Pharmacy Management Drug Policy

SUBJECT: Hepatitis C virus (HCV) Infection (Pegasys, Peg-Intron, ribavirin, Sovaldi, Harvoni, ledipasvir/sofosbuvir, Epclusa, sofosbuvir/velpatasvir, Vosevi, Mavyret)
POLICY NUMBER: Pharmacy-21
EFFECTIVE DATE: 06/2003
LAST REVIEW DATE: 11/12/2026

If the member's subscriber contract excludes coverage for a specific service or prescription drug, it is not covered under that contract. In such cases, medical or drug policy criteria are not applied. This drug policy applies to the following line/s of business:

Policy Application

Category:	☒ Commercial Group (e.g., EPO, HMO, POS, PPO)	☐ Medicare Advantage
	☒ On Exchange Qualified Health Plans (QHP)	☐ Medicare Part D
	☒ Off Exchange Direct Pay	☒ Essential Plan (EP)
	☐ Medicaid & Health and Recovery Plans (MMC/HARP)	☒ Child Health Plus (CHP)
	☐ Federal Employee Program (FEP)	☐ Ancillary Services
	☐ Dual Eligible Special Needs Plan (D-SNP)	

DESCRIPTION:

Hepatitis C virus (HCV) infection may be acute or chronic.

- **Acute HCV** is defined as the occurrence of an HCV infection within the first 6 months after exposure to HCV. Not all individuals with an acute HCV infection will progress to chronic HCV, some individuals will clear the virus on their own.

- **Chronic HCV** is defined as persistent, detectable HCV RNA for more than 6 months.
  - Chronic infection with hepatitis C virus (HCV) is the most common cause of cirrhosis and hepatocellular carcinoma and the most frequent indication for liver transplant in the United States.

Certain terms have been defined in multiple ways in different studies and treatment guidelines. Below are a list of terms and their meanings for the purposes of this policy:

- **Rapid virologic response** (RVR) - undetectable HCV at week 4
- **Sustained virologic response** (SVR) - undetectable HCV at time of test (12, 24, 48 weeks)
- **Relapser**- a person who has achieved an undetectable level of virus during a prior treatment course of PEG/RBV and relapsed after treatment was stopped
- **Non-responder**- patient who fails to achieve undetectable HCV levels at any point during therapy. Non-responders include both **null-responders** and **partial responders**.
  - **Null responders** describe patients who experience a minimal viral suppression (serum HCV RNA levels declined less than 2 log10 IU/mL by week 12 during a prior treatment course)
  - **Partial responders** are patients with a ≥ 2 log10 IU/mL response whose virus remained detectable up to 24 weeks or the end of treatment
- **Slow-responder-** patient who has detectible HCV at weeks 4 and 12 but has undetectable HCV by week 24.
- **Undetectable (or negative) viral load:** viral load is below the limit of detection for the specific test. e.g., a Branched-chain DNA (bDNA) test can only detect viral loads greater than 615 IU/mL.
- **Detectable (or positive) viral load:** the presence of virus is above the limit of detection. This can be expressed as IU/mL, virus/mL, and in logarithmic format.
- **Aviremic** - undetectable HCV RNA on quantitative test (less than 10 IU/mL on Taqman/TMA testing)

Initial Review Criteria – For All Treatment Regimens

Based upon our criteria and assessment of the peer-reviewed literature, **Ribavirin, Peg-Intron, Pegasys, Viekira, Sovaldi, Harvoni, ledipasvir/sofosbuvir, Epclusa, sofosbuvir/velpatasvir, Vosevi, and Mavyret** have been medically proven to be effective and therefore **medically necessary** in the treatment of **Chronic Hepatitis C** if the request meets **ALL** the following criteria and **Mavyret** has been medically proven to be effective and therefore **medically necessary** in the treatment of **Acute Hepatitis C** if the request meets **ALL** the following criteria:

1. HCV genotype and quantitative baseline viral load must be provided with a collection date within six months before the start of therapy.
   - If a patient has received Hepatitis C treatment for an acute or chronic infection within the past 12 months, recent genotype test results taken after the completion of the previous treatment regimen will be required to rule out re-infection.
2. The provider must assert the patient's treatment readiness and ability to adhere to prescribed treatment regimen.
   - At least one scale/assessment tool must have been utilized to evaluate readiness, such as the SAMHSA HRSA Center For Integrated Health Solutions- Drug & Alcohol screen tools (available at https://www.samhsa.gov/resource/dbhis/screening-assessment-tools-chart **OR** the Pyschosocial Readiness Evaluation and Preparation for hepatitis C treatment (PREP-C), available at http://prepc.org/
3. For Ribavirin-containing regimens, female patients of childbearin potential must have a negative pregnancy test collected within 30 days prior to the initiation of therapy **OR** Medical records must be submitted documenting pregnancy status.
4. Patients with limited life expectancy (<12 months due to **non-liver related comorbidities**) are not covered.
5. Progress notes are required on all new starts and recertifications.
6. Per IDSA/AASLD guidelines, Victrelis regimens are not recommended for any indication and therefore will only be authorized if there is documentation of a serious adverse reaction or contraindication to the other medications listed in this policy.
7. Patients who are previously cured will not be covered for any treatment upon reinfection unless the provider attests that risk factors for re-infection have been identified and addressed.

Drug Specific Criteria

Mavyret (glecaprevir and pibrentasvir)
• Patient must be 3 years or older • Mavyret oral pellets will not be covered for patients' weighing 45 kg or greater than 12 years of age and older due to the availability of 100mg-40mg tablets, which can be used in these patients, unless a swallowing evaluation is submitted to confirm a swallowing disorder. • The quantity limit for Mavyret will be 3 tablets per day for the 100mg/40 mg tablets and up to 5 packets per day for the 50mg/20mg oral pellet packets. • Mavyret is not recommended in patients with moderate hepatic impairment (Child- Pugh B) and is contraindicated in patients with severe hepatic impairment (Child- Pugh C) and therefore will not be covered for these patients. • Mavyret is contraindicated with atazanavir or rifampin and therefore will not be covered in patient's taking atazanavir or rifampin. **For the treatment of Acute Hepatitis C** Mavyret (glecaprevir/pibrentasvir) for the treatment of acute hepatitis C will be considered Not Medically Necessary (NMN) due to the potential for spontaneous viral clearance in up to 50% of patients. The Phase 3 Pivotal trial, AbbVie M20-350, was a single-arm study that did not control the natural history of spontaneous clearance. Additionally, clinical outcomes for Chronic Hepatitis C have demonstrated that

deferring treatment until chronic infection is established has no known impact on direct-acting antiviral (DAA) cure rates.

- Exception to NMN requirement
  - Early treatment may be considered in the following clinical scenarios:
    - Immunocompromised Patients
      - ❖ HIV co-infection
      - ❖ History of solid organ transplant
      - ❖ Actively undergoing chemotherapy
    - Increased Risk of Transmission
      - ❖ People who inject drugs (PWID)
      - ❖ High-risk men who have sex with men (MSM)
    - Patients receiving chronic hemodialysis
    - Clinical worsening or concerning laboratory findings
      - ❖ ALT/AST – rapid rise or persistently > 10x ULN
      - ❖ INR > 1.5
      - ❖ T. Bili > 3.0 mg/dL or rising > 1.0 mg/dL between labs
      - ❖ HCV RNA – rising or stable high viral load (> 1 million IU/mL) at 12+ weeks
  - If exception criteria are met for acute hepatitis C treatment, approval will be for **8 weeks** for completion of therapy.

