NC Division of Medical Assistance
Outpatient Pharmacy
Prior Approval Criteria
Hepatitis C Virus Medications

Medicaid and Health Choice
Effective Date: August 15, 2014
Amended Date: October 23, 2019

Therapeutic Class Code: W5Y, W0B, W0D, W0A, W0E
Therapeutic Class Description: Hepatitis C Virus nucleotide analog NS5B RNA Dependent Polymerase Inhibitor, Hepatitis C Virus NS3/4A Serine Protease Inhibitor, and Hepatitis C Virus NS5A Inhibitor and Nucleotide Analog NS5B Polymerase Inhibitor, NS5A, NS3/4A Protease, Nucleotide NS5B Polymerase Inhibitor Combination

Medication
Mavyret™ (glecaprevir and pibrentasvir)
Daklinza™ (daclatasvir)
Epclusa® (sofosbuvir and velpatasvir) and generic sofosbuvir and velpatasvir
Harvoni® 90-400mg tablet (ledipasvir and sofosbuvir) and generic ledipasvir and sofosbuvir
Sovaldi® 400mg tablet (sofosbuvir)
Viekira Pak™ (dasabuvir, ombitasvir, paritaprevir, and ritonavir)
Vosevi™ (Sofosbuvir/Velpatasvir/Voxilaprevir)
Zepatier® (elbasvir and grazoprevir)

Eligible Beneficiaries
NC Medicaid (Medicaid) beneficiaries shall be enrolled on the date of service and may have service restrictions due to their eligibility category that would make them ineligible for this service.

NC Health Choice (NCHC) beneficiaries, ages 6 through 18 years of age, shall be enrolled on the date of service to be eligible, and must meet policy coverage criteria, unless otherwise specified.

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EPSDT Special Provision: Exception to Policy Limitations for Beneficiaries under 21 Years of Age

42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiaries under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed clinician). This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his/her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems. Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the recipient's physician, therapist, or otherlicensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the recipient's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product, or procedure

a. that is unsafe, ineffective, or experimental/investigational.
b. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and/or other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT and Prior Approval Requirements

a. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does **NOT** eliminate the requirement for prior approval.
b. IMPORTANT ADDITIONAL INFORMATION about EPSDT and prior approval is found in the NCTracks Provider Claims and Billing Assistance Guide, and on the EPSDT provider page. The Web addresses are specified below.

NCTracks Provider Claims and Billing Assistance Guide:
https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html

EPSDT provider page: http://dma.ncdhhs.gov/

Health Choice Special Provision: Exceptions to Policy Limitations for Health Choice Beneficiaries ages 6 through 18 years of age

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EPSDT does not apply to NCHC beneficiaries. If a NCHC beneficiary does not meet the clinical coverage criteria within **the Outpatient Pharmacy prior approval** clinical coverage criteria, the NCHC beneficiary shall be denied services. Only services included under the Health Choice State Plan and the DMA clinical coverage policies, service definitions, or billing codes shall be covered for NCHC beneficiaries.

A. Criteria for Coverage of Sovaldi® (sofosbuvir):

Covered for the following conditions:

1. Beneficiary is 18 years old or older with a diagnosis of chronic hepatitis C infection with confirmed genotype 1,2,3, or 4 without cirrhosis or with compensated cirrhosis **OR**
2. Beneficiary is 12 years of age or older or weighs at least 35 kg with diagnosis of chronic hepatitis C with confirmed genotype 2 or 3 without cirrhosis or with compensated cirrhosis **OR**
3. Beneficiary has CHC infection with hepatocellular carcinoma awaiting liver transplant. **AND**
4. Provider has submitted medical records documenting the diagnosis of chronic hepatitis C with genotype and subtype if applicable **AND**
5. Beneficiary has a documented quantitative HCV RNA at baseline that was tested within the past 6 months documented on the Prior Authorization Request **AND**
6. For beneficiaries with a history of alcohol abuse or IV drug use, a commitment to abstinence is required. For beneficiaries with a recent history of alcohol abuse or IV drug use (within the past year) enrollment in a treatment program, and/or counseling and/or an active support group is also required. Beneficiaries must agree to toxicology and/or alcohol screens as needed. **AND**
7. The provider must be reasonably certain that treatment will improve the beneficiary's overall health status. **AND**
8. The provider has completed a Beneficiary Readiness Evaluation with the beneficiary meeting **ALL** of the Beneficiary Readiness Criteria. **AND**
9. Sofosbuvir (Sovaldi®) is prescribed in combination with ribavirin and pegylated interferon alfa for genotypes 1 and 4 **OR**
10. Sofosbuvir (Sovaldi®) is prescribed in combination with ribavirin for patients with genotype 1 who are peginterferon-ineligible (medical record documentation of peginterferon therapy must be submitted for review) **OR**
11. Sofosbuvir (Sovaldi®) is prescribed in combination with ribavirin for genotypes 2 and 3 and/or in CHC patients with hepatocellular carcinoma awaiting liver transplant

Approval limits for sofosbuvir (Sovaldi) for all beneficiaries meeting criteria will be as follows:

	Adult Patient Population	**Regimen and Duration**
Genotype 1 or 4	Treatment-naïve without cirrhosis or with compensated cirrhosis (Child-Pugh A)	SOVALDI + peginterferon alfa + ribavirin 12 weeks
Genotype 1	PEG-interferon ineligible	SOVALDI +ribavirin 24 weeks

