Direct Acting Antivirals for Hepatitis C — Nevada Medicaid

Override(s)	Approval duration
Prior Authorization	Varies (see drug-specific criteria below)

Preferred agents	Non-preferred agents
Zepatier (elbasvir/grazoprevir) for Genotype 1and 4 Epclusa (sofosbuvir/velpatasvir) for Genotype 4	Daklinza (daclatasvir) Harvoni (ledipasvir/sofosbuvir) Mavyret (glecaprevir/pibrentasvir) Olysio (simeprevir) Sovaldi (sofosbuvir) Technivie (ombitasvir/paritaprevir/ritonavir) Viekira Pak and Viekira XR (ombitasvir/paritaprevir/ritonavir;dasabuvir) Vosevi (sofosbuvir/velpatasvir/voxilaprevir)

Note*:* All agents require prior authorization (both preferred and non-preferred).

Approval quantity

Requests for a greater quantity will be reviewed on a case-by-case basis

Medication	Quantity Limit
Daklinza	1 tablet per day
Epclusa	1 tablet per day
Harvoni	1 tablet per day
Mavyret	3 tablets per day
Olysio	1 capsule per day
Sovaldi	1 tablet per day
Technivie	2 tablets per day
Zepatier	1 tablet per day
Viekira Pak	1 pak per 28 days
Viekira XR	3 tablets per day
Vosevi	1 tablet per day

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Approval criteria
Hepatitis C direct-acting antivirals are subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the Social Security Act and/or approved by the DUR Board. Refer to the *Nevada Medicaid and Check Up Pharmacy Manual* for specific quantity limits.

I. Coverage and limitations:

A. Approval will be given if the following criteria are met and documented.

B. Recipients must meet all of the following criteria:

1. The recipient has a diagnosis of chronic Hepatitis C Virus (HCV) infection; and

2. The recipient is 18 years of age or older; **AND**

3. All of the following must be included with the PA request:

a. Medical records and results of laboratory and diagnostic tests which support all of the following:

i. The HCV genotype (and subtype, if applicable); **AND**

ii. The baseline HCV RNA viral load and date drawn; **AND**

iii. The hepatic fibrosis stage, including tests supporting liver disease staging disease staging (such as APRI, Fibroscan, Fibrosure, FIB-4 (Results of diagnostic tests or imaging studies that are inconclusive may require additional testing); **AND**

b. A complete treatment regimen; **AND**

c. The duration of treatment; **AND**

d. Any previous treatment experience and length of treatment, if any, including outcome (such as discontinued due to side effects, relapsed, non-responder, null-responder); **AND**

4. The prescriber must certify that the treatment will be discontinued if the viral load is detectable at week four of treatment and has increased by greater than 10-fold (>1log10 IU/mL) on repeat testing at week six (or thereafter); **AND**

5. Requests for recipients with decompensated cirrhosis (Child Turcotte Pugh (CTP) class B or C) and requests for recipients who have chronic hepatitis C infection status-post liver transplant will be evaluated on a case by case basis.

II. Prior Authorization Guidelines:

A. Prior authorization approval will be for a maximum of 12 weeks (unless the requested regimen is less than 12 weeks long or the remaining duration of therapy is less than 12 weeks).

B. The initial prescription will be limited to a 14-day supply; subsequent refills can be up to 34 days.

III. Recipients who have received previous therapy with an NS5A inhibitor (such as daclatasvir, ledipasvir, ombitasvir)

A. Genotype 1:

1. The recipient must meet one of the following:

a. The recipient has cirrhosis; **OR**
b. Documentation includes the clinical rationale for urgent retreatment.

2. Testing for resistance-associated variants (RAVs) have been done and results have been provided.
3. No NS5A RAVs detected: Harvoni + ribavirin ± peginterferon x 24 weeks.
4. NS5A RAVs detected, no NS3 RAVS detected: Olysio + Sovaldi + ribavirin ±
peginterferon x 24 weeks.
5. For requests for recertification (for treatment beyond 12 weeks), the recipient must meet all of the following:
a. Laboratory results for HCV RNA viral load at week four and week six (if applicable) have been submitted with the PA request; **AND**
b. The recipient's HCV viral load must meet one of the following:
i. Undetectable HCV RNA viral load week four; **OR**
ii. Detectable HCV RNA viral load at treatment week four and HCV RNA increased by ≤ 10-fold (≤1 log10 IU/mL) on repeat testing at treatment week six (or thereafter).
c. And, the recipient is compliant on all drugs in the treatment regimen.

Daklinza

The requested dose is one of the following:
1. 60 mg (one tablet) daily; or
2. 30 mg (one tablet) and the recipient is receiving a strong CYP3A inhibitor;or
3. 90 mg (one 30 mg tablet and one 60 mg tablet) daily and the recipient is receiving a concomitant moderate CYP3A inducer and the clinical rationale has been provided documenting medical necessity for continuing the moderate CYP3A inducer Daklinza therapy.

I. Genotype 1

A. For Genotype 1, individual must have had a prior trial and inadequate response to Zepatier ± ribavirin; **OR**:
B. One of the following:
1. Individual is currently on or completing a course of therapy with the requested regimen; **OR**
2. Individual has a documented hypersensitivity, as manifested by a severe allergic reaction, to any ingredient in the preferred regimen or regimens which is not also in the requested non-preferred regimen; **OR**
3. Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with the preferred regimen or regimens; **AND**
C. The recipient is treatment-naïve and must meet one of the following:
1. No cirrhosis, will be treated with Sovaldi and ribavirin and the requested duration is 12 weeks; **OR**

2. No cirrhosis, will be treated with Sovaldi, the requested duration is 12 weeks and documentation has been provided showing that the recipient is unable to take ribavirin; **OR**

3. Compensated cirrhosis (CTP class A), will be treated with Sovaldi ± ribavirin and the requested duration is 12 weeks; **OR**

d. Compensated cirrhosis (CTP class A), will be treated with Sovaldi + ribavirin and the requested duration is 24 weeks; **OR**

4. Compensated cirrhosis (CTP class A), will be treated with Sovaldi, requested duration is 24 weeks and documentation has been provided showing the recipient is unable to take ribavirin.

D. The recipient is treatment-experienced (failed peginterferon + ribavirin dual t therapy) and must meet one of the following:

1. No cirrhosis, will be treated with Sovaldi and the requested durationis 12 weeks; **OR**

2. Compensated cirrhosis (CTP class A), will be treated with Sovaldi and ribavirin and the requested duration is 24 weeks; **OR**

3. Compensated cirrhosis (CTP class A) will be treated with Sovaldi,requested duration is 24 weeks and documentation is providedshowing that the recipient is unable to take ribavirin.

E. The recipient is treatment-experienced (failed peginterferon + ribavirin + NS3 protease inhibitor), has had no prior treatment with an NS5A polymerase inhibitor (such as daclatasvir, ledipasvir, ombitasvir) and must meet one of the following:

1. No cirrhosis, will be treated with Sovaldi and the requested duration is 12 weeks; **OR**

2. Compensated cirrhosis (CTP class A), will be treated with Sovaldi and ribavirin and the requested duration is 24 weeks; **OR**

3. Compensated cirrhosis (CTP class A), will be treated with Sovaldi, the requested duration is 24 weeks and documentation is provided showing that the recipient is unable to take ribavirin.

