitioner for further assessment. If an individual requests buprenorphine but does not have a diagnosis for opioid use disorder, the Pharmacist will use clinical judgement to determine appropriateness of the request and will prescribe where applicable.

The Pharmacist will refer the patient to a primary care practitioner as appropriate if they need a higher level of care.

In addition to a buprenorphine prescription, patients will be provided with information on the indication, proper use of the medication, potential adverse reactions, and how to follow up with primary care practitioner or seek additional medical assistance.

Each prescription provided will be documented in a patient profile as required by law, and if the patient has a primary care practitioner, that provider will be notified of the service. The pharmacy team will transfer the prescription to be filled at a different pharmacy if requested by the patient.

Medications to be initiated, modified, continued, and/or recommended include:

- Buprenorphine +/- naloxone

Pharmacist Assessment & Monitoring of Drug Therapy

Services Authorized to Perform and Products Authorized to Prescribe:

Qualified Pharmacists may provide the following service in accordance with federal and state regulations.

When a patient presents to the pharmacy/pharmacist, a pharmacist may screen, evaluate and monitor a patient's health, risk factors and drug therapies. This may include but is not limited to evaluating the patient through history taking, physical examination, ordering, administering or reviewing laboratory tests, imaging, and social evaluation.

The Pharmacist will refer the patient to a primary care practitioner as deemed appropriate.

Testing and assessments to be performed may include:

- Blood glucose
- Blood pressure
- CLIA-Waived tests as allowed with certificate of waiver
- Heart rate
- Hemoglobin A1c
- Kidney function tests
- Lipid panel
- Liver functions tests
- Oxygen (O2) saturation
- Point-of-care (POC) tests for home use
- Respiratory rate

Emergency & Adherence Fills

Services Authorized to Perform and Products Authorized to Prescribe:

Qualified Pharmacists may modify or continue any non-controlled medication this is approved by the Food and Drug Administration (FDA) to support continuity of care and medication adherence.

When a patient requests or there is indication of need for a refill of a medication and the Pharmacist cannot readily obtain a prescription from the prescriber, the Pharmacist will assess the patient and determine appropriate refill needs. Providing refills is particularly beneficial for the health of a patient when it is a life-sustaining medication, when abrupt cessation of a medication could result in harm to the health of the patient, or when continuation of therapy supports management of a chronic condition. A patient history will be taken including medical history, duration of therapy, and the last visit with the prescribing provider. The Pharmacist will integrate patient-specific information and disease-state knowledge to decide about continuation of therapy and/or referral to a primary care practitioner for further assessment.

The Pharmacist will refer the patient to a primary care practitioner if the medication is a controlled substance or if the refill is otherwise deemed inappropriate for refill.
In addition to refills to support adherence, patients will be provided with information on monitoring therapy and following up with their prescribers for routine care and refill management.

Each emergency refill prescription provided should be for 7-90 days as appropriate to provide coverage until the soonest available appointment with primary care practitioner. Each prescription provided will be documented in a patient profile as required by law, and if the patient has a primary care practitioner, that provider will be notified of the service. The pharmacy team will transfer the prescription to be filled at a different pharmacy if requested by the patient.

Categories of medications to be initiated, modified, or refilled include:

- Antidepressants
- Antihypertensives
- Blood glucose testing supplies
- Cholesterol management therapies
- Epinephrine autoinjectors
- Hormonal contraception
- Inhalers
- Insulin and other diabetes therapies
- Migraine therapy
- Other non-controlled chronic therapies

Over-the-Counter Therapy

Services Authorized to Perform and Products Authorized to Prescribe:

Qualified Pharmacists may initiate, modify, or continue any over-the-counter (OTC) therapy that has been determined by the Food and Drug Administration (FDA) to be safe and effective, and in accordance with federal and state regulations.

When a patient requests or there is indication of need for an OTC therapy, the Pharmacist will assess the patient and determine appropriate OTC therapy needs. Providing prescriptions per OTC labeled directions is particularly beneficial for the health of a patient that is unable to afford an OTC product and must seek higher level care to obtain a prescription. A patient history will be taken including medical history and allergies as well as encouraging routine primary care practitioner follow-up. The Pharmacist will integrate patient- specific information and disease-state knowledge to determine appropriate therapy and/or if patient requires referral to a primary care practitioner for further assessment.

In addition, patients will be provided with information on monitoring therapy and following up with their prescribers for routine care and refill management.

Each OTC prescription provided should be for 7-90 days as appropriate to provide coverage until the soonest available appointment with primary care practitioner. Each prescription provided will be documented in a patient profile as required by law, and if the patient has a primary care practitioner, that provider will be notified of the service. The pharmacy team will transfer the prescription to be filled at a different pharmacy if requested by the patient.

Categories of medications to be initiated, modified, or refilled include:

- Anticandidal
- Cold, flu, & allergy medications
- Dental & denture care
- Diabetes care
- Digestive health
- Eye & ear care
- First aid & medical supplies
- Footcare
- Hemorrhoidal preparations
- Incontinence supplies
- Pain relief
- Pediculicide (lice treatment)
- Skin care
- Sleep aids
- Vaginal care
- Vitamins

General Supplies

Services Authorized to Perform and Products Authorized to Prescribe:

Qualified Pharmacists may provide the following service in accordance with federal and state regulations.

When a patient presents with a prescription that requires additional supplies, the Pharmacist will assess and determine appropriate needs. A brief patient history will be taken including medical history. The Pharmacist will use patient-specific information and disease-state knowledge to determine appropriate therapy needs.

The Pharmacist will refer the patient to a primary care practitioner as deemed appropriate.

In addition to providing prescription for necessary supplies, the Pharmacist will ensure the patient knows how to use the extra supplies to assist them with monitoring their current disease state and/or to get the most out of their medication.

Each prescription provided will be documented in a patient profile as required by law, and if the patient has a primary care practitioner, that provider will be notified of the service. The pharmacy team will transfer the prescription to be filled at a different pharmacy if requested by the patient.

Categories of supplies to be initiated, modified, continued, and/or recommended include, but are not limited to:

- Alcohol swabs
- Blood pressure monitors
- Control solutions
- Glucometer
- Insulin syringes
- Lancets
- Lancing device
- Peak flow meters
- Pen needles
- Spacers
- Test strips

COVID-19

Services Authorized to Perform and Products Authorized to Prescribe:

Qualified Pharmacists may initiate, modify, continue, and/or administer any test or medication that is approved or authorized by the Food and Drug Administration (FDA) and in accordance with the **National Institute of Health (NIH)** Coronavirus Disease (COVID-19) Treatment Guidelines or **Infectious Diseases Society of America (IDSA)** Guidelines on the Treatment and Management of Patients with COVID-19 and federal and state regulations.

When a patient requests or there is indication of need for COVID-19 testing, and/or COVID-19 treatment, the Pharmacist will assess the patient and determine testing & pharmacotherapy needs. A patient history will be taken including chief complaint, history of present illness, and medical history. The Pharmacist will integrate patient-specific information and disease-state knowledge with **NIH** and **IDSA** recommendations to determine appropriate treatment and/or referral to primary care practitioner for further assessment.

The Pharmacist will refer the patient seeking treatment to a primary care practitioner if the patient has any contraindications to therapy.

In addition to appropriate COVID-19 therapy, patients will be provided with the latest information on monitoring symptoms and preventing the spread of COVID-19 as well as potential adverse reactions and recommendations to seek further follow-up with their primary care practitioner or other healthcare services.

Each prescription provided will be documented in a patient profile as required by law, and if the patient has a primary care practitioner, that provider will be notified of the service. The pharmacy team will transfer the prescription to be filled at a different pharmacy if requested by the patient.

Medications to be initiated, modified, continued, and/or recommended include:

- Paxlovid®

Influenza

Services Authorized to Perform and Products Authorized to Prescribe:

Qualified Pharmacists may initiate, modify, continue, and/or administer any test or medication that is approved or authorized by the Food and Drug Administration (FDA) and in accordance with the **Infectious Diseases Society of America (IDSA)** Clinical Practice Guidelines for the Diagnoses, Treatment, Chemoprophylaxis, and Institutional Outbreak Management of Seasonal Influenza or **Centers for Disease Control and Prevention (CDC)** guidelines and federal and state regulations.

When a patient presents with influenza symptoms and requests, the Pharmacist will provide appropriate screening, testing and treatment. The Pharmacist will integrate patient-specific information and disease-state knowledge with **IDSA** and **CDC** recommendations to determine appropriate therapy (+/- prophylaxis for appropriate close contacts) and/or referral to primary care practitioner for further assessment.

The Pharmacist will refer the patient to a primary care practitioner if they are less than 5 years, are immunocompromised, require oxygen therapy, or have other contraindications to treatment as identified by the manufacturer such as allergy or as deemed appropriate by the Pharmacist.

In addition to the medication(s), patients will be provided with information on the proper use of the medication, potential adverse reactions and how to follow up with primary care practitioner or seek additional medical assistance.

Each prescription provided will be documented in a patient profile as required by law, and if the patient has a primary care practitioner, that provider will be notified of the service. The pharmacy team will transfer the prescription to be filled at a different pharmacy if requested by the patient.

Medications to be initiated, modified, continued, and/or recommended include:

- Oseltamivir
- Baloxavir
- Zanamivir

Streptococcal Pharyngitis

Services Authorized to Perform and Products Authorized to Prescribe:

Qualified Pharmacists may initiate, modify, continue, and/or administer any test or medication that is approved or authorized by the Food and Drug Administration (FDA) and in accordance with the **Infectious Diseases Society of America (IDSA**) Clinical Practice Guidelines for the Diagnoses and Management of Group A Streptococcal Pharyngitis (GAS) or **Centers for Disease Control and Prevention (CDC)** guidelines and federal and state regulations.

When a patient presents with GAS symptoms and requests, the Pharmacist will provide appropriate screening using the Modified/McIsaac Centor Criteria score, testing using rapid strep testing and/or cultures, and treatment. The Pharmacist will integrate patient-specific information and disease-state knowledge with **IDSA** and **CDC** recommendations to determine appropriate therapy and/or referral to primary care practitioner for further assessment.

The Pharmacist will refer the patient to a primary care practitioner if they are less than 3 years, unless + GAS family history; have a history of rheumatic fever, rheumatic heart disease, scarlet fever, or GAS induced glomerulonephritis; or have other contraindications to treatment as identified by the manufacturer such as allergy or as deemed appropriate by the Pharmacist.

In addition to medication(s), patients will be provided with information on the proper use of the medication, potential adverse reactions and how to follow up with primary care practitioner or seek additional medical assistance.

Each prescription provided will be documented in a patient profile as required by law, and if the patient has a primary care practitioner, that provider will be notified of the service. The pharmacy team will transfer the prescription to be filled at a different pharmacy if requested by the patient.

Medications to be initiated, modified, continued, and/or recommended include:

- Penicillin
- Amoxicillin
- Cephalexin
- Azithromycin
- Clindamycin
- Clarithromycin

Asthma and COPD Management

Services Authorized to Perform and Products Authorized to Prescribe:

Qualified Pharmacists may initiate, modify, or continue any medication that is approved or authorized by the Food and Drug Administration (FDA) and in accordance with the **Global Initiative for Asthma (GINA)** Global Strategy for Asthma Management and Prevention or the **Global Initiative for Chronic Obstructive Lung Disease (GOLD)** Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease (COPD) and federal and state regulations. Qualified Pharmacists may order and provide testing related to asthma management including an asthma control test, spirometry, and PFTs.

A patient with asthma or COPD may be referred by the primary care practitioner, self-identified by the patient, or identified by the Pharmacist as needing additional education and care for asthma or COPD management by a Pharmacist. Eligible patients must have a proper diagnosis, and the team will attempt to get access to past visit notes and pertinent laboratory/test results. The Pharmacist will provide additional screening and patient intake to obtain the patient's medical history. The Pharmacist will integrate patient-specific information and disease-state knowledge with **GINA** and **GOLD** recommendations to determine appropriate educational needs, treatment plan and/or referral to other health care practitioners for further assessment.

In addition to medication(s), patients will be provided with information on lifestyle modifications, the proper use of the medication, potential adverse reactions and how to follow up with primary care practitioner or seek additional medical help.

Each prescription provided will be documented in a patient profile as required by law, and if the patient has a primary care practitioner, that provider will be notified of the service. The pharmacy team will transfer the prescription to be filled at a different pharmacy if requested by the patient.

Medications to be initiated, modified, continued, and/or recommended include:

Short-Acting Beta-Agonists
- Albuterol
- Levalbuterol

Long-Acting Beta-Agonists
- Arformoterol
- Formoterol
- Indacaterol
- Olodaterol
- Salmeterol
- Vilanterol

Short-Acting Muscarinic Antagonists
- Ipratropium

Leukotriene Receptor Antagonists
- Montelukast

Long-Acting Muscarinic Antagonists
- Aclidinium
- Glycopyrrolate
- Tiotropium
- Umeclidinium

Inhaled Corticosteroids
- Beclomethasone
- Budesonide
- Ciclesonide
- Fluticasone
- Mometasone

Combination Inhalers
- Includes any combination of medications listed in this protocol

Cholesterol Management

Services Authorized to Perform and Products Authorized to Prescribe:

Qualified Pharmacists may initiate, modify, or continue any medication that is approved or authorized by the Food and Drug Administration (FDA) and in accordance with the **American Heart Association (AHA)** and **American College of Cardiology (ACC)** Guideline on the Management of Blood Cholesterol, federal and state regulations. Qualified Pharmacists may order and provide testing related to cholesterol management including lipid panels and liver function tests.

A patient with hypercholesterolemia may be referred by the primary care practitioner, self-identified by the patient, or identified by the Pharmacist as needing additional education and care for hyperlipidemia management by a Pharmacist. Eligible patients must have a proper diagnosis, and the team will attempt to get access to past visit notes and pertinent laboratory/test results. The Pharmacist will provide additional screening and patient intake to obtain the patient's medical history. The Pharmacist will integrate patient-specific information and disease-state knowledge with **AHA** and **ACC** recommendations to determine appropriate educational needs, treatment plan and/or referral to other health care practitioners for further assessment. The Pharmacist will refer the patient to a primary care practitioner if they are <18 years of age.

In addition to medication(s), patients will be provided with information on the proper use of the medication, potential adverse reactions and how to follow up with primary care practitioner or seek additional medical assistance. They will also be educated regarding beneficial lifestyle modification.

Each prescription provided will be documented in a patient profile as required by law, and if the patient has a primary care practitioner, that provider will be notified of the service. The pharmacy team will transfer the prescription to be filled at a different pharmacy if requested by the patient.

Medications to be initiated, modified, continued, and/or recommended include:

Statins
- Atorvastatin
- Fluvastatin
- Lovastatin
- Pitavastatin
- Pravastatin
- Rosuvastatin
- Simvastatin

Supplements
- Co-Q10

Diabetes Management

Services Authorized to Perform and Products Authorized to Prescribe:

Qualified Pharmacists may initiate, modify, or continue any medication that is approved or authorized by the Food and Drug Administration (FDA) and in accordance with the **American Diabetes Association (ADA)** Standards of Care in Type 1 and 2 Diabetes and federal and state regulations. Qualified Pharmacists may order and provide testing related to Type 1 and 2 Diabetes management including hemoglobin A1c, blood glucose, and kidney and liver function tests.

A patient with diabetes may be referred by the primary care practitioner, self-identified by the patient, or identified by the Pharmacist as needing additional education and care for diabetes management by a Pharmacist. Eligible patients must have a proper diagnosis, and the team will attempt to get access to past visit notes and pertinent laboratory/test results. The Pharmacist will provide additional screening and patient intake to obtain the patient's medical history. The Pharmacist will integrate patient-specific information and disease-state knowledge with **ADA** recommendations to determine appropriate educational needs, treatment plan and/or referral to other health care practitioners for further assessment. The Pharmacist will refer the patient to a primary care practitioner if they are <18 years of age.

In addition to medication(s), patients will be provided with information on lifestyle modifications, the proper use of the medication, potential adverse reactions and how to follow up with primary care practitioner or seek additional medical assistance.

Each prescription provided will be documented in a patient profile as required by law, and if the patient has a primary care practitioner, that provider will be notified of the service. The pharmacy team will transfer the prescription to be filled at a different pharmacy if requested by the patient.

Medications to be initiated, modified, continued, and/or recommended include:

Biguanides
- Metformin

GLP-1 Receptor Antagonists
- Dulaglutide
- Exenatide (IR and ER)
- Liraglutide
- Semaglutide
- Tirzepatide

Sulfonylureas
- Glipizide
- Glimepiride
- Glyburide

SGLT2 Inhibitors
- Canagliflozain
- Dapagliflozin
- Empagliflozin

DPP4 Inhibitors
- Alogliptin
- Linagliptin
- Saxagliptin
- Sitagliptin

Insulin
- Basal insulin
- Mealtime insulin

Combination medications
- Includes any combination of medications listed in this protocol

Hypertension Management

Services Authorized to Perform and Products Authorized to Prescribe:

Qualified Pharmacists may initiate, modify, or continue any medication that is approved or authorized by the Food and Drug Administration (FDA) and in accordance with the **American Heart Association (AHA)** and **American College of Cardiology (ACC)** Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults, and federal and state regulations. Qualified Pharmacists may order and provide testing related to hypertension management including blood pressure and kidney and liver function tests.

A patient with hypertension may be referred by the primary care practitioner, self-identified by the patient, or identified by the Pharmacist as needing additional education and care for hypertension management by a Pharmacist. Eligible patients must have a proper diagnosis, and the team will attempt to get access to past visit notes and pertinent laboratory/test results. The Pharmacist will provide additional screening and patient intake to obtain the patient's medical history. The Pharmacist will integrate patient-specific information and disease-state knowledge with **AHA** and **ACC** recommendations to determine appropriate educational needs, treatment plan and/or referral to other health care practitioners for further assessment based on current guidelines and FDA approved package information. The Pharmacist will refer the patient to a primary care practitioner if they are <18 years of age.

In addition to medication(s), patients will be provided with information on lifestyle modifications, the proper use of the medication, potential adverse reactions and how to follow up with primary care practitioner or seek additional medical assistance.

Each prescription provided will be documented in a patient profile as required by law, and if the patient has a primary care practitioner, that provider will be notified of the service. The pharmacy team will transfer the prescription to be filled at a different pharmacy if requested by the patient.

Medications to be initiated, modified, continued, and/or recommended include:

ACE Inhibitors
- Benazepril
- Captopril
- Enalapril
- Fosinopril
- Lisinopril
- Quinapril
- Ramipril

ARBs
- Candesartan
- Irbesartan
- Losartan
- Olmesartan
- Telmisartan
- Valsartan

Diuretics
- Hydrochlorothiazide
- Chlorthalidone
- Amiloride
- Indapamide
- Eplerenone
- Spironolactone
- Triamterene
- Furosemide
- Torsemide
- Bumetanide

Alpha-Blockers
- Doxazosin
- Prazosin
- Terazosin

Dihydropyridine Calcium Channel Blockers
- Amlodipine
- Felodipine
- Nifedipine
- Nicardipine

Non-dihydropyridine Calcium Channel Blockers
- Diltiazem
- Verapamil

Vasodilators
- Hydralazine
- Minoxidil

Beta Blockers
- Atenolol
- Bisoprolol
- Carvedilol
- Labetalol
- Metoprolol
- Nadolol
- Nebivolol
- Propranolol
- Sotalol

Alpha-2 RAs
- Clonidine
- Guanfacine
- Methyldopa

Bee Stings

Services Authorized to Perform and Products Authorized to Prescribe:

Qualified Pharmacists may initiate, modify, or continue any medication that is approved or authorized by the Food and Drug Administration (FDA), in accordance with the **Mayo Clinic** and **American Academy of Dermatology (AAD)** Bee Sting treatment recommendations, and federal and state regulations.

When a patient presents with suspected bee/hornet/wasp sting, the Pharmacist will assess that patient and determine an appropriate care plan. A patient history will be taken including chief complaint, HPI and medical history to determine pertinent risk factors. The Pharmacist will integrate patient-specific information and disease-state knowledge with **Mayo Clinic** and **AAD** recommendations to determine appropriate treatment and/or referral to their primary care practitioner for further assessment.

The Pharmacist will refer the patient to a primary care practitioner as appropriate if the sting occurred >48 hours ago, sting from alternate insect, or if they present with other signs and symptoms of complicated infection. The Pharmacist will refer the patient to urgent care or ED if the mouth and/or airway are affected.

In addition to providing treatment, patients will be provided with information on their condition, treatment indication and directions as well as appropriate monitoring. The Pharmacist will also discuss potential adverse reactions and recommendations to seek further follow-up with a primary care practitioner or other healthcare services.

Each prescription provided will be documented in a patient profile as required by law, and if the patient has a primary care practitioner, that provider will be notified of the service. The pharmacy team will transfer the prescription to be filled at a different pharmacy if requested by the patient.

Medications to be initiated, modified, continued, and/or recommended include:

Analgesic products
- Acetaminophen
- Ibuprofen
- Naproxen

Anti-pruritic products
- Cetirizine
- Diphenhydramine
- Loratadine
- Fexofenadine

Topical Steroid products
- Clobetasol
- Fluocinonide
- Hydrocortisone
- Mometasone
- Triamcinolone

Human, Canine, & Feline Bites

Services Authorized to Perform and Products Authorized to Prescribe:

Qualified Pharmacists may initiate, modify, or continue any medication that is approved or authorized by the Food and Drug Administration (FDA) and in accordance with the **Infectious Diseases Society of America (IDSA**) Clinical Practice Guidelines for the Diagnosis and Management of Skin and Soft Tissue Infections and federal and state regulations.

When a patient presents with suspected human, canine, or feline bite, the Pharmacist will assess that patient and determine an appropriate care plan. A patient history will be taken including chief complaint, HPI and medical history to determine pertinent risk factors. The Pharmacist will integrate patient-specific information and disease-state knowledge with **IDSA** recommendations to determine appropriate treatment and/or referral to their primary care practitioner for further assessment.

The Pharmacist will refer the patient to a primary care practitioner as appropriate if they are unable to confirm the source of the bite being human, canine, or feline, if severe, and/or if on face or head, patient is immunosuppressed, from an animal with suspected rabies, or if they present with other signs and symptoms of complicated infection.

In addition to providing treatment, patients will be provided with information on their condition, treatment indication and directions as well as appropriate monitoring. The Pharmacist will also discuss potential adverse reactions and recommendations to seek further follow-up with a primary care practitioner or other healthcare services.

Each prescription provided will be documented in a patient profile as required by law, and if the patient has a primary care practitioner, that provider will be notified of the service. The pharmacy team will transfer the prescription to be filled at a different pharmacy if requested by the patient.

Medications to be initiated, modified, continued, and/or recommended include:

Antibiotics

- Amoxicillin-clavulanate
- Cefdinir
- Cefixime
- Cefpodoxime
- Clindamycin
- Ciprofloxacin
- Doxycycline
- Levofloxacin
- Metronidazole
- Moxifloxacin
- Sulfamethoxazole-Trimethoprim

Analgesic products

- Acetaminophen
- Ibuprofen
- Naproxen

Burns

Services Authorized to Perform and Products Authorized to Prescribe:

Qualified Pharmacists may initiate, modify, or continue any medication that is approved or authorized by the Food and Drug Administration (FDA), in accordance with the **American Academy of Family Physicians (AAFP)** Outpatient Burn Care: Prevention and Treatment recommendations, and federal and state regulations for the management of burns.

When a patient presents with a minor burn, the Pharmacist will assess that patient and determine an appropriate care plan. A patient history will be taken including chief complaint, HPI and medical history. The Pharmacist will integrate patient-specific information and disease-state knowledge with **AAFP** recommendations to determine appropriate treatment and/or referral to their primary care practitioner for further assessment.

The Pharmacist will refer the patient to a primary care practitioner, urgent care or ED as appropriate if the burn covers a large surface area (such as >5% of BSA in patients <10 years old or >55 years old, or BSA of >10% in adults), for deep partial-thickness or full thickness burns, burns caused by caustic chemicals, electricity or secondary to a house fire, if there is concern about abuse or neglect, and/or have signs and symptoms of severe burn.

In addition to providing treatment, patients will be provided with information on their condition, treatment indication and directions as well as appropriate monitoring. The Pharmacist will also discuss potential adverse reactions and recommendations to seek further follow-up with a primary care practitioner or other healthcare services.

Each prescription provided will be documented in a patient profile as required by law, and if the patient has a primary care practitioner, that provider will be notified of the service. The pharmacy team will transfer the prescription to be filled at a different pharmacy if requested by the patient.

Medications to be initiated, modified, continued, and/or recommended include:

Topical antimicrobial products
- Bacitracin or Neosporin
- Mupirocin
- Silver sulfadiazine 1% topical cream
- MediHoney

Analgesic products
- Acetaminophen
- Ibuprofen
- Naproxen
- Aloe vera cream

Protective moisturizer for dressing
- Vaseline

Acute Uncomplicated Urinary Tract Infection

Services Authorized to Perform and Products Authorized to Prescribe:

Qualified Pharmacists may initiate, modify, continue, and/or administer any medication that is approved or authorized by the Food and Drug Administration (FDA), in accordance with the **Infectious Diseases Society of America (IDSA)** Clinical Practice Guidelines for the Treatment of Acute Uncomplicated Cystitis in Women, and federal and state regulations.

When a patient presents with suspected acute uncomplicated urinary tract infection (UTI), the Pharmacist will assess that patient and determine an appropriate care plan. A patient history will be taken including chief complaint, HPI and medical history to determine pertinent risk factors as well as urinalysis testing as appropriate. The Pharmacist will integrate patient-specific information and disease-state knowledge with the **IDSA** recommendations to determine appropriate treatment and/or referral to their primary care practitioner for further assessment.

The Pharmacist will refer the patient to a primary care practitioner or urgent care clinic as appropriate if they are male, <12 years old, >54 years old, have fever (T > 38°C), flank pain, shaking chills, nausea, vomiting, history of frequent infections (>3 in previous 6 months) and/or other signs and symptoms of complicated infection.

In addition to providing treatment, patients will be provided with information on their condition, treatment indication and directions as well as appropriate monitoring. The Pharmacist will also discuss potential adverse reactions and recommendations to seek further follow-up with primary care practitioner or other healthcare services.

Each prescription provided will be documented in a patient profile as required by law, and if the patient has a primary care practitioner, that provider will be notified of the service. The pharmacy team will transfer the prescription to be filled at a different pharmacy if requested by the patient.

Medications to be initiated, modified, continued, and/or recommended include:

Antibiotic therapy
- Fosfomycin
- Nitrofurantoin monohydrate/macrocrystals
- Sulfamethoxazole-Trimethoprim
- Ciprofloxacin
- Levofloxacin

Urinary analgesic products
- Phenazopyridine

Vaginal Yeast Infection

Services Authorized to Perform and Products Authorized to Prescribe:

Qualified Pharmacists may initiate, modify, or continue any medication that is approved or authorized by the Food and Drug Administration (FDA), in accordance with the **Centers for disease Control and Prevention (CDC) guidelines** for vulvovaginal candidiasis (VVS), and federal and state regulations.

When a patient presents with suspected vaginal yeast infection, the Pharmacist will assess that patient and determine an appropriate care plan. A patient history will be taken including chief complaint, HPI and medical history to determine pertinent risk factors. The Pharmacist will integrate patient-specific information and disease-state knowledge with **CDC** recommendations to determine appropriate treatment and/or referral to their primary care practitioner for further assessment.

The Pharmacist will refer the patient to a primary care practitioner as appropriate if they are <12 years old, have an allergy to antifungal medications, uncontrolled diabetes, liver or kidney disease, frequent infections (>3 in previous 6 months) and/or other signs and symptoms of complicated infection.

In addition to providing treatment, patients will be provided with information on their condition, treatment indication and directions as well as appropriate monitoring. The Pharmacist will also discuss potential adverse reactions and recommendations to seek further follow-up with primary care practitioner or other healthcare services.

Each prescription provided will be documented in a patient profile as required by law, and if the patient has a primary care practitioner, that provider will be notified of the service. The pharmacy team will transfer the prescription to be filled at a different pharmacy if requested by the patient.

Medications to be initiated, modified, continued, and/or recommended include:

Antifungal products

- Clotrimazole
- Fluconazole
- Miconazole
- Terconazole
- Tioconazole

Hormonal Contraceptives

Services Authorized to Perform and Products Authorized to Prescribe:

Qualified Pharmacists may initiate, modify, or continue any medication that is approved or authorized by the Food and Drug Administration (FDA), in accordance with **American College of Obstetricians and Gynecologists (ACOG)** guidelines, the **Medical Eligibility Criteria (MEC)** recommendations, and federal and state regulations as hormonal or emergency contraception.

When a patient presents with a request for hormonal contraception, the Pharmacist will assess that patient and determine an appropriate care plan. A patient history will be taken including chief complaint, HPI, prior contraceptive use and medical history to determine pertinent risk factors. The Pharmacist will integrate patient-specific information and disease-state knowledge with **ACOG** and **MEC** recommendations to determine appropriate treatment and/or referral to their primary care practitioner for further assessment.

The Pharmacist will refer the patient to a primary care practitioner as appropriate if they are <15 years old, >35 years old and smoke >15 cigarettes a day, or if they present with other MEC risk factors ≥3 or signs.

In addition to a providing refill or new prescription for hormonal contraceptive, patients will be provided with information on birth control, initiation strategies, plans for adherence and missed doses, potential adverse reactions and recommendations to seek further follow-up with primary care practitioner or other healthcare services, including encouraging routine health screenings and sexually transmitted infection (STI) prevention.

Each prescription provided will be documented in a patient profile as required by law, and if the patient has a primary care practitioner, that provider will be notified of the service. The pharmacy team will transfer the prescription to be filled at a different pharmacy if requested by the patient.

Medications to be initiated, modified, continued, and/or recommended include:

Combined oral hormonal contraceptive products:

- Ethinyl estradiol + desogestrel
- Ethinyl estradiol + dienogestrel
- Ethinyl estradiol + drospirenone
- Ethinyl estradiol + drospirenone + levomefolate
- Ethinyl estradiol + ethynodiol diacetate
- Ethinyl estradiol + levonorgestrel
- Ethinyl estradiol + norgestimate
- Ethinyl estradiol + norgestrel

Other hormonal contraceptive products:

- Ethinyl estradiol + etonogestrel (Nuvaring®)
- Norethindrone (Progestin Only)

Emergency contraceptive products:

- Levonorgestrel

PrEP & PEP

Services Authorized to Perform and Products Authorized to Prescribe:

Qualified Pharmacists may initiate, modify, or continue any medication that is approved or authorized by the Food and Drug Administration (FDA), in accordance with the **Centers for Disease Control and Prevention (CDC)** recommendations, and federal and state regulations for pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP). Qualified Pharmacists may order and provide testing related to PrEP and PEP including HIV blood tests, and STI, HBV, HCV, and pregnancy tests.

When a patient presents with a request for PrEP or PEP treatment, the Pharmacist will assess that patient and determine an appropriate care plan. A patient history will be taken including chief complaint, HPI, history of potential exposure, prior PrEP or PEP treatment, and medical history to determine pertinent risk factors. The Pharmacist will integrate patient-specific information and disease-state knowledge with the **CDC** PrEP and PEP treatment recommendations to determine appropriate treatment and/or referral to their primary care practitioner for further assessment.

The Pharmacist will refer the patient to a primary care practitioner or HIV specialist as appropriate if they are pregnant, age < 2 years, have renal disease, and/pr possible antiretroviral resistance.

In addition to a providing a new or refill prescription for PrEP or PEP treatment, patients will be provided with information on HIV prevention, initiation strategies, plans for adherence and missed doses, potential adverse reactions and drug interactions, the critical time frame for starting PEP after a potential exposure, and recommendations to seek further follow-up with primary care practitioner or other healthcare services, including encouraging routine health screenings, HIV, and STI testing.

Each prescription provided will be documented in a patient profile as required by law, and if the patient has a primary care practitioner, that provider will be notified of the service. The pharmacy team will transfer the prescription to be filled at a different pharmacy if requested by the patient.

Medications to be initiated, modified, continued, and/or recommended include:

PrEP products:

- Tenofovir disoproxil fumarate and emtricitabine (Truvada)
- Tenofovir alafenamide and emtricitabine (Descovy)

PEP products:

- Tenofovir disoproxil fumarate and emtricitabine (Truvada)
- Raltegravir (Isentress)
- Dolutegravir (Tivicay)
- Darunavir (Prezista)
- Ritonavir (Norvir)
- Lamivudine / Zidovudine (Combivir)

Uncomplicated STI Management

Services Authorized to Perform and Products Authorized to Prescribe:

Qualified Pharmacists may initiate, modify, or continue any medication that is approved or authorized by the Food and Drug Administration (FDA), in accordance with the **Centers for Disease Control and Prevention (CDC)** recommendations, and federal and state regulations for treatment of uncomplicated sexually transmitted infections (STIs) such as, chlamydia and gonorrhea.

When a patient and their partner present with a request for uncomplicated STI treatment, the Pharmacist will assess that patient and determine an appropriate care plan. A patient history will be taken including chief complaint, HPI, sexual history, prior uncomplicated STI treatment, and medical history to determine pertinent risk factors. The Pharmacist will integrate patient-specific information and disease-state knowledge with the **CDC** STI treatment recommendations to determine appropriate treatment and/or referral to their primary care practitioner for further assessment.

The Pharmacist will refer the patient to a primary care practitioner as appropriate if they are pregnant, age < 8 and weigh < 45 kg, experience persistent or recurrent STI, and/or other signs and symptoms of complicated infection.

In addition to a providing a new or refill prescription for STI treatment, patients will be provided with information on safe sex practices, initiation strategies, plans for adherence and missed doses, potential adverse reactions and recommendations to seek further follow-up with primary care practitioner or other healthcare services, including encouraging routine health screenings and sexually transmitted infection (STI) prevention.

Each prescription provided will be documented in a patient profile as required by law, and if the patient has a primary care practitioner, that provider will be notified of the service. The pharmacy team will transfer the prescription to be filled at a different pharmacy if requested by the patient.

Medications to be initiated, modified, continued, and/or recommended include:

Gonorrhea Antibiotic therapy:

- Ceftriaxone (IM injection)
- Gentamicin
- Azithromycin
- Cefixime

Chlamydia Antibiotic therapy:

- Doxycycline
- Azithromycin
- Levofloxacin

Hypertension Management Service Protocol

Authorization for Use of Protocol
Pharmacists on staff at Peninsula Community Health Services (PCHS) are given authority to prescribe anti-hypertensive medications upon referral after diagnosis is completed by a medical provider. Any physician, nurse practitioner, or physician assistant on staff who have prescribing privileges may elect this referral. All established patients of PCHS clinics with- hypertension are eligible for enrollment in the service.

Training
Pharmacists practicing under this prescriptive authority protocol will complete a blood pressure measurement assessment with the clinical skills trainer.

Clinical Guidelines
The following are guidelines for the prescribing of medications for the treatment of hypertension. These closely reflect the ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults (2017) and the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure (JNC-8). The guidelines are not intended to replace clinical judgement, and at times it will be necessary to deviate from these guidelines due to specific patient characteristics/scenarios.

Clinical Evaluation & Management
A diagnosis must be completed before referral to the pharmacist for hypertension management. The provider may refer the patient to the pharmacist for a blood pressure check without a diagnosis of hypertension, however the pharmacist may not prescribe without a prior diagnosis.

The referring provider will further evaluate the patient at least every 6 months. Recommendation for follow up, medical history, physical examination, and laboratory tests may be included in the referral.

Evaluation of patients with documented HTN has three objectives:

1: To identify known causes of high blood pressure.
2: To assess the presence or absence of target organ damage and cardiovascular disease, the extent of the disease, and the response to therapy.
3: To identify other cardiovascular risk factors or concomitant disorders that may define prognosis and guide treatment recommendations.

The patient's medication list should be reviewed for possible drug interactions.

Baseline labs may be ordered to determine initial drug treatment choice. Periodic labs will be ordered to monitor effects and/or side effects and for adjusting drug therapy.

Lifestyle modifications such as weight reduction, moderation of alcohol intake, physical activity, moderation of dietary sodium, and smoking cessation should be discussed with patient if not already completed.

Drug therapy will follow the drug treatment recommendations in JNC-8. Initial drug therapy should follow these recommendations with special considerations for demographics, concomitant diseases and therapies, quality of life issues, physiologic and biochemical measurements, and economic factors. Dosage adjustment, substitution with another agent, and the addition of another drug is allowed.

Guidelines for special populations and situations are detailed in the JNC-8. These include race, children, elderly, patients with concomitant oral contraception or estrogen replacement therapy, coexisting cardiovascular disease, renal dysfunction, dyslipidemia, diabetes mellitus, asthma, and gout.

During hypertension management visits, the pharmacist will consult with the referring or onsite provider for BP less than 90/60 mmHG or greater than 160/100 mmHg, or for pulse less than 55 beats per minute or greater than 120 beats per minute as patient may require further physical assessment.

Documentation
All patient care interventions and prescribing activity will be documented by the pharmacist in the electronic medical record per PCHS policy and standards of care, and readily available for review by the referring provider. The onsite medical provider will be consulted immediately for any symptoms of immediate concern or blood pressure measurements falling within the parameters outlined above. Any new prescriptions resulting from the pharmacist's clinical judgement will be issued in the pharmacist's name, as per WAC 246-863-100.

Quality Assurance
Activity as documented in a patient's chart will be reviewed periodically upon return visits with the referring or primary care provider.

Any adverse drug reactions or adverse outcomes associated with hypertension management encounters will be tracked and reported to the P&T and/or the Peer Review Committee(s).

Chief Medical Officer's signature: _____ Effective date:_____

Collaborative Practice Agreement for Immunizations

As a licensed health care provider authorized to prescribe medications in the State of Washington, I authorize the listed licensed pharmacists of Kelley-Ross Pharmacy to prescribe and administer the vaccines listed in the protocol to infants, children and adults in accordance with the laws (RCW 18.64.011) and regulations (WAC 246-863-100) of the State of Washington.

Purpose: This agreement will enable pharmacists to provide patients with proper immunizations and individualized information.

National Guidelines: These protocols are developed from the Centers for Disease Control (CDC) guidelines and recommendations of the Advisory Committee on Immunization Practices (ACIP).

Patients and Evaluation:

- This protocol is developed to provide vaccination services to infant, children, and adult patients.

- The Immunization Patient Informed Consent Form or an in depth patient history and consent documented in each patient's electronic health record will be utilized in conjunction with professional judgment and current ACIP Vaccination guidelines to make decisions concerning prescribing and administration of vaccine.

Training and Procedures:

- Current certification of immunization training. Current CPR card and Blood Born Pathogen (BBP) training will be required to participate in this Collaborative Agreement Protocol and maintained by each pharmacist.

- Each patient shall be screened for contraindications – If the pharmacist encounters a patient for whom one of the contraindications or precautions is present, the prescriber must be contacted prior to administration of the vaccine, or the patient must be referred back to the prescriber without the vaccine having been administered. The pharmacist may also contact the Medical Director on the protocol for consult and further direction. The pharmacist will document all vaccines administered as required by statute, and on each patient's personal immunization record.

- In the case of an adverse reaction, the administering pharmacist will have an emergency kit containing 2 epi-pens or epinephrine for injection (prescribed by the administering pharmacist as necessary as part of this protocol) available to them for all immunizations/immunization clinics.

Vaccines to be Administered:

- Vaccinations, doses and schedules available on the protocol are those recommended per the CDC and ACIP guidelines and any other vaccines mutually agreed upon.

Generic Name	Contraindications
COVID-19 Vaccine	-Known history of severe allergic reaction (e.g., anaphylaxis) to any component of COVID-19 Vaccine.
Tetanus, diphtheria, pertussis **(Tdap)**	- SAR to previous dose or vaccine component. - Encephalopathy (coma, decreased consciousness, prolonged seizures) not attributable to another identifiable cause within 7 days of administration of previous dose.
Tetanus, diphtheria **(Td)**	- SAR to previous dose or vaccine

Diphtheria, tetanus, pertussis **(DTaP)**	- SAR to previous dose or vaccine component. - Children unable to tolerate pertussis vaccine. - Encephalopathy (coma, decreased consciousness, prolonged seizures) not attributable to another identifiable cause within 7 days of administration of previous dose.
Tetanus, diphtheria **(DT)**	- SAR to previous dose or vaccine component.
Hepatitis A **(HepA)**	- SAR after previous dose or to vaccine component.
Hepatitis A-B (Hep A-B)	- SAR to previous dose or vaccine component.
Hepatitis B **(HepB)**	- SAR to previous dose or vaccine component.
Haemophilus influenza type b **(Hib)**	- SAR to previous dose or vaccine component. - Age younger than 6 weeks.
Human Papillomavirus , 9-valent vaccine (HPV)	- SAR to previous dose or vaccine component
Influenza inactivated injectable **(IIV)**	- SAR to previous dose or to vaccine component, including egg protein.
Influenza inactivated injectable, high dose	- SAR to previous dose or to vaccine component, including egg protein.
Recombinant or cell based influenza vaccine	- SAR to previous dose or to vaccine component. These DO NOT contain any egg protein.
Measles, mumps, rubella **(MMR)**	- SAR to previous dose or vaccine component. - Known severe immunodeficiency - Pregnancy
Meningococcal **(Men ACWY)**	- SAR to previous dose or vaccine component - Children younger than 2 years of age.
Meningococcal **(MenABCWY)**	- SAR to previous dose or vaccine component - Children younger than 2 years of age.
Meningococcal group b (MenB)	- SAR to previous dose or vaccine component.
Monkeypox and Smallpox Vaccine (Jynneos)	- SAR to previous dose or vaccine component.
Pneumococcal Conjugate Vaccine **(PCV15)**	- SAR to previous dose or vaccine component, including any vaccine containing diphtheria toxoid.
Pneumococcal Conjugate Vaccine **(PCV20)**	- SAR to previous dose or vaccine component, including any vaccine containing diphtheria toxoid.
Pneumococcal Conjugate Vaccine **(PCV21)**	- SAR to previous dose or vaccine component, including any vaccine containing diphtheria toxoid.
Pneumococcal Polysaccharide Vaccine **(PPSV23)**	- SAR to previous dose or vaccine component. - Children less than 2 years of age
Inactivated Polio (IPV)	- SAR to previous dose or vaccine component.
Respiratory Syncytial Virus (RSV)	- SAR to previous dose or vaccine component.
Varicella **(Var)**	- SAR to previous dose or vaccine component - Known severe immunodeficiency - Pregnancy
Zoster Vaccine Recombinant, Adjuvanted **(RZV)**	- SAR to previous dose or vaccine component

SAR = Severe Adverse Reaction

- Additional vaccines and recommendation changes occur periodically and will be prescribed and administered as ACIP and CDC updates occur.