Genotype 2	Treatment-naïve and treatment- experienced without cirrhosis or with compensated cirrhosis (Child-Pugh A)	SOVALDI + ribavirin 12 weeks
Genotype 3	Treatment-naïve and treatment- experienced without cirrhosis or with compensated cirrhosis (Child-Pugh A)	SOVALDI + Ribavirin 24 weeks
Genotype 1,2, 3, or 4	Diagnosis of hepatocellular carcinoma awaiting liver transplantation	SOVALDI +ribavirin up to 48 weeks or until liver transplantation whichever comes first

	Pediatric Patient Population 12 Years of Age and Older or Weighing at Least 35 kg	**Regimen and Duration**
Genotype 2	Treatment-naïve and treatment- experienced without cirrhosis or with compensated cirrhosis (Child-Pugh A)	SOVALDI + ribavirin 12 weeks
Genotype 3	Treatment-naïve and treatment- experienced without cirrhosis or with compensated cirrhosis (Child-Pugh A)	SOVALDI + ribavirin 24 weeks

For initial authorization of Sovaldi® (sofosbuvir) approval will be limited to an 8 week maximum (Note: this may be changed to a 4 week maximum if determined that testing can be done at 3 weeks and results received prior to the end of the 4 week period).

For reauthorization/completion of Sovaldi® (sofosbuvir):

1. Lab results (HCV RNA) collected four or more weeks after the first prescription fill date must indicate a response to therapy (≥ 2 log reduction in HCV RNA or HCV RNA < 25 IU/ml). Copy of results must be submitted. **AND**
2. No sign(s) of high risk behavior (recurring alcoholism, IV drug use, etc.,) or failure to complete HCV disease evaluation appointments and procedures should be evident in follow-up reviews. **AND**
3. Continuation of treatment may be authorized for beneficiaries who are **compliant** to the regimen as verified by the Prescriber and beneficiary's medication fill history (review Rx history and dispensing for compliance).

Exclusions to coverage:

- Sofosbuvir (Sovaldi®) is being used as monotherapy. **OR**
- Sofosbuvir (Sovaldi®) is being used with ledipasvir-sofosbuvir (Harvoni®) **OR**
- Beneficiary has FDA labeled contraindications to sofosbuvir (Sovaldi®) **OR**
- Beneficiary is pregnant **OR**
- Beneficiary has severe renal impairment (CrCl less than 30 mL/min), end stage renal disease, or requires dialysis (AASLD/IDSA 2014) **OR**
- Sofosbuvir (Sovaldi®) is being used in patients with severe hepatic impairment (Child-Pugh Class C) **OR**

- Beneficiary is a non-responder to sofosbuvir **OR**
- Beneficiary has previously failed therapy with a treatment regimen that included sofosbuvir **OR**
- Beneficiary has hepatocellular carcinoma

B. Criteria for Coverage of Harvoni® (ledipasvir/sofosbuvir) and generic ledipasvir/sofobuvir:

Covered for the following conditions:

1. Adults with a diagnosis of hepatitis C (CHC) with genotype 1,4,5,6 infection without cirrhosis or with compensated cirrhosis **OR**
2. Adults with genotype 1 infection with decompensated cirrhosis, in combination with ribavirin **OR**
3. Adults with genotype 1 or 4 infection who are liver transplant recipients without cirrhosis or with compensated cirrhosis, in combination with ribavirin **OR**
4. Pediatric patients 12 years of age or older or weighing at least 35 kg with genotype 1,4,5,or 6 without cirrhosis or with compensated cirrhosis **AND**
5. Provider has submitted medical records documenting the diagnosis of chronic hepatitis C with genotype and subtype if applicable **AND**
6. Beneficiary has a documented quantitative HCV RNA at baseline that was tested within the past 6 months documented on the Prior Authorization Request **AND**
7. For beneficiaries with a history of alcohol abuse or IV drug use, a commitment to abstinence is required. For beneficiaries with a recent history of alcohol abuse or IV drug use (within the past year) enrollment in a treatment program and/or counseling, and/or an active support group is also required. Beneficiaries must agree to toxicology and/or alcohol screens as needed. **AND**
8. Provider must be reasonably certain that treatment will improve the beneficiary's overall health status. **AND**
9. Provider has completed a Beneficiary Readiness Evaluation with the beneficiary meeting **ALL** of the Beneficiary Readiness Criteria

Approval limits for Harvoni® and generic ledipasvir/sofosbuvir for all beneficiaries meeting criteria will be as follows:

	Adult Patient Population	**Regimen and Duration**
Genotype 1	Treatment-naïve without cirrhosis who have pre-treatment HCV RNA less than 6 million IU/mL	HARVONI 8 Weeks

	Treatment-naïve without cirrhosis or with compensated cirrhosis (Child-Pugh A)	HARVONI 12 weeks
	Treatment-experienced without cirrhosis	HARVONI 12 weeks
	Treatment-experienced with compensated cirrhosis (Child-Pugh A)	HARVONI 24 weeks
	Treatment-naïve and treatment-experienced with decompensated cirrhosis (Child-Pugh B or C)	HARVONI + ribavirin 12 weeks

	Pediatric Patient Population 12 Years of Age and Older or Weighing at Least 35 Kg	**Regimen and Duration**
Genotype 1	Treatment-naïve without cirrhosis or with compensated cirrhosis (Child-Pugh A)	HARVONI 12 weeks
	Treatment-experienced without cirrhosis	HARVONI 12 weeks
	Treatment-experienced with compensated cirrhosis (Child-Pugh A)	HARVONI 24 weeks
Genotype 4, 5, or 6	Treatment-naïve and treatment-experienced without cirrhosis or with compensated cirrhosis (Child-Pugh A)	HARVONI 12 weeks

For initial authorization of Harvoni® (ledipasvir/sofosbuvir) and generic ledipasvir/sofosbuvir approval will be limited to an 8 week maximum for 8, 12 or 24 week regimens (Note: this may be changed to a 4 week maximum if determined that testing can be done at 3 weeks and results received prior to the end of the 4 week period).

