Pharmacy Policy Bulletin

Title: Hepatitis C
Policy #: Rx.01.100

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, gender or quantity restrictions. 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 daclatisvir (Daklinza™), elbasvir/ grazoprevir (Zepatier™), ledipasvir/ sofosbuvir (Harvoni®), ombitasvir/ paritaprevir/ ritonavir and dasabuvir (Viekira Pak/ Viekira XR™), ombitasvir/ paritaprevir/ ritonavir (Technivie™), simeprevir (Olysio®), sofosbuvir (Sovaldi®), and velpatasvir/ sofosbuvir (Epclusa®) as provided under the member’s pharmacy 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.

**Daclatisvir (Daklinza™)** is an HCV NS5A replication inhibitor. Daclatisvir binds to the N-terminus of NS5A, inhibiting both viral RNA replication and virion assembly.

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

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

**Ombitasvir/ paritaprevir/ ritonavir (Technivie™)** is a combination product that contains an HCV NS5A replication inhibitor (ombitasivir), an HCV NS3/4A protease inhibitor (parataprevir) and a booster (ritonavir) as a fixed dose tablet.

**Simeprevir (Olysio®)** inhibits HCV NS3/4A protease, which is essential for viral replication.

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

**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.
TREATMENT NAIVE

A. Genotype 1

1. Harvoni or Epclusa is approved when ALL of the following are met:
   a) Age 18 years or older
   b) Diagnosis of chronic HCV genotype 1
   c) absence of decompensated cirrhosis (i.e., compensated cirrhosis or no cirrhosis)
   d) Duration of approval: 12 weeks*

2. Zepatier is approved when ALL of the following are met:
   a) Age 18 years or older
   b) Diagnosis of HCV genotype 1
   c) Results of testing for baseline high fold-change NS5A resistance-associated variant are provided (for genotype 1a)
   d) Absence of decompensated cirrhosis (i.e., compensated cirrhosis or no cirrhosis)
   e) ONE of the following:
      1. Documentation of a dispensed prescription for and inability to tolerate sofosbuvir/ledipasvir (Harvoni) or sofosbuvir/velpatasvir (Epclusa), details of intolerability must be provided; or
      2. Member has severe renal impairment (creatinine clearance < 30ml/min or end stage renal disease)
   f) Used concurrently with ribavirin for genotype 1a when baseline high fold-change NS5A resistance-associated variant are detected
   g) Duration of approval:
      1. Genotype 1a without baseline high fold-change NS5A resistance-associated variant or genotype 1b: 12 weeks*
      2. Genotype 1a with baseline high fold-change NS5A resistance-associated variant: 16 weeks*

3. Viekira Pak/ Viekira XR is approved when ALL of the following are met:
a) Age 18 years or older

b) Diagnosis of chronic HCV genotype 1

c) Absence of decompensated cirrhosis (i.e., compensated cirrhosis or no cirrhosis)

d) ONE of the following:

1. Documentation of a dispensed prescription for and inability to tolerate sofosbuvir/ledipasvir (Harvoni) or sofosbuvir/velpatasvir (Epclusa), details of intolerability must be provided; or

2. Member has severe renal impairment (creatinine clearance < 30ml/min or end stage renal disease)

e) Used concurrently with ribavirin for genotype 1a

f) Duration of approval:

   a. Genotype 1a without cirrhosis and 1b with or without cirrhosis: 12 weeks*
   b. Genotype 1a with compensated cirrhosis: 24 weeks*

4. Olysio and Sovaldi are approved when ALL of the following are met:

a. Age 18 years or older

b. Diagnosis of chronic HCV genotype 1

c. Absence of decompensated cirrhosis (i.e., compensated cirrhosis or no cirrhosis)

d. Documentation of a dispensed prescription for and inability to tolerate sofosbuvir/ledipasvir (Harvoni) or sofosbuvir/velpatasvir (Epclusa), details of intolerability must be provided

e. Absence of Q80K mutation (for genotype 1a with cirrhosis)

f) Duration of approval:

   1. No cirrhosis: 12 weeks*
   2. Compensated cirrhosis: 24 weeks* (ribavirin will be approved if requested)

5. Daklinza and Sovaldi are approved when all of the following are met:

a. Age 18 years or older

b. Diagnosis of chronic HCV genotype 1

c. Absence of decompensated cirrhosis (i.e., compensated cirrhosis or no cirrhosis)
d. Documentation of a dispensed prescription for and inability to tolerate sofosbuvir/ledipasvir (Harvoni) or sofosbuvir/velpatasvir (Epclusa), details of intolerability must be provided

e. Duration of approval:

1. No cirrhosis: 12 weeks*
2. Compensated cirrhosis: 24 weeks* (ribavirin will be approved if requested)

B. Genotype 2

1. Epclusa is approved when all of the following are met:
   a. Age 18 years or older
   b. Diagnosis of chronic HCV genotype 2
   c. Duration of approval: 12 weeks*

2. Daklinza and Sovaldi are approved when all of the following are met:
   a. Age 18 years or older
   b. Diagnosis of chronic HCV genotype 2
   c. Documentation of a dispensed prescription for and inability to tolerate sofosbuvir/velpatasvir (Epclusa), details of intolerability must be provided
   d. Duration of approval:
      1. Without cirrhosis: 12 weeks*
      2. With compensated cirrhosis: minimum 16 weeks; maximum 24 weeks*

C. Genotype 3

1. Epclusa is approved when all of the following are met:
   a. Age 18 years or older
   b. Diagnosis of chronic HCV genotype 3
   c. Duration of approval: 12 weeks*
2. Daklinza and Sovaldi are approved when ALL of the following are met:
   a. Age 18 years or older
   b. Diagnosis of chronic HCV genotype 3
   c. Documentation of a dispensed prescription for and inability to tolerate sofosbuvir/velpatasvir (Epclusa), details of intolerability must be provided
   d. Duration of approval:
      1. No cirrhosis: 12 weeks*  
      2. Compensated cirrhosis: 24 weeks* (ribavirin will be approved if requested)

D. Genotype 4

1. Harvoni or Epclusa is approved when ALL of the following are met:
   a. Age 18 years or older
   b. Diagnosis of chronic HCV genotype 4
   c. Absence of decompensated cirrhosis (i.e., compensated cirrhosis or no cirrhosis)
   d. Duration of approval: 12 weeks*

2. Zepatier is approved when ALL of the following are met:
   a. Age 18 years or older
   b. Diagnosis of chronic HCV genotype 4
   c. Absence of decompensated cirrhosis (i.e., compensated cirrhosis or no cirrhosis)
   d. ONE of the following:
      1. Documentation of a dispensed prescription for and inability to tolerate sofosbuvir/ledipasvir (Harvoni) or sofosbuvir/velpatasvir (Epclusa), details of intolerability must be provided; or
      2. Member has severe renal impairment (creatinine clearance < 30ml/min or end stage renal disease)
   e. Duration of approval: 12 weeks

3. Technivie is approved when ALL of the following are met:
a. Age 18 years or older

b. Diagnosis of chronic HCV genotype 4

c. Absence of decompensated cirrhosis (i.e., compensated cirrhosis or no cirrhosis)

d. Used with ribavirin

e. Documentation of a dispensed prescription for and inability to tolerate sofosbuvir/ledipasvir (Harvoni) or sofosbuvir/velpatasvir (Epclusa), details of intolerability must be provided

f. Duration of approval: 12 weeks*

E. Genotype 5 or 6

1. Harvoni or Epclusa is approved when ALL of the following are met:
   a. Age 18 years or older
   b. Diagnosis of chronic HCV genotype 5 or 6
   c. Absence of decompensated cirrhosis (i.e., compensated cirrhosis or no cirrhosis)
   d. Duration of approval: 12 weeks*

RETREATMENT

A. Genotype 1

   A. Epclusa
      a. Age 18 years or older
      b. Diagnosis of chronic HCV genotype 1
      c. Absence of decompensated cirrhosis (i.e., compensated cirrhosis or no cirrhosis)
      d. Member failed peginterferon and ribavirin with or without an HCV protease inhibitor
      e. Duration of approval: 12 weeks*

2. Harvoni is approved when ALL of the following are met:
a. Age 18 years or older

b. Diagnosis of chronic HCV genotype 1

c. ONE of the following:

1. No cirrhosis AND failed peginterferon and ribavirin with or without an HCV protease inhibitor (duration: 12 weeks)
2. Compensated cirrhosis and failed peginterferon and ribavirin with or without an HCV protease inhibitor and ONE of the following:

   i. Concurrent ribavirin: Duration: 12 weeks*

   ii. Ineligible for ribavirin: Duration: 24 weeks*

   iii. Failed sofosbuvir and ribavirin with or without peginterferon or sofosbuvir and simeprevir and ALL of the following:

      a. Used with ribavirin

      b. Duration of approval:

         a. No cirrhosis: 12 weeks*

         b. Compensated cirrhosis: 24 weeks*

3. Zepatier is approved when ALL of the following are met:

   a. Age 18 years or older

   b. Diagnosis of HCV genotype 1

   c. Member failed peginterferon and ribavirin with or without an HCV protease inhibitor

   d. Results of testing for baseline high fold-change NS5A resistance-associated variant are provided (for genotype 1a)

   e. Absence of decompensated cirrhosis (i.e., compensated cirrhosis or no cirrhosis)

   f. ONE of the following:

      1. Documentation of a dispensed prescription for and inability to tolerate sofosbuvir/ledipasvir (Harvoni) or sofosbuvir/velpatasvir (Epclusa), details of intolerability must be provided; or

      2. Member has severe renal impairment (creatinine clearance < 30ml/min or end stage renal disease)

   g. Used concurrently with ribavirin for either of the following:

      1. Genotype 1a when baseline high fold-change NS5A resistance-associated variant are detected
2. Prior treatment with peginterferon, ribavirin, and an HCV protease inhibitor

h. Duration of approval:

1. Genotype 1a without baseline high fold-change NS5A resistance-associated variant or genotype 1b: 12 weeks*
2. Genotype 1a with baseline high fold-change NS5A resistance-associated variant: 16 weeks: 16 weeks*

4. Viekira Pak/ Viekira XR is approved when ALL of the following are met:

a. Age 18 years or older
b. Diagnosis of chronic HCV genotype 1
c. Member failed peginterferon and ribavirin
d. Absence of decompensated cirrhosis (i.e., compensated cirrhosis or no cirrhosis)
e. Member is HCV protease inhibitor treatment naive
f. ONE of the following:
   a. Documentation of a dispensed prescription for and inability to tolerate sofosbuvir/ledipasvir (Harvoni) or sofosbuvir/velpatasvir (Epclusa), details of intolerability must be provided
   b. Member has severe renal impairment (creatinine clearance < 30ml/min or end stage renal disease)
g. Used concurrently with ribavirin for genotype 1a

h. Duration of approval:
   a. Genotype 1a without cirrhosis and 1b with or without cirrhosis: 12 weeks*
   b. Genotype 1a with compensated cirrhosis: 24 weeks*

5. Olysio and Sovaldi are approved when ALL of the following are met:

a. Age 18 years or older
b. Diagnosis of chronic HCV genotype 1
c. Member failed peginterferon and ribavirin
d. Member is HCV protease inhibitor treatment naive
e. Documentation of a dispensed prescription for and inability to tolerate sofosbuvir/ledipasvir (Harvoni) or sofosbuvir/velpatasvir (Epclusa), details of intolerability must be provided
f. Absence of Q80K mutation (for genotype 1a with cirrhosis)

g. Duration of approval:
   a. Without cirrhosis: 12 weeks*
   b. With compensated cirrhosis: 24 weeks* (with or without ribavirin)

6. Daklinza and Sovaldi are approved when ALL of the following are present:
   a. Age 18 years or older
   b. Diagnosis of chronic HCV genotype 1
   c. Member failed peginterferon and ribavirin with or without an HCV protease inhibitor
   d. Documentation of a dispensed prescription for and inability to tolerate sofosbuvir/ledipasvir (Harvoni) or sofosbuvir/velpatasvir (Epclusa), details of intolerability must be provided
   e. Duration of approval:
      a. Without cirrhosis: 12 weeks*
      b. With compensated cirrhosis: 24 weeks (with or without ribavirin)

B. Genotype 2

1. Epclusa is approved when ALL of the following are met:
   a. Age 18 years or older
   b. Diagnosis of chronic HCV genotype 2
   c. Absence of decompensated cirrhosis (i.e., compensated cirrhosis or no cirrhosis)
   d. Used with ribavirin if failed prior treatment with sofosbuvir and ribavirin
   e. Duration of approval: 12 weeks*

2. Daklinza and Sovaldi are approved when all of the following are met:
   a. Age 18 years or older
   b. Diagnosis of chronic HCV genotype 2
   c. Member failed treatment with peginterferon and ribavirin
d. Documentation of a dispensed prescription for and inability to tolerate sofosbuvir/velpatasvir (Epclusa), details of intolerability must be provided

e. Duration of approval:

1. Without cirrhosis: 12 weeks*
2. With compensated cirrhosis: minimum 16 weeks; maximum 24 weeks

3. Daklinza and Sovaldi are approved when all of the following are met:

   a. Age 18 years or older
   
   b. Diagnosis of chronic HCV genotype 2
   
   c. Member failed treatment with sofosbuvir and ribavirin
   
   d. Documentation of a dispensed prescription for and inability to tolerate sofosbuvir/velpatasvir (Epclusa), details of intolerability must be provided
   
   e. Duration of approval: 24 weeks*

C. Genotype 3

1. Epclusa is approved when ALL of the following are met:

   a. Age 18 years or older
   
   b. Diagnosis of chronic HCV genotype 3
   
   c. Absence of decompensated cirrhosis (i.e., compensated cirrhosis or no cirrhosis)
   
   d. Used with ribavirin if ONE of the following

       a. Failed prior treatment with sofosbuvir and ribavirin
       b. Failed peginterferon and ribavirin and have compensated cirrhosis

   e. Duration of approval: 12 weeks*

2. Daklinza and Sovaldi are approved when ALL of the following are met:

   a. Age 18 years or older
   
   b. Diagnosis of chronic HCV genotype 3
3. Daklinza and Sovaldi are approved when all of the following are met:
   a. Age 18 years or older
   b. Diagnosis of chronic HCV genotype 3
   c. Used with ribavirin
   d. Documentation of a dispensed prescription for and inability to tolerate sofosbuvir/velpatasvir (Epclusa), details of intolerability must be provided
   e. ONE of the following:
      a. Member failed peginterferon and ribavirin and has compensated cirrhosis
      b. Member failed sofosbuvir and ribavirin
   f. Duration of approval: 24 weeks

D. Genotype 4

1. Epclusa is approved when ALL of the following are met:
   a. Age 18 years or older
   b. Diagnosis of chronic HCV genotype 4
   c. Member failed peginterferon and ribavirin
   d. Absence of decompensated cirrhosis (i.e., compensated cirrhosis or no cirrhosis)
   e. Duration of approval: 12 weeks*

2. Harvoni is approved when all of the following are met:
   a. Age 18 years or older
   b. Diagnosis of chronic HCV genotype 4
c. Member failed peginterferon and ribavirin

d. ONE of the following:
   a. Without cirrhosis: duration of approval 12 weeks*
   b. With compensated cirrhosis and concurrent ribavirin: duration of approval 12 weeks*
   c. With compensated cirrhosis and intolerant to or ineligible for ribavirin: duration of approval 24 weeks*

3. Zepatier is approved when ALL of the following are met:
   a. Age 18 years or older
   b. Diagnosis of HCV genotype 4
   c. Member failed peginterferon and ribavirin
   d. Absence of decompensated cirrhosis
   e. ONE of the following:
      a. Documentation of a dispensed prescription for and inability to tolerate sofosbuvir/ledipasvir (Harvoni) or sofosbuvir/velpatasvir (Epclusa), details of intolerability must be provided; or
      b. Member has severe renal impairment (creatinine clearance < 30ml/min or end stage renal disease)
   f. Concurrent use of ribavirin if prior on-treatment virologic failure (failure to suppress or breakthrough)
   g. Duration of therapy:
      a. If no prior on-treatment failure: 12 weeks*
      b. If prior on-treatment virologic failure: 16 weeks*

4. Technivie and ribavirin is approved when all of the following are present:
   a. Age 18 years or older
   b. Diagnosis of chronic HCV genotype 4
   c. Documentation of a dispensed prescription for and inability to tolerate sofosbuvir/ledipasvir (Harvoni) or sofosbuvir/velpatasvir (Epclusa), details of intolerability must be provided
   d. Member failed peginterferon and ribavirin
   e. Duration of approval: 12 weeks*
E. Genotype 5 or 6

A. Harvoni or Epclusa is approved when all of the following are met:

   a. Age 18 years or older
   b. Diagnosis of chronic HCV genotype 5 or 6
   c. Member failed prior treatment
   d. Duration of approval: 12 weeks

