GALLUP INDIAN MEDICAL CENTER
PHARMACY RESPIRATORY CLINIC
COLLABORATIVE PRACTICE AGREEMENT

Statement of Need

Asthma affects more than 300 million people worldwide, and in the United States, it affects 22 million Americans. Gallup Indian Medical Center (GIMC) alone has had 1,142 patients diagnosed with an asthma exacerbation in the past year. The burden not only affects the patient and their families, but also society as a whole due to lost work and/or school, decreased quality of life, and avoidable emergency room (ER) visits, hospitalizations, and deaths. Science has improved our understanding of asthma and has also led to many significant improvements in asthma care. The goal of asthma care and treatment is, simply, to help patients control their asthma so that they may be active all day and sleep well at night all while leading productive, physically active lives with near-normal lung function.

Despite many advances in asthma care, nationally the treatment of asthma remains suboptimal with more than 10 million outpatient visits, over 440,000 hospitalizations, and greater than 3000 deaths occur annually. Utilization of a pharmacist-managed, protocol-driven asthma clinic will accomplish both improved patient outcomes and reduced provider workload while expanding pharmacy clinical services in a financially responsible manner.

To provide more comprehensive services, our clinic will manage disease states associated respiratory diseases, including allergic rhinitis, and gastroesophageal reflux disease (GERD). In addition, preventative services will be offered include assessing patients for any needed immunizations, tobacco cessation, dietary recommendations and exercise counseling.

Goals

1. To manage asthma, COPD, allergic rhinitis and/or GERD in a structured, organized manner and to maintain accurate documentation of the patient visit(s).

2. To provide education and encourage self-management wherever possible.

3. To eliminate or reduce to a minimum respiratory symptoms, maximize lung function, prevent exacerbations, minimize adverse effects of treatment, and provide enough information and support to facilitate patient self-management of their respiratory disease.

4. Achieving and maintaining effective drug therapy in accordance with expert guidelines set forth from the National Heart Lung and Blood Institute (NHLBI), World Health

Organization (WHO), Global Initiative for Chronic Lung Disease (GOLD) and/or Global Initiative for Asthma (GINA).

5. Reduce the risk of undesirable disease-related and therapy-related effects of asthma, COPD, allergic rhinitis or GERD therapy.

6. Promote cost-savings by reducing the incidence of major adverse effects due to drug interactions with foods, disease states, and/or other drugs.
7. Promote cost-savings by reducing the number of school/work sick days and unscheduled respiratory-related visits/hospitalization by this patient population.

8. Improve patient compliance, disease state management, and understanding of respiratory disease through individual and/or family education where appropriate.

Clinic Information

Patient Evaluation and Management

- At the initial and at subsequent visits, the patient's medical history, problem list, and medication profile will be reviewed for interactions and/or conditions, which may affect the choice of therapy.

- The patient will be questioned about the following items at each visit:
    - Medication history including drug allergies, concurrent medications (both prescription and non-prescription, including alternative medications), alcohol, tobacco, and recreational drug use
    - Dietary habits
    - Adverse events
    - Compliance
    - Exercise, physical activity, and/or activities of daily living
    - Trigger factors such as infections, colds, smoke, tobacco, dust mites, pet dander, drugs, foods, pollen/grass, exercise, cold air, etc.
    - Seasonal and/or diurnal variations in symptoms
    - Signs/symptoms of asthma/COPD (cough, wheeze, breathlessness, or tight chest)
    - Allergic Rhinitis signs/ symptoms (sneezing, runny nose, nasal obstruction, and nasal itching, postnasal drip, and cough)
    - GERD symptoms (dysphagia, heart burn, regurgitation, nausea or vomiting)
    - Immunization assessment to include (Pneumonia and Influenza for eligible patients)

- Peak flow readings (best of 3 measurements) will be evaluated and documented at each visit or at the discretion of the Respiratory Clinic pharmacist.
- Asthma Control Test (ACT)/ COPD Assessment Test (CAT) will be given to each patient to assess current asthma or COPD control when applicable.

- Inhaler technique will be assessed at each visit, or at the discretion of the Respiratory Clinic pharmacist.
- Perform limited physical assessments as deemed appropriate.
- Dosage adjustment or changes in asthma medications will be based on frequency, severity of asthma exacerbation(s) and/or adverse events. Step up or down in therapy will follow national guidelines
    - It is important to first review the patient's medication technique, compliance, and avoidance risk factors before stepping-up treatment
    - Decrease treatment to the least medication necessary to maintain control.

- Instances of asthma exacerbations will be evaluated for both frequency and severity.
- Ordering and interpreting laboratory tests to assess the patient's response to medication as needed. Abnormal lab values beyond scope of protocol will be reported to the patient's primary care provider for evaluation and treatment if necessary.