For the treatment of Chronic Hepatitis C

1. For **genotype 1,2,3,4,5 or 6** patients, who are **treatment naïve**, **without cirrhosis**, and have a medical reason why Epclusa/sofosbuvir-velpatasvir (for genotypes 1-6) and Harvoni/ledipasvir-sofosbuvir (for genotypes 1,4,5,6) cannot be used, approval will be **for 8 weeks** for completion of therapy.
2. For **genotype 1,2,3,4,5 or 6** patients, who **are treatment naïve**, **with compensated cirrhosis** (Child Pugh A), and have a medical reason why Epclusa/sofosbuvir-velpatasvir (for genotypes 1-6) and Harvoni/ledipasvir-sofosbuvir (for genotypes 1,4,5,6) cannot be used, approval will be for **8 weeks** for completion of therapy.
3. For **genotype 1,2,4,5, or 6** patients **without cirrhosis** who are **treatment experienced with regimens containing interferon, pegylated interferon, ribavirin, and/or sofosbuvir**, but have no prior treatment experienced with an HCV NS3/4A Protease inhibitor or NS5A inhibitor, and have a medical reason why Epclusa/sofosbuvir-velpatasvir (for genotypes 1-6) and Harvoni/ledipasvir-sofosbuvir (for genotypes 1,4,5,6) cannot be used, approval will be for **8 weeks** for completion of therapy.
4. For **genotype 1,2,4,5, or 6** patients, **with compensated cirrhosis** (Child Pugh A), who are **treatment experienced with regimens containing interferon, pegylated interferon, ribavirin, and/or sofosbuvir**, but have no prior treatment experienced with an HCV NS3/4A Protease inhibitor or NS5A inhibitor, and have a medical reason why Epclusa/sofosbuvir-velpatasvir (for genotypes 1-6) and Harvoni/ledipasvir-sofosbuvir (for genotypes 1,4,5,6) cannot be used, approval will be for **12 weeks** for completion of therapy.
5. For **genotype 3** patients, **without cirrhosis or with compensated cirrhosis** (Child Pugh A), who are **treatment experienced with regimens containing interferon, pegylated interferon, ribavirin, and/or sofosbuvir**, but have no prior treatment experienced with an HCV NS3/4A Protease inhibitor or NS5A inhibitor, and a medical reason why treatment with Epclusa/sofosbuvir-velpatasvir cannot be used, approval will be for **16 weeks** for completion of therapy.
6. For **genotype 1 patients without cirrhosis or with compensated cirrhosis (Child Pugh A),** who have previously failed treatment with a prior regimen containing Harvoni (ledipasvir) or Daklinza (daclatasvir) but have no prior treatment with an HCV NS3/4A Protease inhibitor, the patient must have the same genotype infection on relapse to rule out re-infection**,** and a medical reason why treatment with Vosevi cannot be used, approval will be for **16 weeks** for completion of therapy.
   - The following medications are considered NS3/4A protease inhibitor or NS3/4A inhibitor-

containing products: Olysio (simeprevir capsules), Victrelis (boceprevir capsules), Incivek (telaprevir tablets), Technivie (ombitasvir/paritaprevir/ritonavir tablets), Viekira Pak (ombitasvir/paritaprevir/ritonavir tablets; dasabuvir tablets, co-packaged), Viekira XR (dasabuvir/ombitasvir/paritaprevir/ritonavir extended-release tablets), or Vosevi (sofosbuvir/velpatasvir/voxilaprevir).

7. For **genotype 1** patients **without cirrhosis or with compensated cirrhosis (Child Pugh A),** who have previously failed treatment with an HCV NS3/4A Protease inhibitor but have no prior treatment with an HCV NS5A inhibitor, the patient must have the same genotype infection on relapse to rule out re-infection**.** Approval will be for **12 weeks** for completion of therapy.
   - The following medications are considered NS5A inhibitor or NS5A inhibitor- containing products: Harvoni (ledipasvir/sofosbuvir tablets), Epclusa (sofosbuvir/velpatasvir), Daklinza (daclatasvir tablets), Technivie (ombitasvir/paritaprevir/ritonavir tablets), Viekira Pak (ombitasvir/paritaprevir/ritonavir tablets; dasabuvir tablets, co- packaged), Viekira XR (dasabuvir/ombitasvir/paritaprevir/ritonavir extended- release tablets), or Vosevi (sofosbuvir/velpatasvir/voxilaprevir).
8. For **genotype 1-6 patients** who have had **treatment failure with Mavyret**, Mavyret will not be authorized unless there is documentation of severe intolerance (that prevents completion of therapy) or contraindication with Vosevi (sofosbuvir/velpatasvir/voxilaprevir).

