

Case Number:	CM15-0035234		
Date Assigned:	03/03/2015	Date of Injury:	03/26/1996
Decision Date:	04/08/2015	UR Denial Date:	01/30/2015
Priority:	Standard	Application Received:	02/25/2015

HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to an expert reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. He/she has been in active clinical practice for more than five years and is currently working at least 24 hours a week in active practice. The expert reviewer was selected based on his/her clinical experience, education, background, and expertise in the same or similar specialties that evaluate and/or treat the medical condition and disputed items/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:

State(s) of Licensure: New Jersey

Certification(s)/Specialty: Family Practice

CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

The injured worker is a 63 year old female, who sustained an industrial injury on 3/26/96. She has reported chronic hepatitis C. The diagnoses have included morbid obesity, HCV gt1, well compensated cirrhosis with thrombocytopenia and trace esophageal varices. Treatment to date has included interferon, Pegasys and ribavirin treatment (discontinued 1 month prior to completion due to rash and thyroid problems. Abdominal ultrasound dated 5/30/14 revealed increased echogenicity and coarsening of the liver compatible with steatosis and minimal nodularity with no ascites. Currently, the injured worker is complaining of relapse in HCV after treatment. Physical exam noted morbid obesity, no jaundice and soft, non-distended abdomen. It is also noted the injured worker now also has Childs Pugh Class A cirrhosis. On 1/30/15 Utilization Review non-certified generic prescription drug (Harvoni), noting the request is not supported by evidenced based guidelines as it is comprised of a different medication combination than that indicated for treatment. The ODG was cited. On 2/24/15, the injured worker submitted an application for IMR for review of generic prescription drug (Harvoni).

IMR ISSUES, DECISIONS AND RATIONALES

The Final Determination was based on decisions for the disputed items/services set forth below:

Harvoni one tablet daily for 24 weeks: Overturned

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Smith MA, et al., Ledipasvir-sofosbuvir: interferon-/ribavirin-free regimen for chronic hepatitis C virus infection, *Ann Pharmac other.* 2015 Mar; 49(3): 343-50. doi: 10.1177/1060028014563952. Epub 2014 Dec 16.

Decision rationale: The MTUS is silent regarding treatment of infectious diseases such as hepatitis C. The ODG, however, states that standard therapy has for a long time and should continue to include pegylated interferon (PEG-IFN) and ribavirin (RBV). Newer medications (telaprevir, boceprevir, sofosbuvir or simeprevir) may be added on to this standard regimen, each being capable of inducing an even higher success rate in combination with PEG-IFN and RBV. In the case of this worker, although sofosbuvir is recommended for use, the benefit of a combination drug product such as Harvoni has most recently been shown to be superior in terms of cost, side effect profile and with a very high success rate compared to using in older regimens. After reviewing the latest research in regards to this medication, in the opinion of the reviewer, Harvoni, one tablet daily for 24 weeks is medically necessary and appropriate.