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 or with compensated cirrhosis.

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

II. EXCLUSIONS

Coverage will not be provided for members with decompensated cirrhosis/moderate or severe hepatic impairment (Child Turcotte Pugh Class B or C)

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 with HCV and HIV coinfection when the criteria for approval of the requested regimen in Section A or B above are met.

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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.; July 2018.

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