- Following consultation for specific cases with the authorizing prescriber, the pharmacist may provide care to patients according to authorizing prescriber's guidance.

Allergic response medications to be prescribed:

- Vaccination severe allergic reactions will be treated as needed with oral diphenhydramine, IM epinephrine and/or subsequent referral to emergency services as soon as possible. The SAR will then be reported using the VAER system.
    - Diphenhydramine 50 mg by mouth every 6 to 8 hours as needed.
    - EpiPen 2-Pak (epinephrine) 0.3 mg/0.3 mL – inject 1 pen intramuscularly immediately as needed for several allergic reactions. May repeat every 5 to 15 min if patient does not adequately respond to initial dose.
        - For patients who weigh 30 kg or 66 lbs or more
    - Epinephrine solution for injection 1 mg/1 mL – inject 0.3 or 0.5 mg intramuscularly immediately as needed for severe allergic reactions. May repeat every 5 to 15 min if patient does not adequately respond.

Referrals:

- Vaccination severe allergic reactions will be referred to emergency services. The SAR will then be reported using the VAER system.

Documentation and Quality Assurance:

- The Immunization Patient Informed Consent Form will be utilized to record necessary information regarding the vaccine administered and necessary patient information, and be kept on file at the pharmacy as required by state law. In lieu of a consent form, a detailed consent and patient history with the same information may be taken and documented in the electronic health record.

- Each immunization authorized by the pharmacist will be documented in a patient profile as required by law.

- If the patient has a regular health care provider in the community, the pharmacist may provide the immunization information to that provider. Otherwise, the pharmacy personnel will provide documentation on the administration of vaccines to primary health providers in the community upon request and consent of the patient.

- On an annual basis the authorizing prescriber and the pharmacist will perform a quality assurance review of the prescribing decisions according to mutually acceptable criteria. The prescriber and pharmacist will also maintain a relationship such that the pharmacist may call and make inquiries of the prescriber as appropriate.

Terms: This Agreement shall remain in effect for two years unless rescinded earlier in writing by either party. Any changes in the Agreement must be agreed upon in writing by the participants.

Collaborative Practice Agreement for Immunizations

As a licensed health care provider authorized to prescribe medications in the State of Washington, I authorize the listed licensed pharmacists of Kelley-Ross Pharmacy to prescribe and administer vaccines listed in the protocol to infants, children and adults in accordance with the laws (RCW 18.64.011) and regulations (WAC 246-863-100) of the State of Washington.

Physician:	License Number	Date

Pharmacist:	License Number	Date

Latent Tuberculosis Treatment Protocol

Authorization for Use of Protocol
Pharmacists on staff at Peninsula Community Health Services (PCHS) may manage treatment for latent tuberculosis with appropriate medications and order/monitor pertinent lab work as outlined in the protocol below. Any physician, nurse practitioner, or physician assistant on staff may refer patients for this service. All established medical patients of PCHS clinics with the aforementioned diagnoses are eligible for enrollment in the service, as long as they are not pregnant, HIV negative, and are age 18 or older.

Clinical guidelines
A treatment regimen and duration of therapy currently recommended by the CDC will be used, such as once weekly isoniazid-rifapentine therapy.

Clinical Evaluation & Management
Prior to initiating latent tuberculosis treatment, the patient will complete a Chest X-ray and the following baseline labs: CBC, CMP, HIV, HCG (if applicable).

Once baseline requirements are satisfied, the pharmacist may issue prescriptions for isoniazid-rifapentine once weekly therapy.

- Isoniazid will be dosed15 mg/kg/dose (max 900mg/dose), and
- Rifapentine dosed 10.0–14.0 kg 300 mg
  14.1–25.0 kg 450 mg
  25.1–32.0 kg 600 mg
  32.1–49.9 kg 750 mg
  ≥50.0 kg 900 mg maximum.

Prescriptions will be issued in the referring provider's name. Prescriptions will be filled and stored in the pharmacy where the patient will receive direct observation dosing. All dosing appointments will be scheduled ahead of time to ensure patient can comply with schedule.

Monthly labs will be drawn to monitor elevated baseline lab work or for high risk patients such as those with liver dysfunction or regular alcohol consumption. Isoniazid-rifapentine therapy will be discontinued if a serum aminotransferase concentration is ≥5 times the upper limit of normal even in the absence of symptoms or ≥3 times the upper limit of normal in the presence of symptoms.

Patient will be screened for side effects during each weekly appointment including: fever, yellow eyes, dizziness, rash, aches or >1 day of nausea, vomiting, weakness, abdominal pain, or loss of appetite. If patient is positive for any of the listed symptoms an on-site provider will be consulted. Isoniazid-rifapentine therapy will be withheld while determining the source of the symptom(s).

Documentation
All patient care interventions and prescribing activity will be documented in the electronic medical record and readily available for review by the referring provider, per PCHS policy and

standards of care. The onsite medical provider will be consulted immediately for any symptoms of immediate concern

The following information will be documented by the pharmacist with each patient encounter: screening for side effects, medication doses administered, and any problems with dose administration.

Per CDC guidelines, 12 week direct observation treatment therapy with isoniazid-rifapentine must be completed within 16 weeks. Upon completion of therapy, pharmacist will issue a Latent TB treatment completion letter to the patient for their records and send a communication to the referring provider that the patient has completed the course of therapy. If a patient misses a scheduled dose, they will be recalled as below. If the patient is having adverse effects from the medication and/or elect to stop treatment, the referring provider will be notified.

Recall
Since latent TB treatment must occur within a specified timeframe, pharmacy staff will conduct recalls for patients using the following procedure and document outreach attempts in the electronic health record:

- A weekly, automated report will be generated and sent to the pharmacy department listing the patients who cancelled or did not attend a scheduled appointment.
- Two phone calls on separate days will be made in an attempt to reschedule the patient
- If the patient cannot be contacted after the second phone call, an unable to contact letter will be sent to the patient.
- The above procedure will be performed weekly for two consecutive weeks
- After the second letter is sent to the patient, a task is sent to the pharmacists to determine if the patient will be contacted in the future. The pharmacists will task the patient's provider to determine the next course of action.

Quality Assurance
Any adverse drug reactions or adverse outcomes associated with latent tuberculosis treatment will be recorded and reported to the P&T and/or the Peer Review Committee(s).

This policy and procedure shall remain in effect for all patients of Peninsula Community Health Services until rescinded.

Medical Director's signature: _____ Effective date: _____

MultiCare Ambulatory Care Clinical Pharmacist Collaborative Drug Therapy Agreement

November 2024

MultiCare

Table of Contents

Authorizing Prescriber Statement

The physician or nurse practitioner whose signature appears below authorizes the pharmacist(s) on the attached roster prescriptive authority to manage patients referred for medication management services. The collaborative practice agreement provides written guidelines for initiating, continuing, modifying and/or monitoring drug therapy.

Authority is limited to pharmacist(s) that practice within the MultiCare Medication Management Clinics or embedded within a MultiCare Primary Care or Specialty Clinics whose medication management is the primary responsibility of a MultiCare Provider and only within the scope of the practitioner's current practice.

Prescriptive authority will be granted for a period not to exceed two years from the signed date unless rescinded in writing earlier by either the authorizing prescriber or the pharmacist.

Introduction

Collaborative drug therapy agreements (CDTAs) allow the clinical pharmacist provider to increase patient access and to provide care coordination as a part of the health care team-based approach to improve overall health outcomes for patients. Utilizing evidence-based guidelines agreed upon based practices that cover a variety of chronic disease states, clinical pharmacist providers assist patients and providers in managing their conditions by providing medication management (i.e., dose adjustments, counseling, monitoring) and lifestyle/disease state progression education.

Purpose

The purpose of the service is to improve continuity of care for patients through optimal medication therapy, enhance patient care through education, monitoring and close follow-up, improve therapeutic outcomes, and reduce adverse events associated with chronic disease state therapy.

- These services include but are not limited to:
    - Medication profile review and clinical assessment,
    - Identify opportunities to optimize patient specific therapeutic care plans.
        - Pharmacists may initiate, modify, discontinue, refill prescribed medication therapy (e.g., drug frequency, and dose duration), provide non-pharmacologic therapy, order/interpret laboratory tests and perform other activities required to improve therapeutic outcomes.
    - Provide disease specific drug therapy management for established MultiCare patients that are referred to the pharmacist to achieve therapeutic endpoints (e.g., anticoagulation, hypertension, hyperlipidemia, Heart Failure, COPD, Asthma, Tobacco cessation, etc.)

Clinical Functions and Responsibilities

The clinical pharmacist provider is responsible for the following

- Ensure the patient has appropriately documented consult from consulting provider with clear goals for medication profile review and/or clinical objective(s).
- Developing, documenting and executing therapeutic care plans.
- Ordering, performing, reviewing, monitoring and/or interpreting appropriate laboratory tests and other diagnostic studies necessary to monitor, support and modify the patient's medication therapy and desired therapeutic outcomes.
- Prescribing medications, devices and supplies to include initiation, continuation, discontinuation, monitor and alter therapy.
- Performing physical measurements necessary to ensure the patient's appropriate clinical responses to
  medication therapy.
- Identifying and taking specific corrective action for drug-induced problems according to protocol, procedure, guidelines, or standards of care.
- Recommending consultations, as appropriate to enhance positive medication therapy outcomes (i.e.: dietician, diabetes educator).
- Providing relevant drug information to patients and other health care providers.
- Providing education and support for lifestyle modifications when appropriate.
- Arranging appropriate follow-up.
- Performing phone-based follow-up to monitor changes in medications, enforce lifestyle modifications, or address any disease-related concerns.
- Communicate and coordinate referral back to primary care team for the following reasons: *achievement of therapeutic goals, patient no longer interested in working with clinical pharmacy, frequent no-shows or inability to contact patient (3 events), patient unwilling/unable to make necessary modifications in drug therapy, no improvement in clinical outcomes with consistent interventions (> 4 visits/months), or mutual decision by provider, patient or pharmacist.*
- Ask the patient if they want to enroll patient in Chronic Care Management (CCM) program (if applicable) and follow standard procedures.
- Incidentals found during the encounter will be documented in the visit. Items requiring immediate attention or change will be discussed with the PCP or alternate provider if PCP unavailable. If there is a decision to make changes, those will be documented in the encounter.
    - Incidentals including but not limited to not meeting blood pressure goals, hypoglycemia, falls, Health Maintenance Checklist primary prevention items, drug-interactions, need for renal/hepatic adjustment, etc.
- Review for drug/herbal/supplement-drug, drug/herbal/supplement-disease interactions, adverse drug/herbal/supplement reactions or side effects, renal/hepatic dosing as needed, fall history, non- adherence secondary to cost/dexterity, etc.
    - Any serious safety concerns will be reported to the provider

    - ASAP and all others will be documented as a TE with pertinent items highlighted.
    - The verbal communication will be documented at the time of visit in the encounter/TE; regardless of if referral is in place.
    - If monitoring continued past the initial visit, a referral will be placed.
- When the vitals are taken at the visit, any abnormalities will be noted.
    - Any blood pressure >140/90 or <90/60 will be repeated. Any HR <55 or >110 will be repeated at visit.
        - Pharmacists may ask the patient to log home readings and bring at the next visit.
        - Pharmacists may consult a provider in clinic for action.
- Reviewing the health maintenance checklists and identifying care gaps for primary prevention and educate/counsel accordingly:
    - Smoking, retinal eye exam, statin, immunizations
    - Any labs due: annual LDL, A1C, UDS, Hep C, HIV
        - Pharmacists may order any of the drug monitoring labs
    - Screenings due
- AWV review when a referral has been placed.
    - If the pharmacist notices a patient is due, they can also ask the patient to schedule with the PCP at checkout.
      Review CCM registries and identify care gaps, opportunities for optimization/change and safety. Any reviews will be documented in a TE.
- Pain contract review when a referral has been placed.
    - If the pharmacist notices a patient is due, they can also ask the patient to schedule with the PCP at checkout.
    - Review PMP, collect UDS and review any adverse effects. Identify opportunities for optimization/change and safety. Any reviews /changes will be documented in a TE.

The referring physician is responsible for the following:

- Reviewing the CDTA.
- Generating the initial consult/referral to pharmacist provider.
- Being available for consultation with the pharmacist when an issue beyond the scope of the agreement arises or when the presence of critical lab values or vitals suggests further evaluation and/or intervention.
- Quality Assurance: On an annual basis, or more frequently, the authorizing prescriber and the pharmacist will perform a quality review to assess prescribing trends and indirect measures of quality care (e.g., BP, A1C, INR in target range). This may include review of care notes, evaluation of specific performance metrics, and/or patient satisfaction appraisals.
- The consulting department will coordinate with pharmacy leadership to review and revise collaborative drug therapy agreements to incorporate new evidence-based practices as available.

Consult Procedure

- Consultations may originate from any physician/ARNP who has signed the Collaborative Drug Therapy Agreement (CDTA).

    - Reason for consultation (e.g., medication profile review,

- hypertension therapy management) will be included along with the desired outcome when applicable (e.g., goal BP less than 130/80).

Patient Criteria for Consult

- Patient selection for medication management services is based on consultation from the referring provider or by agreement with provider or group to engage with patients with certain diseases/medical problems.
    - Patients with chronic disease state not meeting goals.
        - Pharmacist provider manages per CDTA to targeted end points.
    - Patient with complex medications regimens.
        - Pharmacist profile review and medication care plan generated and/or medications optimized.
    - Geriatric patient after a fall
        - Pharmacist profile review and medication care plan generated and/or medications optimized.
    - Patient who is in transition of care (i.e.: recent hospital/long term care discharge).
        - Pharmacist profile review and medication care plan generated and/or medications optimized.
        - Medication reconciliation/education.
    - Patients needing anticoagulation management.

Process

- Upon hiring, a pharmacist will be added to the CDTA upon initiating training, which is completed under supervision of a senior pharmacist or physician.
- Clinical consultations will be scheduled for follow-up with pharmacist provider.
- Pharmacist will review the patient chart including medication profile, recent notes, and laboratory results to ensure appropriate indications, dosing, and monitoring and with consideration of interactions, side effects, history of allergies, falls and adherence.
- Pharmacists will conduct visits using standard workflows that includes agenda setting, updating the allergy/medication list/medical history/social history/ROS, patient education, ordering any medications or labs as needed.
- Standard documentation in EMR using templates will include summary of medication-related issues identified and care plan.
- Patients will receive a copy of the care plan upon completion of the visit in the form of a visit summary
- Pharmacists will complete billing as outlined in MultiCare Policy.
- Pharmacist may schedule follow-up visits if the patient is not at clinical goal (e.g. medication proficiency, target BP, A1C, goals etc.). Concurrent disease states may be managed under approved CDTA
- Pharmacists will consult the referring provider or make referrals on an issue that lies outside of the CDTA or in which the patient's condition warrants additional assessment.
- Upon termination of employment, all privileges associated

- CDTA will be discontinued immediately.

Qualifications for practicing with a CDTA:

- Credentialed as a provider prior to seeing patients.
    - Provisional status to practice under direct supervision of a credential pharmacist is permitted (residents).
- He or she has a current Washington State pharmacist's license in good standing.
- The clinical pharmacist provider will complete required education for Washington State licensure and education with a focus on ambulatory care related topics.
- Successful completion of the BCACP review modules and or receipt of BCACP board certification.

Anticoagulation Protocol

Guidelines for the MultiCare Ambulatory Care Clinical Pharmacist

November 2024

1. Purpose

A. The purpose of this collaborative drug therapy agreement is to establish a consistent, efficient, and safe standard in managing anticoagulation in the ambulatory care setting.

B. To establish the MultiCare Health System (MHS) Collaborative Drug Therapy Agreement for Medication Management of Anticoagulation by Pharmacists in compliance with Washington State Law (RCW 18.64.011), and Board of Pharmacy regulations (WAC 246-863-100).

C. Washington State Law enables pharmacists to enter into agreements with prescribers, which authorizes the pharmacist to assist in initiating, modifying, continuing and discontinuing pharmacotherapy for anticoagulation.

D. This Collaborative Drug Therapy Agreement consists of a protocol describing the activities of the pharmacist and an authorizing document (Attachment 1).

2. Length of Agreement

A. This agreement shall remain in place for a period not to exceed two years from the date of the authorizing prescriber's signature or sooner should the authorizing practitioner desire to end the agreement

3. Training

A. Each pharmacist holds a current Washington State pharmacist's license in good standing.

B. Each pharmacist providing anticoagulation care for dosing warfarin, direct-acting oral anticoagulants (DOAC) or LMWH completes a training module that includes the following:

a. Lab/point-of-care training and test. See: MHS policy POCT: Ancillary Laboratory Testing; POCT: Ancillary Testing QA; POCT: Ancillary Proficiency Testing; POCT: Prothrombin Time by Roche CoaguChek XS Pro.

b. A review of the MHS Adult Ambulatory Anticoagulation Management Collaborative Practice Agreement, Standard Operating Procedure for Pharmacist Managed Anticoagulation Clinics and other applicable MHS policies and guidelines

c. A review of the current ACCP guidelines.

d. Successful completion of pharmacy department competency in-service and test for anticoagulation therapy, including case-study reviews.

e. Completion of Anticoagulation Forum Boot Camp, University of Southern Indiana Managing Anticoagulation Therapy Modules is strongly desired.

f. Certified Anticoagulation Care Provider (CACP) national certification encouraged.

g. Anticoagulation Care Providers must keep themselves clinically current with anticoagulation management through continuing education and other educational programs. Pharmacists will be required to maintain a minimum of 0.2 CEU (2 contact hours) yearly relating to anticoagulation. Department education in-services may be used in place of the CEU requirement.

4. Inclusion and Exclusion Criteria

A. Inclusion Criteria:

a. Adult ambulatory patients with a referral from a provider

b. Referrals from MultiCare Inpatient Service (MIS) physicians can be accepted in the following situations:

i. Patient does not have a current primary care provider (PCP) or established healthcare provider and has an appointment set up with a provider for a future date.

ii. The patient has a PCP and the anticoagulation clinic is waiting for a referral.

iii. MIS referrals are valid for 2 weeks if the patient has a PCP or until the patient is able to establish care with a healthcare provider (i.e. if no PCP). Exceptions can be made for patients having difficulty

obtaining a PCP (i.e. Medicaid or uninsured) and are reviewed on a case-by-case basis.

B. Inclusion criteria specific for LMWH management:
   a. Pregnant women
   b. Active cancer
   c. Renal impairment
   d. Morbidly obese (BMI > 40 kg/m^2 or >190 kg)
   e. Underweight (< 18.5 kg/m^2 or <45 kg)
   f. Non-adherence to other anticoagulants
   g. Patients with history of clotting/bleeding on other anticoagulant therapy
   h. All new patients initiating LMWH in the outpatient setting

C. Absolute Exclusion Criteria:
   a. Under 18 years of age
   b. Pregnancy (for warfarin and DOACs)
   c. Active bleeding disorder
   d. Coexisting condition requiring hospital admission
   e. Medication intolerance
   f. Severe hepatic dysfunction (AST/ALT over two times upper normal limits)
   g. Inability to educate the patient or caregiver
   h. Geographic inaccessibility to follow-up in the outpatient setting
   i. Patient does not have a contact phone

D. Relative Exclusion Criteria (Caution):
   a. Frequent falls
   b. History of peptic ulcer disease
   c. Recent/imminent surgery associated with major bleed
   d. BP>180/105
   e. Poor compliance
   f. Injurious behavior
   g. Uncontrolled alcoholism
   h. History of intracranial bleed
   i. Hematocrit of less than 30%
   j. Renal insufficiency with calculated creatinine clearance of less than 30 ml/min (for LMWH)

5. Process

A. Each pharmacist listed in the agreement is authorized to initiate, continue, modify or discontinue pharmacotherapy for anticoagulation. In exercising this authority, the pharmacist will comply with:
   a. Current recommended state and national guidelines
   b. MultiCare policies
   c. Applicable medication package inserts

B. Medications under the authority of this protocol include, but are not limited to:

a. Warfarin (Coumadin)
b. Low Molecular Weight Heparins: Enoxaparin (Lovenox) and Dalteparin (Fragmin)
c. Direct-acting Oral Anticoagulants: Apixaban (Eliquis), Betrixaban (Bevyxxa), Dabigatran (Pradaxa), Edoxaban (Savaysa) and Rivaroxaban (Xarelto)

C. Pharmacists are granted the authority to write new or refill prescriptions for the above medications.

D. Pharmacists are granted the authority to therapeutically interchange DOAC - class medications.

E. Pharmacists are granted the authority to write prescriptions for home INR meters, test strips and other testing supplies for patients who qualify and are referred for home INR monitoring.

F. Pharmacists are granted the authority to order, procure and review necessary laboratory tests to monitor for treatment appropriateness and adverse drug events, including but not limited to:
   a. PT/INR
   b. Comprehensive metabolic panel
   c. Complete blood count
   d. LMWH monitoring
   e. Stool hemoccult
   f. UA dipstick for blood
   g. Chromogenic Factor X activity
   h. Pharmacogenomic testing for warfarin sensitivity

G. Pharmacists are granted the authority to determine the number of days that anticoagulation should be withheld prior to a procedure warranting temporary discontinuation of anticoagulation therapy. This decision may be made by the pharmacist alone or in consultation with the surgeon, dentist or referring provider.

H. The patient will be discharged back to the provider in the following situations:
   a. The pharmacist has concern for an undiagnosed condition
   b. The patient is non-adherent with appointments or medication use/instructions
   c. Patient is no longer able to come into the clinic for management.

I. If non-adherence (e.g., history of no-shows or other non-compliance issues) is noted after admission to a MHS Medication Management Clinic and after the initial education process the following steps may be taken:
   a. Re-education should be initiated and individually tailored to meet any learning needs.
   b. The PCP or referring provider may need to be involved to reinforce and support the clinic's teaching.
   c. A written compliance contract with the patient may be signed.
   d. Prescriptions may be written for a limited supply (one month or less) until adherence is demonstrated.
   e. Patients will be discharged if non-adherence continues.

J. If a patient is discharged from one of the MHS Medication Management Clinics, the patient will be given one additional chance to be readmitted to the clinic after discharge. The patient may be readmitted to the same clinic or a different clinic. Readmission is at the discretion of that clinic's lead pharmacist.
   a. Upon the second admittance, a written compliance contract MUST be signed.
   b. If a patient is discharged for a second time, this discharge will be permanent from all MHS Medication Management Clinics.

K. Calls from patients related to anticoagulation management occurring after clinic hours will be triaged by the MHS Consulting Nurse Service or the appropriate MHS Hospital Pharmacy. The consulting nurse or pharmacist will triage these patients accordingly. Non-emergent questions such as appointment changes or billing questions should be referred to the Medication Management Clinic during business hours.

L. Patient Education: Patients are provided with initial and ongoing education for anticoagulation medications regarding the following: purpose, action, drug-drug and drug-food interactions, signs and symptoms of bleeding, signs and symptoms of thromboembolic events, importance of adherence with therapy, lifestyle concerns, pregnancy, dosage adjustments and injection technique and proper disposal for injectable medications.

6. Documentation

A. Each action including initiation, continuation, modification and/or discontinuation of therapy will be documented in the patient's medical record. A progress note detailing all changes made, complete with care plan, will be written for each patient encounter. The PCP or referring provider is notified of any significant bleeding, thromboembolic event, or use of vitamin K for elevated INR as documented in EPIC. All refill approvals given must be documented in EPIC. Educational topics covered will be documented in the progress note at each visit.

7. Feedback and Quality Assurance

A. Through the EPIC anticoagulation module, quarterly quality assurance reports are generated and data compiled for the ambulatory clinics providing anticoagulation therapy in the Puget Sound Region. These reports are provided to the MultiCare P&T Committee. The QA reports include, but are not limited to the following data:

   a. Current clinic census for each site

   b. Total patient visits at each site for the reporting period

   c. Percentage of visits where INR is within the targeted therapeutic range for warfarin management.

   d. Total number and type of adverse events associated with patients' anticoagulation treatment.

ATTACHMENT 1

Warfarin Maintenance Dosing and INR Recall Algorithms

These algorithms are intended to provide general guidance for warfarin dosing and follow-up after the patient has gone through the initiation period and a chronic maintenance dose has been established. Individualized and tailored management is still advised on a case-by-case basis incorporating clinician judgment and appropriate documentation.

Target INR Range 2.0-3.0

INR	<1.5	1.5-1.9	2.0-3.0	3.1-4.0	4.1-5.0	5.1-10.0	>10.0
Dose Change	Increase by 10-15%	Increase by 5-7.5% **OR** Boost x 1 day **OR** No change**	No change	Decrease by 5-7% **OR** Hold/reduce dose x 1 day **OR** No change**	Hold x 1-2 days then decrease by 7-10%	Hold until INR is therapeutic then decrease by 10-15%	Hold until INR is therapeutic then decrease by 15-20%
Next INR	Within 7 days	7-14 days	See follow up algorithm below	7-14 days	Within 7 days	3-5 days	Within 3 days

Target INR Range 2.5-3.5

INR	<1.8	1.9-2.4	2.5-3.5	3.6-4.5	4.6-5.5	5.6-10.0	>10.0
Dose Change	Increase by 10-15%	Increase by 5-7.5% **OR** Boost x 1 day **OR** No change**	No change	Decrease by 5-7% **OR** Hold/reduce dose x 1 day **OR** No change**	Hold x 1-2 days then decrease by 7-10%	Hold until INR is therapeutic then decrease by 10-15%	Hold until INR is therapeutic then decrease by 15-20%
Next INR	Within 7 days	7-14 days	See follow up algorithm below	7-14 days	Within 7 days	3-5 days	Within 3 days

****Only if slightly out-of-range (i.e., 0.1-0.2 points above or below target), previously stable, and with attributable factor.**

INR Recall Algorithm	
# of Consecutive In Range INRs	**Repeat INR In:**
1	7-10 days
2	2 weeks
3	3-4 weeks
4	4-6 weeks

Providers should consider other clinical factors and their judgment before determining dose changes, including:
· Recent trend in INR values
. Repeated out of range INR
· Dietary changes
· Changes in health status
· Changes in concomitant medications
· Alcohol intake
· Missed doses
· Other explanations for out-of-range INRs

In some cases, a dose change may not be necessary if a probable cause for out-of-range INR is identified.

Additional measures: Attempt to identify reasons for high INR (e.g. drug interactions, change in diet, acute illness), assess for signs/symptoms of bleeding, and counsel patient to avoid excessive physical activity and to report signs/symptoms of bleeding.

Measures in addition to the above: Administer oral vitamin K (2.5-5mg) if patient has no signs of bleeding. If a patient has signs or symptoms of bleeding, send the patient to ED immediately as more aggressive treatments may be required (i.e. IV vitamin K, fresh frozen plasma, or prothrombin complex concentrate). Rapid reversal with four-factor prothrombin complex concentrate is suggested over plasma.[2]

Algorithm may be accelerated for a previously stable patient with a single out-of-range INR.

If the patient has had multiple stable INRs and a consistent weekly warfarin dose for the past 12-week period, it is reasonable to begin waiting up to 6 weeks for the next INR.

Patients should be reminded of the importance of notifying the clinic of changes in medications, diet, alcohol use, or general health and any signs/symptoms of bleeding that would warrant an earlier INR.

References:

1. Adapted from Van Spall HG, Wallentin L, Yusuf S, Eikelboom JW, Nieuwlaat R, Yang S, Kabali C, Reilly PA, Ezekowitz MD, Connolly SJ. Variation in warfarin dose adjustment practice is responsible for differences in the quality of anticoagulation control between centers and

countries: an analysis of patients receiving warfarin in the randomized evaluation of longterm anticoagulation therapy (RE-LY) trial. Circulation. 2012 Nov 6;126(19):2309-16. doi: 10.1161/CIRCULATIONAHA.112.101808. Epub 2012 Oct 1.

2. Ansell et al. Guidance for the practical management of warfarin therapy in the treatment of venous thromboembolism. J Thromb Thrombolysis (2016) 41:187–205. DOI 10.1007/s11239-015-1319-y

ATTACHMENT 2

Direct Oral Anticoagulant Management Guidelines

1. The DOAC referral will be evaluated for appropriateness and indication, specific criteria for use of DOAC if needed for insurance authorization, baseline labs (CBC, LFT, SCr), creatinine clearance (Cockcroft & Gault), needed labs, dosing for the indication, medication list for interactions and birth control if female of child-bearing age. The patient should ideally be scheduled for an appointment 1 week after the start of the medication.
2. At each follow-up visit, the patient is interviewed for dose, adherence, medication changes, signs of bleeding or bruising, falls or trauma and upcoming procedures. The SCr and CBC may be reviewed, needed labs are ordered, which may include CBC, LFT, BMP, CMP, SCr. Clinical judgement, based on patient's overall health, risk factors, adherence, should be used in the decision to order labs.
3. Depending on the DOAC medication and indication, the patient may be scheduled for follow-up at one week, three weeks, 3-6 months or at pharmacist's discretion:
    i. At each follow-up visit, the patient is educated on the medication, dosing, length of therapy, importance of adherence, drug interactions, signs of bleeding to report, and other cautions. Labs are reviewed and ordered if needed. Dosing adjustments are made if indicated by labs, or timing for the indication.
    ii. If at 6 months, patient's CrCl >60 ml/min, the patient only needs monitoring yearly with LFTs.
    iii. If at 6 months, CrCl <60 ml/min, age >75, wt <60 kg, OR medically fragile, an appointment to monitor every 6 months with annual LFTs should be made

ATTACHMENT 3

Optimal Therapeutic Range for Warfarin

Adapted from: Chest 2012;141 (2_suppl) Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-based Clinical Practice Guidelines

Indication	Goal INR/ Therapeutic Range
I. Atrial Fibrillation	
A. In valvular/nonvalvular heart disease	2.5 / 2.0-3.0 (chronic)
B. Atrial fibrillation if age>75	2.5 / 2.0-3.0 (chronic)
C. Pre-cardioversion (for afib>48 hrs)	3.0 / 2.5-3.5 (weekly for at least 3 weeks)
D. Post cardioversion	2.5 / 2.0-3.0 (4 weeks)
II. Cardioembolic Stroke	
A. Large stroke	2.5 / 2.0-3.0 (chronic, delay tx 5-14 days)
B. Small stroke	2.5 / 2.0-3.0 (chronic, delay tx 48 hours)
C. Embolic event despite anticoagulation	3.0 / 2.5-3.5 (chronic, -or- 2.5 / 2.0-3.0 + aspirin 160mg/day)
III. Left ventricular dysfunction	
A. Ejection fraction <30%	2.5 / 2.0-3.0 (1-3 months)
Transient, following MI	2.5 / 2.0-3.0 (1-3 months)
Embolic event despite anticoagulation	3.0 / 2.5-3.5 (chronic) - or- 2.5 / 2.0-3.0 (chronic) + aspirin 160mg/day
D. Mural thrombus	2.5 / 2.0-3.0 (1-3 months)
IV. Myocardial Infarction	
Following anterior MI with high risk of systemic or venous thromboembolism (i.e. a-fib, LV dysfxn, CHF, mural thrombus, hx of systemic or pulmonary embolism)	2.5 / 2.0-3.0 (1-3 months)
Following anterior or inferior MI with continued risk factor(s) such as a-fib, LV dysfxn, CHF, mural thrombus	2.5 / 2.0-3.0 (chronic)
V. Thromboembolism (DVT, PE)	
Reversible/time-limited risk factors Idiopathic DVT	2.5 / 2.0-3.0 (3-6 months)
B. Recurrence of DVT despite anticoagulation	3.0 / 2.5-3.5 (chronic)
C. Continued presence of risk factors (AT-III, protein C or protein S deficiency, malignancy)	2.5 / 2.0-3.0 (>12 months or chronic)
Certain patients with thrombosis, previous arterial or venous thromboembolism and antiphospholipid syndrome	2.5 / 2.0-3.0 (chronic)
E. If recurrent thromboembolic events with therapeutic INR or additional risk factors	3.0 / 2.5-3.5 (chronic)
F. First time idiopathic DVT after 6 months of full anticoagulation (INR 2.0-3.0)	1.5-2.0 (chronic)
VI. Valvular Disease	

A. Aortic valve disease	
W/ concurrent mitral valve disease	2.5 / 2.0-3.0 (chronic)
W/ associated atrial fibrillation	2.5 / 2.0-3.0 (chronic)
W/ history of systemic embolism	2.5 / 2.0-3.0 (chronic)
B. Mitral Annular Calcification	
W/ associated atrial fibrillation	2.5 / 2.0-3.0 (chronic)
W/ hx of systemic embolism	2.5 / 2.0-3.0 (chronic)
C. Mitral Valve Prolapse	
Associated with atrial fibrillation	2.5 / 2.0-3.0 (chronic)
W/ hx systemic embolism	2.5 / 2.0-3.0 (chronic)
W/ hx TIA despite aspirin treatment	2.5 / 2.0-3.0 (chronic)
D. Rheumatic Mitral Valve Disease	
Associated with atrial fibrillation	2.5 / 2.0-3.0 (chronic)
W/ hx of systemic embolism	2.5 / 2.0-3.0 (chronic)
S/P embolic event despite anticoagulation	2.5 / 2.0-3.0 (chronic + aspirin 80-100mg/day, dipyridamole 400mg/day, or clopidogrel 75 mg/day)
E. Mitral Valve Disease NSR and left atrial enlargement >5.5cm	2.5 / 2.0-3.0 (chronic)
VII. Valve Replacement	
A. Mechanical valve in mitral position	3.0 / 2.5-3.5 (chronic) -or- 2.5 / 2.0-3.0 (chronic) + aspirin 80-100mg/day (bileaflet only)
B. Mechanical valve with systemic embolus despite adequate anticoagulation	3.0 / 2.5-3.5 (chronic) + aspirin 81mg/day
C. Tissue valve prosthesis	2.5 / 2.0-3.0 (1-3 months)
D. Tissue valve with association of atrial fibrillation or left atrial thrombus	2.5 / 2.0-3.0 (chronic)
E. Tissue valve with history of systemic embolization	2.5 / 2.5-3.0 (3 -12 months or chronic)
F. Bileaflet mechanical valve (St. Jude bileaflet, Carbomedics bileaflet, or Medtronic Hall tilting disk) in aortic Position (in NSR, with normal left atrium and EF)	2.5 /2.0-3.0 (chronic)
G. Bileaflet mechanical aortic valves with atrial fibrillation	3.0 / 2.5-3.5 (chronic) -or- 2.5 / 2.0-3.0 (chronic) +aspirin 80-100mg/day
H. Caged ball or caged disk valves	3.0 / 2.5-3.5 (chronic) +aspirin 80-100mg/day
I. On-X valve	2.5 / 2.0-3.0 (AVR) for 3 months. May initiate lower range 1.8 / (1.5-2.0) +/- aspirin 81 mg/day in patients without prior valve thrombotic events after 3 months. 3.0 / 2.5-3.5 (MVR)

*INR goal ranges outside those above may be considered for management based on provider discretion. Providers can delegate prescriptive authority to pharmacists for target INR ranges not included in the guideline.

ATTACHMENT 4

Pulse Heart Institute and MHS Medication Management Clinics Bridge Guideline

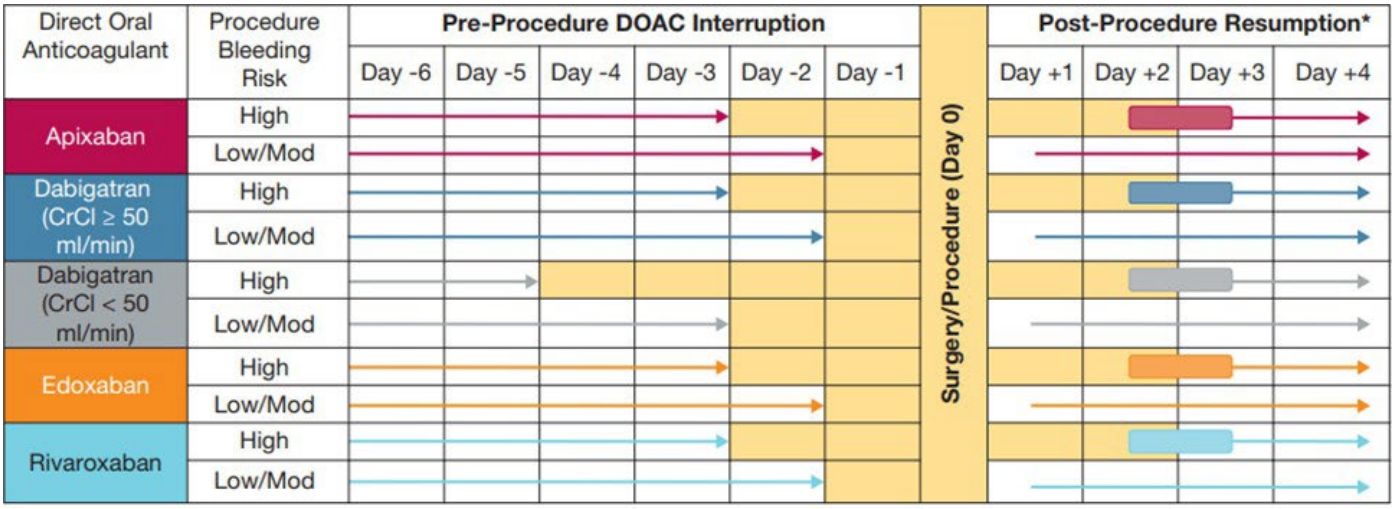
Adapted from the UW bridging guidelines, 2017

RISK STRATIFICATION AND RECOMMENDATONS FOR BRIDGE THERAPY IN PATIENTS ON WARFARIN

Risk Stratum and Recommendations for Use of Bridge Therapy	Indication for Anticoagulant Therapy			
	Venous Thromboembolism	**Atrial Fibrillation**	**Mechanical Heart Valve**	**Low Ejection Fraction with Normal Sinus Rhythm**
	from Peri-operative management of antithrombotic therapy: Antithrombotic Therapy and Prevention of Thrombosis, 9th Edition. American College of Chest Physicians Evidence Based Clinical Practice Guidelines. *Chest* 2012; 141 (suppl 2): e326s – e350s.	*from* 2017 ACC Expert Consensus Decision Pathway for Peri-Procedural Management of Anticoagulation in Patients with Non-Valvular AF. *JACC* 2017;69:	*from* 2014 AHA/ACC Guideline for the Management of Patients with Valvular Heart Disease. *JACC* 2014: 63:e57-e185:	*from* UWMedicine Division of Cardiology
HIGH RISK *Recommendation:* **Use bridging (Grade 2C)**	• recent (within 3 months) VTE • history of VTE or recurrent VTE in the setting of severe thrombophilia *(e.g., protein C or S deficiency, antithrombin deficiency, antiphospholipid antibodies, homozygous factor V Leiden, or multiple abnormalities)*	• CHA_2DS_2-VASc score of ≥ 7 ***OR*** • prior stroke/TIA or systemic embolism within 3 months ***Consider delaying procedure*** *beyond 3 months if prior stroke/TIA or systemic embolism within 3 months.* ***Do not bridge*** *if at increased risk of bleeding due to major bleed/ICH < 3 months ago*	• any mitral valve prosthesis • any tricuspid valve prosthesis • older (caged-ball or tilting disc) aortic valve prosthesis • bileaflet aortic valve prosthesis and any additional risk factor for stroke or thromboembolism *(atrial fibrillation, prior stroke/TIA or thromboembolism, known hypercoagulable condition, LV dysfunction)*	• mural thrombus present on echo • documented mural thrombus in the past 3 months • recent (within 3 months) stroke or transient ischemic attack
RISK MODERATE *Recommendation:* **Determine bridging vs not bridging based on assessment of individual patient and surgery-related factors (Not Graded)**	• VTE within the past 3 to 12 months • recurrent VTE • history of VTE or recurrent VTE in the setting of non-severe thrombophilic conditions *(e.g., heterozygous factor V Leiden, heterozygous factor II mutation)* • active cancer (treated within 6 months or palliative) *NOTE: consider VTE prophylaxis rather than full intensity bridge therapy in these situations and is associated with a lower risk of bleeding*	• CHA_2DS_2-VASc score of 5-6 ***OR*** • prior stroke/TIA or systemic embolism > 3 months ago ***Do not bridge*** *if there is no history of prior stroke/TIA or systemic embolism* ***Do not bridge*** *if at increased risk of bleeding due to major bleed/ICH < 3 months ago; platelet abnormality including aspirin use; INR above therapeutic range; prior bleed from previous bridging*		• history of cardioembolic stroke or transient ischemic attack • history of mural thrombus with persistent risk factors *(apical akinesis, LV aneurysm, dilated LV)*
LOW RISK *Recommendation:* **Do not use bridging (Grade 2C)**	• single VTE occurred greater than 12 months ago and no other risk factors	• CHA_2DS_2-VASc score of 1-4 ***AND*** • no prior stroke/TIA or systemic embolism	• bileaflet aortic valve prosthesis without atrial fibrillation and with no other risk factors for stroke or thromboembolism	• no history of mural thrombus

ATTACHMENT 5

DOAC Periprocedural Recommendations



No DOAC administered that day

*DOAC can be resumed ~24 hours after low/moderate-bleed-risk procedures, and 48-72 hours after high-bleed-risk procedures. In selected patients at high risk for VTE, low-dose anticoagulants (i.e., enoxaparin, 40 mg daily or dalteparin, 5,000 IU daily) can be given for the first 48-72 hours post-procedure.

Periprocedural Management (DOAC)

Bleed Risk Evaluation		
Patient bleeding risk factors? Any one of these: • major bleeding or ICH < 3 months ago • platelet abnormality (including ASA use) • prior bleed during previous bridging or similar procedure	**Procedure bleed risk (see below for examples)**	**Whether or not to interrupt**
No	Minimal, No clinically important risk	-Do Not interrupt DOAC (time procedure at DOAC trough level)
	Low	-Interrupt DOAC -Do not bridge
	Intermediate, high, uncertain	
Yes	Any bleed risk category	

Examples of Procedure Bleed Risk*

Min. bleed risk		Low bleed risk	High bleed risk		
• Minor dental procedures • Cataract/ glaucoma • Superficial skin incisions/ excisions	• Diagnostic GI endoscopy w/ wo biopsy • Central catheter removal	• GI procedures (eg. colonoscopy, gastroscopy) • Cardiac procedures (eg. pacemaker/defib implantation, arterioventricular node ablation, angiography-radial approach)	• Surgery requiring neuraxial anesthesia • Major intracranial or neuraxial surgery (eg. laminectomy) • Major thoracic surgery (eg. lobectomy)	• Major cardiac surgery (eg. CABG) • Major vascular surgery (eg. carotid endarterectomy) • Major orthopedic surgery (eg. arthroplasty)	• Major abdominopelvic surgery (eg. bowel resection) • Other major cancer or reconstructive surgery

* For full list of procedures, see online appendix to the 2017 ACC Expert Consensus Decision Pathway for Periprocedural Management

ATTACHMENT 6

CHA_2DS_2-VASc Score and HAS-BLED Score

CHA_2DS_2-VASc score: a refinement of the CHADS2 score and extends the latter by including additional common stroke risk factors.

