Treatment of Hepatitis C with ombitasvir, paritaprevir, and ritonavir (Technivie™)

Policy # 00478
Original Effective Date: 12/16/2015
Current Effective Date: 12/14/2020

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Treatment of Hepatitis C with Dual Therapy (Ribavirin Plus Pegylated Interferon Alfa) is addressed separately in medical policy 00374.

Note: Pegylated Interferons (Pegasys®, PegIntron®)‡ for Other (Non-Hepatitis C) Uses is addressed separately in medical policy 00375.

Note: Treatment of Hepatitis C with a sofosbuvir (Sovaldi®)‡ Based Regimen is addressed separately in medical policy 00397.

Note: Treatment of Hepatitis C with sofosbuvir/ledipasvir (Harvoni®‡, Authorized Generic) is addressed separately in medical policy 00455.

Note: Treatment of Hepatitis C with ombitasvir, paritaprevir, ritonavir, and dasabuvir (Viekira Pak™/Viekira XR™)‡ is addressed separately in medical policy 00462.

Note: Treatment of Hepatitis C with daclatasvir (Daklinza™)‡ and sofosbuvir (Sovaldi®)‡ is addressed separately in medical policy 00479.

Note: Treatment of Hepatitis C with elbasvir and grazoprevir (Zepatier™)‡ is addressed separately in medical policy 00509.

Note: Treatment of Hepatitis C with sofosbuvir/velpatasvir (Epclusa®‡, Authorized Generic) is addressed separately in medical policy 00514.

Note: Treatment of Hepatitis C with glecaprevir/pibrentasvir (Mavyret™)‡ is addressed separately in medical policy 00593.

Treatment of Hepatitis C with ombitasvir, paritaprevir, and ritonavir (Technivie™)

Policy # 00478
Original Effective Date: 12/16/2015
Current Effective Date: 12/14/2020

Note: Treatment of Hepatitis C with sofosbuvir/velpatasvir/voxilaprevir (Vosevi™)‡ is addressed separately in medical policy 00594.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider treatment with ombitasvir, paritaprevir, and ritonavir (Technivie™)‡ in individuals with chronic hepatitis C virus (HCV) to be **eligible for coverage.****

Patient Selection Criteria

Based on the review of available date, the Company may consider ombitasvir, paritaprevir, and ritonavir (Technivie) when the following criteria are met:

- Patient has a diagnosis of chronic hepatitis C virus (HCV) genotype 4; AND
- Patient does NOT have cirrhosis; AND
- Patient does NOT have moderate to severe hepatic impairment (Child-Pugh B/C); AND
- Patient is using Technivie in combination with ribavirin (UNLESS the patient is treatment naïve AND cannot take or cannot tolerate ribavirin); AND
- Patient is receiving a 12 week regimen of Technivie; AND
- There is clinical evidence or patient history that suggests the use of sofosbuvir/velpatasvir (Epclusa), sofosbuvir/ledipasvir (Harvoni), or glecaprevir/pibrentasvir (Mavyret) will be ineffective or will cause an adverse reaction to the patient.
  *Note that failure to meet this criterion, which is an additional company requirement, will result in a denial of not medically necessary***

When Services Are Considered Not Medically Necessary

Based on review on available data, the Company considers the use of ombitasvir, paritaprevir, and ritonavir (Technivie) in the absence of clinical evidence or patient history that suggests the use of sofosbuvir/velpatasvir (Epclusa), sofosbuvir/ledipasvir (Harvoni), or glecaprevir/pibrentasvir

Treatment of Hepatitis C with ombitasvir, paritaprevir, and ritonavir (Technivie™)

Policy # 00478
Original Effective Date: 12/16/2015
Current Effective Date: 12/14/2020

(Mavyret) will be ineffective or will cause an adverse reaction to the patient to be **not medically necessary.****

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review on available data, the Company considers the use of ombitasvir, paritaprevir, and ritonavir (Technivie) for the treatment of individuals with chronic hepatitis C virus (HCV) when patient selection criteria are not met (with the exception of the criterion denoted in the patient selection criteria above as **not medically necessary****) to be **investigational.***

Background/Overview

Technivie is a fixed dose combination of ombitasvir (a hepatitis C virus NS5A inhibitor), paritaprevir (a hepatitis C virus NS3/4A protease inhibitor), and ritonavir (a CYP3A inhibitor) indicated for the treatment of patients with genotype 4 chronic hepatitis C virus infection without cirrhosis. Technivie is contraindicated in those with moderate to severe hepatic impairment (Child-Pugh B and C). Technivie is supplied as tablets that contain 12.5 mg of ombitasvir, 75 mg of paritaprevir, and 50 mg of ritonavir. Technivie is dosed at two tablets taken orally once daily (in the morning) with a meal without regard to fat or calorie content. Technivie is recommended to be used in combination with ribavirin, however Technivie without ribavirin may be considered for treatment naïve patients who cannot take or tolerate ribavirin.

Hepatitis C

Hepatitis C is the most common blood borne pathogen. In the US, there are approximately 5.2 million people chronically infected with hepatitis C. Hepatitis C, a single-stranded RNA virus, is genetically complex with several recognized genotypes. Genotypes 1, 2, and 3 are the most frequently encountered genotypes worldwide. Type 1a is most frequently found in Northern Europe and North America, while 1b is most common in Japan and Southern and Eastern Europe. There is a 1.14% prevalence of genotype 4 in the United States. Egypt has the highest prevalence (15%) of genotype 4.

Treatment of Hepatitis C with ombitasvir, paritaprevir, and ritonavir (Technivie™)

Policy # 00478
Original Effective Date: 12/16/2015
Current Effective Date: 12/14/2020

Technivie gained FDA approval for the treatment of genotype 4 HCV in mid-2015. Harvoni also gained approval for the treatment of genotype 4 patients in late 2015 (see policy 00455). Another drug regimen approved for genotype 4 HCV is Sovaldi plus pegylated interferon plus ribavirin (see policy 00397) for 12 weeks of therapy. Technivie hasn't been studied in patients with cirrhosis. However, it has an exceptional sustained virologic response (SVR) at 12 weeks in those without cirrhosis. It is also a pegylated interferon free regimen. Harvoni offers a pegylated interferon and ribavirin free regimen. Most recently various new drugs are approved for use in genotype 4 patients. These new drugs include Epclusa (policy 00514), Mavyret (see policy 00593), and Vosevi (see policy 00594).

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Technivie was approved in July of 2015 for the treatment of patients with genotype 4 chronic hepatitis C virus infection without cirrhosis. Technivie is contraindicated in those with moderate to severe hepatic impairment (Child-Pugh B and C).

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, Blue Cross and Blue Shield Association technology assessment program (TEC) and other non-affiliated technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

The safety and efficacy of Technivie was evaluated in a single clinical trial in subjects with genotype 4 chronic HCV infection. This was a randomized, multicenter, open-label trial that included 135 adults with HCV genotype 4 infection without cirrhosis who were either treatment naïve or did not achieve a virologic response with prior treatment of pegylated interferon/ribavirin. There were various arms of the trial in which dosage and use of ribavirin varied. The primary endpoint was sustained virologic response at 12 weeks (SVR12). For subjects that received Technivie plus ribavirin for 12 weeks, there was a 100% SVR12 in both the treatment naïve and treatment experienced groups. In the arm that included ribavirin, there were no on treatment virologic failures or relapses. In the treatment naïve arm in which ribavirin was not used along with Technivie, the

SVR12 was 91%. In that same arm (treatment naïve, no ribavirin), 2% of subjects using Technivie had an on treatment virologic failure and 5% of subjects had a relapse. There were also 2% of patients receiving Technivie in the treatment naïve, no ribavirin arm that had not achieved SVR12, but did experience virologic failure or relapse (e.g. lost to follow up).

References

1. www.cdc.gov
2. Technivie [package insert]. Abbvie, Inc. North Chicago, IL.
3. Recommendations for Testing, Managing, and Treating Hepatitis C. American Association for the Study of liver diseases. Updated September 2017.

Policy History

Original Effective Date: 12/16/2015
Current Effective Date: 12/14/2020

12/03/2015	Medical Policy Committee review
12/16/2015	Medical Policy Implementation Committee approval. New Policy
12/01/2016	Medical Policy Committee review
12/21/2016	Medical Policy Implementation Committee approval. No change to coverage.
11/02/2017	Medical Policy Committee review
11/15/2017	Medical Policy Implementation Committee approval. Changed from Harvoni first to Epclusa, Harvoni, or Mavyret first. Updated background info.
11/08/2018	Medical Policy Committee review
11/21/2018	Medical Policy Implementation Committee approval. No change to coverage.
11/07/2019	Medical Policy Committee review
11/13/2019	Medical Policy Implementation Committee approval. Updated the policy referral section to include mention of the authorized generics in the policy titles for Harvoni and Epclusa. Removed reference to policies 00373, 00396, and 00457 as they are retired.
11/05/2020	Medical Policy Committee review
11/11/2020	Medical Policy Implementation Committee approval. No change to coverage.

Next Scheduled Review Date: 11/2021

Treatment of Hepatitis C with ombitasvir, paritaprevir, and ritonavir (Technivie™)

Policy # 00478
Original Effective Date: 12/16/2015
Current Effective Date: 12/14/2020

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

Treatment of Hepatitis C with ombitasvir, paritaprevir, and ritonavir (Technivie™)

Policy # 00478
Original Effective Date: 12/16/2015
Current Effective Date: 12/14/2020

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.