VENTURA COUNTY
HEALTH CARE PLAN

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):

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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.