Wyoming Drug Utilization Review

Overview of Hepatitis C

L. Joy Ohnstad, PharmD

Hepatitis C is a serious blood born viral infection that the CDC estimates has 29,700 new contractions yearly and is a chronic infection in 2.7 to 3.9 million patients in the United States.[1] Several new or combination medications have been approved by the FDA since 2011.[2] Hepatitis C medications are not considered equivalent and the newer medications are indicated for specific genotypes of Hepatitis C virus.[2] Treatment guidelines for hepatitis C virus (HCV) are constantly changing, and the newest guidelines should always be reviewed from the Infectious Diseases Society of America (IDSA).[2]

IDSA recommends one-time HCV testing for all patients born between 1945 and 1965 without prior ascertainment of risk.[2] All other patients should be screened for risk factors for HCV infections, and one-time testing should be performed for all persons with behaviors, exposures, and conditions associated with an increased risk of HCV infection.[2] CDC and ISDA estimate that 50% of infected patients are unaware of their infection.[1,2] HCV is primarily transmitted through percutaneous exposure to blood, mother-to-child, shared contaminated medical supplies, and sexual transmission.[1,2] There are six major genotype of HCV: genotype 1 (46%), genotype 3 (30%), genotypes 2, 4, 6 combined account for around 23% of cases, and genotype 5 accounts for the remaining 1%. The prevalence for genotype 6 has not yet been determined.[2]

References:

1. Division of viral hepatitis and National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention. Viral hepatitis statistics & surveillance. 2013.CDC website. Atlanta (GA): Center for disease Control and prevention; 2015. Available from: http://www.cdc.gov/hepatitis/statistics/. Atlanta (GA): Center for Disease Control and Prevention; 2015. Accessed September 11, 2015.

2. Clinical guidance for the treatment of hepatitis C. IDSA website. Arlington(VA). Infectious Disease Society of America;2015. Available from: http://www.idsociety.org/HCV_Clinical_Guidance/. Accessed September 14, 2015.

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2017 P & T Committee Meeting Dates

Thursday, February 9
Wednesday, May 10
Thursday, August 10
Thursday, November 9

P & T Committee meetings are held quarterly in Cheyenne at Laramie County Community College, 10 am - 1 pm. Please visit the WY-DUR website at *www.uwyo.edu/DUR* for meeting details. The agenda is posted approximately 2 weeks prior to a meeting.

Newer Treatments for Hepatitis C

Becky Boschee, PharmD Candidate 2017

Testing and Diagnosis:

- Blood testing for the presence of antibodies
  - If positive for antibodies, then testing for presence of HCV-RNA
  - Determination of viral load
- Liver biopsy to determine the presence/level of cirrhosis
- Elastography – measures the severity of liver cirrhosis using sound waves

Treatment Initiation:

- Early treatment of chronic HepC results in better patient outcomes
- Immediate treatment should be considered for patients with HIV or HBV co-infection
- Treatment is recommended prior to liver transplant procedure
- Patients with a history of IV drug abuse should be managed by a multidisciplinary team to reduce chances of reinfection
- Risk vs benefit should be evaluated in pregnancy
- Viral suppression can inhibit transmission to baby
- Treatment should only be deferred in patients with a life expectancy less than 12 months due to non-liver causes

Treatment based on Genotype: (may vary in the presence of cirrhosis and other factors)

