Drug Utilization Review Committee  
11/18/16

Members Present
Jenny Love, MD  
John Pappenheim, MD  
Ryan Ruggles, Pharm D  
Chuck Semling, Pharm D  
Maggie Rader, ANP  
Rebecca Wall, Pharm D (DHSS )

Non-Members Present
Erin Narus, Pharm D (DHSS)  
John McCall RPh (Magellan)

Members Absent
Heath McAnally, MD

Meeting started at approximately 1:00 PM; Attendance was taken.

Review of minutes
• Minutes from April, 29th 2016 approved without modification  
  o Motion to Approve  Dr. Jenny Love, MD, seconded by Chuck Semling, Pharm D  
• Corrections to January 20th, 2016 were reviewed and approved  
  o Motion to Approve  Dr. Jenny Love, MD, seconded by Ryan Ruggles, Pharm D

Review of Agenda
• Approved unanimously

Review of Existing Prior Authorization, Quantity limits, Edits

1. Hepatitis C Direct Acting Antivirals revised criteria were submitted to the committee.

  • DAAs Hep C for Genotype 1 draft for review  
    ▪ Harvoni & Zepatier were submitted as preferred over other DAAs.  
    ▪ Zepatier with appropriate testing for polymorphism (NS5A) in genotype 1a.  
      ▪ A Metavir Fibrosis score of F2-F4 remains necessary for approval  
      ▪ or equivalent severity was added to the criteria  
        ▪ Equivalent severity is defined as :  
          ▪ The patient has a Metavir Fibrosis score of F0-F4 WITH documented extrahepatic manifestations of advancing disease  
          ▪ The patient has a Metavir Fibrosis score of F0-F4 WITH a documented HIV/ AIDS infection.

  • The committee, in reviewing the screening policy for the use of alcohol, illicit drugs, and controlled substances recommended changes.  
    ▪ After discussion, the committee would like to see the criteria reworded to address the meaning of illicit drugs in the policy, and how it relates to marijuana.  
    ▪ Committee wants the criteria to include clear communication with the physician before a potential rejection related to drug and alcohol screening.

  • In regard to limitations and complications that single out the need for a specialist within the criteria the committee would like the phrase “necessity for a specialist “to be clarified as a specialist must be in consultation or involved in treatment.
• The Alaska State Medicaid Pharmacists will address their concerns within the criteria draft and bring the draft back for the committee.

The committee approved the criteria draft for DAAs Hep C for Genotype 1 and the clinical pathway, restrictions. Specifically they approved these changes:
1. Preferred status to Harvoni & Zepatier.
2. A Metavir Fibrosis score of F2-F4 for approval or an equivalent severity.
3. The definition of equivalent severity for select patients with a Metavir Fibrosis score of F2-F4.

The committee would like the criteria draft changed as follows:
1. Wording related to positive drug screens will be changed.
2. Where the criteria calls for a specialist, the statement will be clarified to a specialist must be in consultation or involved in treatment.

John Pappenheim MD made the motion and it was seconded by Ryan Ruggles, Pharm D. The committee approved the motion.

• DAAs Hep C for Genotype 2-3 draft for review
  o Epclusa submitted as preferred agent over other DAAs for Genotypes 2-3.
  o A Metavir Fibrosis score of F2-F4 remains necessary for approval
  o or equivalent severity was added to the criteria
    ▪ Equivalent severity is defined as:
      • The patient has a Metavir Fibrosis score of F0-F4 \textbf{WITH} documented extrahepatic manifestations of advancing disease
      • The patient has a Metavir Fibrosis score of F0-F4 \textbf{WITH} a documented HIV/AIDS infection.

The committee approved the criteria draft for DAAs Hep C for Genotypes 2-3 and the clinical pathway, restrictions.

The committee would like the criteria draft changed as follows:
1. Wording related to positive drug screens will be changed.
2. Where the criteria calls for a specialist, the statement will be clarified to a specialist must be in consultation or involved in treatment.