Harvoni (sofosbuvir/ledipasvir) and authorized generic ledipasvir/sofosbuvir

- Patient **must have genotype 1, 4, 5 or 6** and be 3 years or older.
- Harvoni(ledipasvir/sofosbuvir) is covered as monotherapy or in combination with ribavirin only.
- Harvoni 45mg/200mg tablets or oral pellets will not be covered in patients that weigh 35 kg or more, due to the availability of 90mg/400mg tablets which can be used in these patients, unless a swallowing evaluation is submitted to confirm a swallowing disorder.
- Please see policy guidelines for definition of cirrhosis.
- Drugs that decrease the gastric PH are expected to decrease concentration of Ledipasvir. Proton-pump inhibitor doses comparable to omeprazole 20mg or lower can be administered simultaneously with Harvoni(ledipasvir/sofosbuvir) under fasted conditions. If H2 receptor antagonists are taken, they should be administered simultaneously with or 12 hours apart from Harvoni(ledipasvir/sofosbuvir) at a dose that does not exceed doses comparable to famotidine 40mg twice daily. It is recommended to separate antacid and Harvoni(ledipasvir/sofosbuvir) administration by 4 hours.
- Coadministration of amiodarone with Harvoni is not recommended due to risk of serious symptomatic bradycardia

1. For **genotype 1 treatment-naïve patients <u>without</u> cirrhosis** who have **pre-treatment HCV RNA <u>less</u> than 6 million IU/mL,** approval will be for **8 weeks for completion of therapy.**
   a. For treatment-naive patients who are **HIV-HCV co-infected**, **African American**, or who have documentation of a **CT or TT type IL28B polymorphism**, approval will be for 12 weeks for completion of therapy.
2. For **genotype 1 treatment-naïve patients <u>without</u> cirrhosis** who have **pre-treatment HCV RNA <u>more</u> than 6 million IU/mL,** approval will be for **12 weeks for completion of therapy.**
3. For **genotype 1 treatment-naïve patients <u>with</u> compensated cirrhosis,** approval will be for **12 weeks for completion of therapy** regardless of baseline HCV RNA values**.**
4. For **genotype 1 treatment-experienced** (defined as patients who have failed an interferon-based regimen with or without ribavirin) **<u>without</u> cirrhosis**, approval will be for **12 weeks for completion of therapy** regardless of baseline HCV RNA values.
5. For **genotype 1 treatment-experienced** (defined as patients who have failed an interferon-based regimen with or without ribavirin) **<u>with</u> compensated cirrhosis, initial approval will be for 12 weeks with ribavirin.**
   a. Requests for 24-week monotherapy with Harvoni require documentation of severe intolerance (that prevents completion of therapy) or contraindication to Epclusa/sofosbuvir-velpatasvir. In

addition, documentation of severe intolerance or contraindication to ribavirin is required. Please see policy guidelines for definition of those who are considered ribavirin ineligible.

6. For retreatment of **genotype 1** patients who previously **failed Sovaldi**, the patient must have the same genotype infection on relapse to rule out reinfection**. Approval will be for 12 weeks with Ribavirin** in patients **without cirrhosis**.
7. For **genotype 4**, Harvoni(ledipasvir/sofosbuvir) is approved for 12 weeks in treatment naïve, or treatment experienced (defined as patients who have failed an interferon-based regimen with or without ribavirin) patients, with or without compensated cirrhosis.
8. For **genotype 5 or 6**, Harvoni(ledipasvir/sofosbuvir) is approved for 12 weeks in treatment naïve, or treatment experienced (defined as patients who have failed an interferon-based regimen with or without ribavirin) patients, with or without compensated cirrhosis.
9. For **post-liver transplant** patients, treatment is **covered in combination with ribavirin for 12 weeks.** For treatment naïve patients who are ribavirin ineligible, approval will be for 24 weeks as monotherapy. Please see policy guidelines for definition of those who are considered ribavirin ineligible.
10. For **genotype 1 or 4, 5 or 6** patients who have **decompensated cirrhosis (Class B or C)**, who may or may not be candidates for liver transplantation, including those with Hepatocellular carcinoma, treatment is **covered in combination with ribavirin for 12 weeks.** If patient is ribavirin ineligible, approval will be for 24 weeks as monotherapy. Please see policy guidelines for definition of those who are considered ribavirin ineligible.

