UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2018 P 1170-4
Program	Prior Authorization/Notification
Medication	Daklinza® (daclatasvir)
P&T Approval Date	8/2015, 11/2015, 3/2016, 9/2018
Effective Date	12/1/2018; Oxford only: N/A

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 with Sovaldi for 12 weeks.[1]

2. Coverage Criteria:

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

1. Diagnosis of chronic hepatitis C genotype 1 infection

-AND-

2. **One** of the following:

a. **Both** of the following:

(1) One 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

Authorization will be issued for 12 weeks

B. For the treatment of chronic hepatitis C genotype3 infection, **Daklinza** in combination with Sovaldi will be approved based on **both** of the following criteria:

1. Diagnosis of chronic hepatitis C genotype 3 infection

-AND-

2. **One** of the following:

a. **Both** of the following:

(1) One of the following:

(a) Patient does not have cirrhosis
(b) Patient has compensated liver disease
(c) 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 cirrhosis
(b) Patient has decompensated liver disease
(c) Patient is a liver transplant recipient

-AND-

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

Authorization will be issued for 12 weeks

3. Additional Clinical Rules:

Medical necessity and supply limits may be in place.

4. References:

1. Daklinza [package insert]. Princeton, NJ : Bristol-Myers Squibb; November 2017.

Program	Prior Authorization/Notification - Daklinza (daclatasvir)
Change Control	
8/2015	New program.
11/2015	Revising criteria to align with FDA approved indication section within the product label.
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.
9/2018	Annual review with no changes to coverage criteria. Updated reference.