

GOVERNMENT OF THE DISTRICT OF COLUMBIA
Department of Health Care Finance



Subject: Prior Authorization Approval Criteria for Harvoni (ledipasvir 90mg and sofosbuvir 400mg) Policy Number: HCRA-DEP-02	
Policy Scope: <i>Department- wide</i>	Number of Pages: 2
Responsible Office or Division: <i>Clinicians, Pharmacy and Acute Provider Services</i>	Number of Attachment: 2
Supersedes policy Dated N/A	Number of Effective Date: January 2015
Cross Reference and Related Policies: <i>DHCF Establishment Act of 2007</i>	Expiration Date, if any: N/A

1) PURPOSE

To establish policies and procedures governing the submission of Prior Authorization (PA) requests for Harvoni® (ledipasvir 90mg and sofosbuvir 400mg) for the District of Columbia Medicaid Fee for Service beneficiaries.

2) APPLICABILITY

This applies to all Medicaid providers and beneficiaries that participate in the DC Medicaid Fee for Service (FFS) Program.

3) AUTHORITY

The Department of Health Care Finance (DHCF) is the single state agency that has the authority to administer the District of Columbia Medicaid as set forth in the “DHCF Establishment Act of 2007” effective February 27, 2008 (DC. Law 17-109).

4) DEFINITIONS

- a) **Harvoni® (ledipasvir and sofosbuvir)**-A once-daily fixed-dose combination of the NS5A inhibitor ledipasvir (LDV) 90 mg and the nucleotide analog polymerase inhibitor sofosbuvir (SOF) 400 mg for the treatment of chronic hepatitis C genotype 1 infection in adults.
- b) **Prior Authorization**-Approval from the Department of Health Care Finance that is required before a service or prescription order will be reimbursed to a provider.
- c) **Drug Utilization Review (DUR) Board**- An advisory group of licensed physicians, pharmacists, and allied health professionals established by section 4401, 1927 (9g) of the Omnibus Reconciliation Act of 1990. The DUR board reviews and approves drug use criteria and standards for both retrospective and prospective drug use reviews;

applies these criteria and standards in the application of DUR activities; reviews (DURs) and reports the results of DURs; recommends and evaluates educational intervention programs for covered outpatient drugs under the Medicaid Fee for Service Program.

5) POLICY

Effective January 2015 all PA requests for Harvoni® must be submitted on the designated Prior Authorization Request Form and completed request submission will be reviewed for approval in accordance with clinical criteria attached and incorporated by reference as attachment and developed by the District of Columbia Drug Utilization Review Board.

6) PROCEDURE FOR REQUESTING HARVONI® PRIOR AUTHORIZATION

- a) The requesting physician can obtain the following documents from <http://www.dc-pbm.com/>
 - I. Harvoni® (ledipasvir and sofosbuvir) PA form
 - II. The Clinical Criteria
 - III. DC Medicaid Beneficiary Disclosure and Commitment to Take Hepatitis C Medications
- b) To initiate the PA, the requesting physician should submit a signed, dated, and completed Harvoni® (ledipasvir and sofosbuvir) Prior Authorization Request Form via facsimile to 866-535-7622.
- c) Submission of the following supporting documentation is also required to complete the request:
 - i. A letter of Medical Necessity from prescriber
 - ii. Lab test Results
 1. HCV-RNA level
 2. Other related tests
 - iii. DC Medicaid Beneficiary Disclosure and Commitment Form
 1. Signed and dated by prescriber; and
 2. Signed and dated by Beneficiary (patient)
- d) The requesting prescriber must submit the required supporting documentation to the Clinical Pharmacy Unit at 1-866-535-7622.
- e) The initial review of the PA form and required clinical information will be performed by the Clinical Pharmacy Unit for completeness and to address any missing information.
- f) The DUR Board members will participate in the review process and will make approval recommendations to the DHCF on the initial request.
- g) The decision for prior authorization request is anticipated to occur within ten (10) to fourteen (14) days after receipt of a completed Harvoni® PA request and **ALL** required supporting documentations.
- h) The requesting prescriber will be notified of the disposition of the request.

- i) In the event of a denial of the Prior Authorization, the beneficiary (patient) will be notified of unmet criteria and will be advised of their right to appeal.

7) RESPONSIBILITY

Questions regarding this policy should be directed to Charlene Fairfax, Health Care Delivery Management Administration, Division of Clinician, Pharmacy, and Acute Provider Services at (202) 442-9076 or e-mail: Charlene.fairfax@dc.gov or to Gidey Amare, Pharmacist, Health Care Delivery Management Administration, Division of Clinician, Pharmacy, and Acute Provider Services at (202) 442-5952 or e-mail: gidey.amare@dc.gov.

Claudia Schlosberg
Acting, Senior Deputy Director

Date

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Benefit Coverage Criteria for Harvoni (ledipasvir 90mg and sofosbuvir 400mg)

a) Note to Prescribers:

Please refer to the criteria below when completing a request for prior Authorization for HARVONI and be sure to include **ALL** supporting documentation with the request.

b) Approval Criteria:

A District of Columbia Fee for Service Medicaid beneficiary **may** qualify to receive Harvoni coverage if the following criteria are met:

1. The patient is at least 18 years old. The safety and efficacy of Harvoni have not been established in pediatric patients < 18 years of age;
AND
2. The beneficiary has a documented diagnosis of genotype 1, 4, 5 and 6 chronic hepatitis C infection, supported by clinical assessment to demonstrate liver fibrosis of Metavir score of F2 or greater);
AND
3. The patient is supervised by a Gastroenterologist **OR** Infectious disease specialist **OR** a physician specialized in hepatitis treatment and management **OR** a physician working in consultation with gastroenterologist or infectious disease specialist;
AND
4. The prescribing provider has a documented plan to monitor HCV-RNA levels at weeks 4, 8, and 12 to review the outcome of therapy or assess any conditions that warrant discontinuation of therapy;
AND
5. Beneficiary is not taking a concomitant medication that has a significant clinical interaction with Harvoni. The use of Harvoni with other drugs containing sofosbuvir is not recommended;
AND
6. The beneficiary has agreed to participate in the Hepatitis C monitoring program provided by the District's Pharmacy Benefit Manager;
AND
7. The beneficiary clearly understands that only one course of therapy is allowed in his/her DC Medicaid lifetime; and, unless there is legitimate documented evidence, a request for loss/stolen medication replacement will not be authorized;
AND
8. The recommended duration of treatment is Twelve (12) weeks in treatment-naïve patients with or without cirrhosis; Twelve (12) weeks in treatment-experienced patients without cirrhosis and twenty four (24) weeks in those who have cirrhosis; and eight (8) weeks of treatment *may* be considered in treatment-naïve patients without cirrhosis who have a baseline HCV RNA < 6 million IU/mL. For patients with RNA level less than 6 million, (8) week Harvoni therapy is recommended.