II. Genotype 2

A. Individual must have one of the following:

1. Individual is currently on and completing a course of therapy with the requested regimen; **OR**
2. Individual has had a prior trial and inadequate response to Epclusa ± ribavirin; **OR**
3. One of the following:
   a. Individual has a documented hypersensitivity, as manifested by a severe allergic reaction, to any ingredient in the preferred regimen or regimens which is not also in the requested non-preferred regimen; **OR**
   b. Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with the preferred regimen or regimens; **OR**
   c. Individual is a post-liver allograft transplant recipient **AND**

B. The recipient is treatment-naïve, documentation is provided showing the recipient is unable to take ribavirin, and must meet one of the following:

1. No cirrhosis, will be treated with Sovaldi and the requested duration is 12 weeks; **OR**
2. Compensated cirrhosis (CTP class A), will be treated with Sovaldi and the requested duration is 12 weeks; **OR**
3. Compensated cirrhosis (CTP class A), will be treated with Sovaldi and the requested duration is 24 weeks.

C. The recipient is treatment-experienced (failed Sovaldi + ribavirin dual therapy), documentation has been provided showing that the recipient is unable to receive peginterferon, and must meet one of the following:

1. No cirrhosis, will be treated with Sovaldi and ribavirin and the requested duration is 24 weeks; **OR**
2. No cirrhosis, will be treated with Sovaldi and ribavirin, the requested duration is 24 weeks and documentation has been provided showing that the recipient is unable to take ribavirin; **OR**
3. Compensated cirrhosis (CTP class A), will be treated with Sovaldi and ribavirin and the requested duration is 24 weeks.

III. Genotype 3

A. Individual must have one of the following:

1. Individual is currently on and completing a course of therapy with the requested regimen; **OR**
2. Individual has had a prior trial and inadequate response to Epclusa ± ribavirin; **OR**
3. One of the following:
   a. Individual has a documented hypersensitivity, as manifested by a severe allergic reaction, to any ingredient in the preferred regimen or regimens which is not also in the requested non-preferred regimen; **OR**
   b. Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with the preferred regimen or regimens; **OR**
   c. Individual is a post-liver allograft transplant recipient **AND**

B. The recipient is treatment-naïve and must meet one of the following:

1. No cirrhosis, will be treated with Sovaldi and the requested duration is 12 weeks; **OR**
2. Compensated cirrhosis (CTP class A), will be treated with Sovaldi and ribavirin, the requested duration is 24 weeks and documentation has been provided showing that the recipient is unable to receive peginterferon; **OR**
3. Compensated cirrhosis (CTP class A), will be treated with Sovaldi, the requested duration is 24 weeks and documentation has been provided showing that the recipient is unable to take ribavirin and showing the recipient is unable to receive peginterferon.

C. The recipient is treatment-experienced (failed peginterferon + ribavirin dual therapy), documentation is provided showing that the recipient is unable to receive peginterferon and must meet one of the following:

1. No cirrhosis, will be treated with Sovaldi and the requested duration is 12 weeks; or
2. Compensated cirrhosis (CTP class A), will be treated with Sovaldi and ribavirin and the requested duration is 24 weeks; **OR**
3. Compensated cirrhosis (CTP class A), will be treated with Sovaldi,the requested duration is 24 weeks and documentation has been provided showing the recipient is unable to take ribavirin.

D. The recipient is treatment-experienced (failed Sovaldi + ribavirin therapy dual therapy), documentation is provided that the recipient is unable to receive peginterferon and must meet one of the following:

1. No cirrhosis, will be treated with Sovaldi and ribavirin and the requested duration is 24 weeks; **OR**
2. Compensated cirrhosis (CTP class A), will be treated with Sovaldi and ribavirin and the requested duration is 24 weeks.

Epclusa

I. Genotype 1

A. individual must have had a prior trial and inadequate response to Zepatier ± ribavirin; **OR:**

B. One of the following:

1. Individual is currently on or completing a course of therapy with the requested regimen; OR
2. Individual has a documented hypersensitivity, as manifested by a severe allergic reaction, to any ingredient in the preferred regimen or regimens which is not also in the requested non-preferred regimen; **OR**
3. Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with the preferred regimen or regimens; **OR**
4. The individual has concomitant moderate or severe (Child-Pugh Class B or C hepatic impairment)

Harvoni

The requested dose is one 90 mg/400 mg tablet once daily.

I. Genotype 1:

A. Individual must have had a prior trial and inadequate response to Zepatier ± ribavirin; **OR:**

B. One of the following:

1. Individual is currently on or completing a course of therapy with the requested regimen; **OR**
2. Individual has a documented hypersensitivity, as manifested by a severe allergic reaction, to any ingredient in the preferred regimen or regimens which is not also in the requested non-preferred regimen; **OR**

3. Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with the preferred regimen or regimens; **OR**
4. Individual has concomitant moderate or severe (Child-Pugh Class B or C hepatic impairment) **OR**
5. Individual has the following:
   a. Individual is post-liver allograft transplant recipient; **OR**
   b. Request is for an 8 week course of Harvoni and the individual is eligible for an 8 week treatment course (treatment-naïve, no cirrhosis, baseline HCV RNA level of less than 6 million IU/mL, not HCV-HIV co-infected).

AND

C. The recipient is treatment naïve and must meet one of the following:
1. No cirrhosis, pre-treatment HCV RNA < six million, and the requested duration is eight weeks; **OR**
2. No cirrhosis, pre-treatment HCV RNA ≥ six million, and the requested duration is 12 weeks; **OR**
3. Compensated Cirrhosis (CPT class A), requested duration is 12 weeks.

D. The recipient is treatment-experienced (failed peginterferon + ribavirin) and must meet one of the following:
1. No cirrhosis and the requested duration is 12 weeks; **OR**
2. Compensated cirrhosis (CTP class A) will be treated with ribavirin, and the requested duration is 12 weeks; **OR**
3. Compensated cirrhosis (CTP class A), documentation is provided that the recipient is unable to take ribavirin and the requested duration is 24 weeks.

E. The recipient is treatment-experienced (failed peginterferon + ribavirin + an NS3 protease inhibitor), has had no prior treatment with an NS5A polymerase inhibitor (such as daclatasvir, ledipasvir, ombitasvir) and must meet one of the following:
1. No cirrhosis and the requested duration is 12 weeks; **OR**
2. Compensated cirrhosis (CTP class A), will be treated with ribavirin, and the requested duration is 12 weeks; **OR**
3. Compensated cirrhosis (CTP class A), documentation is provided that the recipient is unable to take ribavirin, and the requested duration is 24 weeks.

F. The recipient is treatment-experienced (failed Olysio + Sovaldi), has had no prior treatment with an NS5A polymerase inhibitor (such as daclatasvir, ledipasvir, ombitasvir), and must meet one of the following:
1. No cirrhosis, will be treated with ribavirin and the requested duration is 12 weeks; **OR**
2. Cirrhosis (CTP class A, B, or C) will be treated with ribavirin and the requested duration is 24 weeks.

G. The recipient is treatment-experienced (failed Sovaldi + ribavirin ± peginterferon) and must meet one of the following:
1. No cirrhosis, will be treated with ribavirin and the requested duration is 12 weeks; **OR**

2. Cirrhosis (CTP class A, B, or C), will be treated with ribavirin and the requested duration is 24 weeks.

II. Genotype 4:

A. Individual must have had a prior trial and inadequate response to Zepatier ± ribavirin or
Epclusa; **OR**

B. One of the following:

1. Individual is currently on or completing a course of therapy with the requested regimen; **OR**
2. Individual has a documented hypersensitivity, as manifested by a severe allergic reaction, to any ingredient in the preferred regimen or regimens which is not also in the requested non-preferred regimen; **OR**
3. Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with the preferred regimen or regimens; **OR**
4. Individual is post-liver allograft transplant recipient.

AND

C. The recipient is treatment-naïve and must meet one of the following:

1. The recipient is treatment-naïve and the requested duration is 12 weeks; **OR**
2. The recipient is treatment-experienced (failed peginterferon + ribavirin ± an NS3 protease inhibitor) and the requested duration is 12 weeks.