	Condition	Points
C	Congestive heart failure (or Left ventricular systolic dysfunction)	1
H	Hypertension: blood pressure consistently above 140/90 mmHg (or treated hypertension on medication)	1
A_2	Age ≥75 years	2
D	Diabetes Mellitus	1
S_2	Prior Stroke or TIA or thromboembolism	2
V	Vascular disease (previous MI, peripheral arterial disease or aortic plaque)	1
A	Age 65-74 years	1
Sc	Sex category (female gender)	1

A high CHA_2DS_2VASc Score corresponds to a greater risk of stroke, while a low CHA_2DS_2-VASc score corresponds to a lower risk of stroke.

Approach to therapy (thromboprophylaxis) in patients with Atrial Fibrillation			
Score	Risk Level	Anticoagulation Therapy	Considerations
0	Low	No antithrombotic therapy (or Aspirin)	No antithrombotic therapy (or Aspirin 75-325mg daily)
1	Intermediate	Oral anticoagulant (or Aspirin)	Oral anticoagulant (warfarin at INR 2.0-3.0 or DOAC) or Aspirin 75-325mg daily, depending on factors such as patient preference.
2 or greater	High	Oral anticoagulant	Oral anticoagulant (warfarin well-controlled at INR 2.0-3.0 or DOAC)

HAS-BLED score: to assess the individual bleeding risk of real-world patients with AF.

Clinical Characteristics Composing the HAS-BLED Bleeding Risk Score

Letter	Clinical Characteristic	Points Awarded
H	Hypertension	1
A	Abnormal renal and liver function (1 point each)	1 or 2
S	Stroke	1
B	Bleeding	1
L	Labile INRs	1
E	Elderly	1
D	Drugs (ie, ASA/Plavix) or alcohol (1 point each)	1 or 2
Maximum possible score is 9		

The risk of major bleeding within one year in atrial fibrillation patients enrolled in the Euro Heart Survey.

HAS-BLED score	n	Bleeds, n	Bleeds/100 patients*
0	798	9	1.13
1	1286	13	1.02
2	744	14	1.88
3	187	7	3.74
4	46	4	8.70
5	8	1	12.50
Any score	3071	48	1.56

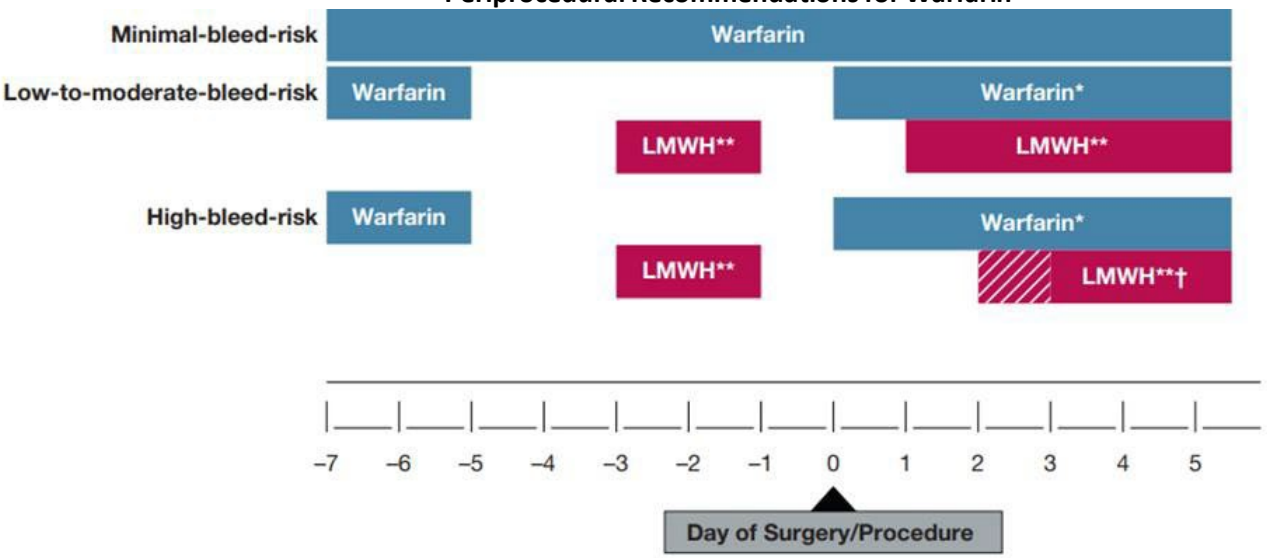
References:

Pisters R, Lane DA, Nieuwlaat R, de Vos CB, Crijns HJ, Lip GY. "A novel user-friendly score (HAS-BLED) to assess one-year risk of major bleeding in atrial fibrillation patients: The Euro Heart Survey." Chest. 2010 Mar 18.

Lip GYH, Frison L, Halperin JL, Lane DA. Comparative validation of a novel risk score for predicting bleeding risk in anticoagulated patients with atrial fibrillation: the HAS-BLED (Hypertension, Abnormal Renal/Liver Function, Stroke, Bleeding History or Predisposition,Labile INR, Elderly, Drugs/Alcohol Concomitantly) score. J Am Coll Cardiol 2011;57:173– 80.

ATTACHMENT 7

Periprocedural Recommendations for Warfarin



Legend

*Warfarin can be resumed on the evening of procedure (D0) for most patients, or the day after procedure (i.e., D1) at the patient's usual maintenance dose.

**Bridging suggested for high thrombotic risk populations with full-dose, subcutaneous LMWH (e.g., enoxaparin, 1 mg/kg bid or 1.5 mg/kg daily or dalteparin, 100 IU/kg bid or 200 IU/kg daily), with the last dose given the AM of the day prior to the procedure (i.e., D-1) at half the total daily dose.

†Low-dose LMWH (e.g., enoxaparin, 40 mg daily or dalteparin 5,000 IU daily) can be used for VTE prophylaxis for first 24-72 hours post-procedure, with full dose LMWH resumed 2-3 days post-procedure.

BLEEDING RISK	THROMBOEMBOLIC RISK	SUGGESTION
LOW	LOW, MODERATE or HIGH	Perform surgery/procedure under therapeutic anticoagulation. - No change in warfarin dose - May use post-op prophylaxis w/ UFH or LMWH if the surgery/procedure itself creates a higher risk of thrombosis
MODERATE	LOW	Perform surgery/procedure with reduced anticoagulation i.e. INR $\leq$ 1.5 - Hold warfarin for 5 days pre-op - Recommend low dose SC LMWH - Resume warfarin 12-24 hours post-operatively
	MODERATE or HIGH	Perform surgery/procedure with reduced anticoagulation i.e. INR $\leq$ 1.5 - Hold warfarin for 5 days pre-op - Initiate LMWH when INR falls below lower limit of therapeutic range while warfarin is being held. - Stop LMWH 24 hours pre-operatively. For the last pre-operative dosage recommend only administering 50% of the total daily dosage. - For minor procedures resume LMWH 24 hours post-operatively or when bleeding risk is judged low enough, and continue until INR > lower limit of therapeutic range - For major procedures or patients who have high bleeding risk delay initiation of therapeutic dose LMWH/UFH for 48 to 72 hours after surgery, administering low dose LMWH/UFH after surgery when hemostasis is secured, or completely avoiding LMWH/UFH - Resume warfarin 12-24 hours post op

HIGH	LOW	Perform surgery/procedure with reversed anticoagulation - Hold warfarin for 5 days pre-operatively - May use post-op prophylaxis if the surgery/procedure itself creates a higher risk of thrombosis (low dose LMWH or UFH) - Resume warfarin 24-48 hours post-op.
	MODERATE or HIGH	Perform surgery/procedure with reversed anticoagulation - Hold warfarin for 5 days pre-operatively – do not use vit K - Alternatively, hold warfarin for 2-3 days pre-op, use vit k to hasten effect - Give vitamin K 1-2.5 mg orally 2 days pre-op (may repeat next day if INR >1.8) - Stop LMWH 24 hours pre-operatively. For the last pre-operative dosage recommend only administering 50% of the total daily dosage. - For minor procedures resume LMWH 24 hours post-operatively or when bleeding risk is judged low enough, and continue until INR > lower limit of therapeutic range - For major procedures or patients who have high bleeding risk delay initiation of therapeutic dose LMWH/UFH for 48 to 72 hours after surgery, administering low dose LMWH/UFH after surgery when hemostasis is secured, or completely avoiding LMWH/UFH - Resume warfarin 12-24 hours post op

Vena cava filter insertion should be considered in patients at very high risk of thromboembolism and in whom effective anticoagulation cannot be started.

See MHS Thrombosis Risk Assessment for Surgical and Medical patients and Adult Thromboembolic Prophylaxis Orders.

ATTACHMENT 8

Warfarin and Dental Procedures

A review of dental surgery literature concluded that the risk of thrombotic complications was three times more likely in patients withdrawn from warfarin therapy than were bleeding complications in patients maintained on warfarin therapy (Wahl MJ. Myths of Dental Surgery in Patients Receiving Anticoagulant Therapy. JADA. 2000; 131: 77-81).

Most dental procedures can be performed at full anticoagulation.

Dental Procedure	Suboptimal INR Range	Suboptimal INR range	Normal Target INR Range	Normal Target INR Range	Normal Target INR Range FOR MVR/AVR	Out of Range
	<1.5	1.6-1.9	2.0-2.5	2.5-3.0	3.1-3.5	>3.5
Exam, X-Ray, Study Models	Safe	Safe	Safe	Safe	Safe	No Data
Simple Restoration, Supragingival Prophylxis	Safe	Safe	Safe	Safe	Safe	NOT ADVISED
Complex Restoration, Scaling, Root Planing, Endodontics	Safe	Safe	Safe	Safe	No Data	NOT ADVISED
Simple Extraction, Curettage, Gingivoplasty	Safe	Safe	Safe	Local Measures	Local Measures	NOT ADVISED
Multiple Extractions, Removal of Single Bony Impaction	Safe	Safe	Local Measures	Local Measures	Local Measures	NOT ADVISED
Gingivecgtomy, Apicoectomy, Minor Periodontal Flap, Single Implant	No Data	No Data	No Data	NOT ADVISED	NOT ADVISED	NOT ADVISED
Full Mouth/Full Arch Extractions	No Data	Local Measures	NOT ADVISED	NOT ADVISED	NOT ADVISED	NOT ADVISED
Extensive Flap Surgery, Multiple Bony Impactions, Multiple Implants	No Data	No Data	NOT ADVISED	NOT ADVISED	NOT ADVISED	NOT ADVISED
Open Fracture Reduction, Orthognathic Surgery	NOT ADVISED	NOT ADVISED	NOT ADVISED	NOT ADVISED	NOT ADVISED	NOT ADVISED

- **Safe** indicates that it is safe to proceed in a routine manner (local factors such as periodontal/gingival inflammation can increase the severity of bleeding; clinician should consider all factors when making a risk assessment.)
- **No Data/Local Measures** indicates that there is insufficient research to draw a conclusion. In many instances the procedure can be performed with judicious use of local measures (sutures, oxidized cellulose, microfibrillar collagen, topical thrombin and/or tranexamic acid.)
- **NOT ADVISED** indicates that it is probably not safe to proceed at the current INR level. Refer to the anticoagulation clinic or physician managing the patient's warfarin therapy.

Reference: Herman WW, Konzelman JL, Sutley SH. Current Perspectives on Dental patients Receiving Coumarin Anticoagulant Therapy. JADA 1997;128(3):327-35. Table 2 on page 329.

It seems unlikely that there would be any additional risk of bleeding at an INR <1.5 since people who have never taken warfarin can have an INR as high as 1.2.

EDITOR'S NOTE: CAREFULLY CONSIDER THE EFFECT THAT STOPPING WARFARIN THERAPY FOR EVEN A FEW DAYS CAN HAVE ON THE PATIENT. A MODERATE AMOUNT OF BLEEDING IS A MINOR INCONVENIENCE COMPARED WITH A PARALYZING STROKE OR DEATH.

ATTACHMENT 9

Self-Testing Patients/Home INR Monitoring Guidelines

Insurance Requirements:

Medicare will cover the use of home PT/INR monitoring for chronic, oral anticoagulation management for patients with mechanical heart valves, chronic atrial fibrillation, or venous thromboembolism (inclusive of deep venous thrombosis and pulmonary embolism) on warfarin. The monitor and the home testing must be prescribed by a treating physician as provided at 42 CFR 410.32(a), and all the following requirements must be met:

1. The patient must have been anticoagulated for at least 3 months prior to use of the home INR device; and,
2. The patient must undergo a face-to-face educational program on anticoagulation management and must have demonstrated the correct use of the device prior to its use in the home; and,
3. The patient continues to correctly use the device in the context of the management of the anticoagulation therapy following the initiation of home monitoring; and,
4. Self-testing with the device should not occur more frequently than once a week for insurance billing. More frequent testing may be necessary based on clinical circumstances but cannot be billed for.
5. An annual office visit is required, including recertification of the home monitoring device.

ATTACHMENT 10

LMWH Monitoring Guidelines

Adapted from University of Washington Monitoring For Long Term LMWH Therapy, Ventura County Medical Center/Santa Paula Hospital (VCMC/SPH): Low Molecular Weight Heparin (Enoxaparin) Protocol, and Wyoming Medical Center: WMC Pharmacy Anticoagulation Protocol.

Follow-ups	
After initial visit	1 month
Clinically stable	q3-6 months
After each hospitalization	within 2 weeks

Lab monitoring	
SCr/CrCl	q3-6 months if CrCl ≥50 mL/min q3 months if CrCl <50 mL/min Adjust LMWH dose if needed
Platelet	q3-6 months Standard: 150,000 - 400,000 Assess for bleeding risk if Plt <50,000 Assess for clotting risk if Plt >400,000
Hemoglobin	q3-6 months Standard: Men: 14 - 18 gm/dL Women: 12 gm/dL and 16 gm/dL
Hematocrit	q3-6 months Standard: For men: 41% to 50% For women: 36% to 44%
Anti-Xa	If measured, check peak anti-Xa level 3-4 hours after a dose observed peak anti-Xa levels for q12h dosing of LMWHs (e.g enoxaparin 1mg/kg q12h) = 0.5-1 units/mL observed peak anti-Xa levels for 1.5mg/kg q24h dosing of LMWHs (e.g enoxaparin 1.5mg/kg q24h) = 1-2 units/mL Obtain lab only q3-6 months for patient with: CrCl < 30 mL/min Pregnancy Morbid obesity (BMI >40 or >190 kg) Low body weight (<45 kg) Patients who are expected to be on LMWH therapy > 6 months Suspected over-anticoagulation (i.e. bleeding complications) as needed

ATTACHMENT 11

Adapted from University of Washington Anticoagulation Services: Monitoring LMWHs In Pregnancy

Monitoring LMWHs In Pregnancy

Use of LMWH in pregnancy 3rd trimester	
Patient weight	q2 weeks
Platelet count	q2 weeks
Hematocrit	q2 weeks
Serum creatinine/CrCl	q2 weeks and adjust LMWH dose if needed
Trough antiXa level	q1 month if CrCl > 60ml/min or q2 weeks if < 60ml/min Goal: <0.5 units/ml (adjust LMWH dose or dosing interval if needed)
Peak antiXa level	q2 weeks (check 4 hrs after dose) Goal: 0.5-1 units/ml (for q12h dosing of LMWH) Adjust LMWH dosing if needed, according to suggestions below

LMWH dosage adjustments based on peak antiXa levels

[from Monagle P et al. Chest 2001; 119 (suppl 1): 344-370]

Peak antiXa level (units/ml)	Hold next dose	Dosage change	Next antiXa level
<0.35	No	Increase 25%	4hrs after next dose
0.35-0.49	No	Increase 10%	4hrs after next dose
0.5-1	No	None	Next day, then within 1 week
1.1-1.5	No	Decrease 20%	Before next dose
1.6-2	For 3 hours	Decrease 30%	Before next dose and 4hrs after next dose
>2	Until antiXa level <0.5	Decrease 40%	Before next dose and q12h until antiXa level <0.5

ATTACHMENT 12

University of Washington Anticoagulation Services: Monitoring LMWH In Obesity

Dosing LMWH in obesity

- Suggested initial dose based on renal function:
    - CrCl >60: 1 mg/kg q12h
    - CrCl 30-60: 0.85 mg/kg q12h
    - CrCl <30: UFH preferred or 1mg/kg q24h
- Based on anti-Xa monitoring studies, enoxaparin doses of 0.7-1 mg/kg BID have achieved expected anti-Xa levels in obese patients with normal renal function
- Enoxaparin 1.5mg/kg once daily dosing should be avoided in patients who weigh >120 kg
- For patients who weigh >190 kg and require treatment doses of enoxaparin, dose based on TBW

ATTACHMENT 13

Adapted from University of Washington Anticoagulation Services: General Dosing Guidelines

UW Medicine
PHARMACY SERVICES

LOW MOLECULAR WEIGHT HEPARIN DOSING RECOMMENDATIONS

CLINICAL SCENARIO	LMWH DOSING RECOMMENDATIONS	
	ENOXAPARIN (preferred LMWH)	**DALTEPARIN (no dose-capping)**
VTE PROPHYLAXIS		
Orthopedic surgery (hip/knee replacement, hip fracture)	30mg q12h	5000 units daily
Trauma	30mg q12h	5000 units daily
Acute spinal cord injury	30mg q12h	5000 units daily
Acute medical illness	40mg daily	5000 units daily
General surgery	40mg daily	5000 units daily
Bariatric surgery	40mg q12h	Not recommended
Morbid obesity (BMI > 40)	40mg q12h	Not recommended
Low body weight (wt ≤ 45 kg or BMI ≤ 18.5)	30mg q24h or 40mg q24h	5000 units daily
Severe renal impairment (CrCl < 30)	30mg daily	5000 units daily
VTE TREATMENT	Use total body weight (TBW) to calculate dosing	
Venous thrombosis *(LMWH for a minimum of 5 days)*	1mg/kg[1] SQ q12h	200 units/kg[2] daily
Cancer-associated venous thrombosis *(LMWH for a minimum of 3-6 months)*	Dalteparin preferred, or enoxaparin 1mg/kg[1] q12h x 1 month, then 1.5 mg/kg[1] daily	200 units/kg[2] daily x 1 month, then 150 units/kg[2] daily
Pregnancy	1mg/kg[1] q12h	100 units/kg[3] q12h
Low body weight (wt ≤ 45 kg)	1mg/kg[1] q12h	200 units/kg[4] daily
Obesity (wt ≥ 99 kg)	1mg/kg[1] q12h	100 units/kg[3] q12h
Moderate renal impairment (CrCl 30-60)	0.85mg/kg[1] q12h	200 units/kg[2] daily
Severe renal impairment (CrCl < 30)	UFH preferred, or 1mg/kg[1] daily	Not recommended
ACUTE CORONARY SYNDROME	Use TBW to calculate dosing	
Unstable angina/NQWMI	1mg/kg[1] q12h	120 units/kg[3] q12h
Renal impairment (CrCl < 60)	UFH preferred	UFH preferred
BRIDGE THERAPY	Use TBW to calculate dosing. UFH preferred, or:	
Atrial fibrillation	1mg/kg[1] q12h	100 Units/kg[3] q12 hrs
Heart valve replacement	1mg/kg[1] q12h	100 Units/kg[3] q12 hrs
History of VTE	1mg/kg[1] q12h	200 units/kg[2] daily
Pregnancy	1mg/kg[1] q12h	100 units/kg[3] q12 hrs
Low body weight (wt ≤ 45 kg)	1mg/kg[1] q12h	100 units/kg[4] q12 hrs
Obesity (wt ≥ 99 kg)	1mg/kg[1] q12h	100 units/kg[3] q12 hrs
Moderate renal impairment (CrCl 30-60)	0.85mg/kg[1] q12h	100 units/kg[3] q12 hrs
Severe renal impairment (CrCl < 30)	UFH preferred, or 1mg/kg[1] q24h	Not recommended

[1] rounded to nearest syringe marking
[2] rounded to nearest syringe size *(see below)*
[3] rounded to nearest 100 units *(use 25,000 unit/ml MDV)*
[4] rounded to nearest 500 units *(use 10,000 unit/ml graduated syringe)*

DALTEPARIN DOSING PER TOTAL BODY WEIGHT		
TBW (kg)	**Recommended syringe size for 200 U/kg daily dose***	**Recommended syringe size for 150 U/kg daily dose**
≤ 45 kg	200 units/kg[4] SQ daily	150 units/kg[4] SQ daily
46-56	10,000 units/1ml (graduated)	7500 units/0.3ml (not graduated)
57-68	12,500 units/0.5ml (not graduated)	10,000 units/1ml (graduated)
69-82	15,000 units/0.6ml (not graduated)	12.500 units/0.5ml (not graduated)
83-98	18,000 units/0.72ml (not graduated)	15,000 units/0.8ml (not graduated)
≥ 99 kg	100 units/kg[2] SQ q12h	150 units/kg[2] SQ daily

University of Washington Medicine Anticoagulation Services
December 2022

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University of Washington Anticoagulation Services: General Dosing Guidelines

University of Washington Anticoagulation Services: Monitoring For Long Term LMWH Therapy University of

Washington Anticoagulation Services: Monitoring LMWH In Obesity

University of Washington Anticoagulation Services: Monitoring LMWHs In Pregnancy

Ventura County Medical Center/Santa Paula Hospital (VCMC/SPH): Attachment C: Low Molecular Weight Heparin (Enoxaparin) Protocol. https://hospitals.vchca.org/images/pharmacy_hca/20200515_LMWH_protocvol.pdf

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Asthma Protocol

Guidelines from the MultiCare Ambulatory Care Clinical Pharmacist

Pharmacist Authors/Editors: Linnea Read, Gary Burton, and Robin Brown

November 2024

Inclusion Criteria: *All criteria must be met*

- Over age 18
- Not pregnant
- Not enrolled in hospice
- Seen or virtually managed by provider within last 12 months.

Patient Evaluation: Initial and Subsequent Visits

- Determine current step of therapy based on GINA stepwise therapy (see Figure 1) and GINA assessment of asthma symptom control (see Figure 2)

Physical Exam:

- Obtain vitals – BP, HR, O2 saturation, Height, Weight

Patient Education:

- Purpose of visits to the Clinical Pharmacist
- Medication use: indication, dosage, administration, possible side effects and monitoring
- Assess inhaler and nebulizer technique at every visit with patient demonstration (with description or inhaler if available) and "teach back" method.
- Red flags that might indicate the start of an exacerbation.
    - Patient seems to be wheezing/SOB during exam.
    - Increased use of rescue inhaler(s) or nebulizer(s)
- Benefits of adherence with medication
- Non-pharmacological strategies
    - Cessation of smoking and environmental smoke exposure
    - Avoidance of medications that make asthma worse, (patient-specific)
        - Beta blockers
        - NSAIDs/aspirin
    - Avoidance of occupational exposures (such as gas, fumes)
    - Regular physical activity
    - Avoidance of indoor allergens is NOT recommended as a general strategy in asthma.
    - Avoidance of indoor air pollutants by using non-polluting heating and cooking sources
    - Avoidance of outdoor allergens, air pollutants, weather conditions (i.e., smog, fire smoke,etc.)
    - Weight reduction in obese patients
- Risk factors for poor asthma outcomes, patient-specific (see Figure 3: Risk factors for poor asthma outcomes)
- Initiate/review asthma action plan (provided in Asthma Visit Resources folder)
- Provide patient education handouts as needed (provided in Asthma Visit Resources folder)
- Discuss importance of follow-up, especially after exacerbations

Adherence:

- Assess barriers to adherence; including, but not limited to patient understanding, finances, and social support

Managing Adverse Effects:

- Anticholinergic side effects: assess based upon side effects and adjust accordingly.
- Shakiness/anxiety/increased heart rate with a short-acting beta agonist: consider switch to levalbuterol or step up in maintenance therapy based on average use.
- Inhaled corticosteroid oral thrush – "swish-and-spit" with water after use for prevention

Referring Provider Consultation:

- If a patient has O_2 sats ≤90%, provider will be consulted.
- If a patient is showing signs of an exacerbation, the provider will be consulted.
- If there is need for a nebulizer or other durable medical equipment
- If a patient demonstrates signs and/or symptoms of oral thrush

Preventative care:

The pharmacist may order or perform the following labs, tests, and referrals as recommended bythe Global Initiative for Asthma:

Spirometry

- yearly or as indicated based on stability of breathing.

Immunizations:

- Annual influenza vaccination is recommended.
- There is insufficient evidence to recommend routine pneumococcal vaccination in all people withasthma; keep patient specific.
  Pneumococcal Vaccine Recommendations | CDC
- COVID19 vaccination per CDC/FDA guidelines
  Vaccines for COVID-19 | CDC

Documentation:

- Document the visit in the electronic medical record per policy.
- Update medication list
- Communicate visit summary with referring provider after each visit if needed (via TE)

Follow Up Intervals:

- Every 1-3 months while gaining control (consider risk factors and frequency of exacerbations)
- Every 3-12 months to monitor control.
- After an exacerbation, a review visit within one week should be scheduled.
- Every 3 months if step down therapy is anticipated.
- Patient to call if they notice worsening dyspnea, increased sputum production, or purulent sputum.
- Once patient's breathing condition is stabilized for 2 consecutive visits or every 12 months, respiratory evaluation and management will be referred to the PCP.

Pharmacotherapy:

The following medications may be initiated, modified, or discontinued by the clinic pharmacists:

- Inhaled corticosteroids (ICS)
- Short- and long-acting $beta_2$ inhalers (SABA and LABA)
- Short- and long-acting anticholinergic inhalers
- Inhalers that combine any of the above
- Leukotriene receptor antagonist (montelukast)

Initiating Therapy:

- Therapy will be started at dose appropriate for asthma based on patient severity and classification.
- Choices will be made with consideration to drug interactions, concomitant disease states, and previous history with blood sugar lowering agents, side effects, or intolerances.
- Treatment decisions will consider patient needs, preferences, and insurance coverage.
- See Figure 1: Asthma Stepwise Therapy for GINA guideline recommendations.

Adjusting Therapy:

- Therapy will be adjusted based on patient response to prescribed medication and its effects on dyspnea and activity.
- Doses will be increased as guided by manufacturer recommendations.
- The option to increase the doses of medications over the phone may be based on patient preference, tolerance of medication, and self-sufficiency.
- See Figure 1: Asthma Stepwise Therapy for GINA guideline recommendations

Step-Down Therapy:

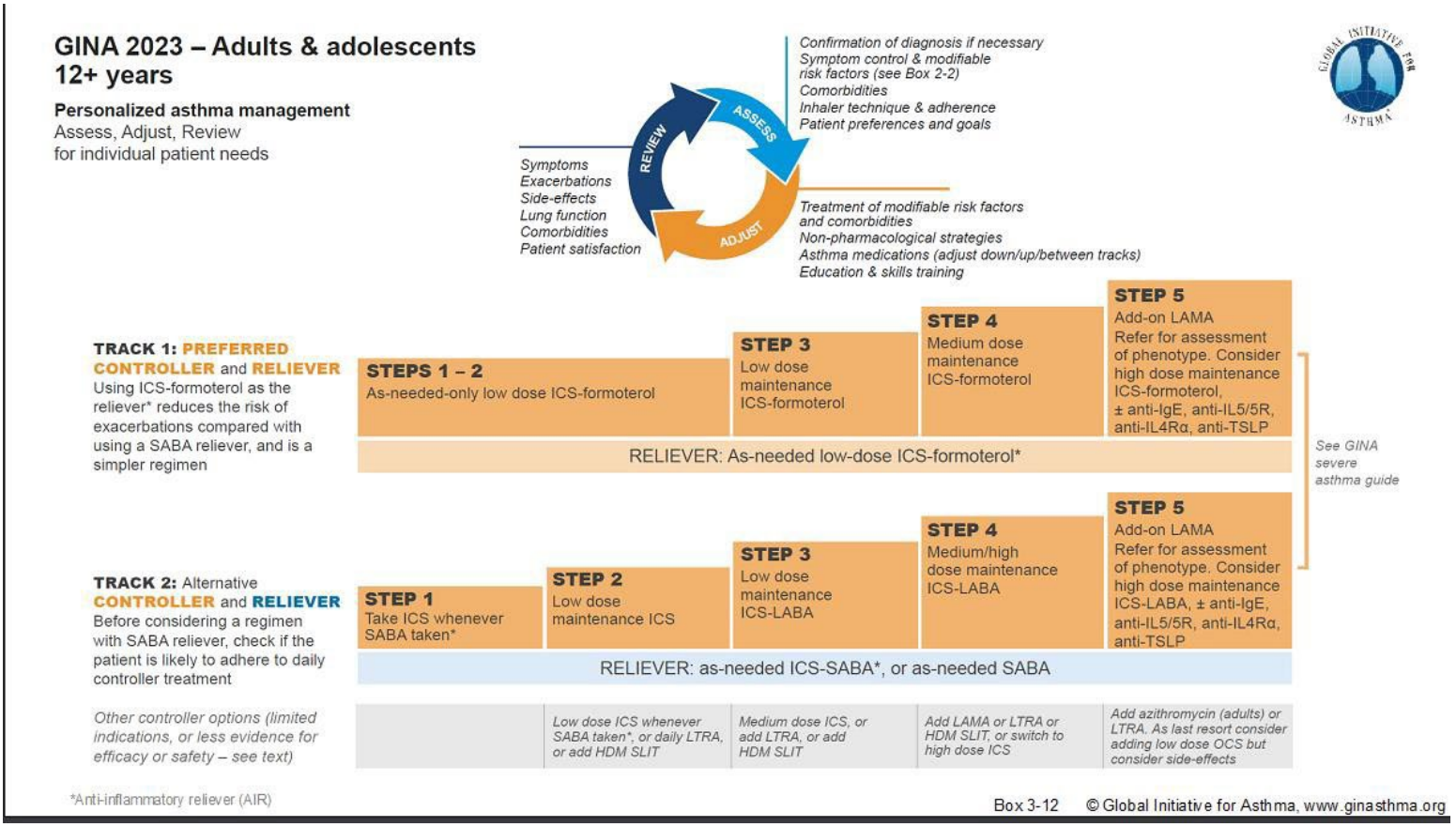
- Consider step-down therapy once good asthma control has been achieved and maintained for three months to find the minimum effective dose that controls both symptoms and exacerbations.
- Any step-down should be considered a therapeutic trial; patients should be provided with an updated asthma action plan and instructions for how and when to resume previous treatment if symptoms worsen.

Training for new pharmacists in asthma management:

Mentorship and training side-by-side with current pharmacist including:

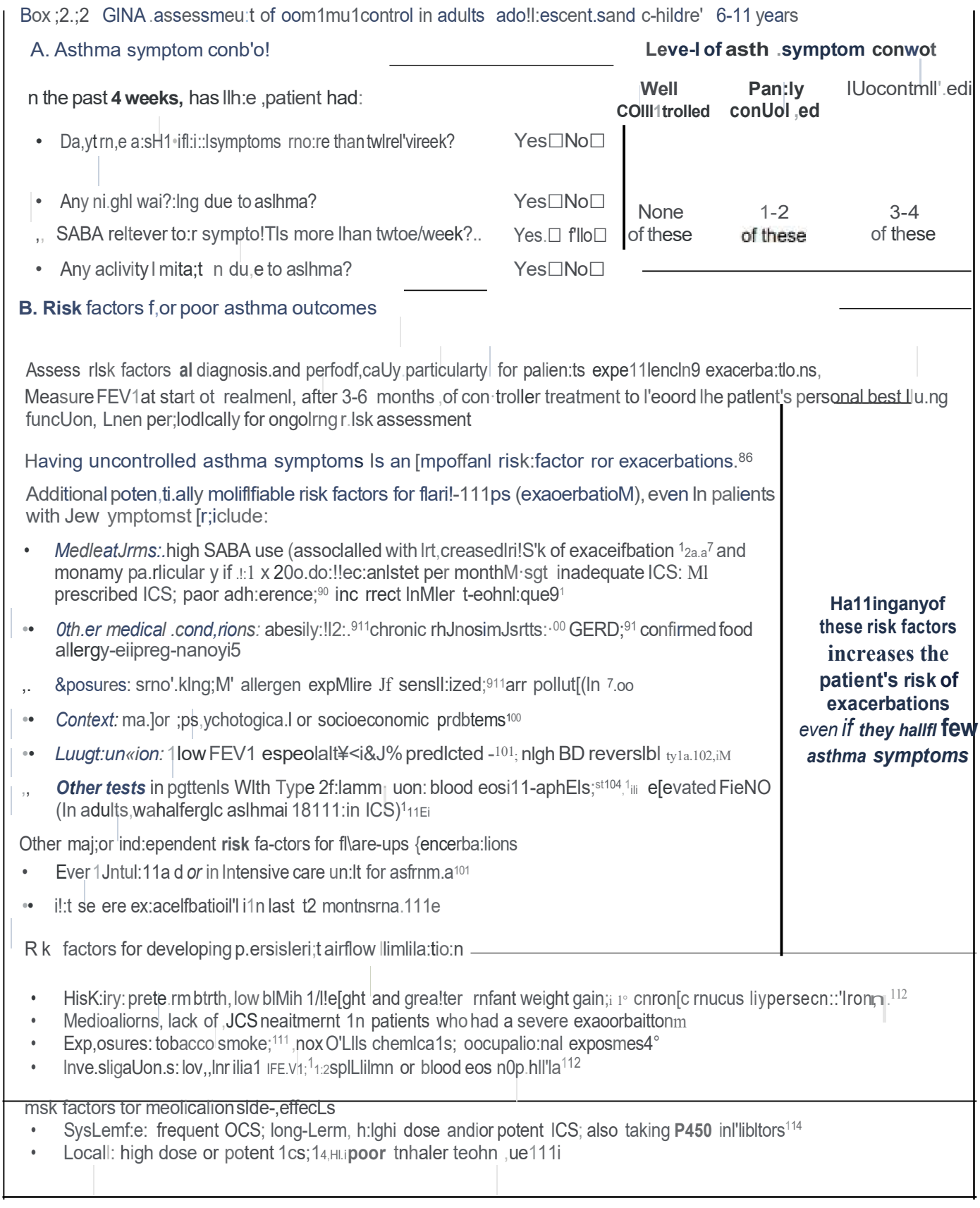
- Validation of clinical competency
- Review of guideline, any guideline updates, and current evidence-based medicine
- Training and bi-annual evaluation completed and documented by management team based on Asthma/COPD Training Resources
- BCACP training module on Pulmonary Disorders

Figure 1: Asthma stepwise therapy



[GINA Slide Set - Global Initiative for Asthma - GINA (ginasthma.org)]

Figure 2: GINA Assessment of Asthma Control



lBD-: bromfmdilator; FEV,: fornad expir:a'lo!y vd:uma **in 1** second; lCS: inhaled oorucoslsliOid; OCS: OJBl olll'libois.!aliOid; f¾5[) lnhilitots: cyl001rnma Pil50 in ibilars such ɛis milona,'l'ir. ketocooamte, iiraconaii!cla,;SABA: **shad-ao'ling** tie- a.gooist **'Based** on, &AB.A (as-needed tcS-fDmlOterlJJI l'EllievE!r not included): axciudss reliaYer taken bsJGilll exe.cise, Fon:hidEl S-11 **ears,** rerar'to Box 2--J, p.37. See Bm; 3-B, p.74 fMspecilic ri6k reduciioo :strategies. 'lndapandellf rralUaciora ar,e lh.ose lhal are ,@gnifimnt aft0J'"adjµstment foclhe 1e...a1al:symplom conlrol.

Figure 3: GINA evidence for as needed low-dose ICS-formoterol.

Track 1, Steps 1–2: As-needed-only low-dose ICS-formoterol

- Risk of severe exacerbations *(Crossingham et al, Cochrane 2021)*
  - Compared with as-needed SABA alone: **55% reduction** (OR 0.45 [0.34–0.60])
  - Compared with daily ICS plus as-needed SABA: (OR 0.79 [0.59–1.07])
- Risk of emergency department visits or hospitalizations *(Crossingham et al, Cochrane 2021)*
  - Compared with as-needed SABA alone: **65% reduction** (OR 0.35 [0.20–0.60])
  - Compared with daily ICS plus as-needed SABA: **37% reduction** (OR 0.63 [0.44–0.91])
  - Large population-level reduction in healthcare utilization

Track 2, Steps 1–2: As-needed-only ICS-SABA

Combination as-needed ICS-SABA

- BEST study, combination BDP-albuterol *(Papi et al, NEJMed 2007, n=445, 6 months)*
  - Mean number of exacerbations per patient per year lower with as-needed combination (0.74) and regular BDP (0.71) compared with as-needed albuterol (1.63, P<0.001) and regular combination BDP-albuterol (1.76, P<0.001)

Taking ICS whenever SABA taken with separate inhalers

- TREXA study, BDP and albuterol, children and adolescents *(Martinez et al, Lancet 2011, n=288, 9 months)*
  - Frequency of exacerbations highest with albuterol alone (49%); lower with daily BDP (28%, p=0.03), daily plus as-needed BDP and SABA (31%, p=0.07) and as-needed BDP+SABA (35%, p=0.07)
  - Growth 1.1cm less in daily and combined groups but not as-needed-only group
- BASALT study, BDP and albuterol, adults *(Calhoun et al, JAMA 2012, n=342, 9 months)*
  - Similar exacerbations with as-needed BDP+SABA as with 6-weekly physician-adjusted or FeNO-adjusted ICS
- ASIST study, BDP and albuterol, African-American children and adolescents *(Sumino et al, Annals ATS 2020, n=206, 12 months)*
  - Similar symptoms control and exacerbations compared with physician-adjusted ICS

BDP: beclometasone dipropionate; ICS: inhaled corticosteroids; SABA: short-acting beta2-agonists

Table 1: GINA 2023 Track 1 Low Dose ICS-formoterol dosing

How to prescribe low-dose ICS-formoterol in GINA Track 1

Example: budesonide-formoterol 200/6 mcg [160/4.5 delivered dose]

- **Steps 1–2**: take 1 inhalation whenever needed for symptoms
- **Step 3**: take 1 inhalation twice a day (or once a day) PLUS 1 inhalation whenever needed for symptoms
- **Steps 4–5**: take 2 inhalations twice a day PLUS 1 inhalation whenever needed for symptoms
- As-needed doses of ICS-formoterol can also be taken before exercise *(Lazarinis et al, Thorax 2014)* or before allergen exposure *(Duong et al, JACI 2007)*

See following slides for medications, doses, and maximum number of inhalations in any day for GINA Track 1

Table 2: GINA 2023 Practical advice for GINA Track 1

Practical advice for GINA Track 1

- At first, patients may be unsure whether ICS-formoterol will work as well as their previous SABA reliever
  - In the PRACTICAL study, 69% patients said ICS-formoterol worked as fast as, or faster than, their previous SABA *(Baggott et al, ERJ 2020)*
  - Suggest to the patient that they try out the new reliever at a convenient time
  - Emphasise that they should use the ICS-formoterol **instead of** their previous SABA, and that they should take an additional inhalation when they have more symptoms
- Advise patients to have two inhalers (if possible), 1 at home, 1 in bag/pocket
- Advise patients to rinse and spit out after maintenance doses, but this is not needed with reliever doses
  - No increased incidence of candidiasis in RCTs with this recommendation (n~40,000)
- Use an action plan customised to MART
  - The patient continues their usual maintenance ICS-formoterol inhalations, but takes more **as-needed** ICS-formoterol inhalations
  - Taking extra as-needed inhalations reduces the risk of progressing to a severe exacerbation needing oral corticosteroids *(Bousquet et al, Respir Med 2007; Buhl et al, Respir Res 2012; O'Byrne et al, Lancet Respir Med 2021)*
- Additional practical advice for MART *(Reddel et al, JACI in Practice 2022)*

Table 3: LABA/ICS Therapeutic Interchange

LABA/ICS patient ≥ 12 years old			
	Low Dose	**Medium Dose**	**High Dose**
Budesonide/Formoterol (Symbicort)	80/4.5 mcg 2 puffs twice daily	160/4.5 mcg 2 puffs twice daily	160/4.5 mcg 2 puffs twice daily
Fluticasone/Salmeterol (Advair HFA)	45/21 mcg 2 puffs twice daily	115/21 mcg 2 puffs BID	230/21 mcg 2 puffs twice daily
Fluticasone/Salmeterol (Advair Diskus)	100/50 mcg 1 inhalation twice daily	250/50 mcg 1 inhalation twice daily	500/50 mcg 1 inhalation twice daily
Mometasone/Formoterol (Dulera)	N/A	100/5 mcg 2 puffs twice daily	200/5 mcg 2 puffs twice daily
Fluticasone/Vilanterol (Breo Ellipta)	N/A	100/25 mcg 1 inhalation daily	100/25 mcg 1 inhalation daily

Table 4: ICS Dosing

Medication	**Adult Daily Dose (≥ 12 years old)**		
	Low Dose	**Medium Dose**	**High Dose**
Beclomethasone HFA (*QVAR Redihaler®*)	80 - 240 mcg	280 - 480 mcg	>480 mcg
Budesonide DPI* (*PulmicortFlexhaler®*)	360 -540 mcg	630 - 1170 mcg	>1200 mcg
Budesonide nebulizer susp. (*PulmicortRespules®*)	---	---	---
Ciclesonide HFA (*Alvesco®*)	160 mcg	240 - 320 mcg	>320 mcg (MDD: 640mcg)
Flunisolide HFA (*Aerospan®*)	320 mcg	400 mcg	MDD: 640 mcg
Fluticasone furoate DPI (Arnuity Ellipta®*)*	100 mcg	NA	200 mcg
Fluticasone propionate DPI* (*FloventDiskus®*)	100 - 300 mcg	350 - 500 mcg	>500 mcg
Fluticasone propionate HFA (*Flovent-HFA)*	176 mcg	264 - 440 mcg	>440 mcg
Mometasone DPI * (*AsmanexTwisthaler®*)	220 mcg	440 mcg	>440 mcg

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ASTIHMA ACTION PLAN

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Action plan for MART with ICS-formoterol

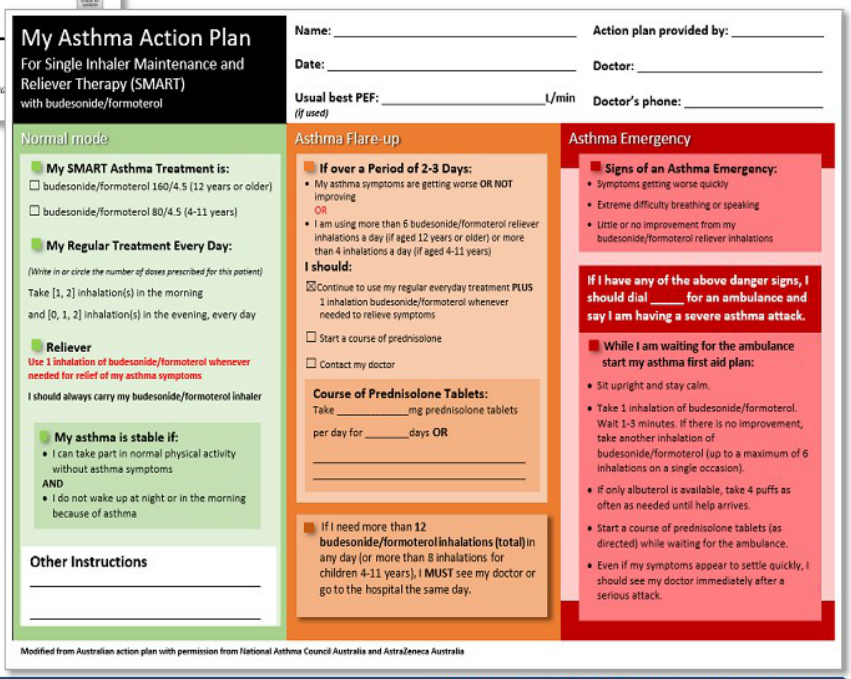
A Practical Guide to Implementing SMART in Asthma Management

Helen K. Reddel, MB, BS, PhD[a,*], Eric D. Bateman, MB, ChB, MD[b,*], Michael Schatz, MD, MS[c], Jerry A. Krishnan, MD, PhD[d], and Michelle M. Cloutier, MD[e] *Sydney, Australia; Cape Town, South Africa; Chicago, Ill; and Farmington, Conn*

Reddel et al, JACI in Practice 2022; 10: S31-s38

This article includes a writable action plan template
That can be modified for other combination ICS-formoterol inhalers, and for as-needed-only ICS-formoterol

For additional action plans with ICS-formoterol reliever, see National Asthma Council Australia Action plan library
www.nationalasthma.org.au/health-professionals/asthma-action-plans



My Asthma Action Plan
For Single Inhaler Maintenance and Reliever Therapy (SMART)
with budesonide/formoterol

Name: _____ Action plan provided by: _____
Date: _____ Doctor: _____
Usual best PEF: _____ L/min (if used) Doctor's phone: _____

Normal mode

My SMART Asthma Treatment is:
☐ budesonide/formoterol 160/4.5 (12 years or older)
☐ budesonide/formoterol 80/4.5 (4-11 years)

My Regular Treatment Every Day:
(Write in or circle the number of doses prescribed for this patient)
Take [1, 2] inhalation(s) in the morning
and [0, 1, 2] inhalation(s) in the evening, every day

Reliever
Use 1 inhalation of budesonide/formoterol whenever needed for relief of my asthma symptoms
I should always carry my budesonide/formoterol inhaler

My asthma is stable if:
- I can take part in normal physical activity without asthma symptoms

AND
- I do not wake up at night or in the morning because of asthma

Other Instructions
_____
_____

Asthma Flare-up

If over a Period of 2-3 Days:
- My asthma symptoms are getting worse OR NOT improving

OR
- I am using more than 6 budesonide/formoterol reliever inhalations a day (if aged 12 years or older) or more than 4 inhalations a day (if aged 4-11 years)

I should:
☒ Continue to use my regular everyday treatment PLUS 1 inhalation budesonide/formoterol whenever needed to relieve symptoms
☐ Start a course of prednisolone
☐ Contact my doctor

Course of Prednisolone Tablets:
Take _____mg prednisolone tablets
per day for _____days OR
_____
_____

If I need more than 12 **budesonide/formoterol inhalations (total)** in any day (or more than 8 inhalations for children 4-11 years), I **MUST** see my doctor or go to the hospital the same day.

