**Diabetes Management Protocol and**

**Collaborative Practice Agreement/Standing Orders**

**Purpose:**

* Provide continuity of care to patients who require diabetes therapy
* Enhance patient care through education, monitoring and follow-up
* Reduce adverse events associated with diabetes therapy

**Procedure:**

* The pharmacist will gather patient specific information from patient’s on-site paper chart and/or electronic chart if available and prior to each visit will determine the scope of services required to fulfill current national guidelines and comprehensive care. If unable to obtain all necessary information the pharmacist will contact the primary care physician (PCP). At each visit the pharmacist will collect subjective and objective data to assess the level of the following:
  + Control of patient’s diabetes
    - Considerations for hyperglycemia: nocturia, polyphagia, polydipsia, irritability, vaginal discharge, skin rash in moist areas, delayed wound healing, headache, blurred vision, etc.
    - Considerations for hypoglycemia: sweating, tachycardia, hunger, confusion, dizziness, headache, blurred vision
  + Compliance with pharmacological, dietary, exercise, and self-management aspects of therapy
    - Assess refill records, self-monitoring records for glucose/blood pressure, directly observe self-monitoring techniques
  + Complications due to disease or drug therapy (see Appendix A)
  + Need for ancillary monitoring and preventative services (Appendix B)
* Based on the findings at each visit the pharmacist will:
  + Modify existing pharmacological regimen for management of diabetes, hypertension, and dyslipidemia and provide education
  + According to patient-specific factors and other recent laboratory values, the pharmacist is authorized to order the following laboratory tests through Memorial Hospital when clinically warranted (can be coordinated with primary care physician). If test is not within normal limits, the patient will be referred to primary care provider for assessment.
    - Blood pressure
    - Fasting blood glucose/Pre- and Post-prandial blood glucose
    - Weight
    - Foot exam/podiatry referral
    - A1c
    - Immunizations
    - Lipid panel/LFTs/Creatinine Kinase
    - CMP/albumin
    - UA/Serum Creatinine/eGFR/Urine glucose/ketones
    - CBC with differential
    - Ophthalmology/optometry referral exam
    - TSH
  + Educate patients in self-management of diabetes
  + Provide other needed educational interventions
  + If patient presents with significant health status changes he or she will be referred to the primary care provider or emergency services as clinically appropriate
  + Eligible patients include patients requiring management of Diabetes Mellitus therapy and are current residents at Hickory Grove and Maple Grove
  + Hickory Grove and Maple Grove’s Medical Director, Dr. Aaron Wesp, MD, will supervise the hyperlipidemia management services and Dr. Douglas Heighton, MD, in his absence.
* Medication Management: the pharmacist will have prescribing privileges to include initiation, modification, discontinuation, and refills of the following classes of medications in the treatment of diabetes, hypertension, and dyslipidemia under authorization of the collaborating provider
  + Biguanides
  + Sulfonylureas
  + Thiazolidinediones
  + Dipeptidyl Peptidase IV (DPP-IV) Inhibitors
  + Incretin Mimetics
  + Insulin
  + Other antidiabetic agents
  + Antihyperlipidemia agents (statins, fibric acid derivatives, bile acid sequestrants, Ezetimibe, and other antilipemic agents)
  + Antihypertensive agents (dopamine receptor agonists, beta-blockers, ACEIs, ARBs, diuretics, CCBs, alpha blockers, and other antihypertensive agents)
* The pharmacist will document all encounters in the patient’s on-site paper chart, electronic medical chart if available, or by fax/phone to physician office

**Quality Assurance**

* Criteria for review of appropriateness of care will include:
  + Concordance with national guidelines for care:
    - American Diabetes Association (Clinical Practice Recommendations – 2016)
    - American Association of Clinical Endocrinologists (Clinical Practice Guidelines for Developing A Diabetes Mellitus Comprehensive Care Plan 2015)
    - The Eighth Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC 8-2013)
    - The 2013 American Heart Association (AHA)/American College of Cardiology (ACC) lipid guidelines
* Appropriateness of monitoring, educational, preventative, and referral activities
* Will track and follow the incidence of development/new diagnosis of macrovascular (CAD, MI, stroke, etc.) and microvascular (neuropathy, retinopathy, nephropathy, etc) complications

