Reference number(s)
2136-A, 2675-A

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 (SVR12) rates are reduced in HCV genotype 3-infected patients with cirrhosis receiving Daklinza in combination with sofosbuvir for 12 weeks.

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR APPROVAL

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

1. Genotype 1 infection
Authorization of up to 12 weeks total may be granted for members without cirrhosis or with compensated cirrhosis.

2. Genotype 3 infection
Authorization of up to 12 weeks total may be granted for members without cirrhosis.

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

1. Genotype 3 infection
Authorization of up to 12 weeks total may be granted for members with compensated cirrhosis.

2. Decompensated cirrhosis (CTP class B or C)
Authorization of up to 12 weeks total may be granted for members with HCV genotype 1, or 3 infection.

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

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

IV. 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

V. REFERENCES

1. Daklinza [package insert]. Princeton, NJ: Bristol Myers Squibb Company; November 2017.