Mountain-Pacific Quality Health

DUR PROGRAM NEWS

SPRING 2018

Lisa Sather, RPh, Editor,
Director of Clinical
Pharmacy Services
406-457-5818

Mark Eichler, RPh,
Director of Pharmacy
Programs
MT DUR Coordinator
406-457-5843

Mountain-Pacific
Quality Health
3404 Cooney Drive
Helena, MT 59602
www.mpqhf.com

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's Medicaid recipients.

Montana Medicaid Drug Prior Authorization Unit
1-800-395-7961

Montana Healthcare Programs Criteria and Preferred Drug List Updates

After a recent review of the clinical evidence, the Montana Drug Utilization Review (DUR) Board recommended implementation of clinical prior authorization criteria for Ingrezza®(valbenazine) and Austedo®(deutetrabenazine). Both medications are vesicular monamine transporter 2 (VMAT2) inhibitors indicated for the treatment of tardive dyskinesia. Austedo® has an expanded indication to also treat chorea associated with Huntington's disease. The following clinical criteria will apply:

Ingrezza®(valbenzine)

- Must be prescribed by, or in consult with, a psychiatrist or neurologist.
- Patient must be at least 18 years old.
- Patient must have a diagnosis of moderate-to-severe **tardive dyskinesia** (TD) according to DSM-5 and must be **antipsychotic (dopamine receptor blocker) induced**, with symptoms of TD present for at least 2 months prior to prescribing.
  - » Tardive dyskinesia is a movement disorder that appears with delayed onset, usually after prolonged use of dopamine receptor blocking agents, mainly antipsychotics (neuroleptics) and the antiemetic drug metoclopramide. The term "tardive" differentiates these dyskinesias from acute dyskinesia, Parkinsonism, and akathisia, which appear very soon after exposure to antipsychotic drugs.
- Documented baseline evaluation of the condition using ONE of the following scoring tools must be completed:
  - » Abnormal Involuntary Movement Scale (AIMS), or
  - » Extrapyramidal Symptom Rating Scale (ESRI).
- Patient must have had an inadequate response to the following treatment modalities, unless all are contraindicated, not tolerated, or are inappropriate to maintain stable psychiatric function:
  - » Discontinuation or dose modification of the offending medication.
  - » Switching from a first-generation antipsychotic to a second-generation antipsychotic.
- The patient must not be at risk for congenital long QT syndrome or arrhythmias associated with a prolonged QT interval.
- No dual therapy with other vesicular monoamine transporter 2 (VMAT2) inhibitors is allowed and patient must not have concomitant use of a MAOI or reserpine.
- **LIMITATIONS**
  - »When approved, authorization will be provided for 12 months with a maximum daily dose of 1-40 mg or 1-80 mg capsule (continuation of 40 mg once daily should

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

be considered for patients known to be poor CYP2D6 metabolizers or patients taking a strong CYP3A4 inhibitor).
» **RENEWAL:** Annual reauthorization will require documentation that TD symptoms have improved evidenced by improved AIMS score.

Austedo®(deutetrabenazine)

For a diagnosis of Huntington's Chorea:

- Xenazine® (tetrabenazine) brand is currently the preferred agent for this movement disorder and the patient must have had an inadequate response or contraindication to Xenazine® prior to consideration for Austedo®.
- Patient must have functional disability resulting from chorea associated with Huntington's disease, which has been confirmed by a neurologist.
- Initial maximum daily dose of 6 mg daily is allowed, up to a max of 48 mg daily.

For a diagnosis of tardive dyskinesia:

- The same clinical criteria as Ingrezza® apply, with the *addition* of the following:
  - » Due to safety warnings, patient must not be at a significant risk for suicidal or violent behavior and must not have unstable psychiatric symptoms.
- **LIMITATIONS**
  - » When approved, authorization will be provided for 12 months with a maximum of 48 mg daily. **Dosing Note:** Initial dose is 6 mg twice daily and dose is titrated upwards weekly based on response and tolerability in increments of 6 mg/day administered in two divided doses if total daily dose is 12 mg or more.
  - » **RENEWAL:** Annual reauthorization will require documentation that TD symptoms have improved as evidenced by improved AIMS score **AND** the patient is not at a significant risk for suicidal or violent behavior and does not have unstable psychiatric symptoms.