**References:**

1. Adapted and used with permission from Community Health Association of Spokane (CHAS) and American College of Clinical Pharmacy (ACCP) Ambulatory Care Manual
2. American Diabetes Association Clinical Practice Recommendations, (ADA-2106)
3. The Eighth Report of the Joint Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure, (JNC 8-2013)
4. 2013 American Heart Association (AHA)/American College of Cardiology (ACC) lipid guidelines
5. American Association of Clinical Endocrinologists (AACE) and American College of Endocrinology (ACE) Clinical Practice Guidelines for Developing A Diabetes Mellitus Comprehensive Care Plan 2015

**Appendix A**

**Complications of Diabetes**

**Subjective Findings**

* Fatigue, malaise, nausea, anorexia **(nephropathy)** (pharmacist or provider)
* Burning pain, numbness, tingling in feet, indigestion, impotence, cuts/bruise on lower extremities **(neuropathy)** (pharmacist or provider)
* Chest pain **(angina)** (pharmacist or provider)
* Ulcers, sores, cuts on feet, leg cramps **(diabetic foot/intermittent claudication)** (pharmacist or provider)
* Dizziness, dysarthria, visual problems **(CVA/TIA)** (pharmacist or provider)
* SOB, DOE, PND, orthopnea **(CHF)** (pharmacist or provider)
* Changes in overall vision, blind spots **(retinopathy)** (ophthalmologist)

**Objective Findings**

* UA/CR ratio for microalbuminuria/proteinuria (pharmacist or provider; responsible party)
* Serum creatinine (GFR) (pharmacist or provider; responsible party)
* Foot examination including unnoticed cuts, bruises, skin rash, monofilament, pulses, temperature, calluses/corns/bunions, nails for fungus, edema (pharmacist or provider; responsible party)
* Auscultation/percussion of chest/heart, CXR, ECG (provider)
* Respiratory and heart rate (pharmacist or provider; responsible party)
* Neurological exam (provider)
* Visual acuity, ophthalmoscopic exam, visual fields (provider or ophthalmologist; responsible party)

**Complications of Drug Therapy**

|  |  |
| --- | --- |
| **Drug Therapy** | **Complications** |
| **Biguanides** | Lactic acidosis: tachypnea, fatigue, malaise, weakness; Electrolytes/Bicarbonate; Renal Function (GFR); Liver Function; Gastrointestinal symptoms; Vitamin B12 deficiency |
| **Sulfonylureas** | Hypoglycemic symptoms, Random blood glucose, Weight gain, Renal function, Photosensitivity |
| **Thiazolidinediones** | Liver Function, ALT, AST**;** Weight gain**;** Edema |
| **Dipeptidyl Peptidase IV (DPP-IV) Inhibitors** | Hypoglycemia, Renal Function (GFR) |
| **Incretin Mimetic** | Nausea/vomiting, Hypoglycemia, Pancreatitis |
| **Insulin** | Hypoglycemia, Lipohypertrophy |
| **Other Antidiabetic Agents** | Gastrointestinal symptoms |
| **Statins** | Muscle aches/pain/weakness, LTFs, CK for rhabdomyolysis if patient presents with symptoms |
| **Fibric Acid Derivatives** | Gastrointestinal symptoms, Muscle aches/pain/weakness, CK for rhabdomyolysis, GFR |
| **Other Antilipemic Agents** | Gastrointestinal symptoms, Flushing, LFT, Constipation |
| **Beta-Blocker** | CNS side effects, Orthostasis, Exercise intolerance, CHF, Claudication precautions, Heart rate |
| **ACE-Inhibitors** | Cough, Hyperkalemia, Renal function, Angioedema, Orthostasis |
| **Angiotensin Receptor Blockers** | Hyperkalemia, Renal function |
| **Diuretics** | Muscle weakness, Renal function, Electrolytes, Photosensitivity |
| **Renin Inhibitor** | Hyperkalemia**,** Renal function |
| **Calcium Channel Blockers** | Edema, GERD, Gastrointestinal symptoms, Heart rate |
| **Alpha Blockers** | CNS side effects, Orthostasis |