III. Genotype 5 and 6

A. The recipient is treatment-naïve and must meet one of the following:

1. The recipient is treatment-naïve and the requested duration is 12 weeks; **OR**
2. The recipient is treatment-experienced (failed peginterferon + ribavirin ± an NS3 protease inhibitor) and the requested duration is 12 weeks.

Mavyret
APPROVAL DURATION

Genotype and Status (HCV mono-infected)	**Associated Treatment Regimens**	**Total Approval Duration for Mavyret**
Genotypes 1, 2, 4, 5, or 6 (treatment-naïve, dual* treatment-experienced, or triple† treatment experienced, without cirrhosis)	Mavyret (glecaprevir/pibrentasvir)	8 weeks
Genotype 1 (DAA treatment-experienced±, without cirrhosis)	Mavyret (glecaprevir/pibrentasvir)	12 weeks

Genotypes 2, 4, 5, or 6 (treatment-naïve, dual* treatment-experienced, or triple† treatment experienced, with compensated cirrhosis)	Mavyret (glecaprevir/pibrentasvir)	12 weeks
Genotype 3 (treatment-naïve, with compensated cirrhosis or without cirrhosis)	Mavyret (glecaprevir/pibrentasvir)	12 weeks
Genotype 3 (dual* treatment-experienced, or triple† treatment-experienced, without cirrhosis)	Mavyret (glecaprevir/pibrentasvir)	12 weeks
Genotype 3 (dual* treatment-experienced, or triple† treatment-experienced, with compensated cirrhosis)	Mavyret (glecaprevir/pibrentasvir)	16 weeks

*The ENDURANCE-1, -2,-4 (AASLD October 2016 abstracts); EXPEDITION-IV (AASLD November 2016 abstract);
SURVEYOR-I (EASL April 2016); and SURVEYOR-II parts 2-4 (EASL April 2016) clinical trials define dual treatment-experienced as a prior trial of interferon/peginterferon and ribavirin and/or Sovaldi and ribavirin.
†The ENDURANCE-1, -2,-4; EXPEDITION-IV; and SURVEYOR-I, -II clinical trials define triple treatment-experienced as a prior trial of peginterferon, ribavirin, and Sovaldi.
±The MAGELLAN-1 part 1 (Poordad et al. 2017) clinical trial defines DAA treatment-experienced as a prior trial of Harvoni;
Daklinza (without Sovaldi); peginterferon, ribavirin, and Incivek or Victrelis or Olysio or Sovaldi; Olysio + Sovaldi; or Viekira Pak/XR.

Approval criteria

Requests for Mavyret (glecaprevir/pibrentasvir) may be approved if the following criteria are met:

I. Individual is 18 years of age or older; **AND**
II. A copy of the baseline quantitative hepatitis C virus (HCV) RNA test result is provided to document baseline level of viremia; **AND**
III. One of the following:
    A. Documentation is provided for a diagnosis of chronic hepatitis C (CHC) infection, which
    includes a positive HCV RNA test result at least 6 months following either a baseline positive HCV RNA result or reactive HCV antibody test (AASLD/IDSA 2016, CDC 2013); **OR**
    B. Individual is unable to delay treatment for 6 months owing to concurrent factors [such as but not limited to, advanced liver disease, post-liver transplant recipients, co-infection with human immunodeficiency virus (HIV) or hepatitis B virus (HBV), coexistent liver diseases (such as nonalcoholic steatohepatitis), chronic HCV infection-associated extrahepatic manifestations (such as membranoproliferative glomerulonephritis, glomerular disease, cryoglobulinemia syndrome)] (AASLD/IDSA 2016); **AND**
    C. Documentation is provided for a diagnosis of chronic CHC infection, which includes a reactive HCV antibody (CDC 2013), and a subsequent positive HCV RNA result (CDC 2013);

AND

IV. Individual does not have a short life expectancy (less than 12 months owing to non-liver related comorbid conditions) that cannot be remediated by treating HCV, by transplantation or other directed therapy (AASLD/IDSA 2016);

AND

V. One of the following:
    A. Individual is a woman of child-bearing potential wishing to become pregnant (Use with ribavirin is contraindicated in pregnancy and pregnancy is not recommended for six months following completion of a ribavirin-based regimen)(AASLD/IDSA 2015);

    OR

    B. Liver transplant recipient; **OR**
    C. Type 2 or 3 essential cryoglobulinemia with end-organ manifestations (for example, vasculitis);

    OR

    D. Glomerular disease [proteinuria (greater than 300 mg/day), nephrotic syndrome, or membranoproliferative glomerulonephritis];

VI. Individual has compensated liver disease[1] (with or without cirrhosis); **AND**
VII. Individual is using in the following antiviral treatment regimen:

A. As monotherapy for **one** of the following:
1. Individual is treatment-naïve, dual (interferon/peginterferon and ribavirin or sofosbuvir and ribavirin) treatment-experienced, or triple (sofosbuvir, peginterferon, and ribavirin) treatment-experienced, without cirrhosis, and Genotypes 1, 2, 3, 4, 5, or 6;
AND
a. For Genotype 1:
i. Individual has had a prior trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response to Zepatier;
OR
ii. Individual is currently on and completing a course of therapy with Mavyret (glecaprevir/pibrentasvir); **OR**
iii. The individual has one of the following:
a. Documented hypersensitivity, as manifested by a severe allergic reaction to any ingredient in Zepatier which is not also in Mavyret (glecaprevir/pibrentasvir); **OR**
b. Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with the preferred regimen or regimens;
OR
iv. Individual has concomitant severe renal impairment (CrCl less than 30 mL/min) or requires dialysis; **OR**
v. Individual failed to achieve a sustained viral response (SVR) or relapsed after achieving a SVR during a prior successfully completed direct-acting antiviral (DAA) treatment regimen;
B. For Genotype 2 or 3:
i. Individual has had a prior trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response to Epclusa; **OR**
ii. Individual is currently on and completing a course of therapy with Mavyret (glecaprevir/pibrentasvir); **OR**
iii. The individual has one of the following:
a. Documented hypersensitivity, as manifested by a severe allergic reaction to any ingredient in Epclusa which is not also in Mavyret (glecaprevir/pibrentasvir); **OR**
b. Individual is concurrently using an agent that cannot be substituted with another agent or

temporarily discontinued and is contraindicated or not recommended for concomitant use with the preferred regimen or regimens; **OR**

iv. Individual has concomitant severe renal impairment (CrCl less than 30 mL/min) or requires dialysis; **OR**

v. Individual failed to achieve a sustained viral response (SVR) or relapsed after achieving a SVR during a prior successfully completed direct-acting antiviral (DAA) treatment regimen;

C. For Genotype 4:

i. Individual has had a prior trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response to Epclusa or Zepatier; **OR**

ii. Individual is currently on and completing a course of therapy with Mavyret (glecaprevir/pibrentasvir); **OR**

iii. The individual has one of the following:

a. Documented hypersensitivity, as manifested by a severe allergic reaction to any ingredient in Epclusa or Zepatier which is not also in Mavyret (glecaprevir/pibrentasvir); **OR**

b. Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with the preferred regimen or regimens; **OR**

iv. Individual has concomitant severe renal impairment (CrCl less than 30 mL/min) or requires dialysis; **OR**

v. Individual failed to achieve a sustained viral response (SVR) or relapsed after achieving a SVR during a prior successfully completed direct-acting antiviral (DAA) treatment regimen;

OR

2. Individual is treatment-experienced with a prior HCV direct-acting antiviral (DAA) regimen (peginterferon with ribavirin, and telaprevir, boceprevir, simeprevir, sofosbuvir; sofosbuvir and simeprevir; an ombitasvir + paritaprevir + ritonavir + dasabuvir regimen; or ledipasvir/sofosbuvir), without cirrhosis and Genotype 1;

AND

a. Individual has had a prior trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response to Zepatier; **OR**

b. Individual is currently on and completing a course of therapy with Mavyret (glecaprevir/pibrentasvir); **OR**

c. The individual has one of the following:
    1. Documented hypersensitivity, as manifested by a severe allergic reaction to any ingredient in Zepatier which is not also in Mavyret (glecaprevir/pibrentasvir); **OR**
    2. Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with the preferred regimen or regimens;
        OR
        i. Individual has concomitant severe renal impairment (CrCl less than
        30 L/min) or requires dialysis; **OR**
        ii. Individual failed to achieve a sustained viral response (SVR) or relapsed after achieving a SVR during a prior successfully completed direct-acting antiviral (DAA) treatment regimen.

