NC Division of Medical Assistance | **Medicaid and Health Choice**
Outpatient Pharmacy | **Effective Date: August 15, 2014**
Prior Approval Criteria | **Amended Date:**
Hepatitis C Virus Medications

DRAFT

Therapeutic Class Code: W5Y, W0B, W0D, W0A, W0E, W0G
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™ tablet (glecaprevir and pibrentasvir)
Mavyret™ pellet packs glecaprevir and pibrentasvir)
Epclusa® tablet (sofosbuvir and velpatasvir) and generic sofosbuvir and velpatasvir
Epclusa® pellet packs (sofosbuvir and velpatasvir)
Harvoni® 90-400mg tablet (ledipasvir and sofosbuvir) and generic ledipasvir and sofosbuvir
Harvoni® pellet packs
Sovaldi® 400mg tablet (sofosbuvir)
Sovaldi® pellet packs
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.
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 other

licensed 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: https://medicaid.ncdhhs.gov/medicaid/get-started/find-programs-and-services-right-you/medicaid-benefit-children-and-adolescents

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

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 has a diagnosis of chronic hepatitis C infections with confirmed genotype:
    a. Genotype 1 or 4 without cirrhosis or with compensated cirrhosis **AND** Beneficiary is 18 years or older **OR**
    b. Genotype 2 or 3 without cirrhosis or with compensated cirrhosis **AND** Beneficiary is 3 years of age or older **OR**
    c. Beneficiary has CHC infection with hepatocellular carcinoma awaiting liver transplant.

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. The provider must be reasonably certain that treatment will improve the beneficiary's overall health status;
   AND
5. Provider attests that beneficiary has been evaluated for readiness for treatment and beneficiary agrees to be compliant with therapy, follow-up appointments and labs;
   AND
6. Sofosbuvir (Sovaldi®) is prescribed in combination with ribavirin and pegylated interferon alfa for genotypes 1 and 4;
   OR
7. Sofosbuvir (Sovaldi®) is prescribed in combination with ribavirin for beneficiaries with genotype 1 who are peginterferon-ineligible (medical record documentation of previous peginterferon therapy or reason for ineligibility must be submitted for review);
   OR
8. Sofosbuvir (Sovaldi®) is prescribed in combination with ribavirin for genotypes 2 and 3 and/or in CHC beneficiaries 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	SOVALDI + Ribavirin 24 weeks
Genotype 3	Treatment-naïve and treatment-experienced 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 3 Years of Age and Older	**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

Exclusions to coverage:

- Sofosbuvir (Sovaldi®) is being used as monotherapy;
  OR
- Sofosbuvir (Sovaldi®) is being used with any other sofosbuvir containing regimen;
  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
- 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 and is not awaiting liver transplant.

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

Covered for the following conditions:

1. Beneficiary is 3 years of age or older with a diagnosis of hepatitis C (CHC) with
   a. genotype 1,4,5,6 infection without cirrhosis or with compensated cirrhosis;
   OR
   b. genotype 1 infection with decompensated cirrhosis, in combination with ribavirin;
   OR
   c. genotype 1 or 4 infection who are liver transplant recipients without cirrhosis or with compensated cirrhosis, in combination with ribavirin;
   AND

2. Provider has submitted medical records documenting the diagnosis of chronic hepatitis C with genotype
3. 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 attests that beneficiary has been evaluated for readiness for treatment and beneficiary agrees to be compliant with therapy, follow-up appointments and labs.

Approval limits for Harvoni® and generic ledipasvir/sofosbuvir for all beneficiaries 3 years of age and older with Genotype 1,4,5, or 6 meeting criteria will be as follows:

	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
Genotype 1 or 4	Treatment-naïve and treatment-experienced liver transplant recipients without cirrhosis, or with compensated cirrhosis (Child-Pugh A)	HARVONI + ribavirin 12 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

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 other drugs containing sofosbuvir.

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

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;
   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 attests that beneficiary has been evaluated for readiness for treatment and beneficiary agrees to be compliant with therapy, follow-up appointments and labs;
   AND
7. Prior to initiation of VIEKIRA PAK™ the provider has assessed for laboratory and clinical evidence of hepatic decompensation;
   AND
8. For beneficiaries with cirrhosis:
   a. Provider is monitoring for clinical signs and symptoms of hepatic decompensation (such as ascites, hepatic encephalopathy, variceal hemorrhage); **and**
   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™ Pak 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, with cirrhosis	VIEKIRA PAK	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.