Asthma Emergency

Signs of an Asthma Emergency:
- Symptoms getting worse quickly
- Extreme difficulty breathing or speaking
- Little or no improvement from my budesonide/formoterol reliever inhalations

If I have any of the above danger signs, I should dial _____ for an ambulance and say I am having a severe asthma attack.

While I am waiting for the ambulance start my asthma first aid plan:
- Sit upright and stay calm.
- Take 1 inhalation of budesonide/formoterol. Wait 1-3 minutes. If there is no improvement, take another inhalation of budesonide/formoterol (up to a maximum of 6 inhalations on a single occasion).
- If only albuterol is available, take 4 puffs as often as needed until help arrives.
- Start a course of prednisolone tablets (as directed) while waiting for the ambulance.
- Even if my symptoms appear to settle quickly, I should see my doctor immediately after a serious attack.

Modified from Australian action plan with permission from National Asthma Council Australia and AstraZeneca Australia

© Global Initiative for Asthma, www.ginasthma.org

References:

1. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2023. Available from:www.ginasthma.org
2. American Lung Association. www.lung.org
3. UpToDate
4. Refill Authorization Protocol for MYVM
5. GINA Slide Set - Global Initiative for Asthma - GINA (ginasthma.org)

COPD Protocol

Guidelines for the MultiCare Ambulatory Care Clinical Pharmacist

Pharmacist Authors/Editors: Linnea Read, Gary Burton, and Robin Brown

November2024

Inclusion Criteria: *All criteria must be met*

- Over age 18
- Not pregnant
- Not enrolled in hospice
- Seen or virtually managed by provider within last 12 months.

Patient Evaluation: Initial and Subsequent Visits

- Determine appropriate COPD treatment based on patient's GOLD classification and stage (see Figures 1 and 2)

Physical Exam:

- Obtain vitals – BP, HR, O2 sat, Height & Weight

Patient Education:

- Purpose of visits to the Clinical Pharmacist
- Medication use: indication, dosage, administration, possible side effects and monitoring
- Assess inhaler and nebulizer technique at every visit with patient demonstration (with description or inhaler if available) and "teach back" method.
- Benefits of smoking cessation, if applicable (see Tobacco Cessation protocol)
  - The effectiveness and safety of using e-cigarettes for smoking cessation is uncertain and should not be recommended.
- Avoiding exposure to triggers: occupational dust, fumes, and gases, and indoor and outdoor pollutants
- Red flags that might indicate an exacerbation.
  - Increased sputum production
  - Increased cough
  - Increased shortness of breath/difficulty breathing
  - Less relief and/or increased use of rescue inhaler
  - O2 sat less than 90%
- Importance of adherence to medications
- Initiate/review COPD action plan.
- Provide patient education handouts as needed (provided in COPD Visit Resources folder)
- Emphasize the importance of follow-up visits, especially right after acute exacerbations.

Adherence

- Assess barriers to adherence; including, but not limited to patient understanding, finances, and social support.

Managing Adverse Effects:

- Anticholinergic side effects: assess based upon side effects and adjust accordingly.
- Shakiness/anxiety/increased heart rate with a short-acting beta agonist: consider switch to levalbuterol or step up in maintenance therapy based on average use.
- Inhaled corticosteroid oral thrush – "swish-and-spit" with water after use for prevention

Referring Provider Consultation During Appointment with the Pharmacist will occur:

- If a patient has O_2 sats ≤90%
- If a patient is showing signs of an exacerbation
- If there is need for a nebulizer or other durable medical equipment
- If a patient shows signs and/or symptoms of oral thrush

Preventative care:

The pharmacist can order or perform the following labs, tests, and referrals as recommended by thecurrent GOLD guidelines:

- Spirometry – yearly or as indicated based on stability of breathing.
- Smoking Cessation
- Physical Activity
- Immunizations per CDC recommendations (including, but not limited to)
    - Annual Flu vaccination
    - Pneumococcal Vaccination
    - Pertussis Vaccination
    - COVID vaccination
    - Shingles

Documentation:

- Document visit in the electronic medical record per Memorial Hospital policy.
- Update medication list
- Communicate visit summary with referring provider after each visit if needed (via TE)

Follow-up Intervals:

- 1-4 weeks after an acute exacerbation
- 12-16 weeks second visit after an acute exacerbation

- Routine follow-up is essential and should be evaluated per patient based on frequency of exacerbations, disease progression, and other risk factors.
- Patient to call if they notice worsening dyspnea, increased sputum production, or purulent sputum.

Pharmacotherapy:

- The following may be initiated, modified, or discontinued by the clinic pharmacist:
- Inhaled corticosteroids (ICS)
- Short- and long-acting beta$_2$ inhalers (SABA)
- Short- and long-acting anticholinergic inhalers
- Inhalers that combine any of the above
- See Table 1 for list of medications available.
- Inhaled bronchodilators are central to symptoms management.
    - LABA/LAMA preferred over short acting agents except for patients with only occasional symptoms.
    - Prefer to initiate treatment with long-acting bronchodilators as a combination LABA/LAMA
    - Using SABAs on a regular basis is not recommended.

- Anti-inflammatory therapy in stable COPD
    - Inhaled corticosteroids
        - Recommend triple therapy with ICS/LAMA/LABA
        - Long-term monotherapy with ICS is NOT recommended.
        - Patients with features of asthma (in addition to COPD) should always receive an ICS
    - Long-term use of oral glucocorticoids has numerous side effects with no evidence of benefits and should NOT be used.

- These are options that could be discussed with the provider on a patient-by-patient basis if appropriate.
    - PDE-4 Inhibitors
        - Consider patients with severe to very severe airflow limitation, chronic bronchitis & exacerbations.
    - Antibiotics
        - Long-term azithromycin (250 mg daily or 500 mg 3x/week) and erythromycin (500 mg BID) therapy may be considered in patients prone to acute exacerbations.
            - Treatment with azithromycin is associated with an increased incidence of bacterial resistanceand hearing test impairments so monitoring will be needed.

Initiating Therapy:

- Use Figure 1 to assess symptoms/risk of exacerbations to determine appropriate ABE group of COPD.
- Use Figure 2 to determine appropriate initial therapy treatment based on ABE.
- Therapy will be started at dose appropriate for COPD based on patient severity and classification.
- Choices will be made with consideration to drug interactions, concomitant disease states, and previous history with blood sugar lowering agents, side effects, or intolerances.
- Treatment decisions will consider patient needs, preferences, and insurance coverage.

Adjusting Therapy:

- Use Figure 3 to guide appropriate therapy adjustments based on dyspnea and exacerbations.
- Therapy will be adjusted based on patient response to prescribed medication and its effects on dyspnea and activity.
- Doses will be increased as guided by manufacturer recommendations.
- The option to increase the doses of medications over the phone may be based on patient preference, tolerance of medication, and self-sufficiency.
- Utilize tools such as the "COPD Follow Up Checklist."

Training for new pharmacists in COPD management:

- Mentorship and training side-by-side with current pharmacist
- Review of guideline, any guideline updates, and current evidence-based medicine
- Training evaluation completed and documented by management team based on Asthma/COPD Training Resources
- Reference BCACP training module on Pulmonary Disorders

COVID and COPD:

- 2023 GOLD Guidelines include a section on COVID-19 including:
    - Symptoms of COPD & COVID-19 infection may overlap. The two main overlapping symptoms are cough and shortness of breath.
    - Pharmacist will not address management issues/diagnosis issues relating to possible COVID-19/COPD symptom overlap but rather would alert the provider that patient required possible evaluation and management.

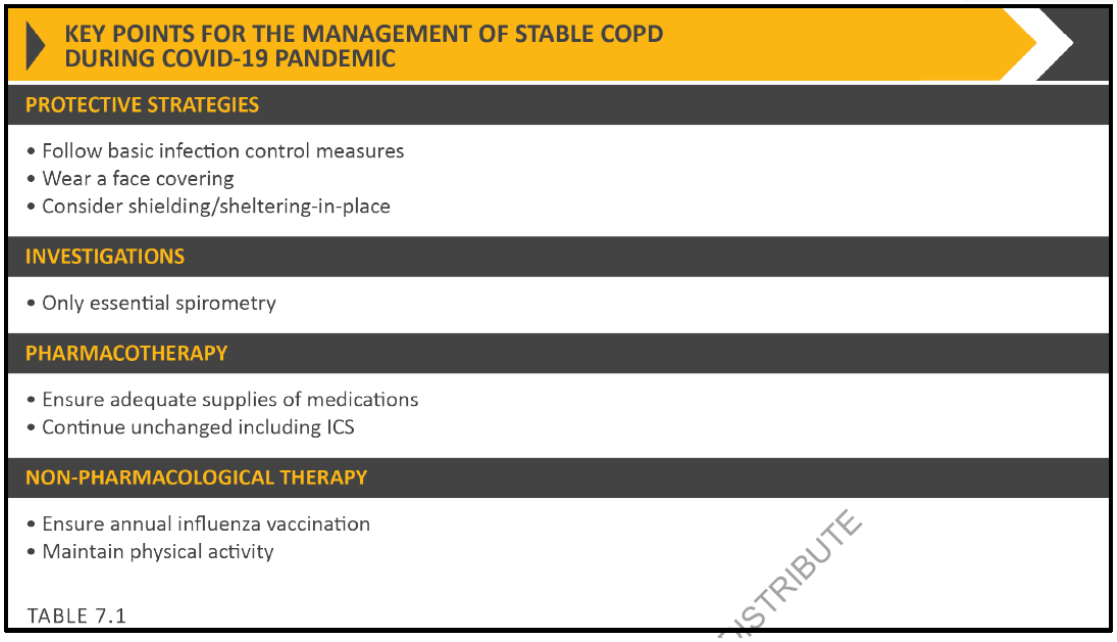


Table 1: COPD Medications by Class

Generic Drug Name	Brand Name	Inhaler Type	Nebulizer	Oral	Duration of Action
BETA-2 AGONISTS					
SHORT-ACTING (SABA)					
Levalbuterol	Xopenex	MDI	√		
Albuterol	Proair, Ventolin	MDI, DPI	√	Pill, syrup	4-6 hours 12 hours (ER)
LONG-ACTING (LABA)					
Arformoterol	Brovana		√		12 hours
Formoterol	Perforomist		√		12 hours
Indacaterol	Arcapta	DPI			24 hours
Olodaterol	Striverdi	SMI			24 hours
Salmeterol	Serevent	MDI, DPI			12 hours
INHALED CORTICOSTEROID					
Budesonide	Pulmicort	DPI	√		
ANTICHOLINERGICS					
SHORT-ACTING (SAMA)					
Ipratropium bromide	Atrovent	MDI	√		6-8 hours
LONG-ACTING (LAMA)					
Aclidinium bromide	Tudorza	DPI, MDI			12 hours
Glycopyrronium bromide	Seebri	DPI			12-24 hours
Revefenacin	Yupelri		√		24 hours

Tiotropium	Spiriva	DPI, SMI			24 hours
Umeclidinium	Incruse Ellipta	DPI			24 hours
COMBINATION SABA/SAMA					
Albuterol/ipratropium	Combivent, Duoneb	MDI, SMI	√		6-8 hours
COMBINATION LABA/LAMA					
Formoterol/ glycopyrronium	Bevespi	MDI			12 hours
Indacaterol/glycopyrronium	Utibron	DPI			12-24 hours
Vilanterol/umeclidinium	Anoro Ellipta	DPI			24 hours
Olodaterol/tiotropium	Stiolto	SMI			24 hours
COMBINATION LABA/ICS					
Formoterol/beclomethasone		MDI			
Formoterol/budesonide	Symbicort	MDI, DPI			
Salmeterol/fluticasone	Advair, Wixela	MDI, DPI			
Vilanterol/fluticasone furoate	Breo Ellipta	DPI			
TRIPLE COMBINATION LABA/LAMA/ICS					
Fluticasone/umeclidinium/vilanterol	Trelegy Ellipta	DPI			
Beclomethasone/ formoterol/glycopyrronium	Breztri Aerosphere	MDI			
PDE-4 INHIBITORS					
Roflumilast	Daliresp			Pill	
MUCOLYTIC AGENTS					
Erdosteine				Pill	
METHYLXANTHINES					
Aminophylline				Solution	
Theophylline (SR)				Pill	

Figure 1: COPD ABE Assessment Tool

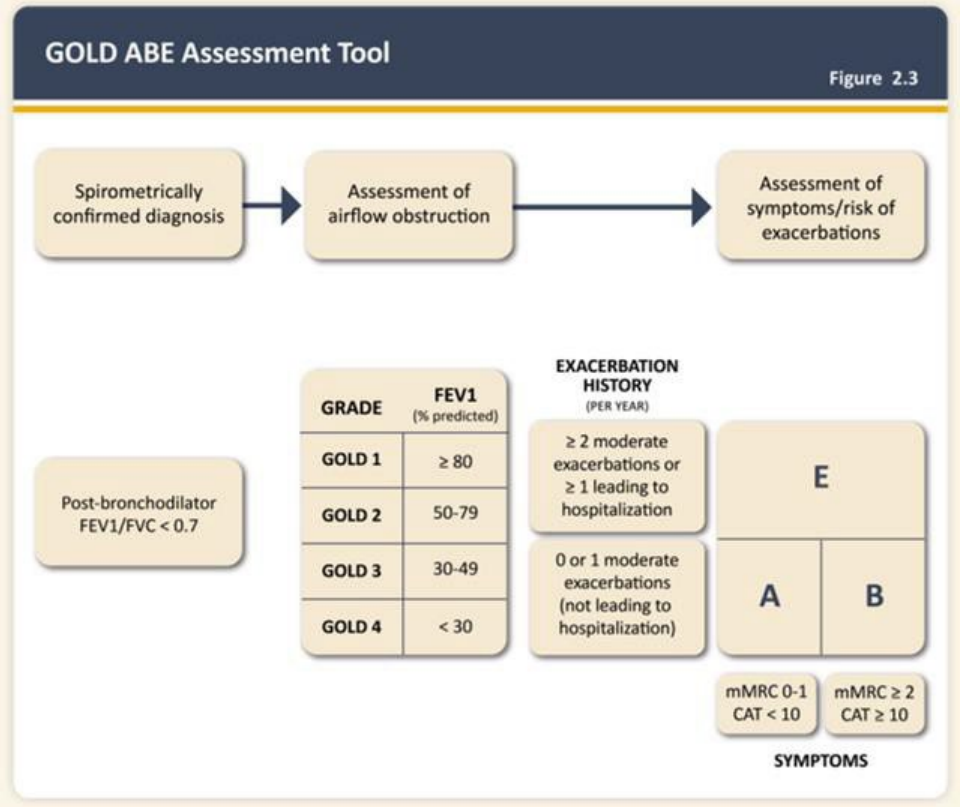
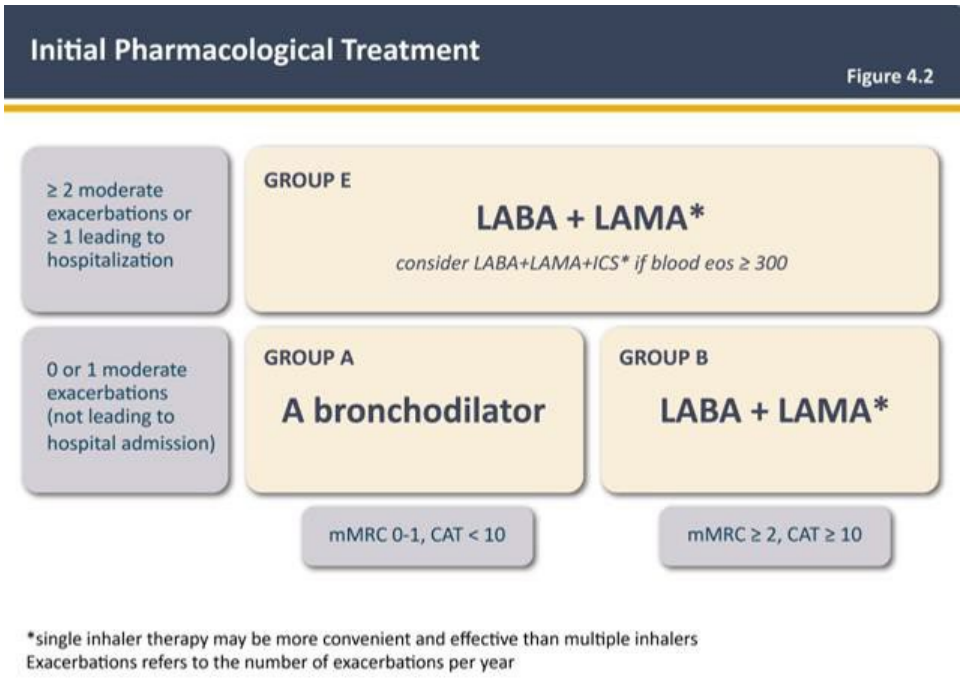
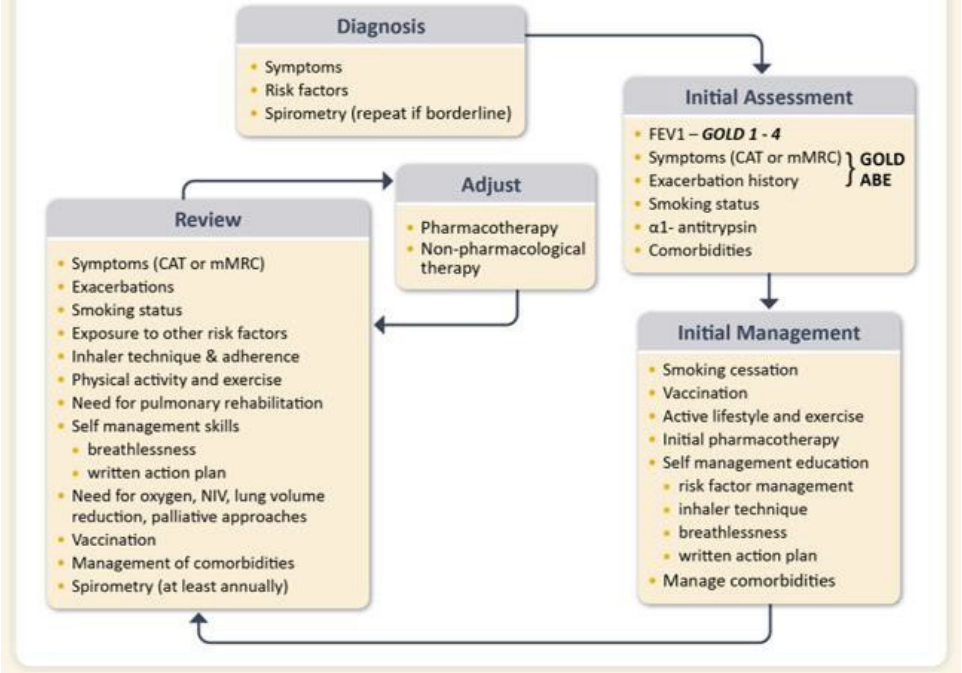


Figure 2: Initial COPD Pharmacological Treatment based on COPD Group ABE



Management of COPD

Figure 4.1



Management Cycle

Figure 4.3

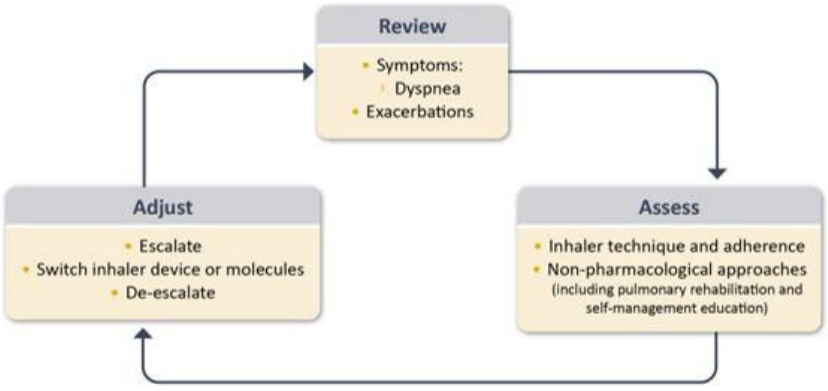


Figure 3: COPD Pharmacological Treatment Modifications

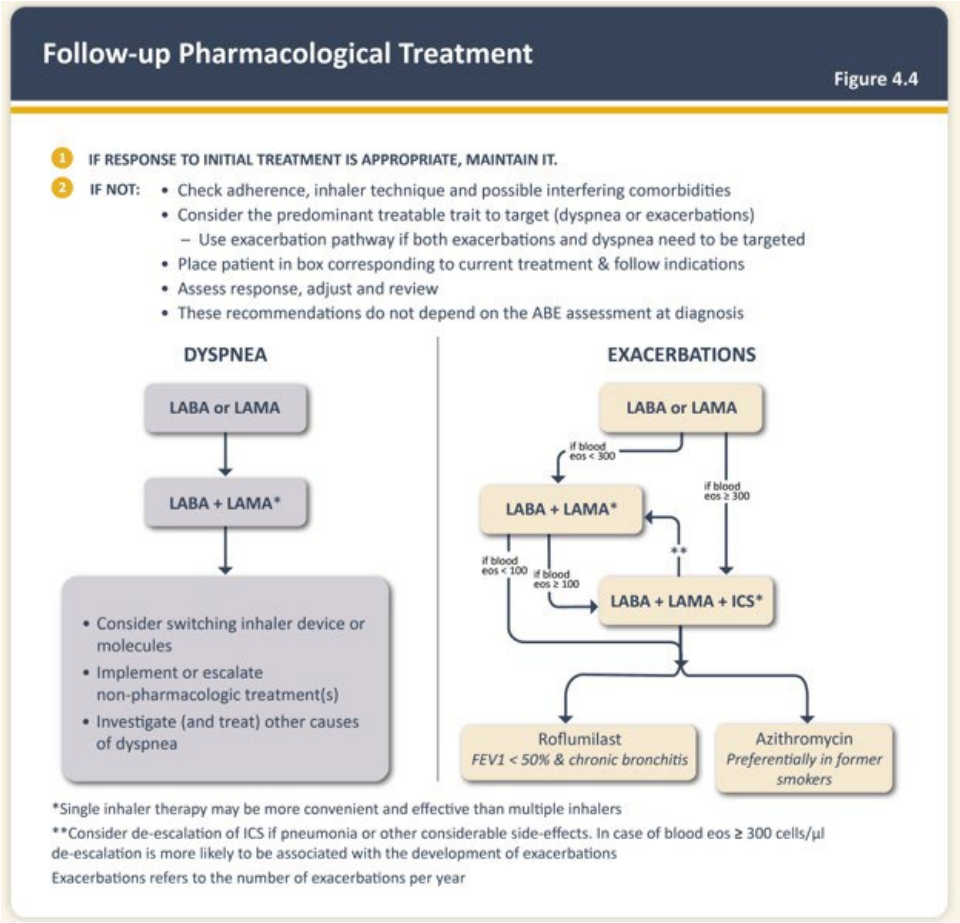


FIGURE 3: MRC Dyspnea Scale Tool

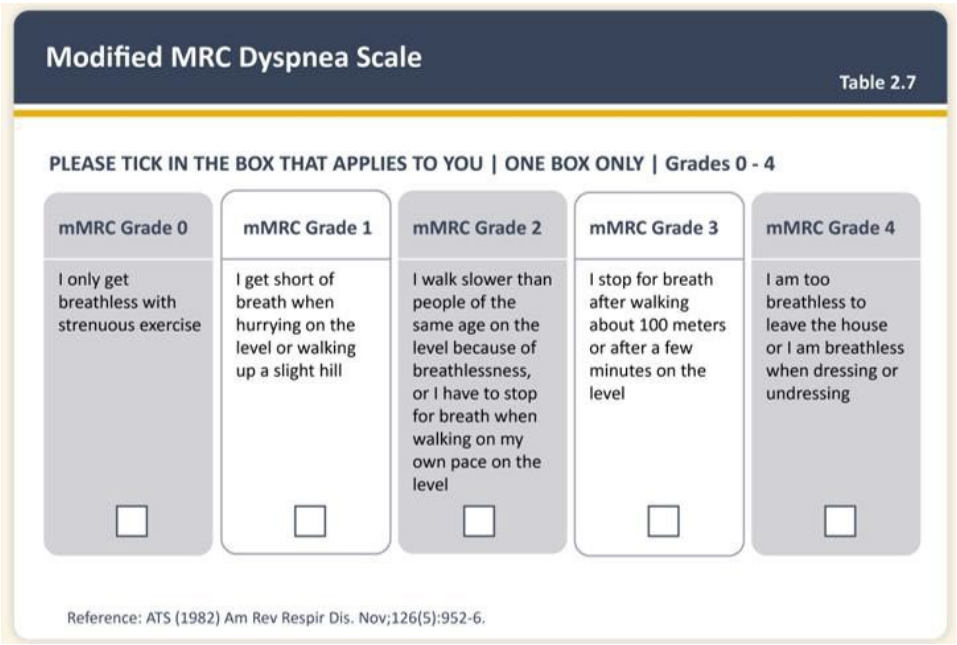
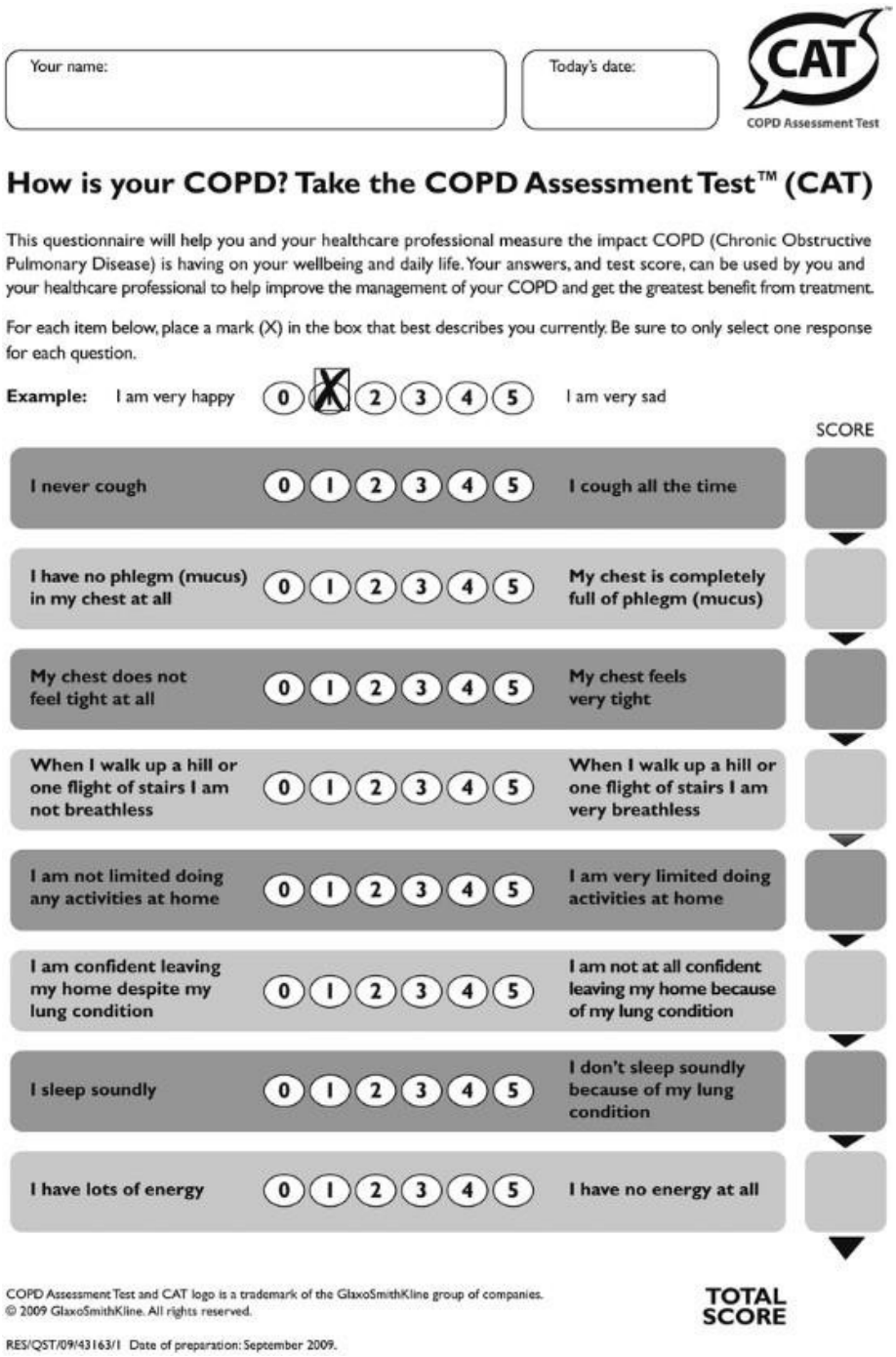


FIGURE 4: CAT (COPD Assessment Tool) **2 options to use**



Your name:

Today's date:

CAT
COPD Assessment Test

How is your COPD? Take the COPD Assessment Test™ (CAT)

This questionnaire will help you and your healthcare professional measure the impact COPD (Chronic Obstructive Pulmonary Disease) is having on your wellbeing and daily life. Your answers, and test score, can be used by you and your healthcare professional to help improve the management of your COPD and get the greatest benefit from treatment.

For each item below, place a mark (X) in the box that best describes you currently. Be sure to only select one response for each question.

Example: I am very happy 0 X 2 3 4 5 I am very sad

			SCORE
I never cough	0 1 2 3 4 5	I cough all the time	
I have no phlegm (mucus) in my chest at all	0 1 2 3 4 5	My chest is completely full of phlegm (mucus)	
My chest does not feel tight at all	0 1 2 3 4 5	My chest feels very tight	
When I walk up a hill or one flight of stairs I am not breathless	0 1 2 3 4 5	When I walk up a hill or one flight of stairs I am very breathless	
I am not limited doing any activities at home	0 1 2 3 4 5	I am very limited doing activities at home	
I am confident leaving my home despite my lung condition	0 1 2 3 4 5	I am not at all confident leaving my home because of my lung condition	
I sleep soundly	0 1 2 3 4 5	I don't sleep soundly because of my lung condition	
I have lots of energy	0 1 2 3 4 5	I have no energy at all	

TOTAL SCORE

RES/QST/09/43163/1 Date of preparation: September 2009.

CAT™ Assessment

Figure 2.2

For each item below, place a mark (x) in the box that best describes you currently.
Be sure to only select one response for each question.

EXAMPLE: I am very happy	0 X 2 3 4 5	I am very sad	Score
I never cough	0 1 2 3 4 5	I cough all the time	
I have no phlegm (mucus) in my chest at all	0 1 2 3 4 5	My chest is completely full of phlegm (mucus)	
My chest does not feel tight at all	0 1 2 3 4 5	My chest feels very tight	
When I walk up a hill or one flight of stairs I am not breathless	0 1 2 3 4 5	When I walk up a hill or one flight of stairs I am very breathless	
I am not limited doing any activities at home	0 1 2 3 4 5	I am very limited doing activities at home	
I am confident leaving my home despite my lung condition	0 1 2 3 4 5	I am not at all confident leaving my home because of my lung condition	
I sleep soundly	0 1 2 3 4 5	I don't sleep soundly because of my lung condition	
I have lots of energy	0 1 2 3 4 5	I have no energy at all	

Reference: Jones et al. ERJ 2009; 34 (3); 648-54.

TOTAL SCORE:

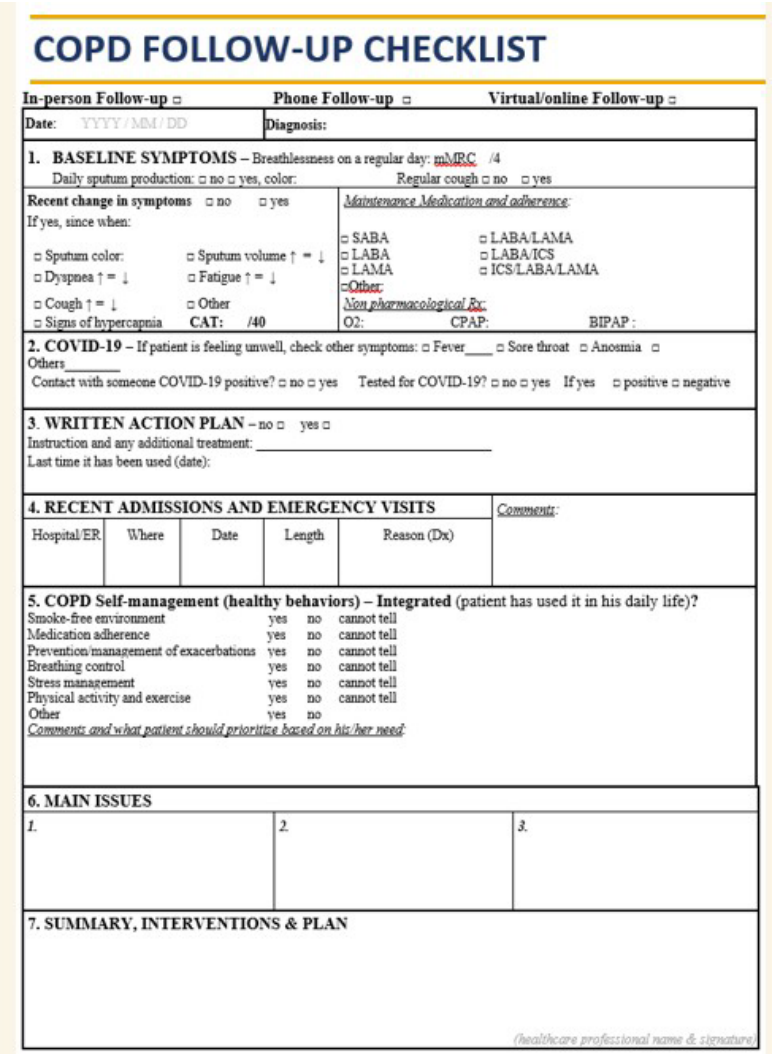
Figure 5: Vaccination for Stable COPD

Vaccination for Stable COPD

Table 3.2

- Influenza vaccination is recommended in people with COPD **(Evidence B)**
- The WHO and CDC recommends SARS-CoV-2 (COVID-19) vaccination for people with COPD **(Evidence B)**
- The CDC recommends one dose of 20-valent pneumococcal conjugate vaccine (PCV20); or one dose of 15-valent pneumococcal conjugate vaccine (PCV15) followed by 23-valent pneumococcal polysaccharide vaccine (PPSV23) in people with COPD **(Evidence B)**
- Pneumococcal vaccination has been shown to reduce the incidence of community-acquired pneumonia and exacerbations in people with COPD **(Evidence B)**
- The CDC recommends Tdap (dTaP/dTPa) vaccination to protect against pertussis (whooping cough) for people with COPD that were not vaccinated in adolescence **(Evidence B)**, and Zoster vaccine to protect against shingles for people with COPD over 50 years **(Evidence B)**

Figure 6: Example follow up chart note information to include in template



COPD FOLLOW-UP CHECKLIST

In-person Follow-up ☐ **Phone Follow-up** ☐ **Virtual/online Follow-up** ☐

Date: YYYY / MM / DD **Diagnosis:**

1. BASELINE SYMPTOMS – Breathlessness on a regular day: mMRC /4
Daily sputum production: ☐ no ☐ yes, color: Regular cough ☐ no ☐ yes

Recent change in symptoms ☐ no ☐ yes
If yes, since when:
☐ Sputum color: ☐ Sputum volume ↑ = ↓
☐ Dyspnea ↑ = ↓ ☐ Fatigue ↑ = ↓
☐ Cough ↑ = ↓ ☐ Other
☐ Signs of hypercapnia **CAT:** /40

Maintenance Medication and adherence:
☐ SABA ☐ LABA/LAMA
☐ LABA ☐ LABA/ICS
☐ LAMA ☐ ICS/LABA/LAMA
☐Other:
Non pharmacological Rx:
O2: CPAP: BIPAP :

2. COVID-19 – If patient is feeling unwell, check other symptoms: ☐ Fever___ ☐ Sore throat ☐ Anosmia ☐
Others_____
Contact with someone COVID-19 positive? ☐ no ☐ yes Tested for COVID-19? ☐ no ☐ yes If yes ☐ positive ☐ negative

3. WRITTEN ACTION PLAN – no ☐ yes ☐
Instruction and any additional treatment: _____
Last time it has been used (date):

4. RECENT ADMISSIONS AND EMERGENCY VISITS *Comments:*

Hospital/ER	Where	Date	Length	Reason (Dx)

5. COPD Self-management (healthy behaviors) – Integrated (patient has used it in his daily life)?

Smoke-free environment	yes	no	cannot tell
Medication adherence	yes	no	cannot tell
Prevention/management of exacerbations	yes	no	cannot tell
Breathing control	yes	no	cannot tell
Stress management	yes	no	cannot tell
Physical activity and exercise	yes	no	cannot tell
Other	yes	no	

Comments and what patient should prioritize based on his/her need:

6. MAIN ISSUES

1.	2.	3.

7. SUMMARY, INTERVENTIONS & PLAN

(healthcare professional name & signature)

References:

1. Global Initiative for Chronic Obstructive Lung Disease. Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Lung Disease (2023 Report)
2. American Lung Association. www.lung.org
3. Gold 2023: Highlights for primary care | npj Primary Care Respiratory Medicine (nature.com)
4. GOLD-2023_teaching-slide-set-v1.2-17Feb23.pptx (live.com)

Diabetes Protocol

Guidelines from the MultiCare Ambulatory Care Clinical Pharmacist

November 2024

1. **Purpose**

   The purpose of this collaborative drug therapy agreement is to establish a consistent, efficient, and safe standard in managing diabetes mellitus in the ambulatory care setting. Diabetes is a common chronic condition and often not well controlled; complications of diabetes are a significant source of morbidity and mortality in the US. Pharmacists can utilize their clinical expertise in monitoring and managing diabetes medications to improve health outcomes and help patients actively manage their health (J Am Pharm Assoc. 2003;43:173–84). In addition to the primary care provider and formal education by diabetes educators, pharmacists can be a beneficial resource to aid patients in medication management of diabetes

   To establish the MultiCare Health System (MHS) Collaborative Drug Therapy Agreement for Medication Management of Diabetes Mellitus by Pharmacists in compliance with professional standards for management of diabetes, Washington State Law (RCW 18.64.011), and Pharmacy Quality Assurance Commission regulations (WAC 246-863-100).

