

Pharmacy Management Drug Policy

SUBJECT: Chronic Hepatitis C (Pegasys, Peg-Intron, ribavirin, Victrelis, Olysio, Sovaldi, Harvoni, Viekira, Viekira XR, Daklinza, Technivie, Zepatier, Epclusa, Vosevi, Mavyret) for Commercial, NYSOH Individual Market, and NYSOH Employer Group Market Products

POLICY NUMBER: Pharmacy-21

EFFECTIVE DATE: 6/03

LAST REVIEW DATE: 04/05/2018

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. Medical or drug policies apply to commercial and Health Care Reform products only when a contract benefit for the specific service exists.

DESCRIPTION:

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 detectable 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)

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Initial Review Criteria – For All Treatment Regimens

Based upon our criteria and assessment of the peer-reviewed literature, **Ribavirin, Peg-Intron, Pegasys, Victrelis, Olysio, Viekira, Viekira XR, Sovaldi, Harvoni, Viekira Pak, Daklinza, Technivie, Zepatier, Epclusa, 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** of the following criteria:

1. Treatment must be prescribed by a gastroenterologist, hepatologist, infectious disease specialist, or HCV/HIV specialist.
 - a. Treatment may also be prescribed by a Primary Care Provider if they have received additional training in the treatment and management of Hepatitis C and/or are working in conjunction with one of the above specialists.
2. HCV genotype and quantitative baseline viral load must be provided with a collection date within twelve months before the start of therapy.
 - A. If a patient has received hepatitis c treatment 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.
3. The provider must assert to the patient's treatment readiness and ability to adhere to prescribed treatment regimen.
 - A. 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 <http://www.integration.samhsa.gov/clinical-practice/screening-tools#drugs>) OR the Pyschosocial Readiness Evaluation and Preparation for hepatitis C treatment (PREP-C), available at <http://prepc.org/>
4. For Ribavirin-containing regimens, female patients of child bearing 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.
5. Patients with limited life expectancy (<12 months due to **non-liver related comorbidities**) are not covered.
6. Progress notes are required on all new starts and recertifications.
7. 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.
8. Patients who are previously cured will not be covered for any treatment upon reinfection.

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Drug Specific Criteria

Mavyret (glecaprevir and pibrentasvir)

- Patient must be 18 years or older
 - 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.
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.
 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 **12 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, 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, 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, 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. Approval will be for **16 weeks** for completion of therapy.

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- 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).

Harvoni (sofosbuvir/ledipasvir)

- Patient **must have genotype 1, 4, 5 or 6** and is 18 years or older
- Harvoni is not covered in patients with severe renal impairment/ESRD (CrCl <30 mL/min) or hemodialysis-patients.
- Harvoni is covered as monotherapy or in combination with ribavirin only.
- 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 under fasted conditions. If H2 receptor antagonists are taken, they should be administered simultaneously with or 12 hours apart from Harvoni at a dose that does not exceed doses comparable to famotidine 40mg twice daily. It is recommended to separate antacid and Harvoni administration by 4 hours.
- Coadministration of amiodarone with Harvoni is not recommended due to risk of serious

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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-naïve 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 without cirrhosis**, approval will be for **12 weeks for completion of therapy** regardless of baseline HCV RNA values.
5. For **genotype 1 treatment-experienced 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 Eplclusa. 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**. Approval will be for 24 weeks in **combination with Ribavirin**, for patients who have **compensated cirrhosis**, in whom a previous Sovaldi containing regimen has failed.
7. For **genotype 4**, Harvoni is approved for 12 weeks in treatment naïve or treatment experienced patients, with or without compensated cirrhosis. .
8. For **genotype 5 or 6**, Harvoni is approved for 12 weeks in treatment naïve or treatment experienced 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**

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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)

- Patient must be 18 years or older
 - Coadministration of amiodarone with Epclusa 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 at a dose that does not exceed doses comparable to famotidine 40mg twice daily. It is recommended to separate antacid and Epclusa administration by 4 hours.
 - The safety and efficacy of Epclusa 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.
 - Coverage of Epclusa 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), Epclusa will be **covered 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**, Epclusa will be covered for 12 weeks.
 3. For **genotype 3 treatment experienced** 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 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 will be covered **in combination with ribavirin** for 12 weeks.

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5. For **genotype 2** patients who are **sofosbuvir and ribavirin experienced**, Epclusa will be covered **in combination with ribavirin** for 12 weeks.
 - a. For all other genotypes, Epclusa will not be covered in patients who have previously received treatment with an NS5B inhibitor

Zepatier (elbasvir and grazoprevir)

- Patient must have genotype 1 or 4 and must be 18 years or older
 - 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.