For reauthorization/completion of Harvoni, (ledipasvir/sofosbuvir) and generic ledipasvir/sofosbuvir:

- Lab results (HCV RNA) collected four or more weeks after the first prescription fill date must indicate a response to therapy (≥ 2 log reduction in HCV RNA or HCV RNA < 25 IU/ml).Copy of results must be submitted.
- No sign(s) of high risk behavior (recurring alcoholism, IV drug use, etc.,) or failure to complete HCV disease evaluation appointments and procedures should be evident in follow-up reviews.
- Continuation of treatment may be authorized for beneficiaries who are **compliant** to the regimen as verified by the Prescriber and beneficiary's medication fill history (review Rx history and dispensing for compliance).

Exclusions to coverage:

- Beneficiary has FDA labeled contraindications to Harvoni® or generic ledipasvir/sofosbuvir; **OR**
- Harvoni® or generic ledipasvir/sofosbuvir is being used in combination with amiodarone **;OR**
- Harvoni® or generic ledipasvir/sofosbuvir is being used in combination with other drugs containing sofosbuvir

C. Criteria for Coverage of Viekira Pak™ (ombitasvir/paritaprevir/ritonavir tablets & dasabuvirtablets):

Covered for the following conditions:

1. Beneficiary is 18 years old or older with a diagnosis of chronic hepatitis C (CHC) infection with confirmed genotype 1b without cirrhosis or with compensated cirrhosis or confirmed genotype 1a without cirrhosis or with compensated cirrhosis in combination with ribavirin **AND**

2. Treatment includes use of ribavirin for all treatment courses **EXCEPT** for genotype 1b, without cirrhosis. **AND**
3. Provider has submitted medical records documenting the diagnosis of chronic hepatitis C with genotype and subtype if applicable. **AND**
4. Beneficiary has a documented quantitative HCV RNA at baseline that was tested within the past 6 months documented on the Prior Authorization Request. **AND**
5. For beneficiaries with a history of alcohol abuse or IV drug use, a commitment to abstinence is required. For beneficiaries with a recent history of alcohol abuse or IV drug use (within the past year) enrollment in a treatment program and/or counseling, and/or an active support group is also required. Beneficiaries must agree to toxicology and/or alcohol screens as needed. **AND**
6. Provider must be reasonably certain that treatment will improve the beneficiary's overall health status. **AND**
7. Provider has completed a Beneficiary Readiness Evaluation with the beneficiary meeting **ALL** of the Beneficiary Readiness Criteria. **AND**
8. Prior to initiation of VIEKIRA PAK™ the provider has assessed for laboratory and clinical evidence of hepatic decompensation **AND**
9. For patients with cirrhosis:
    a. Provider is monitoring for clinical signs and symptoms of hepatic decompensation (such as ascites, hepatic encephalopathy, variceal hemorrhage).

    b. Provider is performing hepatic laboratory testing, including direct bilirubin levels, at baseline and during the first four weeks of starting treatment and as clinically indicated.

Approval limits for Viekira™ for all beneficiaries meeting criteria will be as follows:

Patient Population	Treatment*	Duration
Genotype 1a, without cirrhosis	VIEKIRA PAK + ribavirin	12 weeks
Genotype 1a, with compensated cirrhosis	VIEKIRA PAK + ribavirin	24 weeks **
Genotype 1b, without cirrhosis	VIEKIRA PAK	12 weeks
Genotype 1b, with cirrhosis	VIEKIRA PAK + ribavirin	12 weeks

*Note: Follow the genotype 1a dosing recommendations in beneficiaries with an unknown genotype 1 subtype or with mixed genotype 1 infection

** Viekira Pak administered with ribavirin for 12 weeks may be considered for some beneficiaries based on prior treatment history

- HCV/HIV-1 co-infection: For beneficiaries with HCV/HIV-1 co-infection, follow dosage recommendations in the table above.
- Liver Transplant Recipients: In liver transplant recipients with normal hepatic function and mild fibrosis (Metavir fibrosis < or = 2), the recommended duration of Viekira Pak with ribavirin is 24 weeks.

For initial authorization of Viekira™ approval will be limited to a 8 week maximum for 12 or 24 week regimens (Note: this may be changed to a 4 week maximum if determined that testing can be done at 3 weeks and results received prior to the end of the 4 week period).

For reauthorization/completion of Viekira™

- Lab results (HCV RNA) collected four or more weeks after the first prescription fill date must indicate a response to therapy (≥ 2 log reduction in HCV RNA or HCV RNA < 25 IU/ml). Copy of results must be submitted.
- No sign(s) of high risk behavior (recurring alcoholism, IV drug use, etc.,) or failure to complete HCV disease evaluation appointments and procedures should be evident in follow-up reviews.
- Continuation of treatment may be authorized for beneficiaries who are **compliant** to the regimen as verified by the Prescriber and beneficiary's medication fill history(review Rx history and dispensing for compliance).