Drug	**MOA**	**Genotypes**	**Additional Info**
elbasvir /grazoprevir ***Zepatier***	NS5A inhibitor/nucleotide analog NS5B polymerase inhibitor	1a and 1b	Treat for 12 weeks (Renal safe)
sofosbuvir/velpatasvir ***Epclusa***	nucleotide analog NS5B polymerase inhibitor/NS5A inhibitor	1st line in genotype 2, effective in all types	Treat for 12 weeks
ledipasvir/sofosbuvir ***Harvoni***	NS5A inhibitor/ nucleotide analog NS5B polymerase inhibitor	1	Treat for 12 weeks
daclatasvir plus sofosbuvir	NS5A inhibitor/ nucleotide analog NS5B polymerase inhibitor	3	Treat for 24 weeks
Ombitasvir, Paritaprevir, and Ritonavir **Technivie**	NS5A inhibitor/ protease inhibitor/ CYP-450 inhibitor	4	Treat for 12 weeks
Ombitasvir, Paritaprevir, Ritonavir, and Dasabuvir **Viekira PaK**	See above plus NS3/4A inhibitor/NS5B polymerase inhibitor	1a and 1b	Treat for 12 weeks (24 weeks in cirrhosis)
Ribavirin	Neucleoside	Can be an add on for patients with compensated cirrhosis	Use in combo with Zepatier, Epclusa or Harvoni

Goals of Therapy:

- SVR – Sustained Virologic Response - defined as an undetectable viral load at 12 - 24 weeks post treatment
  - This is considered to be "cured"

References:

1. Jezequel C, Bardou-Jacquet E, Desille Y et al. Survival of patients infected by chronic hepatitis C and F0F1 fibrosis at baseline after a 15 year follow-up. 50th Annual Meeting of the European Association for the Study of the Liver (EASL). April 22-26, 2015;S589; Vienna, Austria.
2. http://www.hcvguidelines.org/full-report/when-and-whom-initiate-hcv-therapy

P & T Committee Meeting Update

The P&T Committee met for its quarterly business meeting on November 10, 2016.

Highlights of this meeting include:

The new Pharmacy Benefit Management system will be implemented in March 2017.

A state plan amendment is in process with the Centers for Medicare and Medicaid Services (CMS) that will change pharmacy reimbursement to the National Average Drug Acquisition Cost (NADAC) or Wholesale Acquisition Cost if there is no established NADAC standard. Along with this change will come an enhanced pharmacist dispensing fee. The amount of this fee cannot yet be announced as it has not been approved by CMS, but is intended to make the pharmacy whole.

Cigna has joined the Patient-Centered Medical Home (PCMH) project. When a provider enrolls in Medicaid's PCMH program, they will automatically be enrolled in Cigna as well. The program is designed to help practices meet the requirements for Medicare enhanced payment.

Zurampic was approved. There is no evidence of an advantage in safety or efficacy over existing agents. A cost analysis will be conducted. Concurrent use of a xanthine oxidase inhibitor at appropriate dose will be required. If Zurampic is non-preferred, a 60 day trial and failure of preferred agents may be required.

The proposed 2017 Preferred Drug List (PDL) was reviewed and will be posted for public comment.

The proposed prior authorization criteria and 2017 PDL will be posted for public comment at www.uwyo.edu/DUR. Comments may be sent by email to alewis13@uwyo.edu or by mail to: Wyoming Drug Utilization Review Board, Dept. 3375, 1000 E. University Avenue, Laramie, WY 82071. Comments should be received prior to December 15, 2016.

The next P&T Committee meeting will be held February 9, 2017 in Cheyenne. An agenda will be posted approximately two weeks prior to the meeting.

Wyoming DUR Program Annual Report

The Wyoming DUR Program Annual Report was submitted to the Centers for Medicare and Medicaid Services for the reporting period of October, 1 2014 – September 30, 2015. Of note are the following topics:

- Prospective DUR edits (including refill too soon, therapeutic duplication, drug-drug interaction, etc.) resulted in an estimated cost avoidance of more than $20,000,000.
- Retrospective DUR activities including comparative provider reports resulted in an estimated cost avoidance of more than $1,000,000, more than double that of the previous reporting period under the former lettering process.
- Generic utilization constitutes 80% of Medicaid claims and 20% of total drug expenditures.
- Educational newsletters were sent to more than 2000 prescribers and pharmacists in Wyoming and the surrounding area.
- More than 1300 retrospective educational letters and reports were sent on topics including narcotic use in pregnancy, monotherapy in COPD patients, RSV prophylaxis guidelines, appropriate use of prophylaxis agents in migraine treatment, high dose narcotic utilization, and chronic narcotic management.

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In This Issue

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