SPECIALTY GUIDELINE MANAGEMENT

DAKLINZA (daclatasvir)

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.

A. FDA-Approved Indication
Daklinza is indicated for use with sofosbuvir, with or without ribavirin, for the treatment of patients with chronic hepatitis C virus (HCV) genotype 1 or genotype 3 infection.

Limitations of Use:
Sustained virologic response (SVR) rates are reduced in HCV genotype 3-infected patients with cirrhosis receiving Daklinza in combination with sofosbuvir for 12 weeks.

B. Compendial Uses
Chronic hepatitis C genotype 2 or 4 infection

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

II. CRITERIA FOR APPROVAL

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

1. Genotype 1 infection

a. Authorization of up to 12 weeks total may be granted for treatment-naive members without cirrhosis.
b. Authorization of up to 12 weeks total may be granted for members without cirrhosis who failed prior treatment with peginterferon alfa (PEG-IFN) and ribavirin (RBV) with or without an HCV protease inhibitor.
c. Authorization of up to 24 weeks total may be granted for treatment-naive members with compensated cirrhosis.
d. Authorization of up to 24 weeks total may be granted for members with compensated cirrhosis who failed prior treatment with PEG-IFN and RBV with or without an HCV protease inhibitor.

2. Genotype 2 infection

a. Authorization of up to 12 weeks total may be granted for treatment-naive members without cirrhosis.
b. Authorization of up to 24 weeks total may be granted for treatment-naïve members with compensated cirrhosis.
c. Authorization of up to 12 weeks total may be granted for members without cirrhosis who failed prior treatment with PEG-IFN and RBV.
d. Authorization of up to 24 weeks total may be granted for members with compensated cirrhosis who failed prior treatment with PEG-IFN and RBV.
e. Authorization of up to 24 weeks total may be granted for members who failed prior treatment with sofosbuvir and ribavirin.

3. Genotype 3 infection

a. Authorization of up to 12 weeks total may be granted for treatment-naive members without cirrhosis.
b. Authorization of up to 12 weeks total may be granted for members without cirrhosis who failed prior treatment with PEG-IFN and RBV.
c. Authorization of up to 24 weeks total may be granted for treatment-naive members with compensated cirrhosis.
d. Authorization of up to 12 weeks total may be granted for members without cirrhosis who failed prior treatment with a sofosbuvir-based regimen.

4. Decompensated cirrhosis (Child Turcotte Pugh [CTP] class B or C)

Authorization of up to 24 weeks total may be granted for members with HCV genotype 1 or 4 infection and documented anemia (baseline hemoglobin [Hgb] below 10 g/dL) or RBV ineligibility (see Section III).

5. Recurrent HCV infection post liver transplantation

a. Authorization of up to 24 weeks total may be granted for treatment-naive members who have recurrent HCV genotype 1 or 4 infection post liver transplantation and documented anemia (baseline Hgb below 10 g/dL) or RBV ineligibility (see Section III).
b. Authorization of up to 24 weeks total may be granted for members who have recurrent HCV genotype 2 or 3 infection post liver transplantation and documented anemia (baseline Hgb below 10 g/dL) or RBV ineligibility (see Section III).

B. **Chronic hepatitis C virus, in combination with Sovaldi and Ribavirin**

1. Genotype 1 infection

a. Authorization of up to 24 weeks total may be granted for treatment-naive members with compensated cirrhosis.
b. Authorization of up to 24 weeks total may be granted for members with compensated cirrhosis who failed prior treatment with PEG-IFN and RBV with or without an HCV protease inhibitor.

2. Genotype 2 infection

Authorization of up to 24 weeks total may be granted for members who failed prior treatment with sofosbuvir and ribavirin.

3. Genotype 3 infection

a. Authorization of up to 24 weeks total may be granted for treatment-naive members with compensated cirrhosis.
b. Authorization of up to 12 weeks total may be granted for members without cirrhosis who failed prior treatment with PEG-IFN and RBV and have the Y93H variant associated with daclatasvir resistance.
c. Authorization of up to 24 weeks total may be granted for members with compensated cirrhosis who failed prior treatment with PEG-IFN and RBV.
d. Authorization of up to 24 weeks total may be granted for members who failed prior treatment with sofosbuvir and RBV.

4. Decompensated cirrhosis (CTP class B or C)

Authorization of up to 12 weeks total may be granted for members with HCV genotype 1, 2, 3 or 4 infection.

5. Recurrent HCV infection post liver transplantation

Authorization of up to 12 weeks total may be granted for members with recurrent HCV genotype 1, 2, 3 or 4 infection post liver transplantation.

C. **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 or B above are met.

III. APPENDIX: RIBAVIRIN INELIGIBILITY

RBV ineligibility is defined as one or more of the below:

- Intolerance to RBV
- Pregnant female or male whose female partner is pregnant

- Hemoglobinopathy
- Coadministration with didanosine
- History of significant or unstable cardiac disease

IV. REFERENCES

1. Daklinza [package insert]. Princeton, NJ: Bristol Myers Squibb Company; April 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 9, 2016.