**Appendix B**

**Monitoring and Preventative Services:**

* **Aspirin Therapy:** Aspirin for men over 50 and women over 60 with diabetes AND at least one additional major risk factor: smoking, hypertension, dyslipidemia, family history of heart disease, albuminuria. As these patients usually have a 10-yr cardiovascular risk over 10 %. ASA is optional for older DM patients WITHOUT risk factors or younger patients WITH risk factors
* **Smoking Cessation:** Screen, advise, and assist initially and then at least annually
* **Vaccinations:** Annual Influenza, Prevnar 13, Pneumovax 23, Zostavax
* **Dental Exams**: Recommended at least twice yearly.
* **Blood Pressure, weight:** Every visit: blood pressure target goal <140/90 mmHg
* **Foot Exam (for adults):** Thorough visual inspection, sensory exam, and pulse exam every "diabetes visit” at least quarterly with a monofilament performed at least yearly
* **Dilated eye exams:** Type 1: 5 years post diagnosis, then every year by an ophthalmologist or optometrist. Type 2: shortly after diagnosis, then every year by an ophthalmologist or optometrist
* **Depression:** Probe for emotional physical factors linked to depression annually; treat aggressively with counseling, medication, and/or referral
* **A1c:** At least annually and quarterly if treatment changes or is not meeting goals. Target goal < 7% or modified (<8.5%) to prevent hypoglycemia in older more frail adults
* **Urinalysis:** At diagnosis; if the urinalysis is positive for protein, a quantitative measure is frequently helpful in the development of a treatment plan. If the urinalysis is negative for protein, a test for the presence of microalbumin is necessary
* **Microalbuminuria (Albumin/Creatinine Ratio):**

Type 1: 5 years post diagnosis, then every year

Type 2: begin at diagnosis, then every year

* **Blood Lipids (for adults):** 2013 ACC / AHA Cholesterol Guidelines

There are four major statin benefit groups:

* Patients with clinical atherosclerotic cardiovascular disease.
* Patients with LDL 190 mg/dL (5 mmol/L) or higher.
* Patients age 40 to 75 years of age with diabetes (but without clinical atherosclerotic cardiovascular disease) and LDL 70 to 189 mg/dL (1.8 to 4.9 mmol/L).
* Patients without clinical atherosclerotic cardiovascular disease or diabetes with LDL 70 to 189 mg/dL (1.8 to 4.9 mmol/L), with an estimated 10-year risk of atherosclerotic cardiovascular disease of 7.5% or higher.
* If a patient does not fit into one of the four statin benefit groups (e.g., LDL 70 to 189 mg/dL [1.8 to 4.9 mmol/L] with 10-year risk 5% to 7.5%), but there is clinical suspicion that they may benefit from a statin, additional factors can be taken into consideration:
  + LDL 160 mg/dL or higher or other evidence of genetic hyperlipidemia
  + Cardiovascular disease onset in a first degree male relative before age 55, or in a first degree female relative before age 65
  + High-sensitivity C-reactive protein 2 mg/dL or higher
  + Ankle-brachial index <0.9
  + Elevated lifetime risk of atherosclerotic cardiovascular disease
  + Coronary artery calcium (CAC) score 300 Agatston units or higher, or 75th percentile or higher for age, gender, and ethnicity
  + Statin adverse effects
  + Statin drug interactions
  + Patient preferences

**Appendix C**

**Diabetes Management Program Objectives**

**Patients will have the following targets/referrals:**

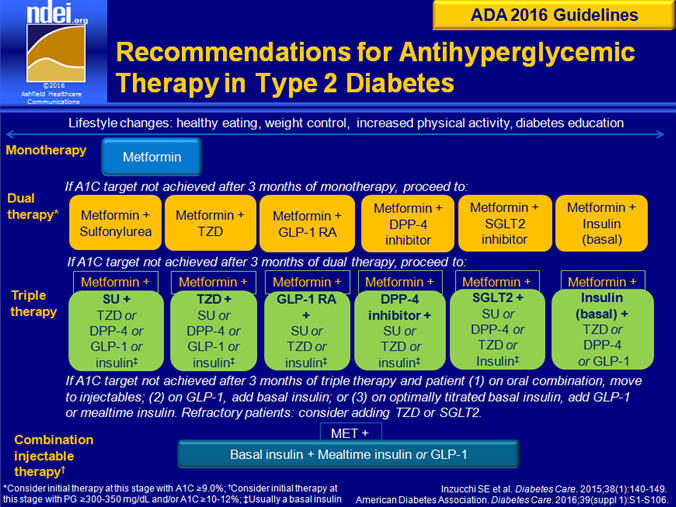
* A1C < 7-8.5% (individualized)
* Systolic Blood Pressure < 140
* Diastolic Blood Pressure < 90
* LDL < 70-100 depending on high or very high risk
* HDL > 40 for men and > 50 for women if LDL controlled
* Triglycerides < 150
* Renal Evaluation Annually at minimum
* Eye Exam Annual referral
* Foot Exam Annual monofilament exam, intermittent visual
* Dental Exam Biannual referral
* Influenza Vaccine Annual
* Pneumococcal Vaccine Prevnar13 and Penumovax23 as appropriate
* Smoking Cessation Patients will be screened and counseled to target

