January 2016 DUR Board Meeting Minutes

Date: January 20, 2016

Members Present: Sather, Caldwell, Anglim, Nauts, McGrane, Harrison, Putsch, Burton, Fitzgerald, Bradley (phone).

Others Present: Dan Peterson, Dave Campana and Katie Hawkins from Medicaid; Woodmansey, Doppler, Barnhill, and Artis from Drug Case Management.

Lisa Sather opened the meeting.

Public Comment:
There was no public comment.

Meeting Minute Review:
Meeting minutes from October 2015 were reviewed and approved as written.

Department Update:
On Sunday, December 6, 2015 Montana Medicaid implemented the new pharmacy claims processing system, FlexibleRX. The Department Pharmacy Team and Mountain Pacific were available that day to monitor the project and be available if providers encountered any issues. The implementation went well.
Less than one month later, the Pharmacy Team implemented Medicaid Expansion into the pharmacy claims processing system. On January 1, the Department Pharmacy Team and Mountain Pacific were available to monitor claims and ensure that the system was processing claims appropriately.
As of January 15, 2016, the HELP Plan has enrolled approximately 23,000 members. Members of the HELP population will be sent one of two cards, depending on their enrollment status. If a member presents with a Montana Access to Health card, their claims will process through Xerox. If a member presents with a Blue Cross card, some of their claims will process through BCBS. I have provided a provider notice that helps to outline what services are handled by BCBS and what services are processed by Xerox.
With the implementation of the HELP Plan, the Basic Medicaid benefit has gone away. Members who formerly had basic coverage are now enrolled under the HELP Plan or other Montana Healthcare Programs.
Previously the Board had requested a brief demographics report. We prepared a brief report that we will provide to the members of the Board. In quick summation, during calendar year 2015, Montana Medicaid had over 200,000 unduplicated members. On average 25.6% of members utilized the pharmacy benefit in a given month. Utilizers averaged 3 claims per month, with an average claim reimbursement per utilizer of $99.14. For all of the pharmacy programs that Department administers the total spend for CY2015 was just over $126 million.

Board Discussion

Hepatitis C

The Board discussed the letter sent out by CMS. The consensus was agreement with open access for treatment for all fibrosis stages, but due to fiscal constraints at this time the State of Montana will continue to triage patients. Special circumstances will continue to be reviewed on a case by case basis.

A comparison chart of currently available Hepatitis C agents was reviewed and discussed.

Updates to the latest AASLD/IDSA Hepatitis C Guidelines were discussed, noting the addition of the 2 newer FDA-approved medications, Daklinza® and Technivie®.

FDA liver warnings regarding Viekira Pak® and Technivie® were discussed.

Summary of MT Medicaid data showed that we have received 261 Hepatitis C requests for 218 patients in the last 2 years. During this time span, we have had a 33% approval rating and a 67% denial rating of all Hepatitis C treatment requests. Denials occurred due to: not meeting liver-staging criteria (must have F3-F4 liver fibrosis), not meeting patient-readiness criteria (abstaining from substance abuse, chronic medication noncompliance, etc.), off-label requests, non-specialty provider requests, non-preferred drug list requests, incomplete paperwork, and Medicaid eligibility issues. Cost-savings related to Hepatitis C case-management equated to $13,420,541.00 in 2015.

Criteria Updates were made as follows:

1. Viekira Pak® is no longer indicated for **moderate or severe** hepatic impairment (Child Pugh **B or C**). Also, PA criteria will now require that hepatic function tests for **ALT, direct bilirubin, alkaline phosphatase, and INR** will need to be drawn and submitted as follows: **pre-treatment baseline and at 2, 4, and 6 weeks after initiation of treatment. This is subsequent to additional FDA updates to the package insert warnings/precautions.**
2. Harvoni® is now approved for the following indications as follows:
    - HCV Genotype 1, treatment-experienced, with cirrhosis: Harvoni® + ribavirin x 12 weeks
    - HCV Genotype 4, 5, and 6, treatment naïve/experienced, with or without cirrhosis: Harvoni® x 12 weeks
3. Olysio® is now indicated along with IFN and RBV for Genotype 4 patients with or/without cirrhosis and HIV co-infection.

