

Prior Authorization DRUG Guidelines

**Daklinza® (daclatasvir tablets – Bristol Meyers
Squibb)**

Effective Date: 7/24/2018

Date Developed: 7/24/2018 by Catherine Sanders, MD and ESI P&T

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(Formulary Exclusion- For Exception Review Use Only)
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Daklinza is a hepatitis C virus (HCV) NS5A inhibitor indicated for use with Sovaldi® (sofosbuvir tablets), with or without ribavirin, for the treatment of chronic HCV genotype 1 or 3 infection.¹ Limitations of use: Sustained virologic response (SVR) rates are reduced in HCV genotype 3-infected patients with cirrhosis receiving Daklinza + Sovaldi for 12 weeks.

Recommended Authorization Criteria:

Coverage of Daklinza is recommended in those who meet the following criteria:

Food and Drug Administration (FDA)-Approved Indications

- 1. Chronic Hepatitis C Virus Genotype 1.** Approve Daklinza for 12 weeks if the patient meets all of the following criteria (A, B, C, D and E):
 - A)** The patient is ≥ 18 years of age; AND
 - B)** Daklinza is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician; AND
 - C)** Daklinza will be used **in combination with Sovaldi (sofosbuvir tablets)**;
 - D)** The patient has a fibrosis score of ≥ 2 , AND
 - E)** The patient meets ONE of the following conditions (i, ii, or iii):
 - i.** The patient does not have cirrhosis; OR
 - ii.** The patient has compensated cirrhosis (Child-Pugh A); OR
 - iii.** The patient has decompensated cirrhosis (Child-B or Child-Pugh C) AND Daklinza will be prescribed **in combination with ribavirin**.
- 2. Chronic Hepatitis C Virus (HCV) Genotype 3.** Approve Daklinza for 12 weeks if the patient meets all of following criteria (A, B, C, D and E):
 - A)** The patient is ≥ 18 years of age; AND
 - B)** Daklinza is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician; AND
 - C)** Daklinza will be used **in combination with Sovaldi (sofosbuvir tablets)**; AND

- D) The patient has a fibrosis score of ≥ 2 , AND
 - E) The patient meets ONE of the following conditions (i or ii):
 - i. The patient does not have cirrhosis; OR
 - ii. The patient has cirrhosis (this includes patients with compensated [Child-Pugh A] OR decompensated [Child-Pugh B or C] cirrhosis) AND Daklinza and Sovaldi will be prescribed **in combination with ribavirin**.
3. **Recurrent HCV Post-Liver Transplantation, Genotype 1 or 3.** Approve Daklinza for 12 weeks in patients who meet all of the following criteria (A, B, C, D and E):
- A) The patient is ≥ 18 years of age; AND
 - B) The patient has genotype 1 or 3 recurrent HCV after a liver transplantation; AND
 - C) Daklinza is prescribed by or in consultation with one of the following prescribers who is affiliated with a liver transplant center², a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician; AND
 - D) Daklinza is prescribed **in combination with Sovaldi AND ribavirin**.

Other Uses with Supportive Evidence

4. **Patient Has Been Started on Daklinza.** Approve for an indication or condition addressed as an approval in the Recommended Authorization Criteria section (FDA-Approved Indications) or Other Uses with Supportive Evidence to complete a course of therapy. Authorization for Daklinza should not exceed 24 weeks of therapy. For example if a patient is eligible for 12 weeks of therapy and has received 3 weeks of therapy, approve 9 weeks of therapy to complete the 12-week course.
5. **Recurrent Hepatitis C Virus (HCV) Post-Liver Transplantation Genotype 2.** Approve Daklinza for 12 weeks in patient who meet all of the following criteria (A, B, C and D):
- A) The patient is ≥ 18 years of age; AND
 - B) The patient has genotype 2 recurrent HCV after a liver transplantation; AND
 - C) Daklinza is prescribed by or in consultation with one of the following prescribers who is affiliated with a liver transplant center, a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician; AND
 - D) Daklinza is prescribed **in combination with Sovaldi AND ribavirin**.

Daklinza is not approved for the following: Combination use with Direct Acting Antivirals (DAAs) Other than Sovaldi or ribavirin, Life Expectancy < 12 Months Due to Non-Liver Related Comorbidities, Monotherapy with Daklinza, Retreatment with Daklinza in Patients Who Have Previously Received Daklinza, Pediatric Patients (Age < 18 years)

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