Exclusions to coverage:

- Beneficiary requires dialysis; **OR**
- Viekira™ is being used in combination with other protease inhibitors used to treat CHC (i.e. boceprevir, simeprevir, or telaprevir) or in combination with another nucleotide NS5B polymerase inhibitor such as Sovaldi® (sofosbuvir); **OR**
- Beneficiary is using Viekira™ in combination with another NS5A inhibitor; **OR**
- Beneficiary 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; **OR**
- Beneficiary 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 ledipasvir. **OR**
- Beneficiary has decompensated liver disease as defined by Child-Pugh classification score of Child Class B or C (VIEKIRA PAK™ is contraindicated in patients with moderate to severe hepatic impairment (Child-Pugh B and C). **OR**
- Beneficiary has attempted a previous course of therapy with Viekira Pak™ **OR**
- Beneficiary has FDA labeled contraindications to Viekira Pak™

D. Criteria for Coverage of Daklinza™ (declatasvir):

Covered for the following conditions:

1. Beneficiary is 18 years old or older with a diagnosis of chronic hepatitis C (CHC) infection with confirmed genotype 1 or genotype 3. **AND**
2. Daklinza™ is used concomitantly with sofosbuvir for all treatment courses. **AND**
3. Provider has submitted medical records documenting the diagnosis of chronic hepatitis C with genotype and subtype if applicable. **AND**
4. Beneficiary has a documented quantitative HCV RNA at baseline that was tested within the past 6 months documented on the Prior Authorization Request. **AND**
5. For beneficiaries with a history of alcohol abuse or IV drug use, a commitment to abstinence is required. For beneficiaries with a recent history of alcohol abuse or IV drug use (within the past year) enrollment in a treatment program and/or counseling, and/or an active support group is also required. Beneficiaries must agree to toxicology and/or alcohol screens as needed. **AND**
6. Provider must be reasonably certain that treatment will improve the beneficiary's overall health status.

AND

7. Provider has completed a Beneficiary Readiness Evaluation with the beneficiary meeting **ALL** of the Beneficiary Readiness Criteria

Approval limits for Daklinza™ for all beneficiaries meeting criteria will be as follows:

Patient Population	Treatment*	Duration
Genotype 1 or Genotype 3	DAKLINZA™ 60 mg once daily with or without food in combination with sofosbuvir with or without ribavirin. If administered with strong **inhibitors** of cytochrome P450 enzyme 3A (CYP3A): DAKLINZA™ 30 mg once daily in combination with sofosbuvir. If administered with moderate CYP3A **inducers**: DAKLINZA™ 90 mg once daily in combination with sofosbuvir.	12 weeks

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For initial authorization of Daklinza™, approval will be limited to a 8 week maximum for 12 week regimens (Note: this may be changed to a 4 week maximum if determined that testing can be done at 3 weeks and results received prior to the end of the 4 week period).

For reauthorization/completion of Daklinza™

- Lab results (HCV RNA) collected four or more weeks after the first prescription fill date must indicate a response to therapy (≥ 2 log reduction in HCV RNA or HCV RNA < 25 IU/ml). Copy of results must be submitted.
- No sign(s) of high risk behavior (recurring alcoholism, IV drug use, etc.,) or failure to complete HCV disease evaluation appointments and procedures should be evident in follow-up reviews.
- Continuation of treatment may be authorized for beneficiaries who are **compliant** to the regimen as verified by the Prescriber and beneficiary's medication fill history (review Rx history and dispensing for compliance).

Exclusions to coverage:

- Beneficiary requires dialysis. **OR**
- Daklinza™ is being used in combination with drugs that strongly induce CYP3A. **OR**
- Beneficiary has decompensated liver disease as defined by Child-Pugh classification score of Child Class B or C. **OR**
- Beneficiary has FDA labeled contraindications to Daklinza™. **OR**
- Daklinza™ is being used in combination with amiodarone**. OR**
- Daklinza™ is being used in combination with another NS5A inhibitor (such as Harvoni ® (ledipasvir/sofosbuvir) or ombitasvir (component of Viekira Pak™/ Viekira XR™). **OR**

- Daklinza™ is being used in combination with a NS3/4A protease inhibitor. **OR**
- Beneficiary 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 daclatasvir (Daklinza™). **OR**
- Beneficiary is requesting the regimen for re-treatment in combination with sofosbuvir (Sovaldi®) 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, ribavirin, and interferon

E. Criteria for Coverage of Zepatier (elbasvirandgrazoprevir):

Covered for the following conditions:

1. Beneficiary is 18 years old or older with a diagnosis of chronic hepatitis C (CHC) infection with confirmed genotype 1 or genotype 4. **AND**
2. Provider has submitted medical records documenting the diagnosis of chronic hepatitis C with genotype and subtype if applicable. **AND**
3. Beneficiary has a documented quantitative HCV RNA at baseline that was tested within the past 6 months documented on the Prior Authorization Request. **AND**
4. For beneficiaries with a history of alcohol abuse or IV drug use, a commitment to abstinence is required. For beneficiaries with a recent history of alcohol abuse or IV drug use (within the past year) enrollment in a treatment program and/or counseling, and/or an active support group is also required. Beneficiaries must agree to toxicology and/or alcohol screens as needed. **AND**
5. Provider must be reasonably certain that treatment will improve the beneficiary's overall health status. **AND**
6. Provider has completed a Beneficiary Readiness Evaluation with the beneficiary meeting **ALL** of the Beneficiary Readiness Criteria.