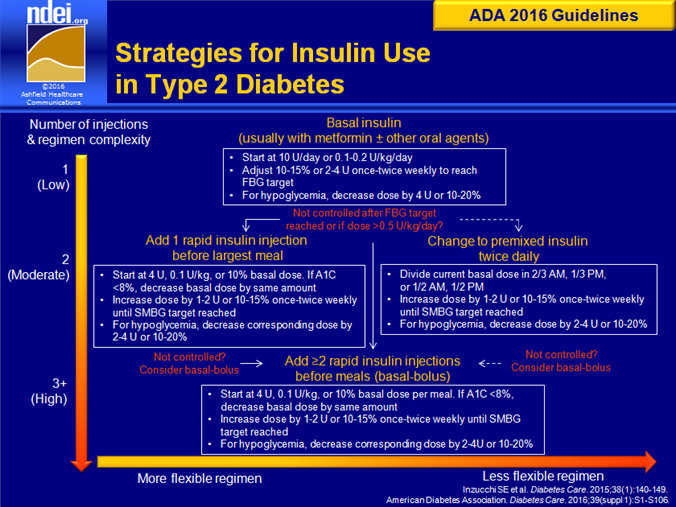
cessation

Aspirin Therapy Consider as primary prevention for patients at increased cardiovascular risk (10-yr risk >10%). Includes most men >50, women aged >60 with at least 1 additional risk factor (famity hx of CVD, HTN, smoking, dyslipidemia, or albuminuria). Use as secondary prevention in pts w/ DM and a hx of CVD. Caution in initiating in pts >80 years

**Appendix D**

**Pharmacology Treatment Guidelines**





By singing this document, the named physicians agree that the named pharmacist may enter into Collaborative Practice with them for the management of diabetes mellitus in residents at Hickory Grove and Maple Grove receiving antihyperglycemic therapy in accordance with policies and procedures outlined in the above document and mutually agreed upon, as well as the Illinois Pharmacy Practice Act 225 ILCS 85/3 (aa).

Clinical Pharmacists:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

LuAnn Haas, RPh Mattie Haas, PharmD, CGP

Physicians:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Dr. Edward McKenney

The prescriptive authority is granted for a period of one year from the date of approval unless rescinded earlier in writing to Nauvoo Pharmacy. A review of the protocol and the prescribing decisions will be conducted yearly.

Approval date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Anticoagulation Management Protocol and**

**Collaborative Practice Agreement/Standing Orders**

**Purpose:**

* To improve patient safety, individualize patient care, and ensure compliance with The Joint Commission’s National Patient Safety Goal to “reduce the likelihood of patient harm associated with use of anticoagulation therapy.”
* The anticoagulation monitoring service provides overall management of anticoagulation therapy including:
  + Provision of comprehensive and ongoing education to patients and/or family members regarding anticoagulation therapy.
  + Education and coordination with Hickory Grove and Maple Grove facilities staff to improve patient care and outcomes.
  + Appropriate monitoring and follow-up of patients.

**Procedures:**

* Patients must allow Hickory and Maple Grove nursing staff to prick his or her finger to conduct a Point-of-Care (POC) test using the CoaguChek® XS Plus device
  + If POC testing is unavailable, patient will require a venous puncture using Memorial Hospital laboratory to complete the test
* Anticoagulation management service
  + The pharmacist will gather patient specific information from patient’s on-site paper chart and/or electronic chart if available. If the clinical pharmacist cannot obtain all necessary information the PCP will provide indication, desired INR goal, expected duration of therapy and pertinent past medical history
  + The patient will be seen by the clinical pharmacist at the next available time or as clinically appropriate.
* Patient Visits:
  + Eligible patients include patients requiring management of anticoagulation therapy and are current residents at Hickory Grove and Maple Grove
  + Hickory Grove and Maple Grove’s Medical Director, Dr. Aaron Wesp, MD, will supervise the anticoagulation management services and Dr. Douglas Heighton, MD, in his absence.
  + At each visit, a patient interview and chart review will be used to assess the following factors:
    - Indication and therapeutic benefit from warfarin
    - Adverse effects
    - Signs and symptoms of bleeding, what to report, when to seek help
    - Evaluate PT/INR, target range and frequency of monitoring
    - Drug-drug interactions (prescription, non-prescription, herbal/dietary supplements, alcohol)
    - Drug-food interactions
    - Affect of acute illness on warfarin and INR
    - Compliance
  + Patient will receive continuous education regarding the safe and effective use of anticoagulants
  + All anticoagulation monitoring encounters will be documented in patient’s on-site paper chart or electronic chart as available
  + The pharmacist and/or nursing staff will be responsible for performing POC testing and/or ordering necessary labs through Memorial Hospital
  + As clinically appropriate, the anticoagulation pharmacist will contact the patient’s PCP, supervising provider or send the patient to the emergency department (ED) for further evaluation depending on patient presentation
  + Dosage adjustments of warfarin will be made following the evaluation and follow-up plan

