

Montana Medicaid September 2015 DUR Board Meeting Minutes

Date: September 30, 2015

Members Present: Lisa Sather, Caldwell, Bradley, Brown, Maxwell, Fitzgerald, Anglim, Nauts, and McGrane.

Others Present: Dan Peterson (phone) from Medicaid; Woodmansey, Doppler, Barnhill, and Artis from Drug Case Management; and representatives of drug manufacturers.

Lisa Sather opened the meeting.

Public Comment:

There was no public comment.

Meeting Minute Review:

Meeting minutes from April were reviewed and approved as written.

Department Update:

Dan Peterson provided the following Department update:

- The dispensing fee increased on July 1 to \$6.78 for preferred drugs and generic drugs not identified on the PDL.
- The annual dispensing fee survey will soon be released; this year features an on-line version.
- The Department and staff from MPQH are currently performing User Acceptance Testing (UAT) for Flexible Rx, our new pharmacy claims processing system. Expected implementation is December 2015.
- Medicaid Expansion will be going live on 01/01/2016 if approved by CMS. If approved, enrollment for members begins in November. The Department is expecting to carve out (manage the benefit in house) the following services: Pharmacy, dental, eyeglasses, home infusion therapy, audiology, hearing aids, non-emergency transportation, FQHC, RHC & IHS reimbursements.
- The Department is working on the demographics report for the DURB in response to questions from the Board during a previous PDL meeting.

Introduction of new members:

Lisa asked the entire Board to introduce themselves since we have two new members. The new members are Dr. Dan Nauts, MD and Ian McGrane, Pharm.D. They replaced Dr. Jim Crichton, MD and Carla Cobb, Pharm.D.

Board Discussion

New Criteria Development:

The Board discussed various criteria options for the following medications. The following final decisions were made:

1. Esbriet®/Ofev®

- Must be prescribed by or in consult with a pulmonologist
- Patient must have a dx of Idiopathic Pulmonary Fibrosis (IPF)
- Patient must be a non-smoker or quit smoking
- Initial PA will be for 6 months, and then update will be obtained from the pulmonologist that the patient is benefitting from treatment and has remained non-smoking. Approval may then be granted every 12 months thereafter.
- Maximum Daily Dose of 9 capsules daily for Esbriet®
- Maximum Daily Dose of 2 capsules daily for Ofev®

2. Orkambi®

- Patient must be 12 years of age or older.
- Genetic testing must be provided indicating patient is homozygous for the F508del mutation in the cystic fibrosis transmembrane (CFTR) gene
- Prescriber must be a pulmonologist specializing in the treatment of Cystic Fibrosis.
- Baseline FEV1 and history of pulmonary exacerbations to be provided upon initiation of therapy.

- **Initial authorization will be granted for 6 months.**
- **Maximum Daily Dose is 4 tablets.**
- **At 6 months, provider will attest patient has achieved a meaningful clinical response with the following:**
 - Lung function improvement as demonstrated by improvement or stability in percent predicted expiratory volume (ppFEV1) or
 - Decline in pulmonary exacerbations (decrease in IV antibiotic use, decrease in hospitalizations) or
 - Stability or increase in body mass index (BMI)

- **Reauthorization will be issued for 12 months if any of the above meaningful clinical response parameters are met.**

3. Jublia®

- Patient must have a diagnosis of onychomycosis of the toenail.
- Patient must be 18 years old and have a documented contraindication to oral terbinafine.
- Patient must have a documented major clinical complication secondary to onychomycosis, i.e. impaired functioning, secondary bacterial infection, etc. (coverage is not approved for cosmetic reasons).
- Other compelling clinical requests will be reviewed on a case by case basis.
- Maximum quantity of 4ml bottle each month. Maximum treatment duration is 48 weeks.

Existing Criteria Updates:

Discussion by the Board was held on changes for the following medications. Changes affected their FDA indications, doses or current Medicaid or professional practice recommendations. The following criteria adjustments were adopted:

1. Intuniv®

- Patient must be between 6 and 17 years of age and have a diagnosis of ADHD.
- After a successful trial (no adverse events) on immediate release guanfacine the patient may be switched to the long acting product if the patient could not comply with IR dosing frequency or had breakthrough symptoms on the IR formulation.
- Maximum daily dose authorized for children 6-12 years old is 4mg and 13-17 years old is 7mg.

2. Kalydeco®

- Patient must be 2 years of age or older.
- Patient must have confirmed G551D, G178R, S549N, S549R, G551S, G1244E, S1251N, S1255P, R117H or G1349D mutation as detected by an FDA-cleared CF mutation test (chart notes documenting mutation test are required)
- Dosing will be limited to a maximum of 2 tablets daily or max 2-75 mg packet granules daily.

3. **Abilify Maintena®** (addition to the MHSP Formulary)

At the last MHSP Formulary review, the DUR Board recommended MHSP not include Abilify Maintena®. The Department elected to go forward with the inclusion of this drug on the Formulary. The PA criteria will be identical to the Medicaid PA criteria for all injectable long acting atypical antipsychotics.

- Patient must be established initially on the immediate release molecule
- Patient must have a documented inability to swallow oral medication or a compliance issue necessitating the injectable formulation.

4. **Topical Calcineurin Inhibitors (TCI's)**

- Patient must have used a prescription topical steroid within the previous 120 days.
- Limit of 1 tube every 6 months unless documentation of greater quantity is provided.
- If requesting for >1 year, dermatologist consult required.
- If child is < 2, *the 2014 American Academy of Dermatology guidelines* recommend TCI'S for **mild-severe atopic dermatitis** when a steroid isn't effective or can't be used (face, anogenital, skin folds) and may be approved for this indication.

PDL Follow-Up Items

1. **Anti-migraine agents utilization study**

In response to questions raised by the Board members at the April 2015 PDL meeting, Case Management reviewed current Montana Medicaid population Triptan usage data, current migraine recommendations and active PA criteria. With this information, the Board determined that appropriate criteria are in place.

2. **Saphris® - pediatric indication specialist input**

During the April 2015 PDL meeting, the board reviewed Saphris® and discussed place in therapy as a first-line agent for children/adolescents aged 10-17 for bipolar mania due to the new age expansion for this indication. The board requested that input was obtained from the pediatric psychiatrist community in Montana. Following input from 3 pediatric psychiatrists in Montana, the board agreed via email discussion not to change the current PDL recommendation (may add).

3. **PDL Anti-convulsants category-specialist review**

After the April PDL meeting, Dr. Ann Marie Collier, MD a Board Certified Epileptologist from the Billings Clinic reviewed the recommendations for anti-convulsant class of drugs. She agreed with the Board's recommendations for preferred agents, and added only that if a request comes from a Board Certified epileptologist that the provider be allowed discretion.

The Board went into executive session to review sensitive case requests.

The next meetings will be October 28 at Mountain Pacific Quality Health. The agenda will be posted on the Medicaid website.

Meeting adjourned at 4:30.