Approval limits for Zepatier® for all beneficiaries meeting criteria will be as follows

Beneficiary Status	Treatment	Total Approval Duration
Genotype 1a: experienced* Treatment-naïve or PegIFN/RBV-isms† without baseline NS5A polymorph	ZEPATIER	12 weeks
Genotype 1a: Treatment-naïve or PegIFN/RBV- experienced* withbaseline NS5Apolymorphisms		
Genotype 1b: Treatment-naïve or PegIFN/RBV-experienced*	ZEPATIER	12 weeks

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Beneficiary Status	Treatment	Total Approval Duration
PegI Genotype 1a or 1b: ced‡ FN/RBV/PI-experienced	ZEPATIER + ribavirin	12 weeks
Genotype 4: Treatment-naïve	ZEPATIER	12 weeks
Genotype 4: PegIFN/RBV-experienced*	ZEPATIER + ribavirin	16 weeks

*Peginterferon alfa + ribavirin.
†Polymorphisms at amino acid positions 28, 30, 31, or 93.
‡Peginterferon alfa + ribavirin + HCV NS3/4A protease inhibitor.
Genotype 1a: Testing for the presence of virus with NS5A resistance-associated polymorphisms is recommended

For initial authorization of Zepatier®, approval will be limited to an 8 week maximum for 12 or 16 week regimens

For reauthorization/completion of Zepatier®

- Lab results (HCV RNA) collected four or more weeks after the first prescription fill date must indicate a response to therapy (≥ 2 log reduction in HCV RNA or HCV RNA < 25 IU/ml). Copy of results must be submitted.
- No sign(s) of high risk behavior (recurring alcoholism, IV drug use, etc.,) or failure to complete HCV disease evaluation appointments and procedures should be evident in follow-up reviews.
- Continuation of treatment may be authorized for beneficiaries who are **compliant** to the regimen as verified by the Prescriber and beneficiary's medication fill history (review Rx history and dispensing for compliance).

Exclusions to coverage:

- Beneficiary has FDA labeled contraindications to Zepatier®. **OR**
- Beneficiary has moderate to severe hepatic impairment (Child-Pugh B or C)**. OR**
- Zepatier is being co administered with organic anion transporting polypeptides 1B1/3 (OATP1B1/3) inhibitors, strong inducers of cytochrome P450 3A (CYP3A), or efavirenz.

F. Criteria for Coverage of Epclusa® (velpatasvir/sofosbuvir) and generic velpatasvir/sofosbuvir:

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Covered for the following conditions:

1. Beneficiary is 18 years old or older with a diagnosis of chronic hepatitis C (CHC) infection with confirmed genotype 1, 2, 3, 4, 5 or genotype 6 without cirrhosis or with compensated cirrhosis or with decompensated cirrhosis for use in combination with ribavirin. **AND**
2. Provider has submitted medical records documenting the diagnosis of chronic hepatitis C with genotype and subtype if applicable. **AND**

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3. Beneficiary has a documented quantitative HCV RNA at baseline that was tested within the past 6 months documented on the Prior Authorization Request. **AND**
4. For beneficiaries with a history of alcohol abuse or IV drug use, a commitment to abstinence is required. For beneficiaries with a recent history of alcohol abuse or IV drug use (within the past year) enrollment in a treatment program and/or counseling, and/or an active support group is also required. Beneficiaries must agree to toxicology and/or alcohol screens as needed. **AND**
5. Provider must be reasonably certain that treatment will improve the beneficiary's overall health status. **AND**
6. Provider has completed a Beneficiary Readiness Evaluation with the beneficiary meeting **ALL** of the Beneficiary Readiness Criteria.

Approval limits for Epclusa® and generic velpatasvir/sofosbuvir for all beneficiaries meeting criteria will be as follows:

Patient Population	Treatment Duration
Genotypes 1,2,3,4,5, or 6 treatment -naïve and treatment -experienced[a] without cirrhosis and with compensated cirrhosis (Child Pugh A)	Epclusa 12 weeks
Genotypes 1,2,3,4,5, or 6 treatment- naïve and treatment -experienced[a] with decompensated cirrhosis (Child-Pugh B and C)	Epclusa + ribavirin for 12 weeks

[a.] In clinical trials, regimens contained peginterferon alfa/ribavirin with or without an HCV NS3/4A protease inhibitor (boceprevir, simeprevir, or telaprevir)

- HCV/HIV-1 coinfection: For beneficiaries with HCV/HIV-1 coinfection, follow the dosage recommendations in the table above.

For initial authorization of Epclusa® (velpatasvir/sofosbuvir) and generic velpatasvir/sofosbuvir approval will be limited to an 8 week maximum.

