CareSource

PHARMACY POLICY STATEMENT **Ohio Medicaid**	
DRUG NAME	Daklinza (daclatasvir)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) Alternative preferred product includes Mavyret QUANTITY LIMIT— 28 for a 28 day supply
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Daklinza (daclatasvir) is a **non-preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

HEPATITIS C (without cirrhosis or with compensated cirrhosis (Child-Turcotte-Pugh Class A))

For **initial** authorization:
Member must meet all criteria below Step 1 and Step 2 and Step 3.

Step 1 (evaluation of member's readiness):

1. Member must be 18 years of age or older; AND
2. Member must be free for 6 months from alcohol use, controlled drug abuse, and illicit drug use before consideration of therapy (laboratory documentation required for month 1 and for month 6 and for one additional month between month 2-5); AND
3. Member must meet kidney function as indicated in package labeling for product (No dosage adjustment of Daklinza is required for members with any degree of renal impairment. Refer also to the sofosbuvir and ribavirin prescribing information for information regarding use in members with renal impairment); AND
4. Member must not be concomitantly taking drugs that have significant clinical interaction as described in the prescribing information (Daklinza contraindicated for use with strong CYP3A inducers such as phenytoin, carbamazepine, rifampin and ST. John's Wort; dose needed to be adjusted if being administered with certain drugs); AND
5. Member must agree to be adherent with office visits, lab testing, imaging, procedures and, if deemed a candidate, the HCV medication regimen. Prescribers must submit documentation demonstrating the member attests to meet these requirements (Office notes documenting this are sufficient to meet this criteria); AND

Step 2 (clinical assessment of disease):

6. Member has tried and failed course of treatment with Mavyret (Dates and HCV RNA values must be documented in chart notes); AND
7. Member has confirmation of chronic hepatitis C (CHC):
   a) Hepatitis C Virus (HCV) antibody test reactive; AND
   b) Provide HCV RNA load measured within 90 days prior to starting DAA therapy; AND
   c) Specify the Genotype:

i) Treatment-naïve or treatment-experienced without cirrhosis or with compensated cirrhosis (Child-Turcotte-Pugh Class A) with Genotype 1 or 3 (laboratory documentation required). If HCV genotype 1a with cirrhosis, consider testing for the presence of virus with NS5A resistance-associated polymorphisms; AND

8. Member has documented progression of disease:
   a) Document the degree of liver fibrosis:
      i) Liver biopsy; OR
      ii) One radiological and one serological test; AND
   b) If cirrhosis is present, indicate whether cirrhosis is compensated or decompensated and provide the Child-Turcotte-Pugh (CTP) score; AND
   c) Daklinza must be used in combination with sofosbuvir, with or without ribavirin. If ribavirin ineligible must submit documentation of ONE of the following results obtained within the past month:
      i) History of severe or unstable cardiac disease
      ii) Pregnant women and men with pregnant partners
      iii) Diagnosis of hemoglobinopathy (e.g., thalassemia major, sickle cell anemia)
      iv) Hypersensitivity to ribavirin
      v) Baseline platelet count <70,000 cells/mm^3
      vi) ANC <1500 cells/mm^3
      vii) Hb <12 gm/dL in women or <13 g/dL in men; AND
9. Document that member does not have limited life expectancy (less than 12 months) due to non-liver-related comorbid conditions; AND
10. Document any previously tried Hepatitis C treatments, dates treated, and response/outcome (member will not be approved if any other HCV treatments have been used in the last 6 months); AND

Step 3 (Direct Acting Antivirals (DAA) conditions for coverage):

11. Medication must be prescribed by, or in consultation with, a hepatologist, gastroenterologist, or infectious disease specialist; AND
12. Member's documented HCV RNA testing is required every 4 weeks and submitted with chart notes; AND
13. Providers of HIV/HCV-coinfected persons should recognize and manage interactions with other antiretroviral medications (e.g. DAAs); AND
14. Only regimens listed as recommended or alternative in the current AASLD guidance (http://hcvguidelines.org) will be approved with duration of approval based upon guidelines. Regimens listed as not recommended will not be approved.
15. **Dosage allowed:** One 60 mg tablet taken orally once daily for 12 weeks in combination with sofosbuvir with or without ribavirin. Reduce dosage to 30 mg once daily with strong CYP3A inhibitors and increase dosage to 90 mg once daily with moderate CYP3A inducers.

If member meets all the requirements listed above, the medication will be approved for 12 weeks.

For **reauthorization**:

1. Daklinza will not be reauthorized for continued therapy.

CareSource considers Daklinza (daclatasvir) not medically necessary for the treatment of the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
12/17/2018	New policy for Daklinza created. Criteria written based Ohio Department of Medicaid requirements.

References:

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

2. Hepatitis C Information | Division of Viral Hepatitis | CDC. (2015, May 31). Retrieved from https://www.cdc.gov/hepatitis/hcv/index.htm.
3. American Association for the Study of Liver Diseases and the Infectious Diseases Society of America (AASLD) and Infectious Diseases Society of America (IDSA). HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C; 2017. Available at: https://www.hcvguidelines.org/.
4. Afdhal, N. (2012). Fibroscan (Transient Elastography) for the Measurement of Liver Fibrosis. Gastroenterology & Hepatology, 8(9), 605-607.

Effective date: 01/01/2019
Revised date: 12/17/2018