   Washington State Law enables pharmacists to enter into agreements with prescribers, which authorize the pharmacist to assist in initiating, modifying, continuing and discontinuing pharmacotherapy for diabetes mellitus.

2. **Length of Agreement**

   This agreement shall remain in place for a period not to exceed two years from the date of the authorizing prescriber's signature or sooner should the authorizing practitioner desire to end the agreement.

3. **Training**

   A. Pharmacist Training Diabetes Management

   a. Mentorship and training side-by-side with current pharmacist including:
   b. Validation of clinical competency
   c. Review of guideline, any guideline updates, and current evidence-based medicine
   d. Training and annual evaluation completed and documented by management team based on Diabetes Training Resources
   e. BCACP training module on Diabetes

4. Inclusions

A. Patients included in this agreement will be adults with diabetes mellitus of any type. Patient must have a provider who refers patient to the clinic for diabetes medication management

A. **Exclusions**

Patients under the care of endocrinologists who are not MultiCare providers are not eligible unless that endocrinologist referring the patient is agreeable to co-management.

B. Patients under the age of 18 years of age and younger. Exception:

a. If pediatric endocrinology refers an adolescent patient explicitly to a CDCES or BCADM pharmacist and they agree, they may be seen with this referral.

5. Clinical Guideline – Process

A. Drug Therapy Initiation and Adjustment

i. Each pharmacist listed in the agreement is authorized to initiate, continue, modify or discontinue pharmacotherapy for the management of diabetes mellitus.

ii. In exercising this authority, the pharmacist will comply with:

a. Current recommended national guidelines

b. Protocol for Medication Management of Diabetes Mellitus

(Attachment 3)

c. Applicable medication package inserts

iii. Medications/supplies under the authority of this protocol include all medications/supplies/DME needed to manage diabetes mellitus, including, but not limited to:

a. Oral anti-diabetic agents

b. Insulin and supplies (pen needles, syringes, subcutaneous infusion systems, patches and supplies)

c. Incretin-mimetics

d. Amylinomimetics

e. Agents for hypoglycemic emergency and/or sick day monitoring

f. Diabetes testing supplies (test strips, meters, lancets, continuous glucose monitoring (supplies)

g. Antihyperlipidemic medications as recommended by the ADA or AACE

h. Controlled substances are not part of this agreement

i. Weight-loss medications are not part of this agreement

iv. Pharmacists are granted the authority to order, procure, and review necessary laboratory tests to assess treatment efficacy and/or to monitor for adverse drug events, including but not limited to:

a. Hemoglobin A1c (must be ordered if not done within previous 3 months)

b. CMP/BMP

c. Lipid panel

d. UACR

e. C-peptide/IA-2/ZN 8, GADA

f. CBC

g. B12

h. Fructosamine

i. Diagnostic professional continuous glucose monitoring

v. The patient may be referred back to the primary care provider in the following situations:

a. The pharmacist has concern for an undiagnosed condition

b. The patient is unable to make appointments, unable to adhere to/follow medication use/instructions, or unable to perform blood glucose monitoring

B. Lipid Medication Prescribing as per ADA and or AACE guidelines

C. Tobacco Cessation Management per Tobacco Cessation CDTA

D. Patient Education

1. Pharmacists will provide diabetes education to patients as appropriate, based upon the patient's needs and level of understanding. A sample of topics is included in Attachment 3.

i. Educational topics covered will be documented in the progress note at each visit.

2. Patients will be referred to a comprehensive diabetes education program.

i. We recognize that nutrition education is an integral part of the self-management of diabetes. A referral will be obtained for all patients who have never attended nutrition education, as well as any patient whom the pharmacist feels would benefit from nutrition education.

ii. Patient may decline the referral and then the pharmacist will document the declination

E. Diabetes Foot Examinations

1. Each pharmacist listed in the agreement is authorized to perform diabetes foot exams as needed.

i. Examination findings will be documented in the medical record and communicated to the referring provider.

ii. Patient will be referred back to PCP or have podiatry referral requested for any abnormal findings and/or a smoker with one or more risk factors.

6. Documentation

A. Each action including initiation, continuation, modification and/or discontinuation of therapy will be documented in the patient's medical record

i. A progress note detailing all changes made, complete with care plan, will be written for each patient encounter

ii. Progress notes will be faxed or electronically sent to the referring provider after each encounter

7. Feedback and Quality Assurance Upon request, a report shall be provided to the authorizing physician regarding the activities of pharmacists providing services under this collaborative drug therapy agreement.

Attachment 1

Protocol for Medication Management of Diabetes Mellitus

Initial Visit

1) Review the patient's medical record and interview the patient:
    - Complete medical history, medication list, allergies, immunizations
    - Past medical history including other chronic conditions and diabetes complications
    - Social history/lifestyle: tobacco, alcohol, SUD, physical activity
    - Pertinent family history
    - Diabetes history: Onset, type, ED visits/hospitalizations, hypoglycemia, last eye exam, last foot exam, last dental exam
2) Obtain height and weight, blood pressure and pulse as necessary
3) Assess:
    - Hyperglycemia and hypoglycemia symptoms and patient's knowledge of how to act upon signs and symptoms
    - Relevant recent labs (including blood glucose, HbA1c, lipid panel, electrolytes, creatinine, liver function, urine microalbumin, etc.) if available
    - Blood pressure (if not at goal, may ask for hypertension referral)
    - Current lifestyle choices pertaining to diabetes including nutrition, physical activity, tobacco use, alcohol, immunizations
    - Appropriateness of diabetes medications including indication, effectiveness, safety, convenience, skin integrity
4) Develop a care plan:
    - Assess patient for presence of contraindications or precautions for using specific diabetes medications
    - Establish treatment goals
        - Blood glucose goals should be individualized for each patient, based on duration of diabetes, age, diabetes medication, and risk of hypoglycemia
        - Appropriate guidelines for blood glucose goals include the American Diabetes Association Standards of Medical Care for Diabetes
    - Initiate, modify, continue, or discontinue medications to meet treatment goals using current appropriate guidelines
        - Medications may also be adjusted based on patient's renal/hepatic function
        - Appropriate treatment guidelines include but are not limited to:
            - American Diabetes Association Clinical Practice Recommendations
            - American Association of Clinical Endocrinologists Comprehensive Diabetes Management Algorithm
    - Order necessary laboratory, diagnostic, or home tests to assess treatment efficacy and/or to monitor for adverse drug events, including self-monitoring of blood glucose or diagnostic continuous glucose monitoring as needed
        - For patients using non-insulin therapies or basal insulin only, frequency of self-monitoring of blood glucose should be individualized for each patient based on their specific needs and goals, consistent with the American Diabetes Association Standards of Medical Care for Diabetes
            - For patients on multiple daily injections of insulin, the American Diabetes Association Standards of Medical Care for Diabetes Prior to meals and snacks
            - Occasionally postprandially
            - At bedtime
            - Prior to physical activity

        - When low blood glucose is suspected
        - After treating low blood glucose until normoglycemic
        - Prior to critical tasks (e.g., driving/operating heavy machinery)
        - Sick Day management
5) Refer for formal diabetes education/support and educate as appropriate (education may take place over several visits):
    - The diabetes disease process/pathophysiology
    - Symptoms, causes, treatment and prevention of hypo- and hyperglycemia
    - General actions of relevant diabetes medications and/or insulin
    - Guidelines for use, maximum dose, and side effects of diabetes medications
    - Self-monitoring blood glucose (timing of tests, goal ranges and keeping records)
    - Long term complications of diabetes and how they develop
    - HbA1c goal ranges, treatment goals
    - Blood pressure and lipid control and goal ranges
    - Role of physical activity in diabetes management
    - Smoking cessation
    - Daily foot care
    - Sick day management
    - Diabetes risk reduction and standards of care (physical, eye exam, dental exam, foot exam)
6) Schedule a follow-up visit within 1- 24 weeks and/or PRN based on care plan and if follow up is planned with referring provider
    - Follow up within 1- 8 weeks after medication addition or adjustment unless the patient preference is another interval
    - Follow up with pharmacist or referring provider at least every 26 weeks
7) Document visit via progress note and forward to referring and/or primary provider

<u>Follow-up Visit</u>

1) Obtain updated medical history and medication list
2) Obtain height and weight, blood pressure and pulse as necessary
3) Assess:
    - Self-monitored blood glucose record
    - Hyperglycemia and hypoglycemia symptoms; recent treatments, hospitalizations, pending procedures, ED visits
    - Relevant recent labs (including blood glucose, HbA1c, lipid panel, electrolytes, creatinine, liver function, urine microalbumin, etc.) if available. Current lifestyle choices as it pertains to diabetes including nutrition, physical activity, tobacco use, alcohol, immunizations
    - Pharmacotherapy effectiveness, adverse effects, adherence issues
    - Appropriateness of diabetic medications including indication, effectiveness, safety, convenience
    - Identify any new drug therapy problems
    - Progression of previous drug therapy problems
    - Skin integrity
4) Develop a care plan:
    - Review treatment goals
    - Assess patient for presence of contraindications or precautions for using specific diabetes medications
    - Initiate, modify, continue, or discontinue medications to meet treatment goals based on current appropriate guidelines
    - Order necessary laboratory tests to assess treatment efficacy and/or to monitor for adverse drug events

8) Refer for formal diabetes education/support and educate as appropriate (education may take place over several visits):
    - The diabetes disease process/pathophysiology
    - Symptoms, causes, treatment and prevention of hypo- and hyperglycemia
    - General actions of relevant diabetes medications and/or insulin
    - Guidelines for use, maximum dose, and side effects of diabetes medications
    - Self-monitoring blood glucose (timing of tests, goal ranges and keeping records)
    - Long term complications of diabetes and how they develop
    - HbA1c goal ranges, treatment goals
    - Blood pressure and lipid control and goal ranges
    - Role of physical activity in diabetes management
    - Readiness to become a non-smoker or non-vapor or non-chewer
    - Daily foot care
    - Sick day management
    - Diabetes risk reduction and standards of care (physical, eye exam, dental exam)
5) Schedule a follow-up visit based on care plan
6) Document visit via progress note and forward to the referring and/or primary provider

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Washington Admin. Code (Chapter 246-945 of WAC) and Revised Code of Washington RCW 18.64.020)

Deprescribing Protocol

Guidelines for the MultiCare Ambulatory Care Clinical Pharmacist

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Deprescribing is defined as the process of medication withdrawal, supervised by a healthcare professional, with the goal of managing polypharmacy and improving outcomes.[1] Deprescribing encourages a systematic, evidence-based, and proactive approach to address medication-related problems that have not previously been identified or satisfactorily managed, ultimately aiming to prevent future complications. The common goals for deprescribing include reducing overall medication burden, decreasing the risk of specific geriatric syndromes (e.g., falls, cognitive impairment), and improving global health outcomes such as reduced hospitalizations and mortality rates.[2] This protocol provides guidance for deprescribing common medications, methods/algorithms for tapering, and other general considerations.

Goal:

The primary goal of deprescribing is to reduce the overall medication burden (e.g., number of pills, regimen complexity, and associated costs) while maintaining or improving quality of life.[3] Targeted deprescribing is an essential part of medication optimization for disease state management, reducing adverse drug effects, and improving outcomes.[3] Deprescribing may involve (1) identifying medications that may no longer provide adequate benefit compared to risk or quality of life impact and (2) down-titration, dose reduction, or discontinuation to mitigate withdrawal risks. The process of deprescribing is often informed by new research or recently published data that may alter the risk-benefit profile of certain medications.

Background:

Polypharmacy continues to be an increasing concern in healthcare systems, leading to higher risks of drug- drug interactions, adverse reactions, reduced quality of life, and increased mortality risks in older adults.[4] Polypharmacy is generally defined as the concurrent use of multiple medications, ranging from five to ten or more (sometimes including over-the-counter medications).[6] Prevalence estimates indicate that up to 50% of Medicare patients receive five or more concurrent medications.[6]

In addition to reducing the number of concurrent medications, deprescribing is also intended as a targeted intervention to minimize inappropriate medication use, especially in older adults. For example, the D- PRESCRIBE trial demonstrated that pharmacist-led interventions can effectively reduce inappropriate medication use; at six months, 43% of intervention patients had stopped taking identified inappropriate medications compared to only 12% in the control group.[7]

A recent study emphasizes the need for deprescribing in patients with multimorbidity and advanced age to improve long-term outcomes, such as reduced fall risk and cognitive preservation, when integrated into regular healthcare practices.[10]

Although potential barriers exist on both patient and provider sides, deprescribing aligns well with patient preferences. In one survey, 92% of patients aged 65 and older indicated willingness to stop at least one medication.[4] Patient acceptance often depends on factors like (1) agreement that a medication may be unnecessary, (2) confidence that it could be restarted if needed, (3) established relationships with healthcare providers, and (4) general aversion to polypharmacy.[4] **A shared decision-making process between patients and health care providers will be useful in ensuring the success of individual deprescribing efforts.**

General Deprescribing Process [4,8]

1. **Complete Medication Review**: Ensure an accurate and comprehensive list of medications with each appropriately documented indication and no therapeutic duplications.
2. **Assess Medication Risks**: Evaluate each medication for potential drug-related harm (e.g., adverse reactions, interactions, renal or hepatic adjustments).
3. **Determine If a Medication is a Candidate for Deprescribing**: (discontinuation, dose reduction). Consider deprescribing medications based on factors like:
    - Medication appropriateness for current indications
    - Medication treating only side effects of other medications
    - Efficacy assessment in specific patients over time
    - Harm-to-benefit balance
    - Evaluate potential fall risk in patients taking antihypertensives or sedative medications and consider alternatives when possible.[11]
4. **Chart Review for Specialist Oversight**: Ensure any medication previously prescribed off- label by a specialist (e.g., PPIs for respiratory conditions) is appropriately reviewed.
5. **Communicate the Deprescribing Plan**: In collaboration with patients and providers, prioritize medications with the greatest risk, including supplements, to foster a trust-building process for subsequent deprescribing steps.
6. **Execute Deprescribing and Monitor for Symptoms**: Initiate medication reduction or discontinuation while monitoring for withdrawal symptoms or symptom recurrence.
7. **Use Algorithms or Online Tools**: Algorithms from sources like *medstopper.com* are recommended for providers to guide individual patient deprescribing.

General Taper Process [10,13]

Certain medications require a gradual, stepwise reduction to assess symptom management at lower doses or determine whether discontinuation is feasible.

1. **See Appendix A** for tapering considerations by drug class.
2. Suggested tapering process: 25% dose reduction weekly or longer with patient monitoring is generally effective.
    - Adjust for patient preferences and needs (e.g., gradual vs. quick taper).
3. **Considerations for Tapering**:
    - Patient's age
    - Comorbidities
    - Concurrent medications
    - Indication/treatment
    - Consider tapering SGLT2 inhibitors and GLP-1 receptor agonists in diabetic patients with recent cardiovascular events due to improved evidence on managing cardiovascular risk outcomes.[12]
4. Documenting in Epic notes for deprescribing and patient monitoring recommendations.

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APPENDIX A: Common Oral Medications That May Need Tapering [11]

Drug or Drug class	Rational for Taper	Suggested Taper
Antidepressants	Withdrawal symptoms (FINISH syndrome): **F**lu-like symptoms, **In**somnia, **I**mbalance, **S**ensory disturbances, **H**yperarousal. Symptoms usually begin & peak within one week, last one day to three weeks, & are usually mild. Most common with paroxetine (*Paxil*) & venlafaxine (*Effexor*).	Consider more prudent approach (e.g., for paroxetine, venlafaxine) of reducing dose by 25% every four to six weeks. Reduce the daily dose of venlafaxine ER by 37.5 to 75 mg weekly or paroxetine CR by 12.5 mg weekly. Limited dosing strengths may present challenges for gradual dose reduction for some antidepressants. Consider these tips: • **Desvenlafaxine**: consider extending the dosing interval. In the U.S., a desvenlafaxine 25 mg extended-release tablet is available to facilitate tapering. • **Duloxetine**: in clinical trials, dose was reduced in two steps. • **Venlafaxine**: discontinue once a daily dose of 25 or 37.5 mg is reached. Tapering may not completely eliminate symptoms. Educate patients symptoms are usually transient and mild. If symptoms are problematic, return to previous dose or switch to fluoxetine In **bipolar mania** consult with the provider to consider stopping immediately since the risk of antidepressant induced mania compared to the risk of uncomfortable but nonlife-threatening withdrawal syndrome In **panic disorder**, reduce by one dosage step every one to two months. In **obsessive compulsive disorder**, reduce by 10% to 25% every one to two months.

Drug or Drug class	Rational for Taper	Suggested Taper
Anticonvulsants	Recurrence or worsening of condition being treated or comorbidities (e.g., seizures, mood disorder, headache and pain). **Gabapentin** or **pregabalin** withdrawal symptoms: anxiety, insomnia, nausea, sweating, pain, irritability, agitation, akathisia, palpitations, diarrhea, headache, flu-like symptoms, increased blood pressure, weakness, mental status changes, catatonia, seizures.	Taking into account safety, quality of life, and lack of evidence, a relatively rapid taper (one to three months) has been suggested in patients with epilepsy. Most seizures occur in the first six months after withdrawal, so a slower taper prolongs the "at risk" relapse period. Taper **gabapentin** or **pregabalin** over at least one week. Some patients (e.g., those with seizures) may need tapered over weeks or months. **Migraine prophylaxis**: consider 25% (of original dose) dose reduction weekly or monthly. **Bipolar disorder**: taper over at least two to four weeks.
Antihyperglycemics (sulfonylureas, metformin, insulin, TZD, etc.)	Risk of hypoglycemia (e.g. due to advancing age, tight glycemic control, multiple comorbidities, drug interactions, hypoglycemia history or unawareness, impaired renal function, or on sulfonylurea or insulin)	A deprescribing plan should be developed with the patient and family. Systematic review did not identify trials that provided optimal tapering approaches. Monitor daily for 1-2 weeks after each change (up to 12 weeks for TZD).
Antipsychotic	Recurrence of neuropsychiatric symptoms. Withdrawal symptoms (best-documented with clozapine): sweating, salivation, runny nose, flu-like symptoms, paresthesia, bronchoconstriction, urination, gastrointestinal symptoms, anorexia, vertigo, insomnia, agitation, anxiety, restlessness, movement disorders, psychosis.	No more than 50% every 2 weeks. Abrupt discontinuation can be appropriate in the hospital setting. If **switching** to a different antipsychotic, most experts suggest cross-tapering: reducing the dose of the old antipsychotic while up titrating the new antipsychotic at about the same rate (e.g., over two to three weeks). Consider starting with the usual initial dose of the new agent and continuing it for at least a week before up titrating, while tapering the old medication over several weeks. **OR** • Wait to begin tapering the first agent until the new agent is up

		titrated to a therapeutic dose

Drug or Drug class	Rational for Taper	Suggested Taper
		(i.e., plateau cross-taper). This method is the most effective for preventing relapse but has the highest risk of adverse effects and drug interactions. The product labeling for some antipsychotics, particularly long-acting injectable formulations, provide switching guidance.

Benzodiazepines (Also, included in this section are the Benzodiazepine Receptor Agonists or "Z drugs" [e.g., eszopiclone, zolpidem, zaleplon, and zopiclone].)	Relapse or rebound of condition being treated; withdrawal symptoms: sweating, tachycardia, muscle cramps, tremor, insomnia, anxiety, agitation, nausea, vomiting, hallucinations, seizures. Risk factors for withdrawal: use over one year, high dose, short duration of action (e.g., triazolam [*Halcion*], alprazolam [*Xanax*; especially if daily dose >4 mg for >12 weeks], lorazepam [*Ativan*]).	**Benzodiazepines**: Consider reducing the dose rather than extending the dosing interval to avoid between-dose withdrawal. Consider using liquid formulations for small doses. Chronic benzodiazepine usually needs to be tapered at a rate of 10% per month. In **panic disorder**, discontinue over two to seven months, at a rate not more than 10% per week. "**Z drugs**" (e.g., eszopiclone [U.S.], zolpidem, zaleplon [U.S.], may need to be tapered (or replaced with a long-acting benzodiazepine, which is then tapered) in patients who have escalated the dose. Product labeling for these drugs suggests that when taken as directed, withdrawal symptoms are uncommon and not serious. Nevertheless, Canadian labeling for zolpidem and zopiclone recommends tapering in patients taking the drug for more than a few weeks. Suggested approaches to discontinuing "Z drugs" include: • Substituting another sleep medication (e.g., melatonin, trazodone, mirtazapine). • Taper to lowest effective dose, then gradually eliminate doses. Takes about eight weeks for patients who take Z drugs nightly. **OR**

Drug or Drug class	Rational for Taper	Suggested Taper
		• Switching to lorazepam and tapering by 10% to 25% per week, or 10% every two to four weeks, depending on reason for discontinuation.

Beta-blockers	Sudden withdrawal has been associated with angina, myocardial infarction, and arrhythmias in patients with coronary artery disease. In patients without coronary artery disease, only mild, short-lived withdrawal symptoms such as anxiety or tachycardia may be seen, but angina and myocardial infarction have been reported. Hypertensive urgency has been reported. It is prudent to taper beta-blockers over about a week even in patients without overt coronary artery disease.	Taper over one to two weeks. For post-MI patients, consider tapering over as long as three weeks, and having sublingual nitroglycerin available. If withdrawal symptoms occur, reinstate therapy, at least temporarily.
Butalbital combination products (e.g., *Fiorinal*)	Headache exacerbation, tremors, delirium, seizures. Note: Death from withdrawal seizure have been reported. Risk factors: continuous, long-term use of seven or more doses daily. Note: Risk for medication overuse headaches when used more than 2 days a month	Taper over four to six weeks. If patient taking 12 or more doses daily, consider referral to specialist.
Calcium Channel Blockers	Exacerbation of angina.	No specific taper suggested.
Carisoprodol Note: This works via GABA A receptors like benzodiazepines	Body aches, sweating, palpitations, sadness, anxiety, restlessness, insomnia.	**Long taper** (for patients with renal or liver impairment, age >65 years, or total daily dose >1400 mg): 350 mg three times daily for three days, then twice daily for three days, then once daily for three days. **Short taper**: 350 mg three times daily for one day, then twice daily for two days, then once daily for one day.

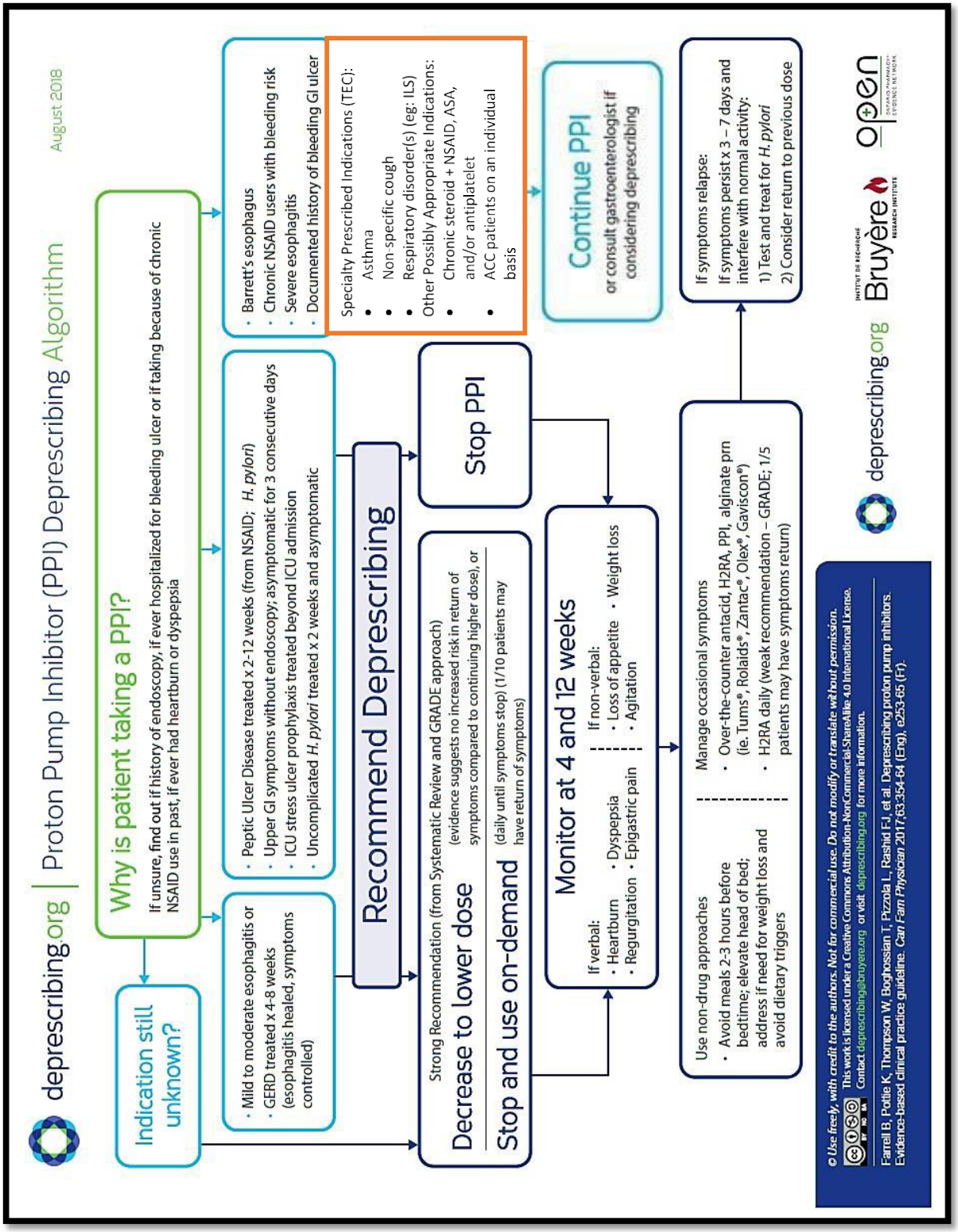
Drug or Drug class	**Rational for Taper**	**Suggested Taper**
Cholinesterase inhibitors (e.g., donepezil)	Discontinuation syndrome: labile mood, agitation, insomnia, trouble concentrating.	Reduce donepezil dose to 5 mg once daily for four weeks, then stop. Monitor closely and restart quickly in the event of deterioration.

Clonidine	Withdrawal syndrome: rebound hypertension, headache, restlessness, anxiety, insomnia, sweating, tachycardia, tremor, muscle cramps, hiccups, nausea, salivation; rarely encephalopathy, stroke, death. Risk factors: use for over one-month, concomitant beta-blocker use, daily dose >1.2 mg daily, hypertension, cardiovascular disease.	Taper over one to two weeks (e.g., 0.1 mg every three to seven days). Beta-blockers increase risk of rebound hypertension during clonidine withdrawal (noncardioselective most problematic [e.g., propranolol) Note: Potential transition plan for patients on beta- blockers and clonidine, taper clonidine and keep the beta-blocker on board Transdermal: Risk of withdrawal lower than with oral but consider tapering patches over two to four days or switching to oral clonidine taper.
Corticosteroids	Adrenal insufficiency or worsening of underlying condition.	Requires individual patient plan dependent on duration of dose and condition.
Guanfacine (*Tenex*, generics)	Catecholamine rebound anxiety, nervousness, transient increase in blood pressure higher than pretreatment level (less problematic than with clonidine). Risk factor: higher doses.	Taper over one to two weeks (e.g., 1 mg every three to seven days).
H2 Blockers	Acid rebound.	No specific taper suggested.
Nitrates	Rebound angina and severe withdrawal headaches.	Not usually tapered.
Memantine (e.g., *Namenda*)	Discontinuation syndrome: insomnia, aggression, delusions, disinhibition.	No specific taper suggested. Concern that symptoms may not be fully reversible if there is a delay in restarting pharmacotherapy if symptoms occur.

Drug or Drug class	Rational for Taper	Suggested Taper
Muscle relaxants (e.g. baclofen, cyclobenzaprine, tizanidine)	Worsening of spasticity, or withdrawal symptoms: delirium, hallucinations, confusion, seizures, movement disorders, psychosis, paranoia, mania, anxiety, tachycardia, sweating, insomnia.	Taper over about one to two weeks. Caution tapering higher dosing of agents that have been used for long period of time (e.g. tizanidine >20 mg/day) may need to be tapered slower/gradually (e.g. over 2-4 weeks vs 1-2 weeks)
Opioids CNS depression	Withdrawal symptoms: flu-like symptoms, insomnia, anxiety, abdominal cramps and other GI symptoms, goose bumps, fatigue, malaise.	Reduce dose rapidly by 10-25% of the daily dose each week, or slowly by 5-25% each month.
Parkinson's disease medications (dopaminergic drugs)	Withdrawal syndrome resembling neuroleptic malignant syndrome.	Taper over about four weeks.
Proton Pump Inhibitors (e.g., omeprazole, pantoprazole)	Rebound acid secretion.	See deprescribing algorithm in APPENDIX B. (*Note orange text box specific to specialty indications*) Taper over four to six weeks. Reduce dose every week or two. Once lowest dose is reached, take it every other day for a week or more. Can further increase the interval to every third day, etc. Consider stepping down to an H2 blocker.
Tramadol (*Ultram*, etc.). Note: The combination MOA opioid and SNRI effect explains side effect.	Withdrawal symptoms: anxiety, restlessness, insomnia, sweating, goose bumps, rigors, pain, nausea, tremors, diarrhea, upper respiratory symptoms, hallucinations (rarely), panic attacks, paresthesias, autonomic dysfunction, abdominal cramps, migraine-like headaches, myoclonus, and restless legs syndrome.	Reduce the dose by 25% every 3 to 4 days. Once at 25% of the original dose and no withdrawal symptoms have been seen, stop the drug. If any withdrawal symptoms occur, go back to approximately 75% of the previously tolerated dose.
Urinary anticholinergics (e.g. oxybutynin, solifenacin, tolterodine, darifenacin)	Withdrawal symptoms (irritability, anxiety, insomnia, sweating and gastrointestinal effects [e.g. nausea]) are usually mild, highly variable and can last up to 6-8 weeks. Severe symptoms (e.g. severe anxiety, tachycardia, orthostatic hypotension, severe insomnia) occur, restart at the previous lowest effective dose.	In general, wean gradually by 25-50% of the daily dose every 1-4 weeks. Consider slower weaning (e.g. 12.5%) when reducing to the final lowest dose. End treatment 2 weeks after administering the lowest dose.

APPENDIX B: PROTON PUMP DEPRESCRIBING ALGORITHM AND NOTES:

Farrell B, Pottie K, Thompson W, Boghossian T, Pizzola L, Rashid J, Rojas-Fernandez C, Walsh K, Welch V, Moayyedi P. (2015). Evidence-based clinical practice guideline for deprescribing proton pump inhibitors.



deprescribing.org | Proton Pump Inhibitor (PPI) Deprescribing Notes

August 2018

PPI Availability

PPI	Standard dose (healing) (once daily)*	Low dose (maintenance) (once daily)
Omeprazole (Losee·)-Capsule	20mg+	lOmg•
Esomeprazole (Nexium·) - Tablet	20' or40b mg	20mg
Lansoprazole (Prevadd')-Capsule	30mg+	15mg+
Dexlansoprazole (Dexilant')- Tablet	30' or60d mg	30mg
Pantoprazole (Tecta", Pantoloc·)- Tablet	40mg	20mg
Rabep,razole (Pariet')- Tablet	20mg	10mg

a Non-erosive reflux disease

b Reflux esophagitis

c Symptomatic non-erosive gastroesophageal reflux disease

d Healing of erosive esophagitis

+ Can be sprinkl'ed on food

• Standard dose PPI taken BID only indicated in treatment of peptiic ulcer c,iused by *H.pylori;* PPI should generally be stopped once eradication therapy is complete unless risk factors warrant continuing PPI (see guideline for details)

GERO= gastroesophageal reflux disease

NSAID = nonsteroidal anti-inflammatory drugs

H2RA = H2 receptor antagonist

SR = systematic review

GRADE= Grading of RecommendaHons Assessment, Development and Evaluation

Engaging patients and caregivers

Patients and/or careg[vers may be more likely to engage if they understand the rationale for deprescribing (risks of continued PPI use; long-term therapy may not be necessary), and the deprescribing process

PPI side effects

Legend

Key

When an ongoing indication is unclear, the risk of side effects may outweigh the chance of benefit

PPIs are associated with higher risk of fractures, *C. difficile* infections and diarrhea, community-acquired pneumonia, vitamin B12 deficiency and hypomagnesemia

Common side effects include headache, nausea, diarrhea and rash

Tapering doses

No evidence that one tapering approach is better than another

Lowering the PPI dose (for example, from twice daily to once daily, or halving the dose, or taking every second day) OR stopping the PPI and using it on-demand are equally recommended strong options

Choose what is most convenient and acceptable to the patient

On-demand definition

Daily intake of a PPI for a period sufficient to achieve resolution of the individual's reflux-related symptoms; following symptom resolution, the medication is discontinued until the individual's symptoms recur, at which point, medication is again taken daily until the symptoms resolve

Farmll B, Potlie K, Toompson **W, Bogtossian** T, Pizzola L. Rashid FJ, et al. Depmscribing proton pump inhibitlls. Evideru:e--based clinical practice guideline. *Gan Fam Phy,idan* 2017;63:354-64{Eng), e253--65 (Fr)

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Heart Failure Protocol

Guidelines for the MultiCare Ambulatory Care Clinical Pharmacist

Pharmacist Authors/Editors: Megan Hodges and Nicholas Eckert

November 2024

Introduction

Heart failure is a progressive clinical syndrome associated with > 1 million hospitalizations annually and a 5-year mortality rate of approximately 50%. MultiCare Yakima Memorial Hospital and MultiCare Yakima Memorial Heart, Lung, and Vascular have developed a team-based approach to provide care for patients with heart failure. Utilizing a collaborative drug therapy agreement, clinical pharmacists assist patients in managing their disease state by providing medication management and lifestyle/disease state progression education. The main objective of heart failure treatment is to improve quality of life and decrease mortality and hospitalizations. Additional goals includeachieving target doses of medications and reducing overall cost to the healthcare system.

Purpose

The purpose of this protocol is to establish guidelines by which clinic pharmacists at MultiCare Yakima Memorial Hospitaland MultiCare Yakima Memorial Heart, Lung, and Vascular provide an evidence-based heart failure management service,thus improving patient outcomes.

Scope

The pharmacist provider is responsible for the following:

- Perform appropriate clinical evaluations.
- Prescribe and or adjust medications according to information contained in this Heart Failure Management Protocol and current evidence.
- Provide relevant drug information to patients and other health care providers.
- Order appropriate laboratory testing and clinical follow-up
- Make appropriate referrals.

The referring provider is responsible for the following:

- Review Heart Failure Management Protocol
- Initiate referral to the pharmacist provider for management of the Heart Failure Protocol
- Be available for consultation with the pharmacist when an issue beyond the scope of the agreement arises or when the presence of critical lab values or vitals suggests further evaluation and/or intervention.

Referrals

Referrals may originate from any licensed Physician or ARNP within the state of Washington. Each practitioner that refers their patient for Pharmacist Medication Management Services agrees to the protocols outlined in the most recent CDTA filed with the WA State Board of Pharmacy. Referrals can be written or transmitted electronically. An agent of the physician (PA-C, nurse, pharmacist, or other staff) may document the verbal order for pharmacy visit referral in the patient chart.

Prescriptions may be initiated and modified for drugs needed for heart failure management. This includes only non-controlled substances.

The referring provider will be consulted for the presence of any acute or serious clinical issue, or the patient will bereferred to primary care for non-cardiac acute illnesses.

Pharmacists with prescriptive authority for concomitant disease states (hypertension, hyperlipidemia, etc.) mayalso manage these conditions when seen for heart failure management if clinically indicated.

Patient Criteria for Referral to Heart Failure Service

- Patient has been diagnosed with heart failure with reduced left ventricular ejection fraction (HFrEF), heart failure with midrange ejection fraction (HFmrEF), orheart failure with preserved ejection fraction (HFpEF)
- Patient is not receiving maximum tolerated medical therapy.
- Patient is experiencing adverse effects from one or more current heart failure medications.

Patient Evaluation: Initial and Subsequent Visits

Physical Exam

- Weight
- Heart rate
- Blood pressure

Patient Education

- Purpose of visits to the clinical pharmacist
- Medication use: indication, dosage, administration, possible side effects and monitoring
- Self-monitoring at home
    - Daily weight
    - Daily BP and HR
    - Sodium and fluid intake
    - Stoplight tool and when to call clinic.
        - Dyspnea, orthopnea, weight, etc
- Benefits of adherence to medication
- Nutrition recommendations; lifestyle modifications (appendix C)
- Encourage smoking cessation, if applicable
- Provide patient education handouts as needed.

Managing Adverse Effects

Symptomatic hypotension	• Spread out administration timing of anti-hypertensive medications. • Decrease dose of diuretic if volume depletion suspected. • Consider reducing the dose of most recently added medication
Fatigue	Adjust beta-blocker dose or increase interval of dose titrations
Hypokalemia	• Consider the following: o Add aldosterone antagonist. o 20mEq potassium chloride daily

	○ Morton's Salt Substitute, ¼ teaspoonful (15 mEq potassium) daily to food • Order repeat BMP in 3 to 7 days
Hyperkalemia	• Stop potassium supplementation, assess dietary K+ intake, reduce or stop ACEI/ARB/ARNI or aldosterone antagonist
Cough due to ACE-I	• Consider changing to ARB

Documentation

- Document visit in the electronic medical record per MultiCare Yakima Memorial Hospital and MultiCareMemorial Heart, Lung, and Vascular
- Update medication list
- Update allergy/adverse reaction database
- Bill for service

Follow Up Intervals

- Follow-up with clinical pharmacist every 1-4 weeks until patient is on optimal guideline directed therapy for HFrEF
- Patients will be disenrolled when medication therapy is at goal or medication therapy is suboptimal but deemed unable to titrate to goal. Follow-up lab monitoring will then be the responsibility of the referring provider.
- Must see managing provider annually.

Referring Provider Consultation

The referring provider will be consulted on any acute or serious clinical issue that lies outside of the outlined protocol or in which the patient's condition warrants additional assessment.

Referring provider will be consulted on any acute or serious clinical issue that lies outside of the outlined protocol or in which the patient's condition warrants additional assessment.

Pharmacotherapy

Pharmacists will provide guideline-directed medical therapy (GDMT) according to ACC/AHA guidelines.
The following medications may be initiated, modified, or discontinued by the clinic pharmacists:

- Angiotensin Converting Enzyme Inhibitors (ACE-I)
- Angiotensin Receptor Blockers (ARBs)
- Angiotensin Receptor -Neprilysin Inhibitor (ARNI)
- Beta-blocker
- Potassium-Sparing Diuretics
- Aldosterone antagonists
- Vasodilators (i.e., hydralazine, nitrates)
- Ivabradine
- Digoxin
- Loop diuretics
- Thiazide diuretics
- Potassium and magnesium supplementation
- SGLT-2 inhibitors
- Vericiguat
- Potassium binders

Initiating Therapy

- Consider initiating with the lowest starting dose.
- Choices will be made to follow guideline directed medical therapy (GDMT) per ACC/AHA Heart failure guideline recommendations, while considering drug interactions, concomitant disease states and previous history, including intolerances side effects (see appendix B)
- Treatment decisions will consider patient needs and preferences.

Adjusting Therapy

- The main objectives of HFrEF are to reduce symptoms and decrease mortality by achieving maximum tolerates doses of GDMT (see appendix A)
- Diuretics will be adjusted as needed for symptom management.

