Mountain Pacific DUR PROGRAM NEWS

SPRING 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

Montana Healthcare Programs Prior Authorization Updates

Atypical Antipsychotics

In 2023, the Montana Medicaid Drug Utilization Review (DUR) Board requested a review of the current prior authorization (PA) criteria for oral atypical antipsychotics. This discussion excluded the long-acting injectable antipsychotics. Board members voiced concerns about inconsistent criteria for drugs in the same class. The criteria for each of these agents were developed over many years when the drugs first became available. In response to that request, Mountain Pacific and Montana Department of Public Health and Human Services (DPHHS) developed several sample criteria to prompt discussion among the board. These were distributed to all board members before the meeting. After discussion, the criteria listed below were agreed upon as the approved criteria.

The following drugs did not fit into the generalized category due to the specialized nature of their mechanism of action or their specialized indication. These drugs' criteria were not changed or were updated for a specific indication:

- Abilify Mycite® will have no criteria change.
- Lybalvi® will have no change at this time, but further review will be scheduled at another DUR board meeting.
- Secuado® will be included in the specialty dosage form rules since it is a patch.
- Symbyax® will continue to require a trial of olanzapine and fluoxetine (preferred products), both dispensed as separate prescriptions but dosed together.

Continued on p. 2

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Mountain Pacific
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www.mpqhf.org

Prior Authorization Updates (cont.)

- Rexulti® for the treatment of agitation from Alzheimer's will not require a failure of a preferred agent.
- Nuplazid® for the treatment of Parkinson's psychosis will not require a failure of a preferred agent.

All other non-preferred oral atypical antipsychotics will be required to meet the following criteria:

- Member must have a diagnosis that matches the U.S. Food and Drug Administration (FDA) approved indication for the requested medication AND
- Member must try and fail two separate, preferred oral atypical antipsychotics that have the same FDA approved indication for the diagnosis being requested.
- For off label indication requests, providers must submit clinical literature that supports safety and efficacy of the requested therapy off-label.

Class-wide criteria that did not change:

- Atypical antipsychotic requests for children 8 years of age and younger are individually reviewed by case management based on a process established to meet the Centers for Medicare & Medicaid Services (CMS) requirements for the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act.
- All atypical antipsychotics remain grandfathered, unless samples, patient assistance or cash pay have been used to bypass criteria.
- Special dosage forms such as patches, dose-packs, dissolvable tablets and liquids require rationale for bypassing oral tablets/capsules.

The board verified diagnosis would not be required if the requested medication is for a preferred oral product. At this time, diagnosis is not required for preferred oral atypical antipsychotics.

Changes to Criteria for Suboxone® and Other Medications for Opioid Use Disorder (MOUD)

Montana DPHHS has updated the criteria for MOUD for Montana Healthcare Programs. Members who are prescribed MOUD will no longer require PA for future opioid prescriptions, as long as the therapy being prescribed is in accordance with the Montana Healthcare Programs Preferred Drug List (PDL) and applicable dose limits. This will also include those members who currently require PA for opioids for historical MOUD treatment. We are in the process of updating the system to prevent claim rejections for opioids for these members, but some may still occur. Therefore, please contact the Drug Prior Authorization Unit at 1-800-395-7961 for approvals of opioids that may continue to be rejected.

This change has resulted in a new Suboxone Film attestation form. All providers who previously signed up for the electronic PA process will NOT be required to resubmit the form. Providers who have not signed the attestation but wish to be automatically enrolled for approval for Suboxone films will need to fill out the new form. A copy of that form can be found at:
https://medicaidprovider.mt.gov/docs/forms/SuboxoneBuprenorphineNaloxoneFilmMOUDProviderAttestationForm.pdf

Prior Authorization Updates (cont.)

