



MARYLAND

DEPARTMENT OF HEALTH
AND MENTAL HYGIENE

HEPATITIS C: SOVALDI/OLYSIO CLINICAL CRITERIA

MAC Meeting

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SCOPE OF THE PROBLEM: FACTS & FIGURES - CHRONIC HEPATITIS C

Worldwide approximately 170 million people living with Hepatitis C

Est. No. of Chronic Cases In the United States	No. of Death Certificates listing HCV as a Cause of Death, 2010*
2.7- 3.9 million	16,627†
Source: CDC.gov, updated 2011	
Approximately half are unaware of their status	

**Maryland Medicaid: approximately 10,500
individuals, June 2013**



HEPATITIS C: NATURAL HISTORY OF INFECTION

- About 15-20% spontaneously clear & do not develop chronic infection
- Defining the natural history of chronic HCV has been difficult because of the long course of the disease and often unknown timing of contracting the disease.¹
- Ultimately, chronic HCV results in liver injury that may lead to fibrosis and variable progression to cirrhosis depending on the population (generally only about 5%, but higher in certain groups such as co-infected).
- However, once advanced fibrosis has developed the annual rate of progression to cirrhosis is approximately 10 percent per year.²⁻⁴



BACKGROUND

- Many new & emerging drugs to treat Hepatitis C
- In May 2011, two protease inhibitors, telaprevir and boceprevir were approved by the FDA for treatment of HCV genotype 1. To be used in combination with pegylated interferon (pegIFN) and ribavirin (RBV)
- These triple combo regimens nearly doubled the chance of response to treatment but at the cost of increased toxicity (anemia, thrombocytopenia, neutropenia, rash, pruritis)
- Then in December 2013 came the “real game-changers”: **sofosbuvir, NS5B polymerase inhibitor** and simeprevir, second generation NS3/4A protease inhibitor.



BACKGROUND

- Recommendations for Testing, Managing, and Treating Hepatitis C jointly published by AASLD & IDSA
- Key sections missing including when and in whom to initiate treatment (previously you would wait until patient had significant fibrosis) and section how to monitor patients on treatment/who have completed treatment
 - 12 week Course of Sofosbuvir: ~\$84,000
 - 12 week Course of Simeprevir: ~\$65,000
- However, contrary to HIV one time treatment not life-long; so although high up-front costs, long-term savings (decrease in ESLD)
- How do Medicaid programs, the VA and other payers absorb the up-front cost of treatment?
- HCV is a disease that like HIV affects marginalized populations; what are the ethical considerations in setting such high drug prices? US Senate and Congress probing Gilead



MARYLAND MEDICAID CRITERIA

- Development process involved internal workgroup and consultation with other state Medicaid programs, VA, University of MD School of Pharmacy/Medicine, John Hopkins SOM Division of Infectious Diseases
- Presented to MCOs and asked to adopt to improve access to patients & make the system easier to navigate for providers



MARYLAND MEDICAID CLINICAL CRITERIA

- Can be found on our Medicaid pharmacy website:
<https://mmcp.dhmh.maryland.gov/pap/SitePages/Hepatitis%20C%20Therapy.aspx>

Diagnosis

- Must have chronic hepatitis C, genotype and sub-genotype specified to determine the length of therapy;
- Liver biopsy or other accepted test demonstrating liver fibrosis corresponding to Metavir score of greater than or equal to 2;
- Consult performed and medication prescribed by a physician specializing in infectious disease or gastroenterology/hepatology.

Patient Treatment Plan

- Patient must have a treatment plan developed by the specialist.
- If patient or partner is of childbearing age, must utilize 2 forms of contraception (secondary to tetragenicity of ribavirin).

Drug Therapy

- Must be in accordance to FDA approved indications.



BACKGROUND

- **What Does METAVIR Score Mean?**
- The fibrosis is graded on a 5-point scale from 0 to 4.
Fibrosis score:
 - F0 = no fibrosis
 - F1 = portal fibrosis without septa
 - F2 = portal fibrosis with few septa
 - F3 = numerous septa without cirrhosis
 - F4 = cirrhosis
- The activity, which is the amount of inflammation (specifically, the intensity of necro-inflammatory lesions), is graded on a 4-point scale from A0 to A3.
Activity score:
 - A0 = no activity
 - A1 = mild activity
 - A2 = moderate activity
 - A3 = severe activity



MARYLAND MEDICAID CLINICAL CRITERIA

- Will be revised as new data & drugs emerge
- Expect first line interferon-free regimens for genotype 1 by October of this year.
- Auditing MCOs to assure our criteria is being followed
- Putting together an info bulletin for providers so all participating MCOs can send to their networks



QUESTIONS

- Questions now?

- Questions later contact:

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REFERENCES

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