MEDICAL POLICY STATEMENT		
Original Effective Date	**Next Annual Review Date**	**Last Review / Revision Date**
5/21/2014	**3/24/2016**	**12/15/2015**
Policy Name		**Policy Number**
Hepatitis C – Oral		**SRx-0003**
Policy Type		
☒ **Medical**	☐ **Administrative**	☐ **Payment**

Medicaid Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) apply to Medicaid health benefit plans administered by CSMG and its affiliates and are derived from literature based on and supported by applicable federal or state coverage mandates, 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 federal or state coverage mandate, Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Medicaid 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 benefit document (i.e., Evidence of Coverage) for the service(s) referenced in the Medical Policy Statement. If there is a conflict between the Medicaid Policy Statement and the plan benefit document, then the plan benefit document will be the controlling document used to make the determination. In the absence of any applicable controlling federal or state coverage mandate, benefits are ultimately determined by the applicable plan benefit document.

A. SUBJECT

Oral Direct-Acting Antiviral (DAA) Hepatitis C Agents

- Simeprevir **(Olysio)**
- Sofosbuvir **(Sovaldi)**
- Ledipasvir and sofosbuvir **(Harvoni)**
- Ombitasvir/paritaprevir/ritonavir with dasabuvir **(Viekira)**
- Ombitasvir/paritaprevir/ritonavir **(Technivie)**
- Daclatasvir **(Daklinza)**

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 members 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.

I. **Chronic Hepatitis C**

A. **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

B. **Sofosbuvir (Sovaldi)** is a hepatitis C virus (HCV) nucleotide analog NS5B polymerase inhibitor indicated for the treatment of genotype 1, 2, 3, or 4 chronic hepatitis C (CHC) infection as a component of a combination antiviral treatment regimen
C. **Ledipasvir and sofosbuvir (Harvoni)** is a fixed dose combination of ledipasvir, a hepatitis C virus (HCV), NS5A inhibitor, and sofosbuvir, an HCV nucleotide analog NS5B polymerase inhibitor, and is indicated for the treatment of chronic hepatitis genotype 1, 4, 5 & 6 in adults
D. **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
E. **Ombitasvir/paritaprevir/ritonavir (Technivie)** is a fixed dose combination of obitasvir, an HCV NSA5A inhibitor, paritaprevir, an HCV NS3/4A protease inhibitor, and ritonavir, a CYP3A inhibitor. It is indicated for use in combination with ribavirin for the treatment of patients with genotype 4 chronic hepatitis C virus infection without cirrhosis
F. **Daclatasvir (Daklinza**) is a hepatitis C virus NS5A inhibitor indicated for use with sofosbuvir for the treatment of chronic HCV genotype 1 (without cirrhosis) and 3 infections

C. DEFINITIONS

- **GFR** - 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.
- **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.
- **APRI** – AST Platelet Ratio Index is used as an alternative to a liver biopsy procedure for treatment indication in chronic hepatitis C.
- **SVR4** – Sustained Virologic Response Rate at week 4 for predictive clearance of virus.
- **SVR12** – Sustained Virologic Response Rate at week 12 for predictive clearance of virus.
- **Elastography (Fibroscan and US Elastography)** - The Fibroscan device (Echosens) works by measuring shear wave velocity using a 50-MHz wave passed into the liver from a small transducer on the end of an ultrasound probe. The probe also has a transducer on the end that can measure the velocity of the shear wave (in meters per second) as the wave passes through the liver. The shear wave velocity is then converted into liver stiffness, which is expressed in kilopascals. This technology measures the velocity of the sound wave passing through the liver and then converts that measurement into a liver stiffness measurement; the entire process is often referred to as liver US (ultrasonographic) elastography.
- **Highest Priority for Treatment Owing to highest Risk for Severe Complications:**
  - advance fibrosis (Metavir F3) or compensated cirrhosis (Metavir F4)
  - organ transplant
  - Type 2 or 3 essential mixed cryoglobulinemia with end organ manifestations
  - Proteinuria, nephrotic syndrome or membraneoproliferative glomerulonephritis

D. POLICY

CareSource will approve the use of simeprevir (Olysio), sofosbuvir (Sovaldi), ledipasvir and sofosbuvir (Harvoni), ombitasvir/paritaprevir/ritonavir with dasabuvir (Viekira), ombitasvir/paritaprevir/ritonavir (Technivie), & daclatasvir (Daklinza) 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:

I. **simeprevir (Olysio)**

Prior Authorization Criteria:

A. Documented diagnosis of Hepatitis C
B. Prescribed by a Board Certified hepatologist, gastroenterologist or infectious disease specialist
C. Adults age 18 and older
D. Once in a lifetime treatment
E. Does not have glomerular filtration rate < 30 mL/minute/1.73m2
F. Not currently enrolled in hospice
G. Negative pregnancy test for female of child bearing potential
H. Not currently participating in alcohol abuse or illicit substance abuse:
    1. One confirmed negative urine drug and alcohol screen within the last 60 days. Laboratory documentation must be provided
    2. Previous abusers must meet **ALL** the following:
        2.1 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
        2.2 Confirmed current monthly negative urine drug and alcohol screen for 3 consecutive months
I. Provided detectable HCV RNA levels are higher than 12 IU/ml
J. Confirmed genotype 1 or 4
K. Evidence of stage 3 or 4 liver fibrosis confirmed by liver biopsy, FibroSURE, FibroTest-ActiTest panel or Fibroscan, only
L. Screening HCV genotype 1a infection for no presence of virus with the NS3 Q80K polymorphism
    AND
M. Patient will be treated with Ribavirin and peginterferon alfa concurrently

II. **Sofosbuvir (Sovaldi)**

Prior Authorization Criteria:

A. Documented diagnosis of Hepatitis C
B. Prescribed by a Board Certified hepatologist, gastroenterologist or infectious disease specialist
C. Does not have glomerular filtration rate < 30 mL/minute/1.73m2
D. Not currently enrolled in Hospice
E. Adults aged 18 and older
F. Once in a lifetime treatment
G. Negative pregnancy test for female of child bearing potential
H. Detectable HCV RNA levels are higher than 12 IU/ml
I. Not currently participating in alcohol abuse or illicit substance abuse:
    1. One confirmed negative urine drug and alcohol screen within the last 60 days - Laboratory documentation must be provided
    2. Previous abusers must meet **ALL** the following:
        2.1 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
        2.2 Confirmed current monthly negative urine drug and alcohol screen for 3 consecutive months. - Laboratory documentation must be provided
J. Confirmed genotype 1,2,3 or 4
K. Evidence of stage 3 or 4 liver fibrosis confirmed by liver biopsy, FibroSURE, FibroTest-ActiTest panel or Fibroscan only

OR any below

L. Hepatocellular carcinoma meeting Milan criteria (awaiting liver transplantation)
M. HCV/HIV-1 co-infection
N. Recurrent HCV infection post liver transplantation

III. **Ledipasvir and sofosbuvir (Harvoni)**

A. Documented diagnosis of Hepatitis C
B. Prescribed by a Board Certified hepatologist, gastroenterologist or infectious disease specialist
C. Does not have glomerular filtration rate < 30 mL/minute/1.73m2
D. Not currently enrolled in Hospice
E. Adults aged 18 years or older
F. Once in a lifetime treatment
G. Negative pregnancy test for female of child bearing potential
H. Detectable HCV RNA levels are higher than 12 IU/ml
I. Not currently participating in alcohol abuse or illicit substance abuse:
    1. One confirmed negative urine drug and alcohol screen within the last 60 days. Laboratory documentation must be provided
    2. Previous abusers must meet **ALL** the following:
        2.1 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
        2.2 Confirmed current monthly negative urine drug and alcohol screen for 3 consecutive months. - Laboratory documentation must be provided
J. Confirmed genotypes 1, 4, 5 & 6
K. Evidence of stage 3 or 4 liver fibrosis confirmed by liver biopsy, FibroSURE, FibroTest-ActiTest panel or Fibroscan only

OR any below

L. Hepatocellular carcinoma meeting Milan criteria (awaiting liver transplantation)
M. HCV/HIV-1 co-infection
N. Recurrent HCV infection post liver transplantation

IV. **Ombitasvir/paritaprevir/ritonavir with dasabuvir (Viekira)**

A. Documented diagnosis of Hepatitis C
B. Prescribed by a Board Certified hepatologist, gastroenterologist or infectious disease specialist
C. Not currently enrolled in Hospice
D. Once in a lifetime treatment
E. Adults aged 18 years or older
F. Negative pregnancy test for female of child bearing potential
G. Detectable HCV RNA levels are higher than 12 IU/ml
H. Not currently participating in alcohol abuse or illicit substance abuse:
    1. One confirmed negative urine drug and alcohol screen within the last 60 days. Laboratory documentation must be provided
    2. Previous abusers must meet **ALL** the following:
        2.1 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
        2.2 Confirmed current monthly negative urine drug and alcohol screen for 3 consecutive months. - Laboratory documentation must be provided
I. No decompensated liver disease (defined as Child-Pugh Class B or C)
J. Confirmed genotype 1

