# Pharmacy Management Drug Policy

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| **SUBJECT: Hepatitis C virus (HCV) Infection (Pegasys, Peg-Intron, ribavirin, Sovaldi, Harvoni, ledipasvir/sofosbuvir, Zepatier, Epclusa, sofosbuvir/velpatasvir, Vosevi, Mavyret)**<br>**POLICY NUMBER: Pharmacy-21**<br>**EFFECTIVE DATE: 06/2003**<br>**LAST REVIEW DATE: 11/13/2025** |
| *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** |

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| **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 is 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, Zepatier, 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 to 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)** |
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| • Patient must be 3 years or older<br>• Mavyret oral pellets will not be covered for patient's weighting 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.<br>• 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.<br>• 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.<br>• Mavyret is contraindicated with atazanavir or rifampin and therefore will not be covered in patient's taking atazanavir or rifampin.<br><br>1. For **genotype 1,2,3,4,5 or 6** patients, who are **treatment naïve**, **without cirrhosis**, approval will be **for 8 weeks** for completion of therapy.<br><br>2. For **genotype 1,2,3,4,5 or 6** patients, who **are treatment naïve**, **with compensated cirrhosis** (Child Pugh A), approval will be for **8 weeks** for completion of therapy.<br><br>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, approval will be for **8 weeks** for completion of therapy.<br><br>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, approval will be for **12 weeks** for completion of therapy.<br><br>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, approval will be for **16 weeks** for completion of therapy.<br><br>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**.** Approval will be for **16 weeks** for completion of therapy.<br>• 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), Vosevi (sofosbuvir/velpatasvir/voxilaprevir), or Zepatier (elbasvir/grazoprevir tablets). |

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), Zepatier (elbasvir/grazoprevir tablets), 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 without cirrhosis** who have **pre-treatment HCV RNA less 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 without cirrhosis** who have **pre-treatment HCV RNA more than 6 million IU/mL,** approval will be for **12 weeks for completion of therapy.**

3. For **genotype 1 treatment-naïve patients with 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) **without 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) **with 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 and Mavyret. 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** |
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- Patient must be 3 years or older
- 200mg/50mg tablets or oral pellets will not be covered in patients that weight 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.

| **Zepatier (elbasvir and grazoprevir)** |
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- Patient must have genotype 1 or 4 and must be 12 years or older or weigh 30 kg or more
  - For genotype 1 patients, the specific subtype (genotype 1a or 1b) must be provided.
- Zepatier will not be covered for patient with moderate or severe hepatic impairment (Child Pugh B or C).
- Zepatier will not be covered when being prescribed in patients who are on OATP1B1/3 inhibitors, strong CYP3A inducers, or efavirenz.
- The safety and efficacy of Zepatier have not been established in patients awaiting liver transplant or in liver transplant recipients.

1. For **genotype 1a patients**:
   a. For **treatment naïve** or **peg-interferon/ribavirin experienced** patients **without** baseline NS5A polymorphisms at amino acid positions 28,30, 31, or 93, approval will be for 12 weeks of Zepatier monotherapy.
   b. For **treatment naïve** or **peg-interferon/ribavirin experienced** patients **WITH** baseline NS5A polymorphisms at amino acid positions 28, 30, 31, or 93, approval will be for 16 weeks **in combination with ribavirin.**
   c. For genotype 1a patients who are **Peg-interferon/ribavirin/protease inhibitor experienced,** approval will be for 12 weeks of Zepatier in **combination with Ribavirin.**

2. For **genotype 1b patients** who are **treatment naïve** or **peg-interferon/ribavirin experienced**, approval will be for 12 weeks of Zepatier monotherapy.

3. For **genotype 1b** patients who are **peg-interferon/ribavirin/protease inhibitor** experienced, approval will be for 12 weeks in **combination with ribavirin.**

4. For **genotype 3, peg interferon/ribavirin treatment experienced** patients, with **compensated cirrhosis**, Zepatier will not be authorized for new starts unless there is documentation of severe intolerance (that prevents completion of therapy) with Epclusa or contraindication to Epclusa. For these patients, approval will be for 12 weeks in combination with Sovaldi.

5. For **genotype 4** patients who are treatment naïve, approval will be for **12 weeks** of Zepatier monotherapy.

6. For **genotype 4** patients who experienced virologic relapse after prior Peg- interferon/ribavirin therapy, approval will be for **12 weeks of Zepatier in combination with Ribavirin**. For geonotype 4 patients who experienced prior on-treatment virologic failure (failure to suppress or breakthrough) while on peg-interferon/ribavirin, approval will be for **16 weeks of Zepatier in combination with ribavirin.**

7. Zepatier will not be authorized for new starts unless there is documentation of severe intolerance (that prevents completion of therapy) with Harvoni/ledipasvir-sofosbuvir and Mavyret and Epclusa/sofosbuvir-velpatasvir or contraindication to Harvoni/ledipasvir-sofosbuvir and Mavyret and Epclusa/sofosbuvir-velpatasvir.

