Clinical Policy: Ombitasvir/Paritaprevir/Ritonavir (Technivie)

Reference Number: PA.CP.PHAR.276
Effective Date: 01/18
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Description
Ombitasvir/paritaprevir/ritonavir (Technivie®) is a combination fixed-dose oral tablet formulation consisting of an NS5A inhibitor (ombitasvir), NS3/4A protease inhibitor (paritaprevir), and CYP3A inhibitor (ritonavir).

FDA-Approved Indication
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

Policy/Criteria
It is the policy of Pennsylvania Health and Wellness ® that Technivie is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria
*** Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria ***

A. Chronic Hepatitis C Infection (must meet all)**:**
1. Age ≥ 18 years;
2. Diagnosis of chronic hepatitis C virus (HCV) infection as evidenced by detectable HCV RNA (ribonucleic acid) levels within the past 3 months;
3. Confirmed HCV genotype is 4;
4. If actively abusing alcohol or IV drugs, or has a history of abuse, has documentation of prescriber counseling regarding the risks of alcohol or IV drug abuse and an offer of a referral for substance use disorder treatment.
5. Has all of the following:
   a. Documented quantitative HCV RNA at baseline that was tested within the past 3 months.
   b. Dose not have a life expectancy of less than 12 months due to non-liver-related comorbid conditions.
   c. Has correct or addressed the causes of non-adherence to a previously prescribed Hepatitis C treatment regimen if the recipient has a history of failed treatment due to non-adherence.
   d. Had all potential drug interactions addressed by the prescriber
6. Prescribed regimen is consistent with an FDA or AASLD-IDSA recommended regimen (*see Section V Dosage and Administration for reference)*;
7. If member is without cirrhosis or with compensated cirrhosis (Child-Pugh A): contraindication or intolerance to Mavyret;
   a. Has a documented commitment to adherence with the planned course of treatment
8. If HCV/HIV-1 (human immunodeficiency virus type-1) co-infection, member is or will be on a suppressive antiretroviral drug regimen to reduce the risk of HIV-1

protease inhibitor drug resistance; or if not being treated for HIV the medical record documents the rationale for not being treated.

9. Member meets one of the following (a or b):
   a. Member is hepatitis B virus (HBV) negative and vaccinated against HBV;
   b. If member is HBV positive, documentation that concurrent HBV infection is being treated (e.g., tenofovir alafenamide, adefovir, entecavir), unless contraindicated or clinically significant adverse effects are experienced (*see Appendix B*);
10. Member has none of the following contraindications:
    a. If prescribed with ribavirin, member has none of the following contraindications:
       i. Pregnancy or possibility of pregnancy - member or partner;
11. Dose does not exceed ombitasvir/paritaprevir/ritonavir 25 mg/15 0mg/100 mg (2 tablets) per day.

Approval duration: 12 weeks*(*Approved duration should be consistent with a regimen in Section V Dosage and Administration)*

B. Other diagnoses/indications: Refer to PA.CP.PHAR.57 - Global Biopharm Policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Approval

*** Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria ***

A. Chronic Hepatitis C Infection (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. If HCV/HIV-1 co-infection, member meets one of the following (a or b):
   a. Member is or will be on a suppressive antiretroviral drug regimen to reduce the risk of HIV-1 protease inhibitor drug resistance;
   b. Medical record documents the rationale for not being treated;
3. Dose does not exceed ombitasvir/paritaprevir/ritonavir 25mg/150mg/100mg (2 tablets) per day.

Approval duration: up to a total of 12 weeks*

*(*Approved duration should be consistent with a regimen in Section V Dosage and Administration)*

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – PA.CP.PHAR.57 or evidence of coverage documents.

IV. Appendices

Appendix A: Abbreviation Key

ALT: alanine aminotransferase
APRI: AST to platelet ratio
AASLD: American Association for the Study of Liver Diseases
CTP: Child Turcotte Pugh
DAA: direct-acting antiviral
FIB-4: Fibrosis-4 index
HBeAg: hepatitis B virus envelope antigen
HBV: hepatitis B virus
HCC: hepatocellular carcinoma
HCV: hepatitis C virus
HIV: human immunodeficiency virus
IDSA: Infectious Diseases Society of America
MRE: magnetic resonance elastography
NS3/4A, NS5A/B: nonstructural protein
RBV: ribavirin

Appendix B: General Information

- Hepatitis B Reactivation is a black box warning for all direct-acting antiviral drugs for the treatment of HCV. The provider must provide either:
  - Documentation of absence of concurrent HBV infection as evidenced by laboratory values showing absence of hepatitis B virus envelope antigen (HBeAg) and HBV DNA;
  - Documentation that HBV co-infected patient may not be candidates for therapy as evidenced by one of the following:
    - Absence of HBeAg, HBV DNA less than 2,000 international units/mL, and alanine aminotransferase (ALT) level within 1 to 2 times the upper limit of normal;
    - HBeAg-positive and HBV DNA greater than 1,000,000 international units/mL and ALT level within 1 to 2 times the upper limit of normal;
  - Documentation that concurrent HBV infection is being treated (e.g., tenofovir alafenamide, adefovir, entecavir), unless contraindicated or clinically significant adverse effects are experienced
- The 2016 AASLD/IDSA treatment guideline for HBV consider ALT levels <30 U/L for men and <19 U/L for women as upper limits of normal.
- The 2016 AASLD/IDSA treatment guideline for HBV recommend adults with compensated cirrhosis, even with low levels of viremia (<2,000 IU/mL) be treated with antiviral therapy to reduce the risk of decompensation, regardless of ALT level. The recommendation extends to adults with decompensated cirrhosis be treated with antiviral therapy indefinitely regardless of HBV DNA level, HBeAg status, or ALT level to decrease the risk of worsening liver-related complications.

Appendix C: Direct-Acting Antivirals (DAAs) for Treatment of HCV Infection

Brand Name	Drug Class				
	NS5A Inhibitor	Nucleotide Analog NS5B Polymerase Inhibitor	Non-Nucleoside NS5B Palm Polymerase Inhibitor	NS3/4A Protease Inhibitor (PI)**	CYP3A Inhibitor
Daklinza	Daclatasvir				
Epclusa*	Velpatasvir	Sofosbuvir			
Harvoni*	Ledipasvir	Sofosbuvir			

Brand Name	Drug Class				
	NS5A Inhibitor	Nucleotide Analog NS5B Polymerase Inhibitor	Non-Nucleoside NS5B Palm Polymerase Inhibitor	NS3/4A Protease Inhibitor (PI)**	CYP3A Inhibitor
Olysio				Simeprevir	
Sovaldi		Sofosbuvir			
Technivie*	Ombitasvir			Paritaprevir	Ritonavir
Viekira XR/PAK*	Ombitasvir		Dasabuvir	Paritaprevir	Ritonavir
Zepatier*	Elbasvir			Grazoprevir	

*Combination drugs
**Additional PIs no longer recommended: Victrelis (boceprevir), Incivek (telaprevir)

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose	Reference
Genotype 4: Treatment-naïve or treatment-experienced with pegylated interferon / ribavirin with or without compensated cirrhosis	Technivie 2 tablets PO qAM plus weight-based ribavirin For 12 weeks	Technivie (paritaprevir 150 mg, ritonavir 100 mg, ombitasvir 25 mg): 2 tablets per day	1) FDA-approved labeling 2) AASLD-IDSA* https://www.hcvguidelines.org/

**AASLD/IDSA treatment guidelines for chronic hepatitis C infection are updated at irregular intervals; refer to the most updated AASLD/IDSA guideline for most accurate treatment regimen.*

VI. Product Availability

Tablet: paritaprevir 75 mg, ritonavir 50 mg, ombitasvir 12.5 mg

References

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