

# SPRING 2022

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The Drug Utilization Review (DUR) Program, administered by **Mountain-Pacific** through a contract with the Allied Health Services Bureau of the Montana **Department of Public Health** and Human Services, is the quality assurance body seeking to assure the quality of pharmaceutical care and to help provide rational, cost-effective medication therapy for Montana Healthcare Programs members.

Montana Healthcare Programs Drug Prior Authorization Unit 1-800-395-7961

# Mountain-Pacific Quality Health

# Montana Healthcare Programs Chronic Obstructive Pulmonary Disease (COPD)

Case management at Mountain-Pacific Quality Health is currently reviewing Montana Healthcare Program members who have a diagnosis of a COPD exacerbation and required a prednisone burst within the past six months. This data is being used to determine if the member is currently using a longacting muscarinic antagonist (LAMA). If it is determined the member is not prescribed a LAMA, is not compliant with their prescribed LAMA or has noted nicotine abuse, then a letter will be sent to the provider reminding him/her of the benefits of a LAMA in the setting of COPD in groups risk stratified into B, C or D, per the Global Initiative for Chronic Lung Disease (GOLD) guidelines.

The following is an outline of the project and the clinical evidence/rationale for the processes involved in the project. If there are any additional questions, please contact Jennifer Miranda, clincial pharmacist with Mountain-Pacific, at <u>jmiranda@mpqhf.org</u>.

#### What is the GOLD report?

The GOLD report is a global, evidence-based document used by professionals to diagnose, manage and prevent COPD.<sup>1</sup> This report is updated yearly, with the most recent update in November 2021.

#### How is COPD diagnosed?

Spirometry measures airflow limitation and is used to diagnose COPD. The volume of air exhaled in one second is measured, after using a bronchodilator, and if <70% of predicted volume of air is exhaled in one second, a member can be diagnosed with COPD. This is referred to as forced expiratory volume in one second (FEV1).<sup>1</sup> In an asthmatic member, spirometry may also show a decreased FEV1 result, although this should improve post bronchodilator. In comparison, patients with COPD will experience zero to minimal improvement in FEV1 post receiving a bronchodilator.

An algorithm for the treatment of COPD has been published within the GOLD report and is based on a patient's risk stratification and is determined by spirometry. The three criteria needed to classify a patient into an appropriate COPD group classification (A, B, C or D) include: spirometry, when possible, to assess the severity of airflow limitation; the mMRC dyspnea scale or CAT score to assess dyspnea; and history of moderate to severe exacerbations, including hospitalizations within the past 12 months. ABCD groups are based on patient symptoms (via Modified Medical Research Council [mMRC]/COPD assessment test [CAT]) and exacerbation history (<2 or  $\geq$ 2).<sup>1</sup>

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Montana Healthcare Pharmacy Programs Link (Current Montana Healthcare Programs Preferred Drug List, Provider Notices, DUR Board/Meeting Information, Resources) <u>http://medicaidprovider.mt.gov/19</u>

## Montana Healthcare Programs COPD (cont.)

#### **Treatment of COPD:**

At this time, there are no medications to reverse COPD, although there are numerous medications which can be used to help symptoms of breathlessness, decrease exacerbations and decrease mortality.<sup>1</sup>

Short-acting beta agonists (SABAs) bind to Beta-2 receptors in the lung to relax bronchial smooth muscle with duration lasting an average of three to six hours.<sup>2</sup> Due to the short acting nature of this medication, it is for acute, as needed use.

Short-acting muscarinic antagonists (SAMAs) work to improve COPD symptoms by unselectively binding to pulmonary muscarinic receptors 1, 2, 3 in the lungs, which decreases smooth muscle contraction. Time for effect is four to six hours.<sup>2</sup> Due to the short acting nature of this medication, it is for acute, as needed use.



Long-acting muscarinic antagonists (LAMAs) provide a longer lasting decrease in smooth muscle contraction by blocking the action of acetylcholine at pulmonary muscarinic 1, 2, 3 receptors.<sup>2</sup> Duration varies depending on the formulation of the LAMA. However, effects are much longer as compared to a SAMA or SABA. (For example, the half-life for tiotropium is 25 hours.) Tiotropium, for example, dissociates rapidly from the M2 receptor and has slower dissociation from M1 and M3 receptors than occurs with a SAMA.<sup>3</sup>

Inhaled corticosteroids (ICS) should be reserved for patients in Group D who also have an eosinophil count >300 cells/mcl.<sup>1</sup>

LABA/LAMA combo is recommended to reserve for patients who have a CAT score >20.1

#### What is the importance of a LAMA?

Clinical trials have shown a greater effect on exacerbation rates for LAMA treatment (tiotropium) versus LABA treatment.<sup>1,4,5</sup>

As has been for the past several years, the guidelines continue to recommend a LAMA for patients risk-stratified into Groups B, C and D.<sup>1</sup> Dual agents, including ICS/LABA and LAMA/LABA combinations are reserved for COPD patients who are in Group D.<sup>1</sup>

#### COPD Clinical Pearls:

- Address/ensure compliance.
- Educate patient on inhaler technique and/or provide a spacer for hydrofluoroalkane (HFA) inhalers.
- Remind patient to rinse, gargle and spit after using an ICS-containing steroid to decrease the risk of oral or esophageal thrush.
- A spacer may decrease the risk of vocal cord dysfunction and/or oral thrush associated with ICS inhalers. It can also help to improve appropriate deposition of the medication particles by providing improved inhaler technique with an HFA inhaler.
- · Smoking cessation should be discussed and encouraged at every office visit.
- When choosing which inhaler device to order, it is important to consider a patient's inspiratory capacity, as this may be a barrier to receiving the appropriate amount of medication upon inspiration. In patients, with a poor inspiratory capacity, an HFA with spacer is the preferred inhaler choice.

