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

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Therapeutic Class Code: W5Y, W5V, 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

Medication	Generic Code Number(s)	NDC Number(s)
Sovaldi® 400mg tablet (sofosbuvir)	35708	
Olysio® 150mg tablet (simeprevir)	35648	
Harvoni® 90-400mg tablet (ledipasvir and sofosbuvir)	37179	
Viekira Pak®	37614	
Daklinza®	37073, 37074	
Technivie®	37844	
Zepatier®	40615	

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

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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 *Basic Medicaid and NC Health Choice Billing Guide*, sections 2 and 6, and on the EPSDT provider page. The Web addresses are specified below.

***Basic Medicaid and NC Health Choice Billing Guide*:**
http://www.ncdhhs.gov/dma/basicmed/

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

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 is 18 years old or older with a diagnosis of chronic hepatitis C (CHC) infection with confirmed genotype 1,2,3, or 4 **OR**
2. Beneficiary has CHC infection with hepatocellular carcinoma awaiting liver

transplant.

AND

3. Provider has submitted medical records documenting the diagnosis of chronic hepatitis C with genotype and subtype if applicable AND submitted medical records documenting any **one** of the following related to staging of liver disease:

    a. Metavir scores
    b. Batts-Ludwig scores
    c. IASL scores
    d. Ishak scores
    e. Fibroscan score
    f. FibroSURE score
    g. APRI scores
    h. Radiological imaging consistent with cirrhosis (i.e. evidence of portal hypertension)
    i. Physical findings or clinical evidence consistent with cirrhosis as attested by the prescribing physician

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. Beneficiary has F2 or higher on the IASL, Batts-Ludwig, or Metavir fibrosis staging scales (medical record documentation required); **OR** has F3 or higher on the Ishak fibrosis staging scale or has equivalent stage on different scoring system(medical recorddocumentation required)

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 **OR**
12. Beneficiary must have a clinical reason why they cannot use ledipasvir-sofosbuvir (Harvoni®) before using sofosbuvir (Sovaldi®) in combination with simeprevir (Olysio®). (only approved in

combination for genotype 1)

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

HCV Mono-infected and HCV/HIV Co-infected genotype	Treatment	Duration
Genotype 1 or 4	**Sovaldi® + peg interferon alfa +**	**12 weeks**
Genotype 2	**Sovaldi® + ribavirin**	**12 weeks**
Genotype 3	**Sovaldi® + ribavirin**	**24 weeks**
Genotype 1-peg interferon ineligible	**Sovaldi® + ribavirin**	**24 weeks**
Genotype 1,2,3 or 4 with diagnosis of hepatocellular carcinoma meeting Milan Criteria (awaiting liver transplantation)	**Solvaldi® + ribavirin**	**Up to 48 weeks or until liver transplantation whichever comes first**

For initial authorization of Sovaldi® (sofosbuvir), approval will be limited to a 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):

- 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:

- Sofosbuvir (Sovaldi®) is being used in combination with (boceprevir) Victrelis® **OR**
- 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**
- Sovaldi®® (sofosbuvir) 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 Olysio® (simeprevir):

Covered for the following conditions:

1. Beneficiary is 18 or older
   AND
2. Beneficiary has confirmed diagnosis of HCV genotype 1 without NS3 Q80K polymorphism
   AND
3. Provider has submitted medical records documenting the diagnosis of chronic hepatitis C with genotype and subtype if applicable AND submitted medical records documenting any **one** of the following related to staging of liver disease:
   a. Metavir scores
   b. Batts-Ludwig scores
   c. IASL scores
   d. Ishak scores
   e. Fibroscan score
   f. FibroSURE score
   g. APRI scores
   h. Radiological imaging consistent with cirrhosis (i.e. evidence of portal hypertension)
   i. Physical findings or clinical evidence consistent with cirrhosis as attested by the prescribing physician

   AND
4. Beneficiary has F2 or higher on the IASL, Batts-Ludwig, or Metavir fibrosis staging scales (medical record documentation required); **OR** has F3 or higher on the Ishak fibrosis staging scale or has equivalent stage on different scoring system (medical recorddocumentation required).
   AND
5. Beneficiary has no previous HCV NS3/4A protease inhibitor treatment for Hepatitis C
   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. Beneficiary must have a clinical reason why they cannot use ledipasvir-sofosbuvir (Harvoni®) before using sofosbuvir (Sovaldi®) in combination with simeprevir (Olysio.)
   AND
8. 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

9. Provider must be reasonably certain that treatment will improve the beneficiary's overall health status. **AND**
10. Provider has completed a Beneficiary Readiness Evaluation with the beneficiary meeting **ALL** of the Beneficiary Readiness Criteria.