Training for new pharmacists in heart failure

- Mentorship and side-by-side training with current pharmacist including but not limited to:
    - Validation of clinical competency
    - Validation of blood pressure measurement
- Review of guidelines and other key evidence

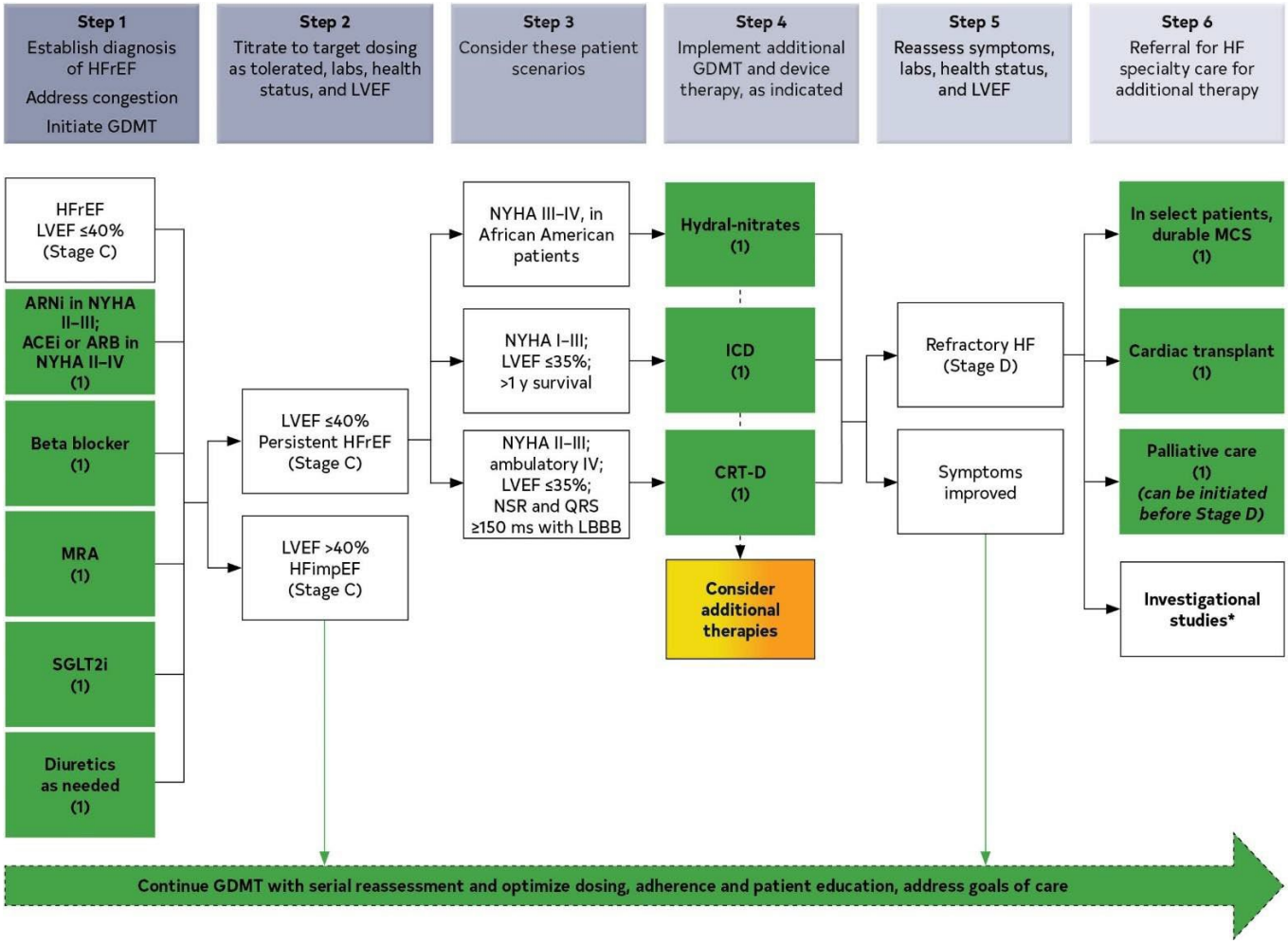
Appendix A

	Initial Dose	Max/Target Dose	Mean doses in clinical trials	Notes and Monitoring
ACE Inhibitors				
captopril	6.25 mg tid	50 mg tid	122.7 mg/day	K+ and Cr 5-10 days after initiation or titration Women of pregnant bearing potential should be asked about BC and counseled on teratogenic effects if these medications are started
enalapril	2.5 mg bid	10-20 mg bid	16.6 mg/day	
fosinopril	5-10 mg once	40 mg once		
lisinopril	2.5-5 mg once	20-40 mg once	32.5-35 mg/day	
perindopril	2 mg once	8-16 mg once		
quinapril	5 mg bid	20 mg bid		
ramipril	1.25-2.5 mg once	10 mg once		
trandolapril	1 mg once	4 mg once		
ARBs				
candesartan	4-8 mg once	32 mg once	24 mg/day	K+ and Cr 5-10 days after initiation or titration Women of pregnant bearing potential should be asked about BC and counseled on teratogenic effects if these medications are started
losartan	25-50 mg once	50-150 mg once	129 mg/day	
valsartan	20-40 mg bid	160 mg bid	254 mg/day	
Aldosterone Antagonists				
spironolactone	12.5-25 mg once	25 mg once or bid	26 mg/day	• K+ and Cr monthly x 3 mo, then every 3 mo • BMP 5-10 days after initiation or titration
eplerenone	25 mg once	50 mg once	42.6 mg/day	
Beta Blockers				
bisoprolol	1.25 mg once	10 mg once	8.6 mg/day	Titrate no more than Q 2 wks to decrease risk of short-term worseningHF sxs
carvedilol	3.125 mg bid	25mg bid (wt <85kg) 50mg bid (wt >85kg)	37 mg/day	
carvedilol CR	10 mg once	80 mg once		
metoprolol ER	12.5-25 mg once to BID	200 mg once to BID	159 mg/day	
Digitalis				
digoxin	0.125-0.25 mg once	0.125-0.25 mg once		BMP and trough (goal 0.5-0.9 ng/mL) 7-10 days after dose change and at least annually
Neprilysin inhibitor				
sacubitril/ valsartan (Entresto®)	24/26 mg bid (if ACEI or ARB naïve, on low dose - ≤ enalapril 10mg, valsartan 160 or equivalent, age ≥ 75, eGFR < 30ml/min) 49/51 mg bid	97/103 mg bid		• Recommended to replace ACEI orARB • Allow 36 hr washout from ACEI • Double dose q 2-4 wks • K+ and Cr 5-10 days after initiation or titration • Pro-BNP will need to be utilized in place of BNP

				• Consider reducing the dose of diuretics when imitating in a euvolemic patient Women of pregnant bearing potential should be asked about BC and counseled on teratogenic effects if these medications are started
Vasodilators				
fixed-dose combination	37.5/20 mg tid	75/40 mg tid	175/90 mg/day	
hydralazine	25-50 mg tid	300 mg in divided doses		
isosorbide dinitrate	20-30 mg tid-qid	120 mg daily in divided doses		
SGLT-2 Inhibitors				
dapagliflozin (Farxiga)	10 mg	10 mg		Contraindicated in T1DM, dialysis, lactation Caution: • Dapagliflozin: eGFR <30 • Empagliflozin: eGFR <20 • Sotagliflozin: eGFR < 25 • Pregnancy • Increased risk of mycotic genital infections • May contribute to volume depletion, consider altering diuretic dose if applicable • Ketoacidosis in patient with diabetes ▪ Recommend temporary discontinue before scheduled surgery to avoid potential risk of ketoacidosis ▪ Assess patient who present with s/sxof metabolic acidosis for ketoacidosis, regardless of blood glucose levels • Urosepsis and pyelonephritis
Empagliflozin (Jardiance)	10 mg	10 mg		
Sotagliflozin (Inpefa)	200 mg (not more than 1 hour before the first meal of the day) -Can increase digoxin concentrations. Consider reducing the dose of digoxin by 15 to 30% or modify the dosing interval -May decrease serum concentration of hormonal contraceptives	400 mg		
Miscellaneous				
Vericiguat (Verquvo)	2.5 mg once daily with food; double the dose every 2 weeks to target of 10 mg once daily			• Decrease dose in half for SBP < 90 • Avoid use with long-acting nitrates and PDE 5 inhibitors
Ivabradine (Corlanor)	2.5mg BID for age $\geq$ 75 or history of conduction defects 5mg BID for age < 75	Max 7.5mg BID to achieve heart rate of 50-60 bpm		• Take with food • HR < 50 --reduce by 2.5mg BID • HR > 60 – increase by 2.5mg BID every 2-4 weeks to achieve HR of50-60 bpm

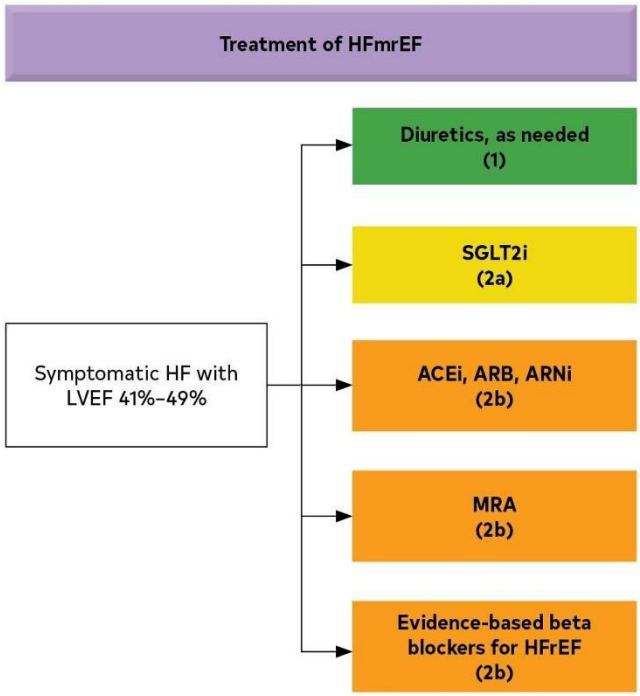
Appendix B

GDMT for HFrEF



GDMT for HFmrEF

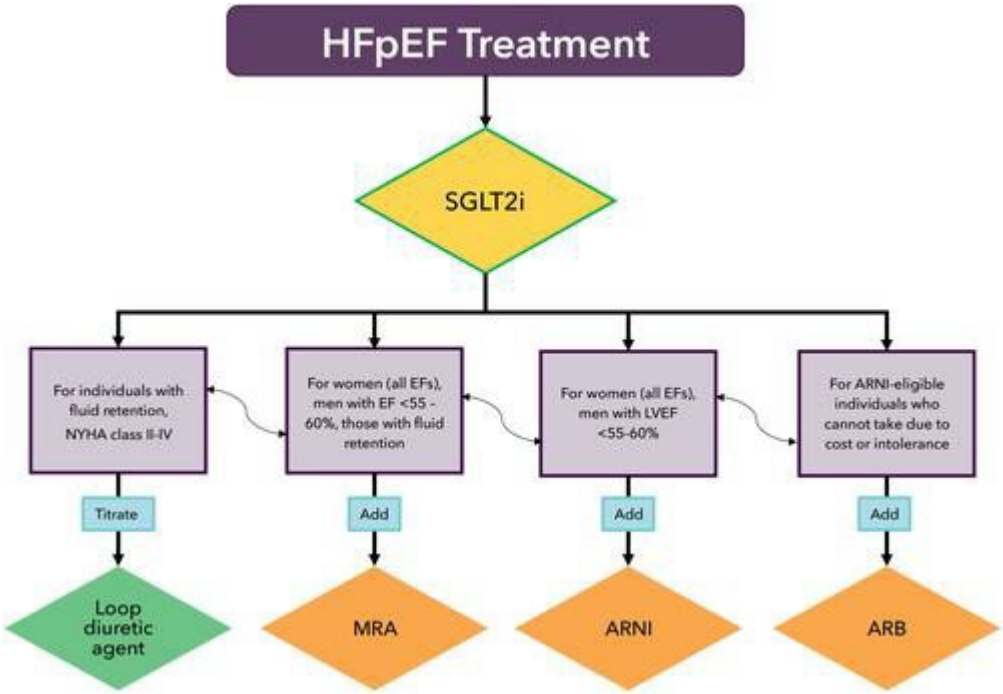
COR	LOE	Recommendations
2a	B-R	1. In patients with HFmrEF, SGLT2i can be beneficial in decreasing HF hospitalizations and cardiovascular mortality.[1]
2b	B-NR	2. Among patients with current or previous symptomatic HFmrEF (LVEF, 41%–49%), use of evidence-based beta blockers for HFrEF, ARNi, ACEi, or ARB, and MRAs may be considered to reduce the risk of HF hospitalization and cardiovascular mortality, particularly among patients with LVEF on the lower end of this spectrum.[2–9]



GDMT for HFpEF

COR	LOE	Recommendations
1	C-LD	1. Patients with HFpEF and hypertension should have medication titrated to attain blood pressure targets in accordance with published clinical practice guidelines to prevent morbidity.[1–3]
2a	B-R	2. In patients with HFpEF, SGLT2i can be beneficial in decreasing HF hospitalizations and cardiovascular mortality.[4]
2a	C-EO	3. In patients with HFpEF, management of AF can be useful to improve symptoms.
2b	B-R	4. In selected patients with HFpEF, MRAs may be considered to decrease hospitalizations, particularly among patients with LVEF on the lower end of this spectrum.[5–7]
2b	B-R	5. In selected patients with HFpEF, the use of ARB may be considered to decrease hospitalizations, particularly among patients with LVEF on the lower end of this spectrum.[8,9]
2b	B-R	6. In selected patients with HFpEF, ARNi may be considered to decrease hospitalizations, particularly among patients with LVEF on the lower end of this spectrum.[10,11]
3: No-Benefit	B-R	7. In patients with HFpEF, routine use of nitrates or phosphodiesterase-5 inhibitors to increase activity or QOL is ineffective.[12,13]

*See Section 7.2, "Diuretics and Decongestion Strategies in Patients with HF," and Section 10.2, "Management of Atrial Fibrillation (AF) in HF" for recommendations for use of diuretics and management of AF in HF.



Appendix C

Lifestyle Changes	
Fluid restriction	1.5 -2 L/day for stage D or patients with hyponatremia
DASH Diet	Eat a lower-fat diet rich in vegetables, fruits, and low-fat dairy foods
Exercise	Get 30 minutes per day of aerobic activity as tolerated
Limit sodium	Eat no more than 2,000 mg per day
Limit alcohol	Have no more than 2 drinks per day for men or 1 drink per day for women (1 drink = 12 oz beer, 5 oz wine, or 1.5oz 80-proof whisky)

References:

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Hyperlipidemia Protocol

Guidelines for the MultiCare Ambulatory Care Clinical Pharmacist

Pharmacist Authors/Editors: Megan Hodges and Nicholas Eckert

November 2024

Introduction

Elevated blood lipid levels are a modifiable risk factor for atherosclerotic cardiovascular disease (ASCVD.) The Memorial Physicians Group and Yakima Heart Center has developed a team-based approach to provide care for patients reduce ASCVD risk which includes lipid management. Utilizing a collaborative drug therapy agreement, clinical pharmacists assist patients in managing their disease state by providing medication management (dose adjustments, counseling, monitoring) as well as lifestyle and disease state progression education.

Purpose

The purpose of this protocol is to establish guidelines by which clinic pharmacists at MultiCare Yakima Memorial Hospital and Yakima Heart Center provide an evidence-based hyperlipidemia management service, thus improving patient outcomes.

The pharmacist provider is responsible for the following:

- Perform appropriate clinical evaluations.
- Order appropriate follow-up clinical and laboratory testing
- Refer patients to the referring physician, primary care physician (PCP), or another provider such as dieticianas clinically indicated.
- Provide relevant drug information to patients and other health care providers.
- Prescribe and/or adjust lipid medications according to information contained in this protocol and best practices.

The referring provider is responsible for the following:

- Review Hyperlipidemia Management Protocol and sign Collaborative Practice agreement.
- Initiate referral to the pharmacist provider for management of the Hyperlipidemia Protocol
- Be available for consultation with the pharmacist provider when an issue beyond the scope of the protocol arises.
- Reevaluate patient at yearly intervals.

Referrals

Referrals may originate from any physician or ARNP with Yakima Heart Center or Memorial Physicians Group who has signed the Collaborative Drug Therapy Agreement. Referrals will be written or transmitted electronically.

Prescriptions may be initiated and modified for drugs needed for hyperlipidemia management. All prescriptions will be completed by the pharmacist but include the name of the referring provider or PCP. Pharmacists utilizing protocols for concomitant disease states (hypertension, heart failure, etc) may also manage these conditions when seeing patients for HLD management if clinically indicated.

The supervising physician or designee will be consulted for the presence of any potentially serious consequences of hyperlipidemia or its treatment, including, but not limited to the following:

- Symptoms of cerebral infarct or thrombosis
- Any acute and/or potentially serious manifestations of atherosclerotic disease
- Lab work abnormalities including elevated liver enzymes (greater than 3x UNL) or signs and symptoms of liver dysfunction.

Patient Criteria for Referral to Hyperlipidemia Service

- Patient has dyslipidemia.
  - Patient not on lipid lowering therapy requires risk assessment and treatment if needed.
  - Patient recently started on lipid lowering medication.
  - Patient currently on sub-optimal lipid lowering medication.
  - Patient has adverse effects on lipid lowering medication.
- Patient diagnosed with ASCVD and requires lipid lowering to reduce secondary risk.

Referring Provider's Responsibilities at Time of Referral

- Evaluate and treat possible secondary causes of hyperlipidemia: hypothyroidism, nephrotic syndrome, obstructive liver disease.
- Order lipid panel with LDL if not performed in last 3 months.
- Refer to Clinical Pharmacist Service for hyperlipidemia management though the EMR.
- Referring provider, care manager RN, or support staff will explain the purpose of the referral to the patient and instruct patient to bring BP logbook and home blood pressure monitor to pharmacist appointment.
- The referring provider may initiate treatment or modify current regimen (along with the appropriate follow-up labs) in conjunction with referral.

Pharmacist Hyperlipidemia Management Appointment

Limited Physical Exam

- One BP measure in either arm
- If BP is above target goal, take a second BP

Develop Care Plan through Shared Decision Making

- ASCVD risk reduction considerations/tools
  - Patient's history of past and present hyperlipidemia management strategies
  - Consider barriers to adherence, including, but not limited to patient understanding, finances and social support.
  - Evaluate concomitant factors that may affect lipid panel including steroid therapy, recent trauma, development of hypothyroidism, acute illness or infection, blood glucose control, venipuncture issues, new myocardial infarction, changes in estrogen status.

- Lipid Care Pathway (appendix b) based on 2018 ACC/AHA Guideline on the Management of Blood Cholesterol
- Other evidence-based guidelines may be consulted.
- Utilization and dosing of aspirin will be based on the most recent guidelines.

- Pancreatitis Risk Reduction consideration/tools
  - Patient's history of past and present hypertriglyceridemia management strategies
  - Diet, exercise, and alcohol consumption patterns as well as blood glucose control
  - Utilize 2012 Clinical Practice Guideline: Evaluation and Treatment of Hypertriglyceridemia: An Endocrine Society Clinical Practice Guideline
    https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3431581/

Patient Education

- Purpose of visits to the Clinical Pharmacist Service
- Medication use: indication, dosage, administration, possible side effects and monitoring
- Lifestyle recommendations (Appendix C)
  - Heart Healthy Diet: DASH, Mediterranean Diet
  - AHA Regular exercise habits.
  - Avoidance of tobacco products
  - Maintenance of a healthy weight
- Refer patient to dietician for further medical nutrition therapy as appropriate.
  - Highly recommended for triglycerides >1000

Pharmacotherapy

The following medications may be initiated, modified, or discontinued by the clinic pharmacists.

- HMG-CoA Reductase Inhibitors
- Ezetimibe
- Bile Acid Sequestrants
- Fibrates
- Niacin
- Fish Oil
- Phytosterols
- PCSK-9 inhibitors (Yakima Heart Center only)

Initiating Therapy (See Appendix A for Lipid Care Pathway and Appendix B for non-statin and supplement strategies)

- Choices will be made with consideration to drug interactions, concomitant disease states and previous history with lipid lowering agents, side effects or intolerances, pill burden and cost.
- Treatment decisions will consider patient needs and preferences and referring provider guidance.
- ASCVD drug of choice is appropriate strength statin. For those determined to be statin-intolerant, ezetimibe is preferred among available secondary choices.
- Pancreatitis risk reduction medication for triglycerides >1000 is a fibrate. Secondary treatment recommendations (either as monotherapy or combined therapy) include fish oil and niacin.

Medication Adjustments may be needed to optimize response or address patient concerns which may include side effects or cost.

Follow Up Intervals

- 6 weeks to 12 months for patients utilizing only lifestyle measures to reduce cardiovascular risk
- For patients started on LDL lowering medication
    - 4-12 weeks after medication initiation or medication adjustment
    - Thereafter, every 3-12 months as clinically indicated to assess adherence and responsiveness to therapy.
- Patient may be graduated back to referring provider once on an effective, tolerated regimen, usually within 3-12 months, considering level of risk, patient's past history of medication tolerance and whether the referring provider is already closely monitoring lipid levels.

Documentation

- Documents visit in the electronic medical record per MYVM or YHC policy.
- Update medication list
- Update allergy/adverse reaction database
- Forward completed clinic note to referring provider for review.
- Complete billing charge

Referring Provider Consultation

Referring provider will be consulted on any issue that lies outside of the outlined protocol or in which the patient's condition warrants additional assessment including:

- Symptoms of cerebral infarct or thrombosis
- Any acute and/or potentially serious manifestations of atherosclerotic disease
- Signs and symptoms of liver dysfunction, elevated liver enzymes (greater than 3x UNL)

Statin Induced Muscle Effects Management

- More likely when one or more of the following characteristics are present.
    - Advanced age (>65 years old)
    - Female sex
    - Low body mass index
    - Multisystem diseases
    - Diseases affecting liver or kidney (including renal function impairment)
    - Hypothyroidism (untreated)
    - Vitamin D deficiency
    - Polypharmacy

- Approach to suspected statin induced myopathy.
    - Assess changes in physical activity, acute injury or illness.
    - Lab work Evaluation when patient reports muscle pain or weakness
        - CPK (preferably greater than 72 hours after exercise) If >3x UNL, stop statin and notify referring provider.
        - TSH, if hypothyroid, refer to provider for treatment. Consider stopping statin until resolved.
        - 25 hydroxy vitamin D, if low, refer to provider for treatment, consider stopping statin until resolved

    - Review patient's medication list for medications that either interact with statins or medications that are also related to muscular side effects.

    - Adjust statin
        - Consider stopping statin for 2 to 6 weeks.
        - After statin holiday, consider changing from lipophilic statin to hydrophilic statin, statin retrial at previous dose, or retrial with a lower dose of the same statin.
        - Titrate patient to recommended statin intensity or to maximum dose tolerated.

- Alternate statin dosing strategies (ASCVD outcomes have not been studied)
    - Best suited to long-acting statins: rosuvastatin as little as once weekly, atorvastatin as little as twice weekly
    - Utilizing shared decision making, may gradually titrate up as tolerated.
    - May consider ezetimibe 5-10mg on statin "off days," especially high-risk patients with non-optimumLDL-C lowering on maximum tolerated statin dose.
    - May consider the addition of phytosterols and/or soluble fiber to further lower LDL-C if needed (see appendix B)

- To increase statin tolerability, Coenzyme Q 10 100-200mg daily may be safely utilized althoughdata supporting efficacy is weak.
    - Begin 2 weeks before statin restarted.

Training for new pharmacists in hyperlipidemia management

- Mentorship and training side-by-side with current pharmacist
- Review of updated guidelines

Appendix A

LIPID CARE PATHWAY

STEP 1

DIAGNOSE and ASSESS RISK

- Assess current lipid profile (non-fasting is acceptable unless TG > 400mg/dL)
- Calculate 10 year ASCVD risk if indicated

STEP 2

CUSTOMIZE management of hyperlipidemia

- Therapeutic Lifestyle Changes (TLC) – smoking cessation, weight control, exercise, healthy diet (DASH Diet)
- Dispense a 3 month supply and follow-up with PCP or clinical pharmacist in 1-3 months

Clinical ASCVD	**LDL > 190**	**DM aged 40-75 years**	**LDL 70-189 + 40-75 years of age**
Age ≤ 75: High intensity statin Age ≥75: High or moderate intensity statin	High intensity	Moderate intensity Consider high intensity in 50-70 years of age and multiple CV risk factors or ASCVD risk > 20%	10 yr ASCVD risk 7.5-19.9%: moderate intensity 10 yr ASCVD risk 20%: high intensity

High-Intensity Statin Therapy	Moderate-Intensity Statin Therapy	Low-Intensity Statin Therapy
Daily dose lowers LDL–C on average, by approximately ≥50%	Daily dose lowers LDL–C on average, by approximately 30% to <50%	Daily dose lowers LDL–C on average, by <30%
Atorvastatin 40–80 mg **Rosuvastatin** 20-40 mg	**Atorvastatin** 10-20mg **Rosuvastatin** 5-10 mg **Simvastatin** 20–40 mg **Pravastatin** 40-80 mg **Lovastatin** 40mg	**Simvastatin** 10 mg **Pravastatin** 10–20 mg **Lovastatin** 20mg

STEP 3

REASSESS:

- Initial evaluation 1-3 months after medication initiation to monitor adherence and % LDL drop
- Subsequent evaluation of LDL and ASCVD Risk as needed or when there is a dosage change

LDL % lowering goal met?

YES → Continue current management, f/u yearly with PCP or Pharmacist

NO ↓

SET Follow-Up Schedule and STEP UP Therapy

1. Assess adherence to statin and assess for side effects
2. Assess adherence to TLC
3. Maximize dose of statin or switch to a more potent statin
4. If still not achieving percent drop from baseline LDL refer to clinical pharmacist, specialist, or CWC for workup

Lipid Care Pathway - Sep 2014

*Consider adding ezetimibe to patients on maximum tolerated statin therapy in the following circumstances:

- LDL > 70 mg/dl with clinical ASCVD
- LDL > 100 mg/dl with baseline LDL > 190mg/dl
- Diabetes and 10 year ASCVD risk ≥ 20% to achieve LDL lowering of ≥ 50%

Medication Cost *(subject to change)*			
Statins			
Medication	**Optimal Dosing Range**	**Estimated Cost***	**Considerations**
Pravastatin	10mg – 80mg daily	$	• Calcium Channel Blocker interaction: o Do not exceed simvastatin 20mg with amlodipine o Do not exceed lovastatin 20mg or simvastatin 10mg with verapamil or diltiazem o Consider limiting atorvastatin dose with diltiazem or verapamil • Amiodarone interaction: o Do not exceed 40mg lovastatin or 20mg simvastatin; limited atorvastatin dose o Consider using pravastatin or Rosuvastatin • Macrolide Antibiotic interaction (↑ risk of rhabdomyolysis) o HOLD lovastatin and simvastatin o Do not exceed pravastatin 40mg or atorvastatin 20mg with clarithromycin o Consider Rosuvastatin in patients needing long-term macrolide use • Use statins with caution with niacin ≥1000mg/day
Simvastatin	20 mg – 40mg daily	$	
Atorvastatin	10mg – 80mg daily	$	
Rosuvastatin	10mg – 40mg daily	$	
Lovastatin	10mg – 80mg daily	$	

Patients not achieving clinical goals on statin monotherapy, or have intolerance to statins, a provider may consider other treatment options. However, it is important to note that current literature does not support the routine use of non-statin medication as monotherapy, or in combination with a statin, resulting in further reduction of ASCVD risk or events.

Alternative Medication Options			
Medication	**Optimal Dosing Range**	**Estimated Cost***	**Considerations**
Gemfibrozil	600mg twice daily	$	• Do not use with statins (↑ risk of rhabdomyolysis) • Avoid in patient with severe renal failure (GFR <10mL/min) • Dose reduction by 50% at usual dosing intervals in patients with moderate renal failure (GFR 10-50mL/min)
Fenofibrate	160mg daily	$$	• Potential increased risk of myalgias when used with statins • Dose reduction in moderate renal failure and avoid in patients with severe renal failure
Fenofibrate	145mg daily	$$$$	
Omega-3-Acid Ethyl Esters (Lovaza)	4 grams daily or 2 grams twice daily	$$$$	• Caution in patients with known allergy or sensitivity to fish • Swallow whole
Ezetimibe	10mg daily	$$	

* Estimated **Cost** is based on average for a 30-day supply
$ → $1-$25; $$ → $26-$75; $$$ → $76-$150; $$$$ → >$151

Appendix B

Medication Class	Drug (Trade Name)	Usual Dosage (mg/ day)	Special Considerations
Ezetimibe	Zetia®	10mg QD	First line non-statin therapy for highly statin intolerant or those not meeting goals with statin monotherapy Generic now available
PCSK-9 Inhibitors	Praluent	75mg-150mg SQ every 2 weeks or 300mg SQ monthly	Second line non-statin therapy for statin intolerant or those not meeting goals with statin monotherapy
	Repatha (Evolcumab®)	140mg SQ every 2 weeks or 420mg SQ monthly	
Bile Acid Sequestrants	Cholestyramine (Questran®)	Initial: 4 gm QD or BID Maintenance: 8-16 gm in divided doses, MAX: 24 gm/day	Second or Third-line alternative to Zetia or PCSK-9 inhibitors for highly statin intolerant. Modest hypoglycemic effect. Do not start if fasting triglycerides >300. Once started, continue triglyceride monitoring Use in conjunction with psyllium and careful instruction to prevent constipation Avoid in patients with gastroparesis Instruct patient regarding drug interactions
	Colestipol (Colestid®)	Powder: 5-30 gm PO QD or divided doses Tab: 2-16 gm QD or divided doses	
	Colesevelam HCl(WelChol™)	1875mg BID or 3750mg QD	
Niacin	Niacin	Immediate Release: 1-2 grams TID, MAX: 6gm/day Extended Release: 1000mg- 2000mg QD, MAX 2000mg/ day	No longer routinely combined with statins Transaminase elevations (AST/ALT) may occur. Liver function tests should be monitored in all patients before, every 6 to 8 weeks for the first year, and periodically thereafter during extended-release niacin treatment. If symptomatic elevations of serum liver enzymes rise to 3 times the ULN niacin therapy should be discontinued Second or third line agent for hypertriglyceridemia Caution should be used in patients with diabetes, peptic ulcer disease, or gout

Non-statin Hyperlipidemia Medications - continued			
Medication Class	Drug (Trade Name)	Usual Dosage (mg/ day)	Special Considerations
Fibric Acid Derivatives	Gemfibrozil (Lopid®)	600mg BID	• Use only in patients with hypertriglyceridemia (triglycerides ≥ 500 mg/dl) as indicated • Can be considered for LDL reduction if unable to tolerate/afford statins, ezetimibe, BAS, and PCSK-9 inhibitors • No longer routinely used with statins. If combination deemed necessary, fenofibrate preferred. • Renal status should be taken into account. eGFR <30 mL/min, avoid use eGFR 30-59 mL/min, max dose of 54mg
	Fenofibrate (Tricor®)	48-145mg QD	
Omega-3-acid Ethyl Esters	Lovaza®	4gm QD or 2gm BID	• Use only in patients with hypertriglyceridemia (triglycerides ≥ 500 mg/dl) as indicated • Caution in patients with known allergy or sensitivity to fish
Non Prescription Strategies			
Supplements	Phytosterols	1-3 grams per day (once daily or divided)	• 2 grams/day lowers LDL-C by 5-15% • Generally Recognized as Safe (GRAS) status in US • Potential safety concern in patients with phytosterolemia • Side effects: mild bloating, diarrhea, constipation • Effect on cardiovascular morbidity and mortality has not been determined
	Soluble/viscous fiber	Sourced from foods or fiber laxatives	• 3-12.4 g/day, mean TC and LDL-C levels decreased by 9.7 and 11.6mg/dl, respectively • Consume with adequate fluid • Effect of soluble/viscous fiber on cardiovascular morbidity and mortality has not been demonstrated
	Red Yeast Rice	Follow package instructions	• Generally, not recommended • Well-designed RCT (n=4870) in China demonstrated significantly reduced CV events • Tolerability rates exceed 90% in statin-intolerant patients • US available commercial products vary substantially and one study found supplements containing nephrotoxic toxin citirinin • RYR in natural state contains lovastatin. All supplements containing prescription products are considered by the FDA to be unapproved drugs and illegal

Appendix C

Lifestyle recommendations and resources

LDL lowering Headlines

- Limit saturated fat consumption to 10-15g daily for women or 15-20g daily for men. Cut back on cheese, butter, and other full fat dairy products. Choose lower fat cuts of meat and portion control meat (an ideal meat portion is just 3 oz's after cooked.)
- No amount of trans fats is healthy. Even if packaging says, "no trans fats," check the ingredientlist for partially hydrogenated oils which is a source of trans fats.
- Avoid eating out.
- Avoid fried foods.
- Eat 1 oz nuts daily (for example 23 almonds) or 2 tablespoonsful nut butter daily.
- Increase soluble fiber to 10-25g per day.

  Fruits

  Vegetables: especially carrots, broccoli, cauliflower, Brussel sprouts
  Grains: oatmeal, oat bran, barley, ground flaxseed
  Legumes: black beans, white beans etc, hummus
  Fiber supplement: Metamucil (psyllium)
  Foods made with fiber: bread, some pastas, etc

Triglyceride Lowering Headlines:

Eat foods lower in fats.
Avoid or limit refined or concentrated sweets.

- Regular sweetened soft drinks
- Juice (including 100% fruit juice)
- Sugar (white table sugar, brown sugar, honey, jam/jelly, syrup, candy, corn syrup)
- Dried fruit (raisins, dried blueberries, dried cranberries)
- Ice cream and frozen yogurt

Avoid or limit alcohol.
Generally, avoid processed foods, and portion control pasta, bread, and rice
Any level of exercise will bring triglycerides down, including walking.

AHA Heart Healthy Exercise Recommendations:

<u>For Overall Cardiovascular Health:</u>

At least 30 minutes of moderate-intensity aerobic activity at least 5 days per week for a total of 150

-OR-

At least 25 minutes of vigorous aerobic activity at least 3 days per week for a total of 75 minutes; or a combination of moderate- and vigorous-intensity aerobic activity

-AND-

Moderate- to high-intensity muscle-strengthening activity at least 2 days per week for additional health benefits.

For Lowering Blood Pressure and Cholesterol

An average 40 minutes of moderate- to vigorous-intensity aerobic activity 3 or 4 times per week

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Hypertension Management Protocol

Guidelines for the MultiCare Ambulatory Care Clinical Pharmacist

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Introduction

Hypertension is the most common condition seen in primary care and leads to myocardial infarction, stroke, renal failure, and death if not detected early and treated appropriately. The MultiCare Primary Care Clinics and Heart, Lung, and Vascular has developed a team-based approach to provide care for patients with hypertension. Utilizing a collaborative drug therapy agreement, clinical pharmacists assist patients in managing their disease state by providing medication management (i.e., dose adjustments, counseling, monitoring) and lifestyle/disease state progression education.

Purpose

The purpose of this protocol is to establish guidelines by which clinic pharmacists at MultiCare Yakima Memorial Hospital and Heart, Lung, and Vascular provide an evidence-based hypertension management service, thus improving patient outcomes.

The pharmacist provider is responsible for the following:

- Perform appropriate clinical evaluations.
- Order appropriate follow-up clinical and laboratory testing
- Refer patients to the referring physician, primary care physician (PCP), or other provider such as dietician as indicated by severity of condition and/or scope of practice.
- Provide relevant drug information to patients and other health care providers.
- Prescribe and or adjust blood pressure lowering medications according to information contained in this Hypertension Management Protocol and best practices.
- Arrange for appropriate follow-up.

The referring provider is responsible for the following:

- Review Hypertension Management Protocol and sign Collaborative Practice agreement.
- Initiate referral to the pharmacist provider for management of the Hypertension Protocol
    - The referral can also be proposed and initiated by the referring provider's flow manager (medical assistant) or nurse care manager.
- Be available for consultation with the pharmacist provider when an issue beyond the scope of the protocol arises.
- Reevaluate patient at yearly intervals.
- Identify blood pressure goal if not standard.

Referrals

Referrals may originate from any physician or ARNP with MultiCare Yakima Memorial Hospital who has signed the Collaborative Drug Therapy Agreement. Referrals will be written or transmitted electronically.

Appointment times with the pharmacist provider will be determined based on patient and clinic needs.

Prescriptions may be initiated and modified for drugs needed for hypertension management. This includes only non-controlled substances. All prescriptions will be completed by the pharmacist but include the name of the referring provider or PCP. Pharmacists utilizing protocols for concomitant disease states (hyperlipidemia, heart failure, etc.) may also manage these conditions when seeing patients for HTN management if clinically indicated.

The supervising physician or designee will be consulted for the presence of any potentially serious consequences of hypertension or its treatment, including, but not limited to the following:

- Symptoms of cerebral infarct or thrombosis
- Any acute and/or potentially serious manifestations of atherosclerotic disease

Patient Criteria for Referral to Hypertension Service
(Appendix B for MYVM DPC Hypertension Care Pathway Tool)

- Patient has hypertension not at goal.
    - Not on blood pressure lowering medications but ready to initiate.
    - Blood pressure lowering medication initiated.
    - On blood pressure lowering medication but not at goal
- Patient has hypertension at goal but is experiencing adverse effects from current therapy.

Referring Provider's Responsibilities

- Identify blood pressure goal. If a goal is not specified, the following goals will be used:
    - MultiCare Yakima Memorial Hospital and Heart, Lung, and Vascular:
        - <130/80
            - All patients < 65 years of age
            - All patients with diabetes and microalbuminuria
        - <150/90
            - Adults ≥ 65 years of age with a high burden of comorbidity and limited life expectancy will be considered for a higher blood pressure goal.

- Order BMP if not performed in the last six months.
- Include referral to Clinical Pharmacist in clinic visit documentation in EMR.
- The referring provider may initiate treatment or modify current regimen (along with the appropriate follow-up labs) in conjunction with referral.
- Referring provider, care manager RN, or support staff will explain the purpose of the referral to the patient and instruct patient to bring BP logbook and home blood pressure monitor to pharmacist appointment.

Patient Evaluation: Initial

Confirm patient's blood pressure goal. Use ASCVD Risk Estimator or Mayo Clinic Statin/ Aspirin Choice Decision Aid to assist in determining cardiovascular risk.

Identifiable causes of Hypertension

- Sleep apnea
- CKD
- Primary aldosteronism
- Renovascular disease
- Chronic steroid therapy or Cushing syndrome
- Pheochromocytoma
- Coarctation of the aorta
- Thyroid or parathyroid disease
- Drug-induced or related causes
    - NSAIDs
    - Amphetamines
    - Sympathomimetics (ie, decongestants)
    - Oral contraceptives
    - Adrenal steroids
    - Cyclosporin or tacrolimus
    - Erythropoietin

Physical Exam

- One BP measurement in each arm and resting heart rate. If BP differs by >10 mmHg, the higher pressure more accurately reflects intra-arterial pressure. Arm choice should be noted and once chosen, it is not necessary to measure BP in both arms at subsequent visits.
- If unable to take a BP measurement on the arm, a medical assistant or nurse will be consulted.

Patient Education

- Purpose of visits for hypertension management
- Medication use: indication, dosage, administration, possible side effects and monitoring
- Home blood pressure monitor use: selection, appropriate technique, and testing
- Benefits of adherence with medication
- Nutrition recommendations: lifestyle modifications (see Appendix C)
- Encourage smoking cessation, if applicable
- Provide patient education handouts as needed.

Adherence

- Assess barriers to adherence; including, but not limited to, patient understanding, finances and social support.
- Evaluate concomitant factors that may affect blood pressure, including other medications, renal function, diet, smoking status, and alcohol use.
    - Refer patient to dietician for further medical nutrition therapy as appropriate.
    - Refer patient to smoking cessation program as appropriate and available.
    - Message the referring provider regarding a potential need for a sleep apnea work-up

Managing Adverse Effects

Symptomatic hypotension

- Consider reducing the dose of most recently added medication by half

Cough on ACEI

- Change to ARB

Edema

- Consider decreasing dose of non-dihydropyridine calcium channel blocker

Hypokalemia

- Consider the following:
    - 20mEq potassium chloride daily
    - Morton's Salt Substitute, ¼ teaspoonful (15 mEq potassium) daily to food
    - Change to triamterene 37.5/hydrochlorothiazide 25mg (generic Dyazide®)
- Order a BMP 3 to 7 days before visit or within one month

Home Blood Pressure Monitoring (HBPM)

Preparation	Patients should refrain from smoking or ingesting caffeine 30 minutes prior to measurement
Body Positioning	Patients should be seated quietly for at least 5 minutes in a chair with their backs supported
	Arms should be supported at heart level. If the cuff is above heart level, the reading may be falsely low; if below heart level, it may be falsely high.
Cuff Size	A cuff that is too small can lead to falsely elevated readings
	A cuff that is too large can may lead to falsely low readings
Repeat Measurements	Multiple readings should be recorded individually
BP Log	Patients should log blood pressure readings for review by provider

In rare patients, or in those with arrhythmias, home blood pressure monitors may not sense accurately.

Home blood pressure monitors should be validated by staff in the clinic. A difference of +/- 5 mmHg is acceptable to validate a home monitor. A monitor should be validated periodically throughout the lifetime of the machine, per the pharmacist's discretion.

When using HBPM or Ambulatory Blood Pressure Monitoring (ABPM) to evaluate the response to treatment (for example, in people identified as having a 'white-coat effect'* and people who choose to monitor their blood pressure at home), aim for a target average blood pressure during the person's usual waking hours of:

- Below 135/85 mmHg for people aged under 65 years
- Below 145/85 mmHg for people aged 65 years and over

Documentation

- Documents visit in the electronic medical record per YHC or MYVM policy.
- Update medication list
- Update allergy/adverse reaction database
- Forward completed clinic note to referring provider for review.
- Complete billing charge

Follow Up Intervals

- Patient to bring home BP monitor to initial visit and if suspected readings at home are not correct.
- Patient to bring logbook to visit

Referring Provider Consultation

The referring provider will be consulted on any issue that lies outside of the outlined protocol or in which thepatient's condition warrants additional assessment.
This includes:

- Suspected undiagnosed or uncontrolled sleep apnea.
    - Consider sleep apnea if the patient has resistant hypertension (3+ blood pressure lowering medications)

Special Populations

White Coat Hypertension

"White coat" hypertension is seen in approximately 15-20% of hypertensive patients. Self-monitoring of blood pressure is warranted for evaluation of "white coat" hypertension. For individuals identified as having a 'white-coat effect'*, consider ABPM or HBPM as an adjunct to clinic blood pressure measurements to monitor the response to antihypertensive treatment with lifestyle modification or drugs.

Geriatric Patients

Increases in DPB or SBP are directly associated with increased CVD risk in younger population, but in those older than 60 years, increased SBP and *decreased* DBP mark increased risk. Accordingly, in the elderly, pulse pressure is a stronger predictor of CVD risk.

In elderly patients at high risk for falls, assessing for postural hypotension should be considered. Minimizing the number of medications may reduce fall risk.

Pharmacotherapy

The following medications may be initiated, modified, or discontinued by the clinic pharmacists:

- Angiotensin Converting Enzyme (ACE) Inhibitors
- Angiotensin Receptor Blockers (ARBs)
- Calcium Channel Blockers (CCBs)
- Thiazide-type diuretic
- Loop Diuretics
- Potassium-Sparing Diuretics
- Beta Blockers
- Aldosterone antagonists
- Renin Inhibitors
- Alpha1 antagonists
- Alpha2 agonists

- Vasodilators
- Potassium and magnesium supplement

Initiating Therapy

(See Appendix A for additional information regarding drug selection; see Appendix B for care pathway)

- Choices will be made with consideration to drug interactions, concomitant disease states and previous history with blood pressure lowering agents, side effects or intolerances.
- Treatment decisions will consider patient needs and preferences.
- Consider starting two antihypertensives for patients with blood pressure $\geq$ 160/100

Adjusting Therapy

- The main objective of hypertension treatment is to attain and maintain the goal BP. If the goal BP is not reached within a month of treatment, increase the dose of initial drug, or add a second drug from theinitial therapy options.
- If goal blood pressure cannot be reached using only the drugs from the initial therapy options because of a contraindication or the need to use more than three drugs to reach goal blood pressure, antihypertensive drugs from other classes can be used.