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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 genotype 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 and Mavyret and Eplclusa or contraindication to Harvoni and Mavyret and Eplclusa.

Viekira Pak (ombitasvir, paritaprevir, and ritonavir tablets; dasabuvir tablets) and Viekira XR

- Patient **must have genotype 1** and must be 18 years or older
 - Must have compensated liver disease (Child-Pugh A). Moderate to severe hepatic impairment is a contraindication (Child-Pugh B and C).
 - Not covered in hemodialysis-patients.
 - Drug interactions must be assessed. Strong inducers of CYP3A and CYP2C8; and strong inhibitors of CYP2C8 are contraindicated.
 - Must be naïve to Viekira/Viekira XR.
 - Viekira/Viekira XR is covered as monotherapy or in combination with ribavirin only.
 - For indeterminate or mixed genotype 1, follow the genotype 1A dosing guidelines.
 - Please see policy guidelines for definition of cirrhosis.
1. For **genotype 1A with or without cirrhosis**, approval is for 12 weeks in **combination with ribavirin**. This includes treatment experienced patients who had a partial response or relapse on prior HCV therapy.
 - a. **Requests for 24 weeks** of treatment are **only** approved for **genotype 1A** patients **with cirrhosis** who is a **null responder** to previous HCV therapy. Documentation of null response to HCV therapy is needed.
 2. For **genotype 1B with/without cirrhosis**, approval is for 12 weeks monotherapy
 3. For post-liver transplant, patient must have mild fibrosis (Metavir fibrosis score 2 or lower). Approval is for 24 weeks in combination with ribavirin.
 4. Viekira pak/Viekira XR will not be authorized for new starts unless there is documentation of severe intolerance (that prevents completion of therapy) with Harvoni and Mavyret and Eplclusa or contraindication to Harvoni and Mavyret and Eplclusa.

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Sovaldi-Based Regimens

- Patient must be 18 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.
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 and Mavyret. For patient patients who have documentation of severe intolerance (that prevents completion of therapy) or contraindication to Epclusa and Mavyret, coverage will be provided as follows:
 - a. For **genotype 2 and 3** patients who are treatment naïve or Peg-interferon/ribavirin experienced **without cirrhosis**, Sovaldi will be covered in combination with daclatasvir (Daklinza) for 12 weeks.
 - b. For **genotype 2 patients** who are treatment naïve or peginterferon/ribavirin experienced with **compensated cirrhosis**, Sovaldi will be approved in combination with daclatasvir (Daklinza) for 16 or 24 weeks¹.
 - c. For **genotype 3 patients** who are treatment naïve with compensated cirrhosis, Sovaldi will be covered in combination with daclatasvir (Daklinza), with or without ribavirin for 24 weeks¹.
 - d. For **genotype 3 patients** who are Peg interferon and ribavirin experienced with compensated cirrhosis, Sovaldi will be covered in combination with daclatasvir (Daklinza) and Ribavirin for 24 weeks¹.
 - e. For **genotype 2 patients** who are **Sofosbuvir (Sovaldi) plus ribavirin treatment experienced**, Sovaldi will be approved in combination with daclatasvir (Daklinza) with or without weight based ribavirin for 24 weeks¹.
 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.
 4. Regimens made up of **Sovaldi and ribavirin** or **peg –interferon with ribavirin and Sovaldi** will **not be covered**. These regimens are no longer recommended by the AASLD guidelines due to inferiority to the current recommended regimens.

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¹ For 16 or 24 week regimens, initial approval will be for 6 weeks. Recertification is approved until the completion of therapy (16 or 24 weeks from the start date). Recertification requires a viral load of ≥ 2 log reduction in HCV RNA from baseline collected two or more weeks after starting therapy