Sublocade®(buprenorphine extended-release [CIII])

Sublocade® is a once-monthly subcutaneous depot injection which is FDA-indicated for the treatment of moderate-to-severe opioid use disorder in patients who have initiated treatment with a transmucosal buprenorphine containing product. It is part of a comprehensive treatment program, which includes counseling and psychosocial support. Use is limited under the Drug Addiction Treatment Act. It is a specialty medication available through a limited distribution program only to providers enrolled in the Sublocade® REMS program. After a review of the clinical evidence, the Montana DUR Board has recommended implementation of clinical prior authorization criteria for Sublocade®.

The following clinical criteria will apply:

- The provider must be enrolled in the Sublocade® REMS program.
- Patient must be 18 years of age or older.
- Patient must have been stabilized on a buprenorphine transmucosal dose delivering an equivalent of 8-24 mg for a minimum of 28 days.
- Concurrent use of strong CYP inhibitors is not recommended and provider must have evaluated potential drug interactions.
- Clinical rationale must be provided documenting necessity to switch to an injectable product.
- The provider must attest that the patient treatment plan includes all of the following:
  - » Patient assessment supports a diagnosis of moderate-to-severe opioid use disorder per DSM-V criteria.
  - » Patient will be referred for counseling assessment and counseling.
  - » The proposed monitoring plan includes random urine drug screens to include both buprenorphine and drugs of abuse.
  - » A treatment contract has been signed by the patient and the patient also understands that concurrent opioids, tramadol or carisoprodol will not be covered with buprenorphine-containing products. If the buprenorphine-containing product is discontinued, all opioids/tramadol/carisoprodol will remain on non-covered status and will require prior authorization for future prescriptions.
  - » Risk/benefit will be discussed with pregnant or nursing patients and the patient's OB provider will be contacted to establish a post-delivery plan for neonatal withdrawal syndrome.
  - » Consideration will be made to offer the patient a naloxone rescue prescription and education.

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- **LIMITATIONS**
  - » Initial authorization will be for 6 months.
  - » The maximum dose authorized will be 300 mg monthly, followed by 100 mg x 4 months.
  - » For renewal, the provider must attest that the patient is making clinically meaningful progress towards treatment goals.
  - » Subsequent authorizations will be for one year.

Upcoming Preferred Drug List Meetings . . .

March 28th, April 25th and May 23rd
Great Northern Hotel in Helena from 1-5 p.m.