<sup>1</sup> Global Initiative for Chronic Obstructive Lung Disease (GOLD). Global Strategy For The Diagnosis, Managment, and Prevention of COPD: 2022 Update. <u>www.goldcopd.org</u> (Accessed on March 17, 2022).

<sup>2</sup> King Han, M, Dransfield MT, Martinez FJ, et al. Chronic obstructive pulmonary disease: Definition, clinical manifestations, diagnosis, and staging. In: UpToDae, Post TW (Ed), UpToDate, Waltham, MA. (Accessed on March 17, 2022).

<sup>3</sup> Olin, JL. Tiotropium: An Inhaled Anticholinergic for Chronic Obstructive Pulmonary Disease. Am J Health Syst Pharm. 2005;62(12):1263-1269.

<sup>4</sup> Lipson DA, Barnhart F., Brealey N, et al. Once-Daily Single-Inhaler Triple verus Dual Therapy in Patients with COPD. N Engl J Med 2018; 378(18):1671-80.

<sup>5</sup> Rabe KF, Martinez FJ, Ferguson GT, et al. Triple Inhaled Therapy at Two Glucocorticoid Doses in Moderate-to-Very Sevvere COPD. N Engl J Med 2020; 383(1):35-48.



### **Sleep Disorders**



Sleep disorders present themselves in various ways. Per the Centers for Disease Control and Prevention (CDC), short sleep duration is defined as less than seven hours of sleep per 24-hour period. The prevalence of sleep disorders varies greatly from population to population, and the percentage from state to state. Montana presents as a state with a fairly low incidence of short sleep duration, although the percentage of adults affected by it is still between 28.5 and 31.9%.<sup>1</sup>

Overall, there have been more than 80 different disorders classified by the International Classification of Sleep

Disorders (ICSD). The third edition of the ICSD breaks them into the following seven major categories (further broken down into sub-categories):<sup>2</sup>

- Insomnia short-term, chronic and other insomnia disorders
- Sleep-related breathing disorders sleep apnea, obstructive sleep apnea, sleep-related hypoventilation and sleep-related hypoxemia disorders
- Central disorders of hypersomnolence includes narcolepsy, hypersomnia and insufficient sleep syndrome
- Circadian rhythm sleep-wake disorders generally alteration of the circadian system or issues with the environment affecting a sleep-wake cycle; includes non-24 when a patient is not able to participate in a 24-hour light/dark cycle
- Parasomnias unable to sleep due to undesirable physical events or experiences that generally happen when someone is going into sleep or being awoken from sleep; sleepwalking, sleep terrors and sleep-related eating disorder
- Sleep-related movement disorders restless leg syndrome, sleep-related cramps, teeth grinding, etc.
- Other sleep disorders cannot clearly be defined by any other sleep disorder diagnosis

While treatment for each of these conditions can vary from patient to patient, it is important to try to identify any predisposing factors that may be causing the insomnia. This can include side effects from medications (stimulants, anti-depressants, opioids and steroids) as well as dietary and alcohol consumption. Underlying medical conditions such as pain or shortness of breath could also be causing insomnia as well as any psychiatric disorder and history of trauma. Without identifying and attempting to treat the underlying cause of the insomnia, any attempts to remedy the disorder may not have positive clinical outcomes. Additionally, a patient's sleep hygiene (habits) should be evaluated, and a sleep diary is often helpful in monitoring bedtime activity.

While acute insomnia is often self-limiting, some patients do find short-term use of insomnia medication helpful. For chronic insomnia, cognitive behavioral therapy (CBT) is often the firstline therapy for patients. Use of CBT has proven to be more efficacious than using medication alone<sup>3</sup> and should be discussed with the patient prior to utilizing pharmacologic therapies.

Should a pharmacologic therapy be needed, the following algorithm may be used for selecting an appropriate agent (see page 4).

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# Sleep Disorders (cont.)

#### Algorithm for Selecting Appropriate Agent



When using a pharmacologic agent, it is important to use the lowest effective dose, assess the response of the therapy, monitor for any potential side effects and follow up to ensure positive clinical outcomes. Again, a sleep diary is effective in monitoring effectiveness. It is also important to attempt to taper off the medications as roughly 75% of people with insomnia will experience symptoms for less than one year.<sup>4</sup> Many patients will also need to be treated for a comorbid condition and potentially referred for treatment in that area.

Overall, the prevalence of sleep disorders is thought to be on the rise. Identifying the underlying causes and having the patient practice good sleep hygiene and cognitive behavioral therapy is recommended as first line treatment. If a pharmacologic treatment is needed, a thorough risk-benefit assessment for each medication is needed, as is frequent evaluation of the care plan.

<sup>1</sup><u>https://www.cdc.gov/sleep/data\_statistics.html</u>

<sup>2</sup> <u>https://www.uptodate.com/contents/classification-of-sleep-disorders?search=sleep%20disorders&source=search\_result&selectedTitle=1~150&usa ge\_type=default&display\_rank=1</u>

<sup>3</sup> https://pubmed.ncbi.nlm.nih.gov/28364426/



<sup>&</sup>lt;sup>4</sup> https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1894656/