For reauthorization/completion of Epclusa®, (velpatasvir/sofosbuvir) and generic velpatasvir/sofosbuvir:

- Lab results (HCV RNA) collected four or more weeks after the first prescription fill date must indicate a response to therapy (≥ 2 log reduction in HCV RNA or HCV RNA < 25 IU/ml).Copy of results must be submitted.
- No sign(s) of high risk behavior (recurring alcoholism, IV drug use, etc.,) or failure to complete HCV disease evaluation appointments and procedures should be evident in follow-up reviews.
- Continuation of treatment may be authorized for beneficiaries who are **compliant** to the regimen as verified by the Prescriber and beneficiary's medication fill history (review Rx history and dispensing for compliance).

Exclusions to coverage:

- Beneficiary has FDA labeled contraindications to Epclusa® or generic velpatasvir/sofosbuvir; **OR**
- Epclusa® or generic velpatasvir/sofosbuvir is being used in combination with amiodarone **OR**
- Epclusa® or generic velpatasvir/sofosbuvir is being used in combination with other drugs containing sofosbuvir

G. Criteria for Coverage of Mavyret™ (glecaprevir and pibrentasvir)

Covered for the following conditions:

1. Beneficiary is 12 years old or older or weighing at least 45 kg with a diagnosis of chronic hepatitis C (CHC) infection with confirmed genotype 1,2,3,4,5, or 6 without cirrhosis or with compensated cirrhosis (Child-Pugh A). **AND**
2. Provider has submitted medical records documenting the diagnosis of chronic hepatitis C with genotype and subtype if applicable. **AND**
3. Beneficiary has a documented quantitative HCV RNA at baseline that was tested within the past 6 months documented on the Prior Authorization Request. **AND**
4. For beneficiaries with a history of alcohol abuse or IV drug use, a commitment to abstinence is required. For beneficiaries with a recent history of alcohol abuse or IV drug use (within the past year) enrollment in a treatment program and/or counseling, and/or an active support group is also required. Beneficiaries must agree to toxicology and/or alcohol screens as needed. **AND**
5. Provider must be reasonably certain that treatment will improve the beneficiary's overall health status. **AND**
6. Provider has completed a Beneficiary Readiness Evaluation with the beneficiary meeting **ALL** of the Beneficiary Readiness Criteria. **AND**
7. Mavyret is not being coadministered with atazanavir and rifampin.

Mavyret™
Recommended Duration for Treatment-Naïve Patients

HCV Genotype	Treatment Duration	
	No Cirrhosis	Compensated Cirrhosis (Child Pugh-A)
1,2,3,4,5, or 6	8 weeks	12 weeks

Recommended Duration for Treatment-Experienced Patients

1	An NS5A inhibitor[1] without prior treatment with an NS3/4A protease inhibitor	16 weeks	16 weeks
	An NS3/4A PI[2] without prior treatment with an NS5A inhibitor	12 weeks	12 weeks
1,2,4,5, or 6	PRS[3]	8 weeks	12 weeks
3	PRS[3]	16 weeks	16 weeks

		Treatment Duration	
HCV Genotype	Patients Previously Treated with a Regimen Containing:	No Cirrhosis	Compensated Cirrhosis (Child Pugh A)

1. In clinical trials, subjects were treated with prior regimens containing ledipasvir and sofosbuvir or daclatasvir with pegylated interferon and ribavirin.
2. In clinical trials, subjects were treated with prior regimens containing simeprevir and sofosbuvir, or simeprevir, boceprevir, or telaprevir with pegylated interferon and ribavirin.
3. PRS=Prior treatment experience with regimens containing interferon, pegylated interferon, ribavirin, and/or sofosbuvir, but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor.

For initial authorization of Mavyret ™ approval will be limited to an 8 week maximum. (for all beneficiaries)

For reauthorization/completion of Mavyret™ (for beneficiaries requiring greater than 8 weeks of therapy)

Lab results (HCV RNA) collected four or more weeks after the first prescription fill date must indicate a response to therapy (≥ 2 log reduction in HCV RNA or HCV RNA < 25 IU/ml).Copy of results must be submitted.

- No sign(s) of high risk behavior (recurring alcoholism, IV drug use, etc.,) or failure to complete HCV disease evaluation appointments and procedures should be evident in follow-up reviews.
- Continuation of treatment may be authorized for beneficiaries who are **compliant** to the regimen as verified by the Prescriber and beneficiary's medication fill history (review Rx history and dispensing for compliance).

H. Criteria for Coverage of Vosevi™:

Covered for the following conditions:

1. Beneficiary is 18 years old or older with a diagnosis of chronic hepatitis C (CHC) infection with confirmed genotype 1, 2, 3, 4, 5 or genotype 6. without cirrhosis or with compensated cirrhosis

(Child-Pugh A). **AND**

2. Beneficiary has previously been treated with an HCV regimen containing an NS5A inhibitor (genotype 1,2,3,4,5, or 6) or has previously been treated with an HCV regimen containing sofosbuvir without an NS5A inhibitor (genotype 1a or genotype 3). **AND**
3. Provider has submitted medical records documenting the diagnosis of chronic hepatitis C with genotype and subtype if applicable. **AND**
4. Beneficiary has a documented quantitative HCV RNA at baseline that was tested within the past 6 months documented on the Prior Authorization Request. **AND**
5. Provider must be reasonably certain that treatment will improve the beneficiary's overall health status. **AND**
6. Provider has completed a Beneficiary Readiness Evaluation with the beneficiary meeting **ALL** of the Beneficiary Readiness Criteria.

Approval limits for Vosevi ™ all beneficiaries meeting criteria will be as follows:

Genotype	Beneficiaries previously treated with an HCV Regimen Containing:	Vosevi Duration
1,2,3,4,5, or 6	An NS5A inhibitor[a]	12 weeks
1a or 3	Sofosbuvir without an NS5A inhibitor[b]	12 weeks

a. In clinical trials, prior NS5A inhibitor experience included daclatasvir, elbasvir, ledipasvir, ombitasvir, or velpatasvir.
b. In clinical trials, prior treatment experience included sofosbuvir with or without any of the following: peginterferon alfa/ribavirin, ribavirin, HCV NS3/4A protease inhibitor (boceprevir, simeprevir or telaprevir).

For initial authorization of Vosevi™ approval will be limited to an 8 week maximum

For reauthorization/completion of Vosevi™:

- Lab results (HCV RNA) collected four or more weeks after the first prescription fill date must indicate a response to therapy (≥ 2 log reduction in HCV RNA or HCV RNA < 25 IU/ml).Copy of results must be submitted.
- No sign(s) of high risk behavior (recurring alcoholism, IV drug use, etc.,) or failure to complete HCV disease evaluation appointments and procedures should be evident in follow-up reviews.
- Continuation of treatment may be authorized for beneficiaries who are **compliant** to the regimen as verified by the Prescriber and beneficiary's medication fill history (review Rx history and dispensing for compliance).

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Exclusions to coverage:

- Beneficiary has FDA labeled contraindications to Vosevi™; **OR**
- Vosevi™ is being used in combination with amiodarone

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Scoring System Charts:
Compensated Liver Disease

Child Pugh Classification (AASLD/IDSA 2014)

Parameters			
Points Assigned	1 point	2 points	3 points
Total Bilirubin	<34	34-50	>50
Serum Albumin	>35	28-35	<28
Prothrombin Time/INR	INR<1.7	1.71-2.30	>2.30
Ascites	None	Mild	Moderate to Severe
Hepatic Encephalopathy	None	Grade I-II (or suppressed with medication)	Grade III-IV (or refractory)

Grade	Points	One-year patient survival (%)	Two-year patient survival (%)
A: well-compensated disease	5-6	100	85
B: significant functional compromise	7-9	80	60
C: decompensated disease	10-15	45	35

Scoring Systems for Fibrosis Staging (AASLD 2009)

Stage (F)	**IASL (The International Association for the Study of Liver)**	**Batts-Ludwig**	**Metavir**
0	No fibrosis	No fibrosis	No fibrosis
1	Mild fibrosis	Fibrosis portal expansion	Periportal fibrotic expansion
2	Moderate fibrosis	Rare bridges or septae	Periportal septae 1 (septum)
3	Severe fibrosis	Numerous bridges or septae	Porto-central septae

4	Cirrhosis	Cirrhosis	Cirrhosis

Stage (F)	Ishak
0	No fibrosis
1	Fibrosis expansion of some portal areas with or without short fibrous septae
2	Fibrosis expansion of most portal areas with or without short fibrous septae
3	Fibrosis expansion of most portal areas with occasional portal to portal bridging
4	Fibrosis expansion of most portal areas with marked bridging (portal to portal and portal to central)
5	Marked bridging (portal to portal and portal to central) with occasional nodules (incomplete cirrhosis)
6	Cirrhosis

Beneficiary Readiness Evaluation:

Beneficiary psychosocial readiness is a critical component for Hepatitis C treatment success. It is important that any potential impediments to the effectiveness of treatment have been identified and that a plan for dealing with these impediments has been developed. The beneficiary must be educated that abuse of alcohol may cause further liver damage and that abuse of IV injectable drugs will increase the risk of re-infection of Hepatitis C if the virus is cleared. Both the provider and the beneficiary should feel that the beneficiary is committed to effectively start and successfully adhere to treatment.

Please discuss the following questions with your beneficiary, document their responses, and have beneficiary sign:

1. Does beneficiary have a history of alcohol abuse? Yes No

- If yes, how long has it been since beneficiary last used alcohol?
- If yes, is beneficiary attending a support group or receiving counseling? Yes No

2. Does beneficiary have a history of injectable drug abuse? Yes No

- If yes, how long has it been since beneficiary last used an injectable drug?
- If yes, is beneficiary attending a support group or receiving counseling? Yes No

3. Does beneficiary have a history of any other controlled-substance abuse? Yes No

- If yes, how long has it been since beneficiary last used this substance?
- If yes, is beneficiary attending a support group or receiving counseling? Yes No

4. Does beneficiary have difficulties with medication compliance and/or showing up for appointments? Yes No

- If yes, how will compliance/ involvement be improved?

5. Does beneficiary have mental health conditions that are not being adequately treated? Yes No

- If yes, please explain, and state the plan for treatment:

6. Does beneficiary have adequate social support? Yes No

- If not, please state a plan to improve support:

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Hepatitis C Beneficiary Readiness Criteria:

1. For beneficiaries with a history of alcohol abuse or IV drug use, a commitment to abstinence is required. For beneficiaries with a recent history of alcohol abuse or IV drug use (within the past year) enrollment in a treatment program, and/or counseling, and/ or an active support group is also required. Beneficiaries must agree to toxicology and/or alcohol screens as needed.

2. Beneficiary must be reasonably compliant with all current medications that are being prescribed for all disease states/conditions to be considered eligible for Hepatitis C treatment.

3. Beneficiary must have a history of showing up for scheduled appointments/labs leading up to the prescribing of Hepatitis C treatment.

4. If beneficiary has mental health conditions, beneficiary must be compliant with mental health medications and/or psychotherapy. If beneficiary has mental health conditions that are not currently being treated, then a mental health consult to assess for beneficiary readiness will be required before Hepatitis C treatment can begin.

Beneficiary signature:_____ Date: _____

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References:

1. Prescriber Information-Sovaldi ® (sofosbuvir) Gilead Sciences, Inc. Foster, City California 94404. December 2013. Revised April 2017.

2. Sofosbuvir for the Treatment of Hepatitis C and Evaluation of the 2014 American Association for the Study of Liver Diseases Treatment Guidelines, Allison Leof, PhD; Martha Gerrity, MD, MPH, PhD; Aasta Thielke, MPH; Valerie King, MD, MPH - Center for Evidence---based Policy Oregon Health & Science University, 3455 SW US Veterans Hospital Road, Mailstop SN---4N, Portland, OR 97239-2941.

3. Prescriber Information-Olysio ® (simeprevir) Janssen Therapeutics, Titusville, New Jersey 08560. November 2013.

4. Prescriber Information- Harvoni ® (ledipasvir/sofosbuvir) Gilead Sciences, Inc. Foster City, California 94404. October 2014. Revised April 2017.

5. American Association for the Study of Liver Diseases and Infectious Disease Society of America Recommendations for Testing, Managing, and Treating Hepatitis C. When and in Whom to Initiate HCV Therapy. https://www.hcvguidelines.org/evaluate
6. Prescriber Information – Viekira Pak™ (ombitasvir, paritaprevir and ritonavir tablets; dasabuvir tablets) AbbVie, Inc. North Chicago, Illinois 60064. December 2014.
7. Prescriber Information- Daklinza™ (declatasvir) Bristol-Myers Squibb Company, Princeton, NJ 08543, USA. July 2015.
8. Prescriber Information- Technivie™ (ombitasvir, paritaprevir, ritonavir) AbbVie, Inc. North Chicago, Illinois 60064. USA. October 2015.
9. FDA Safety Announcement. Available at: http://www.fda.gov/Drugs/DrugSafety/ucm468634.htm. Accessed October 23, 2015.
10. Viekira Pak™ Label. Available at: http://www.rxabbvie.com/pdf/viekirapak_pi.pdf. Accessed October 26, 2015.
11. Prescriber Information- Zepatier® (elbasvir and grazoprevir) Merck and Co., Inc. Whitehouse Station, NJ 08889. USA. January 2016.
12. Prescriber Information - Epclusa® (velpatasvir/sofosbuvir) Gilead Sciences, Inc. Foster City, CA 94404. USA. June 2016.
13. Prescriber Information- Viekira XR™ (ombitasvir, paritaprevir and ritonavir tablets; dasabuvir extended release tablets) AbbVie, Inc. North Chicago, Illinois 60064. July 2016.
14. Prescriber Information- Mavyret™ (glecaprevir and pibrentasvir)AbbVie, Inc. North Chicago, Illinois 60064. August 2017.
15. Prescriber Information- Vosevi™ (Sofosbuvir/Velpatasvir/Voxilaprevir) Gilead Sciences, Inc. Foster City, California 94404. July 2017

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Criteria Change Log

08/15/2014	Criteria effective date (Sovaldi® and Olysio® were in separate criteria)
01/22/2015	Combined Hepatitis C meds together and added coverage criteria for Harvoni®
03/23/2015	Added Viekira™ coverage criteria
03/14/2016	Added Daklinza™ and Technivie™ coverage criteria
05/18/2016	Added Zepatier® coverage criteria
02/07/2017	Added Epclusa® and Viekira XR™ coverage criteria
08/31/2017	Added dosing for pediatrics-Harvoni® and Sovaldi®.
11/01/2017	Removed requirements for fibrosis score
11/01/2017	Added criteria for coverage Mavyret™ and Vosevi™
10/23/2019	-Removed Olysio, -Add generic for Epclusa -Removed Viekira XR, -Add generic for Harvoni -Removed under Sovaldi criteria statement #11 that states beneficiary must have a clinical reason why they cannot use Harvoni before using Olysio with Sovaldi -Removed Beneficiary is 12 years old or older with a diagnosis of chronic hepatitis C (CHC) infection with confirmed genotype 1, 4, 5, or 6 -Add Adults with a diagnosis of hepatitis C (CHC) with genotype 1,4,5,6 infection without cirrhosis or with compensated cirrhosis OR Adults with genotype 1 infection with decompensated cirrhosis, in combination with ribavirin OR Adults with genotype 1 or 4 infection who are liver transplant recipients without cirrhosis or with compensated cirrhosis, in combination with ribavirin Pediatric patients 12 years of age or older or weighing at least 35 kg with genotype 1,4,5,or 6 without cirrhosis or with compensated cirrhosis -Add pediatric regimen and duration for Harvoni -Removed contraindicated/interaction charts throughout the criteria -Changed age of Mavyret to 12 and older or weighing at least 45 kg -Clarified age ranges for Sovaldi -Clarified Viekira Pak dosing chart -Removed GCN for Daklinza 90 because termed Removed Technivie- termed -Epclusa clarified without cirrhosis or with compensated cirrhosis or with decompensated cirrhosis for use in combination with ribavirin. -Vosevi clarified genotypes