VENTURA COUNTY HEALTH CARE PLAN

Prior Authorization DRUG Guidelines

Mavyret (glecaprevir/pibrentasvir)

Effective Date:10/24/2017

Date Developed: 9/15/2017 by Catherine Sanders, MD and ESI P&T

Date Approved by P&T Committee:10/24/17, 1/23/18, 1/22/19

(Archived 1/22/19)

Mavyret is a combination of glecaprevir and pibrentasvir. It is a direct acting antiviral (DAA). Glecaprevir inhibits hepatitis C virus NS3/4A protease which is essential for viral replication. Pibrentasvir inhibits HCV NS5A which is essential for viral RNA replication and virion assembly.

Pre-Authorization Criteria:

1. Chronic Hepatitis C Virus (HCV) Genotype 1, 2, 3, 4, 5, or 6 , **Treatment Naïve** when meets all of the following criteria (A, B, C, D, and E):
   A) The patient is ≥ 18 years of age, AND
   B) Mavyret is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious disease physician or a liver transplant physician, AND
   C) The patient is HCV treatment naïve (the patient has not had previously received treatment for their chronic HCV infection), AND
   D) The patient has a fibrosis score of ≥ 2, AND
   E) The patient meets ONE of the following criteria (i or ii):
      i) Approve for 8 weeks if the patient does not have cirrhosis, OR
      ii) Approve for 12 weeks if the patient has compensated cirrhosis (Child-Pugh A).

2. Chronic Hepatitis C Virus, Genotype 1, **Treatment Experienced** when meets the following criteria (A, B, C, and D):
   A) The patient is ≥ 18 years of age, AND
   B) Mavyret is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious disease physician or a liver transplant physician, AND
   C) The patient has a fibrosis score of ≥ 2, AND
   D) The patient meets ONE of the following conditions (I, ii, or iii):
   NS5A experienced, NS3/4 naïve
      i) Approve for 16 weeks if the patient meets all of the following criteria (a, b, and c):
         a) The patient had a prior null response, prior partial response, or had relapse after prior treatment with Daklinza or Harvoni; AND
         b) The patient has not previously been treated with one of the following NS43/4A inhibitor or NS3/4A inhibitor-containing products: Olysio, Victrelis or Incivek, Technivie, Viekira-Pak, Viekira XR, Vosevi, or Zepatier AND;
         c) The patient does not have cirrhosis or has compensated cirrhosis (Child-Pugh A).
      OR
   NS3/4-experienced, NS5A naïve
      ii) Approve for 12 weeks if the patient meets all of the following criteria (a, b, and c):

a) The patient has not previously been treated with Daklinza, Epclusa, Harvoni, Technivie, Viekira-Pak, Viekira XR, Vosevi, or Zepatier; AND
b) The patient has a prior null response, prior partial response, or had relapse after prior treatment with one of the following NS3/4A inhibitor or NS3/4A inhibitor-containing products: Olysio, Victrelis, or Incivek; AND
c) The patient does not have cirrhosis or has compensated cirrhosis (Child-Pugh A) OR

Pegylated Interferon/Interferon, Ribavirin, Sovaldi-experienced

iii) Approve for the specified duration below if patients meet both of the following criteria (a and b):
a) The patient had a prior null response, prior partial response, or had relapse after prior treatment with one of the following regimens: interferon ± ribavirin, pegylated interferon ± ribavirin, Sovaldi + ribavirin, Sovaldi + pegylated interferon + ribavirin, AND
b) The patient meets ONE of the following (1 or 2):
1) Approve for 8 weeks for patients who do not have cirrhosis, OR
2) Approve for 12 weeks for patients who have compensated cirrhosis (Child-Pugh A).

3. Chronic Hepatitis C Virus, Genotype 2, 4, 5, or 6, **Treatment-Experienced**
Approve for the duration specified below if the patient meets the following criteria (A, B, C, D and E):
A) The patient is ≥ 18 years of age, AND
B) Mavyret is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious disease physician or a liver transplant physician, AND
C) The patient has a fibrosis score of ≥ 2, AND
D) The patient had a prior null response, prior partial response, or had relapse after prior treatment with one of the following regimens: interferon ± ribavirin, pegylated interferon ± ribavirin, Sovaldi + ribavirin, Sovaldi + pegylated interferon + ribavirin, AND
E) The patient meets ONE of the following (i or ii):
i) Approve for 8 weeks for patient who do not have cirrhosis; OR
ii) Approve for 12 weeks for patients who have compensated cirrhosis (Child-Pugh A).

4. Chronic Hepatitis C Virus, Genotype 3, **Treatment-Experienced**
Approve for 16 weeks if the patient meets the following criteria (A, B, C, D, and E):
A) The patient is ≥ 18 years of age, AND
B) Mavyret is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious disease physician or a liver transplant physician, AND
C) The patient has a fibrosis score of ≥ 2, AND
D) The patient had a prior null response, prior partial response, or had relapse after prior treatment with one of the following regimens: interferon ± ribavirin, pegylated interferon ± ribavirin, Sovaldi + ribavirin, Sovaldi + pegylated interferon + ribavirin, AND
E) The patient does not have cirrhosis or has compensated cirrhosis (Child-Pugh A).

Mavyret is not to be approved for the following: HCV Child-Pugh Class C liver disease (severe hepatic impairment), HCV treatment in combination with any other direct acting antivirals (DAAs), Life expectancy less than 12 months due to non-liver related comorbidities, pediatric patients (age <18 years)

Dosing Forms:
Oral tablet: Glecaprevir 100mg and pibrentasvir 40mg

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