**Warfarin Dosage:**

* Appropriateness of warfarin dosage is assessed based upon INR within the context of compliance, patient’s anticoagulation history, possible interactions and complications.
* Dosage of warfarin is adjusted as necessary.
  + Usually small dosage adjustments (~10%) of the weekly dose are made.
  + Supratherapeutic INRs: assess compliance, drug interactions, diet changes, alcohol consumption, and then recheck lab (>4.5), hold doses, use oral vitamin K antidote (as indicated by provider), decrease dose, or contact PCP or supervising provider based on patient clinical status.
    - Elevated INRs will be managed according to the ACCP Antithrombotic and Thrombolytic Therapy Guidelines.1 If Vitamin K is indicated, the patient’s PCP or anticoagulation management services supervising provider will be contacted to authorize the need for Vitamin K administration
    - Oral Vitamin K tablets will be available through Nauvoo Pharmacy
  + Subtherapeutic INRs: assess compliance, drug interactions, diet changes, recheck lab as appropriate, restart medication, increase dose or contact PCP or supervising provider based on patient clinical status.
* The patient is advised of the dosage change and the new dose is recorded in the patient chart and communicated to the physician office and providing pharmacy for correction.
* The medication profile is reviewed to determine if a new warfarin prescription or a renewal is needed.
  + Warfarin prescription refills will be provided by the anticoagulation manage pharmacist, under the authorization of the collaborating provider
  + Prescriptions will be phoned into Nauvoo Pharmacy immediately following visit.

**Determining Future INR Labs:**

* The next PT/INR check is determined based upon the patient’s INR and the need for dosage change.
  + If dosage change is required, the patient will usually receive follow-up in 1-3 weeks
  + If no dosage change is required, patient will be followed-up with in approximately 4 weeks.
* Anticoagulation management clinical pharmacist will make follow-up appointments

**Duration of Therapy:**

* For short-term therapy, the patient’s PCP will evaluate the need to continue warfarin when warfarin therapy has reached the expected discontinuation date and this decision will be documented.
* Chronic therapy, if there have been changes in the patient’s status (fall risk, bleeding complications, adherence, etc.) the anticoagulation management pharmacist will notify the PCP or supervising provider for evaluation of risk vs. benefit of continued warfarin therapy or recommendation for other anticoagulation therapy (i.e. newer oral anticoagulation medications)

**Non-compliance:**

* If a patient is unable to keep a scheduled appointment, the appointment will be rescheduled by either speaking with the patient or with the aid of the nursing staff.
* If a patient is consistently non-compliant with the anticoagulation pharmacist’s recommendations, the pharmacist will discuss the patient with the PCP to determine appropriate action.

**Hospitalizations:**

* Anticoagulation patients hospitalized at any facility will be followed-up with as soon as discharged back to Hickory or Maple Grove facilities or as clinically appropriate.