For initial authorization of Olysio® (simeprevir) approval will be limited to a 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 Olysio®, (simeprevir):

- 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).
  - Maximum total approval period is 12 weeks for beneficiaries without cirrhosis and 24 weeks for beneficiaries with cirrhosis.

Exclusions to coverage:

- Olysio® (simeprevir) is being used as monotherapy. **OR**
- Beneficiary has HCV genotype 1a with an NS3 Q80K polymorphism. **OR**
- Olysio® (simeprevir) is being used in patients with severe hepatic impairment (Child-Pugh Class C). **OR**
- Beneficiary has previously failed therapy with a treatment regimen that included Olysio® (simeprevir) or other HCV protease inhibitors. **OR**
- Beneficiary is pregnant. **OR**
- Beneficiary is a non-responder to simeprevir **OR**
- Beneficiary has hepatocellular carcinoma **OR**
- Beneficiary has severe renal impairment (CrCl less than 30 mL/min), end stage renal disease, or requires dialysis **OR**
- Beneficiary has FDA labeled contraindications to simeprevir

C. Criteria for Coverage of Harvoni® (ledipasvir/sofosbuvir):

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 submitted medical records documenting any **one** of the following related to staging of liver disease:
    a. Metavir scores
    b. Batts-Ludwig scores
    c. IASL scores
    d. Ishak scores
    e. Fibroscan score
    f. FibroSURE score
    g. APRI scores
    h. Radiological imaging consistent with cirrhosis (i.e. evidence of portal hypertension)
    i. Physical findings or clinical evidence consistent with cirrhosis as attested by the prescribing physician

AND

3. Beneficiary has F2 or higher on the IASL, Batts-Ludwig, or Metavir fibrosis staging scales (medical record documentation required); **OR** has F3 or higher on the Ishak fibrosis staging scale or has equivalent stage on different scoring system(medical recorddocumentation required)

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

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

HCV Mono-infected and HCV/HIV Co-infected genotype (Treatment and Cirrhosis Status)	Total Approval Duration
Genotype 1 Treatment-naïve without cirrhosis who have pre-treatment HCV RNA less than 6 million IU/mL	8 weeks
Genotype 1 Treatment-naïve with or without cirrhosis	12 weeks
Genotype 1 Treatment-experienced without cirrhosis who have failed treatment with either peginterferon alfa+ ribavirin or an HCV protease inhibitor + peginterferon alfa+ riba	12 weeks
Genotype 1 Treatment-experienced with cirrhosis who have failed treatment with either peginterferon alfa+ ribavirin or an HCV protease inhibitor + peginterferon alfa+ riba	24 weeks
Genotype 4 with or without cirrhosis	12 weeks
Liver Transplant (must have Fibrosis Stage 3 or Stage 4)	24 weeks

For initial authorization of Harvoni® (ledipasvir/sofosbuvir), approval will be limited to a 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):

- 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**
- Harvoni® is being used in combination with amiodarone **;OR**

- Harvoni is being used in combination with other drugs containing sofosbuvir

D. 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 1 or genotype 4.
   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 submitted medical records documenting any **one** of the following related to staging of liver disease:
   a. Metavir scores
   b. Batts-Ludwig scores
   c. IASL scores
   d. Ishak scores
   e. Fibroscan score
   f. FibroSURE score
   g. APRI scores
   h. Radiological imaging consistent with cirrhosis (i.e. evidence of portal hypertension)
   i. Physical findings or clinical evidence consistent with cirrhosis as attested by the prescribing physician

   AND
4. Beneficiary has F2 or higher on the IASL, Batts-Ludwig, or Metavir fibrosis staging scales (medical record documentation required); **OR** has F3 or higher on the Ishak fibrosis staging scale or has equivalent stage on different scoring system(medical recorddocumentation required)
   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. Provider must be reasonably certain that treatment will improve the beneficiary's overall health status.
   AND
8. Provider has completed a Beneficiary Readiness Evaluation with the beneficiary meeting **ALL** of the Beneficiary Readiness Criteria

AND

9. Prior to initiation of VIEKIRA PAK®, the provider has assessed for laboratory and clinical evidence of hepatic decompensation

AND

10. For patients with cirrhosis:

    • Provider is monitoring for clinical signs and symptoms of hepatic decompensation (such as ascites, hepatic encephalopathy, variceal hemorrhage).

