CareSource

PHARMACY POLICY STATEMENT **Marketplace**	
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 products include Mavyret and Sofosbuvir/velpatasvir (generic for Epclusa) 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:

1. Member is treatment-naïve or treatment-experienced, without cirrhosis or with compensated cirrhosis (Child-Turcotte-Pugh Class A); AND
2. Member must be 18 years of age or older; AND
3. Member has genotype 1 or 3 (laboratory documentation required); AND
4. Member will be prescribed Daklinza in combination with Sovaldi (prior authorization required); AND
5. Medication must be prescribed by a board certified hepatologist, gastroenterologist, infectious disease specialist or a nurse practitioner working with the above specialists; AND
6. Member's documented viral load taken within 6 months of beginning therapy and submitted with chart notes; AND
7. Member has documented current monthly negative urine drug and alcohol screens for 3 consecutive months (laboratory documentation required); AND
8. Member does not have moderate to severe hepatic impairment (Child-Turcotte-Pugh B and C); AND
9. Member has tried and failed course of treatment with Sofosbuvir/velpatasvir (generic for Epclusa) and with Mavyret (Dates and HCV RNA values must be documented in chart notes); AND
10. Member must have evidence of liver fibrosis stage 3 or 4 confirmed by liver biopsy, or elastography only (lab chart notes required) unless one of the following (fibrosis stage F0-4 covered):
    a) Hepatocellular carcinoma meeting Milan criteria (awaiting liver transplantation);
    b) Post liver transplantation;
    c) Extrahepatic disease (i.e., kidney disease: proteinuria, nephrotic syndrome or membranoproliferative glomerulonephritis; cryoglobulinemia with end- organ manifestations (e.g., vasculitis));
    d) HIV or HBV coinfection.
11. **Dosage allowed:** Daklinza one tablet taken orally once daily for 12 weeks.

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.
05/01/2019	Sofosbuvir/velpatasvir (generic for Epclusa) trial added.
03/11/2021	Annual review, no changes

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: 01/01/2022
Revised date: 03/11/2021