MEDICAL POLICY STATEMENT

Original Effective Date	Next Annual Review Date	Last Review / Revision Date
5/21/2014	3/24/2016	3/24/2015
Policy Name		**Policy Number**
Hepatitis C – Oral		**SRx-0003**

Medical Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) are derived from literature based on and supported by clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Medical Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced in the Medical Policy Statement. If there is a conflict between the Medical Policy Statement and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination.

For Medicare plans please reference the below link to search for Applicable National Coverage Descriptions (NCD) and Local Coverage Descriptions (LCD):

A. SUBJECT

Oral Direct-Acting Antiviral (DAA) Hepatitis C Agents

- **Simeprevir (Olysio)**
- **Sofosbuvir (Sovaldi)**
- **Boceprevir (Victrelis)**
- **Ledipasvir and sofosbuvir (Harvoni)**
- **Ombitasvir/paritaprevir/ritonavir with dasabuvir (Viekira)**

B. BACKGROUND

The CareSource Medication Policies are therapy class policies that are used as a guide when determining health care coverage for our members with benefit plans covering prescription drugs. Medication Policies are written on selected prescription drugs requiring prior authorization or Step-Therapy. The Medication Policy is used as a tool to be interpreted in conjunction with the member's specific benefit plan.

The intent of the oral Hepatitis C Medication (PA) Program is to encourage appropriate selection of therapy for patients according to product labeling and/or clinical guidelines and/or clinical studies, and also to encourage use of preferred agents.

Chronic Hepatitis C

boceprevir (Victrelis) and simeprevir (Olysio) are hepatitis C virus (HCV) protease inhibitors indicated, in combination with peginterferon alfa and ribavirin, for the treatment of genotype 1 chronic hepatitis C (CHC) in adult patients with compensated liver disease, including cirrhosis, who are treatment-naïve or who have been previously treated with interferon-based treatment, including prior null responders, partial responders and relapsers. **Sofosbuvir (Sovaldi)** is a hepatitis C virus (HCV) nucleotide analog NS5B polymerase inhibitor indicated for the treatment

of chronic hepatitis C (CHC) infection as a component of a combination antiviral treatment regimen.

Ledipasvir and sofosbuvir (Harvoni) is a fixed dose combination of ledipasvir, a hepatitis C virus9 (HCV) NS5A inhibitor, and sofosbuvir, an HCV nucleotide analog NS5B polymerase inhibitor, and is indicated for the treatment of chronic hepatitis genotype 1 in adults.
Ombitasvir/paritaprevir/ritonavir with dasabuvir (Viekira) is indicated for genotype 1 chronic hepatitis. Viekira Pak includes ombitasvir, an HCV NSA5A inhibitor, paritaprevir, an HCV NS3/4A protease inhibitor, ritonavir, a CYP3A inhibitor and dasabuvir, an HCV non-nucleoside NS5B palm polymerase inhibitor.

C. **DEFINITIONS**

1. GRF - Glomerular Filtration Rate is a test to estimate how much blood passes through the glomeruli each minute. Glomeruli are tiny filters in the kidneys that filter waste from the blood.
2. RNA – Ribonucleic Acid is a polymeric molecule. It is involved in a varied kind of biological role in coding, decoding, regulation, and expression of genes.
3. APRI – AST Platelet Ratio Index is used as an alternative to a liver biopsy procedure for treatment indication in chronic hepatitis C.
4. SVR4 – Sustained Virologic Response Rate at week 4 for predictive clearance of virus.
5. SVR12 – Sustained Virologic Response Rate at week 12 for predictive clearance of virus.

D. POLICY

CareSource will approved the use of boceprevir (Victrelis), simeprevir (Olysio), & Sofosbuvir (Sovaldi) and consider their use as medically necessary when used in combination with peginterferon alfa and/or ribavirin when the following criteria have been met for Chronic Hepatitis C.

<u>boceprevir (Victrelis), simeprevir (Olysio)</u>
Prior Authorization Criteria:

- Documented diagnosis of Hepatitis C
- Prescribed by a Board Certified hepatologist, gastroenterologist or infectious disease specialist
- Once in a lifetime treatment
- Negative pregnancy test for female of child bearing potential
- Does not have glomerular filtration rate < 30 mL/minute/1.73m2
- Not current enrolled in hospice
- Not currently participating in alcohol abuse or illicit substance abuse:
  - One confirmed negative urine drug screen within the last 60 days. - Laboratory documentation must be provided
  - Previous abusers must meet **ALL** the following:
    - Enrolled for at least 6 months in counseling services or receiving therapy from an addiction specialist prior to starting hepatitis treatment – Documentation must be provided
    - Confirmed current monthly negative urine drug screen for 3 consecutive months. - Laboratory documentation must be provided.
- Provided detectable HCV RNA levels are higher than 50 IU/ml
- Confirmed genotype 1

- Evidence of stage 3 or 4 liver fibrosis confirmed by liver biopsy, FibroSURE or APRI score, only
- Screening HCV genotype 1a infection for presence of virus with the NS3 Q80K polymorphism. (Olysio only)
  AND
- Patient will be treated with Ribavirin and peginterferon alfa concurrently or with Sofosbuvir (Olysio only)

Sofosbuvir (Sovaldi)

Prior Authorization Criteria:

- Documented diagnosis of Hepatitis C
- Prescribed by a Board Certified hepatologist, gastroenterologist or infectious disease specialist
- Does not have glomerular filtration rate < 30 mL/minute/1.73m2
- Not current enrolled in Hospice
- Once in a lifetime treatment
- Negative pregnancy test for female of child bearing potential
- Detectable HCV RNA levels are higher than 50 IU/ml
- Not currently participating in alcohol abuse or illicit substance abuse:
  - One confirmed negative urine drug screen within the last 60 days. - Laboratory documentation must be provided
  - Previous abusers must meet **ALL** the following:
    - Enrolled for at least 6 months in counseling services or receiving therapy from an addiction specialist prior to starting hepatitis treatment – Documentation must be provided
    - Confirmed current monthly negative urine drug screen for 3 consecutive months. - Laboratory documentation must be provided.
- No decompensated liver disease (defined as Child-Pugh Class B or C)
- Confirmed genotype 1,2,3 or 4
- Evidence of stage 3 or 4 liver fibrosis confirmed by liver biopsy, FibroSURE or APRI score, only
  OR
- Hepatocellular carcinoma meeting Milan criteria (awaiting liver transplantation)
  OR
- HCV/HIV-1 co-infection
  OR
- Recurrent HCV infection post liver transplantation

Ledipasvir and sofosbuvir (Harvoni)

- Documented diagnosis of Hepatitis C
- Prescribed by a Board Certified hepatologist, gastroenterologist or infectious disease specialist
- Does not have glomerular filtration rate < 30 mL/minute/1.73m2
- Not current enrolled in Hospice
- Once in a lifetime treatment
- Negative pregnancy test for female of child bearing potential
- Detectable HCV RNA levels are higher than 50 IU/ml
- Not currently participating in alcohol abuse or illicit substance abuse:

- One confirmed negative urine drug screen within the last 60 days. - Laboratory documentation must be provided
- Previous abusers must meet **ALL** the following:
  - Enrolled for at least 6 months in counseling services or receiving therapy from an addiction specialist prior to starting hepatitis treatment – Documentation must be provided
  - Confirmed current monthly negative urine drug screen for 3 consecutive months. - Laboratory documentation must be provided.

- No decompensated liver disease (defined as Child-Pugh Class B or C)
- Confirmed genotype 1
- Evidence of stage 3 or 4 liver fibrosis confirmed by liver biopsy, FibroSURE or APRI score, only
  OR
- Hepatocellular carcinoma meeting Milan criteria (awaiting liver transplantation)
  OR
- HCV/HIV-1 co-infection
  OR
- Recurrent HCV infection post liver transplantation

Ombitasvir/paritaprevir/ritonavir with dasabuvir (Viekira)

- Documented diagnosis of Hepatitis C
- Prescribed by a Board Certified hepatologist, gastroenterologist or infectious disease specialist
- Not current enrolled in Hospice
- Once in a lifetime treatment
- Negative pregnancy test for female of child bearing potential
- Detectable HCV RNA levels are higher than 50 IU/ml
- Not currently participating in alcohol abuse or illicit substance abuse:
  - One confirmed negative urine drug screen within the last 60 days. - Laboratory documentation must be provided
  - Previous abusers must meet **ALL** the following:
    - Enrolled for at least 6 months in counseling services or receiving therapy from an addiction specialist prior to starting hepatitis treatment – Documentation must be provided
    - Confirmed current monthly negative urine drug screen for 3 consecutive months. - Laboratory documentation must be provided.
- No decompensated liver disease (defined as Child-Pugh Class B or C)
- Confirmed genotype 1
- Evidence of stage 3 or 4 liver fibrosis confirmed by liver biopsy, FibroSURE or APRI score, only
  OR
- Hepatocellular carcinoma meeting Milan criteria (awaiting liver transplantation)
  OR
- HCV/HIV-1 co-infection
  OR
- Recurrent HCV infection post liver transplantation

Note: Documented diagnosis must be confirmed by portions of the individual's medical record which will confirm the presence of disease and will need to be supplied with prior authorization request. These medical records may include, but not limited to test reports, chart notes from provider's office or hospital admission notes.

Refer to product package insert for dosing, administration and safety guidelines.
ALL other uses of oral Hepatitis C medications are considered experimental/investigational and therefore, will follow CareSource's off label policy.

For Medicare Plan members, reference the below link to search for Applicable National Coverage Descriptions (NCD) and Local Coverage Descriptions (LCD):

If there is no NCD or LCD present, reference the CareSource Policy for coverage.

CONDITIONS OF COVERAGE

HCPCS N/A
CPT

PLACE OF SERVICE
Office, Home
This medication can be self-administered and can be billed through the pharmacy benefit.

AUTHORIZATION PERIOD
Initial authorization:
Coverage of Victrelis will be 28 to 48 weeks with, peginterferon, and/or ribavirin (triple therapy) is provided for 28 weeks at which time a viral load (SVR8 and 24) must be reported.

Renewal authorization:
Coverage after treatment week 28 is based on the following criteria: Viral load at treatment week 24 is reported. If the viral load is greater than 25 IU/ml, then no further coverage will be approved. Those who have been treated in the past and who have undetectable viral levels at weeks 8 and 24 will continue VICTRELIS, peginterferon alfa, and ribavirin for a total of 36 weeks of treatment. People without cirrhosis of the liver who have detectable viral levels at week 8 but undetectable levels at week 24 will receive VICTRELIS, peginterferon alfa, and ribavirin for a total of 36 weeks, and then peginterferon alfa and ribavirin for an additional 12 weeks, for a total 48 weeks of treatment.

Some people may receive 4 weeks of peginterferon alfa and ribavirin followed by 44 weeks of VICTRELIS, peginterferon alfa, and ribavirin. These people include those who:

- Were previously treated with peginterferon alfa and ribavirin, but did not have an adequate viral decrease after 12 weeks
- Respond poorly to the initial four-week treatment with peginterferon alfa and ribavirin
- Have liver cirrhosis at the start of treatment.

Initial authorization:
Coverage of **Olysio** will be 12 to 24 weeks.

Renewal authorization:
Coverage after treatment week 6 is based on the following criteria: Viral load at treatment week 4 is reported. If the viral load is greater than 25 IU/ml, then no further coverage will be approved

If the viral load is less than or equal to 25 IU/ml then coverage for an additional 6 weeks of triple therapy without cirrhosis, or 18 weeks with cirrhosis.

Initial authorization:
Coverage of **Sovaldi, Harvoni or Viekira** will be 12 to 24 weeks.

- Initial authorization approved then SVR 4 level is required by 6th week of treatment for renewal.

Renewal authorization:

- Treatment duration greater than 12 weeks will require reauthorization between 12 and 14 weeks with an SVR 12 level submission
- Renewal authorization approved if **ALL** of the following are met:
  - Compliant with drug therapy regimen by paid pharmacy claims
  - HCV RNA levels < 25 iu/ml at 4 weeks and 12 weeks respectively

ALL authorizations are subject to continued eligibility.

E. REVIEW/REVISION HISTORY

Date Issued:	05/21/2014
Date Reviewed:	05/21/2014, 01/13/2015, 03/24/2015
Date Revised:	01/13/2015-Revisions of off market medications, criteria change. 03/24/2015 – Add Harvoni and Viekira

F. REFERENCES

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9. *Gastroenterology*. June 2011:13-27.
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12. Harvoni [package Insert] Foster City, CA, Gilead Sciences, Inc.: Revised March 2015.
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14. Olysio [package Insert]. Titusville, NJ, Janssen Therapeutics, Division of Janssen Products, LP: Revised April 2015.

The medical Policy Statement detailed above has received due consideration as defined in the Medical Policy Statement Policy and is approved.

Independent medical review – 5/7/2014