Daklinza (daclatasvir)/Sovaldi (sofosbuvir) combination

- Daklinza will not be authorized as monotherapy
 - Daklinza is contraindicated in combination with drugs that strongly induce CYP3A and may lead to lower exposure and loss of efficacy. These medications include phenytoin, carbamazepine, rifampin, and St. John's wort.
1. Due to the availability of other equally effective, but more cost-effective FDA approved treatment regimens, Daklinza will **NOT** be covered for **genotype 1** patients.
 2. For **genotypes 2 or 3**, Daklinza will not be covered unless there is documentation of a severe intolerance (that prevents completion of therapy) or contraindication to Epclusa and Mavyret. For patient patients who have documentation of severe intolerance (that prevents completion of therapy) or contraindication to Epclusa and Mavyret, coverage will be provided as follows:
 - a. For **genotype 2 and 3** patients who are treatment naïve or Peg-interferon/ribavirin experienced **without cirrhosis**, Daklinza will be covered in combination with Sobosbuvir (Sovaldi) for 12 weeks.
 - b. For **genotype 2 patients** who are treatment naïve or peginterferon/ribavirin experienced with **compensated cirrhosis**, Daklinza will be approved in combination with Sofosbuvir (Sovaldi) for 16 or 24 weeks¹.
 - c. For **genotype 3 patients** who are treatment naïve with compensated cirrhosis, Daklinza will be covered in combination with Sofosbuvir (Sovaldi), with or without ribavirin for 24 weeks¹.
 - d. For **genotype 3 patients** who are Peg interferon and ribavirin experienced with compensated cirrhosis, Daklinza will be covered in combination with Sofosbuvir (Sovaldi) and Ribavirin for 24 weeks¹.
 - e. For **genotype 2 patients** who are **Sofosbuvir (Sovaldi) plus ribavirin treatment experienced**, Daklinza will be approved in combination with sofosbuvir (Sovaldi) with or without weight based ribavirin for 24 weeks¹.
 3. For patients with decompensated cirrhosis, Daklinza will not be covered unless there is documentation of a severe intolerance (that prevents completion of therapy) or contraindication to Epclusa.

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¹ For 16 or 24 week regimens, initial approval will be for 6 weeks. Recertification is approved until the completion of therapy (16 or 24 weeks from the start date). Recertification requires a viral load of ≥ 2 log reduction in HCV RNA from baseline collected two or more weeks after starting therapy

Technivie (ombitasvir, paritaprevir, and ritonavir tablets)

- Must have compensated liver disease (Child-Pugh A). Moderate to severe hepatic impairment is a contraindication (Child-Pugh B and C).
1. For **Genotype 4** patients, **without cirrhosis or with compensated cirrhosis**, approval will be for 12 weeks **in combination with Ribavirin**.
 2. Due to higher relapse rates, Technivie will only be authorized **as monotherapy in genotype 4** patients who are **treatment Naïve, without cirrhosis** AND who are **ineligible to receive Ribavirin**. Please see policy guidelines for definition of those who are considered ribavirin ineligible.
 3. Technivie will not be authorized for new starts unless there is documentation of severe intolerance (that prevents completion of therapy) with Harvoni and Mavyret and Epclusa or contraindication to Harvoni and Mavyret and Epclusa.

SOVALDI / OLYSIO COMBINATION

1. Patient must have documentation of severe intolerance or contraindication to Harvoni, Mavyret, Zepatier, Epclusa and Viekira.
2. For **Genotype 1**, will be authorized as **combination therapy** for those that are **ineligible to receive interferon (IFN)** for an **initial approval of 6 weeks**. **Please see policy guidelines for definition of those who are considered interferon ineligible**. Recertification is approved until the completion of therapy (12 weeks from the start date).
 1. Recertification requires a viral load of ≥ 2 log reduction in HCV RNA from baseline collected two or more weeks after starting therapy.
3. This regimen will not be approved for patients who had therapeutic failure to any protease inhibitor (Incivek, Victrelis, Olysio).
4. Simeprevir use is limited to patients with compensated liver disease (Child-Pugh Class A). This regimen will not be authorized for individuals with moderate to severe liver impairment (Child-Pugh Class B or C).
5. All other genotypes (2-6) utilizing Sovaldi/Olysio combination will be evaluated as off-label.

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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. 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. Approval will be for **12 weeks for completion of therapy**.

POLICY GUIDELINES:

1. Prior-authorization is contract dependent.
2. Policy may not be applicable to all contracts. Coverage criteria may differ for select contracts.
3. Cirrhosis as defined as any one of the following:
 - a. Liver biopsy showing cirrhosis (e.g., Metavir score = 4 or Ishak score \geq 5) OR
 - b. FibroTest® score of > 0.75 AND an APRI > 2 OR
 - c. Nodular liver morphology on abdominal ultrasound or CT scan.
4. 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.

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5. 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

6. Ineligibility to interferon therapy are 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/ μ L or
- d. A baseline platelet count below 90,000/ μ L 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).

7. No early refills will be allowed without a prior authorization to document necessity.

8. 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.

9. Triple therapy with Olysio is not recommended for any genotype and therefore is not included in the policy.

UPDATES:

Date:	Revision:
4/18	Revision
9/17	P & T Approval & Revision
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

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11/14

Revision

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