Other Criteria Additions, Changes and Removals since January 2023

CRITERIA ADDITIONS		EXPANSIONS, CHANGES, UPDATES and NEW FORMULATIONS		CRITERIA REMOVED
Uzedy®	Motpoly XR®	Lucemyra®	Fasenra®	Ampyra®
Velsipity®	Bimzelx®	Kevzara®	Trikafta®	Zinplava®
Zurzuvae®	Agamree ®	Doptelet®	Linzess®	Entresto®
Omvoh®	Tzield®	Nucala®	Savella®	Ocrevus®
Lumyrz®	Zavzpret®	Xeljanz®	Cibinqo®	calcineurin inhibitors
Leqembi®	Vowst®	Adbry®	Ingrezza®	
Abilify Asimtufii®	Austedo XR®	Entyvio SQ®	Rinvoq®	
		Diacomit®	Leqvio®	
		Evkeeza®	Qulipta®	
		Zoryve® Foam and Cream		

For PA information, go to **www.mpqhf.org** or call the Drug Prior Authorization Unit at 1-800-395-7961.

2024 Updates from the American Diabetes Association

In a December 2023 press release, the American Diabetes Association (ADA) announced the release of the *Standard of Care in Diabetes – 2024* (at **https://diabetesjournals.org/care/issue/47/Supplement_1**).[1,2] The new guidelines contain several noteworthy updates and include Figures 9.3 and 9.4, which offer comprehensive flow diagrams detailing medication therapy for type 2 diabetes (DM2). Some updates will be addressed in this newsletter; however, the full summary of revisions may be accessed at **Summary of Revisions: Standards of Care in Diabetes—2024 | Diabetes Care | American Diabetes Association (diabetesjournals.org)**.[3]

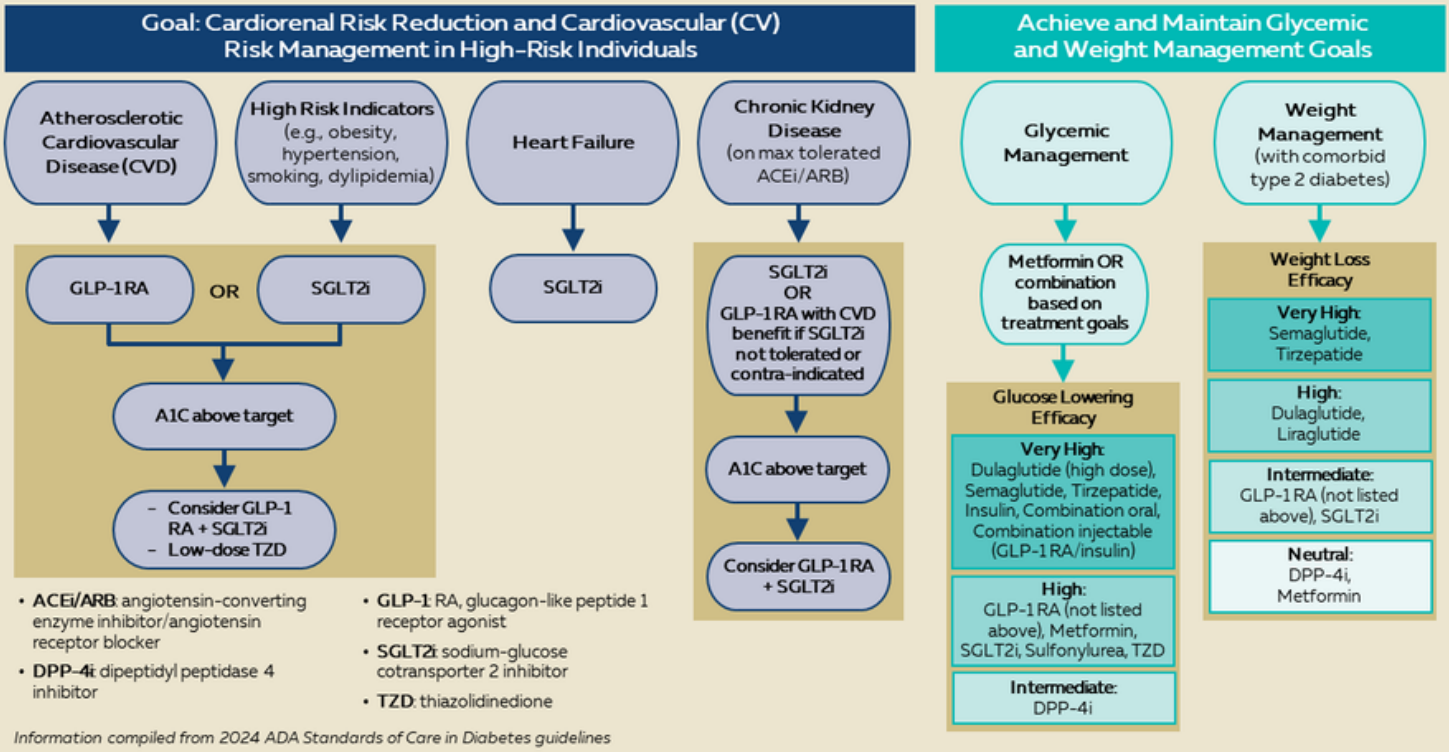
The revised standard of care emphasizes tailored, patient-centered treatments and thorough evaluations for adjusting treatment intensification or deintensification in individuals, such as those with obesity, chronic kidney disease (CKD) or cardiovascular disease (CVD) in the setting of diabetes. It is essential to assess all coexisting conditions that could affect or be affected by a diabetes diagnosis and to deliver treatments supported by the most robust clinical evidence for each unique circumstance. This principle extends beyond medical conditions to include evaluating psychosocial factors and situations of disability that could pose challenges to treatment adherence.

