

January 2014 Montana Medicaid DUR Board Meeting Minutes

Date: January 29, 2014

Members Present: Lisa Sather, Caldwell, Burton, Brown (phone), Cobb (phone), Putsch, Bradley (phone), Fitzgerald, Maxwell (phone)

Others Present: Dave Campana, Katie Hawkins and Dan Peterson from Medicaid, Woodmansey, Toner, Barnhill Drug PA/Case Management, and representatives of drug manufacturers.

Lisa Sather opened the meeting.

Public Comment:

There was no public comment.

Meeting Minute Review:

Some of the Board members did not have copies of the October minutes, so they will be reviewed and addressed by e-mail.

Department Update:

Dave Campana gave the Board the following update:

Due to a notice from CMS the Department has been working on a change in reimbursement rate for pharmacies. CMS would like the Medicaid Agency to reimburse pharmacies with the National Average Drug Acquisition Cost (NADAC) or the Average Manufacturer Price Federal Upper Limit. The Department is reviewing options, as the Department does not believe the NADAC offers fair reimbursement to pharmacies in Montana.

In process is the new Smart PA algorithm for oxycodone maximum daily dose and also a conflict of interest disclosure statement for DUR Board members to sign.

Board Discussion:

- Pediatric atypical antipsychotic criteria update-
 - Prior authorization for atypical antipsychotics for children under six was approved by the board last summer and implementation is upcoming. It was agreed that physicians who specialized in child psychiatry would be exempt from this PA.
 - Ashley Toner also updated the Board on the Foster Care pharmacy case management program. It has been in place for one year and has had a very positive impact on outcomes as well as a positive reception from case workers.

- Criteria Development: The board reviewed and approved the following drug criteria and recommended implementation to the Department:

Oral Anticoagulants:

Xarelto® (rivaroxaban)

- DVT prophylaxis: No previous therapy required
 - LIMITATIONS:
 - Max 10 mg once daily
 - Hip replacement –max 39 days duration
 - Knee replacement –max 15 days duration

- A fib:
 - 1. Pt must have diagnosis of non-valvular A fib AND
 - 2. Have had an inadequate response to warfarin OR have a contraindication to warfarin OR if warfarin naïve, patient must be at moderate-to-high risk of stroke (prior history of TIA, stroke, or systemic embolism or ≥2 additional risk factors for stroke)
 - 3. Renal function assessment (CrCl) has been performed
 - Inability to provide monitoring for warfarin alone is not information enough to allow Xarelto® first line.
 - Patients currently stable on warfarin are not appropriate candidates for switching unless criteria are met.
 - LIMITATIONS:
 - Max 20 mg once daily
 - 15 mg daily if CrCl 15-50 ml/min.

- DVT/PE Treatment and Reduction in risk or recurrence of DVT/PE:
 - Allowed if patient has a contraindication to warfarin or low molecular weight heparin
 - LIMITATIONS:
 - 15 mg twice daily x 21 days, then once daily thereafter

Eliquis® (apixaban)

- 1. Pt must have diagnosis of non-valvular A fib AND
- 2. Have had an inadequate response to warfarin OR have a contraindication to warfarin OR if warfarin naïve, must have the presence of at least **one** additional risk factor for stroke (i.e. CHF, HTN, DM, previous stroke/TIA) AND
- 3. Renal function assessment (CrCl) has been performed
- Inability to provide monitoring for warfarin alone is not information enough to allow Eliquis® first line.
- Patients currently stable on warfarin are not appropriate candidates for switching unless criteria are met.
 - LIMITATIONS:
 - Max 5 mg twice daily
 - Max 2.5 mg twice daily if two of the following: SrCr>1.5 mg/dL, weight <60 kg, age >80 yrs

Hepatitis C agents:

These criteria will be revisited as new guidelines are released and newer medications gain approval by the FDA.