| **Sovaldi-Based Regimens** |
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| • Patient must be 3 years or older.<br>• Sovaldi will not be authorized as monotherapy.<br>• 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.<br>• 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.<br><br>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.<br><br>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 and Mavyret.<br><br>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.<br><br>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)** |
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| • Patient must be 18 years or older<br>• Coadministration of amiodarone with Vosevi is not recommended due to risk of serious symptomatic bradycardia.<br>• Coadministration of Vosevi with HIV regimens containing atazanavir, lopinavir, tipranavir/ritonavir, and efavirenz is not recommended.<br>• 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.<br>• 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.<br>• Vosevi will not be covered in patients with moderate or severe hepatic impairment (Child-Pugh B or C).<br><br>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.**<br><br>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.**<br><br>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 are contract dependent and coverage criteria may be dependent on the contract renewal date. Additionally, coverage of drugs listed in this policy are contract dependent. Refer to specific contract/benefit language for exclusions.
2. Policy may not be applicable to all contracts. Coverage criteria may differ for select contracts.
3. Clinical documentation must be submitted for each request (initial and recertification) unless otherwise specified (e.g., provider attestation required). Supporting documentation includes, but is not limited to, progress notes documenting previous treatments/treatment history, diagnostic testing, laboratory test results, genetic testing/biomarker results, imaging and other objective or subjective measures of benefit which support continued use of the requested product is medically necessary. Also, ongoing use of the requested product must continue to reflect the current policy's preferred formulary. Recertification

reviews may result in the requirement to try more cost-effective treatment alternatives as they become available (i.e., generics, biosimilars, or other guideline supported treatment options). Requested dosing must continue to be consistent with FDA-approved or off-label/guideline-supported dosing recommendations.

4. For contracts where Insurance Law § 4903(c-1), and Public Health Law § 4903(3-a) are applicable, if trial of preferred drugs(s) is the only criterion that is not met for a given condition and one of the following circumstances can be substantiated by the requesting provider, then trial of the preferred drug(s) will not be required.
    - The required prescription drug(s) is (are) contraindicated or will likely cause an adverse reaction or physical or mental harm to the member;
    - The required prescription drug is expected to be ineffective based on the known clinical history and conditions and concurrent drug regimen;
    - The required prescription drug(s) was (were) previously tried while under the current or a previous health plan, or another prescription drug or drugs in the same pharmacologic class or with the same mechanism of action was (were) previously tried and such prescription drug(s) was (were) discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event;
    - The required prescription drug(s) is (are) not in the patient's best interest because it will likely cause a significant barrier to adherence to or compliance with the plan of care, will likely worsen a comorbid condition, or will likely decrease the ability to achieve or maintain reasonable functional ability in performing daily activities;
    - The individual is stable on the requested prescription drug. The medical profile of the individual (age, disease state, comorbidities), along with the rational for deeming stability as it relates to standard medical practice and evidence-based practice protocols for the disease state will be taken into consideration.
    - The above criteria are not applicable to requests for brand name medications that have an AB rated generic. We can require a trial of an AB-rated generic equivalent prior to providing coverage for the equivalent brand name prescription drug.
5. 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.
6. 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.
7. 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
8. 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).

9. No early refills will be allowed without a prior authorization to document necessity.
10. 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.
11. Triple therapy with Olysio is not recommended for any genotype and therefore is not included in the policy.
12. 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).
13. 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.

**UPDATES:**

| Date: | Revision: |
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| 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 |
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| 6/19 | Revision |
| 2/19 | Revision |
| 1/19 | P&T Committee Review & Approval |
| 10/18 | Revision |
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| 2/16 | Revision |
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| 7/15 | Revision |
| 5/15 | Revision |
| 2/15 | Revision |
| 1/15 | Revision |
| 11/14 | Revision |