Continued on p. 4

2024 Updates from the American Diabetes Association (cont.)

Figure 1 below offers a broad overview of medications for managing glycemic levels in Diabetes Mellitus Type 2 (DM2).

Figure 1. Glycemic Management Medications in Type 2 Diabetes



- First-line therapy now consists of initial or early combination therapy to expedite the achievement of treatment goals in adults with DM2. This recommendation stems from findings in the VERIFY trial, which compared sequential metformin monotherapy with the combination of metformin and vildagliptin in individuals newly diagnosed with DM2.[4]
- The section addressing prediabetes and DM2 now advocates for screening individuals taking medications associated with an elevated risk of developing these conditions. Notably mentioned are glucocorticoids, statins, thiazide diuretics, certain human immunodeficiency virus (HIV) medications and second-generation antipsychotics. Regarding second-generation antipsychotics, there is now an explicit recommendation to conduct diabetes screening at baseline, 12-16 weeks after initiation and annually thereafter.
- As indicated in Figure 1, a sodium-glucose cotransporter 2 (SGLT2) inhibitor is recommended for those

Continued on p. 5

with diabetes and established heart failure along with patient education regarding risks and signs of ketoacidosis when taking these medications.

- Glucagon-like peptide 1 (GLP-1) receptor agonists or dual glucose insulinotropic polypeptide (GIP) and GLP-1 receptor agonists (e.g., semaglutide, tirzepatide) present an alternative for enhancing glycemic management and are also the preferred pharmacotherapy for individuals with DM2 who are overweight or obese. However, it is vital to review insulin dosage when incorporating these agents. They are not advised for individuals with a gastroparesis history, and patients should be educated about the risk of ileus.
- Immunizations now include the approved respiratory syncytial virus (RSV) vaccines for adults over 60 years old with diabetes.

The *Standard of Care in Diabetes* also offers new guidance for screening of various comorbidities, encompassing heart failure, peripheral arterial disease (PAD), nonalcoholic fatty liver disease (NAFLD) and nonalcoholic steatohepatitis, individuals with disabilities and conducting psychosocial screening to detect diabetes distress. In addition, bone health has been recently included in the roster of comorbidities requiring monitoring, with a focus on assessing and treating bone health issues, particularly addressing fracture risks associated with diabetes. This expanded guidance on comorbidities once more promotes individualized, patient-centered care.

