XXXXXXX XXXXXX

Pharmacy Department

Outpatient Anticoagulation Service

Collaborative Practice Agreement

Under NYS law, the Pharmacy Practice Act allows pharmacists to practice under a Collaborative Practice Agreement with individual physicians. Pharmacists may participate in the practice of managing and modifying drug therapy on a case-by-case basis, according to written protocol between the specific pharmacist and the individual physician(s) who is/are responsible for the patient's care.

I. SCOPE:

1. This protocol for drug therapy management is limited to patients of individual providers seen at the XXXXXXXXXX XXXXX.
2. Physicians with patients requiring anticoagulation must agree that their patients can be managed by a qualified pharmacist.
3. Patients must agree to have their anticoagulation managed by a pharmacist.
4. Pharmacists must meet approved qualification requirements to provide anticoagulation management services.

II. PURPOSE:

To document the written protocol for outpatient anticoagulation drug therapy management authorized by the physicians at the XXXX and delegated to the Clinical Pharmacist. Pharmacist participation in this agreement is expected to providecontinuity of care to patients who require anticoagulation and enhancement of patient care through education, monitoring and follow-up.

III. OBJECTIVES:

Via this agreement, the pharmacist will be able to:

1. Manage outpatient anticoagulation therapy by evaluating and adjusting medication levels to achieve the desired level of anticoagulation in relation to confounding factors, including but not limited to diet, lifestyle, medications, and general health status.
2. Provide education for medical, nursing, and pharmacy staff regarding basic principles and new developments in the field of anticoagulation.
3. Provide education to patients/family members about the proper use of anticoagulants in order to maximize therapy and minimize complications.
4. Serve as an educational site preceptor for post-doctorate pharmacy residents and doctor of pharmacy students.
5. Assist in research programs relating to anticoagulation.

IV. DESIGN:

1. Any patient on chronic anticoagulation therapy can be referred for outpatient anticoagulation management by their individual PCPs.
2. The XXXX Coumadin Clinic is staffed by three Nurse Practitionersfrom the TP2 program and a Clinical Pharmacist. All patients referred to the clinic are ultimately under the care of Dr. XXXXX, Hematologist and Director of the TP2 program for management of their anticoagulation.
3. Once the patient presents for their Coumadin Clinic appointment, a point-of-care INR is done in the lab prior to conducting the patient interview. All findings are documented on the Coumadin Worksheet in the CEMR which is always available to the PCP responsible for the patient. Anticoagulant dosage regimens will be maintained or adjusted as appropriate per lab values.

4. Patients will be assessed for thrombotic or hemorrhagic complications at each visit. A complete blood count will be performed at an interval of no less than three months. In addition, any new medical issues or new therapies since the last visit will be documented and assessed for interactions.
5. The pharmacist will be authorized to renew and/or adjusta patient's warfarin prescription.
6. The pharmacist will be aware of anticoagulation therapy guidelines regarding duration of anticoagulation and will refer patients at appropriate times for possible discontinuation or change in therapy.

V. PROCEDURES:

1. Protocol initiation
   The scheduling of the initial clinic visit,laboratory testing and initial patient assessment are performed by the Nurse Practitioners of the TP2 Program. This protocol will be initiated for all patients who are seen at subsequent clinic visits provided that the patient agrees to the management of their anticoagulation by the Clinical Pharmacist as documented on the Patient-Pharmacist Contract.

2. Scheduled Clinic Days
   The Clinical Pharmacist participates in the TP2/ Hematology anticoagulation management service on Thursdays @ 8:30am – 1 pm except on holidays. Patients are instructed to contact the medical provider, TP2 on-call personnel and/or go to the emergency department if a relevant emergency arises after hours.

3. Therapeutic initiation and adjustments
   a. The therapeutic goal of anticoagulant therapy is to prevent disease state exacerbation while minimizing adverse effects. The patient's individual INR goal will be taken into consideration as the goal for all adjustments.
   b. Patients will be seen on an as-needed basis but no less than q4week intervals.
   c. If the INR is sub-therapeutic and the patient has been stable in the past, the patient will be evaluated for new drug interactions, dietary alterations, alcohol or tobacco consumption or non-adherence. If no responsible factor can be identified, the patient will be counseled on factors that affect warfarin therapy and rescheduled for a follow-up visit in 1-2 weeks.
   d. If the INR is supra-therapeutic, dosage adjustments will be determined based upon patient's bleeding status. Patients without clinically significant bleeding may only require a decrease in dose; others may require a decrease in dose and one or more doses held. Patients with clinical bleeding or at increased risk of bleeding might need a more rapid reversal of anticoagulation usingoral phytonadione and more frequent INR monitoring (Appendix B). If significant bleeding occurs, the patient will be sent to the Emergency Department for parenteral therapy.

e. The responsible physician will be contacted as a courtesy for all INR values > 6 with reports of clinically significant bleeding.
f. The pharmacist will document observations, lab data, and the therapeutic plan in the patient's Coumadin Clinic Worksheet following evaluation.
g. If temporary medications are initiated that present potential drug interaction problems (i.e. antibiotics), the pharmacist will adjust the dose of warfarin to accommodate the interaction and schedule more frequent lab monitoring to assess the INR during and after discontinuation of the interacting medication.
h. For additions of chronic medications prescribed but not yet not yet initiated that present a potential for significant interaction, the pharmacist may attempt to contact the prescribing physician and recommend a suitable substitute if available, based on clinical significance of the problem. Otherwise, the dose of Coumadin will be readjusted to accommodate the new medication and attain the goal INR.

4. Laboratory tests
   Under this agreement, the Clinical Pharmacist will be able to order tests under the Hematology list of tests and imaging and ultrasound as appropriate.

