

Prior Authorization DRUG Guidelines

**Technivie™ (ombitasvir/paritaprevir/ritonavir
tablets – AbbVie)**

Effective Date: 7/24/2018

Date Developed: 7/24/2018 by Catherine Sanders, MD and ESI P&T

Date Approved by P&T Committee: 7/24/2018

(Archived 1/22/19)

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.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Technivie is recommended in those who meet the following criteria:

FDA-Approved Indications

1. **Chronic Hepatitis C Virus (HCV) Genotype 4.** Approve for 12 weeks if patients meet all of the following criteria (A, B, C and D):
 - A) The patient is ≥ 18 years of age; AND
 - B) Technivie is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician; AND
 - C) The patient has a fibrosis score of ≥ 2 , AND
 - D) If the patient has compensated cirrhosis (Child-Pugh A), Technivie must be prescribed **in combination with ribavirin.**

Technivie is indicated in combination with ribavirin for the treatment of patients with genotype 4 chronic hepatitis C virus (HCV) infection without cirrhosis and with compensated cirrhosis. Guidelines from the American Association for the Study of Liver Diseases (AASLD) recommend Technivie + weight-based ribavirin (WBR) for treatment-experienced and treatment-naïve patients, including those with cirrhosis. In the AGATE-1 trial, in patients with cirrhosis, Technivie was studied in combination with WBR.⁷

Other Uses with Supportive Evidence

2. **Patient Has Been Started on Technivie.** Approve for an indication or condition addressed as an approval in the Recommended Authorization Criteria section (FDA-Approved Indication). Approve

the duration described above to complete a 12-week course therapy (e.g., a patient who should receive 12 weeks, and has received 3 weeks should be approved for 9 weeks to complete their 12-week course).

Technivie is not approved for the following: Hepatitis C Virus (HCV) with Child-Pugh Class B or Child-Pugh Class C Liver Disease (Moderate or Severe Hepatic Impairment); Hepatitis C Virus (HCV), non-genotype 4; Hepatitis C Virus (HCV) [any genotype], Combination with Any Other DAAs (Not Including Ribavirin); Life Expectancy < 12 Months Due to Non-Liver Related Comorbidities; Pediatric Patients (Age < 18 Years); Retreatment with Technivie in Patients Who Have Previously Received Viekira Pak (paritaprevir/ritonavir/ombitasvir + dasabuvir) or Technivie

Revision History:

Date Created: 7/24/18 by C. Sanders, MD

Date Approved by P&T Committee: 7/24/18

Date Reviewed/Archived: 1/22/19 by C. Sanders, MD; R. Sterling, MD

Date Approved by P&T Committee: 1/22/19

Revision Date	Content Revised (Yes/No)	Contributors	Review/Revision Notes
7/24/18	No	Catherine Sanders, MD	Created
1/22/19	No	Catherine Sanders, MD; Robert Sterling, MD	Archived – check ESI