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**Title:** Hepatitis C Agents

**Policy #:** Rx.01.100

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***Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.***

***This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.***

***Members are advised to use participating pharmacies in order to receive the highest level of benefits.***

**Intent:**

The intent of this policy is to communicate the medical necessity criteria for **elbasvir/ grazeprevir (Zepatier®), ledipasvir/ sofosbuvir (Harvoni®), ombitasvir/ paritaprevir/ ritonavir and dasabuvir (Viekira Pak®), sofosbuvir (Sovaldi®), velpatasvir/ sofosbuvir (Epclusa®), glecaprevir/pibrentasvir (Mavyret™), and sofosbuvir/velpatasvir/voxilaprevir (Vosevi®)** as provided under the member's prescription drug benefit.

**Description:**

In the United States, it is estimated that 2.7 to 3.9 million people are chronically infected with HCV. Chronic HCV infection occurs after acute infection with the virus. It is estimated that approximately 75%-85% of acute infections become chronic. The remaining 15%-25% clear the virus without treatment and do not develop chronic HCV. Genotype (GT) 1 is the most prevalent, with the breakdown as follows: GT 1a: 46.2%, GT1b: 26.3%, GT2: 10.7%, GT3: 8.9%, GT4: 6.3%, GT6: 1.1%, mixed GT/ other: 0.5%.

The goal of treating chronic HCV is to "reduce all-cause mortality and liver-related health adverse consequences, including end-stage liver disease and hepatocellular carcinoma, by the achievement of virologic cure as evidenced by a sustained virologic response (SVR)." SVR is defined as the "continued absence of detectable HCV RNA at least 12 weeks after completion of therapy" and is considered a marker for cure of HCV. Several benefits are associated with HCV cure, including decreases in liver inflammation, progression to liver fibrosis, hepatocellular carcinoma, liver-related mortality and liver transplantation.

This policy follows the AASLD/IDSA guidelines. Current treatment regimens consist of at least 2 agents. Monotherapy is not recommended.

**Elbasvir/ grazeprevir (Zepatier®)** is a product containing an HCV NS5A inhibitor (elbasvir) and an HCV NS3/4A protease inhibitor in a fixed dose combination.

**Glecaprevir/pibrentasvir (Mavyret™)** is a fixed-dose combination of glecaprevir, an HCV NS2/4A inhibitor, and pibrentasvir, an HCV NS5A inhibitor.

**Ledipasvir/ sofosbuvir (Harvoni®)** is a combination product that contains an HCV NS5A replication inhibitor (ledipasvir) and an HCV NS5B RNA-dependent polymerase inhibitor (sofosbuvir) in a fixed dose combination.

**Ombitasvir/ paritaprevir/ ritonavir and dasabuvir (Viekira Pak®)** is a combination product that contains an HCV NS5A replication inhibitor (ombitasvir), an HCV NS3/4A protease inhibitor (paritaprevir) and a booster (ritonavir) as a fixed dose tablet along with an HCV NS5B RNA-dependent RNA polymerase inhibitor (dasabuvir) as a separate tablet.

**Sofosbuvir (Sovaldi®)** inhibits HCV NS5B RNA-dependent RNA polymerase, which is essential for viral replication.

**Sofosbuvir/velpatasvir/voxilaprevir (Vosevi®)** is a fixed-dose combination of sofosbuvir, an HCV nucleotide analog NS5B polymerase inhibitor; velpatasvir, an HCV NS5A inhibitor; and voxilaprevir, an HCV NS3/4A protease inhibitor.

**Velpatisvir/ sofosbuvir (Epclusa®)** is a combination product that contains an HCV NS5A replication inhibitor (velpatisvir) and an HCV NS5B RNA-dependent polymerase inhibitor (sofosbuvir) in a fixed dose combination.

#### **Policy:**

#### **TREATMENT NAIVE**

#### **A. Genotype 1**

Mavyret™ is approved when ALL of the following are met:

1. Age 3 years or older; and
2. Diagnosis of chronic HCV genotype 1; and
3. Absence of decompensated cirrhosis (i.e., compensated cirrhosis or no cirrhosis); and
4. Approved length of therapy: 56 days (8 weeks)

Velpatasvir/ sofosbuvir (Epclusa®) is approved when ALL of the following are met:

1. Age 3 years or older; and
2. Diagnosis of chronic HCV genotype 1; and
3. Absence of decompensated cirrhosis (i.e., compensated cirrhosis or no cirrhosis); and
4. Approved length of therapy: 84 days (12 weeks)\* ; and
5. Inadequate response or inability to tolerate brand Epclusa® (applies to velpatasvir/sofosbuvir only), details of intolerability must be provided

Ledipasvir/ sofosbuvir (Harvoni®) is approved when ALL of the following are met:

1. Age 3 years or older; and
2. Diagnosis of chronic HCV genotype 1; and
3. Absence of decompensated cirrhosis (i.e., compensated cirrhosis or no cirrhosis); and
4. Approved length of therapy: 84 days (12 weeks)\* ; and
5. Inadequate response or inability to tolerate brand Harvoni® (applies to ledipasvir/sofosbuvir only), details of intolerability must be provided

Zepatier® is approved when ALL of the following are met:

1. Age 12 years or older or weighing at least 30kg; and
2. Diagnosis of HCV genotype 1; and
3. Results of testing for baseline high fold-change NS5A resistance-associated variant are provided (for genotype 1a); and
4. Absence of decompensated cirrhosis (i.e., compensated cirrhosis or no cirrhosis); and
5. Documentation of a dispensed prescription for and inability to tolerate glecaprevir/ pibrentasvir (Mavyret™), brand Harvoni® or brand Epclusa®, details of intolerability must be provided; and
6. Used concurrently with ribavirin for genotype 1a when baseline high fold-change NS5A resistance-associated variant are detected; and
7. Approved length of therapy:
  - a. Genotype 1a without baseline high fold-change NS5A resistance-associated variant or genotype 1b: 84 days (12 weeks)\*; or
  - b. Genotype 1a with baseline high fold-change NS5A resistance-associated variant: 112 days (16 weeks)\*

Viekira Pak® is approved when ALL of the following are met:

1. Age 18 years or older; and
2. Diagnosis of chronic HCV genotype 1; and
3. ONE of the following:
  - a. Genotype 1a without cirrhosis; or
  - b. Genotype 1b with absence of decompensated cirrhosis (i.e., compensated cirrhosis or no cirrhosis); and
4. Documentation of a dispensed prescription for and inability to tolerate glecaprevir/ pibrentasvir (Mavyret™), brand Harvoni® or brand Epclusa®, details of intolerability must be provided; and
5. Used concurrently with ribavirin for genotype 1a; and
6. Approved length of therapy: 84 days (12 weeks) \*

## **B. Genotype 2**

Mavyret™ is approved when all of the following are met:

1. Age 3 years or older; and
2. Diagnosis of chronic HCV genotype 2; and
3. Absence of decompensated cirrhosis (i.e., compensated cirrhosis or no cirrhosis); and
4. Approved length of therapy: 56 days (8 weeks)\*

Velpatasvir/ sofosbuvir (Epclusa®) is approved when ALL of the following are met:

1. Age 3 years or older; and
2. Diagnosis of chronic HCV genotype 2; and
3. Absence of decompensated cirrhosis (i.e., compensated cirrhosis or no cirrhosis); and
4. Inadequate response or inability to tolerate brand Epclusa® (applies to velpatasvir/sofosbuvir only), details of intolerability must be provided; and
5. Approved length of therapy: 84 days (12 weeks)\*

Sovaldi® is approved when ALL of the following are met:

1. Pediatric member 3 years of age and older; and
2. Diagnosis of chronic HCV genotype 2; and
3. Concurrent use of ribavirin; and
4. Absence of decompensated cirrhosis (i.e., compensated cirrhosis or no cirrhosis); and
5. Approved length of therapy: 84 days (12 weeks)\*

## **C. Genotype 3**

Mavyret™ is approved when ALL of the following are met:

1. Age 3 years or older; and
2. Diagnosis of chronic HCV genotype 3; and
3. Absence of decompensated cirrhosis (i.e., compensated cirrhosis or no cirrhosis); and
4. Approved length of therapy: : 56 days (8 weeks)\*

Velpatasvir/ sofosbuvir (Epclusa®) is approved when ALL of the following are met:

1. Age 3 years or older; and
2. Diagnosis of chronic HCV genotype 3; and
3. Absence of decompensated cirrhosis (i.e. compensated cirrhosis or no cirrhosis); and
4. Inadequate response or inability to tolerate brand Epclusa® (applies to velpatasvir/sofosbuvir only), details of intolerability must be provided; and
5. Concurrent use of ribavirin if compensated cirrhosis and Y93H substitution present; and
6. Approved length of therapy: 84 days (12 weeks)

Sovaldi® is approved when ALL of the following are met:

1. Pediatric member 3 years of age and older; and
2. Diagnosis of chronic HCV genotype 3; and
3. Concurrent use of ribavirin; and
4. Absence of decompensated cirrhosis (i.e., compensated cirrhosis or no cirrhosis); and
5. Approved length of therapy: 168 days (24 weeks)\*

Vosevi® is approved when ALL of the following are met:

1. Age 18 years or older; and
2. Diagnosis of chronic HCV genotype 3; and
3. Compensated cirrhosis; and
4. Presence of Y93H; and
5. Approved length of therapy: 84 days (12 weeks)\*

#### **D. Genotype 4**

Mavyret™ is approved when ALL of the following are met:

1. Age 3 years or older; and
2. Diagnosis of chronic HCV genotype 4; and
3. Absence of decompensated cirrhosis (i.e., compensated cirrhosis or no cirrhosis); and
4. Approved length of therapy: 56 days (8 weeks)

Velpatasvir/ sofosbuvir (Epclusa®) is approved when ALL of the following are met:

1. Age 3 years or older; and
2. Diagnosis of chronic HCV genotype 4; and
3. Absence of decompensated cirrhosis (i.e., compensated cirrhosis or no cirrhosis); and
4. Inadequate response or inability to tolerate brand Epclusa® (applies to velpatasvir/sofosbuvir only), details of intolerability must be provided; and
5. Approved length of therapy: 84 days (12 weeks)\*

Ledipasvir/ sofosbuvir (Harvoni®) is approved when ALL of the following are met:

1. Age 3 years or older; and
2. Diagnosis of chronic HCV genotype 4; and
3. Absence of decompensated cirrhosis (i.e., compensated cirrhosis or no cirrhosis); and
4. Inadequate response or inability to tolerate brand Harvoni® (applies to ledipasvir/sofosbuvir only), details of intolerability must be provided; and
5. Approved length of therapy: 84 days (12 weeks)\*

Zepatier® is approved when ALL of the following are met:

1. Age 12 years or older or weighing at least 30kg; and
2. Diagnosis of chronic HCV genotype 4; and
3. Absence of decompensated cirrhosis (i.e., compensated cirrhosis or no cirrhosis); and
4. Documentation of a dispensed prescription for and inability to tolerate glecaprevir/ pibrentasvir (Mavyret™), brand Harvoni® or brand Epclusa®, details of intolerability must be provided; and

5. Approved length of therapy: 84 days (12 weeks)\*

## **E. Genotype 5 or 6**

Mavyret™ is approved when ALL of the following are met:

1. Age 3 years or older; and
2. Diagnosis of chronic HCV genotype 5 or 6; and
3. Absence of decompensated cirrhosis (i.e., compensated cirrhosis or no cirrhosis); and
4. Approved length of therapy: 56 days (8 weeks)

Velpatasvir/ sofosbuvir (Epclusa®) is approved when ALL of the following are met:

1. Age 3 years or older; and
2. Diagnosis of chronic HCV genotype 5 or 6; and
3. Absence of decompensated cirrhosis (i.e., compensated cirrhosis or no cirrhosis); and
4. Inadequate response or inability to tolerate brand Epclusa® (applies to velpatasvir/sofosbuvir only), details of intolerability must be provided; and
5. Approved length of therapy: 84 days (12 weeks)\*

Ledipasvir/ sofosbuvir (Harvoni®) is approved when ALL the following are met:

1. Age 3 years or older; and
2. Diagnosis of chronic HCV genotype 5 or 6; and
3. Absence of decompensated cirrhosis (i.e., compensated cirrhosis or no cirrhosis); and
4. Inadequate response or inability to tolerate brand Harvoni® (applies to ledipasvir/sofosbuvir only), details of intolerability must be provided; and
5. Approved length of therapy: 84 days (12 weeks)\*

## **RETREATMENT**

### **A. Genotype 1: peginterferon and ribavirin with or without NS3 protease inhibitor experienced**

Ledipasvir/ sofosbuvir (Harvoni®) is approved when ALL of the following are met:

1. Age 3 years or older; and
2. Diagnosis of chronic HCV genotype 1; and
3. Absence of decompensated cirrhosis (i.e., compensated cirrhosis or no cirrhosis) ; and
4. Used with ribavirin if compensated cirrhosis; and
5. Member failed peginterferon and ribavirin with or without an HCV protease inhibitor; and
6. Inadequate response or inability to tolerate brand Harvoni® (applies to ledipasvir/sofosbuvir), details of intolerability must be provided; and
7. Approved length of therapy: 84 days (12 weeks)

Velpatasvir/sofosbuvir (Epclusa®) is approved when ALL of the following are met:

1. Age 3 years or older; and
2. Diagnosis of chronic HCV genotype 1; and
3. Absence of decompensated cirrhosis (i.e., compensated cirrhosis or no cirrhosis) ; and
4. Member failed peginterferon and ribavirin with or without an HCV protease inhibitor; and
5. Inadequate response or inability to tolerate brand Epclusa® (applies to velpatasvir/sofosbuvir) details of intolerability must be provided; and

6. Approved length of therapy: 84 days (12 weeks)

Mavyret™ is approved when ALL of the following are met:

1. Age 3 years or older; and
2. Diagnosis of chronic HCV genotype 1; and
3. Absence of decompensated cirrhosis (i.e. compensated cirrhosis or no cirrhosis); and
4. Member failed peginterferon and ribavirin with or without an HCV protease inhibitor; and
5. Approved length of therapy:
  - a. Without cirrhosis: 56 days (8 weeks)\*; or
  - b. With compensated cirrhosis: 84 days (12 weeks)\*

Zepatier® is approved when ALL of the following are met:

1. Age 12 years or older or weighing at least 30kg; and
2. Diagnosis of HCV genotype 1; and
3. Member failed peginterferon and ribavirin with or without an HCV protease inhibitor; and
4. Results of testing for baseline high fold-change NS5A resistance-associated variant are provided (for genotype 1a); and
5. Absence of decompensated cirrhosis (i.e., compensated cirrhosis or no cirrhosis); and
6. Documentation of a dispensed prescription for and inability to tolerate glecaprevir/ pibrentasvir (Mavyret™), brand Harvoni® or Epclusa®, details of intolerability must be provided; and
7. Used concurrently with ribavirin for either of the following:
  - a. Genotype 1a when baseline high fold-change NS5A resistance-associated variant are detected; or
  - b. Prior treatment with peginterferon, ribavirin, and an HCV protease inhibitor; and
8. Approved length of therapy:
  - a. Genotype 1a without baseline high fold-change NS5A resistance-associated variant or genotype 1b: 84 days (12 weeks)\*; or
  - b. Genotype 1a with baseline high fold-change NS5A resistance-associated variant: 112 day (16 weeks)\*

Viekira Pak® is approved when ALL of the following are met:

1. Age 18 years or older; and
2. Diagnosis of chronic HCV genotype 1; and
3. Member failed peginterferon and ribavirin; and
4. ONE of the following:
  - a. Genotype 1a and absence of cirrhosis; or
  - b. Genotype 1b and absence of decompensated cirrhosis (i.e., compensated cirrhosis or no cirrhosis); and
5. Member is HCV protease inhibitor treatment naïve; and
6. Documentation of a dispensed prescription for and inability to tolerate glecaprevir/ pibrentasvir (Mavyret™), brand Harvoni® or brand Epclusa®, details of intolerability must be provided; and
7. Used concurrently with ribavirin for genotype 1a; and
8. Approved length of therapy: 84 days (12 weeks)\*

