FORMULARY EXCEPTION POLICY

POLICY: Daklinza® (daclatasvir tablets – Bristol Meyers Squibb)

DATE REVISED: 10/03/2018

EFFECTIVE DATE: 01/01/2019

Documentation: Documentation will be required for patients requesting Daklinza where noted in the criteria as [documentation required]. Documentation may include, but is not limited to, chart notes, prescription claims records, prescription receipts and/or laboratory data.

CRITERIA

1. Hepatitis C Virus (HCV). Patients who meet any of the following criteria do not qualify for treatment with Daklinza (A, B, C, D or E): [Note: for patients who do not meet one of the following criteria A through D, review using the appropriate criteria 2 through 7 below]
   A. Combination use with any other direct-acting antivirals (DAAs) not including ribavirin or Sovaldi; OR
   B. Life expectancy < 12 months due to non-liver related comorbidities; OR
   C. Age < 18 years; OR
   D. Retreatment with Daklinza in patients previously treated with Daklinza such as prior null responders, prior partial responders, prior relapsers, patients who have not completed a course of therapy due to adverse events or other reasons. This does NOT include patients who are in the middle of a course of therapy with Daklinza and prior to their current course of therapy had not previously been treated for HCV; or
   E. Monotherapy with Daklinza.

2. Chronic Hepatitis C Virus (HCV) Genotype 1, No Cirrhosis: Approve Daklinza for 12 weeks if the patient meets all of the following criteria (A, B, C, and D):
   A. The patient does not have compensated (Child-Pugh A) or decompensated (Child-Pugh B or C) cirrhosis. (See Criteria 3); AND
   B. The patient has completed a course of therapy with ONE of Epclusa, Harvoni, or Vosevi and has documentation that he/she did not achieve a sustained viral response (SVR; virus undetectable 12 weeks following completion of therapy)[documentation required]. AND
   C. Daklinza will be prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician; AND
   D. Daklinza will be used in combination with Sovaldi (sofosbuvir tablets).

3. Chronic Hepatitis C Virus (HCV) Genotype 1, Compensated or Decompensated Cirrhosis: Approve for 12 weeks if the patient meets the following criteria (A, B, C, and D):
   A. The patient has compensated (Child-Pugh A) or decompensated (Child-Pugh B or C) cirrhosis. [documentation required]; AND
   B. The patient has completed a course of therapy with ONE of Epclusa or Harvoni and has documentation that he/she did not achieve a sustained viral response (SVR; virus undetectable 12 weeks following completion of therapy)[documentation required]. AND
   C. Daklinza is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician; AND
   D. The patient meets ONE of the following criteria (i or ii below):
      i. Approve for 12 weeks in patients who meet ONE of the following (a or b below):
                      01/01/2019
a) The patient has decompensated (Child-Pugh B or C) cirrhosis AND Daklinza will be prescribed in combination with Sovaldi AND ribavirin.
b) The patient has compensated (Child-Pugh A) cirrhosis AND Daklinza will be prescribed in combination with Sovaldi.

4. Chronic Hepatitis C Virus (HCV) Genotype 3, No Cirrhosis. Approve Daklinza for 12 weeks if the patient meets all of following criteria (A, B, C, and D):
   A. The patient does not have compensated (Child-Pugh A) or decompensated (Child-Pugh B or C cirrhosis. (See Criteria 5); AND
   B. The patient has completed a course of therapy with ONE of Epclusa, or Vosevi and has documentation that he/she did not achieve a sustained viral response (SVR; virus undetectable 12 weeks following completion of therapy) [documentation required]. AND
   C. Daklinza is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician; AND
   D. Daklinza will be used in combination with Sovaldi (sofosbuvir tablets).

5. Chronic Hepatitis C Virus (HCV) Genotype 3, Compensated or Decompensated Cirrhosis. Approve Daklinza for 12 weeks if the patient meets all of following criteria (A, B, C, and D):
   A. The patient has compensated (Child-Pugh A) or decompensated (Child-Pugh B or C) cirrhosis [documentation required]. AND
   B. The patient has completed a course of therapy with Epclusa and has documentation that he/she did not achieve a sustained viral response (SVR; virus undetectable 12 weeks following completion of therapy) with Epclusa [documentation required]. AND
   C. Daklinza is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician; AND
   D. Daklinza will be used in combination with Sovaldi (sofosbuvir tablets) and ribavirin.

6. Recurrent Hepatitis C Virus (HCV) Post-Liver Transplantation, Genotype 1, 2, or 3. Approve Daklinza for 12 weeks in patients who meet all of the following criteria (A, B, and C):
   A. The patient has genotype 1, 2, or 3 recurrent HCV after a liver transplantation; AND
   B. 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
   C. Daklinza is prescribed in combination with Sovaldi AND ribavirin.

7. Patient already started on Daklinza. Approve to complete the 12 week course of therapy.