UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2018 P 2070-9
Program	Prior Authorization/Medical Necessity
Medication	Daklinza® (daclatasvir)
P&T Approval Date	8/2015, 11/2015, 3/2016, 8/2016, 12/2016, 9/2017, 11/2018
Effective Date	2/1/2019; Oxford only: 2/1/2019

1. Background:

Daklinza® (daclatasvir) is a hepatitis C virus (HCV) NS5A inhibitor indicated for use with Sovaldi® (sofosbuvir), with or without ribavirin, for the treatment of chronic HCV genotype 1 or 3 infection.

Limitations of Use: Sustained virologic response (SVR) rates are reduced in HCV genotype 3-infected patients with cirrhosis receiving Daklinza in combination withSovaldi for 12 weeks.[1]

2. Coverage Criteria[a]:

A. For the treatment of chronic hepatitis C genotype 1 infection, **Daklinza in combination with Sovaldi** will be approved based on **all** of the following criteria:

1. Diagnosis of chronic hepatitis C genotype 1 infection

-AND-

2. For quality purposes only, please provide stage of liver disease (e.g., APRI score, FibroSure score, Fibroscan score, or other methods) – this information will not be considered as part of the coverage decision

-AND-

3. **One** of the following:

a. **Both** of the following:

(1) **Both** of the following:

(a) Patient has compensated liver disease
(b) Patient is not a liver transplant recipient

-AND-

(2) Used in combination with Sovaldi (sofosbuvir)

-OR-

b. **Both** of the following:

(1) **One** of the following:

(a) Patient has decompensated liver disease
(b) Patient is a liver transplant recipient

-AND-

(2) Used in combination with Sovaldi (sofosbuvir) plus ribavirin

-AND-

4. **One** of the following:

   a. Prescribed by **one** of the following:

      (1) Hepatologist

      (2) Gastroenterologist

      (3) Infectious Disease Specialist

      (4) HIV Specialist Certified through the American Academy of HIV Medicine

      (5) Transplant physician

-OR-

   b. For UnitedHealthcare New York or Oxford New York Fully Insured only: Prescribed by a provider with clinical experience* in the management and treatment of hepatitis C virus (HCV) infection and listed on the New York Hepatitis C Medicaid Practitioner List found at https://www.health.ny.gov/health_care/medicaid/program/dur/hepa_c_virus.htm

-AND-

5. Physician/provider asserts patient demonstrates treatment readiness, including the ability to adhere to the treatment regimen

-AND-

6. Patient has not failed a prior HCV NS5A-containing regimen (e.g. Daklinza)

-AND-

7. **One** of the following:

   a. **All** of the following:

(1) History of intolerance or contraindication to Epclusa (sofosbuvir/velpatasvir) therapy

-AND-

(2) History of intolerance or contraindication to Harvoni (sofosbuvir/ledipasvir) therapy

-AND-

(3) History of intolerance or contraindication to Mavyret (glecaprevir/pibrentasvir) therapy

-OR-

b. Patient is currently on Daklinza plus Sovaldi therapy

Authorization will be issued for 12 weeks.

B. For the treatment of chronic hepatitis C genotype 3 infection, **Daklinza in combination with Sovaldi** will be approved based on **all** of the following criteria:

1. Diagnosis of chronic hepatitis C genotype 3 infection

-AND-

2. For quality purposes only, please provide stage of liver disease (e.g., APRI score, FibroSure score, Fibroscan score, or other methods) – this information will not be considered as part of the coverage decision

-AND-

3. **One** of the following:

a. **Both** of the following:

(1) **Both** of the following:

(a) Patient does not have cirrhosis
(b) Patient is not a liver transplant recipient

-AND-

(2) Used in combination with Sovaldi (sofosbuvir)

-OR-

b. **Both** of the following:

(1) **One** of the following:

(a) Patient has compensated cirrhosis
(b) Patient has decompensated liver disease
(c) Patient is a liver transplant recipient

-AND-

(2) Used in combination with Sovaldi (sofosbuvir) plus ribavirin

-AND-

4. **One** of the following:

a. Prescribed by **one** of the following:

(1) Hepatologist

(2) Gastroenterologist

(3) Infectious Disease Specialist

(4) HIV Specialist Certified through the American Academy of HIV Medicine

(5) Transplant physician

-OR-

b. For UnitedHealthcare New York or Oxford New York Fully Insured only: Prescribed by a provider with clinical experience* in the management and treatment of hepatitis C virus (HCV) infection and listed on the New York Hepatitis C Medicaid Practitioner List found at https://www.health.ny.gov/health_care/medicaid/program/dur/hepa_c_virus.htm

-AND-

5. Physician/provider asserts patient demonstrates treatment readiness, including the ability to adhere to the treatment regimen

-AND-

6. Patient has not failed a prior HCV NS5A-containing regimen (e.g. Daklinza)

-AND-

7. **One** of the following:

   a. **Both** of the following:

      (1) History of intolerance or contraindication to Epclusa (sofosbuvir/velpatasvir) therapy

      -AND-

      (2) History of intolerance or contraindication to Mavyret (glecaprevir/pibrentasvir) therapy

      -OR-

   b. Patient is currently on Daklinza plus Sovaldi therapy

Authorization will be issued for 12 weeks.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

*Defined as the management and treatment of at least 10 patients with HCV infection within the past 12 months and at least 10 HCV-related CME credits in the last 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply Limits may be in place.

4. References:

1. Daklinza [package insert]. Princeton, NJ : Bristol-Myers Squibb ; November 2017
2. Sovaldi [package insert]. Foster City, CA: Gilead Sciences, Inc.; November 2017.
3. American Association for the Study of Liver Diseases and the Infectious Diseases Society of America. Recommendations for Testing, Managing, and Treating Hepatitis C. http://www.hcvguidelines.org/full-report-view. Accessed September 25, 2018.

Program	Prior Authorization/Medical Necessity - Daklinza® (daclatasvir)
Change Control	
8/2015	New program.
11/2015	Revised criteria to remove Sovaldi plus ribavirin step for cirrhotic patients, changed program title to include all lines of business and updated language regarding documentation of liver fibrosis.
3/2016	Revised criteria to add genotype 1 infection and addition of decompensated liver disease along with post liver transplant as new FDA-approved indications.
7/2016	Added Indiana and West Virginia coverage information.
8/2016	Added step requirement of Epclusa for genotypes 1 or 3 infection.
11/2016	Added California coverage information.
12/2016	Removed abstinence-based criteria and replaced with treatment readiness screening criteria.
9/2017	Revised step therapy criteria based on new product availability, included NY prescriber requirement, removed treatment readiness screening tools and removed medical record submission requirements.
11/2018	Annual review with no changes to clinical criteria. Updated references.