SPECIALTY GUIDELINE MANAGEMENT

TECHNIVIE
(ombitasvir/paritaprevir/ritonavir)

POLICY

A. 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.

B. REQUIRED DOCUMENTATION
The following information is necessary to initiate the prior authorization review:
• Presence of viral load (HCV RNA) in the serum prior to treatment with the requested regimen
• Genotype and subtype (if applicable)
• Baseline or current viral load
• Laboratory testing for resistance-associated variants (if applicable)
• METAVIR fibrosis score (if applicable)
• Liver transplantation status
• Treatment plan including treatment regimen and duration
• Prior treatment regimen(s) and response
• Prescriber specialty

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

D. CRITERIA FOR APPROVAL
1. Chronic hepatitis C virus infection, in combination with ribavirin (RBV)
   1.1 Genotype 4 infection
      a. Authorization of up to 12 weeks total may be granted for members without cirrhosis or with compensated cirrhosis who meet one of the following criteria:
         i. Treatment-naïve
         ii. Failed prior treatment with peginterferon alfa and RBV

2. Chronic hepatitis C virus infection, without RBV
   2.1 Genotype 4 infection
      a. Authorization of up to 12 weeks total may be granted for members without cirrhosis who meet all of the following criteria:
         i. Treatment-naïve
         ii. Member has intolerance to RBV, has documented anemia (baseline hemoglobin below 10 g/dL) or RBV ineligibility (see Section G for ribavirin ineligibility)
3. HCV and HIV coinfection
   a. Authorization may be granted for members who meet all of the following criteria:
      i. Member meets the criteria for approval for the requested regimen in section D.1. or D.2.
      ii. Member is currently receiving antiretroviral therapy

E. CONTINUATION OF THERAPY
   All members (including new members) requesting authorization for continuation of therapy must meet ALL initial authorization criteria.

F. DOSAGE AND ADMINISTRATION
   Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

   Dispensing Limits
   A 28-day supply dispense limit applies to all targeted hepatitis C agents in order to better manage the therapy regimen.

G. 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

REFERENCES