Sovaldi® (sofosbuvir)

Initial Requirements:

Patient must meet ALL of these criteria:

- Diagnosis of chronic hepatitis C infection with HCV genotype 1, 2, 3, or 4
- Never had previous treatment with HCVNS3/4A protease inhibitors [ex: Incivek® (telaprevir), Victrelis® (boceprevir), or Olysio® (simeprevir)]
- Patient is 18 years of age or older
- Must be prescribed by (or had a documented consult with) a gastroenterologist, infectious disease specialist, or a practitioner specializing in the treatment of hepatitis. Notes of consultation with specialist must be attached.
- Female patient or male patient's female partner must not be pregnant or planning to become pregnant during treatment or within 6 months after stopping treatment (due to ribavirin).
- Sovaldi® must be taken along with required concomitant meds (ex: ribavirin or ribavirin + peginterferon alfa) depending on HCV genotype.
- Patient is not receiving dialysis or does not have severe renal failure (CrCl <30 ml/min)
- Patient must not have a history of liver transplant
- Patient must not be taking any of the following medications (please circle if patient is taking): carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifabutin, rifampin, rifapentine, St. John's wort, or tipranavir/ritonavir.

Patient must meet ONE of these criteria, as well as ALL criteria listed above:

- HCV Genotype 1: Sovaldi® will be used with peginterferon alfa and ribavirin for 12 weeks
- HCV Genotype 1 (interferon ineligible): Sovaldi® in combination with ribavirin (without peg interferon alfa) for 24 weeks may be considered for Genotype 1 patients who have an interferon contraindication. Rationale why interferon cannot be used must be provided.
- HCV Genotype 2: Sovaldi® will be used with ribavirin for 12 weeks
- HCV Genotype 3: Sovaldi® will be used with ribavirin for 24 weeks
- HCV Genotype 4: Sovaldi® will be used with peginterferon alfa and ribavirin for 12 weeks
- HCV Genotype 1,2, 3, or 4 with hepatocellular carcinoma meeting Milan criteria awaiting liver transplantation: Sovaldi® will be used in combination with ribavirin for UP TO 48 weeks or until liver transplantation occurs, whichever occurs first, to prevent post-transplant HCV reinfection.

Initial Limitations:

- Quantity Limit of 28 tablets per 28 days (one 400 mg tablet daily).
- Initial approval will be granted for 8 weeks.
- Continuation of therapy beyond 8 weeks will require completion of Sovaldi® Renewal Form.

Renewal Requirements: All of the following requirements must be met:

- Required concomitant medications (ribavirin or peginterferon alfa + ribavirin, depending on the HCV genotype) must not have been discontinued.

- Patient must have been compliant with Sovaldi[®] and required concomitant medications (ribavirin or peginterferon + ribavirin) as per protocol

Renewal Limitations:

1. Quantity Limit of 28 tablets per 28 days (one 400 mg tablet daily).
2. If patient meets criteria, Sovaldi[®] will be approved as follows:
 - HCV Genotype 1, 2, and 4: Will be authorized for the remaining 4 weeks of Sovaldi[®] (for a maximum total of 12 weeks)
 - HCV Genotype 1 (interferon ineligible) and Genotype 3: Will be authorized in 8 week increments (for a maximum total of 24 weeks of Sovaldi[®]). Note: Sovaldi[®] Renewal Form will need to be submitted for each 8 week authorization.
 - HCV Genotype 1,2,3, or 4 with hepatocellular carcinoma meeting Milan criteria awaiting liver transplantation: Will be authorized in 8 week increments (for a maximum total of 48 weeks or until liver transplantation occurs, whichever occurs first). Note: Sovaldi[®] Renewal Form will need to be submitted for each 8 week authorization.