Ryan Ruggles, Pharm made the motion and it was seconded by John Pappenheim MD. The committee approved the motion.

• DAAs Hep C for Genotype 4 draft for review
  o Harvoni & Zepatier submitted as preferred agent over other DAAs for Genotypes 4.
  o A Metavir Fibrosis score of F2-F4 remains necessary for approval
  o or equivalent severity was added to the criteria
    ▪ Equivalent severity is defined as:
      • The patient has a Metavir Fibrosis score of F0-F4 \textbf{WITH} documented extrahepatic manifestations of advancing disease
      • The patient has a Metavir Fibrosis score of F0-F4 \textbf{WITH} a documented HIV/AIDS infection.

The committee approved the criteria draft for DAAs Hep C for Genotypes 4 and the clinical pathway, restrictions.

The committee would like the criteria draft changed as follows:
1. Wording related to positive drug screens will be changed.
2. Where the criteria calls for a specialist, the statement will be clarified to a specialist must be in consultation or involved in treatment.

John Pappenheim MD made the motion and it was seconded by Ryan Ruggles, Pharm D. The committee approved the motion.

- **DAAs Hep C for Genotype 5 & 6 draft for review**
  - Harvoni submitted as preferred agent over other DAAs for Genotypes 5 & 6.
  - A Metavir Fibrosis score of F2-F4 remains necessary for approval
  - or equivalent severity was added to the criteria
    - equivalent severity is defined as:
      - The patient has a Metavir Fibrosis score of F0-F4 **WITH** documented extrahepatic manifestations of advancing disease
      - The patient has a Metavir Fibrosis score of F0-F4 **WITH** a documented HIV/AIDS infection.

The committee approved the criteria draft for DAAs Hep C for Genotype 5 and the clinical pathway, restrictions.

The committee would like the criteria draft changed as follows:
1. Wording related to positive drug screens will be changed.
2. Where the criteria calls for a specialist, the statement will be clarified to a specialist must be in consultation or involved in treatment.

John Pappenheim MD made the motion and it was seconded by Ryan Ruggles Pharm D. The committee approved the motion.

2. **Botulinum Toxin revised criteria was submitted to the committee.**
   - Botox and Dysport added indication
     - Lower limb spasticity refractory to oral medications
   - Chronic migraine, headache prophylaxis
     - Committee decided to table discussion related to these agents for migraine
       - Currently prescribing is restricted to neurologists.

John Pappenheim MD made the motion to approve criteria with the exception of no change to current pathway & restrictions on migraine/ headache prophylaxis. Jenny Love MD seconded

3. **Hereditary Angioedema (Cinryze, Berinert, Firazyr)**
   - Criteria was presented for Firazyr® (icatibant injection) & Kalbitor® (ecallantide injection)
     - for the treatment of for treatment of acute attacks of hereditary angioedema (HAE)

John Pappenheim MD made the motion to approve criteria. Jenny Love MD seconded

4. **Iron Chelators- Exjade® (deferasirox), Jadenu™ (deferasirox)**
   - Criteria was presented for the use of these oral agents for iron overload.
     - Criteria for approval can be based on diagnosis code.
       - diagnosis of transfusion iron overload

DUR Committee Meeting Minutes November 18th 2016
John Pappenheim MD made the motion to approve criteria. Jenny Love MD seconded.

5. Opioid Strategic Task Force
   • Erin Narus introduced an initiative of the Opioid task force
     o Prevention of Neonatal Abstinence Syndrome
       ▪ Initially will begin as an awareness campaign
       ▪ Educating women of child bearing age who are at risk
     o Committee members see this as a need and the potential is great because it is reaching child and mother.
     o In addition opioid dependence, illicit drug use can coincide with alcohol abuse an even greater risk to the unborn child.

Meeting was adjourned.

Motion to adjourn Chuck Semling Pharm D, seconded by Ryan Ruggles Pharm D. Contested by no one.