References

[1] The American Diabetes Association releases the Standards of Care in Diabetes—2024. (2023, December 11). Retrieved March 13, 2024, from https://diabetes.org/newsroom/press-releases/american-diabetes-association-releases-standards-care-diabetes-2024?gad_source=1&gclid=Cj0KCQjwncWvBhD_ARIsAEb2HW-lqmecoVhcmzaWw61oQoLDSjUMy3GJf926LBGxtrA6DodUpkyKRgQaAu-LEALw_wcB

[2] Standards of Care in Diabetes—2024. Diabetes Care, 47(Supplement_1), S1–S322.

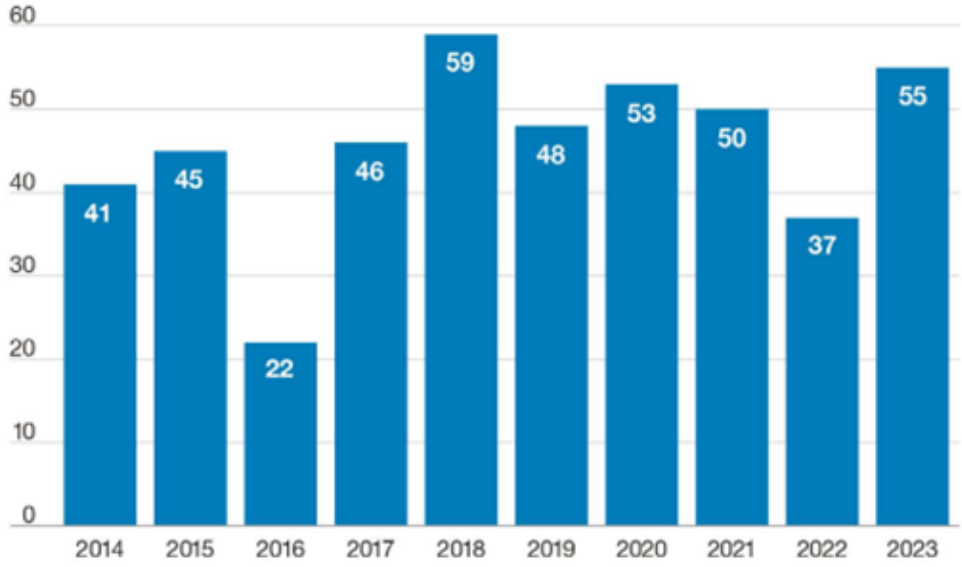
[3] Summary of Revisions: Standards of Care in Diabetes—2024. Diabetes Care 2024;47(Suppl. 1): S5–S10 | https://doi.org/10.2337/dc24-SREV

[4] Matthews DR, Paldánius PM, Proot P, Chiang Y, Stumvoll M, Del Prato S; VERIFY study group. Glycaemic durability of an early combination therapy with vildagliptin and metformin versus sequential metformin monotherapy in newly diagnosed type 2 diabetes (VERIFY): a 5-year, multicentre, randomised, double-blind trial. Lancet. 2019 Oct 26;394(10208):1519-1529. doi: 10.1016/S0140-6736(19)32131-2. Epub 2019 Sep 18. PMID: 31542292.

Risk vs. Benefit: Prescription Drug Development

In 2023, the FDA Center for Drug Evaluation and Research (CDER) approved 55 novel drugs. In 2022 the number of novel drugs approved was only 37, the second lowest number in the past decade.[1]

Figure 2. CDER Novel Drug Approvals by Year



The Global COVID-19 pandemic, which, according to the World Bank, precipitated the deepest recession since World War II, is considered one of the major reasons for the low number of drugs approved in 2022. The pandemic affected clinical trials, testing and data collection/review and disrupted the supply chain, which slowed the process for a drug to come to market.