**Warfarin Protocol:**

* Recognized indications for warfarin: prophylaxis and treatment of thromboembolic disorders and complications
* Contraindications:
  + Hypersensitivity to warfarin or any component of the medication
  + Pregnancy, known or suspected
  + Unreliable, non-compliant patient
  + Warfarin-induced necrosis
  + High bleed risk or active bleeding
    - Eclampsia, preeclampsia, threatened abortion
    - Alcoholism; lack of patient cooperation
    - Anesthesia; major, regional, or lumbar block
    - Aneurysms; cerebral, dissecting aorta
    - Bacterial endocarditis
    - Bleeding tendencies of the gastrointestinal, genitourinary, or respiratory tract
    - Blood dyscrasias
    - Cerebrovascular hemorrhage
    - Severe uncontrolled or malignant hypertension
    - Pericarditis and pericardial effusion
    - Spinal puncture and other procedures with potential for uncontrollable bleeding
    - Surgery of central nervous system or eye, recent or potential
    - Traumatic surgery resulting in large open surface
    - History of falls or high fall risk
  + Use with caution: there are multiple patient populations where warfarin should be used with caution. Together, the patient’s PCP and the anticoagulation management pharmacist will evaluate these individuals on a case-by-case basis and take the appropriate actions to ensure patient safety.
  + Warfarin initiation: the patient’s PCP is responsible for obtaining a baseline INR, initiating warfarin, determining goal INR range, expected duration of therapy, and contacting the anticoagulation pharmacist for immediate enrollment and subsequent management.
  + All baseline INRs must be obtained within 7 days of warfarin initiation.
    - Pharmacist will check for baseline INR prior to warfarin initiation
    - Baseline INR will be drawn by nursing staff using CoaguChek® XS Plus device or by Memorial Hospital laboratory if no previous, appropriate INR is available
  + It is recommended that providers follow the current CHEST guidelines to determine goal INR range and expected duration of therapy.2
  + Loading doses of warfarin are NOT recommended, as loading doses are associated with erratic INR changes and a higher incidence of supratherapeutic INRs, thus increasing bleed risk.3
* INRs will be checked at least 1-2 times per week, or as clinically indicated during initial warfarin titration until INR stabilizes.
* If warfarin is being bridged with Low-Molecular-Weight Heparin (LMWH), warfarin needs to be initiated within 72 hours and the parenteral anticoagulant should be used concomitantly for at least 5 days and until the INR is therapeutic for 24 hours.

**Warfarin Maintenance:**

* All efforts will be made to manage patients using one tablet strength of warfarin
* All patients are required to have their INR checked at least every 42 days in order to continue receiving anticoagulation management services

**Monitoring of Warfarin Use:**

* Anticoagulation management services will perform/order INR and complete blood count (CBC)
  + INR will be performed/ordered at baseline and every 0-6 weeks or as clinically appropriate
  + CBC will be ordered at baseline and every 6-12 months or as clinically appropriate
  + Abnormal CBC and/or acute changes will be discussed with PCP for evaluation
* If a patient is currently receiving subcutaneous LMWH, and INR will be checked 1-2 times per week until stable, or as clinically appropriate
  + Anticoagulation pharmacist will consult with PCP when INR is therapeutic and subcutaneous LMWH therapy can be discontinued, this will be documented in patient chart.
* If no change is made to the warfarin dose, or if a one-time dose adjustment is made, the INR should be re-checked at least every 4 weeks or as clinically appropriate. The maximum allowed interval between INR checks is 6 weeks.
* If the patient is started on a NEW “significant” and “critical” interacting medication, the INR will be checked more frequently, as indicated by the nature and degree of the drug-drug interaction.

**Critical INRs:**

* If the CoaguChek® XS Plus device results an INR level exceeding 4.5 (critical INR) the test will be repeated and/or the patient will be sent to Memorial Hospital laboratory for a venous puncture to confirm results.
* The patient will be assessed for signs and symptoms of excessive bleeding/bruising
  + Excessive anticoagulation will be managed according to current guidelines and if Vitamin K is recommended consent will be obtained from physician
    - For patients taking Vitamin K Antagonists (VKAs) with INRs between 4.5 to 10.0 and no evidence of bleeding recommendation is against the routine use of Vitamin K
    - For patients taking VKAs with INRs greater than 10.0 and no evidence of bleeding recommendation is to prescribe Vitamin K
    - If assessment yields significant/acute findings the PCP, supervising provider, or Emergency Department will be consulted for immediate appropriate action

**Dose Adjusting Warfarin Based upon INR Results:**

* Anticoagulation pharmacist will adjust warfarin therapy based on INR and clinical judgment and the approved algorithms.
  + Anticoagulation pharmacist may choose not to adjust a warfarin dose in response to a non-therapeutic INR if any of the following are present:
    - The INR is within 5% of goal
    - The patient has missed doses or taken extra doses in the last week
    - The patient has/had temporarily taken a mediation that interacts with warfarin
    - The patient had a temporary change in dietary vitamin K intake
    - The patient had a temporary change in alcohol consumption
    - The patient has/had significant diarrhea or vomiting in the last week that has now resolved
  + If a warfarin dose adjustment is deemed necessary by the anticoagulation pharmacist, the attached guidelines will be considered in the clinical decision-making process.

