Drug Utilization Review (DUR) Committee

September 25th 2015

Members Present

Jenny Love, MD
John Pappenheim, MD
Chuck Semling, PharmD
Erin Narus, PharmD (DHSS)
Maggi Rader, CNM

Members Absent

Non-Members Present

Tolu Balogun, PharmD (Magellan)

Meeting started at approximately 1:15 pm; Attendance was taken

Welcome
Review of minutes from April 17th meeting
Approved unanimously without modification
Review of agenda
Approved unanimously without modification
Open floor to members for comments, questions, concerns
No issues brought forward

Letters to Committee

- Request from a pharmacist to remove the HIV medications Tivicay, Triumeq and Isentress from the Interim PA drug list
- Request from a drug company to remove Purixan an oral liquid form of mercaptopurine used for acute lymphoblastic leukemia from the prior authorization list.
- *Committee action* – move toward diagnosis driven auto-PAs utilizing ICD-10 codes once available

ProDUR

- **Review of existing Prior Authorizations, Quantity Limits, Edits**
  - Hepatitis C (HCV) Criteria for Genotype 1a and 1b Review
    - **Inclusion Criteria**
      - HCV genotype 1 patients age ≥ 18 years , Metavir score F2-F4
      - Patient must abstain from alcohol and illicit drugs, confirmed by a drug test within 90 days prior to treatment.
      - If HCV/HIV co-infected documentation of the following are required: CD4 count, HIV viral load, and the treatment regimen for HIV.
      - Documentation of prior treatment regimens for HCV and duration is required.
      - The use of simeprevir in the regimen to treat HCV genotype 1a requires testing for NS3 Q80K polymorphism . The patient must be simeprevir naïve.
    - **Renewal Criteria**
      - Regimens with durations longer than 8 weeks will be renewed if:
        - HCV RNA < 25 IU/mL at treatment week 4.
        - **OR** If HCV RNA detectable at treatment week 4 then HCV RNA at week 6 must be lower than week 4 or undetectable.
    - **Treatment Criteria with Preferred agents is as follows**
      - Genotype 1 a & b
        - Treatment Naïve,without cirrhosis, Metavir F2-F3
          - HCV RNA ≤ 6 million IU/mL Harvoni **8 weeks**
          - HCV RNA > 6 million IU/mL Harvoni **12 weeks**
        - Treatment Naïve with cirrhosis, Metavir score F4
          - Harvoni **12 weeks**

- Treatment experienced,without cirrhosis, Metavir F2-F3
  - Harvoni **12 weeks**
- **.** Treatment experienced, with cirrhosis, Metavir F4
  - Harvoni + Ribavirin **12 weeks**
  - Harvoni **24 weeks**

- Genotype 1 a Treatment Naïve or Treatment Experienced
  - Without cirrhosis, Metavir F2-F3
    - Viekira Pak + Ribavirin **12 weeks**
  - With cirrhosis , Metavir F4
    - Viekira Pak + Ribavirin **24 weeks**
- Genotype 1 b Treatment Naïve or Treatment Experienced
  - Without cirrhosis, Metavir F2-F3
    - Viekira Pak **12 weeks**
  - With cirrhosis , Metavir F4
    - Viekira Pak + Ribavirin **12 weeks**
- Genotype 1, s/p liver transplant
  - Viekira Pak + Ribavirin **24 weeks**
- Genotype 1 Decompensated cirrhosis
  - restricted to specialists
    - Criterias include Harvoni and ribavirin
- Genotype 1 Hepatocellular Carcinoma
  - restricted to specialists
    - Sovaldi

- **Exclusion Criteria**
  - Reviewed and approved using evidence based standard clinical guidelines
- **Limits**
  - Retreatment will not be authorized within 2 years

After discussion a motion was made to approve criteria as presented.

Approved unanimously

- Hepatitis C (HCV) Criteria for Genotypes 2,3,4 Review
  - **Inclusion Criteria**
    - HCV genotype 2,3,4 patients age ≥ 18 years , Metavir score F2-F4
    - Patient must abstain from alcohol and illicit drugs, confirmed by a drug test within 90 days prior to treatment.
    - If HCV/HIV co-infected documentation of the following are required: CD4 count, HIV viral load, and the treatment regimen for HIV.
    - Documentation of prior treatment regimens for HCV and duration is required.
  - **Renewal Criteria**
    - Regimens with durations longer than 8 weeks will be renewed if:
      - HCV RNA < 25 IU/mL at treatment week 4.
      - **OR** If HCV RNA detectable at treatment week 4 then HCV RNA at week 6 must be lower than week 4 or undetectable.
  - **Treatment Criteria with preferred agents is as follows**
    - Genotype2 Metavir score F2-F4
      - Sovaldi + ribavirin for **12 weeks**
    - Genotype 3 Metavir score F2-F4
      - Sovaldi + ribavirin **for 24 weeks**

- Genotype4 Metavir score F2-F4
    - Sovaldi + peginterferon alfa + ribavirin **for 12 weeks**
- Genotype 2,3,4 Hepatocellular Carcinoma
    - Awaiting liver transplant AND
    - Meets Milan Criteria
        - Sovaldi + ribavirin
            - For 48 weeks OR
            - Until liver transplant.
- Genotype 2,3,4 with decompensated cirrhosis
    - Restricted to specialist
- Mixed Genotype
    - Restricted to specialist

- **Exclusion Criteria**
    - Reviewed and approved using evidence based standard clinical guidelines
- **Limits**
    - Retreatment will not be authorized within 2 years

After discussion a motion was made to approve criteria as presented.

Approved unanimously

Meeting adjourned at 3:35pm
Next Meeting: TBD