5. Prescription Refills / Orders
   Under this agreement, the clinical pharmacist may order or refill prescriptions for warfarin and/or phytonadione if indicated.

6. Missed appointments
   The clinical pharmacist will counsel the patient when appointments are missed repeatedly without good reason or prior notification. Excessive non-adherence with clinic visits will be reported to the TP2 team for follow up.

7. Documentation
   a. An electronic cEMR worksheet will be documented with each visit. A pharmacist will review the patient's medical chart for recent health and medication changes based on conversation with the patient.
   b. Patients will be evaluated based on verbal conversations and the INR value done at or prior to each visit. Patients will be questioned using the same basic criteria, with emphasis on current or potential problems. These criteria include:

      i. Recent alterations in diet, medication, or alcohol intake.
      ii. Changes in lifestyle or health status.
      iii. Adherence to medication regimen.
      iv. Status of other patient problems which could potentially alter INR.

8. Patient Education

a. Education is one of the key aspects of successful anticoagulation management in the ambulatory population. Each educational session will be individualized depending on the patient's ability to comprehend the subject. The patient should be knowledgeable of the following during the course of therapy:
    i. The name, strength, description and purpose of the anticoagulant therapy
    ii. The desired INR goal range
    iii. The importance of warfarin INR monitoring
    iv. How to administer anticoagulant(s) timely, safely and appropriately
    v. How agents work together to attain adequate anticoagulation
    vi. Interacting foods, disease states, and drugs including herbals and supplements
    vii. Recognition of excessive anticoagulation or disease state exacerbation and procedure to follow in these instances
    viii. Recognition of side effects of therapy and the importance of notifying his/her physician/ TP2 team if any should occur
    ix. Procedure to follow if surgery/dental work is anticipated
    x. Importance of adherence to the regimen and Coumadin Clinic procedures
    xi. How to use aids to aid adherence
    xii. What to do if a dose is missed

9. Communicating with CollaboratingPhysicianor designee
   Verbal communication with the responsible physician or designee will occur during the patient visit if any patient reports any side effects/concerns that may require further medical or diagnostic follow-up that is beyond the scope of practice of the pharmacist.

10. Clinical Pharmacist Educational Requirements
    Each pharmacist who will be working in the XXXX clinic must complete the minimum educational requirements as outlined in CDTM bill S.3292/A6448 prior to working independently in the Clinic.
    a. A minimum of a BS degree in Pharmacy with experience, as outlined in the CDTM bill
    b. Successfully completion of a PGY-1 pharmacy residency or an instructional module on anticoagulation (e.g., certificate program)
    c. A two-week rotation in the clinic under the guidance of an experienced clinical specialist.
    d. Continuing education in anticoagulation management on a yearly basis, as per the CDTM bill

11. Quality Assurance
    a. The Collaborating Physician reviews all dose modifications on a routine basis with the TP2 team members.
    b. The Time-in-therapeutic Range (TTR) for clinic patients is assessed monthly as a measure of the quality of care provided.

VI. APPENDICES:

Appendix A - Dosing and Monitoring Warfarin

Appendix B - Management of Supra-therapeutic INR

Appendix C - References

Appendix A (Dosing and Monitoring Warfarin)

Dosing and Monitoring: Warfarin

- For patients started on warfarin, a baseline International Normalized Ratio (INR) must be available. For all patients receiving warfarin therapy, a current INR must be available and used to monitor and adjust this therapy.
- Initial dose 5–10 mg or ≤ 5mg in elderly, or debilitated or those with CHF, liver disease, recent surgery, or with an expected drug interaction
- Adherence may improve with a constant daily dosage
- Lower dosages required as age increases[5]:
    - age <75: 4.9 mg/day
    - age 75–84: 4.0 mg/day
    - age 85+: 3.5 mg/day.
- Initial dose 1–2 days, INR day 2–3, then daily - q3 days until 2 INRs therapeutic, then weekly, then every 3-4 weeks, but not less than q 4 weeks, if INR stable
- Monitor hemoglobin periodically
- Monitor INR often with drug &, diet change, and illness.
- Alter dose if 2 consecutive INR results are more than 0.3 above/below the target, or if the INR >0.4 out-of-range
- Adjust the dose by 5-20% of the weekly total dose
- For those on long-term warfarin with unstable INRs due to diet, can add daily low dose oral Vitamin K (100 - 200µgm) and adjust warfarin dose.
- Regularly reassess need for therapy and duration

Appendix B (Management of Supra-therapeutic INR)

Management of Supratherapeutic INRs

INR 3 to ≤5; No bleeding	↓ or hold dose; monitor more, resume at same or lower dose when in range
INR 5 to <9; No bleeding	Omit 1 – 2 doses, monitor more, resume at adjusted dose when INR therapeutic; OR Omit 1 dose and administer Vitamin K* 1 - 2.5 mg po if at increased bleeding risk.
INR > 9 no bleeding	Stop warfarin, Vitamin K* 5-10 mg, monitor INR, INR will fall in 24 – 48 hrs. Increase monitoring, additional Vitamin K as needed. Resume at an adjusted dose when the INR therapeutic.
Bleeding, elevated INR	Evaluate INR, extent of bleeding, initiate Rx accordingly – slow IV Vitamin K 10 mg, with FFP, other Rx as per hematology (prothrombin complex concentrate, recombinant factor VIIa).

*Vitamin K 5 mg scored tablets. Oral dosing preferred over subcutaneous.

Appendix C

References

1. XXXXX. et al. XXXXXXXXX Medical Center. Anticoagulation Management Protocol.
2. Hirsh et al. Executive Summary ACCP Evidence-based Clinical Practice Guidelines 8th Ed.