SPECIALTY GUIDELINE MANAGEMENT

TECHNIVIE (ombitasvir/paritaprevir/ritonavir)

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
Technivie is indicated in combination with ribavirin for the treatment of patients with genotype 4 chronic hepatitis C virus (HCV) infection without 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. CRITERIA FOR APPROVAL

A. **Chronic hepatitis C virus infection, in combination with ribavirin (RBV)**
Genotype 4 infection
Authorization of up to 12 weeks total may be granted for members without cirrhosis or with compensated cirrhosis who are either of the following:
1. Treatment-naïve
2. Failed prior treatment with peginterferon alfa and RBV

B. **Chronic hepatitis C virus infection, without RBV**
Genotype 4 infection
Authorization of up to 12 weeks total may be granted for members without cirrhosis who meet all of the following criteria:
1. Treatment-naïve
2. Member has intolerance to RBV, has documented anemia (baseline hemoglobin below 10 g/dL) or RBV ineligibility (see Section V for ribavirin ineligibility)

C. **HCV and HIV coinfection**
Authorization may be granted for members who meet all of the following criteria:
1. Member meets the criteria for approval for the requested regimen in section A or B above
2. Member is currently receiving antiretroviral therapy

IV. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet ALL

initial authorization criteria.

V. APPENDIX: RIBAVIRIN INELIGIBILITY

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

- Pregnant female or male whose female partner is pregnant
- Hemoglobinopathy
- Coadministration with didanosine
- History of significant or unstable cardiac disease

VI. REFERENCES

1. Technivie [package insert]. North Chicago, IL: AbbVie Inc.; June 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.