## **B. Genotype 1 Non-NS5A inhibitor, sofosbuvir-containing regimen experienced**

Mavyret™ is approved when ALL of the following are met:

1. Age 3 years or older; and
2. Diagnosis of chronic HCV genotype 1; and
3. Absence of decompensated cirrhosis (i.e., compensated cirrhosis or no cirrhosis); and
4. Member failed a non-NS5A, sofosbuvir-containing regimen; and

5. Approved length of therapy: 84 days (12 weeks)\*

Velpatasvir/ sofosbuvir (Epclusa®) is approved when ALL the following are met:

1. Age 3 years or older; and
2. Diagnosis of chronic HCV genotype 1b; and
3. Absence of decompensated cirrhosis (i.e., compensated cirrhosis or no cirrhosis) ; and
4. Member failed a non-NS5A, sofosbuvir-containing regimen; and
5. Inadequate response or inability to tolerate brand Epclusa® (applies to velpatasvir/sofosbuvir only), details of intolerance must be provided; and
6. Approved length of therapy: 84 days (12 weeks)\*

Vosevi® is approved when ALL the following are met:

1. Age 18 years or older; and
2. Diagnosis of chronic HCV genotype 1a; and
3. Absence of decompensated cirrhosis (i.e., compensated cirrhosis or no cirrhosis) ; and
4. Member failed a non-NS5A, sofosbuvir-containing regimen; and
5. Approved length of therapy: 84 days (12 weeks)\*

Ledipasvir/ sofosbuvir (Harvoni®) is approved when all the following are met:

1. Age 3 years or older; and
2. Diagnosis of chronic HCV genotype 1b; and
3. Absence of cirrhosis; and
4. Member is naïve to simeprevir; and
5. Member failed a non-NS5A, sofosbuvir-containing regimen; and
6. Used with ribavirin; and
7. Inadequate response or inability to tolerate brand Harvoni® (applies to ledipasvir/sofosbuvir only), details of intolerance must be provided; and
8. Approved length of therapy: 84 days (12 weeks)\*

### **C. Genotype 1 NS5A inhibitor experienced**

Mavyret™ is approved when ALL of the following are met:

1. Age 3 years or older; and
2. Diagnosis of chronic HCV genotype 1; and
3. Absence of decompensated cirrhosis (i.e., compensated cirrhosis or no cirrhosis) ; and
4. Member failed a NS5A containing regimen not containing a protease inhibitor; and
5. Approved length of therapy: 112 days (16 weeks)

Vosevi® is approved when ALL the following are met:

1. Age 18 years or older; and
2. Diagnosis of chronic HCV genotype 1; and
3. Absence of decompensated cirrhosis (i.e., compensated cirrhosis or no cirrhosis) ; and
4. Member failed a NS5A containing regimen; and
5. Approved length of therapy: 84 days (12 weeks)

### **D. Genotype 2**

Mavyret™ is approved when ALL of the following are met:

1. Age 3 years or older; and
2. Diagnosis of chronic HCV genotype 2; and
3. Absence of decompensated cirrhosis (i.e., compensated cirrhosis or no cirrhosis) ; and
4. Member failed prior treatment with peginterferon and ribavirin or sofosbuvir and ribavirin; and
5. Approved length of therapy:
  - a. Without cirrhosis and failed peginterferon and ribavirin with or without sofosbuvir: 56 days (8 weeks);  
or
  - b. With compensated cirrhosis and failed peginterferon and ribavirin with or without sofosbuvir: 84 days (12 weeks)\*

Velpatasvir/ sofosbuvir (Epclusa®) is approved when ALL of the following are met:

1. Age 3 years or older; and
2. Diagnosis of chronic HCV genotype 2; and
3. Absence of decompensated cirrhosis (i.e., compensated cirrhosis or no cirrhosis) ; and
4. Member failed prior treatment with peginterferon and ribavirin or sofosbuvir and ribavirin; and
5. Inadequate response or inability to tolerate brand Epclusa® (applies to velpatasvir/sofosbuvir only), details of intolerability must be provided; and
6. Approved length of therapy: 84 days (12 weeks)\*

Vosevi® is approved when ALL of the following are met:

1. Age 18 years or older; and
2. Diagnosis of chronic HCV genotype 2; and
3. Absence of decompensated cirrhosis (i.e., compensated cirrhosis or no cirrhosis) ; and
4. Member failed prior treatment with NS5A containing regimen; and
5. Approved length of therapy: 84 days (12 weeks)

Sovaldi® is approved when ALL of the following are met:

1. Pediatric member 3 years of age and older; and
2. Diagnosis of chronic HCV genotype 2; and
3. Member has failed treatment with interferon; and
4. Concurrent use of ribavirin; and
5. Absence of decompensated cirrhosis (i.e., compensated cirrhosis or no cirrhosis) ; and
6. Approved length of therapy: 84 days (12 weeks)\*

### **E. Genotype 3**

Mavyret™ is approved when ALL of the following are met:

1. Age 3 years or older; and
2. Diagnosis of chronic HCV genotype 3; and
3. Absence of decompensated cirrhosis (i.e., compensated cirrhosis or no cirrhosis) ; and
4. Approved length of therapy: 112 days (16 weeks)\*

Velpatasvir/ sofosbuvir (Epclusa®) is approved when ALL of the following are met:

1. Age 3 years or older; and
2. Diagnosis of chronic HCV genotype 3; and
3. Absence of decompensated cirrhosis (i.e. compensated cirrhosis or no cirrhosis) ; and

4. Used with ribavirin if compensated cirrhosis; and
5. Inadequate response or inability to tolerate brand Epclusa® (applies to velpatasvir/sofosbuvir only), details of intolerability must be provided; and
6. Approved length of therapy: 84 days (12 weeks)\*

Vosevi® is approved when ALL of the following are met:

1. Age 18 years or older; and
2. Diagnosis of chronic HCV genotype 3; and
3. ONE of the following:
  - a. Member failed peginterferon and ribavirin and ONE of the following:
    - i. Y93H substitution is present and absence of cirrhosis; or
    - ii. Compensated cirrhosis; or
  - b. Member failed prior treatment with NS5A inhibitor and ONE of the following:
    - i. Presence of compensated cirrhosis and concurrent use of ribavirin or the member is not a suitable candidate for ribavirin therapy; or
    - ii. Absence of cirrhosis; or
  - c. Member failed prior treatment with a non-NS5A inhibitor, sofosbuvir-containing regimen with absence of decompensated cirrhosis (i.e. compensated cirrhosis or no cirrhosis) ; and
4. Approved length of therapy: 84 days (12 weeks)\*

Sovaldi® is approved when ALL of the following are met:

1. Pediatric member 3 years of age and older; and
2. Diagnosis of chronic HCV genotype 3; and
3. Member has failed treatment with interferon; and
4. Concurrent use of ribavirin; and
5. Absence of decompensated cirrhosis (i.e., compensated cirrhosis or no cirrhosis) ; and
6. Approved length of therapy: 168 days (24 weeks)\*

#### **F. Genotype 4**

Mavyret™ is approved when ALL of the following are met:

1. Age 3 years or older; and
2. Diagnosis of chronic HCV genotype 4; and
3. Member failed peginterferon and ribavirin
4. Absence of decompensated cirrhosis (i.e., compensated cirrhosis or no cirrhosis) ; and
5. Approved length of therapy:
  - a. Without cirrhosis: 56 days (8 weeks)\*; or
  - b. With compensated cirrhosis: 84 days (12 weeks)\*

Ledipasvir/ sofosbuvir (Harvoni®) is approved when ALL of the following are met:

1. Age 3 years or older; and
2. Diagnosis of chronic HCV genotype 4; and
3. Member failed peginterferon and ribavirin; and
4. Absence of decompensated cirrhosis (i.e., compensated cirrhosis or no cirrhosis) ; and
5. Used with ribavirin if compensated cirrhosis; and
6. Inadequate response or inability to tolerate brand Harvoni® (applies to ledipasvir/sofosbuvir only), details or intolerability must be provided; and
7. Approved length of therapy: 84 days (12 weeks)\*

Velpatasvir/sofosbuvir (Epclusa®) is approved when ALL of the following are met:

1. Age 3 years or older; and
2. Diagnosis of chronic HCV genotype 4; and
3. Member failed peginterferon and ribavirin; and
4. Absence of decompensated cirrhosis (i.e., compensated cirrhosis or no cirrhosis) ; and
5. Inadequate response or inability to tolerate brand Epclusa® (applies to velpatasvir/sofosbuvir only), details of intolerability must be provided; and
6. Approved length of therapy: 84 days (12 weeks)\*

Zepatier® is approved when ALL the following are met:

1. Age 12 years or older or weighing at least 30kg; and
2. Diagnosis of HCV genotype 4; and
3. Member failed peginterferon and ribavirin; and
4. Absence of decompensated cirrhosis; and
5. Documentation of a dispensed prescription for and inability to tolerate glecaprevir/ pibrentasvir (Mavyret™), brand Harvoni® or brand Epclusa®, details of intolerability must be provided; and
6. Concurrent use of ribavirin if prior on-treatment virologic failure (failure to suppress or breakthrough) ; and
7. Approved length of therapy:
  - a. If no prior on-treatment failure: 84 days (12 weeks)\*; or
  - b. If prior on-treatment virologic failure: 112 days (16 weeks)\*

Vosevi® is approved when ALL of the following are met:

1. Age 18 years or older; and
2. Diagnosis of chronic HCV genotype 4; and
3. Member failed prior treatment with direct acting antivirals (including NS5A inhibitors) ; and
4. Absence of decompensated cirrhosis (i.e., compensated cirrhosis or no cirrhosis) ; and
5. Approved length of therapy: 84 days (12 weeks)\*

## **G. Genotype 5 or 6**

Mavyret™ is approved when ALL of the following are met:

1. Age 3 years or older; and
2. Diagnosis of chronic HCV genotype 5 or 6; and
3. Member failed prior treatment with peginterferon and ribavirin; and
4. Absence of decompensated cirrhosis (i.e., compensated cirrhosis or no cirrhosis) ; and
5. Approved length of therapy:
  - a. Without cirrhosis: 56 days (8 weeks); or
  - b. With compensated cirrhosis: 84 days (12 weeks)\*

Ledipasvir/ sofosbuvir (Harvoni®) is approved when ALL of the following are met:

1. Age 3 years or older; and
2. Diagnosis of chronic HCV genotype 5 or 6; and
3. Member failed prior treatment with peginterferon and ribavirin; and
4. Absence of decompensated cirrhosis (i.e., compensated cirrhosis or no cirrhosis) ; and
5. Inadequate response or inability to tolerate brand Harvoni® (applies to ledipasvir/sofosbuvir only), details or intolerability must be provided; and
6. Approved length of therapy: 84 days (12 weeks)\*

