VENTURA COUNTY HEALTH CARE PLAN

Preferred Specialty Management (PSM) Policy for Hepatitis C Virus (HCV) Direct-Acting Antivirals (DAAs)

Effective Date: 7/24/18

Date Developed: 6/22/18 by Catherine Sanders, MD

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PREFERRED SPECIALTY MANAGEMENT (PSM) POLICY FOR HEPATITIS C VIRUS (HCV) DIRECT-ACTING ANTIVIRALS (DAAs)

DRUGS AFFECTED:

- Daklinza™ (daclatasvir tablets – Bristol Meyers Squibb)
- Epclusa® (velpatasvir/sofosbuvir – Gilead)
- Harvoni® (ledipasvir/sofosbuvir tablets – Gilead)
- Mavyret (glecaprevir/pibrentasvir-AbbVie)
- Olysio® (simeprevir tablets – Janssen)
- Sovaldi® (sofosbuvir tablets – Gilead)
- Technivie ™ (co-formulated ombitasvir, paritaprevir, and ritonavir tablets – AbbVie)
- Viekira Pak™ (ombitasvir/paritaprevir/ritonavir tablets; dasabuvir tablets, co-packaged – AbbVie)
- Viekira XR™ (dasabuvir/ombitasvir/paritaprevir/ritonavir extended-release tablets – AbbVie)
- Vosevi (sofosbuvir/velpatasvir/voxilaprevir tablets-Gilead)
- Zepatier™ (grazoprevir/elbasvir tablets – Merck)

Initial criteria required:

1. The patient is ≥ 18 years of age, or for Harvoni or Sovaldi + Ribavirin, patient is ≥ 12 years of age or weighting ≥ 35 kg, AND
2. The medication is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious disease physician, or a liver transplant physician; AND
3. The patient meets ONE of the following conditions (A, B or C)
   A. The patient has been documented as having a hepatic fibrosis score correlating with **Metavir Stage F2** or higher as assessed by an invasive (liver biopsy) OR non-invasive method (e.g. aspartate aminotransferase-to-platelet ratio index [APRI] score, fibrosis-4 index [FIB-4], FibroScan, FibroTest/FibroSURE); OR
   B. The patient has severe extrahepatic manifestations placing them at high risk for severe complications of their HCV (patient must meet criteria i or ii)
      i. Type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (e.g. vasculitis); OR
      ii. Proteinuria, nephrotic syndrome, or membranoproliferative glomerular nephritis; OR
   C. The patient meets BOTH of the following conditions (i and ii)
      i. The patient is at high-risk of transmitting HCV (patient must meet ONE of the following criteria a or b):
         a. The patient is on long-term (≥ 3 months) hemodialysis; OR
         b. The patient is a healthcare worker whose daily activities put them in contact with blood and/or needles; AND

ii. The patient has been counseled on ways to decrease transmission of HCV and minimize the risk of reinfection with HCV

Preferred Products:

Genotype 1: Epclusa, Harvoni, Mavyret, Viekira pak (with or without ribavirin), Viekira XR (with or without ribavirin), and Vosevi. *Patients with genotype 1 requesting Daklinza, Olysio, Sovaldi or Zepatier will be directed to a preferred product.*

Genotype 2: Epclusa, Mavyret, and Vosevi.

Genotype 3: Epclusa, Mavyret and Vosevi. *Patients with genotype 3 requesting Daklinza and/or Sovaldi will be directed to a preferred product*

Genotype 4: Epclusa, Harvoni, Mavyret, Technivie, and Vosevi. *Patients with genotype 4 requesting Zepatier will be directed to a preferred product.*

Genotype 5 or 6: Epclusa, Harvoni, Mavyret, and Vosevi.

Secondary criteria required:

Please see the individual PRIOR AUTHORIZATION DRUG GUIDELINES for the drug requested if it meets initial criteria.

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