



PHARMACY POLICY STATEMENT North Carolina Marketplace

DRUG NAME	Harvoni (ledipasvir/sofosbuvir)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
STATUS	Prior Authorization Required

Harvoni is a fixed-dose combination of ledipasvir, a hepatitis C virus (HCV) NS5A inhibitor, and sofosbuvir, an HCV nucleotide analog NS5B polymerase inhibitor. It was initially approved by the FDA in 2014 and is indicated for the treatment of chronic hepatitis C virus (HCV) in adults and pediatric patients 3 years of age and older.

Harvoni (ledipasvir/sofosbuvir) will be considered for coverage when the following criteria are met:

Hepatitis C

For initial authorization:

1. Member must be 3 years of age or older; AND
2. Member is treatment-naïve or treatment-



- 4. 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; 2021. Available at: <https://www.hcvguidelines.org/>.

Effective date: 01/01/2023
Revised date: 02/24/2022

Appendix I. Treatment Duration

Genotype	Patient Population	Regimen and Duration
Genotype 1	Treatment-naïve without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Harvoni 12 weeks
	Treatment-experienced without cirrhosis	Harvoni 12 weeks