Exclusions to coverage:

- Viekira Pak™ 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 Pak™ 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 beneficiaries 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 Zepatier (elbasvir and grazoprevir):

Covered for the following conditions:

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Hepatitis C Virus Medications

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. Beneficiaries with Genotype 1a baseline NS5A polymorphisms, Genotype 1a or 1b who are treatment experienced with Peginterferon alfa + ribavirin + HCV NS3/4A protease inhibitor or Genotype 4 who are treatment experienced with Peginterferon alfa + ribavirin, Zepatier must be prescribed with ribavirin;
   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 attests that beneficiary has been evaluated for readiness for treatment and beneficiary agrees to be compliant with therapy, follow -up appointments and labs.

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

Beneficiary Status	Treatment	Total Approval Duration
Genotype 1a: Treatment-naïve or PegIFN/RBV-experienced* **without** baseline NS5A polymorphisms†	ZEPATIER	12 weeks
Genotype 1a: Treatment-naïve or PegIFN/RBV- experienced* **with** baseline NS5A polymorphisms†	ZEPATIER + Ribavirin	16 weeks
Genotype 1b: Treatment-naïve or PegIFN/RBV-experienced*	ZEPATIER	12 weeks
Genotype 1a or 1b: PegIFN/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

Exclusions to coverage:

- Beneficiary has FDA labeled contraindications to Zepatier®;
  OR
- Beneficiary has moderate to severe hepatic impairment (Child-Pugh B or C) or those with any history of prior hepatic decompensation;
  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.

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

Covered for the following conditions:

1. Beneficiary is ~~6~~ 3 years if age or older ~~weighing at least 17kg~~ with a diagnosis of chronic hepatitis C (CHC) infection with 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 (documentation of genotype waived for treatment naïve patients);
   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. Provider must be reasonably certain that the treatment will improve the beneficiary's overall health status;
   AND
5. Provider attests that beneficiary has been evaluated for readiness for treatment and beneficiary agrees to be compliant with therapy, follow-up appointments and labs.

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 and generic velpatasvir/sofosbuvir for 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 and generic velpatasvir/sofosbuvir + ribavirin for 12 weeks
For treatment-naïve and treatment-experienced liver transplant recipients without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Epclusa and generic velpatasvir/sofosbuvir 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.

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 other drugs containing sofosbuvir.

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

Covered for the following conditions:

1. Beneficiary is ~~12~~ 3 years old or older or ~~weighing at least 45 kg~~ with a diagnosis of chronic hepatitis C (CHC) infection with 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 (documentation of genotype waived if treatment naïve patient);
   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. Provider must be reasonably certain that treatment will improve the beneficiary's overall health status;

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	8 weeks

Liver or kidney transplant recipients: 12 weeks

Mavyret™
Recommended Duration for Treatment-Experienced Patients

		Treatment Duration	
HCV Genotype	Patients Previously Treated with a Regimen Containing:	No Cirrhosis	Compensated Cirrhosis (Child Pugh A)
1	An NS5A inhibitor1 without prior treatment with an NS3/4A protease inhibitor (including liver or kidney transplant recipients)	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] (including liver or kidney transplant recipients)	16 weeks	16 weeks

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.

Exclusions to coverage:

- Beneficiary has FDA labeled contraindications to Mavyret®;
  OR
- Mavyret is being used in combination with atazanavir and rifampin;
  OR
- Beneficiary has moderate-severe hepatic impairment (Child-Pugh B or C;)
  OR
- Beneficiary has any history of prior hepatic decompensation;
  OR
- Beneficiary has been previously treated with regimens containing BOTH a NS5A inhibitor and aNS3/4A protease inhibitor.

G. 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 attests that beneficiary has been evaluated for readiness for treatment and beneficiary agrees to be compliant with therapy, follow-up appointments and labs.

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 inhib
itor (boceprevir, simeprevir or telaprevir).

Exclusions to coverage:

- Beneficiary has FDA labeled contraindications to Vosevi™;

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

References:

1. Prescriber Information-Sovaldi ® (sofosbuvir) Gilead Sciences, Inc. Foster, City California 94404. December 2013. Revised August 2019.

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- Harvoni ® (ledipasvir/sofosbuvir) Gilead Sciences, Inc. Foster City, California 94404. October 2014. Revised August 2019.