Montana Implements Standing Order for Naloxone Opioid Antagonists

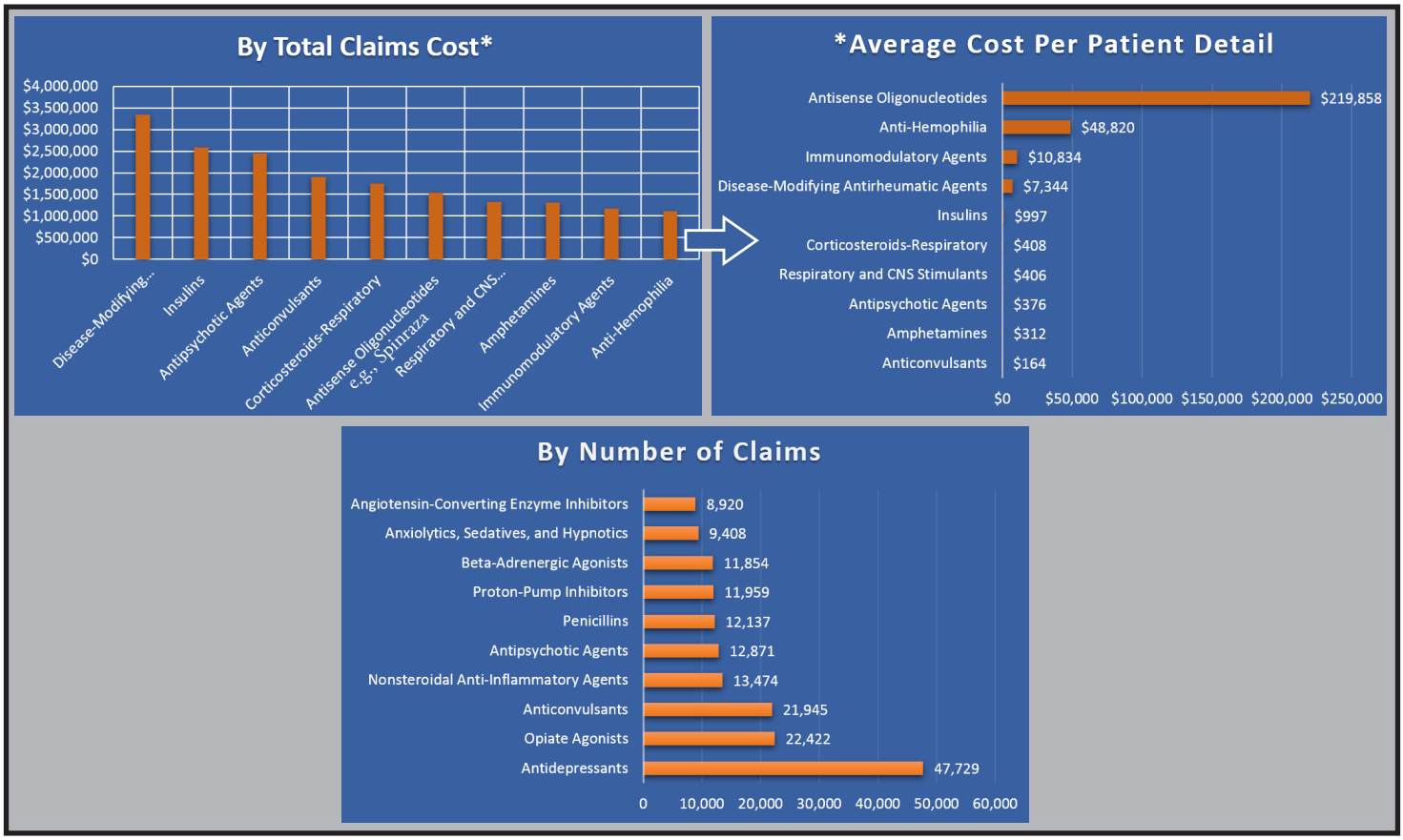
House Bill 333 (the Help Save Lives from Overdose Act) was passed into law during the 2017 Montana Legislative Session. The intent of the law is to provide wide-spread access to the opioid reversal agent naloxone for use in instances of opioid overdose.

- The law requires the Montana Department of Health and Human Services (DPHHS) to issue a state-wide standing order to allow pharmacists to dispense naloxone prescriptions (issued October 2017).
- The bill also addresses immunity, Good Samaritan laws and amends additional provisions within Montana Code Annotated to allow medical practitioners to dispense naloxone.
- Pharmacists who maintain a current active license practicing in a pharmacy in Montana may initiate a prescription and dispense a naloxone opioid antagonist formulation listed in the standing order to an eligible recipient. Eligible recipients include:
  - » an individual at risk of experiencing an opioid-related overdose,
  - » a family member or friend or other person who can assist an individual at risk,
  - » a person with job duties that may require them to assist an individual at risk.

HB 323 was also passed into law, which authorizes emergency use of opioid antagonist in a school setting.

For detailed information, please see the Montana Implementation Guide for Access to Naloxone Opioid Antagonists located at:
https://dphhs.mt.gov/Portals/85/publichealth/documents/EMSTS/Opioids/Montana%20Implementation%20Guide%20for%20Increased%20Naloxone%202017.pdf
The Montana Standing Order for Naloxone Opioid Antagonists can be accessed at
http://dphhs.mt.gov/Portals/85/publichealth/documents/EMSTS/Opioids/Montana%20Standing%20Order%20for%20Naloxone%20Opioid%20Antagonists%202017.pdf

Montana Medicaid Top Therapeutic Classes YTD 2018



The Montana DUR Program News is also available online: http://mpqhf.com/corporate/montanans-with-medicaid/pharmacy/

Mountain-Pacific Quality Health
3404 Cooney Drive
Helena, MT 59602

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