**REFERENCES:**

1. Pegasys prescribing information- Hoffmann-Roche, Inc. May 2013
2. Peg-Intron prescribing information - Schering Corporation April 2008
3. Everson GT et al. Impact of disease severity on outcomes of antiviral therapy for chronic hepatitis C: lessons from the HALT-C trial. Hepatology. 44(6):1675-84, 2006 Dec.
4. Alsatie M et al. Management of hepatitis C infection after liver transplantation. Drugs. 67(6):871-85, 2007.
5. Moucari R. et al. High predictive value of early viral kinetics in retreatment with peginterferon and ribavirin of chronic hepatitis C patients' non-responders to standard combination therapy. Journal of Hepatology. 46(4):596-604, 2007 Apr.
6. Gross JB Jr. "Maintenance" treatment for patients with cirrhosis related to hepatitis C. Clinical Gastroenterology & Hepatology. 5(4):427-9, 2007 Apr.
7. Fartoux L et al. Effect of prolonged interferon therapy on the outcome of hepatitis C virus-related cirrhosis: a randomized trial. Clinical Gastroenterology & Hepatology. 5(4):502-7, 2007 Apr.
8. Nunez M et al. Role of weight-based ribavirin dosing and extended duration of therapy in chronic hepatitis C in HIV-infected patients: the PRESCO trial. AIDS Research & Human Retroviruses. 23(8):972-82, 2007 Aug.
9. Victrelis Prescribing Information – Merck. February 2013
10. Incivek Prescribing Information – Vertex Pharmaceuticals, April 2013
11. Pawlotsky JM. The results of Phase III clinical trials with telaprevir and boceprevir presented at the Liver Meeting 2010: a new standard of care for hepatitis C virus genotype 1 infection, but with issues still pending. Gastroenterology. 140(3):746-54, Mar 2011.
12. Kwo PY. Efficacy of boceprevir, an NS3 protease inhibitor, in combination with peginterferon alfa-2b and ribavirin in treatment-naïve patients with genotype 1 hepatitis C infection (SPRINT-1): an open-label, randomized, multicentre phase 2 trial. Lancet. 376(9742):705-16, Aug 28, 2010.
13. Poordad f. et al. Boceprevir for untreated chronic HCV genotype 1 infection (SPRINT-2). NEJM. 364(13):1195-1206. Mar 31, 2011.
14. Bacon BR, et al. Boceprevir for previously treated chronic HCV genotype 1 infection (RESPOND-2). NEJM. 364(13):1207-17, Mar 31, 2011
15. FDA approves combination drug for pediatric HCV infection. Medscape. Aug 24, 2011.
16. www.europeanaidsclinicalsociety.org/
17. Myers, RP, et al. An update on the management of chronic hepatits C: consensus guidelines from the Canandian Association for the Study of the Liver. Can J Gastroenterol. 26(6): 359-375, Jun 2012.

18. Joshi, D, et al. Review article: the treatment of genotype 1 chronic hepatitis C virus infection in liver transplant candidates and recipients. Aliment Pharmacol Ther. 37(7): 659-671, 2013.
19. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents. Department of Health and Human Services. Available at http://www.aidsinfo.nih.gov/contentfiles/lvguidelines/adultandadolescentgl.pdf (Accessed on October 1, 2014).
20. www.natap.org/2011/HCV/020511_04.htm
21. www.hcvadvocate.org/hepatitis/factsheets_pdf/viralload.pdf
22. Wosen, Aman, et. al. Current status and future directions in the management of chronic hepatitis C. Virol J. 9: 57.
23. www.hep-druginteractions.org/
24. Recommendations for Testing, Managing, and Treating Hepatitis C. AASLD/IDSA. Downloaded from: http://www.hcvguidelines.org/ on12/11/18.
25. Franciscus, Alan. An Overview of Extrahepatic Manifestations of Hepatitis C. HCSP Version 6.2. 11/2013. http://www.hcvadvocate.org/hepatitis/factsheets_pdf/Extrahepatic.pdf
26. Fujie Xu. Estimating the Number of Patients with Chronic Hepatitis C (HCV) Infection Meeting 'Highest' or 'High' Priority Treatment Criteria in the United States. 65th Annual Meeting of the American Association for the Study of Liver Diseases. http://natap.org/2014/AASLD/AASLD_74.htm
27. Ira M. Jacobson. Virologic Response Rates to All Oral Fixed-Dose Combination Ledipasvir/Sofosbuvir Regimens Are Similar in Patients With and Without Traditional Negative Predictive Factors in Phase 3 Clinical Trials. http://www.natap.org/2014/AASLD/AASLD_67.htm
28. Steven L. Flamm. Ledipasvir/Sofosbuvir With Ribavirin for the Treatment of HCV in Patients With Decompensated Cirrhosis: Preliminary Results of a Prospective, Multicenter Study. http://www.natap.org/2014/AASLD/AASLD_36.htm
29. Daklinza Prescribing Information – Bristol Meyers Squibb. Accessed February 2016
30. Technivie Prescribing Information- AbbVie Inc. Accessed March 6, 2017
31. FDA Drug Safety Communication: FDA warns of serious liver injury risk with hepatitis C treatments Viekira Pak and Technivie. http://www.fda.gov/Drugs/DrugSafety/ucm468634.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery. October 22, 2015.
32. Viekira Prescribing Information- AbbVie Inc. Accessed October 2015.
33. Harvoni Prescribing Information- Gilead Sciences Inc. Accessed May 2019
34. Zepatier Prescribing Information-Merck. Accessed February 2015.
35. Epclusa Prescribing Information- Gilead Sciences Inc. Accessed July 2016.
36. Viekira XR Prescribing Information-AbbVie Inc. Accessed August 2016.
37. Vosevi Prescribing Information- Gilead Sciences Inc. Accessed July 2017
38. Mavyret Prescribing Information- AbbVie Inc. Accessed May 2019
39. Sovaldi Prescribing Information- Gilead Sciences Inc. Accessed May 2019