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

A. Genotype 1 or 4

1. Harvoni or Epclusa is approved when ALL of the following are met:

   a. Age 18 years or older
   b. Diagnosis of chronic HCV genotype 1 or 4
   c. Documentation of decompensated cirrhosis (defined as Child Turcotte Pugh class B or C) or hepatocellular carcinoma
   d. Used with ribavirin
   e. Prescribed by a hepatitis C expert (i.e., hepatologist, liver transplant surgeon)
   f. Duration of approval:
      a. Member failed prior sofosbuvir containing regimen: 24 weeks*
      b. Member failed NS5A based regimen: 24 weeks* (applies to Epclusa only)
      c. All others: 12 weeks*

2. Harvoni or Epclusa is approved when ALL of the following are met:

   a. Age 18 years or older
   b. Diagnosis of chronic HCV genotype 1 or 4
   c. Documentation of decompensated cirrhosis (defined as Child Turcotte Pugh class B or C) or hepatocellular carcinoma
d. Prescribed by a hepatitis C expert (i.e., hepatologist, liver transplant surgeon)

e. Intolerant to or ineligible for ribavirin

f. Duration of approval: 24 weeks*

3. Daklinza and Sovaldi are approved when ALL of the following are met:

a. Age 18 years or older

b. Diagnosis of chronic HCV genotype 1 or 4

c. Documentation of a dispensed prescription for and inability to tolerate sofosbuvir/ledipasvir (Harvoni) or sofosbuvir/velpatasvir (Epclusa), details of intolerability must be provided

d. Documentation of decompensated cirrhosis (defined as Child Turcotte Pugh class B or C) or hepatocellular carcinoma

e. Used with ribavirin

f. Prescribed by a hepatitis C expert (i.e., hepatologist, liver transplant surgeon)

g. Duration of approval: 12 weeks*

4. Daklinza and Sovaldi are approved when ALL of the following are met:

a. Age 18 years or older

b. Diagnosis of chronic HCV genotype 1 or 4

c. Documentation of a dispensed prescription for and inability to tolerate sofosbuvir/ledipasvir (Harvoni) or sofosbuvir/velpatasvir (Epclusa), details of intolerability must be provided

d. Documentation of decompensated cirrhosis (defined as Child Turcotte Pugh class B or C) or hepatocellular carcinoma

e. Prescribed by a hepatitis C expert (i.e., hepatologist, liver transplant surgeon)

f. Intolerant to or ineligible for ribavirin

g. Duration of approval: 24 weeks*

B. Genotype 2 or 3

1. Epclusa is approved when ALL of the following are met:
a. Age 18 years or older

b. Diagnosis of chronic HCV genotype 2 or 3

c. Documentation of decompensated cirrhosis (defined as Child Turcotte Pugh class B or C) or hepatocellular carcinoma

d. Used with ribavirin

e. Prescribed by a hepatitis C expert (i.e., hepatologist, liver transplant surgeon)

f. Duration of approval: 12 weeks*

2. Daklinza and Sovaldi, are approved when ALL of the following are met:

a. Age 18 years or older

b. Diagnosis of chronic HCV genotype 2 or 3

c. Documentation of a dispensed prescription for and inability to tolerate sofosbuvir/velpatasvir (Epclusa), details of intolerability must be provided

d. Documentation of decompensated cirrhosis (defined as Child Turcotte Pugh class B or C) or hepatocellular carcinoma

e. Used with ribavirin

f. Prescribed by a hepatitis C expert (i.e., hepatologist, liver transplant surgeon)

g. Duration of approval: 12 weeks*

RECURRENT HCV POST LIVER TRANSPLANT

A. Genotype 1 or 4

1. Harvoni is approved when there is documentation of all of the following:

a. Age 18 years or older

b. Diagnosis of HCV genotype 1 or 4

c. Documentation of liver transplant

d. Used with ribavirin
2. Harvoni is approved when all of the following are met:
   a. Age 18 years or older
   b. Diagnosis of HCV genotype 1 or 4
   c. Documentation of liver transplant
   d. Intolerant to or ineligible for ribavirin
   e. Treatment naive
   f. Absence of decompensated cirrhosis (i.e., compensated cirrhosis or no cirrhosis)
   g. Duration of approval: 24 weeks*

3. Daklinza and Sovaldi are approved when ALL of the following are met:
   a. Age 18 years or older
   b. Diagnosis of HCV genotype 1 or 4
   c. Documentation of liver transplant
   d. Absence of decompensated cirrhosis (i.e., compensated cirrhosis or no cirrhosis)
   e. Used with ribavirin
   f. Documentation of a dispensed prescription for and inability to tolerate sofosbuvir/ledipasvir
      Harvoni), details of intolerability must be provided
   g. Duration of approval: 12 weeks*