Velpatasvir/sofosbuvir (Epclusa®) is approved when ALL of the following are met:

1. Age 3 years or older; and
2. Diagnosis of chronic HCV genotype 5 or 6; and
3. Member failed prior treatment with peginterferon and ribavirin; and
4. Absence of decompensated cirrhosis (i.e., compensated cirrhosis or no cirrhosis) ; and
5. Inadequate response or inability to tolerate brand Epclusa® (applies to velpatasvir/sofosbuvir only) details of intolerability must be provided; and
6. Approved length of therapy: 84 days (12 weeks)\*

Vosevi® is approved when ALL of the following are met:

1. Age 18 years or older; and
2. Diagnosis of chronic HCV genotype 5 or 6; and
3. Member failed prior treatment with direct acting antivirals (including NS5A inhibitors) ; and
4. Absence of decompensated cirrhosis (i.e., compensated cirrhosis or no cirrhosis) ; and
5. Approved length of therapy: 84 days (12 weeks)\*

## **DECOMPENSATED CIRRHOSIS (moderate to severe hepatic impairment; Child Turcotte Pugh B or C)**

### **A. Genotype 1, 4, 5, or 6**

Ledipasvir/ sofosbuvir (Harvoni®) is approved when ALL of the following are met:

1. Age 3 years or older; and
2. Diagnosis of chronic HCV genotype 1, 4, 5, or 6; and
3. Documentation of decompensated cirrhosis (defined as Child Turcotte Pugh class B or C) or hepatocellular carcinoma; and
4. Used with ribavirin; and
5. Prescribed by a hepatitis C expert (i.e., hepatologist, liver transplant surgeon) ; and
6. Inadequate response or inability to tolerate brand Harvoni® (applies to ledipasvir/sofosbuvir only), details or intolerability must be provided; and
7. Approved length of therapy:
  - a. Member failed prior sofosbuvir containing regimen: 168 days (24 weeks)\*; or
  - b. All others: 84 days (12 weeks)\*

Velpatasvir/sofosbuvir (Epclusa®) is approved when ALL of the following are met:

1. Age 3 years or older; and
2. Diagnosis of chronic HCV genotype 1, 4, 5, or 6; and
3. Documentation of decompensated cirrhosis (defined as Child Turcotte Pugh class B or C) or hepatocellular carcinoma; and
4. Used with ribavirin; and
5. Prescribed by a hepatitis C expert (i.e., hepatologist, liver transplant surgeon) ; and
6. Inadequate response or inability to tolerate brand Epclusa® (applies to velpatasvir/sofosbuvir only), details of intolerability must be provided; and
7. Approved length of therapy:
  - a. Member failed prior sofosbuvir containing regimen: 168 days (24 weeks)\*; or
  - b. Member failed NS5A based regimen: 168 days (24 weeks)\*; or
  - c. All others: 84 days (12 weeks)\*

Ledipasvir/ sofosbuvir (Harvoni®) is approved when ALL of the following are met:

1. Age 3 years or older; and
2. Diagnosis of chronic HCV genotype 1, 4, 5, or 6; and
3. Documentation of decompensated cirrhosis (defined as Child Turcotte Pugh class B or C) or hepatocellular carcinoma; and
4. Prescribed by a hepatitis C expert (i.e., hepatologist, liver transplant surgeon) ; and
5. Intolerant to or ineligible for ribavirin; and

6. Inadequate response or inability to tolerate brand Harvoni® (applies to ledipasvir/sofosbuvir only), details or intolerability must be provided; and
7. Approved length of therapy: 168 days (24 weeks)\*

Velpatasvir/sofosbuvir (Epclusa®) is approved when ALL of the following are met:

1. Age 3 years or older; and
2. Diagnosis of chronic HCV genotype 1, 4, 5, or 6; and
3. Documentation of decompensated cirrhosis (defined as Child Turcotte Pugh class B or C) or hepatocellular carcinoma; and
4. Prescribed by a hepatitis C expert (i.e., hepatologist, liver transplant surgeon) ; and
5. Intolerant to or ineligible for ribavirin; and
6. Inadequate response or inability to tolerate brand Epclusa® (applies to velpatasvir/sofosbuvir only) details of intolerability must be provided; and
7. Approved length of therapy: 168 days (24 weeks)\*

## **B. Genotype 2 or 3**

Velpatasvir/ sofosbuvir (Epclusa®) is approved when ALL of the following are met:

1. Age 3 years or older; and
2. Diagnosis of chronic HCV genotype 2 or 3; and
3. Documentation of decompensated cirrhosis (defined as Child Turcotte Pugh class B or C) or hepatocellular carcinoma; and
4. Used with ribavirin; and
5. Prescribed by a hepatitis C expert (i.e., hepatologist, liver transplant surgeon) ; and
6. Inadequate response or inability to tolerate brand Epclusa® (applies to velpatasvir/sofosbuvir only), details of intolerability must be provided; and
7. Approved length of therapy:
  - a. Prior treatment with sofosbuvir or NS5A based therapy: 168 days (24 weeks); or
  - b. All others: 84 days (12 weeks)\*

Velpatasvir/ sofosbuvir (Epclusa®) is approved when ALL the following are met:

1. Age 3 years or older; and
2. Diagnosis of chronic HCV genotype 2 or 3; and
3. Documentation of decompensated cirrhosis (defined as Child Turcotte Pugh class B or C) or hepatocellular carcinoma; and
4. Prescribed by a hepatitis C expert (i.e., hepatologist, liver transplant surgeon) ; and
5. Intolerant to or ineligible for ribavirin; and
6. Inadequate response or inability to tolerate brand Epclusa® (applies to velpatasvir/sofosbuvir only), details of intolerability must be provided; and
7. Approved length of therapy: 168 days (24 weeks)\*

## **RECURRENT HCV POST LIVER TRANSPLANT**

### **A. Genotype 1, 4, 5, or 6**

Mavyret™ is approved when there is documentation of ALL of the following:

1. Age 3 years or older; and
2. Diagnosis of HCV genotype 1, 4, 5, or 6; and
3. Documentation of liver transplant; and
4. Absence of decompensated cirrhosis (i.e., compensated cirrhosis or no cirrhosis) ; and
5. Approved length of therapy: 84 days (12 weeks)\*

Ledipasvir/ sofosbuvir (Harvoni®) is approved when there is documentation of ALL of the following:

1. Age 3 years or older; and
2. Diagnosis of HCV genotype 1, 4, 5, or 6; and
3. Documentation of liver transplant; and
4. Used with ribavirin; and
5. Inadequate response or inability to tolerate brand Harvoni® (applies to ledipasvir/sofosbuvir only), details of intolerance must be provided; and
6. Approved length of therapy: 84 days (12 weeks)\*

Viekira Pak® is approved when ALL of the following are met:

1. Age 18 years or older; and
2. Diagnosis of HCV genotype 1; and
3. Documentation of liver transplant; and
4. Documentation of normal hepatic function; and
5. Documentation of mild fibrosis; and
6. Used with ribavirin; and
7. Documentation of a dispensed prescription for and inability to tolerate glecaprevir/ pibrentasvir (Mavyret™) or brand Harvoni®, details of intolerance must be provided; and
8. Approval length: 24 weeks

### **B. Genotype 2 or 3**

Mavyret™ is approved when ALL of the following are met:

1. Age 3 years or older; and
2. Diagnosis of HCV genotype 2 or 3; and
3. Documentation of liver transplant; and
4. Absence of decompensated cirrhosis (i.e., compensated cirrhosis or no cirrhosis) ; and
5. Approved length of therapy: 84 days (12 weeks)\*

Velpatasvir/ sofosbuvir (Epclusa®) is approved when ALL the following are met:

1. Age 3 years or older; and
2. Diagnosis of HCV genotype 2 or 3; and
3. Documentation of liver transplant; and
4. Used with ribavirin; and
5. Presence of cirrhosis; and
6. Inadequate response or inability to tolerate brand Epclusa® (applies to velpatasvir/sofosbuvir only), details of intolerance must be provided; and
7. Approved length of therapy: 84 days (12 weeks)\*

## KIDNEY TRANSPLANT RECIPIENT

### A. Genotype 1 or 4

Mavyret™ is approved when there is documentation of ALL of the following:

1. Age 3 years or older; and
2. Diagnosis of HCV genotype 1 or 4; and
3. Documentation of kidney transplant; and
4. Absence of decompensated cirrhosis (i.e., compensated cirrhosis or no cirrhosis) ; and
5. Approved length of therapy: 84 days (12 weeks)\*

Ledipasvir/ sofosbuvir (Harvoni®) is approved when there is documentation of ALL of the following:

1. Age 3 years or older; and
2. Diagnosis of HCV genotype 1 or 4; and
3. Documentation of kidney transplant; and
4. Absence of decompensated cirrhosis (i.e., compensated cirrhosis or no cirrhosis) ; and
5. Inadequate response or inability to tolerate brand Harvoni® (applies to ledipasvir/sofosbuvir only), details of intolerance must be provided; and
6. Approved length of therapy: 84 days (12 weeks)\*

### B. Genotype 2,3,5, or 6

Mavyret™ is approved when there is documentation of ALL of the following:

1. Age 3 years or older; and
2. Diagnosis of HCV genotype 2,3,5, or 6; and
3. Documentation of kidney transplant; and
4. Absence of decompensated cirrhosis (i.e., compensated cirrhosis or no cirrhosis) ; and
5. Approved length of therapy: 84 days (12 weeks)\*

\*Approved length of therapy: if therapy was initiated prior to coverage with the plan, authorization will only be granted to allow completion of the specified therapy. Authorizations will end 180 days after receipt of request.

### Maximum doses per day apply

Drug	Maximum dose per day (tablets)
velpatasvir/ sofosbuvir (Epclusa®)	1
velpatasvir/ sofosbuvir (Epclusa®) pack 200-50mg	2
velpatasvir/ sofosbuvir (Epclusa®) pack 150-37.5mg	1
Mavyret™	3
Mavyret™ pak 50-20mg	5
Ledipasvir/sofosbuvir (Harvoni®)	1
Sovaldi®	1
Viekira Pak®	6
Zepatier®	1

HCV Treatment Regimens that are not recommended and considered not medically necessary

- A. Sofosbuvir with ribavirin x 24 weeks (except in genotype 2 post liver transplant)
- B. Peg-interferon and ribavirin with or without sofosbuvir, simeprevir, telaprevir, or boceprevir)
- C. Monotherapy with peg-interferon, ribavirin, or a direct-acting antiviral
- D. Simeprevir, paritaprevir, or elbasvir/grazoprevir based regimens in those decompensated cirrhosis

**Black Box Warning as shown in the drug Prescribing Information:**

**Epclusa® (velpatasvir/sofosbuvir), Sovaldi® (sofosbuvir), Viekira Pak® (ombitasvir/paritaprevir/ritonavir/dasabuvir), Harvoni® (ledipasvir/sofosbuvir), Zepatier® (elbasvir/grazoprevir), Mavyret™ (glecaprevir and pibrentasvir) & Vosevi® (sofosbuvir/velpatasvir/voxilaprevir):**

**RISK OF HEPATITIS B REACTIVATION IN PATIENTS COINFECTED WITH HCV AND HBV:**

Hepatitis B virus (HBV) reactivation has been reported, in some cases resulting in fulminant hepatitis, hepatic failure, and death.