Epclusa (sofosbuvir/velpatasvir) and authorized generic sofosbuvir/velpatasvir

- Patient must be 3 years or older
- 200mg/50mg tablets or oral pellets will not be covered in patients weighing at least 30 kg, due to the availability of 400mg/100mg tablets which can be used in these patients, unless a swallowing evaluation is submitted to confirm a swallowing disorder.
- Coadministration of amiodarone with Epclusa(sofosbuvir/velpatasvir) is not recommended due to risk of serious symptomatic bradycardia.
- Drugs that increase the gastric PH are expected to decrease concentrations of Velpatasvir. Coadministration of omeprazole or other proton-pump inhibitors is not recommended. If H2 receptor antagonists are taken, they should be administered simultaneously with or 12 hours apart from Epclusa(sofosbuvir/velpatasvir) at a dose that does not exceed doses comparable to famotidine 40mg twice daily. It is recommended to separate antacid and Epclusa(sofosbuvir/velpatasvir) administration by 4 hours.
- Coverage of Epclusa(sofosbuvir/velpatasvir) is excluded in patients who have previously received treatment with a NS5A inhibitor.

1. For **genotype 1, 2, 4, 5, or 6** patients **without cirrhosis**, or with **compensated cirrhosis** (Child-Pugh A), coverage will be **for 12 weeks**, in patients who are treatment naïve, or treatment experienced (defined as patients who have received treatment with peg interferon alfa/ribavirin with or without an HCV protease inhibitor).
2. For **genotype 3 treatment naïve** patients, with or without compensated cirrhosis and for genotype 3 **treatment experienced** (defined as patients who have received treatment with peg interferon alfa/ribavirin with or without an HCV protease inhibitor) patients **without cirrhosis**, coverage will be for 12 weeks.
3. For **genotype 3 treatment experienced** (defined as patients who have received treatment with peg interferon alfa/ribavirin with or without an HCV protease inhibitor) patients with **compensated cirrhosis**, Epclusa will be **covered in combination with ribavirin** for 12 weeks. AASLD guidelines recommend the addition of ribavirin to increase SVR12 rates, unless contraindicated. If a patient is ineligible to receive ribavirin, Epclusa(sofosbuvir/velpatasvir) will be covered alone for 12 weeks.
4. For **genotype 1, 2, 3, 4, 5, or 6** patients with **decompensated** cirrhosis (Child-Pugh B or C), Epclusa(sofosbuvir/velpatasvir) will be covered **in combination with ribavirin** for 12 weeks.

- If patient is ribavirin ineligible, approval will be for 24 weeks as monotherapy. Please see policy guidelines for definition of those who are considered ribavirin ineligible.

5. For **genotype 2** patients who are **sofosbuvir and ribavirin experienced**, Epclusa(sofosbuvir/velpatasvir) will be covered **in combination with ribavirin** for 12 weeks.

Sovaldi-Based Regimens

- Patient must be 3 years or older.
- Sovaldi will not be authorized as monotherapy.
- The safety and efficacy of Sovaldi is not recommended in patients with severe renal impairment/ESRD (CrCl <30 mL/min) or hemodialysis-patients in treatment guidelines and therefore is not covered.
- Sovaldi 200mg tablets will not be covered in patients weighing 35 kg or more due to the availability of 400mg tablets, which can be used in these patients.

1. Due to the availability of other equally effective, but more cost-effective FDA approved treatment regimens, Sovaldi will **NOT** be covered for **genotype 1** patients.
2. For **genotypes 2 or 3**, Sovaldi will not be covered unless there is documentation of a severe intolerance (that prevents completion of therapy) or contraindication to Epclusa/sofosbuvir-velpatasvir.
3. For patients with **decompensated cirrhosis**, Sovaldi will not be covered unless there is documentation of a severe intolerance (that prevents completion of therapy) or contraindication to Epclusa/sofosbuvir-velpatasvir.
4. For **Genotype 1-6 patients** who have **had treatment failure with Mavyret** (glecaprevir/pibrentasvir), Sovaldi will not be covered unless there is documentation of severe intolerance (that prevents completion of therapy) or contraindication to Vosevi (sofosbuvir/velpatasvir/voxilaprevir).

