STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OMBITASVIR/PARITAPREVIR/RITONAVIR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OMBITASVIR/ PARITAPREVIR/ RITONAVIR	TECHNIVIE	41734		GPI-10 (1235990360)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of hepatitis C, genotype 4 and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is treatment naïve or treatment experienced (previous treatment with peginterferon/ribavirin)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient have one or more of the following conditions?
   - The patient is on hemodialysis
   - Moderate or severe liver impairment (Child-Pugh B or Child-Pugh C), or decompensated liver disease
   - A limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (e.g., physician attestation)
   - Concurrent use with any of these medications (contraindicated or not recommended by the manufacturer): alfuzosin, carbamazepine, phenytoin, phenobarbital, rifampin, ergotamine, dihydroergotamine, ergonovine, methylergonovine, ethinyl estradiol containing medications (such as combined oral contraceptives, NuvaRing, Ortho Evra or Xulane transdermal patch system), lovastatin, simvastatin, pimozide, efavirenz (Atripla, Sustiva), Revatio (sildenafil dose of 20mg and/or dosed TID for PAH), triazolam, oral midazolam, lopinavir/ritonavir, rilpivirine, salmeterol
   - Prior use (failure of a full course of therapy) or concurrent use of any HCV protease inhibitors including Olysio (simeprevir), Victrelis (boceprevir), or Incivek (telaprevir)
   - Prior use (failure of a full course of therapy) or concurrent use of any NS5B polymerase inhibitor including Sovaldi (sofosbuvir)
   - Prior use (failure of a full course of therapy) of concurrent use of any NS5B polymerase inhibitor/NS5A inhibitor including Harvoni (ledipasvir/sofosbuvir)
   - Prior use (short trial or failure of a full course of therapy) of Viekira Pak or Viekira XR

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.
   If no, continue to #3.

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GUIDELINES FOR USE (CONTINUED)

3. Does the patient have an HCV RNA level within the past 6 months?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Does the patient meet **ONE** of the following criteria?
   - Patient has a contraindication to therapy with Epclusa, Harvoni, **AND** Mavyret
   - Patient has previously failed a short trial with Epclusa, Harvoni or Mavyret (e.g., adverse effect early in therapy); [**NOTE:** An individual who has completed a full course of therapy with Epclusa, Harvoni or Mavyret that did not achieve SVR will not be approved.]

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

5. Is the requested medication being used with ribavirin?

   If yes, **approve for 12 weeks by HICL or GPI-10 for #56 tablets (1 monthly carton) per 28 days.**
   (**NOTE:** Approval allows patients to complete a total maximum of 12 weeks of therapy.)

   If no, continue to #6.

6. Is the patient treatment naïve and without cirrhosis?

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

7. Does the patient have an intolerance or contraindication to ribavirin?

   If yes, **approve for 12 weeks by HICL or GPI-10 for #56 tablets (1 monthly carton) per 28 days.**
   (**NOTE:** Approval allows patients to complete a total maximum of 12 weeks of therapy.)

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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OMBITASVIR/PARITAPREVIR/RITONAVIR

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OMBITASVIR/PARITAPREVIR/RITONAVIR (Technivie)** requires the following rule(s) be met for approval:

A. You have chronic hepatitis C, genotype 4 without cirrhosis (liver damage) or with compensated cirrhosis (you do not have symptoms related to liver damage; Child-Pugh A)
B. You are treatment naïve (never previously treated) or treatment experienced (previous treatment with peginterferon/ribavirin)
C. The requested medication will be used with ribavirin, unless you are treatment naïve without cirrhosis (you have never been previously treated and do not have liver damage) and you have an intolerance or contraindication to (medical reason why you cannot use) ribavirin
D. You are 18 years of age or older
E. You have previously failed a short trial of Harvoni or Epclusa or Mavyret. Reasons for failure may include adverse effect, intolerance to therapy, or contraindication to (medical reason why you cannot use) all 3 drugs (**NOTE:** If you completed a full course of therapy with Mavyret and you did not achieve sustained virologic response [no virus can be detected in blood], the request will not be approved)
F. You have an HCV RNA level (amount of virus in your blood) within the past 6 months

A total of 12 weeks of therapy will be approved.

The medication will NOT be approved for the following:

A. You are using any of the following medications at the same time while on Technivie: alfuzosin, carbamazepine, phenytoin, phenobarbital, rifampin, ergotamine dihydroergotamine, ergonovine, methylergonovine, ethinyl estradiol containing medications (such as combined oral contraceptives, NuvaRing, Ortho Evra or Xulane transdermal patch system), lovastatin, simvastatin, pimozide, efavirenz, Revatio, triazolam, oral midazolam, lopinavir/ritonavir, rilpivirine, or salmeterol
B. You have moderate or severe liver impairment (Child Pugh B or Child Pugh C)
C. You are on hemodialysis (process of purifying the blood of a person whose kidneys are not working normally)
D. You have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions

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OMBITASVIR/PARITAPREVIR/RITONAVIR

GUIDELINES FOR USE (CONTINUED)

E. You have previously used (failed a full course of therapy) or are currently using any of the following regimens:
   1. A nucleotide NS5B polymerase inhibitor (type of hepatitis C drug) including Sovaldi (sofosbuvir)
   2. A combination NS5B polymerase inhibitor/NS5A inhibitor (type of hepatitis C drug) including Harvoni (ledipasvir/sofosbuvir)
   3. Any HCV protease inhibitor including Olysio (simeprevir), Victrelis (boceprevir), and Incivek (telaprevir)
   4. Viekira Pak (dasabuvir/ombitasvir/paritaprevir/ritonavir) or Viekira XR

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Technivie.

REFERENCES

- Technivie [Prescribing Information]. North Chicago, IL: Abbvie Inc.; December 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/23
Created: 08/15
Client Approval: 11/22
P&T Approval: 04/17