4. Daklinza and Sovaldi are approved when ALL of the following are met:
   a. Age 18 years or older
   b. Diagnosis of HCV genotype 1 or 4
   c. Documentation of liver transplant
   d. Absence of decompensated cirrhosis (i.e., compensated cirrhosis or no cirrhosis)
   e. Intolerant to or ineligible for ribavirin
f. Treatment naive

g. Documentation of a dispensed prescription for and inability to tolerate sofosbuvir/ledipasvir (Harvoni), details of intolerability must be provided

h. Duration of approval: 24 weeks*

B. Genotype 1

1. Sovaldi and Olysio are approved when ALL of the following are met:
   a. Age 18 years or older
   b. Diagnosis of HCV genotype 1
   c. Documentation of liver transplant
   d. Absence of decompensated cirrhosis (i.e., compensated cirrhosis or no cirrhosis)
   e. Documentation of a dispensed prescription for and inability to tolerate sofosbuvir/ledipasvir (Harvoni), details of intolerability must be provided
   f. Duration of approval: 12 weeks*

2. Viekira Pak/ Viekira XR and ribavirin are approved when all of the following are met:
   a. Age 18 years or older
   b. Diagnosis of HCV genotype 1
   c. Documentation of liver transplant
   d. Member is HCV protease inhibitor treatment naïve
   e. Metavir fibrosis stage F0-F2
   f. Absence of cirrhosis
   g. Documentation of a dispensed prescription for and inability to tolerate sofosbuvir/ledipasvir (Harvoni), details of intolerability must be provided
   h. Duration of approval: 24 weeks*
C. Genotype 2

1. Sovaldi is approved when all of the following are met:
   a. Age 18 years or older
   b. Diagnosis of HCV genotype 2
   c. Documentation of liver transplant
   d. Used with ribavirin
   e. Duration of approval: 24 weeks*

2. Daklinza and Sovaldi are approved when ALL of the following are met:
   a. Age 18 years or older
   b. Diagnosis of HCV genotype 2
   c. Documentation of liver transplant
   e. Used with ribavirin
   f. Absence of decompensated cirrhosis (i.e., compensated cirrhosis or no cirrhosis)
   g. Duration of approval: 12 weeks*

3. Daklinza and Sovaldi are approved when ALL of the following are met:
   a. Age 18 years or older
   b. Diagnosis of HCV genotype 2
   c. Documentation of liver transplant
   d. Intolerant to or ineligible for ribavirin
   e. Absence of decompensated cirrhosis (i.e., compensated cirrhosis or no cirrhosis)
   f. Duration of approval: 24 weeks*

D. Genotype 3
1. Daklinza and Sovald are approved when ALL of the following are met:
   a. Age 18 years or older
   b. Diagnosis of HCV genotype 3
   c. Documentation of liver transplant
   d. Used with ribavirin
   e. Absence of decompensated cirrhosis (i.e., compensated cirrhosis or no cirrhosis)
   f. Duration of approval: 12 weeks*

2. Daklinza and Sovaldi are approved when ALL of the following are met:
   a. Age 18 years or older
   b. Diagnosis of HCV genotype 3
   c. Documentation of liver transplant
   d. Absence of decompensated cirrhosis (i.e., compensated cirrhosis or no cirrhosis)
   e. Inability to tolerate ribavirin
   f. Treatment naive
   g. Duration of approval: 24 weeks*

*Duration of approval: if therapy was initiated prior to coverage with the plan, authorization will only be granted to allow completion of the specified therapy

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 with decompensated cirrhosis

⚠️ Black Box Warning:
N/A
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 pharmacy 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:


Viekira Pak (ombitasvir/paritaprevir/ritonavir and dasabuvir) [package insert]. North Chicago, IL: AbbVie, Inc; June 2016. Available from:
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.

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daklinza</td>
<td>daclatisvir</td>
</tr>
<tr>
<td>Epclusa</td>
<td>velpatasvir/ sofosbuvir</td>
</tr>
<tr>
<td>Harvoni</td>
<td>ledipasvir/ sofosbuvir</td>
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<td>Viekira Pak/ Viekira XR</td>
<td>ombitasvir/ paritaprevir/ ritonavir and dasabuvir</td>
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<td>Technivie</td>
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<tr>
<td>Olysio</td>
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<tr>
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<tr>
<td>Zepatier</td>
<td>elbasvir/grazoprevir</td>
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Cross References: