Mountain Pacific DUR PROGRAM NEWS

WINTER 2023-2024

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

For current drug prior authorization criteria:
https://www.mpqhf.org/corporate/montanans-with-medicaid/pharmacy/

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

Updates to Chronic Obstructive Pulmonary Disease (COPD) Classifications and Treatments

2023 Global Initiative for Chronic Obstructive Lung Disease (GOLD) Report Update

The GOLD report is a global, evidenced-based document used by professionals to diagnose, manage and prevent COPD. This report is updated yearly, with the most recent update in February 2023.[1]

New evidence that emerged from IMPACT[2] and ETHOS[3] trials, two trials specifically mentioned within the GOLD 2023 updates, supports pharmacotherapy recommendations to prefer inhaled fixed-dose triple combinations (long-acting beta2 agonists [LABA] + long-acting muscarinic antagonist [LAMA] + inhaled corticosteroids [ICS]) for symptomatic patients with frequent (≥ 2 moderate exacerbations) or severe exacerbations (≥ 1 requiring hospitalization) to reduce all-cause mortality. Eligible trial participants in both trials had a COPD Assessment Test (CAT) score ≥ 10.

Although these studies support triple therapy for the above-mentioned members, the updated GOLD 2023 algorithm only recommends it for specific subcategories.

For the most up-to-date information and updates to the GOLD report, please visit **www.goldcopd.org**.

Notable Changes to COPD Treatment Algorithm and Classification

The algorithm for COPD treatment has been published within the GOLD report and is based on a patient's risk stratification.

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This information is brought to you by:
Mountain Pacific Quality Health
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www.mpqhf.org

Updates to COPD Classifications and Treatments (cont.)

This algorithm represents significant changes to both COPD group classification and subsequent changes to medication therapy recommendations.

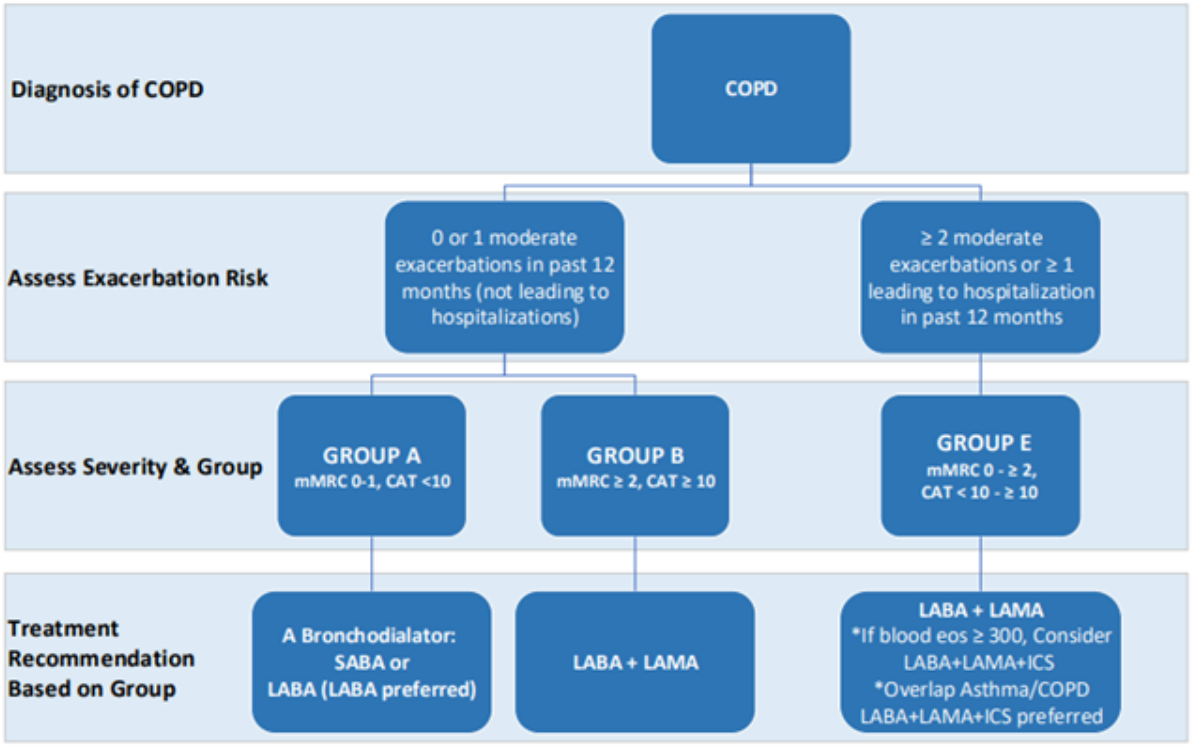
Notable changes include:

- COPD classification groups C and D have been eliminated and combined into a single group E. Severity of symptoms is not part of categorization, only number of exacerbations and emergency department (ED) visits/hospitalizations.
- A LABA is the preferred bronchodilator for group A, although a short-acting beta2-agonist (SABA) is still acceptable.
- A LAMA alone is no longer an optional regimen for any COPD group.
- Dual therapy with a LAMA + LABA is recommended in group E, if non-asthmatic and eosinophils < 300. If asthmatic and/or eosinophils ≥ 300, it is recommended an ICS be added to the regimen. Dual therapy with ICS + LABA is no longer recommended for any COPD group.

The two criteria needed to classify a patient into an appropriate COPD group classification (A, B or E) include: the Modified Medical Research Council (mMRC) dyspnea scale or CAT score to assess dyspnea and history of moderate to severe exacerbations, including hospitalizations within the past 12 months. A, B and E groups are based on patient symptoms (via mMRC/CAT) and exacerbation history (<2 or ≥2).[1]

Pharmacological Treatment Plan

Once the appropriate group for the patient is determined, the best pharmacological treatment plan can be determined, as follows:[1]



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Updates to COPD Classifications and Treatments (cont.)

Group A: All patients should be offered bronchodilator treatment based on effectiveness. This can be either a SABA or LABA, with LABA being preferred if available and affordable.

Group B: LABA in combination with a LAMA (LABA + LAMA) is preferred therapy for this group based on a randomized controlled trial showing superiority to a LAMA alone.[4]

Group E: **LABA + LAMA was ranked highest** in a Cochrane systematic review for decreasing COPD exacerbations and is therefore the preferred treatment of choice for this group.[5]

- If there is an indication for inhaled corticosteroid (ICS), as noted above, then LABA + LAMA + ICS is preferred, and ICS + LABA is not encouraged.[3,6]
- LABA + LAMA + ICS is preferred for patients with concurrent diagnosis of asthma or if eosinophils are ≥ 300 to effectively treat both diagnoses.

References:

[1] Global Initiative for Chronic Obstructive Lung Disease (GOLD). Global Strategy For The Diagnosis, Management, and Prevention of COPD: 2023 Update. www.goldcopd.org (Accessed on August 7, 2023).

[2] Lipson DA, Barnhart F, Brealey N, et al. Once-Daily Single-Inhaler Triple versus Dual Therapy in Patients with COPD. N Engl J Med 2018; 378(18): 1671-80.

[3] Rabe KF, Martinez FJ, Ferguson GT, et al. Triple Inhaled Therapy at Two Glucocorticoid Doses in Moderate-to-Very-Severe COPD. N Engl J Med 2020; 383(1): 35-48

[4] Maltais F, Bjermer L, Kerwin EM, et al. Efficacy of umeclidinium/vilanterol versus umeclidinium and salmeterol monotherapies in symptomatic patients with COPD not receiving inhaled corticosteroids: the EMAX randomized trial. Respir Res 2019; 20(1): 238

[5] Oba Y, Keeney E, Ghatehorde N, Dias S. Dual combination therapy versus long-acting bronchodilators alone for chronic obstructive pulmonary disease (COPD): a systematic review and network meta-analysis. Cochrane Database Syst Rev 2018; 12(12): CD012620

[6] Lipson DA, Barnhart F, Brealey N, et al. Once-Daily Single-Inhaler Triple versus Dual Therapy in Patients with COPD. N Engl J Med 2018; 378(18): 1671-80.

Montana Healthcare Programs Provider Notice

AMP Cap Removal and Medication Access

Effective January 2024, the 2021 American Rescue Plan Act removes the limits from mandatory Medicaid rebates. Manufacturers must pay Medicaid rebates on the medications Medicaid pays for based on, among other things, how much the drug's average manufacturer price (AMP) has increased over the rate of inflation. Currently, this is capped at 100%, meaning manufacturers never pay a rebate greater than their AMP. With that cap removed, manufacturers could owe Medicaid rebates greater than 100% of the purchase price, resulting in a net loss for the company.

Manufacturers may respond to this change in several ways:

- Do nothing
- Reduce the list price to reduce inflationary rebates
- Discontinue the product
- Divest product rights to another manufacturer or terminate its rebate agreement with the federal government so its products will no longer be covered by state Medicaid agencies

Several manufacturers have already discontinued products, divested them or announced their intention to do so or have terminated their rebate agreement with the Centers for Medicare & Medicaid Services (CMS). These changes may result in

- temporary access issues, as seen with Focalin XR was divested to a new manufacturer;
- permanent access issues when a product is discontinued, as will be seen soon with Levemir or
- Montana Healthcare Programs' preferred drug list (PDL) changes as supply and prices change.

Providers will likely see an increase in prescription change requests to alternate products as pharmacists react to drug discontinuations and shortages, sometimes with very little notice. Montana Healthcare Programs maintains communication with participating manufacturers and will make necessary PDL changes when made aware of product discontinuations.

While Montana Healthcare Programs is trying to monitor drug supply and act preemptively, there will be unforeseen shortages. Reach out to the prior authorization call center with these issues, both to make us aware and for assistance in finding a resolution. Call (406) 443-6002 or 1-800-395-7961.

For questions about this provider notice, contact:

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For claims questions or additional information, contact:

Montana Provider Relations
1-800-624-3958 | (406) 442-1837
MTPRHelpdesk@conduent.com

Visit the Montana Healthcare Programs Provider Information website to access your provider type page. Choose Resources by Provider Type in the left-hand menu. Visit the Contact Us page on the Provider Information website for additional Department of Public Health and Human Services (DPHHS) contact numbers.

Compounded Medications: Not Without Risks

More than a decade has passed since the unforgettable meningitis outbreak that led to 753 infections and 63 deaths. The outbreak was linked to a compounded medication distributed by the New England Compounding Center (NECC).[1] Since that time, the U.S. Food and Drug Administration (FDA) continues to receive reports of adverse events related to compounded medications, prompting the issuance of compounding risk alerts and warnings.[2] In October 2023 alone, the FDA issued a warning regarding compounded ketamine and also addressed safety concerns around compounded semaglutide.

Compounded Ketamine

On October 10, 2023, the FDA issued a warning regarding the potential risk of compounded ketamine used for the treatment of psychiatric disorders.[3] Of concern in this warning is the compounding of oral formulations for at-home use. Currently, the only FDA-approved formulation of ketamine is for intravenous or intramuscular injection to be administered by a licensed health care professional.

The warning discusses a patient who experienced respiratory depression in April 2023 after consuming compounded oral ketamine outside of a supervised health care setting. The patient's blood levels were found to be double the typical concentration achieved when ketamine is used for anesthesia.[3] Other concerns noted within the warning include additional risks associated with not appropriately monitoring for sedation, dissociation, increased blood pressure and heart rate within a health care setting.

On February 16, 2022, the FDA had previously issued a compounding risk alert regarding potential risks of compounded ketamine nasal spray for in-home use. Due to the serious side effects involved, the FDA approved ketamine isomer, Spravato® (esketamine), which is administered as a nasal spray under strict requirements outlined in the Spravato® Risk Evaluation and Mitigation Strategies (REMS) program. This program requires that "Spravato® is only dispensed and administered to patients in a medically supervised healthcare setting that monitors these patients."[4] Unapproved ketamine compounds lack such regulation and consequently pose higher safety risks.

Compounded Semaglutide

The diabetes medication Ozempic® (semaglutide) has been highly sought after due to its remarkable weight loss effects. In fact, the demand is so great that the manufacturer, Novo Nordisk, recently announced its plans to reduce production of a similar medication, Victoza® (liraglutide), and concentrate efforts on Ozempic®. Regardless of such efforts, shortages of both medications are predicted to persist through 2024.[5] This situation creates a lucrative and potentially dangerous scenario where various pharmacies or facilities may offer their own compounded version of semaglutide. To exacerbate matters, illegally marketed and counterfeit semaglutide has also been identified and offered for sale online.[6]

On October 31, 2023, the FDA released a statement addressing compounded semaglutide, emphasizing patients should refrain from using compounded medication if an approved alternative is available. They also remind the audience the FDA does not review compounds for safety, efficacy or quality.[6] Furthermore, compounded products frequently vary in their ingredients from the approved form, often using different salt forms that lack proven effectiveness. They warn that individuals should exclusively obtain semaglutide with a prescription from a state-licensed pharmacy or FDA-registered outsourcing

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Compounded Medications: Not Without Risks (cont.)

facility adhering to the requirements of the Federal Food, Drug and Cosmetic (FD&C) Act, which was further amended after the unfortunate deaths of 63 individuals.

Conclusion

The FDA recognizes the role compounded medications play in meeting the specific needs of patients that cannot be met by an FDA-approved drug product. They serve as alternatives for patients unable to swallow pills, have an allergy to inactive ingredients in the FDA-approved version or for several other valid reasons. However, the FDA warnings noted above, along with many others, indicate compounded medication can carry risks. The FDA strongly encourages the exploration of FDA-approved alternatives prior to resorting to compounds. Patients and health care providers alike must use caution when considering compounded medications and ensure these medications are being obtained through safe and trusted sources.

References:

[1] Donna M. Lisi, PharmD, BCPS, BCGP, BCPP, BCACP Hackensack Meridian Health Eatontown, New Jersey. (2021, November 19). Pros and Cons of Pharmacy Compounding. U.S. Pharmacist: the Pharmacist's Resource For Clinical Excellence. Retrieved November 22, 2023, from https://www.uspharmacist.com/article/pros-and-cons-of-pharmacy-compounding-1

[2] Research, C. F. D. E. A. (2023, October 10). Compounding risk alerts. FDA. https://www.fda.gov/drugs/human-drug-compounding/compounding-risk-alerts

[3] Research, C. F. D. E. A. (2023b, October 10). FDA warns patients and health care providers about potential risks associated with compounded ketamine products, including oral formulations, for the treatment of psychiatric disorders. FDA. https://www.fda.gov/drugs/human-drug-compounding/fda-warns-patients-and-health-care-providers-about-potential-risks-associated-compounded-ketamine

[4] Approved Risk Evaluation and Mitigation Strategies (REMS). (n.d.). FDA. https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=386

[5] Burger, L., & Mathews, E. (2023, November 21). Novo rations Ozempic starter kits amid surge in use for weight loss. Reuters. https://www.reuters.com/business/healthcare-pharmaceuticals/novo-nordisk-says-diabetes-drugs-shortages-will-persist-through-2024-2023-11-21/

[6] Research, C. F. D. E. A. (2023c, October 31). Medications containing semaglutide marketed for type 2 diabetes or weight loss. FDA. https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/medications-containing-semaglutide-marketed-type-2-diabetes-or-weight-loss

[7] Research, C. F. D. E. A. (2023a, March 24). Drug compounding and drug shortages. FDA. https://www.fda.gov/drugs/human-drug-compounding/drug-compounding-and-drug-shortages

Help Corner

Montana Healthcare Programs does not provide vacation overrides for medications. Prescriptions for non-controlled substances may be refilled after 75% of the estimated therapy days have elapsed. Prescriptions for controlled substances (CII-CV) and gabapentin may be refilled after 90% of the estimated therapy days have elapsed. Lost or stolen medications replacement is also not provided.

An emergency 72-hour supply may be dispensed for emergency, after-hours, weekend and holiday requests. Payment will be authorized by using a value of "3" in the Days Supply field and a value of "8" in the Prior Authorization Type Code field.

Montana Healthcare Programs' PDL is updated regularly. The most recent version is from November 22, 2023, and is located at https://medicaidprovider.mt.gov/19.

Montana Healthcare Programs' criteria and prior authorization (PA) forms are available at https://www.mpqhf.org/corporate/montanans-with-medicaid/pharmacy/.

Synagis® may require a PA but cannot be submitted until a claim is denied at the pharmacy. The pharmacy must first process the claim. If the claim denies, then the PA process may begin.

Update on Stimulant Shortages

On November 1, 2023, U.S. Drug Enforcement Administration (DEA) Administrator Anne Milgram sent an open letter on the ongoing stimulant shortages. This is a follow-up to the letter she and Commissioner of Food and Drugs Robert M. Califf, MD, publicly posted August 1, 2023, which promised action by government agencies to address these shortages. She announced the following changes the FDA will take to address and attempt to avoid further issues:

- Quota regulations have been changed to reduce the amount of a drug that a manufacturer must keep in inventory, which will allow manufactures to voluntarily relinquish their quota allotments if they are unable to produce a drug.
- Drug manufacturers will be required to submit their anticipated production timelines for medications to the DEA in advance of receiving their quota allotments.

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Update on Stimulant Shortages (cont.)

- Quota allotment applications from manufacturers will be switched from yearly requests to quarterly. This will allow the DEA to provide quota allotments to those that are actually actively producing medication for current use.
- The DEA will require monthly digital reporting from manufacturers and distributors on the amount of drugs being produced and shipped.
- Manufacturers will be required to specify whether the quota allotment is for domestic production or export production. This will allow the DEA to track how much of a drug is available to Americans.
- To reduce the burden on patients, the DEA revised their regulations and now allow patients to transfer electronic prescriptions from one pharmacy to another without having to obtain a new prescription from their provider.

The letter is available online at Quota-Shortages Letter.pdf (dea.gov).