Training for new pharmacists in hypertension management

- Mentorship and training side-by-side with current pharmacist including:
    - Validation of blood pressure measurement
    - Validation of clinical competency
- Review of guidelines, any guideline updates, and current evidence-based medicine

Appendix A

Outpatient Hypertensive Medications			
Medication Class	Drug (Trade Name)	Usual Dosage (mg/day)	Special Considerations
ACE Inhibitors	Benazepril (Lotensin)	10-40 mg once (max 80 mg)	Monitor K+ and Cr 7-14 days after initiation or increase to dose Creatinine increase of 25% expected Change to ARB if cough occurs Women of pregnant bearing potential should be asked about BC and counseled on teratogenic effects if these medications are started May reduce recurrence of stroke when used in combination with thiazide diuretics
	Captopril (Capoten)	25-150 mg in two or three divided doses	
	Enalapril (Vasotec)	10-40 mg once or two divided doses	
	Fosinopril (Monopril)	10-40 mg once (max 80 mg)	
	Lisinopril (Prinivil, Zestril)	10-40 mg once	
	Moexipril (Univasc)	7.5-30 mg once	
	Perindopril (Aceon)	4-8 mg once (max 16 mg)	
	Quinapril (Accupril)	10-40 mg once	
	Ramipril (Altace)	2.5-10 mg once (max 20 mg)	
	Trandolapril (Mavik)	1-4 mg once (max 8 mg)	
Angiotensin II Antagonists	Azilsartan **(Edarbi)**	80 mg once	Check K+ and Cr 7-14 days post-initiation Women of pregnant bearing potential should be asked about BC and counseled on teratogenic effects if these medications are started
	Candesartan (Atacand)	8-32 mg once	
	Eprosartan (Teveten)	600-800 mg once	
	Irbesartan (Avapro)	150-300 mg once	
	Losartan (Cozaar)	50-100 mg once	
	Olmesartan (Benicar)	20-40 mg once	
	Telmisartan (Micardis)	40-80 mg once	
	Valsartan (Diovan)	80-320 mg once	

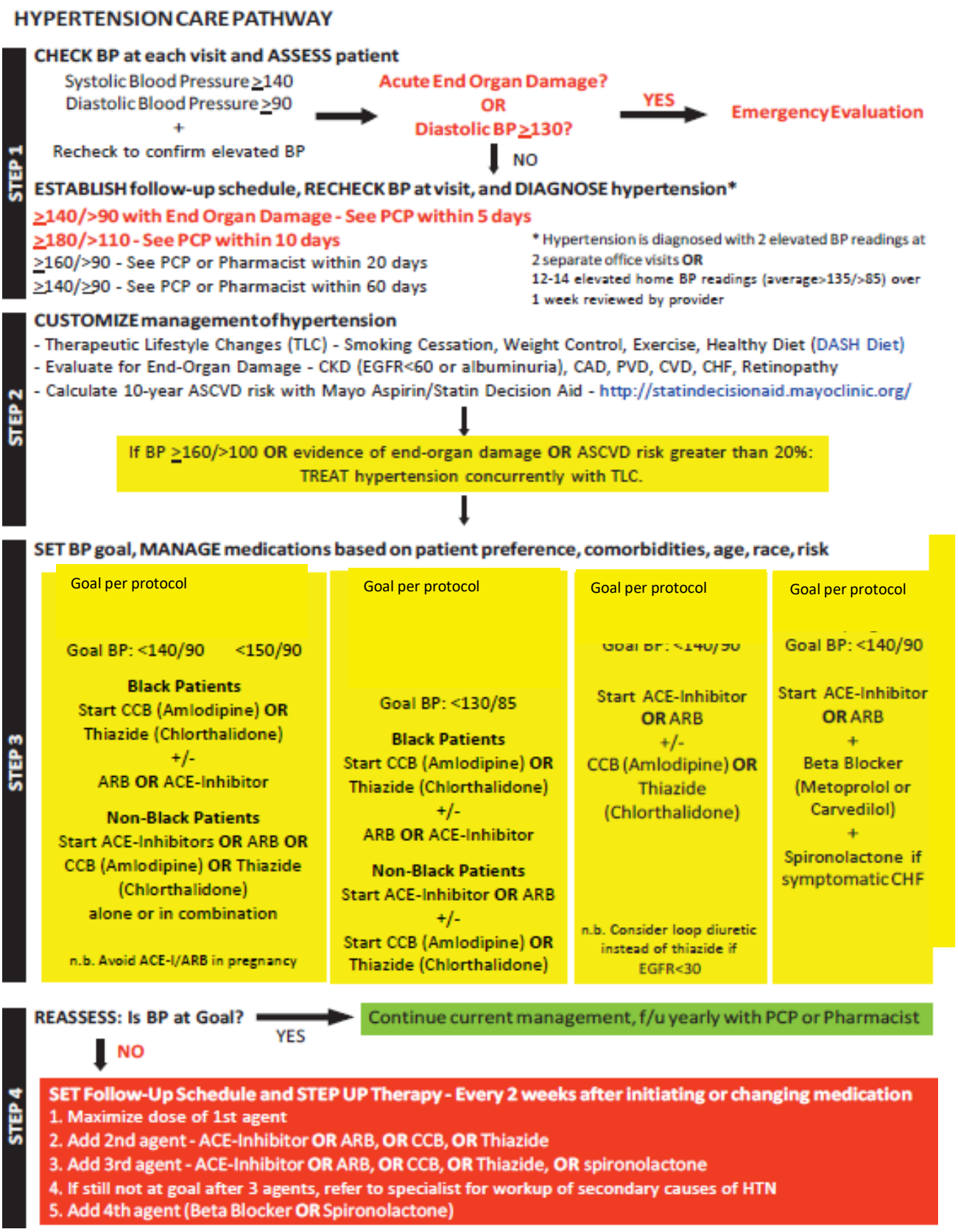
Outpatient Hypertensive Medications			
Medication Class	Drug (Trade Name)	Usual Dosage (mg/day)	Special Considerations
Thiazide and Thiazide-Like Diuretics	Chlorthalidone (Thalitone)	12.5-25 mg once	Check BMP 7-14 days post-initiation Higher doses may increase triglycerides and/or LDL Caution with gout May reduce recurrence of stroke when used with ACE inhibitor
	Hydrochlorothiazide (Microzide)	12.5-25 mg once	
	Indapamide (Lozol)	1.25-2.5 mg once	
	Metolazone (Zaroxylyn)	2.5-20 mg once	
Loop Diuretics	Furosemide (Lasix)	20-80 mg BID	HTN management for patient with heart failure and/or CKD Check BMP 7-14 days post-initiation
	Bumetanide (Bumex)	0.5-2 mg BID	
	Torsemide (Demadex)	5-10 mg once	
	Ethacrynic acid (Edecrin)	25-100 mg once	
Potassium-Sparing Diuretics	Triamterene with HCTZ (Dyazide, Maxzide)	Triamterene/HCTZ 25/37.5 mg- 50/75 mg once	Typically used in combination with thiazide diuretic for K+ balance Check BMP 7-14 days post-initiation
	Amiloride with HCTZ (Moduretic)	Amiloride/HCTZ 5/50 mg- 10/100 mg once or divided twice daily	

Outpatient Hypertensive Medications			
Medication Class	Drug (Trade Name)	Usual Dosage (mg/day)	Special Considerations
Beta-Blockers	Acebutolol (Sectral)	200-800 mg once or two divided doses	Caution with severe bronchospastic disease and with concurrent treatment with verapamil Teach patient to monitor HR, patient to call if HR less than 50 bpm Metoprolol and bisoprolol only agents with evidence for CAD BBs, particularly propranolol, have been associated with impotence but at a very low incidence; this is less likely to happen with atenolol. Lowering blood pressure has been associated with best quality of life, including sexual function.
	Atenolol (Tenormin)	25-100 mg once or two divided doses	
	Betaxolol (Kerlone)	10-40 mg once	
	Bisoprolol (Zebeta)	2.5-20 mg once	
	Carvedilol (Coreg)	6.25-25 mg BID	
	Labetalol (Trandate)	100-400 mg BID	
	Metoprolol tartrate (Lopressor)	25-200 mg BID	
	Metoprolol succinate (Toprol XL)	25-400 mg once	
	Nadolol (Corgard)	40-320 mg once	
	Nebivolol **(Bystolic)**	5-10 mg once	
	Pindolol	10-30mg BID	
	Propranolol (Inderal, Inderal LA)	IR: 120-240 mg in two or three divided doses ER: 80-160 mg once	
	Timolol (Blocadren)	10-30 mg BID	
Non-Dihydropyridine Calcium Channel Blockers	Verapamil (Calan, Calan SR)	120-240 mg once	Caution pre-existing treatment with BB Do not use with concomitant systolic heart failure Contraindicated with heart block
	Diltiazem ER (Cardizem CD, Dilacor XR, Tiazac)	120-240 mg once	

Outpatient Hypertensive Medications			
Medication Class	Drug (Trade Name)	Usual Dosage (mg/day)	Special Considerations
Dihydropyridine Calcium Channel Blocker	Amlodipine (Norvasc)	2.5-10 mg once	Evaluate for edema Reflex tachycardia with nifedipine
	Felodipine (Plendil)	2.5-20 mg once	
	Isradipine (Dynacirc CR)	2.5-10 mg divided twice daily	
	Nicardipine SR (Cardene SR)	60-120 mg divided twice daily	
	Nifedipine LA (Adalat CC, Procardia XL)	30-60 mg once	
	Nisoldipine (Sular)	10-40 mg once	
Aldosterone-receptor blockers	Eplerenone (Inspra)	50-100 mg once or two divided doses	Check BMP 7-14 days post-initiation
	Spironolactone (Aldactone)	25-100 mg once or two divided doses	
Direct Renin Inhibitors	Aliskirin (**Tekturna**)	150-300 mg once	Women of pregnant bearing potential should be asked about BC and counseled on teratogenic effects if these medications are started Do not use with ARBs or ACEIs in patients with diabetes
Alpha 1 Blockers (excluding those for BPH)	Doxazosin (Cadura) *Note: Cardura XL indicated for BPH only*	1-16 mg once	Orthostatic hypotension/syncope especially with first dose. May occur usually within 90 minutes of the initial dose or dose increase Not recommended for geriatric pts due to increased fall risk. Caution women to report any new onset urinary incontinence
	Prazosin (Minipress)	2-20 mg in two or three divided doses	
	Terazosin (Hytrin)	1-5 mg once or two divided doses	
Alpha-2 Adrenergic Agonist	Clonidine (Catapres)	0.1-0.3 mg BID	CAUTION in patients with recent MI, sinus node dysfunction, or bradycardia When discontinuing, reduce dose gradually to reduce risk of rebound hypertension Not recommended for geriatric pts due to increased fall risk.
	Clonidine Patch (Catapres-TTS)	0.1-0.6 mg/day patch applied once weekly	
Vasodilators	Hydralazine (Apresoline)	40-200 mg divided 4 times daily Max 300mg/day	CAUTION in patients with CAD; increase in tachycardia may increase myocardial oxygen demand Titrate to lowest effective maintenance dose
Vasodilators	Minoxidil	2.5-100 mg	CAUTION – may cause pericardial effusion and exacerbate angina. Generally used with concomitant beta-blocker and diuretic. Reserve for resistant hypertension.

*__Bolded__ medications are available BRAND ONLY.

Appendix B


HYPERTENSION CARE PATHWAY
STEP 1
CHECK BP at each visit and ASSESS patient
Systolic Blood Pressure ≥140
Diastolic Blood Pressure ≥90
+
Recheck to confirm elevated BP
Acute End Organ Damage?
OR
Diastolic BP ≥130?
YES
Emergency Evaluation
NO
ESTABLISH follow-up schedule, RECHECK BP at visit, and DIAGNOSE hypertension*
≥140/>90 with End Organ Damage - See PCP within 5 days
≥180/>110 - See PCP within 10 days
≥160/>90 - See PCP or Pharmacist within 20 days
≥140/≥90 - See PCP or Pharmacist within 60 days
* Hypertension is diagnosed with 2 elevated BP readings at 2 separate office visits OR
12-14 elevated home BP readings (average>135/>85) over 1 week reviewed by provider
STEP 2
CUSTOMIZE management of hypertension
- Therapeutic Lifestyle Changes (TLC) - Smoking Cessation, Weight Control, Exercise, Healthy Diet (DASH Diet)
- Evaluate for End-Organ Damage - CKD (EGFR<60 or albuminuria), CAD, PVD, CVD, CHF, Retinopathy
- Calculate 10-year ASCVD risk with Mayo Aspirin/Statin Decision Aid - http://statindecisionaid.mayoclinic.org/
If BP ≥160/>100 OR evidence of end-organ damage OR ASCVD risk greater than 20%:
TREAT hypertension concurrently with TLC.
STEP 3
SET BP goal, MANAGE medications based on patient preference, comorbidities, age, race, risk
Goal per protocol
Goal BP: <140/90 <150/90
Black Patients
Start CCB (Amlodipine) OR Thiazide (Chlorthalidone)
+/-
ARB OR ACE-Inhibitor
Non-Black Patients
Start ACE-Inhibitors OR ARB OR CCB (Amlodipine) OR Thiazide (Chlorthalidone)
alone or in combination
n.b. Avoid ACE-I/ARB in pregnancy
Goal per protocol
Goal BP: <130/85
Black Patients
Start CCB (Amlodipine) OR Thiazide (Chlorthalidone)
+/-
ARB OR ACE-Inhibitor
Non-Black Patients
Start ACE-Inhibitor OR ARB
+/-
Start CCB (Amlodipine) OR Thiazide (Chlorthalidone)
Goal per protocol
Start ACE-Inhibitor OR ARB
+/-
CCB (Amlodipine) OR Thiazide (Chlorthalidone)
n.b. Consider loop diuretic instead of thiazide if EGFR<30
Goal per protocol
Goal BP: <140/90
Start ACE-Inhibitor OR ARB
+
Beta Blocker (Metoprolol or Carvedilol)
+
Spironolactone if symptomatic CHF
STEP 4
REASSESS: Is BP at Goal?
YES
Continue current management, f/u yearly with PCP or Pharmacist
NO
SET Follow-Up Schedule and STEP UP Therapy - Every 2 weeks after initiating or changing medication
1. Maximize dose of 1st agent
2. Add 2nd agent - ACE-Inhibitor OR ARB, OR CCB, OR Thiazide
3. Add 3rd agent - ACE-Inhibitor OR ARB, OR CCB, OR Thiazide, OR spironolactone
4. If still not at goal after 3 agents, refer to specialist for workup of secondary causes of HTN
5. Add 4th agent (Beta Blocker OR Spironolactone)

Appendix C

Nonpharmacologic Invervention		Goal	Approximate SBP lowering	
			HTN	Normotension
Weight Loss	**Weight/body fat**	Best goal is ideal body weight, but aim for at least a 2.2-pound reduction in body weight for most adults who are overweight. Expect about 1mm/Hg for every 2.2 pounds lost in body weight	-5 mm/Hg	- 2/3 mm/Hg
Healthy Diet	**DASH lifestyle**	Consume a diet rich in fruits, vegetables, whole grains, and low-fat dairy, with reduced content of saturated and total fat	-11 mm/Hg	-3 mm/Hg
Less sodium	**Dietary sodium**	Optimal goal is < 1500 mg/day, but aim for at least 1000 mg/day reduction in most adults	- 5/6 mm/Hg	-2 mm/Hg
More potassium	**Dietary potassium**	Aim for 3500-5000 mg/day preferably by consumption of a diet rich in potassium	- 4/5 mm/Hg	-2 mm/Hg
Physical Activity	**Aerobic**	90-150 minutes/week; 65-75% heart rate reserve	- 5/8 mm/Hg	-2/4 mm/Hg
	Dynamic resistance	90-150 minutes/week; 50-80% 1 rep maximum; 6 exercises, 3sets/exercise, 10 repetitions/set	- 4 mm/Hg	-2 mm/Hg
	Isometric resistance	4 x 2 minute (hand grip), 1 minute rest between exercises, 30-40% maximum voluntary contractions, 3 sessions/week; 8-10 weeks	- 5 mm/Hg	-4 mm/Hg
Moderation in alcohol intake	**Alcohol consumption**	In individuals who drink alcohol, reduce alcohol to: Men: ≤2 drinks/day; Women: ≤1 drink/day	-4 mm/Hg	-3 mm/Hg

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Therapeutic Substitution Protocol

Guidelines from the Ambulatory Pharmacy Department MultiCare

Pharmacist Authors/Editor: Jennifer Daniels

November 2024

PURPOSE:

Provide a therapeutic medication substitution policy for medications to optimize quality and cost effectiveness.

The Pharmacy and Therapeutics Committee, Clinical Pharmacy Managers and Medical Director share responsibility for reviewing and approving of this policy.

PROCEDURE:

1. A review of patient record will occur before a medication is switched and should include allergies, medication profile for previous use or contraindication, interactions, appropriate labs or needed follow up due.
2. If the patient has tried and failed the preferred medication, no switch will be performed. If it is decided that the patient can be switched to a less expensive/equivalent quality medication, the following tables will be used to make equivalent conversion.
3. The clinical staff member will contact the patient to educate the patient about this therapeutic substitution.
4. The clinical staff member will initiate an order in Epic to send to the patient's preferred pharmacy and notify the pharmacy to discontinue old medication order.
5. The provider will be notified of switch via telephone encounter or appropriate means.
6. The clinical staff member will update the medication list as appropriate.
7. Appropriate follow up will be scheduled with the patient.
8. If a patient is not interested in switching medications the clinical staff member will record this in a telephone encounter in Epic.
9. For medication combinations, medication products may be switched into the individual medications (i.e. losartan-hydrochlorothiazide 100mg-25mg to losartan 100mg and hydrochlorothiazide 25mg) based on product availability, patient request or other reasons.

Preferred agents are **bolded.**
NTE=Not to Exceed. HRME= High Risk Medications in the Elderly

Cardiovascular Agents

Drug Class	Agent	Starting Dose	Maximum Dose	Substitution Information	Notes
ACE Inhibitors	Lisinopril (Prinivil/Zestril)	10 mg	40 mg	Unit-for-unit substitution within ACE inhibitors	Reduce dose in renal impairment
	Enalapril (Vasotec)	5 mg	40 mg		Effective for hypertension and heart failure
	Benazepril (Lotensin)	10 mg	40 mg		Common for hypertension
	Fosinopril (Monopril)	10 mg	40 mg		Suitable for hepatic clearance needs
	Ramipril (Altace)	2.5 mg	10 mg		Post-MI management indication
	Quinapril (Accupril)	10 mg	80 mg		Dose adjust for renal impairment
	Trandolapril	1 mg	4 mg		Frequently used in heart failure
ARBs	Losartan (Cozaar)	50 mg	100 mg	Limited conversion with valsartan due to dose differences	Lower max dose than valsartan
	Valsartan (Diovan)	80 mg	320 mg		For hypertension and heart failure
	Irbesartan (Avapro)	150 mg	300 mg		Useful in nephropathy for T2DM
	Candesartan (Atacand)	8 mg	32 mg		Hypertension and heart failure use
	Olmesartan (Benicar)	20 mg	40 mg		Avoid in pregnancy or renal artery stenosis
	Telmisartan (Micardis)	40 mg	80 mg		Reduces cardiovascular risk
Beta Blockers	Atenolol (Tenormin)	50 mg	100 mg		Requires renal adjustment
	Metoprolol succinate (Toprol XL)	25-100 mg daily	400 mg		Hypertension and heart failure indications
	Metoprolol tartrate (Lopressor)	25 mg BID	100 mg BID		Not preferred for heart failure
	Carvedilol (Coreg)	3.125 mg BID	50 mg BID		Indicated for heart failure

	Nebivolol (Bystolic)	2.5 mg	40 mg		Cardioselective with less beta-2 impact
	Bisoprolol (Zebeta)	5 mg	10 mg		Also suitable for heart failure
	Nadolol	40 mg	240 mg		Preferred for patients with liver disease
	Propranolol (Inderal)	40 mg BID (IR)	320 mg (LA)		Useful for migraines, essential tremor
Statins	Rosuvastatin (Crestor)	5-10 mg	40 mg	LDL goal-based dosing, reduce in renal impairment	High potency, adjust in Asian populations
	Atorvastatin (Lipitor)	10-20 mg	80 mg		No renal adjustment needed
	Pravastatin (Pravachol)	10-20 mg	80 mg		Lower myopathy risk
	Simvastatin (Zocor)	20-40 mg	40 mg		High interaction risk with CCBs
	Fluvastatin (Lescol)	20-80 mg	80 mg (XL)		Often well-tolerated
	Lovastatin (Mevacor)	20 mg	80 mg		Take with food to enhance absorption
	Pitavastatin (Livalo)	1-4 mg	4 mg		Lower interaction risk
Fibric Acid Derivatives	Fenofibrate (TriCor)	145 mg daily	160 mg daily	Adjust for renal function, avoid in severe renal disease	Used for hypertriglyceridemia
	Gemfibrozil (Lopid)	600 mg BID	1200 mg daily	Avoid with statins due to rhabdomyolysis risk	Take 30 minutes before meals

Diabetes Agents

Drug Class	Agent	Initial Dose	Maximum Dose	Substitution Information	Notes
Biguanides	Metformin (regular release)	500 mg BID	2550 mg daily	Convert to ER at equivalent total daily dose	Commonly 500 mg or 850 mg tabs; GI side effects may limit dose
	Metformin extended release (Glucophage XR)	500-1000 mg daily	2000 mg daily	Convert to same total daily dose	Reduced GI side effects, take with evening meal
	Metformin extended release (Fortamet, Glumetza)	1000 mg daily	2000 mg daily	Convert to same total daily dose	Fortamet for those needing higher end of dosing range
SGLT2 Inhibitors	Empagliflozin (Jardiance)	10 mg	25 mg		Renal protective in T2DM with CVD; preferred with heart failure
	Dapagliflozin (Farxiga)	5 mg	10 mg		Benefits for HF and kidney disease, check eGFR >45 for use
	Canagliflozin (Invokana)	100 mg	300 mg		Take before first meal, check eGFR <45
	Ertugliflozin (Steglatro)	5 mg	15 mg		Avoid if eGFR <45, limited HF benefit
	Bexagliflozin (Brenzavvy)	20 mg	20 mg		Newly approved, benefits in T2DM with CVD
Sulfonylureas	Glipizide IR	5 mg	40 mg daily	Convert IR to ER with same total daily dose	High risk in elderly; risk of hypoglycemia
	Glimepiride	2 mg	8 mg daily		Start low in elderly patients
	Glyburide	5 mg	20 mg daily		Avoid in elderly due to prolonged hypoglycemia risk
DPP-4 Inhibitors	Sitagliptin (Januvia)	100 mg daily	100 mg daily	Avoid combining with GLP-1s	Preferred in HF patients with T2DM
Thiazolidinediones	Pioglitazone (Actos)	15mg daily	45mg daily		Risk of edema and HF; avoid in advanced HF

Insulins

Insulin Type	Agent	Starting Dose	Action Speed	Substitution Guidelines	Notes
Rapid-Acting	Insulin Aspart (NovoLog, Fiasp)	As per TDD, per meal	Onset: 10-20 min, Peak: 1-3 hrs, Duration: 3-5 hrs	Convert unit-for-unit with other rapid-acting insulins	Adjust for meal timing, flexibility preferred
	Insulin Lispro (Humalog, Admelog)	As per TDD, per meal	Onset: 15-30 min, Peak: 0.5-2.5 hrs, Duration: 3-6 hrs	Convert unit-for-unit with other rapid-acting insulins	Available in U-100 and U-200 pen formats
	Insulin Glulisine (Apidra)	As per TDD, per meal	Onset: 15-20 min, Peak: 1-3 hrs, Duration: 3-5 hrs	Convert unit-for-unit with other rapid-acting insulins	Use for flexible meal timing
	Inhaled Insulin (Afrezza)	Initial: 4 units per meal	Onset: 12-15 min, Peak: 30 min, Duration: 2-3 hrs	Convert per dosing chart for SQ to inhaled insulin	Avoid in respiratory conditions, dosing varies per unit SQ
Short-Acting	Regular Insulin (Humulin R, Novolin R)	As per TDD, per meal	Onset: 30-60 min, Peak: 2-4 hrs, Duration: 5-8 hrs	Convert unit-for-unit with rapid-acting if longer post-meal control needed	Less common for intensive insulin therapy
Intermediate-Acting	NPH Insulin (Humulin N, Novolin N)	0.2-0.4 units/kg/day, divided	Onset: 1-2 hrs, Peak: 4-12 hrs, Duration: 12-18 hrs	Convert with long-acting basal insulin if adjusting to overnight basal use	Use for basal control in twice-daily regimens
Long-Acting	Insulin Glargine U-100 (Lantus, Basaglar)	10 units or 0.2 units/kg	Onset: 1-2 hrs, No Peak, Duration: 24 hrs	Convert unit-for-unit to other long-acting insulins	Can reduce dose by 20% if switching from U-300 or U-200
	Insulin Detemir (Levemir)	0.2-0.4 units/kg/day	Onset: 1-2 hrs, Minimal peak, Duration: 16-24 hrs	May require twice-daily dosing for full 24-hour coverage	Discontinuation planned by end of 2024
	Insulin Glargine U-300 (Toujeo)	Start 10-20% lower if switching from U-100	Onset: 6 hrs, No Peak, Duration: 24-36 hrs	Convert with a 20% lower dose when switching from other long-acting	Preferred in those needing high doses or long duration

Ultra Long-Acting	Insulin Degludec (Tresiba)	10 units or 0.2 units/kg	Onset: 1 hr, No Peak, Duration: 42 hrs	Start 10-20% lower than other basal insulins to avoid hypoglycemia	Ideal for flexible timing or dose adjustments
Mixed Insulins	NPH/Regular Insulin 70/30 (Humulin 70/30, Novolin 70/30)	Based on individual requirements	Onset: 30 min, Peak: Dual, Duration: up to 18 hrs	Convert unit-for-unit if maintaining same dosing ratio	Provides both basal and bolus in one injection
	Lispro Protamine/Lispro 75/25 (Humalog Mix)	Based on individual requirements	Onset: 15 min, Peak: Dual, Duration: up to 18 hrs	Convert unit-for-unit based on coverage need	Only available in pen injector format
	Aspart Protamine/Aspart 70/30 (Novolog Mix)	Based on individual requirements	Onset: 10-20 min, Peak: Dual, Duration: up to 18 hrs	Convert unit-for-unit based on insulin needs	Provides rapid and intermediate-acting combination

GLP-1 Receptor Agonists

Agent	Initial Dose	Intermediate Dose	Maximum Dose	Notes on Indications and Use	Special Considerations
Dulaglutide (Trulicity)	0.75 mg weekly x 4-8 wks	1.5 mg weekly x 4 wks	4.5 mg weekly	Approved for CV risk reduction in T2DM, lowers A1c and weight	Dose escalation required to reduce GI side effects
Liraglutide (Victoza)	0.6 mg daily x 1 week	1.2 mg daily x 1 week	1.8 mg daily	Approved for T2DM, reduces CV risk in those with CVD	Avoid in thyroid cancer history; also used for weight loss
Semaglutide (Ozempic)	0.25 mg weekly x 4 weeks	0.5 mg weekly x 4 weeks	2 mg weekly	CV benefit and renal protection in T2DM with CVD	Also available as oral (Rybelsus), requires fasting pre-dose
Exenatide ER (Bydureon)	2 mg once weekly	N/A	2 mg weekly	Not indicated for CV risk reduction	Available as extended-release only, once-weekly dosing
Exenatide IR (Byetta)	5 mcg BID x 1 month	10 mcg BID	10 mcg BID	Used primarily for T2DM and modest weight loss	Administer within 60 mins before meals
Lixisenatide (Adlyxin)	10 mcg daily x 14 days	20 mcg daily	20 mcg daily	Lower A1c reduction compared to others in class	Preferred for patients requiring milder glucose control
Tirzepatide (Mounjaro)	2.5 mg weekly x 4 weeks	5 mg weekly x 4 weeks	15 mg weekly	Dual GLP-1/GIP agonist, with high efficacy in weight loss and A1c reduction	Dose escalation to prevent GI side effects; new option for T2DM with weight focus

Respiratory and Allergy Agents

Inhaled Corticosteroids (ICS)	Fluticasone HFA (Flovent)	1 inhalation BID (44 mcg)	1 inhalation BID (220 mcg)	Do not substitute without equivalent dosing	Mainstay for persistent asthma, reduces airway inflammation
	Budesonide DPI (Pulmicort)	1 inhalation BID (90 mcg)	Up to 360 mcg per inhalation BID	Available as DPI, suitable for children	Use with proper technique to avoid oral thrush
	Beclomethasone (QVAR Redihaler)	1 inhalation BID (40 mcg)	Up to 2 inhalations BID (80 mcg)	Suitable for daily asthma maintenance	Breathe-actuated inhaler; avoid with poor lung function
Inhaled LABA + ICS Combinations	Budesonide/Formoterol (Symbicort)	2 inhalations BID (80/4.5 mcg)	Up to 2 inhalations BID (160/4.5 mcg)	Easy substitution for other ICS/LABA combos in asthma/COPD	MART protocol can use Symbicort as both controller/reliever
	Fluticasone/Salmeterol (Advair Diskus)	1 inhalation BID (100/50 mcg)	1 inhalation BID (500/50 mcg)	Used as controller therapy in asthma and COPD	Diskus form requires proper technique
	Fluticasone/Vilanterol (Breo Ellipta)	1 inhalation daily (100/25 mcg)	1 inhalation daily (200/25 mcg)	Long-acting once-daily dosing, good for COPD	Effective for persistent asthma requiring daily control

Gastrointestinal Agents

Drug Class	Agent	Initial Dose	Maximum Dose	Substitution Information	Special Considerations

Histamine-2 Receptor Antagonists (H2RAs)	Famotidine (Pepcid)	20 mg QD to BID	80 mg daily	Substitute with other H2RAs based on dosing equivalency	Adjust dose in renal impairment; less risk of CNS effects
	Cimetidine	400 mg QD to BID	800 mg BID	Avoid if possible due to significant drug interactions	Multiple interactions and side effects; less commonly used
	Nizatidine	150 mg BID	300 mg daily	Equivalency dosing possible with famotidine	Higher side effect rate than other H2 blockers
Proton Pump Inhibitors (PPIs)	Omeprazole (Prilosec)*	20 mg daily	40 mg daily	Substitute within PPIs based on insurance/formulary availability	Limit use duration; 8-week maximum for GERD
	Pantoprazole (Protonix)	40 mg daily	40 mg daily	Preferred in patients with H. pylori or Barrett's esophagus	Lower interaction profile than omeprazole
	Esomeprazole (Nexium)*	20 mg daily	40 mg daily	Substitutable within PPI class, similar action to omeprazole	Higher potency, available OTC
	Lansoprazole (Prevacid)*	15 mg daily	30 mg daily	OTC availability; equivalency with other PPIs	Take 30-60 minutes before meals for best effect
	Rabeprazole (Aciphex)	20 mg daily	20 mg daily	Often more costly, but fewer drug interactions	Avoid in long-term use without regular reassessment

* **Note**: PPIs such as **omeprazole**, **pantoprazole**, and **esomeprazole** are commonly preferred for moderate to severe GERD and peptic ulcer disease. They should be used cautiously long-term due to risks of osteoporosis, hypomagnesemia, and gastrointestinal infections.

Antiviral Agents

Infection Type	Agent	Initial Dose	Episodic Dose	Suppression Dose	Special Considerations
Herpes Simplex Virus - Immunocompetent (Genital & Orolabial)	Acyclovir (Zovirax)	400 mg TID x 7-10 days	Genital: 800 mg BID x 5 days	400 mg BID	Adjust dose in renal impairment; high frequency may require dose adjustments
			Orolabial: 400 mg TID		
	Valacyclovir (Valtrex)	1000 mg BID x 7-10 days	Genital: 500 mg	500 mg to 1000 mg daily	Better absorption and dosing

			BID x 3 days		convenience than acyclovir
			Orolabial: 2000 mg BID x 1 day		
Herpes Simplex Virus - Immunocompromised (incl. HIV+)	Acyclovir (Zovirax)	400 mg TID x 7-10 days	400-800 mg BID	400-800 mg BID	Requires dose adjustment in renal impairment
	Valacyclovir (Valtrex)	1000 mg BID x 10 days	1000 mg BID	500-1000 mg BID	Consider higher doses for severe cases
Herpes Zoster Virus (Shingles)	Acyclovir (Zovirax)	800 mg five times daily x 7-10 days			Immunocompetent patients ≥12 years
	Valacyclovir (Valtrex)	1000 mg TID x 7 days			May require dose adjustments in elderly
	Famciclovir (Famvir)	500 mg TID x 7 days			Alternative to acyclovir or valacyclovir
Varicella-Zoster Virus (Chickenpox)	Acyclovir (Zovirax)	Adults: 800 mg 5x daily x 5-7 days			Requires prompt initiation within 24 hours of rash onset
		Children: 20 mg/kg QID x 5 days			Consult pediatric guidelines for dosing in children
Cytomegalovirus (CMV) - Retinitis	Ganciclovir (Cytovene)	Induction: 5 mg/kg IV BID x 14-21 days	Maintenance: 5 mg/kg IV daily	Maintenance or alternative dosing	Monitor for neutropenia and renal impairment
	Valganciclovir (Valcyte)	Induction: 900 mg BID x 21 days	Maintenance: 900 mg daily		Oral option for CMV, requires renal adjustment

Urinary Antispasmodic Agents

Drug Class	Agent	Initial Dose	Maximum Dose	Substitution Information	Special Considerations
Antimuscarinics	Oxybutynin (Ditropan)	IR: 5 mg BID	IR: 5 mg TID	Substitute within class if similar efficacy and side effect profile	May cause dry mouth, constipation; available as ER for tolerance
		ER: 10 mg daily	ER: 30 mg daily		ER form has lower peak concentrations, reducing side effects
	Tolterodine (Detrol)	IR: 2 mg BID	IR: 2 mg BID	Similar efficacy as oxybutynin, adjust for hepatic impairment	Lower anticholinergic side effects than oxybutynin
		LA: 4 mg daily	LA: 4 mg daily		LA preferred for fewer dosing requirements
	Solifenacin (Vesicare)	5 mg daily	10 mg daily	Preferred for improved tolerability	Avoid in severe renal impairment
	Darifenacin (Enablex)	7.5 mg daily	15 mg daily		Higher selectivity for bladder, fewer systemic side effects
	Trospium (Sanctura)	IR: 20 mg BID	IR: 20 mg BID	Avoid in severe renal impairment	Take on empty stomach for best absorption
		XL: 60 mg daily	XL: 60 mg daily		XL formulation preferred in older adults
	Fesoterodine (Toviaz)	4 mg daily	8 mg daily		May cause dry mouth, constipation; adjust for renal function
Beta-3 Agonists	Mirabegron (Myrbetriq)	25 mg daily	50 mg daily	Newer class, minimal anticholinergic effects	Monitor BP in patients with uncontrolled hypertension
	Vibegron (Gemtesa)	75 mg daily	75 mg daily	Alternative to mirabegron for beta-3 agonist therapy	No titration required; minimal anticholinergic side effects

Oral Triptans

Agent	Initial Dose	Repeat Dose Interval	Maximum Daily Dose	Special Considerations
Sumatriptan (Imitrex)	25, 50, or 100 mg at onset	May repeat in 2 hours if needed	200 mg	Available in tablet, nasal spray, and injectable forms
Rizatriptan (Maxalt)	5-10 mg at onset	May repeat in 2 hours if needed	30 mg	Dose reduction required with propranolol
Eletriptan (Relpax)	20-40 mg at onset	May repeat in 2 hours if needed	80 mg	Avoid with strong CYP3A4 inhibitors

Zolmitriptan (Zomig)	2.5 mg at onset	May repeat in 2 hours if needed	10 mg	Available as tablet, nasal spray, and ODT
Frovatriptan (Frova)	2.5 mg at onset	May repeat in 2 hours if needed	5 mg	Longer half-life, preferred for prolonged or recurrent migraines
Almotriptan	6.25-12.5 mg at onset	May repeat in 2 hours if needed	25 mg	Lower side effect profile, suitable for mild-moderate migraines
Naratriptan (Amerge)	2.5 mg at onset	May repeat in 4 hours if needed	5 mg	Slower onset but longer duration of action

Antidepressants

Drug Class	Agent	Initial Dose	Maximum Dose	Substitution Information	Special Considerations
Selective Serotonin Reuptake Inhibitors (SSRIs)	Citalopram (Celexa)	20 mg daily	40 mg daily	Substitute within SSRIs based on efficacy and tolerability	QT prolongation risk at higher doses, caution in older adults
	Sertraline (Zoloft)	50 mg daily	200 mg daily	Often preferred due to low interaction profile	Well-tolerated; first-line for anxiety comorbid with depression
	Paroxetine (Paxil)**	20 mg daily	60 mg daily	Higher risk of discontinuation syndrome	Avoid in elderly; sedating, may help with insomnia
	Escitalopram (Lexapro)	10 mg daily	20 mg daily	Generally well-tolerated, less dose-dependent QT risk	Preferred in elderly and patients with cardiac risk
	Fluoxetine (Prozac)	20 mg daily	80 mg daily	Long half-life, easier to taper off	May cause activation; good option for those needing energizing
	Fluvoxamine (Luvox)	50 mg daily	300 mg daily (divided doses)	Primarily used for OCD, higher interaction risk	Dose in divided amounts for better tolerability
Serotonin-Norepinephrine Reuptake Inhibitors (SNRIs)	Venlafaxine IR (Effexor)	37.5 mg daily	225 mg daily (IR)	Switching may require gradual cross-taper	Caution with high BP, often effective for neuropathic pain

	Venlafaxine ER (Effexor XR)	37.5 mg daily	225 mg daily	Similar effects as IR but fewer doses needed	Taper slowly to avoid withdrawal
	Duloxetine (Cymbalta)	30 mg daily	120 mg daily	Often used for neuropathic pain, chronic pain conditions	Avoid in hepatic impairment; can increase BP
	Desvenlafaxine (Pristiq)	50 mg daily	100 mg daily	No major interactions, well-tolerated in many patients	Minimal dose adjustments needed in renal impairment
	Levomilnacipran (Fetzima)	20 mg daily	120 mg daily	Newer SNRI, adjust dose in renal impairment	Higher cost; may cause more nausea
Atypical Antidepressants	Mirtazapine (Remeron)	15 mg at bedtime	45 mg at bedtime	Can be substituted with other sedating agents in low doses	Sedating at lower doses, may increase appetite
	Bupropion XL (Wellbutrin XL)	150 mg daily	450 mg daily	Energizing effect; switch carefully in patients with anxiety	Avoid in seizure risk or eating disorders
	Trazodone	50 mg at bedtime	300 mg daily	May substitute for sleep at low doses	Commonly used as a sleep aid at lower doses
	Vilazodone (Viibryd)	10 mg daily with food	40 mg daily	Avoid abrupt discontinuation; benefits in anxious depression	Start with food to minimize GI upset
	Vortioxetine (Trintellix)	10 mg daily	20 mg daily	Newer antidepressant with minimal side effects	May have cognitive benefits; taper to avoid withdrawal

** **Note**: Paroxetine is often considered a high-risk medication in elderly patients (HRME) due to anticholinergic and sedative effects, and is generally avoided in this population unless necessary.

CNS Stimulants

Agent	Initial Dose	Dose Titration Increments	Maximum Daily Dose	Special Considerations
Methylphenidate ER (Concerta)	18 mg daily	Increase by 18 mg weekly	72 mg daily	Long-acting formulation, provides stable release over 12 hours
Methylphenidate ER (Ritalin LA)	10 mg daily	Increase by 10 mg weekly	60 mg daily	May be opened and sprinkled on applesauce for easy administration

Methylphenidate IR	5-10 mg BID to TID	Increase by 5-10 mg increments	60 mg daily	Short-acting; may require multiple daily doses
Methylphenidate Patch (Daytrana)	10 mg patch applied daily	Increase by 5 mg increments every week	30 mg daily (worn for 9 hours)	Alternative for patients who cannot swallow pills
Dexmethylphenidate (Focalin XR)	5 mg daily	Increase by 5 mg weekly	40 mg daily	XR version offers once-daily dosing
Lisdexamfetamine (Vyvanse)	10 mg daily	Increase by 10 mg weekly	70 mg daily	Longer duration of action, less risk of abuse
Dextroamphetamine/Amphetamine ER (Adderall XR)	5 mg daily	Increase by 5 mg increments	30 mg daily	Caution in patients with hypertension; long-acting option
Dextroamphetamine (Dexedrine)	5 mg daily	Increase by 5 mg weekly	40 mg daily	May increase dose in divided amounts; short and long-acting available
Mixed Amphetamine Salts	5 mg daily	Increase by 5 mg increments	30 mg daily	Both IR and XR forms available, XR offers smoother dosing

Sleep Aids

Drug Class	Agent	Initial Dose	Maximum Dose	Special Considerations
Z-Drugs (Non-benzodiazepine hypnotics)	Zolpidem (Ambien)	5 mg qhs (females), 5-10 mg qhs (males)	10 mg qhs	High risk for sleep-related behaviors; use lowest effective dose
	Zolpidem CR (Ambien CR)	6.25 mg qhs (females), 6.25-12.5 mg qhs (males)	12.5 mg qhs	Offers longer sleep maintenance; adjust in elderly
	Eszopiclone (Lunesta)	1 mg qhs	3 mg qhs	Longer half-life, effective for sleep maintenance
	Zaleplon (Sonata)	5 mg qhs	10 mg qhs	Short half-life, best for middle-of-the-night awakenings
Other Sleep Aids	Doxepin (Silenor)	6 mg qhs	6 mg qhs	Lower doses effective for insomnia without antidepressant effects
	Ramelteon (Rozerem)	8 mg qhs	8 mg qhs	Melatonin receptor agonist; minimal abuse potential

	Trazodone	50 mg qhs	200 mg qhs	Often used at low doses as sleep aid in depression patients
	Mirtazapine (Remeron)	15 mg qhs	45 mg qhs	Sedating at lower doses, can increase appetite
	Suvorexant (Belsomra)	10 mg qhs	20 mg qhs	Orexin receptor antagonist; can cause next-day drowsiness

* **Note**: Many sleep aids are considered high-risk in the elderly due to potential for falls, cognitive impairment, and next-day sedation. Use the lowest effective dose and limit use duration whenever possible.

Bisphosphonates

Agent	Initial Dose	Maximum Dose	Dosing Schedule	Special Considerations
Alendronate (Fosamax)	70 mg once weekly	70 mg once weekly	Weekly	Take with full glass of water, remain upright for 30 minutes
Alendronate Solution	70 mg once weekly	70 mg once weekly	Weekly	Alternative for those with swallowing difficulties
Risedronate (Actonel)	35 mg once weekly	35 mg once weekly	Weekly	Remain upright 30 minutes post-dose; available in delayed-release form
Ibandronate (Boniva)	150 mg once monthly	150 mg once monthly	Monthly	No proven benefit for hip fracture reduction
Zoledronic Acid (Reclast)	5 mg IV once yearly	5 mg IV once yearly	Yearly infusion	Alternative for those unable to tolerate oral bisphosphonates

* **Note**: All bisphosphonates require adequate calcium and vitamin D intake and are contraindicated in patients with severe renal impairment (CrCl < 30-35 mL/min). Regular monitoring for osteonecrosis of the jaw and atypical femur fractures is recommended in long-term use.