OR

3. Individual is treatment-naïve, dual (interferon/peginterferon and ribavirin or sofosbuvir and ribavirin) treatment-experienced, or triple (sofosbuvir, peginterferon, and ribavirin) treatment-experienced, with compensated cirrhosis[1], and Genotypes 2, 3, 4, 5, or 6; **AND**
    a. For Genotype 2 or 3:
        i. Individual has had a prior trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response to Epclusa; **OR**
        ii. Individual is currently on and completing a course of therapy with Mavyret (glecaprevir/pibrentasvir); **OR**
        iii. The individual has one of the following:
            1. Documented hypersensitivity, as manifested by a severe allergic reaction to any ingredient in Epclusa which is not also in Mavyret (glecaprevir/pibrentasvir); **OR**
            2. Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with the preferred regimen or regimens; **OR**
        iv. Individual has concomitant severe renal impairment (CrCl less than 30 mL/min) or requires dialysis; **OR**
        v. Individual failed to achieve a sustained viral response (SVR) or relapsed after achieving a SVR during a prior successfully completed direct-acting antiviral (DAA) treatment regimen;
    b. For Genotype 4:
        i. Individual has had a prior trial (medication samples/coupons/discount cards are excluded from

consideration as a trial) and inadequate response to Epclusa or Zepatier; **OR**

ii. Individual is currently on and completing a course of therapy with Mavyret (glecaprevir/pibrentasvir); **OR**

iii. The individual has one of the following:

1. Documented hypersensitivity, as manifested by a severe allergic reaction to any ingredient in Epclusa or Zepatier which is not also in Mavyret (glecaprevir/pibrentasvir); **OR**
2. Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with the preferred regimen or regimens; **OR**

iv. Individual has concomitant severe renal impairment (CrCl less than 30 mL/min) or requires dialysis; **OR**

v. Individual failed to achieve a sustained viral response (SVR) or relapsed after achieving a SVR during a prior successfully completed direct-acting antiviral (DAA) treatment regimen.

Mavyret (glecaprevir/pibrentasvir) may **not** be approved for the following:

I. Individual is using in combination with a regimen containing a non-nucleoside NS5B polymerase inhibitor (such as dasabuvir) or nucleotide NS5B polymerase inhibitor [such as sofosbuvir, ledipasvir/sofosbuvir, sofosbuvir/velpatasvir, or sofosbuvir/velpatasvir/voxilaprevir]; **OR**

II. Individual is using in combination with a regimen containing another NS5A inhibitor [such as daclatasvir, ledipasvir/sofosbuvir, elbasvir/grazoprevir, sofosbuvir/velpatasvir, ombitasvir, or sofosbuvir/velpatasvir/voxilaprevir]; **OR**

III. Individual is using in combination with a regimen containing another NS3/4A protease inhibitor [such as simeprevir, elbasvir/grazoprevir, paritaprevir, or sofosbuvir/velpatasvir/voxilaprevir]; **OR**

IV. Individual is requesting the regimen for re-treatment and either failed to achieve a SVR (defined as a lower limit HCV RNA of 25 IU/mL) or relapsed after achieving a SVR during a prior successfully completed treatment regimen consisting of sofosbuvir/velpatasvir, elbasvir/grazoprevir, daclatasvir in combination with sofosbuvir, sofosbuvir/velpatasvir/voxilaprevir, glecaprevir, or pibrentasvir.

Olysio

I. The requested dose is 150 mg (one capsule) daily.

II. Genotype 1a

A. Individual must have had a prior trial and inadequate response to Zepatier ± ribavirin; **OR**:

B. One of the following:

1. Individual is currently on or completing a course of therapy with the requested regimen; **OR**

2. Individual has a documented hypersensitivity, as manifested by a severe allergic reaction, to any ingredient in the preferred regimen or regimens which is not also in the requested non-preferred regimen; **OR**

3. Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with the preferred regimen or regimens; **AND**

C. The recipient is treatment-naïve and must meet one of the following:
1. No cirrhosis, will be treated with Sovaldi and ribavirin, and the requested duration is 12 weeks; **OR**
2. No cirrhosis, will be treated with Sovaldi, the requested duration is 12 weeks, and documentation has been provided showing that the brecipient is unable to take ribavirin; **OR**
3. Compensated cirrhosis (CTP class A), will be treated with Sovaldi and ribavirin, the requested duration is 24 weeks, and the recipient is negative for the Q80K polymorphism; **OR**
4. Compensated cirrhosis (CTP class A) will be treated with Sovaldi, the requested duration is 24 weeks, the recipient is negative for the Q80K polymorphism, and documentation has been provided showing that the recipient is unable to take ribavirin.

D. The recipient is treatment-experienced (failed peginterferon + ribavirin dual therapy) and must meet one of the following:
1. No cirrhosis, will be treated with Sovaldi and the requested duration is 12 weeks; **OR**
2. Compensated cirrhosis (CTP class A), will be treated with Sovaldi and ribavirin, the requested duration is 24 weeks, and the recipient is negative for the Q80K polymorphism; **OR**
3. Compensated cirrhosis (CTP class A), will be treated with Sovaldi, the requested duration is 24 weeks, and the recipient is negative for the Q80K polymorphism, and documentation has been provided showing that the recipient is unable to take ribavirin.

III. Genotype 1b

A. Individual must have had a prior trial and inadequate response to Zepatier ± ribavirin; **OR:**
One of the following:

B. Individual is currently on or completing a course of therapy with the requested regimen; **OR**
1. Individual has a documented hypersensitivity, as manifested by a severe allergic reaction, to any ingredient in the preferred regimen or regimens which is not also in the requested non-preferred regimen; **OR**
2. Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with the preferred regimen or regimens; **AND**
3. The recipient is treatment-naïve and must meet one of the following:
a. No cirrhosis, will be treated with Sovaldi, and the requested duration

b. Compensated cirrhosis (CTP class A), will be treated with Sovaldi and ribavirin, and the requested duration is 24 weeks; **OR**
c. Compensated cirrhosis (CTP class A), will be treated with Sovaldi, the requested duration is 24 weeks, and documentation has been provided showing that the recipient is unable to take ribavirin.

4. The recipient is treatment-experienced (failed peginterferon + ribavirin dual therapy) and must meet one of the following:
a. No cirrhosis, will be treated with Sovaldi and the requested duration is 12 weeks; **OR**
b. Compensated cirrhosis (CTP class A), will be treated with Sovaldi and ribavirin, and the requested duration is 24 weeks; **OR**
c. Compensated cirrhosis (CTP class A), will be treated with Sovaldi, the requested duration is 24 weeks, and documentation has been provided showing that the recipient is unable to take ribavirin.

