

Discussion of Coverage Policy Developed by
the Employee Benefits Division (EBD)
Regarding Hepatitis-C Drugs

March 23, 2015

**What are the long-term effects of
Hepatitis C?**

Of every 100 people infected with the Hepatitis C virus, about

- 75–85 people will develop chronic Hepatitis C virus infection; of those,
 - 60–70 people will go on to develop chronic liver disease
 - 5–20 people will go on to develop cirrhosis over a period of 20–30 years
 - 1–5 people will die from cirrhosis or liver cancer

Source: Centers for Disease Control and Prevention

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What do national guidelines recommend?

- Treatment is recommended for patients with chronic HCV infection
- Immediate 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, immediate 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

Sources: American Association for the Study of Liver Diseases (AASLD), Infectious Disease Society of America (IDSA), International Antiviral Society - USA

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Limitations in the Clinical Trials

- Small sample sizes w/wide confidence intervals for sustained viral responses
- Small number of patients with cirrhosis
- Lack of concurrent control arm in some studies
- Lack of head-to-head trials of newer oral agents
- Exclusion of patients with chronic hepatitis B, HIV, HCC, decompensated cirrhosis
- Lack of follow-up data to determine long-term virologic and clinical outcomes

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EBD's Coverage Policy

- Documented Chronic Hepatitis C diagnosis
- Free of abusing illicit drugs and alcohol
- Not have liver disease due to other defined causes
- Metavir score F3-F4 (Metavir score indicates progressive scarring of the liver with 0=no fibrosis and 4= cirrhosis)
- Assessment of liver disease by non-invasive method
- Be actively enrolled in case management

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Criteria for local/regional plans

Health Plan / Group	Criteria requiring Metavir Score of 3 or 4
EBD	Yes
Arkansas Medicaid	Yes
QualChoice	Yes
ABCBS	Unknown
United Healthcare	Yes
University of Arkansas System	Yes

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On the Horizon

- HCV infection is a growing cause of illness and deaths among Arkansans.
- Approximately 1.8% of adult Arkansans, or nearly 38,000 persons, have been infected with HCV.
- The Centers for Disease Control and Prevention (CDC) estimate that 45% – 85% of persons with HCV are unaware of their infection.

Source: Arkansas Department of Health – Hepatitis C Epidemiologic Profile 2014

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Comparative Costs of Agents used to treat Hepatitis C

Drug	Estimated Cost per course of therapy*
Interferon / Ribavirin	\$43,000 per 48 weeks
Sovaldi®	\$86,000 per 12 weeks
Harvoni®	\$96,000 per 12 weeks
Viekira Pak®	\$85,000 per 12 weeks

* Average Wholesale Price less 15%

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