

**TECHNIVIE™ (ombitasvir, paritaprevir, and ritonavir tablets),
tablets for oral use
Medicaid Testimony
July, 2015**

Note to MOSL: It is mandatory to read all of the boxed sections of this testimony; unboxed sections may also be included as situation and time permits.

Hello. My name is Dr. _____ from Medical Affairs at AbbVie. Thank you for the opportunity to speak about TECHNIVIE.

TECHNIVIE in combination with ribavirin for 12 weeks is approved for the treatment of patients with Genotype 4 chronic hepatitis C infection without cirrhosis. TECHNIVIE is not recommended for use in patients with moderate hepatic impairment (Child-Pugh B). TECHNIVIE may also be considered for use without ribavirin in treatment-naïve patients who cannot tolerate ribavirin.

Hepatitis C is estimated to affect between 2.7 and 5.2 million individuals in the United States, with Genotype 4 accounting for approximately 1.1% of all cases. Successful HCV treatment results in sustained virologic response (SVR), which is equivalent to virologic cure; virologic cure is expected to benefit chronically infected persons

TECHNIVIE with and without ribavirin was studied in 135 genotype 4 patient in a randomized, global multicenter, open-label clinical trial. Patients in the trial were non-cirrhotic and could be either treatment-naïve or treatment-experience, defined as those patients who did not achieve a virologic response with prior treatment with pegylated interferon in combination with ribavirin.

A SVR₁₂ rate of 100% was seen in both treatment-naïve and treatment-experienced patients who received TECHNIVIE in combination with ribavirin. When TECHNIVIE was utilized without ribavirin in treatment-naïve patients, a SVR₁₂ rate of 91% was achieved.

Adverse reactions observed with treatment that occurred in subjects treated with ombitasvir, paritaprevir for 12 weeks (with and without ribavirin) include asthenia (29% vs. 25%), fatigue (15% vs. 7%), nausea (14% vs. 9%), insomnia (13% vs. 5%), pruritus (7% vs. 5%), and skin reactions (7% vs. 5%).

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Four patients in the clinical trial that were on ribavirin did receive ribavirin dose reductions; however, all four patients achieved a SVR₁₂. None of the subjects receiving ombitasvir, paritaprevir and ritonavir with or without ribavirin discontinued treatment due to an adverse reaction

TECHNIVIE with ribavirin is recommended by the AASLD/ISDA guidelines for treatment of non-cirrhotic HCV GT4 infection and was given a grade of Class I, Level B, which is the highest level of supporting evidence currently granted to GT4 treatment in treatment-naïve patients. Technivie with ribavirin has a class IIa, level B, recommendation for patients in whom prior Peg-IFN/RBV has failed.

In summary, I am requesting the Committee consider TECHNIVIE with or without ribavirin for the following benefits:

- TECHNIVIE plus ribavirin achieved an SVR₁₂ of 100% in both treatment-naïve and treatment-experienced patients
- TECHNIVIE is the only interferon-free product available that is FDA-approved for Genotype 4 and recommended by the AASLD Guidelines

Thank you for your consideration and time.