- Initiation and changes of COPD medication will follow national published guidelines.
    - All COPD patients will be encouraged to stop smoking if appropriate
        - Patients who smoke will be ask about quitting
        - Advised how to quit
        - Assessed at each visit to see if they are ready to quit
        - Assisted with information on how to quit which may include counseling and how to obtain pharmacotherapy
        - Arranged for follow up

    - COPD patients will be encouraged to start or maintain an exercise program as appropriate to their disease status
    - Immunization assessment will be completed at initial visit and at minimum annually thereafter.

- Initiation and changes to Allergic Rhinitis therapy will follow the Clinical Practice Guidelines for Allergic Rhinitis from the American Academy of Otolaryngology- Head and Neck Surgery.
    - Therapy will include counseling on avoiding or trying to control environmental causes (e.g., removal of pets, the use of air filtration systems, bed covers, and eradication of dust mites).
    - Intranasal steroids will be recommended for patients with symptoms affecting their quality of life.
    - Second generation antihistamines will be recommended to patients who primarily complain of sneezing and itching.
    - Intranasal antihistamines will be recommended to patients with seasonal, perineal, or episodic symptoms.
    - Montelukast will not be offered as monotherapy for allergic rhinitis.
    - Combination therapy will be recommended patients who have uncontrolled symptoms with monotherapy.
    - Patient uncontrolled on combination therapy will be referred to their PCP for possible referral to an Immunologist for immune therapy.

- Initiation and changes to GERD therapy will follow the Clinical Practice Guidelines for the Diagnosis and Management of Gastroesophageal Reflux Disease from The American Journal of Gastroenterology and GIMC policy.
    - Patients will be counseled on non-pharmacological interventions, including weight loss if applicable.
    - Omeprazole will be ordered for patients with GERD symptoms who fail a trial of non-pharmacological therapy.
    - Omeprazole will be prescribed per GIMC omeprazole use policy/restrictions.
    - Patients with initial response to therapy will be referred to their PCP for further refills due to GIMC Omeprazole use policy.
    - Patient who fail therapy will be recommended to their PCP for further evaluation.

Patient Education

Education will take up the majority of the patient's visit, and it will be added to and reviewed at each subsequent appointment, at the discretion of the Respiratory Clinic pharmacist. The education that will be provided may include, but is not limited to:

- Determination of the level of knowledge the patient has about asthma, COPD allergic rhinitis or GERD as appropriate and an explanation, where appropriate, its nature, course, therapy, and management.
- Explanation of the difference between preventative and relief medication(s) and the appropriate use of each.
- Importance of medication compliance and identify any barriers that may exist to compliance to the treatment plan.
- Inhaler technique.
- Peak flow technique and purpose of the peak flow test.
- Recognition and treatment of acute exacerbations.
- Self-management plans, will be given according to each patient's individual needs, at the discretion of the Respiratory Clinic pharmacist.
- Advice on avoidance of allergens/triggers.
- Smoking cessation/avoidance.
- Lifestyle advice where appropriate, such as weight loss, healthy eating, exercise, etc. and to encourage the patient to lead a normal life and not be too over-protective.
- Importance of annual influenza vaccination and pneumonia vaccination if indicated.

The goals of patient education at the initial and at subsequent visit(s) are to ensure that the patient:

- Accepts that asthma is a long-term treatable disease.
- Be able to accurately describe asthma, COPD, allergic rhinitis and/or GERD and its treatment.
- Actively participate in the control and management of their respiratory related disease.
- Identify factors that make their respiratory disease worse.
- Be able to describe strategies for avoidance or reduction of exacerbating factors.
- Recognize the signs and symptoms of worsening respiratory disease.

- Follow a prescribed, written treatment plan, where appropriate.
- Use correct technique when using metered dose inhalers (MDI), dry powder inhalers (DPI), spacer devices, peak flow meters, etc.
- Use medical resources appropriately for routine and acute care.
- Identify barriers to compliance to the treatment plan.
- Identifies needed vaccination and their importance to therapy

Appointments/Referrals

- Referral Process
  - A patient's primary care provider (PCP) at GIMC or a Respiratory Clinic pharmacist may refer patients to the Respiratory Clinic.
  - Emergency Department (ED) or Walk-in Primary Care Clinic (WIPCC) providers may refer patients to the Respiratory Disease Clinic for a limited referral, usually 1-2 visits. After that patient's PCP can place a referral for continued care in clinic.
  - Referrals will be made using the GIMC Referral/Consult in the Electronic Health Record (EHR).
  - Patients who miss three (3) consecutive appointments (DNKAs), or at the discretion of the Respiratory Clinic Pharmacist, will be released from the Respiratory Clinic and referred back to their PCP.
  - Stable patients may be released from clinic back to their primary care provider.