    • 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 cirrhosis and treatment naïve	VIEKIRA PAK + ribavirin	12 weeks
Genotype 1a, with cirrhosis and treatment experienced	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 patients mixed genotype 1 infection.		

Use in Liver Transplant Recipients

- Must have Fibrosis Stage of 2 or lower
- Treatment: VIEKIRA PAK with ribavirin is 24 weeks, irrespective of HCV genotype 1 subtype

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®

E. 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 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 submitted medical records documenting any **one** of the following related to staging of liver disease:
   a. Metavir scores
   b. Batts-Ludwig scores
   c. IASL scores
   d. Ishak scores
   e. Fibroscan score
   f. FibroSURE score
   g. APRI scores
   h. Radiological imaging consistent with cirrhosis (i.e. evidence of portal hypertension)

i. Physical findings or clinical evidence consistent with cirrhosis as attested by the prescribing physician

AND

4. Beneficiary has F2 or higher on the IASL, Batts-Ludwig, or Metavir fibrosis staging scales (medical record documentation required); **OR** has F3 or higher on the Ishak fibrosis staging scale or has equivalent stage on different scoring system(medical recorddocumentation required)

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. Provider must be reasonably certain that treatment will improve the beneficiary's overall health status.

AND

8. 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 3	DAKLINZA® 60 mg once daily in combination with sofosbuvir. 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 Rxhistory 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 Daklenza®; **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); **OR**
- Daklinza® is being used in combination with a NS3/4A protease inhibitor (such as Olysio® (simeprevir); **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

F. Criteria for Coverage of Technivie® (ombitasvir, paritaprevir, ritonavir):

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 4**.
   AND
2. Provider has submitted medical records documenting the diagnosis of chronic hepatitis C with genotype and subtype if applicable AND submitted medical records documenting any **one** of the following related to staging of liver disease:
   a. Metavir scores
   b. Batts-Ludwig scores
   c. IASL scores

d. Ishak scores
e. Fibroscan score
f. FibroSURE score
g. APRI scores
h. Radiological imaging consistent with cirrhosis (i.e. evidence of portal hypertension)
i. Physical findings or clinical evidence consistent with cirrhosis as attested by the prescribing physician

AND

3. Beneficiary has F2 or higher on the IASL, Batts-Ludwig, or Metavir fibrosis staging scales (medical record documentation required); **OR** has F3 or higher on the Ishak fibrosis staging scale or has equivalent stage on different scoring system(medical recorddocumentation required)

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
8. Prior to initiation of Technivie®, the provider has assessed for laboratory and clinical evidence of hepatic decompensation

AND

9. For patients with cirrhosis:

• Provider is monitoring for clinical signs and symptoms of hepatic decompensation (such as ascites, hepatic encephalopathy, variceal hemorrhage).

• 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 Technivie® for all beneficiaries meeting criteria will be as follows:

Patient Population	Treatment*	Duration
Genotype 4 without cirrhosis	TECHNIVIE® + ribavirin*	12 weeks
. *TECHNIVIE administered without ribavirin for 12 weeks may be considered for treatment-naïve patients who cannot take or tolerate ribavirin		

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For initial authorization of Technivie®, 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 Technivie®

- 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 Rxhistory and dispensing for compliance).

Exclusions to coverage:

- Beneficiary requires dialysis; **OR**
- Technivie® is being used with drugs that are highly dependent on CYP3A for clearance and for which elevated plasma concentrations are associated with serious and/or life-threatening events: **OR**
- Technivie® is being used with drugs that are moderate or strong inducers of CYP3A and may lead to reduced efficacy of TECHNIVIE®: **OR**
- Technivie® is being used in patients with known hypersensitivity to ritonavir (e.g. toxic epidermal necrolysis(TEN) or Stevens-Johnson syndrome); **OR**
- Beneficiary has decompensated liver disease as defined by Child-Pugh classification score of Child Class B or C (Technivie® is contraindicated in patients with moderate to severe hepatic impairment (Child-Pugh B and C) ;**OR**
- Beneficiary has FDA labeled contraindications to Technivie®; **OR**
- Technivie® is being requested in combination a nucleotide NS5B polymerase inhibitor (such as Harvoni (ledipasvir/sofosbuvir);**OR**
- Technivie® is being used in combination with another NS5A inhibitor (such as Harvoni (ledipasvir/sofosbuvir) or ombitasvir (component of Viekira Pak); **OR**
- Technivie® is being used in combination with a NS3/4A protease inhibitor (such as Olysio® (simeprevir); **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 Technivie® .