**Guidelines:**

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

**BENEFIT APPLICATION**

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

**References:**

American Association for the Study of Liver Disease, Infectious Diseases Society of America, International Antiviral Society-USA. Recommendations for testing, managing and treating Hepatitis C. Available from <https://www.hcvguidelines.org/>. Accessed August 10, 2022

Epclusa® (velpatasvir/sofosbuvir) [package insert]. Forest City, CA: Gilead Sciences, Inc; May, 2022. Available from: [https://www.gilead.com/-/media/Files/pdfs/medicines/liver-disease/epclusa/epclusa\\_pi.pdf](https://www.gilead.com/-/media/Files/pdfs/medicines/liver-disease/epclusa/epclusa_pi.pdf). Accessed August 10, 2022

Harvoni® (ledipasvir/sofosbuvir) [package insert]. Forest City, CA: Gilead Sciences, Inc; March 2020. Available from: [https://www.gilead.com/-/media/Files/pdfs/medicines/liver-disease/harvoni/harvoni\\_pi.pdf](https://www.gilead.com/-/media/Files/pdfs/medicines/liver-disease/harvoni/harvoni_pi.pdf). Accessed August 10, 2022

Hepatitis C Information for Health Professionals. Centers for Disease Control and Prevention. July 2019. Available from: <http://www.cdc.gov/hepatitis/HCV/HCVfaq.htm>. Accessed August 10, 2022

Mavyret™ (glecaprevir/pibrentasvir) [package insert]. North Chicago, IL: AbbVie, Inc.; June 2021. Available from [https://www.rxabbvie.com/pdf/mavyret\\_pi.pdf](https://www.rxabbvie.com/pdf/mavyret_pi.pdf). Accessed August 10, 2022

Sovaldi® (sofosbuvir) [package insert]. Forest City, CA: Gilead Sciences, Inc; April 2021. Available from: [https://www.gilead.com/-/media/files/pdfs/medicines/liver-disease/sovaldi/sovaldi\\_pi.pdf?evo\\_source=SOVALDI](https://www.gilead.com/-/media/files/pdfs/medicines/liver-disease/sovaldi/sovaldi_pi.pdf?evo_source=SOVALDI). Accessed August 10, 2022

Viekira Pak® (ombitasvir/ paritaprevir/ ritonavir and dasabuvir) [package insert]. North Chicago, IL: AbbVie, Inc; Nov 2020. Available from: [https://www.rxabbvie.com/pdf/viekirapak\\_pi.pdf](https://www.rxabbvie.com/pdf/viekirapak_pi.pdf). Accessed August 10, 2022

Vosevi™ (sofosbuvir/velpatasvir/voxilaprevir) [package insert]. Foster City, CA: Gilead Sciences, Inc.; November 2019. Available from: [http://www.gilead.com/-/media/Files/pdfs/medicines/liver-disease/vosevi/vosevi\\_pi.pdf](http://www.gilead.com/-/media/Files/pdfs/medicines/liver-disease/vosevi/vosevi_pi.pdf). Accessed August 10, 2022

Zepatier® (elbasvir/ grazeprovir) [package insert]. Whitehouse Station, NJ: Merck & Co, Inc; May 2022. Available from: [https://www.merck.com/product/usa/pi\\_circulars/z/zepatier/zepatier\\_pi.pdf](https://www.merck.com/product/usa/pi_circulars/z/zepatier/zepatier_pi.pdf). Accessed August 10, 2022

**Applicable Drugs:**

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

<b>Brand Name</b>	<b>Generic Name</b>
Epclusa®	velpatasvir/ sofosbuvir
Harvoni®	ledipasvir/ sofosbuvir
Viekira Pak®	ombitasvir/ paritaprevir/ ritonavir and dasabuvir
Sovaldi®	sofosbuvir
Zepatier®	elbasvir/grazoprevir
Mavyret™	glecaprevir/pibrentasvir
Vosevi®	sofosbuvir/velpatasvir/voxilaprevir

**Cross References:**

Off-label Drug Use Rx.01.33

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<b>Policy Version Number:</b>	27.00
<b>P&amp;T Approval Date:</b>	June 09, 2022
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<b>Next Required Review Date:</b>	June 09, 2023

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The Policy Bulletins on this web site were developed to assist the Company in administering the provisions of the respective benefit programs, and do not constitute a contract. If you have coverage through the Company, please refer to your specific benefit program for the terms, conditions, limitations and exclusions of your coverage. Company does not provide health care services, medical advice or treatment, or guarantee the outcome or results of any medical services/treatments. The facility and professional providers are responsible for providing medical advice and treatment. Facility and professional providers are independent contractors and are not employees or agents of the Company. If you have a specific medical condition, please consult with your doctor. The Company reserves the right at any time to change or update its Policy Bulletins.

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