The expected cost to develop a new drug, including all costs and expenditures on drugs that succeed and those that fail to reach the market, has been estimated to range from less than $1 billion to more than $2 billion.[2] The path to market is long for each new prospective product. This process can take years, and only 10% of products that enter phase one research, succeed and get approval.[3]

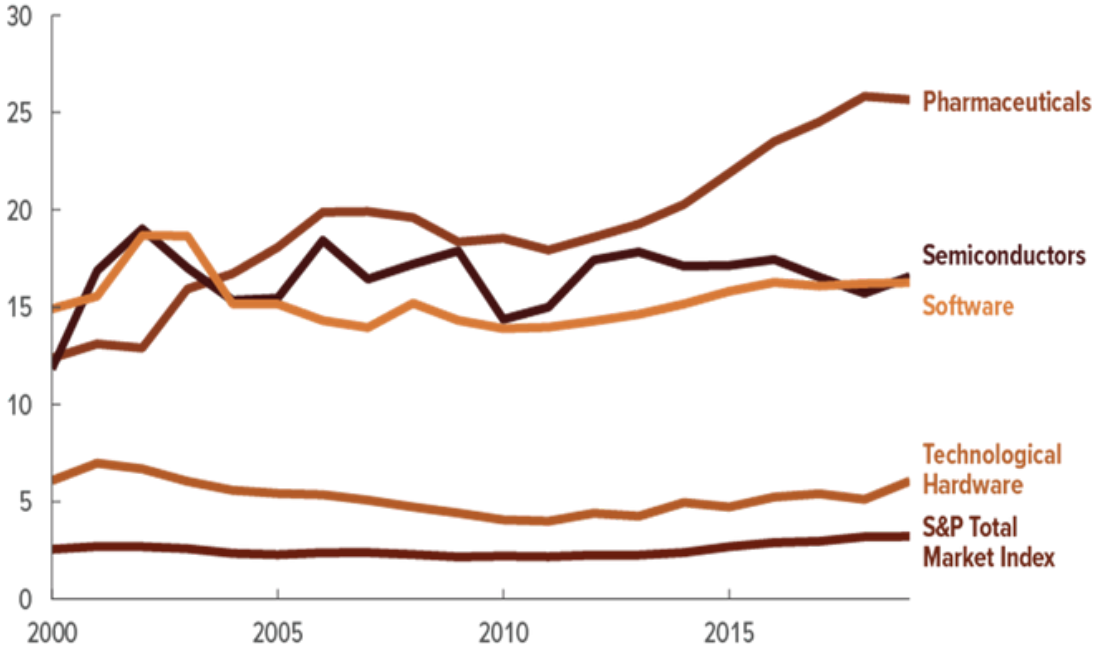
Between 2000 and 2019 the share of net revenue dedicated to research and development (R&D) dramatically outpaced the percent spent by other industry (semiconductor, software and technical hardware companies and the Standard and Poor's [S&P] Market Index).

Including the full R&D process, the Pharmaceutical Research and Manufacturers of America (PhRMA) reported in their 2020 Annual Survey that in 2019 the total spent for R&D was more than $82 billion.[4] This dollar amount includes trials beginning at the pre-human/pre-clinical review and going through phase four clinical trials, as well as the cost of FDA approval and additional costs labeled "uncategorized."

Continued on p. 7

Figure 3. Average R&D Intensities for Publicly Traded U.S. Companies, by Industry

Percent of net revenue



Data source: Congressional Budget Office, using data from Bloomberg, limited to U.S. firms as identified by Aswath Damodaran, "Data: Breakdown" (accessed January 13, 2020), https://tinyurl.com/yd5hq4t6. See www.cbo.gov/publication/57025#data.
R&D intensity is research and development spending as a share of net revenues (sales less expenses and rebates).

Manufacturers of potential new drugs are aware of all of the barriers they face but are also well versed in the success and rewards of those drugs that become "blockbusters." Encouraged by the success of Lipitor®, Eliquis®, Lyrica® and Humira®, the first drug to exceed $20 billion in sales, the number of potential new drugs continues to grow. The opportunity for a dramatic increase in profit was demonstrated by Novo Nordisk in 2023. Fifty-five percent of their $33.7 billion in sales came from just two products: Ozempic and Wegovy.[5] Both contain semaglutide but carry different FDA indications. Ozempic was approved in 2017 for type 2 diabetes and Wegovy in 2021 for weight loss.