Vosevi (sofosbuvir/velpatasvir/voxilaprevir)

- Patient must be 18 years or older
- Coadministration of amiodarone with Vosevi is not recommended due to risk of serious symptomatic bradycardia.
- Coadministration of Vosevi with HIV regimens containing atazanavir, lopinavir, tipranavir/ritonavir, and efavirenz is not recommended.
- Drugs that increase the gastric PH are expected to decrease concentrations of Velpatasvir. Antacids should be separated from Vosevi administration by 4 hours. H2 receptor Antagonists may be administered simultaneously with or staggered from Vosevi at a dose that does not exceed doses comparable with famotidine 40mg twice daily. Omeprazole 20mg can be administered with Vosevi. Use with other proton Pump- inhibitors has not been studied.
- The safety and efficacy of Vosevi is not recommended in patients with severe renal impairment/ESRD (CrCl <30 mL/min) or hemodialysis-patients in FDA labeling, and therefore, is not covered.
- Vosevi will not be covered in patients with moderate or severe hepatic impairment (Child-Pugh B or C).

1. For **genotypes 1,2,3,4,5 or 6** patients **without cirrhosis** or **with compensated cirrhosis,** who have previously failed treatment with an NS5A inhibitor, (daclatasvir, elbasavir, ledipasvir, ombitasvir, or velpatasvir), the patient must have the same genotype infection on relapse to rule out re-infection**.** For Commercial, NYSOH Individual Market, and NYSOH Employer Group Market products, approval will be for **12 weeks for completion of therapy.**
2. For **genotypes 1a or 3** patients **without cirrhosis** or **with compensated cirrhosis,** who have previously failed treatment with a Sovaldi (Sofosbuvir) containing regimen without an NS5A inhibitor, the patient must have the same genotype on relapse to rule out re-infection. For Commercial, NYSOH Individual Market, and NYSOH Employer Group Market products approval will be for **12 weeks for completion of therapy.**
3. For **genotype 1-6 patients without compensated cirrhosis**, who have had **previous treatment failure with Mavyret**, the patient must have the same genotype on relapse to rule out re-infection.

Vosevi will be covered for 12 weeks. For **genotype 1-6 patients with compensated cirrhosis**, who have had **previous treatment failure with Mavyret**, the patient must have the same genotype on relapse to rule out re-infection. For Commercial, NYSOH Individual Market, and NYSOH Employer Group Market products Vosevi will be covered for 12 weeks **in combination with ribavirin.**

POLICY GUIDELINES:

1. Utilization Management is contract dependent. Refer to specific contract/benefit language for exclusions.
   a. Coverage criteria may be dependent on the contract renewal date.
   b. Coverage of drugs listed in this policy are contract dependent.
   c. Not all contracts/benefits allow coverage of healthcare professional administered drugs as part of their pharmacy benefit.
   d. Not all contracts/benefits cover all medical infusible drugs.
   e. Not all policy criteria may apply if treatment of specific disease states or conditions is not a covered benefit.
2. Clinical documentation must be submitted for each request (initial and recertification [if applicable]) unless otherwise specified (e.g., provider attestation required). Supporting documentation includes, but is not limited to, progress notes documenting previous treatments and treatment history, diagnostic testing, laboratory test results, genetic testing or biomarker results, imaging and other objective or subjective measures of benefit. For recertification, continued approval requires documentation demonstrating that the requested product is providing ongoing benefit to the patient, evidenced by improvement or stability in disease state or condition, and that continued use remains medically necessary. Ongoing use of the requested product must continue align with the current policy's preferred formulary. Recertification reviews may result in a requirement to trial more cost-effective treatment alternatives as they become available (i.e., generics, biosimilars, or other guideline-supported treatment options). Requested dosing must remain consistent with FDA-approved or off-label/guideline-supported dosing recommendations.
3. All requests will be reviewed to ensure they are being used for an appropriate indication and may be subject to an off-label review in accordance with our Off-Label Use of FDA Approved Drugs Policy (Pharmacy-32).
4. Dose and frequency should be in accordance with the FDA label or recognized compendia (for off-label uses). When services are performed in excess of established parameters, they may be subject to review for medical necessity.
5. This policy is applicable to drugs that are included on a specific drug formulary (Pharmacy benefit only). If a drug referenced in this policy is non-formulary, please reference the Non-Formulary Medication Exception Review Policy for review guidelines.
6. All utilization management requirements outlined in this policy are compliant with applicable New York State insurance laws and regulations. Policies will be reviewed and updated as necessary to ensure ongoing compliance with all state and federally mandated coverage requirements.
7. For commercial contracts, medical necessity determinations align with the Certificate of Coverage issued by the Health Plan, which states that covered services must be clinically appropriate and not primarily for the convenience of the member, the member’s family, or the provider.
8. This policy is based on available evidence as of the last review date. Coverage determinations are subject to applicable plan documents, state and federal regulations, and individual patient circumstances. This policy does not constitute medical advice.
9. This policy is subject to ongoing revision. Newly marketed drugs and existing drugs with new indications may be subject to prior authorization until formal coverage criteria are established. Inclusion of a drug in this policy does not guarantee its current availability on the market, as some agents may be discontinued, withdrawn, or otherwise unavailable. As product status changes, drugs may be removed from the policy.