**Patients Requiring Temporary Warfarin Discontinuation:**

* Patients undergoing surgeries/procedures, who are anticoagulated with warfarin, may need to discontinue therapy for a short time.
  + Temporary discontinuation of warfarin will be the responsibility of the patient’s PCP or surgeon
  + PCP is to notify Hickory and Maple Grove nursing staff or anticoagulation pharmacist of any patients requiring discontinuation
  + It is recommended that providers follow the 9th edition of ACCP Antithrombotic and Thrombolytic Therapy Guidelines (CHEST) in determining appropriate discontinuation and/or need for bridge therapy.4

**Quality Assurance:**

* Anticoagulants will be monitored using a comprehensive and continuous quality assurance process that at a minimum tracks the following:
  + Percentage of time patient is within therapeutic INR range
  + Evaluation and management of critical INRs
  + Bleeding events
  + Thromboembolic events

**Newer Oral Anticoagulants:**

* The clinical pharmacist will not routinely monitor anticoagulation specific laboratory values as no regular clinical monitoring is recommended. The pharmacist will monitor for safety and efficacy at each monthly review.
* If the pharmacist identifies physical findings whether objective or subjective from the patient, the pharmacist will review relevant laboratory values, order appropriate laboratory values, and notify the PCP of the health status change (monitoring for sxs bleeding, renal changes, hepatic changes, interacting medications). Clinically warranted laboratory tests the pharmacist may order through Memorial Hospital include:
  + Basic Metabolic Panel (BMP) or Serum Creatinine (SCr)
  + Complete Blood Count (CBC) or Hemoglobin and Hematocrit (H&H)
  + Weight
  + Hepatic Function (INR/PT, total protein, albumin, bilirubin, ALP, AST, ALT)
* If deemed applicable, the pharmacist will recommend the most appropriate therapeutic interchange from warfarin to the newer oral anticoagulants and transition schedule to ensure safety and efficacy of therapy

**References:**

1. Ageno W, Gallus AS, Wittkowsky A, et al. Oral Anticoagulant Therapy.

CHEST. 2012; 141(2)(Suppl): e44S-e88S.

1. Guyatt GH, Akl EA, Crowther M, et al. Executive Summary: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines (9th edition). CHEST 2012; 141:7S-47S.
2. Crowther MA, Ginsberg JB, Kearon C, Harrison L, Johnson J, Massicotte P, et al. A Randomized Trial Comparing 5-mg and 10-mg Warfarin Loading Doses. Arch Inern Med. 1999; 159:46-8.
3. Douketis JD, Spyropoulos AC, Spencer FA, et al. Perioperative Management of Antithrombotic Therapy. CHEST 2012; 141:e326S-e350S.
4. Adapted and used with permission from Community Health Association of Spokane (CHAS) and American College of Clinical Pharmacy (ACCP) Ambulatory Care Manual

**Appendix A**

**Indication for Anticoagulation and INR Goal Range**

|  |  |  |
| --- | --- | --- |
| **INR Goal Range** | **Indications** | **Duration of Therapy** |
| 2.0-3.0 | Antiphospholipid Syndrome  (recurrent thromboembolism 2.5-3.5 range) | Lifetime |
| 2.0-3.0 | Atrial Fibrillation | Lifetime |
| 2.0-3.0 | Venous thromboembolism (PE, DVT)  treatment and prophylaxis | Usually 6-12 months, if recurrent consider lifetime |
| 2.5-3.5 | Aortic and Mitral Prosthetic Valve (goal range may vary depending on type of valve) | Lifetime |

**Appendix B**

**Initiation of Warfarin when daily INRs are not possible**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| INR | Day 1 | Day 3 or 4 | Day 5-7 | Day 8-10 | INR | Day 11-14 |
| < 1.5 | Initiate warfarin at 2.5-5mg daily  (Consider lower dose as patient age increases and body habitus decreases, high bleed risk, interacting medications, hepatic dysfunction | Increase weekly dose 10-25% | Increase weekly dose 10-25% | Increase weekly dose 25% | < 1.6 | Increase weekly dose 15-35% |
| 1.5-1.9 | Continue dose unchanged | Increase weekly dose by 0-20% | Increase weekly dose 5-20% | 1.6-1.9 | Increase weekly dose 5-20% |
| 2.0-2.5 | Decrease weekly dose 25-50% | Continue dose unchanged | Continue dose unchanged | 2.0-2.5 | Continue dose unchanged |
| 2.6-3.0 | Decrease weekly dose 50% or hold next dose | Continue dose unchanged | Continued dose unchanged | 2.6-3.0 | Continue dose unchanged |
| > 3.0 | Decrease weekly dose 50% or hold next dose | Decrease weekly dose 10-25%, hold next dose, continue dose unchanged (if goal INR 2.5-3.5) | Decrease weekly dose 10-25%, hold next dose, continue dose unchanged (if goal INR 2.5-3.5) | > 3.0 | Decrease weekly dose 10-25%, hold next dose, continue dose unchanged (if goal INR 2.5-3.5) |