Chemotherapy Agents, Infusions, and Biologics

Drug Class	Agent	Standard Dose	Dosing Schedule	Special Considerations
Chemotherapy-Induced Antiemetics	Ondansetron (Zofran)	8 mg IV infusion	Pre-chemotherapy and as needed	Commonly used for nausea/vomiting, monitor for QT prolongation
	Palonosetron (Aloxi)	250 mcg IV push	Single dose pre-chemotherapy	Long-acting, effective for delayed nausea
	Granisetron (Kytril)	1 mg IV infusion	Pre-chemotherapy	Available as patch for prolonged antiemetic effect
Erythropoiesis-Stimulating Factors	Epoetin Alfa (Epogen, Procrit)	Dose varies by indication (e.g., 50-100 units/kg 3x/week)	Based on hemoglobin level	Adjust based on hemoglobin response, avoid in patients

				with uncontrolled hypertension
Granulocyte Colony-Stimulating Factors (G-CSF)	Filgrastim (Neupogen)	5 mcg/kg daily	Daily during neutropenia recovery	Used to reduce infection risk in chemotherapy-induced neutropenia
	Pegfilgrastim (Neulasta)	6 mg single dose post-chemotherapy	Once per cycle (24 hours post-chemo)	Long-acting; do not administer within 14 days before next chemo
Monoclonal Antibodies	Bevacizumab (Avastin)	5-10 mg/kg IV	Every 2-3 weeks	Monitor for hypertension, proteinuria, bleeding complications
	Trastuzumab (Herceptin)	8 mg/kg loading dose, 6 mg/kg maintenance	Weekly or every 3 weeks	HER2+ breast cancer; monitor for cardiac function
	Rituximab (Rituxan)	375 mg/m² IV	Weekly or biweekly	Commonly used for lymphoma; monitor for infusion reactions
TNF Inhibitors	Infliximab (Remicade)	5 mg/kg IV	Every 6-8 weeks after loading	Used in autoimmune diseases; monitor for infections
	Adalimumab (Humira)	40 mg SC every other week	Maintenance therapy in RA, psoriasis	Screen for TB and hepatitis B before initiation
Immunomodulators	Denosumab (Prolia, Xgeva)	60 mg SC (Prolia) every 6 months	Every 6 months (osteoporosis)	Risk of hypocalcemia, monitor calcium, magnesium, and phosphorus

* **Note**: Many biologics and chemotherapy agents have high-risk profiles with potential for severe adverse effects, including immunosuppression and infection risk. Close monitoring is essential, and pre-treatment screening (e.g., for TB, hepatitis) is often required for biologic agents.

Anticoagulants

Indication	Agent	Initial Dose	Maintenance Dose	Special Considerations
VTE Treatment	Apixaban (Eliquis)	10 mg BID for 7 days	5 mg BID	Avoid use in CrCl <15 mL/min, dose adjust for renal function
	Rivaroxaban (Xarelto)	15 mg BID for 21 days	20 mg daily	Take with food for better absorption, avoid in CrCl <15 mL/min
	Dabigatran (Pradaxa)	After 5-10 days of parenteral anticoagulation	150 mg BID	Avoid in CrCl ≤30 mL/min, administer with food to reduce GI upset

	Edoxaban (Savaysa)	After 5-10 days of parenteral anticoagulation	60 mg daily	Avoid in CrCl >95 mL/min; adjust dose for low body weight
Stroke Prevention in Atrial Fibrillation	Apixaban (Eliquis)	5 mg BID	5 mg BID	Dose reduce to 2.5 mg BID for age >80, weight <60 kg, or SCr >1.5 mg/dL
	Rivaroxaban (Xarelto)	20 mg daily	20 mg daily	Take with evening meal to improve absorption
	Dabigatran (Pradaxa)	150 mg BID	150 mg BID	Dose adjust for renal function, avoid in advanced renal impairment
	Warfarin	Dose individualized based on INR	Target INR 2-3	Bridging required for initiation; frequent monitoring needed
Peri-Procedural Bridging Therapy	Enoxaparin (Lovenox)	1 mg/kg SC q12h or 1.5 mg/kg SC daily	Peri-procedure only	Avoid in severe renal impairment (CrCl <30 mL/min)
VTE Prophylaxis	Apixaban (Eliquis)	2.5 mg BID	2.5 mg BID	Indicated for high-risk patients (e.g., post-hip/knee replacement)
	Rivaroxaban (Xarelto)	10 mg daily	10 mg daily	Avoid use if CrCl <30 mL/min
	Fondaparinux (Arixtra)	2.5 mg SC daily	2.5 mg SC daily	Use in patients with heparin-induced thrombocytopenia
	Heparin	5000 units SC q8-12h	5000 units SC q8-12h	Preferred in patients with severe renal impairment

* **Note**: All anticoagulants have a risk of bleeding, and renal function should be monitored regularly. For patients requiring reversal in case of major bleeding, specific reversal agents are available for DOACs (e.g., idarucizumab for dabigatran, andexanet alfa for apixaban and rivaroxaban).

Ophthalmic Agents

Drug Class	Agent	Initial Dose	Dosing Frequency	Special Considerations
Prostaglandin Analogs	Latanoprost (Xalatan)	1 drop in affected eye(s)	Once daily, typically in the evening	First-line for glaucoma; can cause iris darkening and eyelash growth
	Travoprost (Travatan Z)	1 drop in affected eye(s)	Once daily, typically in the evening	Preservative-free option available, avoid in pregnancy
	Bimatoprost (Lumigan)	1 drop in affected eye(s)	Once daily, typically in the evening	May cause ocular irritation; also used for eyelash growth

	Tafluprost (Zioptan)	1 drop in affected eye(s)	Once daily, typically in the evening	Preservative-free, single-use vials
Beta Blockers	Timolol (Timoptic)	1 drop in affected eye(s)	Once or twice daily	Systemic absorption possible; may lower blood pressure
	Levobunolol	1 drop in affected eye(s)	Once daily	Similar efficacy to timolol, avoid in asthma/COPD
	Betaxolol	1 drop in affected eye(s)	Once or twice daily	Less systemic absorption, preferred in patients with pulmonary issues
Carbonic Anhydrase Inhibitors	Dorzolamide (Trusopt)	1 drop in affected eye(s)	Twice or three times daily	May cause bitter taste; avoid in patients with sulfa allergies
	Brinzolamide (Azopt)	1 drop in affected eye(s)	Twice or three times daily	Better tolerated than dorzolamide
Alpha Agonists	Brimonidine (Alphagan P)	1 drop in affected eye(s)	Twice or three times daily	Can cause ocular redness, avoid in children under 2 years
Combination Agents	Dorzolamide/Timolol (Cosopt)	1 drop in affected eye(s)	Twice daily	Combines carbonic anhydrase inhibitor and beta blocker
	Brimonidine/Timolol (Combigan)	1 drop in affected eye(s)	Twice daily	Alpha agonist and beta blocker combo
	Brinzolamide/Brimonidine (Simbrinza)	1 drop in affected eye(s)	Twice daily	Carbonic anhydrase inhibitor and alpha agonist combination

* **Note**: Many ophthalmic agents, especially beta blockers, may have systemic effects. To reduce systemic absorption, instruct patients to use punctal occlusion (closing the tear duct by pressing on the inner corner of the eye) for 1-2 minutes after application

Hormonal Therapy

Drug Class	Agent	Initial Dose	Maximum Dose	Special Considerations
Estrogen Therapy	Estradiol Oral (Estrace)	1 mg daily	2 mg daily	Typically used for postmenopausal symptoms; avoid in history of estrogen-dependent cancer
	Estradiol Transdermal Patch (Vivelle-Dot)	0.05 mg patch applied twice weekly	0.1 mg twice weekly	Lower risk of clotting and liver issues vs. oral estrogen
	Conjugated Estrogens (Premarin)	0.3 mg daily	1.25 mg daily	Often used for menopausal symptoms; avoid in clotting disorders
Thyroid Replacement Therapy	Levothyroxine (Synthroid, Levoxyl)	25-50 mcg daily	Titrate to TSH goal, typically up to 200 mcg	Dosing individualized based on TSH; take on empty stomach
	Liothyronine (Cytomel)	25 mcg daily	100 mcg daily	Rapid onset, may be combined with levothyroxine
	Desiccated Thyroid (Armour Thyroid)	30 mg daily	Titrate based on TSH and symptoms	Contains both T3 and T4; variability in potency
	Liotrix (Thyrolar)	25 mcg T3/100 mcg T4	Titrate based on TSH	Synthetic T3 and T4 combo; less common due to stable T4 preference

* **Note**: Estrogen therapy is generally contraindicated in patients with a history of hormone-sensitive cancers, thromboembolic disorders, and untreated hypertension. Thyroid medications should be taken consistently on an empty stomach, ideally in the morning, to ensure optimal absorption.

Xanthine Oxidase Inhibitors

Agent	Initial Dose	Maximum Dose	Special Considerations
Allopurinol	100 mg daily	Up to 800 mg daily (divided doses)	Start at lower dose in renal impairment to avoid toxicity; titrate slowly based on serum uric acid levels. Risk of hypersensitivity, especially in patients of Asian descent (consider HLA-B*5801 testing).
Febuxostat (Uloric)	40 mg daily	80 mg daily	Alternative for patient's intolerant to allopurinol. Associated with increased cardiovascular risk; consider periodic liver function monitoring. Generally does not require dose adjustment for mild-to-moderate renal impairment.

* **Note**: Both agents should be titrated based on target uric acid levels (typically <6 mg/dL). Allopurinol may cause hypersensitivity reactions, which are more common in those with renal impairment and certain genetic backgrounds. Febuxostat has a boxed warning for cardiovascular risk and is often reserved for patients who cannot tolerate allopurinol.

Acetylcholinesterase Inhibitors

Agent	Initial Dose	Maximum Dose	Special Considerations
Donepezil (Aricept)	5 mg daily	10 mg daily (23 mg for severe cases)	Can be taken once daily, often at bedtime. Common side effects include GI upset; avoid in patients with bradycardia.
Rivastigmine (Exelon)	1.5 mg BID (oral) or 4.6 mg/day (patch)	6 mg BID (oral) or 13.3 mg/day (patch)	Patch formulation may be better tolerated than oral form. Adjust dose for renal or hepatic impairment; common side effects include nausea and weight loss.
Galantamine (Razadyne)	4 mg BID (IR) or 8 mg daily (ER)	12 mg BID (IR) or 24 mg daily (ER)	Must be taken with food to minimize GI side effects. Adjust dose in renal or hepatic impairment; avoid in severe renal impairment.

* **Note**: Acetylcholinesterase inhibitors are generally used to slow cognitive decline in mild-to-moderate Alzheimer's disease. They may not be effective for all patients and should be discontinued if no benefit is observed. All agents carry risks of GI upset, bradycardia, and weight loss, and require regular monitoring for side effects, especially in older adults.

Immune Globulin (IVIG)

Agent	Typical Dose	Dosing Schedule	Special Considerations
Gammagard	1-2 g/kg	Every 3-4 weeks (depending on condition)	Monitor for infusion-related reactions; pre-medicate if needed. Monitor renal function and adjust dose in patients with renal impairment.
Gamunex-C	1-2 g/kg	Every 3-4 weeks	Can be administered IV or SC; SC may be preferred in patients with high risk of infusion reactions.
Octagam	1-2 g/kg	Every 3-4 weeks	Requires close monitoring for thromboembolic events; may require slower infusion rate for tolerance.
Gammaked	1-2 g/kg	Every 3-4 weeks	Administer with caution in patients with a history of thrombosis, monitor serum viscosity.
Gammagard S/D	1-2 g/kg	Every 3-4 weeks	Lyophilized form; often preferred for patients with IgA deficiency as it has lower IgA content.

* **Note**: IVIG therapy is associated with infusion reactions (e.g., fever, chills, nausea), thromboembolic events, and risk of renal impairment. Pre-medication with antihistamines and corticosteroids can reduce reaction rates. Patients should be monitored during and after infusions, especially in the first few doses.

Oral Anticoagulants for Stroke and VTE Prevention

Indication	Agent	Initial Dose	Maintenance Dose	Special Considerations
Stroke Prevention in Atrial Fibrillation	Apixaban (Eliquis)	5 mg BID	5 mg BID	Dose reduction to 2.5 mg BID for age >80, weight <60 kg, or SCr >1.5 mg/dL

	Rivaroxaban (Xarelto)	20 mg daily	20 mg daily	Take with evening meal to improve absorption
	Dabigatran (Pradaxa)	150 mg BID	150 mg BID	Dose adjust for renal impairment; avoid in CrCl ≤30 mL/min
	Warfarin (Coumadin)	Dose individualized based on INR	Target INR 2-3	Requires frequent INR monitoring and dose adjustment
	Edoxaban (Savaysa)	60 mg daily	60 mg daily	Avoid in CrCl >95 mL/min due to reduced efficacy
VTE Treatment	Apixaban (Eliquis)	10 mg BID for 7 days	5 mg BID	Adjust for renal impairment; avoid use in CrCl <15 mL/min
	Rivaroxaban (Xarelto)	15 mg BID for 21 days	20 mg daily	Requires food intake to ensure adequate absorption
	Dabigatran (Pradaxa)	After 5-10 days of parenteral anticoagulation	150 mg BID	Bridging required with initial parenteral anticoagulation
	Edoxaban (Savaysa)	After 5-10 days of parenteral anticoagulation	60 mg daily	Avoid in CrCl <15 mL/min; reduce dose for low body weight
	Warfarin (Coumadin)	Dose individualized to target INR	Target INR 2-3	Bridge with parenteral agent until therapeutic INR achieved

* **Note**: All anticoagulants carry a risk of bleeding, and renal function monitoring is essential, especially with DOACs (Direct Oral Anticoagulants). Reversal agents, such as idarucizumab (for dabigatran) and andexanet alfa (for apixaban and rivaroxaban), may be required in cases of major bleeding.

Ophthalmic Agents - Prostaglandin Analogs

Agent	Initial Dose	Dosing Frequency	Special Considerations
Latanoprost (Xalatan)	1 drop in affected eye(s)	Once daily (evening)	May cause iris color changes; first-line for glaucoma.
Travoprost (Travatan Z)	1 drop in affected eye(s)	Once daily (evening)	Preservative-free option available; not for use in pregnancy.
Bimatoprost (Lumigan)	1 drop in affected eye(s)	Once daily (evening)	Known for eyelash growth; also available as cosmetic (Latisse).
Tafluprost (Zioptan)	1 drop in the affected eye(s)	Once daily, typically in the evening	Available in preservative-free single-use vials; suitable for sensitive eyes.
Latanoprostene bunod (Vyzulta)	1 drop in the affected eye(s)	Once daily, typically in the evening	Dual mechanism for IOP reduction; relaxes trabecular meshwork to enhance fluid outflow.

* **Note**: Prostaglandin analogs are typically dosed once daily and are considered the first-line treatment for glaucoma due to their efficacy and low systemic absorption. These agents can cause permanent changes in eye color, particularly in light-colored irises, and may increase eyelash length and thickness.

Ophthalmic Beta Blockers

Agent	Initial Dose	Dosing Frequency	Special Considerations
Timolol (Timoptic)	0.25%-0.5%, 1 drop in affected eye(s)	Once or twice daily	Avoid in asthma, COPD; may cause bradycardia and hypotension.
Levobunolol (Betagan)	0.25%-0.5%, 1 drop in affected eye(s)	Once daily	Similar to timolol; avoid in respiratory conditions.
Carteolol	1%, 1 drop in affected eye(s)	Once or twice daily	Less systemic absorption; preferred in patients needing beta-blocker therapy with a lower risk of systemic side effects.
Metipranolol (OptiPranolol)	0.3%, 1 drop in affected eye(s)	Twice daily	Effective but has a higher risk of causing ocular irritation compared to other beta blockers.
Betaxolol (Betoptic)	0.25% or 0.5%, 1 drop in affected eye(s)	Once or twice daily	Beta-1 selective, thus safer in patients with asthma or COPD; however, it may be less effective in lowering intraocular pressure compared to non-selective beta blockers.

* **Note**: Ophthalmic beta blockers can be absorbed systemically, potentially causing adverse cardiovascular and respiratory effects. To minimize systemic absorption, instruct patients to use punctal occlusion (pressing on the inner corner of the eye) for 1-2 minutes after administering each drop.

Ophthalmic Alpha-2 Agonists

Agent	Initial Dose	Dosing Frequency	Special Considerations
Brimonidine (Alphagan P)	0.1%, 0.15%, or 0.2%, 1 drop in affected eye(s)	Twice to three times daily	Avoid in young children; can cause redness and irritation.
Apraclonidine (Iopidine)	0.5%-1%, 1 drop in affected eye(s)	Three times daily	Short-term use due to tachyphylaxis; risk of allergic reactions.

* **Note**: Alpha-2 agonists are effective at reducing intraocular pressure, but they can cause significant ocular side effects, such as redness, itching, and dryness. Systemic side effects are possible, including dry mouth and fatigue. Brimonidine is generally better tolerated for long-term use, whereas apraclonidine is used more often for short-term or adjunctive therapy.

Ophthalmic Combination Glaucoma Agents

Combination	Components	Dosing Frequency	Special Considerations
Dorzolamide/Timolol (Cosopt)	2% Dorzolamide / 0.5% Timolol	Twice daily	Combines a carbonic anhydrase inhibitor with a beta blocker. Avoid in patients with respiratory or cardiac conditions due to timolol's systemic effects.

Brimonidine/Timolol (Combigan)	0.2% Brimonidine / 0.5% Timolol	Twice daily	Alpha agonist and beta blocker combination. Caution in patients with asthma or COPD; monitor for ocular redness and irritation.
Brinzolamide/Brimonidine (Simbrinza)	1% Brinzolamide / 0.2% Brimonidine	Three times daily	Carbonic anhydrase inhibitor and alpha-2 agonist combination. Useful for patients who need beta blocker alternatives. May cause ocular redness and dry mouth.
Latanoprost/Timolol (Xalacom)	0.005% Latanoprost / 0.5% Timolol	Once daily (evening)	Prostaglandin analog and beta blocker combination. Ideal for patients who need both evening and continuous control. Avoid in patients with respiratory or cardiac conditions.

*** Note**: Combination agents simplify dosing for patients requiring multiple therapies, potentially improving adherence. However, these agents carry the risks associated with each component drug, including systemic absorption and associated side effects. Punctal occlusion is recommended to reduce systemic exposure, particularly with timolol-containing combinations.

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Tobacco Cessation Protocol

Guidelines for the MultiCare Ambulatory Care Clinical Pharmacist

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Purpose

- Maintain a pharmacist-managed tobacco cessation program at MYMH, in collaboration with patients and their providers.
- Provide procedures and responsibility for those involved in providing care to patients referred by authorized prescribers to pharmacist for selection, initiation, modification, continuation, and/or discontinuation of tobacco cessation medications.

Responsibilities

A. Authorizing prescriber responsibilities

a. Understand the pharmacists' roles and responsibilities when referring patients for tobacco cessation management.
b. Document initial referral to pharmacist
    i. Targets are defined by the protocol, unless otherwise specified in referral.
c. Provide consultation/feedback to managing pharmacist as needed.
d. Primary responsibility for follow-up on abnormal laboratory test
e. Reevaluate patient at yearly intervals.

B. Pharmacist's roles and responsibilities

a. Verify that patients meet protocol inclusion criteria.
b. Optimize and monitor medication therapy per this protocol.
    i. Select, initiate, modify, continue, discontinue, and monitor medication, devices, and supplies.
    ii. Order and evaluate appropriate baseline and follow-up labs to assess appropriateness of therapy, therapeutic response and/or adverse reactions.
    iii. Providing education and support for lifestyle modifications when appropriate for tobacco cessation.
c. Continuity in Care
    i. The pharmacist (or delegate within scope of practice) and patient will communicate at regular intervals and work collaboratively with authorizing prescriber.
    ii. If appropriate, refer patients to specialty, primary care or other multidisciplinary providers.
d. Electronic medical record (EMR) documentation
    i. Maintain documentation of performed services in the electronic medical record (EMR)

Inclusion Criteria – ALL criteria must be met.

- Age 18 or older and patient is ready to attempt to quit smoking.
- Not pregnant
- Not enrolled in Hospice
- Seen or virtually managed by provider within last 12 months.

Referring patient back to authorizing prescriber (after any of the following met)

1. Patient is at goal or managed for greater than 12 months and goal not met.
2. No longer meets protocol criteria or protocol meds are maximized.
3. Concerning symptoms arise
4. Patient declines to be seen.
5. Prescriber request patient back

Follow-up

- Per standards of care, sufficient to monitor and titrate medication and get patient to goals. Followup may include clinic visits, portal contact, or telephonic monitoring.

Pharmacist training

- Pharmacists practicing under protocol will receive ongoing training facilitated by MYMH pharmacy administration.

Quality assurance protocols

- Clinical quality will be evaluated using quality markers.
- Patients managed by the protocol will be monitored by pharmacists to ensure they safely achieve or progresstowards their goals.
- Pharmacists will provide feedback to authorizing prescriber.

PATIENT INITIAL EVALUATION:

The 5 A's – a useful model for making a brief intervention (3-10 minutes)

1. Ask every patient about tobacco use, including type of tobacco and duration of use.
2. Advise patients to quit, providing them with personally relevant and clear statements of benefits.
3. Assess willingness to quit (confidence level), use motivational interviewing to empower them to quit (5 R's)
4. Assist patients with quitting, using the STAR system, providing resources, offering pharmacologic therapy.
5. Arrange follow-up with patients, assessing their progress and providing further support/resources/encouragement.

The 5 R's – a model for motivational interviewing

1. Relevance: focus on risks/benefits specific to the patient (i.e. family, health, money)
2. Risks: ask the patient their perspective on the risks/consequences if they continue smoking
3. Rewards: ask the patient what benefits they think they would have from quitting, share with them the benefits of quitting that are most relevant to them
4. Roadblocks: ask the patient about barriers to quitting and offer ways to overcome those barriers
5. Repetition: continue to discuss tobacco cessation at future visits

STAR – a model for assisting patients, which should be supplemented by offering additional support.

- **Set** a target quit date (within the next 30 days, ideal would be within next 2 weeks)
- **Tell** their support network (family, friends, coworkers, etc.) about their plan to quit and ask for their support.
- **Anticipate** challenges of quitting, such as nicotine withdrawal symptoms. The first few weeks are critical to the quitting attempt being successful but are also difficult.
- **Remove** tobacco from their environment, including their home/car/work surroundings. Being around tobacco or other smoker's increases risk of relapse.

For additional patient support, see Appendix A
For tobacco cessation benefits, see Appendix B

Medications and Considerations

Table 1. Outpatient Tobacco Cessation Medications		
Medication	Dosing	Special Considerations
Nicotine Patch 7mg/24hr patch 14mg/24hr patch 21mg/24hr patch	>10 cigarettes/day: 21mg patch daily x 4-6 weeks, then 14mg patch daily for 2-6 weeks, then 7mg patch daily x 2-6 weeks 10 or less: 14mg patch daily x 6 weeks, then 7mg patch daily x 2 weeks	ϒ Reduces physical withdrawal symptoms, which typically start 24-48 hrs after quitting, persist for 2-4 weeks (cravings can persist much longer, over years) ϒ Slower release of nicotine than gum/lozenge so not as useful for an acute craving but, once daily dosing can be more convenient for patient. Studies show using combination of patch+ PRN gum and/or lozenge and or inhaler or nasal spray➔ increased abstinence rates/efficacy. ϒ Counsel patient to apply patch to a clean, dry, and hairless area of non-irritated skin, pressing it to the skin for 10 seconds. They should wash their hands after applying the patch, and should rotate sites. Patch should be removed before MRI. ϒ AE: site reactions/irritation are specific to patch. Nausea, vomiting, diarrhea, headache, insomnia, headache, palpitations, and abdominal pain are AE that apply to any nicotine products.
Nicotine Gum 2mg, 4mg gum	Time to first cigarette upon waking: <30minutes use 4mg, >30minutes use 2mg OR >20 cigarettes/day use 4mg <20 cigarettes/day use 2mg 1-2 pieces q1-2 hrs x 6 wks (10-12/day), then 1 piece q2-4hrs x 3 wks, then 1 piece q4-8 hrs x 3 wks	ϒ Can be helpful in addressing oral cravings. ϒ Counsel patients that it should NOT be chewed like normal gum, it is meant to be chewed 15-30 times and then placed between the teeth and cheek; this should cause a tingling sensation. When the sensation is gone, repeat the process again, until there is no more tingling sensation. "Ball and Park method". Discard gum after 30 minutes. ϒ Acidic beverages can interfere with absorption of nicotine via mouth, patients should avoid eating or drinking anything 15 minutes before and after chewing gum ϒ If patients cannot chew something as this is meant to be used or have dental/jaw problems, they are not good candidates for the gum so patch/lozenge should be considered instead. ϒ Longer durations of therapy have been associated with better success rates, though the standard duration is 12 weeks ϒ Gum is a commonly used method, but as a monotherapy has been found to have lowest abstinence rate. ϒ The maximum number of pieces is 24 in a day ϒ AE: mouth irritation, jaw pain, hiccups, dyspepsia
Nicotine Lozenge 2mg, 4mg lozenge	Time to first cigarette upon waking: <30minutes use 4mg, >30minutes use 2mg OR >20 cigarettes/day use 4mg <20 cigarettes/day use 2mg 1-2 lozenges q1-2hrs x 6 wks, then 1 q2-4hrs x 3 wks, then 1 q4-8 hours x 3 wks	• Can be helpful in addressing oral cravings • Counsel patient that the lozenge should be allowed to dissolve over about 30 mins, and they should not chew or swallow the lozenge. They should rotate the location of the lozenge in their mouth • Initially they should use at least 9 lozenges a day to prevent withdrawal symptoms, and then they should titrate usage down as they can tolerate • Acidic beverages can interfere with absorption of nicotine via mouth, patients should avoid eating or drinking anything 15 minutes before and after using lozenge • The maximum number of lozenges they should use is 5 in a 6-hour period, and 20 in a day. AE: mouth irritation/ulcers, hiccups, heartburn. The systemic effects are dose dependent.

Nicotine Inhaler	Initial dosage: At least 6 cartridges (4 mg nicotine delivered/cartridge) per day, inhaled w/frequent continuous puffing over 20 min for the first 3 - 6 weeks	• Discontinuing treatment if unable to quit smoking by the fourth week and provide a therapeutic holiday before the next quit attempt • Maintenance dosage: Patients may self-titrate based on signs of nicotine withdrawal or excess by using 6 to 16 cartridges/day • Discontinuing therapy: Discontinue after 12 wks of therapy by gradually reducing the daily dose over 6 - 12 wks
Nicotine Nasal Spray	Initial dosage: Initial, 1 spray (0.5 mg nicotine/spray) in each nostril (1 dose equal to 2 sprays total or 1 mg nicotine) 1 - 2 times per hour, with 1 spray in each nostril (1 dose) being administered at least 8 times/day	• Discontinuing treatment if unable to quit smoking by the fourth week and provide a therapeutic holiday before the next quit attempt • Maximum dosage: 5 doses (5 mg nicotine) per hour and 40 doses (40 mg nicotine) per day for 3 months • Discontinuing therapy: Successful patients should be treated at the selected dosage for up to 8 weeks, following which use of the spray should be discontinued over the next 4 - 6 weeks with gradual reduction of dosage; some patients may abruptly stop treatment successfully • Counsel that nasal irritation may occur
Bupropion 150mg tabs, comes in SR too	150mg QD x 3 days, then 150mg BID x 3 days, then from quit date 150mg BID x 3-6 months For long-term therapy, consider 150 mg BID for up to 6 months post-quitting Renally/hepatically dosed	ϒ Start about 1 - 2 weeks before target quit date ϒ Can be used in combination with NRT, and may be good option for patients who have untreated depression ϒ Counsel patients to avoid taking near HS (insomnia) and avoid alcohol use. ϒ Avoid in patients with hx of bulimia/anorexia, stroke, and seizures ϒ AE: insomnia, xerostomia, mental status changes, arrhythmias, nausea, agitation, tremor, anxiety dizziness ϒ If progress has not been made by week 7, consider tobacco cessation success as unlikely ϒSecond dose of medication should be given at noon to avoid risk of insomnia ϒ Can combine with another NRT single agent + varenicline
Varenicline 0.5mg, 1mg tablets	Start 1 week before quit date at 0.5mg QD x 3 days, then 0.5mg BID x 4 days, then on quit date start 1mg BID x 11 weeks, with option to continue for 12 more wks If patient has successfully quit by the end of week 12, they may continue therapy for another 12 weeks to maintain success. If CrCl<30ml/min start with 0.5mg QD, titrate to BID If ESRD on HD, max dose is 0.5 mg/day	ϒ Highest efficacy of all options when used as monotherapy ϒ Start a week before target quit date. Target quit date should be day 8 ϒ Counsel patient to take with food, full glass water. They should avoid smoking, NRT, limit EtOH. ϒ Doesn't require tapering off, can be stopped abruptly. • Monitor all patients for behavioral and psychiatric signs and symptoms (agitation, depression, suicidal ideation, mood swings, etc). If patient exhibits any of these signs or symptoms, DC treatment and contact PCP immediately. • AE: nausea, vomiting, constipation, flatulence, insomnia, vivid dreams ➔ to reduce nausea, take on a full stomach ϒ Can combine with another NRT single agent ϒ Can combine with another NRT single agent + bupropion

APPENDIX A

Available Online Resources for Patients

https://www.cdc.gov/tobacco/quit_smoking/how_to_quit/resources/index.htm

- Multiple free resources, including English and Spanish language versions, versions geared toward military personnel, women, young adults
- Tips from Former Smokers – could be a great way to encourage and motivate someone to quit

https://www.doh.wa.gov/SmartQuit

- Washington State Department of Health Tobacco Quitline: 1-800-QUIT-NOW (784-8669)
- For Spanish Speakers: 1-855-DEJELO-YA (335-3569) and web: https://dejeloya.org/
- For Asians (Cantonese, Mandarin: 1800-838-8917, Vietnamese: 1-800-778-8440, Korean: 1-800-778-8440) : https://www.asiansmokersquitline.org/

https://smokefree.gov/

- Multiple free resources, tools for patients, informational articles written for the layperson on topics such as managing cravings, coping with emotions when quitting, etc.
- Free texting to support quitting, free smartphone apps
- Follow-up
- Check in around their planned quit date or during the first week, and again during the first month
- If they are using pharmacologic therapy, assess efficacy/safety
- Continue to offer additional resources to patients to support them in quitting
- Offer ways to manage any challenges that come up
- Encourage them and congratulate them on their progress, and reinforce the benefits of quitting
- If they use tobacco products or relapse, remind them that they can continue their plan to quit and haven't failed

https://www.becomeanex.org

- Web based support program that includes and online community and experts (developed in collaboration with the Mayo Clinic)
- Offered in English and Spanish

APPENDIX B

Benefits of Tobacco Cessation

Educate the patient on the benefits of tobacco cessation appropriately by using the according below:

- Tobacco cessation has a short time to benefit!
  - 20 minutes: decreased heart rate, decreased blood pressure
  - 12 hours: carbon monoxide level in blood normalizes.
  - 2 weeks - 3 months: circulation and lung function improve.
  - 1 - 9 months: reduction in coughing and shortness of breath, recovering ability of cilia to clear lungs of mucus and potentially infectious organisms
  - 1 year: risk of coronary heart disease almost halved! Big reduction in risk of a heart attack
  - 2 – 5 years: stroke risk reduced to that of a non-smoker
  - 5 years: mouth/throat/esophagus/bladder cancer risks halved, cervical cancer risk that of a non-smoker.
  - 10 years: risk of dying of lung cancer halved, risk of pancreas/larynx cancer reduced.
  - 15 years: risk of coronary heart disease that of a non-smoker
- Other benefits:
  - Lower risk of diabetes, better control of diabetes
  - Reduce risk of emphysema, prevent worsening of emphysema.
  - Mortality benefit for patients with COPD
  - Better quality of life: easier to do ADLs, improved sense of taste/smell.
  - Lower risk of erectile dysfunction and improved fertility
  - Improved immune system and healing.
  - Lower risk of fractures
  - May need to quit to have surgery if surgeon will not operate prior.
  - Even if they do not manage to quit, each attempt to quit increases the chance of future success.

Reference:

1. In-Depth Answers. IBM Micromedex [database online]. Truven Health Analytics/IBM Watson Health; 2021. Accessed September 2021. https://www.micromedexsolutions.com
2. Lexi-Drugs. Lexicomp Online. Lexicomp; 2021. September 2021. https://online.lexi.com
3. Hartmann-Boyce J, Chepkin SC, Ye W, Bullen C, Lancaster T. Nicotine replacement therapy versus control for smoking cessation. *Cochrane Database Syst Rev*. 2018;5(5):CD000146. Published 2018 May 31.
4. Chang SS. Re: Smoking Cessation: A Report of the Surgeon General. *J Urol*. 2020;204(2):384.
5. Tobacco Use. Agency for Healthcare Research and Quality (AQHR). Accessed September 2021. https://www.ahrq.gov/topics/tobacco-use.html
6. Cinciripini PM, Minnix JA, Green CE, et al. An RCT with the combination of varenicline and bupropion for smoking cessation: clinical implications for front line use [published online ahead of print, 2018 Apr 21]. *Addiction*. 2018;10.1111/add.14250.

PHARMACY TOBACCO CESSATION SERVICE

Commented [ASC1]: Name adjusted to be consistent/specific

Authorization for Use of Protocol

Pharmacists on staff at Peninsula Community Health Services (PCHS) who have demonstrated competence in tobacco cessation management are given prescriptive authority to initiate and modify tobacco cessation therapy with appropriate counseling, medication and monitoring for all adult, non-pregnant patients diagnosed with tobacco dependence. Any current patient under care of any physician, nurse practitioner, or physician assistant who has prescriptive privileges and is employed by PCHS is eligible to use the tobacco cessation education service. Pharmacy tobacco cessation services will commence after a referral of the patient for tobacco cessation is made by the following mechanisms: provider referral, self-referral by the patient or any other request made on behalf of a current PCHS patient.

Training & Continuing Education

Pharmacists practicing under the tobacco cessation prescriptive authority protocol will complete a training program approved by the Director of Pharmacy Services and the P&T committee. Proof of training will be maintained in the Pharmacist's credentialing file**.**

Clinical Guidelines

Guidelines for the treatment of tobacco dependence and patient follow-up are based on the most recent recommendations by the U.S. Department of Health and Human Services "Treating Tobacco Use and Dependence: 2008 Update." The guidelines are not intended to replace clinical judgment, and, at times, it will be necessary to deviate from the guidelines due to specific patient characteristics/scenarios.

Clinical Evaluation & Management

Pharmacists may coordinate and optimize the delivery of tobacco cessation by:

- Assessing patient's tobacco use, discussing key issues such as triggers and coping strategies, and facilitating the quit process.
- Initiating, modifying, and/or discontinuing tobacco cessation medications based on the assessment of patient specific progress and medication-related problems or contraindications. The patient's medication list should be reviewed for possible drug interactions.
- Providing ongoing education to the patient and caregivers about tobacco dependence, stressing the importance of self-care behavior to optimize outcomes.
- Communicating with other healthcare providers involved in the care of the patient to maximize counseling and medication efficacy and minimize adverse effects.
- Evaluating patients for eligibility for lung cancer screening recommended by the U.S. Department of Health and Human Services and immunization recommended by the Center for Disease Control and Prevention (CDC).

Commented [ASC2]: "coping"?

Commented [ASC3]: Be consistent

Commented [ASC4]: Is this just about medication efficacy? (i.e., What about counseling efficacy?) I would broaden this statement to include communication of both medication + counseling (since this is your intervention)

Documentation
All patient care interventions and prescribing activity will be documented in the Electronic Health Record (EHR) per PCHS policy and standards of care, and readily available for review by the referring provider. The onsite medical provider will be consulted immediately for any symptoms of immediate concern. Any new prescriptions resulting from the pharmacist's clinical judgement will be issued in the pharmacist's name, as per WAC 246-863-100.

Pharmacists will document the following information with each patient visit[2,3]

- Date of service
- ICD-10 diagnosis code
- Amount of time spent counseling
- Patient plan that may include lab work ordered, immunizations needed, referrals to other providers.
- Resources made available to the patient
- Next follow-up visit

Patient education on initial visit will include the following:

- Patient's willingness to attempt to quit
- Patient's assessment information
- Patient's medication choice
- Anticipated quit date

Follow-up visits will include:

- Patient's progress
- Any reported side effects to medication
- Medication adherence
- Medication adjustment and refills

At the end of each tobacco cessation encounter, the patient will be provided the patient plan outlining the visit. This plan may include any of the following recommendations if applicable: medication changes, lifestyle changes/goals, self-monitoring goals, immunizations needed, information for support groups, and/or referral to local or state tobacco cessation programs.

The patient plan from the previous visit will be reviewed and assessed at the next tobacco cessation visit. The assessment will be documented in the EHR in order to provide a contiguous care plan.

Quality Assurance Evaluation and outcomes will be reported at regular interval. Evaluation should include patient participation, summary of medication regimen, patient success rate, as well as any expected adverse events. These will be shared with the quality department in line with the goals of the PCHS Quality Improvement Plan.

Patient Recall
A weekly, automated report will be generated and sent to the pharmacy department listing the patients who cancelled or did not attend a scheduled appointment. The pharmacy department will conduct recalls for patients using the following procedure:

Commented [ASC5]: Are there minimum documentation elements required for billing tobacco cessation services?

Commented [ASC6]: How much time do you anticipate for visit documentation?

Commented [PTL7]: We use EHR – edited to be consistent with PCHS policies

Commented [ASC8]: "office visit" is inconsistent with the fact that these may not be in-person. (Workflow vs. protocol question: How will patients receive this patient plan if telephone visit?)

Commented [ASC9]: Be consistent. "EMR"

Commented [PTL10R9]: EHR not EMR

- Two phone calls on separate days will be performed weekly for two consecutive weeks in an attempt to reschedule the patient.
- If the patient cannot be contacted after the second week phone calls, patients will be discharged from tobacco cessation services.
- Patients may be accepted back into the program at any time, acknowledging that tobacco dependence is recognized as a chronic disease with a relapsing nature.

Chief Medical Officer's signature: _____ Effective date:_____

References:

1. Fiore MC, Jaén CR, Baker TB, et al. Treating Tobacco Use and Dependence: 2008 Update. Clinical Practice Guideline. Rockville, MD: U.S. Department of Health and Human Services. Public Health Service. May 2008.
2. Integrating Tobacco Use Treatment into Practice – Billing and Documentation. Frank Leone, et. al. Chest, 149, #2, pages 568-575, February 2016
3. Indian Health Services. (2013, May). Adapted based on IHS PIMC Example Pharmacy Tobacco Cessation Clinic Protocol. California.
4. Rx for Change: Clinician-assisted tobacco cessation. The Regents of the University of California, University of Southern California and Western University of Health Sciences.
5. Veteran Affairs Primary Care Tobacco Cessation Handbook

Commented [ASC11]: Where does this fit into the protocol? You mentioned IHS as a potential "Pharmcist-led Tobacco Cessation" resource. You also mentioned that you saw it was implemented in one IHS clinic in Wisconsin (I hinted strongly at the time, that you needed to figure out which WI clinic, because it is likely I know the Pharmacy Directors and/or the resident who implemented this WI program as it was likely the resi project of a classmate of mine).

Commented [ASC12]: VA reference? If you are going to say this was "adapted from" VA -- suspected should have a reference.

IMPLEMENTATION OF PROTOCOL

Purpose:
To safely and effectively initiate a plan of care for patients on parenteral nutrition at Seattle Children's Hospital.

Procedure:
The provider will:

1. Initiate the process by placing an order for "TPN consult."
2. Discuss with the pharmacist, any special considerations while managing patient's TPN.

The pharmacist will:

1. Review the nutritional assessment from the clinical dietitian.
2. Write an order for TPN after consultation with the provider and dietitian.
3. Monitor fluid status, weight, I&O, blood sugars and labs, and consult daily with clinical dietitian and provider, and adjust TPN daily as appropriate.
4. Recommend changes in TPN-related laboratory orders and monitoring parameters when appropriate.
5. Consult with the provider, nurse and dietician on complications of therapy where appropriate.

The clinical dietician will:

1. Perform a nutritional assessment on all patients prior to initiation of TPN.
2. Document nutritional assessment and recommendations and confer with the provider, pharmacist, and nurse daily.
3. Recommend nutritional screening tests.
4. Recommend adjustments to plan of care according to clinical status and ability to transition to enteral intake.

Documentation:
Documentation in the Electronic Health Record is completed by the pharmacist or dietitian upon initiation of TPN, when a change is made, and when deemed necessary for communication.

Quality Assurance:
TPN orders will be screened for quality periodically and in response to TPN order-related errors. Orders will be screened by a pharmacist and dietitian for compliance with Seattle Children's TPN ordering guidelines according to the following criteria:

- Follow protocol for heparin, trace elements, and multivitamins
- Follow parameters to maintain calcium/phosphate solubility
- Follow parameters for potassium rate and concentration maximums
- Substrates ordered within recommended range
- Reference weight provided

Deviations found to not be supported by reasonable clinical rationale will be discussed with the prescribing pharmacist and an improvement plan will be established.

Data gathered from the Quality Assurance screening will be summarized and presented, at least annually, to the Nutrition Committee, as well as the authorizing prescriber upon request.

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Training:

1. Pharmacists will be authorized to prescribe and monitor TPN therapy under this prescriptive authority protocol upon completion of a core competency training module which includes:
    a. Receipt of a copy of the following Seattle Children's guidelines and policies to be read:
        i. Guideline of Care for Parenteral Nutrition
        ii. Total Parenteral Nutrition policy
        iii. Maintenance Fluids to Replace Parenteral Nutrition Job Aid
    b. Completion of a didactic program with Parenteral Nutrition CDTA Lead Pharmacist or delegate
    c. Completion of an in-house practicum conducted by a Seattle Children's-credentialed prescriber in which a minimum of seven TPN orders are appropriately written by the trainee.
    d. Successful completion of a competency evaluation knowledge-based post-test and case-based post test for the TPN training module
    e. Review of strategies for converting outside TPN orders to in-house TPN orders and successful completion of at least two practice cases.

2. Credentialed prescribers will participate in an ongoing educational effort which may include:
    a. Selected chapters from the most current A.S.P.E.N. parenteral nutrition publications
    b. Selected journal articles on aspects of TPN therapy or patient comorbidities encountered at Seattle Children's
    c. In-services from other credentialed prescribers on aspects of TPN therapy or patient comorbidities encountered at Seattle Children's.
    d. Continuing education presentations from Parenteral Nutrition CDTA Lead Pharmacist

Attachments:

Seattle Children's Total Parenteral Nutrition Policy
Seattle Children's Pediatric Parenteral Nutrition Order form
Seattle Children's Infant Parenteral Nutrition Order form

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