G. Criteria for Coverage of Zepatier® (elbasvir and grazoprevir):

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 submitted medical records documenting any **one** of the following related to staging of liver disease:
    a. Metavir scores
    b. Batts-Ludwig scores
    c. IASL scores
    d. Ishak scores
    e. Fibroscan score
    f. FibroSURE score
    g. APRI scores
    h. Radiological imaging consistent with cirrhosis (i.e. evidence of portal hypertension)
    i. Physical findings or clinical evidence consistent with cirrhosis as attested by the prescribing physician

AND

3. Beneficiary has F2 or higher on the IASL, Batts-Ludwig, or Metavir fibrosis staging scales (medical record documentation required); **OR** has F3 or higher on the Ishak fibrosis staging scale or has equivalent stage on different scoring system(medical recorddocumentation required)

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 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

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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

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

Drugs that are Contraindicated with ZEPATIER

Drug Class	Drug(s) within Class that are Contraindicated	Notes
Anticonvulsants	Phenytoin Carbamazepine	May lead to loss of virologic response to ZEPATIER due to significant decreases in elbasvir and grazoprevir plasma concentrations caused by strong CYP3A induction.

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Antimycobacterials	Rifampin	May lead to loss of virologic response to ZEPATIER due to significant decreases in elbasvir and grazoprevir plasma concentrations caused by strong CYP3A induction.
Herbal Products	St. John's Wort (Hypericum perforatum)	May lead to loss of virologic response to ZEPATIER due to significant decreases in elbasvir and grazoprevir plasma concentrations caused by strong CYP3A induction.
HIV Medications	Efavirenz†	May lead to loss of virologic response to ZEPATIER due to significant decreases in elbasvir and grazoprevir plasma concentrations caused by CYP3A induction.
HIV Medications	Atazanavir Darunavir Lopinavir Saquinavir Tipranavir	May increase the risk of ALT elevations due to a significant increase in grazoprevir plasma concentrations caused by OATP1B1/3 inhibition.
Immunosuppressants	Cyclosporine	May increase the risk of ALT elevations due to a significant increase in grazoprevir plasma concentrations caused by OATP1B1/3 inhibition.

*This table is not a comprehensive list of all drugs that inhibit OATP1B1/3 or strongly induce CYP3A.
†Efavirenz is included as a strong CYP3A inducer in this table, since co-administration reduced grazoprevir exposure by ≥80%

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:

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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- **Inducers of CYP3A4,5,7**[1,2,3]
  - **Strong**
    - Avasimibe
    - Carbamazepine
    - Phenytoin
    - Rifampin
    - St. John's wort
  - **Moderate**
    - Bosentan
    - Efavirenz
    - Etravirine
    - Modafinil
    - Nafcillin
  - **Weak**
    - Amprenavir
    - Aprepitant
    - Armodafinil
    - Echinacea
    - Pioglitazone
    - Prednisone
    - Rufinamide
  - **Other Inducers**
    - Clobazam

- **Inhibitors of CYP3A4,5,7**[1,2,3]
  - **Strong**
    - Boceprevir
    - Clarithromycin
    - Conivaptan
    - Indinavir
    - Itraconazole
    - Ketoconazole
    - Lopinavir/ritonavir
    - Nefazodone
    - Nelfinavir
    - Posaconazole
    - Ritonavir
    - Saquinavir
    - Suboxone
    - Telaprevir
    - Telithromycin
    - Voriconazole
  - **Moderate**
    - Amprenavir
    - Aprepitant
    - Atazanavir
    - Ciprofloxacin

▪ Dexamethasone ▪ Enzalutamide ▪ Flutamide ▪ Garlic supplements ▪ Griseofulvin ▪ Nevirapine ▪ Oxcarbazepine ▪ Perampanel ▪ Phenobarbital ▪ Primidone ▪ Rifabutin ▪ Rifapentine ▪ Topiramate ▪ Vemurafenib		▪ Diltiazem ▪ Darunavir/ritonavir ▪ Dronedarone ▪ Erythromycin ▪ Fluconazole ▪ Fosamprenavir ▪ Grapefruit ▪ Imatinib ▪ Verapamil
***These lists are not exhaustive and are subject to change**.		

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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

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