Criteria Development was discussed as follows:

4. Daklinza® + Sovaldi® PA form has now been reviewed and approved by the board. Combination will not be allowed for patients with F4 cirrhosis due to the decreased efficacy in cirrhotic patients. Genotype 3 NS5A Y93H polymorphism testing will be required as part of PA criteria once the test becomes available.
5. Technivie® PA form has now been reviewed and approved by the board. Technivie® is not indicated for F4 cirrhotic patients. Also, PA criteria will now require that hepatic function tests for **ALT, direct bilirubin, alkaline phosphatase, and INR** will need to be drawn and submitted as follows: **pre-treatment baseline and at 2, 4, and 6 weeks after initiation of treatment. This is subsequent to additional FDA updates to the package insert warnings/precautions.**

Other New Criteria Development:

1. **Rexulti®**
    - Patients must be ≥18 years of age
    - Covered diagnoses are MDD and schizophrenia
    - MDD adjunctive treatment:
        i. Patient must have an inadequate response, after at least four weeks of therapy, to at least two preferred antidepressant agents AND
        ii. Patient must have had an inadequate response or contraindication to aripiprazole and quetiapine as add-on therapy AND
        iii. Patient is concurrently using an antidepressant.
        iv. MDD 1 tablet, up to maximum of 3 mg daily.
    - Schizophrenia:
        i. Patient must have had an inadequate response, after at least six weeks of therapy, to at least two preferred FDA-approved medications for schizophrenia
        ii. MDD 1 tablet, up to maximum of 4 mg daily.

2. **Invega Trinza®**
    - Patient must be ≥ 18 years of age
    - Must have diagnosis of schizophrenia
    - Patient must have been treated with Invega Sustenna for at least **6 months***
    - Approve on case by case basis: ie injection site reaction

- Compliance issues alone do not warrant coverage because patient must be compliant with Sustenna prior to initiating Trinza.*

3. **Aristada®**
    - Patient must be ≥18 years of age
    - Must have diagnosis of schizophrenia
    - Must meet Medicaid criteria for long-acting atypical injectable: compliance issue with oral medication, tolerability established with corresponding oral molecule, etc.
    - Provide clinical rationale why preferred agent Abilify Maintena® can't be prescribed. Example: patient not adequately controlled on 400mg Abilify Maintena® and needs higher dose Aristada 882mg (equivalent to 600mg aripiprazole).
    - Approve concurrent oral aripiprazole for 21 days.

Sampling/grandfathering policy:

Currently, patients sampled on atypical antipsychotics are allowed to continue under the Medicaid grandfathering policy. This was implemented when few agents were available. After review of the preferred agents available, the Board decided that this was no longer appropriate. Samples will no longer be considered for grandfathering purposes. Samples do not qualify for grandfathering in any other classes as well.

PDL/DURB meeting follow-up items:

RDUR study of concurrent use of 2 or more atypical antipsychotics was presented to the Board. Over the review period, 6 months, only twelve patients were isolated. The Board was pleased with the judicious use of these medications and no action was recommended.

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

The Board reviewed eight cases. Multiple cases for similar requests resulted in several recommendations from the Board to Medicaid and the case management department.

Form letter requests for non-preferred products will continue to be denied unless new information is made available supporting the non-preferred agent over the existing preferred product.

Patient who are currently on drug not covered restrictions for controlled substances will be allowed subsequent trials only if the requesting prescriber can show the benefit of the treatment exceeds the risk to the patient and population at large. Providers will need to show the treatment improves functionality, while limiting the risk of inappropriate use.

The next meeting will be for the Preferred Drug List. It will be at the Great Northern on February 17, 2016 at 1:00 P.M. The agenda has been posted on the Medicaid website.

Meeting adjourned at 4:55.