



PHARMACY POLICY STATEMENT North Carolina 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.

Qualified Health Plans offered in North Carolina by CareSource North Carolina Co., d/b/a CareSource.



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: 01/01/2023

Revised date: 03/11/2021