SPECIALTY GUIDELINE MANAGEMENT

OLYSIO (simeprevir)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications
Olysio is indicated for the treatment of adults with chronic hepatitis C virus (HCV) infection:

A. in combination with sofosbuvir in patients with HCV genotype 1 without cirrhosis or with compensated cirrhosis
B. in combination with peginterferon alfa (PEG-IFN) and ribavirin (RBV) in patients with HCV genotype 1 or 4 without cirrhosis or with compensated cirrhosis

All other indications are considered experimental/investigational and are not a covered benefit.

II. EXCLUSIONS

A. Decompensated cirrhosis/moderate or severe hepatic impairment (Child Turcotte Pugh Class B or C)
B. Prior treatment failure with an HCV protease inhibitor (eg, telaprevir, boceprevir, simeprevir, paritaprevir) despite adequate dosing and duration of therapy

Note: When the requested drug is being used in a combination therapy regimen, exclusions to the other antiviral drugs also apply.

III. INITIAL CRITERIA FOR APPROVAL

A. **Chronic hepatitis C virus infection, in combination with PEG-IFN and RBV**
   1. **Genotype 1 or 4 infection**
      Authorization of up to 6 weeks total may be granted for initiation of therapy in members who are treatment-naïve or failed prior treatment with PEG-IFN and RBV AND meet one of the following criteria:
      a. Genotype 1a infection without the NS3 Q80K polymorphism
      b. Genotype 1b infection
      c. Genotype 4 infection

B. **Chronic hepatitis C virus infection, in combination with Sovaldi**
   1. **Genotype 1a infection**
      a. Authorization of up to 12 weeks total may be granted for members without cirrhosis who are treatment-naïve or failed prior treatment with PEG-IFN and RBV.
      b. Authorization of up to 24 weeks total may be granted for members with compensated cirrhosis without the NS3 Q80K polymorphism who are treatment-naïve or failed prior treatment with PEG-IFN and RBV.
   2. **Genotype 1b infection**
      a. Authorization of up to 12 weeks total may be granted for members without cirrhosis who are treatment-naïve or failed prior treatment with PEG-IFN and RBV.

b. Authorization of up to 24 weeks total may be granted for members with compensated cirrhosis who are treatment-naïve or failed prior treatment with PEG-IFN and RBV.

3. Recurrent HCV infection post liver transplantation
Authorization of up to 12 weeks total may be granted for members without cirrhosis or with compensated cirrhosis who have recurrent HCV genotype 1 infection post liver transplantation.

C. **Chronic hepatitis C virus infection, in combination with Sovaldi and RBV**

1. Genotype 1a infection
Authorization of up to 24 weeks total may be granted for members with compensated cirrhosis without the NS3 Q80K polymorphism who are treatment-naïve or failed prior treatment with PEG-IFN and RBV.

2. Genotype 1b infection
Authorization of up to 24 weeks total may be granted for members with compensated cirrhosis who are treatment-naive or who have failed prior treatment with PEG-IFN and RBV.

3. Genotype 1 infection and previous failure of HCV NS5A inhibitor therapy
Authorization of up to 24 weeks total may be granted for members with compensated cirrhosis who failed prior treatment with an HCV NS5A inhibitor and have NS5A inhibitor RAVs but do not have NS3 protease inhibitor RAVs.

4. Recurrent HCV infection post liver transplantation
Authorization of up to 12 weeks total may be granted for members without cirrhosis or with compensated cirrhosis who have recurrent HCV genotype 1 infection post liver transplantation.

D. **HCV and HIV Coinfection**
Authorization may be granted for members with HCV and HIV coinfection when the criteria for approval of the requested regimen in Section A, B or C above are met.

IV. CONTINUATION OF THERAPY

A. **Chronic hepatitis C virus infection, in combination with PEG-IFN and RBV**
Genotype 1 or 4 infection at week 4 assessment
Authorization of up to 12 weeks total may be granted for members with HCV-RNA < 25 IU/mL at week 4 of treatment.

V. REFERENCES

1. Olysio [package insert]. Titusville, NJ: Janssen Products, LP; May 2016.
2. AASLD/IDSA/IAS–USA. Recommendations for testing, managing, and treating hepatitis C. http://www.hcvguidelines.org. Last changes made July 8, 2016. Accessed September 6, 2016.