4. 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. http://www.hcvguidelines.org/fullreport

5. Prescriber Information – Viekira Pak™ (ombitasvir, paritaprevir and ritonavir tablets; dasabuvir tablets) AbbVie, Inc. North Chicago, Illinois 60064. July 2018.
6. Prescriber Information- Daklinza™ (declatasvir) Bristol-Myers Squibb Company, Princeton, NJ 08543, USA. November 2017
7. FDA Safety Announcement. Available at: http://www.fda.gov/Drugs/DrugSafety/ucm468634.htm. Accessed October 23, 2015.
8. Viekira Pak™ Label. Available at: http://www.rxabbvie.com/pdf/viekirapak_pi.pdf. Accesses September 9, 2019.
9. Prescriber Information- Zepatier® (elbasvir and grazoprevir) Merck and Co., Inc. Whitehouse Station, NJ 08889. USA. June 2018.
10. Prescriber Information- Epclusa® (velpatasvir/sofosbuvir) Gilead Sciences, Inc. Foster City, CA 94404. USA. November 2017. Updated March 2020. Updated June 2021.
11. Prescriber Information- Mavyret™ (glecaprevir and pibrentasvir)AbbVie, Inc. North Chicago, Illinois 60064. June 2019. Updated June 2021.
12. Prescriber Information- Vosevi™ (Sofosbuvir/Velpatasvir/Voxilaprevir) Gilead Sciences, Inc. Foster City, California 94404. November 2017.

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Outpatient Pharmacy | **Effective Date: August 15, 2014**
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Hepatitis C Virus Medications

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™
04/21/2020	-Remove Olysio, -Add generic for Epclusa -Remove Viekira XR, -Add generic for Harvoni -Remove under Sovaldi criteria statement #11 that states beneficiary must have a clinical reason why they cannot use Harvoni before using Olysio with Sovaldi -Remove 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 beneficiaries 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 -Remove contraindicated/interaction charts throughout the criteria -change 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 -remove Technivie- termed -Epclusa clarified without cirrhosis or with compensated cirrhosis or with decompensated cirrhosis for use in combination with ribavirin. -Vosevi clarified genotypes

04/21/2020	Remove GCN's Sovaldi- add coverage criteria genotype 1 or 3 with decompensated cirrhosis or post-liver transplant in combination with daclatasvir and ribavirin lower minimum age from 12 years old to 3 years old Harvoni- lower age to 3 years of age add exclusion to coverage for severe renal impairment (CrCl less than 30mL/min, end stage renal disease, or on dialysis Viekira- remove dialysis as exclusion for coverage Daklinza- add decompensated cirrhosis or post-transplant beneficiaries Daklinza™ must be prescribed concomitantly with ribavirin remove exclusion to coverage for beneficiaries on dialysis remove exclusion to coverage for beneficiaries with decompensated liver disease (Child Pugh B or C) Zepatier- add coverage for beneficiaries with Genotyple 1a baseline NS5A polymorphisms, Genotype 1a or 1b who are treatment experienced with Peginterferon alfa + ribavirin + HCV NS3/4A protease inhibitor or Genotype 4 who are treatment experienced with Peginterferon alfa + ribavirin Mavyret- add exclusions to coverage for beneficiaries with FDA labeled contraindications to Mavyret®; or if Mavyret is being used in combination with atazanavir and rifampin; or if beneficiary has severe hepatic impairment (Child-Pugh C); or if beneficiary has been previously treated with regimens containing BOTH a NS5A inhibitor and a NS3/4A protease inhibitor added dosing for liver and kidney transplant recipients All Hep C- Remove requirement for provider submitting a completed Beneficiary Readiness Form, however, provider does attest that beneficiary has been evaluated for readiness for treatment and beneficiary agrees to be compliant with therapy, follow-up appointments and labs. Remove exclusion to coverage for severe renal impairment (CrCl less than 30mL/min, end stage renal disease, or on dialysis Add those with history of prior decompensation as exclusion for coverage of Zepatier

11/17/2020	-Updated age for Epclusa to 6 & older or weighing at least 17 kg -Removed Daklinza -Ribavirin not required in combination with Viekira for genotype 1b -Removed drug interactions with amiodarone as exclusions -Add Harvoni pellet packs -Add Sovaldi pellet packs -Removed requirement for beneficiaries with history in the last year of alcohol abuse to be in a treatment program -Updated chart for Epclusa for transplant recipients
xx/xx/xxxx	Removed "Beneficiaries must agree to toxicology and/or alcohol screens as needed" Changed from "No sign(s) of high- risk behavior (recurring alcoholism, IV drug use, etc.,) or failure" to "Beneficiary has completed HCV disease evaluation appointments and procedures as requested by provider"
xx/xx/xxxx	Removed requirement for genotype testing for Mavyret, Epclusa (and generic) for treatment naïve patients Removed criteria for reauthorization labs at4 weeks for all agents
xx/xx/xxxx	Clarified duration of therapy for Mavyret for treatment experienced genotype 1 & 3 patients includes patients with liver and kidney transplant Minimum age for Epclusa changed from 6 to 3 years of age; minimum weight requirement removed; Added Epclusa pellet packs Minimum age for Mavyret changed from 12 to 3 years of age; minimum weight requirement removed; Added Mavyret pellet packs