**Appendix C**

**INR Goal of 2.0-3.0**

|  |  |  |
| --- | --- | --- |
| **INR** | Adjustment | Comments |
| **> 1.5** | Day 1: Boost dose by 10-20% of TWD;  Weekly: Increase TWD by 10-20%;  Repeat INR: 1-2 weeks | Generally, dose adjustments are made in increments of 2.5-5mg/week |
| **1.5-1.9** | Day 1: Boost dose by 5-10% of TWD;  Weekly: Increase TWD by 5-10%;  Repeat INR: 2-3 weeks | 10-14 days are required for INR to become stable on a given dose of warfarin. Dose changes should not be made more frequently unless warfarin is being initiated |
| **2.0-3.3** | No dose change; Repeat INR in 4-6 weeks |  |
| **3.3-4.0** | Day 1: Hold dose or reduce dose by 5-10% of TWD;  Weekly: Reduce TWD by 5-10%;  Repeat INR: 2 weeks |  |
| **> 4.0** | Day 1: Hold warfarin 1-2 days;  Weekly: Reduce TWD by 10-20%;  Repeat INR: 1-2 weeks |  |
| TWD = Total Weekly Dose | | |

**INR Goal of 2.5-3.5**

|  |  |  |  |
| --- | --- | --- | --- |
| **INR** | **Adjustments** | **Comments** | |
| **< 1.5** | Day 1: Boost dose of 10-20% of TWD;  Weekly: Increase TWD by 10-20%;  Repeat INR: 1-2 weeks |  | |
| **1.5-2.4** | Day 1: Boost dose by 5-10% of TWD;  Weekly: Increase TWD by 5-10%;  Repeat INR: 2-3 weeks |  | |
| **2.5-3.7** | No dose change; Repeat INR 4-6 weeks |  | |
| **3.8-4.5** | Day 1: Hold dose or reduce dose by 5-10% of TWD;  Weekly: Reduce TWD by 5-10%;  Repeat INR: 2-3 weeks |  | |
| **> 4.5** | Day 1: Hold warfarin 1-2 days;  Weekly: Reduce TWD by 10-20%;  Repeat INR: 1-2 weeks |  | |
| TWD = Total Weekly Dose | | |

By singing this document, the named physicians agree that the named pharmacist may enter into Collaborative Practice with them for the management of anticoagulation in residents at Hickory Grove and Maple Grove receiving warfarin therapy in accordance with policies and procedures outlined in the above document and mutually agreed upon, as well as the Illinois Pharmacy Practice Act 225 ILCS 85/3 (aa).

Clinical Pharmacists:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

LuAnn Haas, RPh Mattie Haas, PharmD, CGP

Physicians:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Dr. Edward McKenney

The prescriptive authority is granted for a period of one year from the date of approval unless rescinded earlier in writing to Nauvoo Pharmacy. A review of the protocol and the prescribing decisions will be conducted yearly.

Approval date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Anticoagulation Management Patient Demographic Form

Patient’s Name:

Patient’s Address:

Date of Birth:

Indication for anticoagulation therapy

|  |  |  |
| --- | --- | --- |
| Atrial Fibrillation: <Chronic <New Onset | DVT: <1st time <Recurrent | PE: <1st time <Recurrent |
| Prosthetic Valve: <Mitral <Aortic  Type: | <DVT Prophylaxis | Cerebrovascular Disease: <TIA <Stroke |
| Other: | | |

Past Medical History

* Heart Failure
* Peptic Ulcer Disease
* Gastrointestinal Bleeds
* History/active bleeding/hemorrhage events
* Liver Dysfunction
* IVDA/Alcohol Abuse
* History of Falls
* Cancer
* MI
* TIA/Stroke

INR (baseline or most recent): \_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Anticipated Duration: <Indefinite <3 months <6 months <Other (specify):\_\_\_\_\_\_\_\_

INR Goal: <2.0-3.0 <2.5-3.5 <Other (specify):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

I, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (print physician name), am referring \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(patient name) to the clinical pharmacist caring for Hickory Grove and Maple Grove residents for anticoagulation monitoring per protocol.

Physician Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Please fax to 217-453-6543 when complete. Thank you.