Olysio[®] (simeprevir)

Initial Requirements: All of the following criteria must be met for authorization:

- Diagnosis of chronic Hepatitis C, genotype 1.
- IF patient is Genotype 1a, must provide lab result of screening of NS3 Q80K polymorphism. If polymorphism is present, alternative therapy should be considered due to decreased efficacy.
- Must not be of East Asian ancestry.
- Never had previous treatment with Olysio[®] or other HCV NS3/4A protease inhibitors [ex: Victrelis[®] (boceprevir) or Incivek[®] (telaprevir)]
- Patient is 18 years of age or older.
- Must receive concomitant peg-interferon and ribavirin
- Must be prescribed by (or had a documented consult with) a gastroenterologist, infectious disease specialist, or a practitioner specializing in the treatment of hepatitis. Notes of consultation with specialist must be attached.
- Patient must not have a history of liver transplant
- Must not have moderate or severe hepatic impairment (Child-Pugh Class B or C)
- Female patient or male patient's female partner must not be pregnant or planning to become pregnant during treatment or within 6 months after stopping treatment.
- Patient must not be taking any of the following medications that are not recommended to be coadministered with Olysio[®]. Please circle medication name if patient is taking any of the following:
Article I. erythromycin, clarithromycin, telithromycin, itraconazole, ketoconazole, posaconazole, voriconazole, fluconazole, rifampin, rifabutin, rifapentine, carbamazepine, oxcarbazepine, phenobarbital, phenytoin, dexamethasone, cisapride, cobicistat-containing product, efavirenz, delavirdine, etravirine, nevirapine, darunavir/ritonavir, atazanavir, fosamprenavir, lopinavir, indinavir, nelfinavir, saquinavir, tipranavir, ritonavir, milk thistle, or St. John's wort.

Initial Limitations:

- Total duration of therapy to be authorized is 12 weeks.
- Initial approval will be granted for 8 weeks. This allows for 4 week HCV RNA viral load lab results to be received. Dosing will be limited to 1 capsule per day (28 capsules/28 days).
- Continuation of therapy will require documentation of HCV RNA viral load at 4 weeks in therapy.

Renewal Requirements: All of the following requirements must be met:

- Peg-interferon alfa and/or ribavirin must not have been discontinued
- Patient must have been compliant with peg-interferon alfa, ribavirin, and Olysio[®] therapy as per protocol
- Week 4 HCV RNA level must be documented.

Renewal Limitations:

- If week 4 HCV RNA is \geq 25 IU/ml, further authorization will be denied.
- If week 4 HCV RNA is $<$ 25 IU/ml, Olysio[®] therapy will be authorized for 4 weeks (for a maximum total of 12 weeks of Olysio[®] therapy). Dosing will be limited to 1 capsule per day (28 capsules per 28 days).

Pulmozyme, TOBI, and Cayston

- Prior authorization will not be required with a diagnosis of cystic fibrosis.
 - Patients without a cystic fibrosis diagnosis will require a current (within the last 12 months) specialist consult (pulmonologist or infectious disease).
- The Board discussed the upcoming prior authorization requirement for greater than 8 tablets daily of short acting single ingredient opiates. The Department plans to implement oxycodone as the first agent in the next several months. The Board reviewed and approved the educational materials that will assist in this process.
- Stimulant 14-day initial supply limitations were approved by the Board. All new starts will be allowed for a 14 day trial only. Subsequent prescriptions of the same medication will be approved for a month's supply. Discussion was also held about the current issue with dose titrations causing unnecessary PA requests. This is being addressed in coding so it will no longer impede dose adjustment.
- OTC coverage recommendation follow-up discussion.
Dave Campana R.Ph., Medicaid Pharmacist, brought information back to the Board about possible coverage of doxylamine and pyridoxine over-the-counter (but by prescription only). Dave is working on a new state amendment which is required to allow over the counter medications to be covered by Medicaid. He anticipates it will be in place this summer.

Executive Session:

The Board discussed case sensitive issues in a closed session.

The next three meetings will be Preferred Drug List.

They are scheduled for February 19, March 26, and April 23. All will be held at the Great Northern Hotel.

Meeting adjourned at 4:00.