Sovaldi

I. The requested dose is 400 mg daily.

II. Genotype 1

A. Individual must have had a prior trial and inadequate response to Zepatier ± ribavirin; **OR:**

One of the following:

1. Individual is currently on or completing a course of therapy with the requested regimen; **OR**
2. Individual has a documented hypersensitivity, as manifested by a severe allergic reaction, to any ingredient in the preferred regimen or regimens which is not also in the requested non-preferred regimen; **OR**
3. Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with the preferred regimen or regimens;

AND

B. The recipient is treatment-naïve and must meet one of the following:

1. No cirrhosis, will be treated with Daklinza and ribavirin and the requested duration is 12 weeks; **OR**
2. No cirrhosis, will be treated with Daklinza, the requested duration is 12 weeks and documentation has been provided showing the recipient is unable to take ribavirin; **OR**
3. No cirrhosis, genotype 1a, will be treated with Olysio and ribavirin, and the requested duration is 12 weeks; **OR**
4. No cirrhosis, genotype 1a, will be treated with Olysio, the requested duration is 12 weeks, and documentation has been provided showing the recipient is unable to take ribavirin; **OR**
5. No cirrhosis, genotype 1b, will be treated with Olysio, and the requested duration is 12 weeks; **OR**
6. Compensated cirrhosis (CTP class A), will be treated with Daklinza + ribavirin and the requested duration is 12 weeks; **OR**

7. Compensated cirrhosis (CTP class A), will be treated with Daklinza + ribavirin, and the requested duration is 24 weeks; **OR**
8. Compensated cirrhosis (CTP class A), will be treated with Daklinza, requested duration is 24 weeks, and documentation has been provided showing the recipient is unable to take ribavirin; **OR**
9. Compensated cirrhosis (CTP class A), genotype 1a, will be treated with Olysio and ribavirin, the requested duration is 24 weeks, and the recipient is negative for the Q80K polymorphism; **OR**
10. Compensated cirrhosis (CTP class A), genotype 1a, will be treated with Olysio, the requested duration is 24 weeks, the recipient is negative for the Q80K polymorphism, and documentation has been provided showing the recipient is unable to take ribavirin; **OR**
11. Compensated cirrhosis (CTP class A), genotype 1b, will be treated with Olysio and ribavirin, and the requested duration is 24 weeks;
OR
12. Compensated cirrhosis (CTP class A), genotype 1b, will be treated with Olysio, the requested duration is 24 weeks, and documentation has been provided that the recipient is unable to take ribavirin

C. The recipient is treatment-experienced (failed peginterferon + ribavirin dual therapy) and must meet one of the following:

1. No cirrhosis, will be treated with Daklinza, and the requested duration is 12 weeks; **OR**
2. No cirrhosis, will be treated with Olysio, and the requested duration is 12 weeks; **OR**
3. Compensated cirrhosis (CTP class A), will be treated with Daklinza and ribavirin, and the requested duration is 24 weeks; **OR**
4. Compensated cirrhosis (CTP class A), will be treated with Daklinza, requested duration is 24 weeks, and documentation is provided showing that the recipient is unable to take ribavirin; **OR**
5. Compensated cirrhosis (CTP class A), genotype 1a, will be treated with Olysio and ribavirin, the requested duration is 24 weeks and the recipient is negative for the Q80K polymorphism; **OR**
6. Compensated cirrhosis (CTP class A), genotype 1a, will be treated with Olysio, the requested duration is 24 weeks, the recipient is negative for the Q80K polymorphism and documentation has been provided showing that the recipient is unable to take ribavirin; **OR**
7. Compensated cirrhosis (CTP class A), genotype 1b, will be treated with Olysio and ribavirin, and the requested duration is 24 weeks;
OR
8. Compensated cirrhosis (CTP class A), genotype 1b, will be treated with Olysio, the requested duration is 24 weeks, and documentation has been provided showing that the recipient is unable to take ribavirin.

D. The recipient is treatment-experienced (failed peginterferon + ribavirin +

NS3 protease inhibitor), has had no prior treatment with an NS5A polymerase inhibitor (e.g, daclatasvir, ledipasvir, ombitasvir) and must meet one of the following:

1. No cirrhosis, will be treated with Daklinza and the requested duration is 12 weeks; **OR**
2. Compensated cirrhosis (CTP class A), will be treated with Daklinza and ribavirin, and the requested duration is 24 weeks; **OR**
3. Compensated cirrhosis (CTP class A) will be treated with Daklinza, the requested duration is 24 weeks and documentation has been provided showing the recipient is unable to take ribavirin.

III. Genotype 2

A. Individual must have one of the following:

1. Individual is currently on and completing a course of therapy with the requested regimen; **OR**
2. Individual has had a prior trial and inadequate response to Epclusa ± ribavirin; **OR**
3. One of the following:
   a. Individual has a documented hypersensitivity, as manifested by a severe allergic reaction, to any ingredient in the preferred regimen or regimens which is not also in the requested non-preferred regimen; **OR**
   b. Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with the preferred regimen or regimens; **OR**
   c. Individual is a post-liver allograft transplant recipient

AND

B. The recipient is treatment-naïve and must meet one of the following:

1. No cirrhosis, will be treated with ribavirin, and the requested duration is 12 weeks; **OR**
2. No cirrhosis, will be treated with Daklinza, the requested duration is 12 weeks and documentation has been provided showing that the recipient is unable to take ribavirin; **OR**
3. Compensated cirrhosis (CTP class A), will be treated with ribavirin and the requested duration is 16 weeks; **OR**
4. Compensated cirrhosis (CTP class A), will be treated with Daklinza, the requested duration is 12 weeks and documentation has been provided showing that the recipient is unable to take ribavirin; **OR**
5. Compensated cirrhosis (CTP class A), will be treated with Daklinza, the requested duration is 24 weeks and documentation has been provided showing that the recipient is unable to take ribavirin.

C. The recipient is treatment-experienced (failed peginterferon + ribavirin dual therapy), and must meet one of the following:

1. No cirrhosis, will be treated with ribavirin and the requested duration is 16 weeks; **OR**

2. No cirrhosis, will be treated with ribavirin and peginterferon, the requested duration is 12 weeks; **OR**
3. Compensated cirrhosis (CTP class A), will be treated with ribavirin, the requested duration is 16 weeks; **OR**
4. Compensated cirrhosis (CTP class A), will be treated with ribavirin and the requested duration is 24 weeks; **OR**
5. Compensated cirrhosis (CTP class A), will be treated with ribavirin and peginterferon, and the requested duration is 12 weeks.

4. The recipient is treatment-experienced (failed Sovaldi + ribavirin dual therapy and must meet one of the following:

a. No cirrhosis, will be treated with Daklinza and ribavirin, the requested duration is 24 weeks and documentation has been provided showing the recipient is unable to receive peginterferon; **OR**

b. No cirrhosis, will be treated with Daklinza, the requested duration is 24 weeks and documentation has been provided showing that the recipient is unable to take ribavirin and documentation has been provided showing that the recipient is unable to receive peginterferon; **OR**

c. No cirrhosis, will be treated with ribavirin and peginterferon and the requested duration is 12 weeks; **OR**

d. Compensated cirrhosis (CTP class A), will be treated with Daklinza and ribavirin, the requested duration is 24 weeks and documentation has been provided showing that the recipient is unable to receive peginterferon; **OR**

e. Compensated cirrhosis (CTP class A), will be treated with ribavirin and peginterferon, and the requested duration is 12 weeks.