K. Evidence of stage 3 or 4 liver fibrosis confirmed by liver biopsy, FibroSURE, FibroTest-ActiTest panel or Fibroscan only
OR any below
L. Hepatocellular carcinoma meeting Milan criteria (awaiting liver transplantation)
M. HCV/HIV-1 co-infection
N. Recurrent HCV infection post liver transplantation
O. ESRD (End Stage Renal Disease)

V. **Ombitasvir/paritaprevir/ritonavir (Technivie)**
A. Documented diagnosis of Hepatitis C
B. Prescribed by a Board Certified hepatologist, gastroenterologist or infectious disease specialist
C. Not currently enrolled in Hospice
D. Adults aged 18 years or older
E. Once in a lifetime treatment
F. Negative pregnancy test for female of child bearing potential
G. Detectable HCV RNA levels are higher than 12 IU/ml
H. Not currently participating in alcohol abuse or illicit substance abuse:
1. One confirmed negative urine drug and alcohol screen within the last 60 days. Laboratory documentation must be provided
2. Previous abusers must meet **ALL** the following:
2.1 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
2.2 Confirmed current monthly negative urine drug and alcohol screen for 3 consecutive months. - Laboratory documentation must be provided
I. No decompensated liver disease (defined as Child-Pugh Class B or C)
J. Confirmed genotype 4
K. No evidence of cirrhosis (all stages of fibrosis)
L. Hepatocellular carcinoma without cirrhosis (stage 0)

VI. **Declatasvir (Daklinza)**
A. Documented diagnosis of Hepatitis C
B. Prescribed by a Board Certified hepatologist, gastroenterologist or infectious disease specialist
C. Not currently enrolled in Hospice
D. Adults aged 18 or older
E. Once in a lifetime treatment
F. Negative pregnancy test for female of child bearing potential
G. Detectable HCV RNA levels are higher than 12 IU/ml
H. Not currently participating in alcohol abuse or illicit substance abuse:
I. One confirmed negative urine drug and alcohol screen within the last 60 days. Laboratory documentation must be provided
M. Not currently participating in alcohol abuse or illicit substance abuse:
1. One confirmed negative urine drug and alcohol screen within the last 60 days. Laboratory documentation must be provided
2. Previous abusers must meet **ALL** the following:
2.1 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

2.2 Confirmed current monthly negative urine drug and alcohol screen for 3 consecutive months. - Laboratory documentation must be provided

J. No decompensated liver disease (defined as Child-Pugh Class B or C)
K. Confirmed genotype 1 (without cirrhosis) and 3 (without cirrhosis)
L. No evidence of cirrhosis
M. Hepatocellular carcinoma without cirrhosis (stage 0)
OR any below
N. HCV/HIV-1 co-infection
O. 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 Applicable National Coverage Determinations (NCD) and Local Coverage Determinations (LCD). Compliance with NCDs and LCDs is required where applicable.

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 **Olysio** will be 12 to 24 weeks.

Renewal authorization:
Recommended coverage after treatment week 6 is based on the following criteria: Viral load at treatment week 4 is recommended. 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.

Renewal authorization:
- Extension of initial request of 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 12 weeks

Initial authorization:
Coverage of **Daklinza and Technivie** will be 12 weeks.

Renewal authorization:

- Extension of initial request of 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 12 weeks

ALL authorizations are subject to continued eligibility.

E. RELATED POLICIES/RULES

F. REVIEW/REVISION HISTORY

Date Issued:	05/21/2014
Date Reviewed:	05/21/2014, 01/13/2015, 03/24/2015, 06/02/2015, 11/11/2015
Date Revised:	01/13/2015 - Revisions of off market medications, criteria change 03/24/2015 – Add Harvoni and Viekira 06/02/2015 – Add Elastography testing information 11/11/2015 – Add Technivie and Daklinza 12/15/2015 – Revision to RNA level and removal of hepatic decompensation for Olysio

G. REFERENCES

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This guideline contains custom content that has been modified from the standard care guidelines and has not been reviewed or approved by MCG Health, LLC.

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