

United Health Care - F3/F4 - AASLD/IDSA Guidance

Effective Date 10/15/2014.....Prior Authorization/Medical Necessity.....Harvoni™
(ledipasvir/sofosbuvir)

Based on current evidenced-based guidance from professional specialty societies and physician subject matter experts, UnitedHealthcare will provide benefit coverage in cases of hepatitis C infection when there is documented evidence of stage 3 or stage 4 hepatic fibrosis.

UnitedHealthcare's coverage criteria for the new direct-acting agents are based on careful consideration of the evidence-based guidance of professional specialty societies, published guidelines and physician subject matter experts. The Infectious Diseases Society of America (IDSA) and American Association for the Study of Liver Diseases (AASLD) have jointly published evidence-based, expert-developed recommendations for hepatitis C which stated the following about prioritization of treatment with direct acting agents: " Treatment is assigned the highest priority for those patients with advanced fibrosis (Metavir F3), those with compensated cirrhosis (Metavir F4), liver transplant recipients, and patients with severe extrahepatic hepatitis C. Based on available resources, treatment should be prioritized as necessary so that patients at high risk for liver-related complications and severe extrahepatic hepatitis C complications are given high priority ."1 In addition, a report issued in February 2014 by the Institute for Clinical and Economic Review (ICER) for the California Technology Assessment Forum (CTAF) recommended that Olysio and Sovaldi be used only for patients with severe hepatitis complications, such as liver cirrhosis.2

References:

1. American Association for the Study of Liver Diseases and the Infectious Diseases Society of America. Recommendations for When and In Whom to Initiate HCV Therapy. August 2014.
<http://www.hcvguidelines.org/full-report-view>. Accessed October 13, 2014.

I added this link:

<http://www.hcvguidelines.org/full-report/when-and-whom-initiate-hcv-therapy>

2. California Technology Assessment Forum. The Comparative Clinical Effectiveness and Value of Simeprevir and Sofosbuvir in the Treatment of Chronic Hepatitis C Infection.
<http://www.ctaf.org/reports/treatments-hepatitis-c> Accessed October 13, 2014.

-AND-

5. One of the following:

a. Patient has no known history of illicit drug abuse or alcohol abuse

-OR

b. For a patient with a known prior history of illicit drug abuse or alcohol abuse:

(1) Patient has abstained from the use of illicit drugs and alcohol abuse for the past 6 months

-AND-

(2) For a patient with a prior history of illicit drug abuse, submission of a negative urine drug screen collected within 30 days prior to onset of treatment**

One of the following:

(1) Submission of medical records (e.g., chart notes, laboratory values) documenting stage 3 hepatic fibrosis including one of the following:

(a) Liver biopsy confirming a METAVIR score of F3, or alternative scoring equivalent*

-OR-

(b) Transient elastography (Fibroscan) score greater than or equal to 9.5 kPa

-OR-

(c) FibroTest (FibroSURE) score of greater than or equal to 0.58

-OR-

(d) APRI score greater than 1.5

-OR-

(2) Submission of medical records (e.g., chart notes, laboratory values) documenting genotype 1 HCV reinfection following liver transplantation

-OR-

(3) Submission of medical records (e.g., chart notes, laboratory values) documenting that patient has serious extrahepatic manifestations of HCV infection (i.e., leukocytoclastic vasculitis, membranoproliferative glomerulonephritis, or symptomatic cryoglobulinemia)

-OR-

(4) Patient is co-infected with HIV