IV. Genotype 3

A. Individual must have one of the following:

1. Individual is currently on and completing a course of therapy with the requested regimen; **OR**
2. Individual has had a prior trial and inadequate response to Epclusa ± ribavirin; **OR**
3. One of the following:
    a. Individual has a documented hypersensitivity, as manifested by a severe allergic reaction, to any ingredient in the preferred regimen or regimens which is not also in the requested non-preferred regimen; **OR**
    b. Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with the preferred regimen or regimens; **OR**
    c. Individual is a post-liver allograft transplant recipient

AND

B. The recipient is treatment-naive and must meet one of the following:

1. No cirrhosis, will be treated with ribavirin and peginterferon and the requested duration is 12 weeks; or
2. No cirrhosis, will be treated with ribavirin, the requested duration is 24 weeks and documentation has been provided showing that the recipient is unable to receive peginterferon; or
3. No cirrhosis, will be treated with Daklinza and the requested duration is 12 weeks; or
4. Compensated cirrhosis (CTP class A), will be treated with ribavirin and peginterferon and the requested duration is 12 weeks; or
5. Compensated cirrhosis (CTP class A) will be treated with ribavirin, the requested duration is 24 weeks and documentation has been provided the recipient is unable to receive peginterferon; or
6. Compensated cirrhosis (CTP class A) will be treated with Daklinza and ribavirin, the requested duration is 24 weeks and documentation has been provided showing that the recipient is unable to receive peginterferon; or
7. Compensated cirrhosis (CTP class A) will be treated with Daklinza, the requested duration is 24 weeks and documentation has been provided showing that the recipient is unable to take ribavirin and showing the recipient is unable to receive peginterferon.

C. The recipient is treatment-experienced (failed peginterferon + ribavirin dual therapy) and must meet one of the following:

1. No cirrhosis, will be treated with peginterferon and ribavirin and the requested duration is 12 weeks; or
2. No cirrhosis, will be treated with Daklinza and the requested duration is 12 weeks; or
3. Compensated cirrhosis (CTP class A), will be treated with peginterferon and ribavirin and the requested duration is 12 weeks; or
4. Compensated cirrhosis (CTP class A), will be treated with Daklinza and ribavirin and the requested duration is 24 weeks; or
5. Compensated cirrhosis (CTP class A), will be treated with Daklinza, the requested duration is 24 weeks and documentation has been provided showing that the recipient is unable to take ribavirin.

D. The recipient is treatment-experienced (failed Sovaldi + ribavirin therapy dual therapy) and must meet one of the following:

1. No cirrhosis, will be treated with peginterferon and ribavirin and the requested duration is 12 weeks; or
2. No cirrhosis, will be treated with Daklinza and ribavirin and the requested duration is 24 weeks; or
3. Compensated cirrhosis (CTP class A), will be treated with peginterferon and ribavirin and the requested duration is 12 weeks; or
4. Compensated cirrhosis (CTP class A), will be treated with Daklinza and ribavirin and the requested duration is 24 weeks.

V. Genotype 4

A. Individual must have had a prior trial and inadequate response to Zepatier ± ribavirin or Epclusa; OR
B. One of the following:
1. Individual is currently on or completing a course of therapy with the requested regimen;
OR
2. Individual has a documented hypersensitivity, as manifested by a severe allergic reaction, to any ingredient in the preferred regimen or regimens which is not also in the requested non-preferred regimen; OR
3. Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use the preferred regimen or regimens;
AND
4. The recipient is treatment-naïve and must meet one of the following:
a. No cirrhosis, will be treated with ribavirin and peginterferon, and the requested duration is 12 weeks; or
b. No cirrhosis, will be treated with ribavirin and the requested duration is 24 weeks; or
c. Cirrhosis, will be treated with ribavirin and peginterferon and the requested duration is 12 weeks; or
d. Cirrhosis, will be treated with ribavirin and the requested duration is 24 weeks.
5. The recipient is treatment- experienced (failed peginterferon alfa + ribavirin dual therapy) and must meet one of the following:
a. No cirrhosis, will be treated with ribavirin and peginterferon and the requested duration is 12 weeks; or
b. No cirrhosis, will be treated with ribavirin and the requested duration is 24 weeks; or
c. Cirrhosis, will be treated with ribavirin and peginterferon, and the requested duration is 12 weeks;
d. Cirrhosis, will be treated with ribavirin, and the requested duration

VI. Genotype 5, 6
A. The recipient is treatment-naïve and must meet one of the following:
1. No cirrhosis, will be treated with ribavirin and peginterferon and the requested duration is 12 weeks; or
2. Cirrhosis, will be treated with ribavirin and peginterferon and the requested duration is 12 weeks.
B. The recipient is treatment-experienced and must meet one of the following:
1. No cirrhosis, will be treated with ribavirin and peginterferon and the requested duration is 12 weeks; or
2. Cirrhosis, will be treated with ribavirin and peginterferon and the requested duration is 12 weeks.

Technivie

I. The requested dose is two ombitasvir/paritaprevir/ritonavir 12.5/75/50 mg tablets once daily (25/150/100 mg); and

II. The recipient does not have cirrhosis.
III. Genotype 4:
A. Individual must have had a prior trial and inadequate response to Zepatier ± ribavirin or
Epclusa; OR
B. One of the following:
1. Individual is currently on or completing a course of therapy with the requested regimen;
OR
2. Individual has a documented hypersensitivity, as manifested by a severe allergic reaction, to any ingredient in the preferred regimen or regimens which is not also in the requested non-preferred regimen; OR
3. Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with the preferred regimen or regimens; OR
4. Request is for Harvoni and the individual is post-liver allograft transplant recipient.
AND
C. The recipient must meet one of the following:
1. The recipient is treatment-naïve, will be treated with ribavirin and the requested duration is 12 weeks; or
2. The recipient is treatment-naïve, provided documentation shows the recipient is unable to take ribavirin and the requested duration is 12 weeks; or
3. The recipient is treatment-experienced (failed peginterferon and ribavirin dual therapy) will be treated with ribavirin and the requested duration is 12 weeks.

Viekira Pak
I. The requested dose is two ombitasvir/paritaprevir/ritonavir 12.5/75/50 mg tablets once daily (25/150/100 mg) and one dasabuvir 250 mg tablet twice daily.
II. Genotype 1a:
A. Individual must have had a prior trial and inadequate response to Zepatier ± ribavirin; OR:
B. One of the following:
1. Individual is currently on or completing a course of therapy with the requested regimen; OR
2. Individual has a documented hypersensitivity, as manifested by a severe allergic reaction, to any ingredient in the preferred regimen or regimens which is not also in the requested non-preferred regimen; OR
3. Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with the preferred regimen or regimens;
AND

C. The recipient is treatment-naïve and must meet one of the following:
1. No cirrhosis, will be treated with ribavirin, and the requested duration is 12 weeks; or 2. Compensated cirrhosis (CTP class A), will be treated with ribavirin and the requested duration is 12 weeks.

D. The recipient is treatment experienced (failed peginterferon + ribavirin dual therapy) and must meet one of the following:
1. No cirrhosis, recipient will be treated with ribavirin and the requested duration is 12 weeks; or
2. Compensated cirrhosis (CTP class A), will be treated with ribavirin, the recipient was a partial responder to peginterferon and ribavirin dual therapy and the requested duration is 12 weeks; or
3. Compensated cirrhosis (CTP class A), will be treated with ribavirin, the recipient was a relapser after peginterferon and ribavirin dual therapy and the requested duration is 24 weeks.

III. Genotype 1b:

A. Individual must have had a prior trial and inadequate response to Zepatier ± ribavirin; OR:

B. One of the following:
1. Individual is currently on or completing a course of therapy with the requested regimen; OR
2. Individual has a documented hypersensitivity, as manifested by a severe allergic reaction, to any ingredient in the preferred regimen or regimens which is not also in the requested non-preferred regimen; OR
3. Individual is concurrently using an agent that cannot be substituted with another agent temporarily discontinued and is contraindicated or not recommended for concomitant use with the preferred regimen or regimens;

AND

C. The recipient is treatment-naïve and must meet one of the following:
1. No cirrhosis and the requested duration is 12 weeks; or
2. Compensated cirrhosis (CTP class A) and the requested duration is 12 weeks.

D. The recipient is treatment experienced (failed peginterferon + ribavirin dual therapy) and must meet one of the following:
1. No cirrhosis and the requested duration is 12 weeks; or
2. Compensated cirrhosis (CTP class A) and the requested duration is 12 weeks.

