



STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
BUREAU FOR MEDICAL SERVICES



Office of Pharmacy Services Prior Authorization Criteria

TECHNIVIE[®] (ombitasvir/parataprevir/ritonavir) **Effective 1/28/2016**

[Prior Authorization Request Form](#)
[Prior Authorization Continuation Request Form](#)
[Patient Consent Form](#)
[Preferred HepC Regimens \(Attachment A\)](#)

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 and is indicated in combination with ribavirin for the treatment of patients with genotype 4 chronic hepatitis C virus (HCV) infection without cirrhosis.

Criteria for Approval

- 1) All documentation must be fully completed, including the patient consent form. A fibrosis score substantiated by a validated evidence-based method must be reported when requesting prior authorization; **AND**
- 2) Patient must have a documented **fibrosis level \geq F3 without cirrhosis**; **AND**
- 3) Patient must be eighteen (18) years of age or older; **AND**
- 4) Technivie[®] must be prescribed by, or in conjunction with, a board certified gastroenterologist, hepatologist or infectious disease physician; **AND**
- 5) Patient must be non-cirrhotic and be diagnosed with chronic Hepatitis C Genotype 4; **AND**
- 6) Patient has abstained from the use of illicit drugs and alcohol for a minimum of three (3) months, as indicated by their signature on the Patient Consent form; **AND**
- 7) Patient must agree to complete the full regimen and the patient and the provider must agree that an SVR12 and SVR24 will be collected and submitted to WV Medicaid to verify therapy success; **AND**

Duration of Approval

- A list of accepted regimens and treatment duration for chronic Hepatitis C therapy may be found in [Attachment A](#).
- Initial approval is for 6 weeks and requires submission of the starting HCV RNA level
- Continued coverage after week 6 depends upon receipt of an HCV RNA level at treatment week 4 (TW4), documentation of patient compliance, continued



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abstinence and an HCV RNA < 25 IU/ml. **Failure to obtain and report a treatment week 4 HCV RNA load will result in denial of further coverage.**

Criteria for Denial

- 1) Prior authorization requests submitted with incomplete documentation will be denied.
- 2) Failure to report a fibrosis score.
- 3) Patient is on dialysis.
- 4) Patient has cirrhosis.
- 5) Patient has been previously treated with **ombitasvir/parataprevir/ritonavir**.
- 6) Evidence exists that the patient has abused any illicit substance or alcohol in the past three (3) months.
- 7) Patient is taking a concomitant medication that has a significant clinical interaction with Technivie® (refer to package insert for a listing of interacting medications).
- 8) **Requests for continuation of coverage will be denied if the patient has an HCV RNA level >25 IU/ml OR if the prescriber has not submitted or has not obtained a viral load at treatment week 4.**

Additional Considerations

- 1) It is highly recommended that the patient vaccinated against Hepatitis A and Hepatitis B.
- 2) Coverage shall be for one successful course of therapy in a lifetime. Success of therapy shall be judged by undetectable SVR12 and SVR24 HCV RNA levels. If RNA levels have not been submitted, then it will be assumed that therapy was successful. Re-infection will not be covered. Exceptions may be allowed on a case-by-case basis.
- 3) **For HCV/HIV co-infections all requests must be reviewed for drug-drug interactions prior to approval. Please submit a list of the patient's current HIV regimen along with your request for coverage of Technivie.**
- 4) Lost or stolen medication replacement request will not be authorized.

References

- 1) Lexi-Comp Clinical Application 09/21/2015
- 2) Technivie® [package insert]. Abbvie, Revised 7/2015
- 3) AASLD 2015 Recommendations for Testing, Managing and Treating Hepatitis C (<http://www.hcvguidelines.org>)