- Time allocated:
  - 20 minutes for follow-up patients.
  - New patients will generally be allocated 40 – 60 minutes.

- Follow-up visits will be scheduled as determined by clinical judgment and availability.
- Higher Level Referral
  - Patients presenting to clinic with symptoms or medical situations where higher level medical care is needed will be referred to ED, WIPCC or PCP.

Documentation

Progress notes will be documented in the facility's Electronic Health Record (EHR) for each patient seen by the Respiratory Clinic pharmacist. The PCP for each patient will be identified as an additional signer for the progress note, which will allow the provider to see the actions of the pharmacist and note any changes to therapy.

The progress note may include, but is not limited to:

- Patient name
- Date
- Brief history of present complaints
- Medication profile

- Problem list
- Frequency and/or severity of any respiratory or respiratory disease associated exacerbations
- Peak flow readings
- Patient Education on asthma, COPD, allergic rhinitis and GERD
- Compliance
- Adverse events
- Triggers
- Inhaler technique
- Evaluation of current therapy and any adjustments of therapy
- Dietary counseling
- Immunizations given
- Follow-up appointment

CONTINUOUS QUALITY IMPROVEMENT

The goal of the Respiratory Disease Clinic will be to report outcomes and quality improvement to the P&T Committee annually. Possible areas included in this review are appropriate follow-up care, appropriate therapy, emergent care visits and hospitalizations related to respiratory disease and patient/provider satisfaction. The pharmacist will follow-up on implemented improvement measures to assure outcomes continue to improve and desired outcomes are maintained. A minimum a 5 peer reviews will be done annually and reviewed with the pharmacists to identify any areas for improvement.

Respiratory Management Outcomes Measures

Outcomes data will be recorded and reported at minimum annually to National Clinical Pharmacy Specialist (NCPS) Committee, Gallup Indian Medical Center Pharmacy P&T Committee and Chief of Pharmacy.

1. Decrease in:
    a. Emergency Room or Urgent Care Clinic visits related to asthma, COPD, allergic rhinitis or GERD
    b. Hospital admissions related to asthma, COPD, allergic rhinitis, or GERD

2. Amount of short-acting $beta_2$ agonists (i.e. albuterol) use per month
3. Asthma Control Test (ACT Score)/COPD Assessment Test (CAT)
4. Other quality improvement measures as deemed necessary

Peer Review

- Each privileged pharmacist will be required to participate in peer reviews to assess individual pharmacist performance and competency and ensure patient safety.
    - Minimum of 5 peer reviews annually
    - Minimum of 5 chart reviews via EHR by clinic medical director.

Training/Education

Each Respiratory Clinic Pharmacist must receive hands-on training within the clinic while by being supervised by an existing Respiratory Clinic Pharmacist Provider, and must maintain, at a minimum, two (2) respiratory-related continue education credits per year in order to maintain their status as an Respiratory Clinic Pharmacist Provider.

- Each pharmacist will maintain a file on site with documentation of completed supervised training and 2 hours of CE annually. The files will be reviewed at the end of each calendar year for completeness.
- Each pharmacist will have 5 chart reviews through EHR by the clinic's medical director to determine competency to continue to be able to work in the clinic.
- Formal respiratory disease state management training is preferred but not required.
- NCPS certification will be encouraged.
- Respiratory Clinic Protocol Agreement wherein the PCP, or designated authority, authorizes and delegates to the pharmacist the authority to conduct specific initiation, modification, or discontinuation of drug therapy for individual patients within the Pharmacy Respiratory Clinic.

REFERENCES

Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2020. Available from www.ginasthma.org.

Global Strategy for the Diagnosis, Management and Prevention of COPD 2020 Update. Available from www.goldcopd.org.

COPD Assessment Test (CAT). http://www.catestonline.org/images/pdfs/CATest.pdf. Accessed August 9, 2018.

From the Global Strategy for the Diagnosis, Management and Prevention of COPD, Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2017. Available from: https://goldcopd.org.

Global Strategy for Asthma Management and Prevention. Global Initiative for Asthma (GINA). 2018.

Katz et al. *Guidelines for the Diagnosis and Management of Gastroesophageal Reflux Disease*. Am J Gastroenterol; 108:308 – 328. 2013. DOI: 10.1038/ajg.2012.444

National Asthma Education and Prevention Program Expert Panel Report 3 - Guidelines for the Diagnosis and Management of Asthma. National Heart Lung and Blood Institute (NHLBI). 2007.

Pharmacy-Based Asthma Services. World Health Organization (WHO). 1998.

Seidman et al. *Clinical Practice Guideline: Allergic Rhinitis*. Otolaryngology–Head and Neck Surgery, Vol. 152(1S) S1–S43. 2015. DOI: 10.1177/0194599814561600 http://otojournal.org