Vosevi
Approval duration

Genotype and status (HCV mono-infected)	Associated treatment regimens	Total approval duration for Vosevi (sofosbuvir/velpatasvir/voxilaprevir)
Genotypes 1, 1a, 3, or 4 (treatment-experienced*,†, with compensated cirrhosis or without cirrhosis)	Vosevi (sofosbuvir/velpatasvir/voxilaprevir)	12 weeks
Genotype 2 (treatment experienced†, with compensated cirrhosis or without cirrhosis)	Vosevi (sofosbuvir/velpatasvir/voxilaprevir)	12 weeks
Genotypes 5 or 6 (treatment experienced* with compensated cirrhosis or without cirrhosis)	Vosevi (sofosbuvir/velpatasvir/voxilaprevir)	12 weeks

Approval criteria
Requests for Vosevi (sofosbuvir/velpatasvir/voxilaprevir) may be approved if the following criteria are met:
I. Individual is 18 years of age or older; **AND**
II. A copy of the baseline quantitative hepatitis C virus (HCV) RNA test result is provided to document baseline level of viremia; **AND**
III. One of the following:

A. Documentation is provided for a diagnosis of chronic hepatitis C (CHC) infection, which includes a positive HCV RNA test result at least 6 months following either a baseline positive HCV RNA result or reactive HCV antibody test (AASLD/IDSA 2016, CDC 2013);

AND

B. Individual does not have a short life expectancy (less than 12 months owing to non-liver related comorbid conditions) that cannot be remediated by treating HCV, by transplantation or other directed therapy (AASLD/IDSA 2016);

AND

C. Individual has been assessed for readiness and adherence to therapy and meets the following criteria:

1. Individual has been evaluated for readiness to initiate treatment; **AND**
2. Individual selected for treatment shall be able and willing to strictly adhere to treatment protocols prescribed by their provider; **AND**
3. Individual has been educated regarding potential risks and benefits of hepatitis C virus therapy, as well as the potential for resistance and failed therapy if medication is not taken as prescribed;

AND

D. Individual has compensated liver disease[1] (with or without cirrhosis); **AND**

E. Individual is using in the following antiviral treatment regimen:

1. As monotherapy for **one** of the following:

a. Individual is treatment-experienced [ledipasvir/sofosbuvir ± ribavirin; daclatasvir with sofosbuvir± ribavirin; an ombitasvir + paritaprevir + ritonavir ± ribavirin;

elbasvir/grazoprevir ± ribavirin; telaprevir, peginterferon, and ribavirin; or boceprevir, peginterferon, and ribavirin], with compensated[1] cirrhosis or without cirrhosis, and Genotype 1; **AND**

b. Individual has had a prior trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response to Zepatier; **OR**

c. Individual is currently on and completing a course of therapy with Vosevi; **OR**

d. The individual has one of the following:

1. Documented hypersensitivity, as manifested by a severe allergic reaction to any ingredient in Zepatier which is not also in Vosevi; **OR**
2. Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with the preferred regimen or regimens; **OR**

e. Individual failed to achieve a sustained viral response (SVR) or relapsed after achieving a SVR during a prior successfully completed Hepatitis C regimen containing an NS5A inhibitor[a] or a Hepatitis C regimen containing sofosbuvir without an NS5A inhibitor[b] **OR**

f. Individual is treatment experienced [sofosbuvir and simeprevir ± ribavirin, or

simeprevir and peginterferon/interferon + ribavirin], with compensated[1] cirrhosis or without cirrhosis, and Genotype 1a; **AND**

g. Individual has had a prior trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response to Zepatier; **OR**

h. Individual is currently on and completing a course of therapy with Vosevi; **OR**

a. The individual has one of the following:

1. Documented hypersensitivity, as manifested by a severe allergic reaction to any ingredient in Zepatier which is not also in Vosevi; **OR**
2. Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with the preferred regimen or regimens; **OR**
3. Individual failed to achieve a sustained viral response (SVR) or relapsed after achieving a SVR during a prior successfully completed

Hepatitis C regimen containing an NS5A inhibitor[a] or a Hepatitis C regimencontaining sofosbuvir without an NS5A inhibitor[b]. **OR**

4. Individual is treatment-experienced [sofosbuvir and daclatasvir or sofosbuvir/velpatasvir ± ribavirin], with compensated[1] cirrhosis or without cirrhosis, and Genotype 2; **AND**
    a. Individual has had a prior trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response to Epclusa; **OR**
    b. Individual is currently on and completing a course of therapy with Vosevi; **OR**
    c. The individual has one of the following:
        1. Documented hypersensitivity, as manifested by a severe allergic reaction to any ingredient in Epclusa which is not also in Vosevi; **OR**
        2. Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with the preferred regimen or regimens; **OR**
    d. Individual failed to achieve a sustained viral response (SVR) or relapsed after achieving a SVR during a prior successfully completed Hepatitis C regimen containing an NS5A inhibitor[a] or a Hepatitis C regimen containing sofosbuvir without an NS5A inhibitor[b]. **OR**
    e. Individual is treatment-experienced [daclatasvir with sofosbuvir ± ribavirin, elbasvir/grazoprevir + sofosbuvir ± ribavirin, or sofosbuvir/velpatasvir ± ribavirin], with compensated[1] cirrhosis or without cirrhosis, and Genotype 3; **AND**
    f. Individual has had a prior trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response to Epclusa; **OR**
    g. Individual is currently on and completing a course of therapy with Vosevi; **OR**
    h. The individual has one of the following:
        1. Documented hypersensitivity, as manifested by a severe allergic reaction to any ingredient in Epclusa which is not also in Vosevi; **OR**
        2. Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with the preferred regimen or regimens; **OR**

i. Individual failed to achieve a sustained viral response (SVR) or relapsed after achieving a SVR during a prior successfully completed Hepatitis C regimen containing an NS5A inhibitor[a] or a Hepatitis C regimen containing sofosbuvir without an NS5A inhibitor[b]. **OR**
j. Individual is treatment-experienced [sofosbuvir/velpatasvir, ledipasvir/sofosbuvir ± ribavirin, elbasvir/grazoprevir ± ribavirin, or ombitasvir + paritaprevir + ritonavir ± ribavirin], with compensated[1] cirrhosis or without cirrhosis, and Genotype 4; **AND**
k. Individual has had a prior trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response to Epclusa or Zepatier; **OR**
l. Individual is currently on and completing a course of therapy with Vosevi; **OR**
m. The individual has one of the following:
    1. Documented hypersensitivity, as manifested by a severe allergic reaction to any ingredient in Epclusa or Zepatier which is not also in Vosevi; **OR**
    2. Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with the preferred regimen or regimens; **OR**
n. Individual failed to achieve a sustained viral response (SVR) or relapsed after achieving a SVR during a prior successfully completed Hepatitis C regimen containing an NS5A inhibitor[a] or a Hepatitis C regimen containing sofosbuvir without an NS5A inhibitor[b]**. OR**
o. Individual is treatment-experienced (ledipasvir/sofosbuvir or interferon/peginterferon and ribavirin), with compensated[1] cirrhosis or without cirrhosis, and Genotypes 5 or 6.