10. Cirrhosis as defined as any one of the following:
    a. Liver biopsy showing cirrhosis (e.g., Metavir score = 4 or Ishak score ≥ 5) **OR**
    b. FibroTest® score of > 0.75 AND an APRI > 2 **OR**
    c. Nodular liver morphology on abdominal ultrasound or CT scan.
11. In the absence of a definitive diagnosis of presence or absence of cirrhosis by the above criteria, a liver biopsy is required; liver biopsy results will supersede blood test results and be considered definitive.
12. Ineligibility to ribavirin is defined as:
    a. Neutrophils <750 cells/mm3, results within the past month or
    b. Hemoglobin < 10g/dL, results within the past month or
    c. Platelets <50 000 cells/ mm3, results within the past month or
    d. Autoimmune hepatitis or other autoimmune condition known to be exacerbated by Ribavirin
    e. Severe intolerance to past ribavirin therapy
13. Ineligibility to interferon therapy is defined as:
    a. Comorbid autoimmune hepatitis or other autoimmune disorders or
    b. Decompensated hepatic disease or history of preexisting cardiac disease or
    c. A baseline neutrophil count below 1500/µL or
    d. A baseline platelet count below 90,000/µL or
    e. Baseline hemoglobin below 10 g/dL or
    f. Major uncontrolled depressive illness **despite pharmacologic treatment**, or
    g. **Severe intolerance to past IFN therapy** (such as urticaria, angioedema, broncho constriction, anaphylaxis, Stevens-Johnson syndrome, ophthalmologic disorder, thyroid disorder, or refractory diabetes mellitus).
14. No early refills will be allowed without a prior authorization to document necessity.
15. Treatment regimens that are not listed within the policy will be evaluated based on current treatment guidelines for safety and efficacy.
    a. Treatment regimens must be listed as a class IIa or higher recommendation in the AASLD HCV guidance or DrugDex to be considered for coverage.
16. Triple therapy with Olysio is not recommended for any genotype and therefore is not included in the policy.
17. Approval timeframes may be extended to align authorization periods for drugs administered as part of a multidrug regimen, including when regimen components are administered across different benefits. This provision does not apply when the approval timeframe reflects a drug-specific limitation on duration of therapy.

UPDATES:

Date:	Revision:
11/12/2026	Reviewed / P&T Committee Approval
09/14/2026	Revised
08/03/2026	Revised
03/13/2026	Revised
01/01/2026	Revised
11/13/2025	P&T Committee Review & Approval
08/12/2025	Revised
06/20/2025	Revised
03/06/2025	Revised
01/16/2025	Revised
11/21/2024	P&T Committee Review & Approval
09/13/2024	Revised

12/06/2023	Revised
11/30/2023	P&T Committee Review & Approval
11/29/2023	Revised
11/08/2023	Review
04/01/2023	Revision
11/17/2022	P&T Committee Review & Approval
03/2022	Revision
11/2021	P&T Committee Review & Approval
10/2021	Revision
12/2020	Revision
11/2020	P&T Committee Review & Approval
4/20	Revision
1/20	Revision
11/19	Revision
10/19	Revision
6/19	Revision
2/19	Revision
1/19	P&T Committee Review & Approval
10/18	Revision
8/18	Revision
4/18	Revision
9/17	P&T Committee Review & Approval
8/17	Revision
7/17	Revision
3/17	Revision
8/16	Revision
6/16	Revision
4/16	Revision
3/16	Revision
2/16	Revision
11/15	Revision
8/15	Revision
7/15	Revision
5/15	Revision
2/15	Revision
1/15	Revision
11/14	Revision

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