References

[1] Center For Drug Evaluation and Research: Advancing Health Through Innovation: New Drug Therapy Approvals 2023, https://www.fda.gov/media/175253/download

Continued on p. 8

Risk vs. Benefit: Prescription Drug Development (cont.)

[2] United States Congressional Budget Office: Research and Development in the Pharmaceutical Industry, April 2021 https://www.cbo.gov/publication/57025

[3] University of Chicago Booth School of Business, Why New Drugs are Worth Pursuing-Even When They Fail. Tyler Burke, November 8, 2023. https://www.chicagobooth.edu/review/why-new-drugs-are-worth-pursuing-even-when-they-fail#

[4] R&D by Function, PhRMA Member Companies: 2019 (dollar figures in millions) Notes: All figures include company-financed R&D only. Total values may be affected by rounding. Source: Pharmaceutical Research and Manufacturers of America, PhRMA Annual Membership Survey, 2020.

[5] https://www.fiercepharma.com/pharma/novo-nordisk-eli-lilly-lead-industry-wide-sales-surge-fourth-quarter accessed March 15, 2023.

Help Corner

1. The Mountain Pacific Pharmacy Program fields many questions about medications for opioid use disorder (OUD). The most frequently asked questions are about Suboxone® film for OUD and pain management. Suboxone® has an FDA indication for OUD only; therefore, the Montana Healthcare Programs only covers it for OUD. For pain management, Butrans® patches or Belbuca® should be used. (Please refer to the Montana Healthcare Programs Preferred Drug List for preferred product information.) Providers requesting Suboxone® film for OUD are encouraged to fill out and sign the MOUD provider attestation form that indicates they agree to prescribe Suboxone® film for OUD and the provider is an enrolled Montana Healthcare Programs provider. By doing so, the provider will be added to a list of automatically approved prescribers, which will remove the PA process for the provider when ordering Suboxone® film. If you have questions on the attestation requirements, please refer to the updated Attestation form.
https://medicaidprovider.mt.gov/docs/forms/SuboxoneBuprenorphineNaloxoneFilmMOUDProviderAttestationForm.pdf

2. In February 2024 the most frequent calls to the Drug Prior Authorization unit were about gabapentin, the GLP-1 receptor agonists and Lidocaine patches. Here is additional information that may answer some of those questions:
   - Gabapentin is a preferred drug on the Montana Healthcare Programs PDL, but it does have some criteria limits for coverage:
     - Maximum dose limit for gabapentin is 3,600mg daily.
     - Maximum day's supply allowed per prescription is 34 days.

Continued on p. 9

  - Gabapentin refills will not pay until 90% of the previous supply has been used. This is the same rule as for controlled substances and gabapentin is included even though it remains a non-controlled substance.
  - Gabapentin and Lyrica will not be covered at the same time. This is a therapeutic duplication and will deny at point-of-sale.
- The GLP-1 receptor agonist category has some agents that are preferred and some that are non-preferred on the Montana Healthcare Programs PDL. Go to 19 (mt.gov) for the current PDL. The criteria for these agents are:
  - Diagnosis of type 2 diabetes.
  - Member has tried metformin or a metformin-containing product in the previous two years.
  - Member has tried a preferred agent in the previous six months.

- Lidocaine topical patch triggers calls to the Drug Prior Authorization Unit, so here is some information to help:
  - Lidocaine 5% patches are covered, but 4% over-the-counter patches are NOT covered.
  - For new starts, there is a quantity limit of 30 patches.
  - If member has had a prescription within the last six months, the maximum prescription quantity allowed is 90 patches for a 30-day supply.

3 As noted in the winter DUR newsletter, the AMP Cap Removal has affected prescription drug access. Some products have changed manufacturers and have a new NDC number; some have been discontinued; others are just in short supply. What can you do?

- Check the current Montana Healthcare Programs PDL, even if you believe you know what the current preferred drugs are. The PDL meetings are in March, April and May, and the list changes frequently. Check updates at 19 (mt.gov). There is a new PDL as of March 5!
- Call the Drug Prior Authorization Unit at 1-800-395-7961 to find out about any options to help meet our members' needs.