Vosevi (sofosbuvir/velpatasvir/voxilaprevir) may **not** be approved for the following:

I. Individual has severe renal impairment (eGFR less than 30 mL/min/1.73m2), end stage renal disease, or requires dialysis; **OR**
II. Individual has moderate or severe hepatic impairment; **OR**
III. Individual is requesting in concurrent therapy with contraindicated or not recommended agents, such as but not limited to the following: rifampin, amiodarone, atazanavir- or lopinavir containing regimens, tipranavir/ritonavir, efavirenz, co-administration with HMG-CoA reductase inhibitors pravastatin, rosuvastatin, and pitavastatin, cyclosporine, poly glycoprotein (P-gp) inducers and moderate or strong cytochrome (CYP) 3A4 (such as but not limited to, phenytoin, St. John's Wort, efavirenz-based regimens, phenobarbital, rifampin, rifabutin, rifapentine, carbamazepine, oxcarbazepine), or Breast Cancer

Resistance Protein (BCRP) substrates (such as but not limited to, methotrexate, mitoxantrone, imatinib, irinotecan, lapatinib, rosuvastatin, sulfasalazine, topotecan); **OR**

IV. Individual is using in combination with a regimen containing a non-nucleoside NS5B polymerase inhibitor (such as dasabuvir) or another nucleotide NS5B polymerase inhibitor [such as sofosbuvir, ledipasvir/sofosbuvir, or sofosbuvir/velpatasvir]; **OR**

V. Individual is using in combination with a regimen containing another NS5A inhibitor [such as daclatasvir, ledipasvir/sofosbuvir, elbasvir/grazoprevir, sofosbuvir/velpatasvir, or ombitasvir]; **OR**

VI. Individual is using in combination with a regimen containing another NS3/4A protease inhibitor [such as simeprevir, elbasvir/grazoprevir, or paritaprevir]; **OR**

VII. Individual is requesting the regimen for re-treatment and either failed to achieve a SVR (defined as a lower limit HCV RNA of 25 IU/mL) or relapsed after achieving a SVR during a prior successfully completed treatment regimen consisting of sofosbuvir/velpatasvir; elbasvir/grazoprevir; interferon/peginterferon, ribavirin, and boceprevir, simeprevir, or sofosbuvir; or voxilaprevir.

Zepatier

I.The requested dose is one tablet (50/100 mg) daily.

II. Genotype 1a

A. The recipient is treatment-naïve and must meet one of the following:

1. No cirrhosis, the requested duration is 12 weeks and there are no baseline NS5A RAVs for elbasvir detected; or
2. No cirrhosis, will be treated with ribavirin, the requested duration is 16 weeks, baseline NS5A RAVs for elbasvir have been detected and documentation is provided as to why the recipient cannot use a guideline-recommended regimen; or
3. Compensated cirrhosis (CTP class A), requested duration is 12 weeks and there are no baseline NS5A RAVs for elbasvir detected; or
4. Compensated cirrhosis (CTP class A), will be treated with ribavirin, the requested duration is 16 weeks, baseline NS5A RAVs for elbasvir have been detected and documentation is provided as to why the recipient cannot use a guideline-recommended regimen.

B. The recipient is treatment-experienced (failed peginterferon + ribavirin dual therapy) and must meet one of the following:

1. No cirrhosis, the requested duration is 12 weeks and there are no baseline NS5A RAVs for elbasvir detected; or
2. No cirrhosis, will be treated with ribavirin, the requested duration is 16 weeks, baseline NS5A RAVs for elbasvir have been detected and documentation is provided as to why the recipient cannot use a guideline-recommended regimen; or
3. Compensated cirrhosis (CTP class A), requested duration is 12 weeks, and there are no baseline NS5A RAVs for elbasvir detected; or
4. Compensated cirrhosis (CTP class A), will be treated with ribavirin, the requested duration is 16 weeks, baseline NS5A RAVs for elbasvir have

been detected and documentation is provided as to why the recipient cannot use a guideline-recommended regimen.

C. The recipient is treatment-experienced (failed peginterferon + ribavirin + NS3 protease inhibitor) and must meet one of the following:

1. No cirrhosis, will be treated with ribavirin, the requested duration is 12 weeks and there are no baseline NS5A RAVs for elbasvir detected; or
2. No cirrhosis, will be treated with ribavirin, the requested duration is 16 weeks, baseline NS5A RAVs for elbasvir have been detected; or
3. Compensated cirrhosis (CTP class A), will be treated with ribavirin, requested duration is 12 weeks, and there are no baseline NS5A RAVs for elbasvir detected; or
4. Compensated cirrhosis (CTP class A), will be treated with ribavirin, the requested duration is 16 weeks, baseline NS5A RAVs for elbasvir have been detected.

III. Genotype 1b

A. The recipient is treatment-naïve and must meet one of the following:

1. No cirrhosis and the requested duration is 12 weeks; or
2. Compensated cirrhosis (CTP class A) and the requested duration is 12 weeks.

B. The recipient is treatment-experienced (failed peginterferon + ribavirin dual therapy) and must meet one of the following:

1. No cirrhosis and the requested duration is 12 weeks; or
2. Compensated cirrhosis (CTP class A) and the requested duration is 12 weeks.

C. The recipient is treatment-experienced (failed peginterferon + ribavirin + NS3 protease inhibitor) and must meet one of the following:

1. No cirrhosis, will be treated with ribavirin, the requested duration is 12 weeks and there are no baseline NS5A RAVs for elbasvir detected; or
2. No cirrhosis, will be treated with ribavirin, the requested duration is 16 weeks and baseline NS5A RAVs for elbasvir have been detected; or
3. Compensated cirrhosis (CTP class A), will be treated with ribavirin, requested duration is 12 weeks and there are no baseline NS5A RAVs for elbasvir detected; or
4. Compensated cirrhosis (CTP class A), will be treated with ribavirin, the requested duration is 16 weeks, baseline NS5A RAVs for elbasvir have been detected.

IV. Genotype 4

A. The recipient is treatment-naïve and must meet one of the following:

1. No cirrhosis and the requested duration is 12 weeks; or
2. Compensated cirrhosis (CTP class A) and the requested duration is 12 weeks.

B. The recipient is treatment-experienced (failed peginterferon + ribavirin dual therapy) and must meet one of the following:

1. No cirrhosis, the requested duration is 12 weeks and documentation is provided showing the recipient experienced virologic relapse to peginterferon + ribavirin dual therapy; or
2. No cirrhosis, will be treated with ribavirin, the requested duration is 16 weeks and documentation has been provided showing the recipient experienced on-treatment virologic failure to peginterferon + ribavirin dual therapy; or
3. Compensated cirrhosis (CTP class A), the requested duration is 12 weeks and documentation is provided showing the recipient experienced virologic relapse to peginterferon + ribavirin dual therapy; or
4. Compensated cirrhosis (CTP class A), will be treated with ribavirin, the requested duration is 16 weeks and documentation has been provided showing the recipient experienced on-treatment virologic failure to peginterferon + ribavirin dual therapy.

State specific mandates		
State name	**Date effective**	**Mandate details (including specific bill if applicable)**
Nevada Medicaid	3/1/2016	As of 3/1/16, Nevada Division of Health Care Financing and Policy (DHCFP) has mandated all MCOs to comply with the FFS criteria for DAAs. The MCO criteria can be no more stringent than the FFS criteria. MCOs can maintain their own PDL status.

1 Nevada Medicaid Services Manual Chapter 1200: Prescribed Drugs
2 American Association for the Study of Liver Diseases. Diagnosis, Management, and Treatment of Hepatitis C: An Update. AASLD Practice Guidelines. *Hepatology*. 2009; 49(4):1335-74. Available from: http://onlinelibrary.wiley.com/doi/10.1002/hep.22759/pdf. Accessed on: May 13, 2016.
Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2015. URL: **http://www.clinicalpharmacology.com**. Updated periodically.
3 DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. **http://dailymed.nlm.nih.gov/dailymed/about.cfm**. Accessed: July 14, 2015.
4 DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5 Drug Facts and Comparisons. Facts and Comparisons [database online]. St. Louis, MO: Wolters Kluwer Health, Inc; 2015. Updated periodically.
6 Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2015; Updated periodically.