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Hepatitis C

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Objectives

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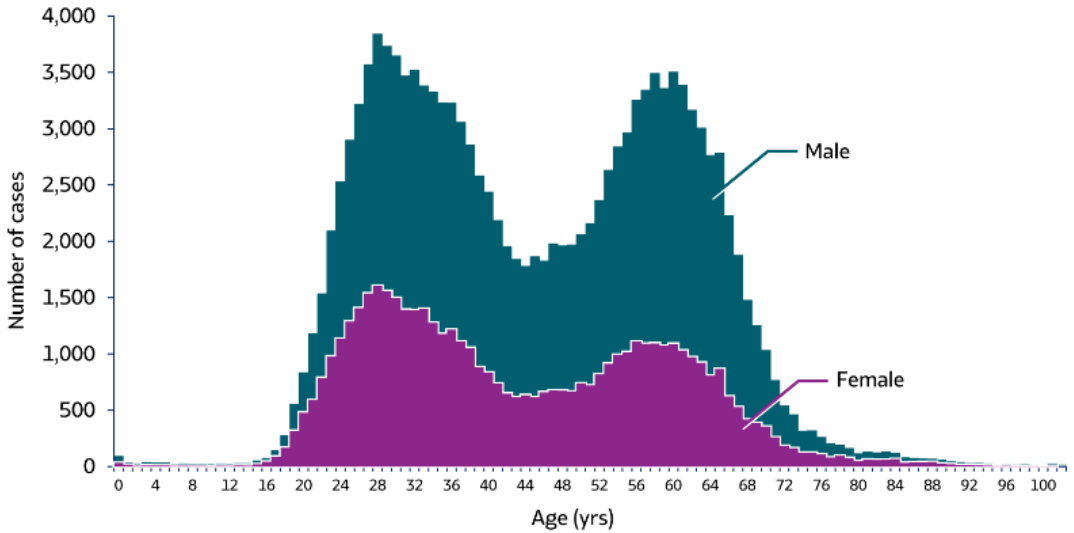
- Recognition of Hepatitis C prevalence in the U.S
- Understanding the impact of untreated hepatitis C on the healthcare system
- Awareness of new testing recommendations
- Familiarization with new treatments & treatment protocol

Epidemiology

Prevalence

- HCV is considered the most common blood born infection in the U.S. thus requiring health service utilization
- The incidence and prevalence of HCV is increasing in young adults associated with an increase in Injectable drug use among the younger population
- 15% to 25% of patients with previously unidentified HCV infection were born after 1965

Number of newly reported* chronic hepatitis C cases† by sex and age — United States, 2018 (N=137,713)



What is Hepatitis C

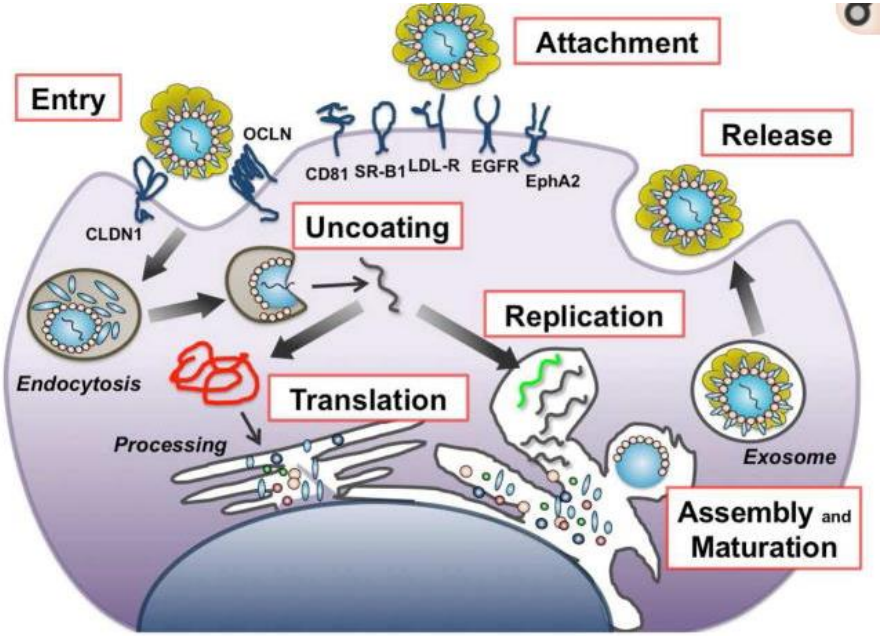
Hepatitis C: Liver infection attributed to the hepatitis C virus (HCV)

- Can manifest in an acute or chronic form. Acute forms typically resolve themselves but chronic forms can result in an array of hepatic or extrahepatic complications.
  - Enveloped virus belonging to the Flaviviridae family
  - Positive single-stranded RNA virus consisting of 9500 nucleotides
  - Polyprotein precursor consists of about 3,000 amino acids
  - Contains structural and non-structural proteins
- Chronic HCV can vary from person to person depending on the strain to which an individual is exposed. HCV strains are categorized into genetically distinct groups, thus assorted into genotypes ranging from 1 to 6

Methods of transmission:

Pathophysiology

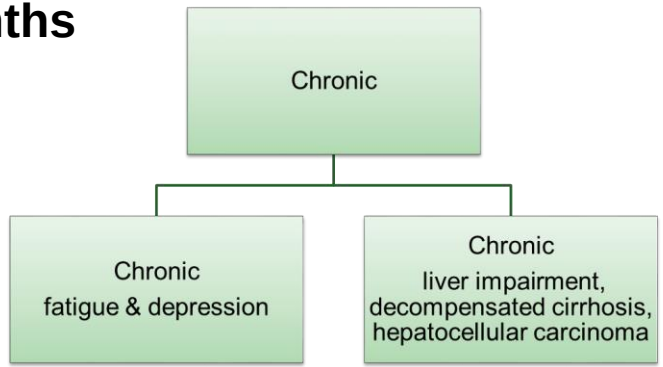
- As a result of viral infection, the innate immune system causes an inflammation and a fibrotic response often for years undetected due to a lack of apparent symptoms until the liver progresses to irreversible liver damage (cirrhosis) and on to terminal illness (end stage liver disease)



Clinical Signs & Symptoms

HCV can manifest itself in either of the following stages**:**

- **Short-term Infection (Acute) <6 months**
  - Mild illness lasting a few weeks
    - No symptoms
    - Yellow skin/eyes, stomach pain, fever, dark urine, light-colored stool, joint pain, and feeling tired
- **Long term Infection (Chronic) > 6 months**
  - Serious, long-term illness



Who should get tested for Hepatitis C

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- One-time routine HCV testing for all ≥ 18 years of age
- Anyone ≤ 18 years of age at increased risk
- Pregnant women with each pregnancy
- Periodic HCV testing for all those at increased risk

Recommendations for Initial HCV Testing

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Initial HCV testing	• PCR testing is recommended
At risk of reinfection after previous viral clearance	• PCR testing is recommended
Persons at risk of reinfection after previous spontaneous or treatment-related viral clearance	• HCV-RNA testing is recommended
Individuals with a Negative HCV-antibody test who were exposed to HCV within the prior 6 months	• HCV-RNA or follow-up HCV-antibody testing 6 months or longer after exposure is recommended.

All individuals undergoing HCV screening should initially be tested for HCV antibodies via a laboratory-based assays and a point-of-care assay

Complications of Hepatitis C

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- Hematological disorders
- Dermatologic disease
- Autoimmune disorders
- Diabetes mellitus
- Ocular disease
- Renal disease
- Musculoskeletal
- Cardiovascular disease
- Neurological & Neuropsychiatric disease

Impact of Hepatitis C

Hospitalization

- **Average costs, length of stay, and the proportion of in-hospital deaths in 2014 were all higher for stays involving hepatitis C than stays without hepatitis C.**
  - Compared with stays that did not involve hepatitis C, stays involving hepatitis C were, on average:
    Higher cost ($13,300 vs. $11,600)
  - Longer (5.8 vs. 4.7 days)
  - More likely to result in death in the hospital (2.9 vs. 2.2 percent of stays)
- In 2019 HCV was the leading cause of liver transplants in the U.S. confirming an estimated 2.7 million adults suffering from liver disease progression due to HCV

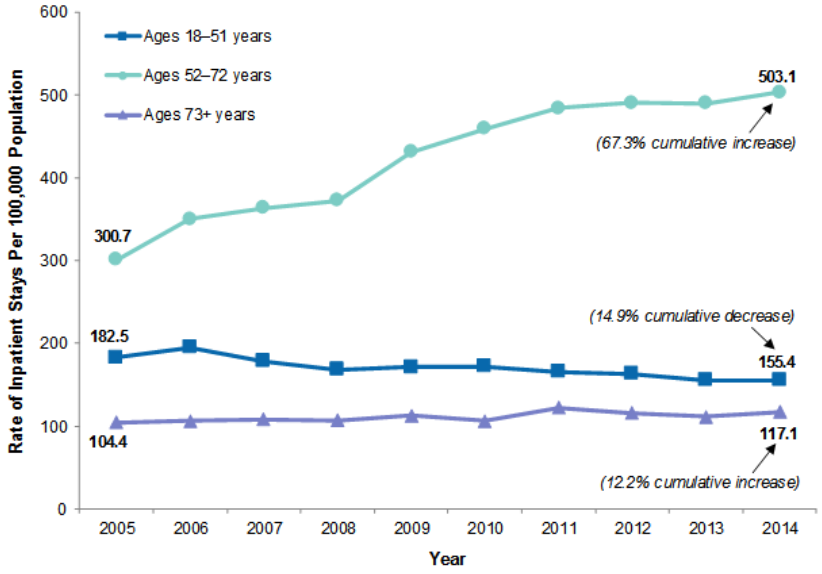
Table 1. Characteristics of inpatient stays involving hepatitis C by patient age group, 2014

Characteristic	Hepatitis C				No hepatitis C
	18-51 years	52-72 years	73+ years	All adults 18+ years	All adults 18+ years
Number of stays	225,900	383,200	27,800	636,900	29,115,100
Rate of stays (per 100,000 population)	155.4	503.1	117.1	259.7	11,870.5
Utilization characteristics					
Cost per stay, mean $	11,000	14,600	14,500	13,300	11,600
Length of stay, mean days	5.5	6.0	6.1	5.8	4.7
Died during hospital stay, %	1.5	3.5	5.3	2.9	2.2

Impact of Hepatitis C

Hospitalization - continued

Figure 2. Rate of inpatient stays involving hepatitis C by patient age group, 2005-2014



The rate of stays involving hepatitis C increased the most between 2005 and 2014 among patients aged 52-72 years (67.3 percent cumulative increase), followed by patients aged 73 years and older (12.2 percent increase). In contrast, the rate of stays involving hepatitis C decreased by 14.9 percent among patients aged 18-51 years over the same 10-year period

Impact of Hepatitis C

Patients with cirrhosis treated with DAA group had significantly lower liver-related health care costs compared with those who are untreated

Unadjusted Liver-related Costs per Person per Year Before & After Treatment in the Propensity Score-Matched Patients with and without Cirrhosis, by Treatment Status

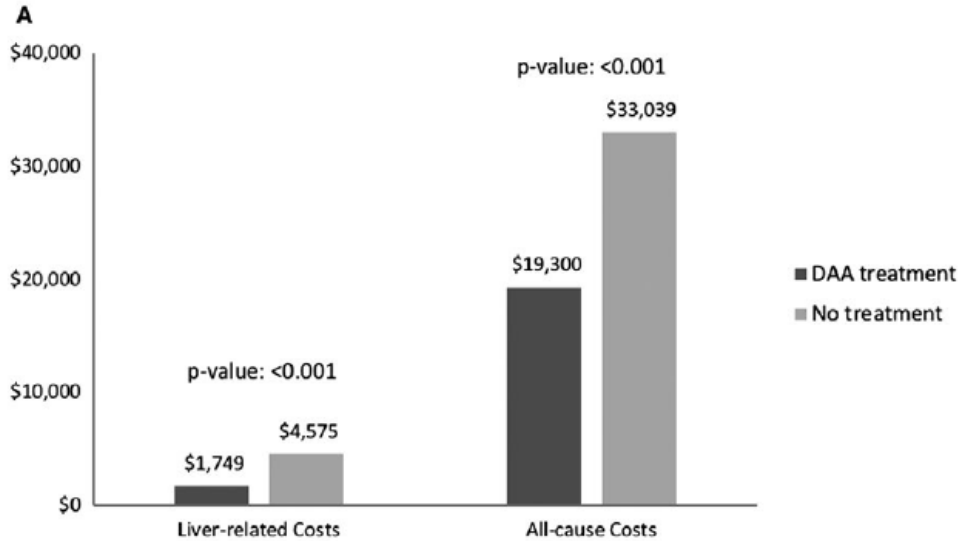
	Pretreatment		Posttreatment		
Health care costs*	Mean	SD	Mean	SD	*P* Value†
Liver-related costs, $					
Patients with cirrhosis (n = 682)					
DAA treatment (n = 341)	1742	2291	1863	8157	<0.001
No treatment (n = 341)	1450	2420	4079	23,623	
Patients without cirrhosis (n = 7382)					
DAA treatment (n = 3691)	1051	1506	737	3819	<0.001
No treatment (n = 3691)	315	825	436	6727	

In patients with cirrhosis (n = 682), liver-related total medical costs were significantly lower in the DAA group ($1863) compared with the untreated group ($4079; $P < 0.001$).

Patients without cirrhosis, (n = 7382), liver-related costs were significantly higher in the DAA group ($737) compared with the untreated group ($436; $P < 0.001$), which was driven by a higher rate of outpatient visits in the DAA group compared with the untreated group (3.2 vs. 0.7; $P < 0.001$; data not shown).

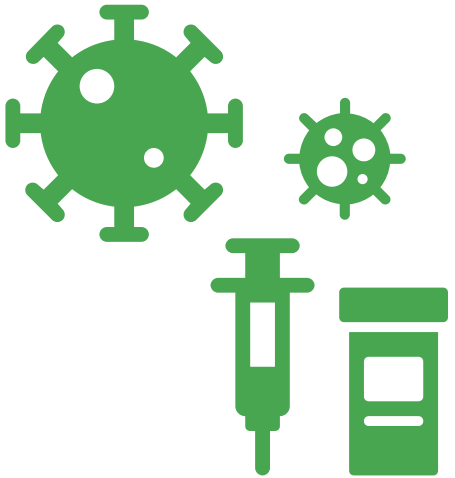
Impact of Hepatitis C

FIG. 2. Adjusted liver-related and all-cause costs per person per year by treatment status in propensity score–matched cohorts. (A)Medical costs in patients with cirrhosis.



- After adjusting for covariates, patients with cirrhosis in the DAA-treated group had a 72% decreased risk of developing hepatic cellular carcinoma compared with those who received no treatment (hazard ratio [HR], 0.28; 95% CI, 0.15-0.52)
- After adjusting for covariates, it was determined that patients without cirrhosis in the DAA-treated group had a 57% decreased risk of developing hepatic cellular carcinoma compared with those who received no treatment (HR, 0.43; 95% CI, 0.26-0.72).

HCV Therapy



Direct-acting Antiviral Agents & How they work!

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Nucleotide analog NS5B polymerase inhibitor (NS5B inhibitors)

- MOA: Inhibits HCV NS5B RNA-dependent RNA polymerase necessary for viral replication
- **BBW: HBV reactivation**
- ADRs: Fatigue headache, nausea, insomnia
- DDI: P-glycoprotein inducers (rifampin, carbamazepine, phenytoin,etc.,) amiodarone
- Consult notes: may cause hypoglycemia in diabetics

Protein inhibitor (NS5A inhibitors)

- MOA: Binds to N-terminus of NS5A protein blocking both viral RNA replication and virion assembly
- **BBW: HBV reactivation**
- ADRs: Headache, fatigue, nausea
- DDI: CYP3A inducers (rifampin, phenytoin, carbamazepine, St. John's wort)
- Consult notes: Bradycardia may occur when used with sofosbuvir & amiodarone

Protease inhibitor antiviral medications (NS3/4A inhibitors)

- MOA: Blocks proteolytic activity of NS3/4A serine protease stopping HCV replication
- **BBW: HBV reactivation**
- ADRs Photosensitivity and rash
- DDI: CYP3A4 inducers or inhibitors, cyclosporine
- Consult notes: Should not be used **without** other antiviral agents, take with food

Summary of Therapy Approach

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1st line HCV DAA Medications

DAA Trade Name	DAA Generic Name	Genotypes Treated
Harvoni®	ledipasvir/sofosbuvir	1,4,5,or 6
Zepatier®	elbasvir/grazoprevir	1,3,4
Epclusa®	sofosbuvir/velpatasvir	1,2,3,4,5, or 6
Vosevi™	sofosbuvir/velpatasvir/voxilaprevir	1,2,3,4,5, or 6
Mavyret™	glecaprevir/pibrentasvir	1,2,3,4,5, or 6

Treatment Naïve:

Genotype 1 Recommended Treatment Regimens **Without Cirrhosis**

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1a Treatment	Duration	1b Treatment	Duration
Daily fixed-dose combination of elbasvir/grazoprevir **(Zepatier®)** for patients without baseline NS5A RASs for elbasvir	12 weeks	Daily fixed-dose combination of elbasvir/grazoprevir **(Zepatier®)**	12 Weeks
Daily fixed-dose combination of glecaprevir/pibrentasvir **(Mavyret™)**	8 weeks	Daily fixed-dose combination of glecaprevir/pibrentasvir **(Mavyret™)**	8 weeks
Daily fixed-dose combination of ledipasvir/sofosbuvir **(Harvoni®)**	12 weeks	Daily fixed-dose combination of ledipasvir/sofosbuvir **(Harvoni®)**	12 weeks
Daily fixed-dose combination of sofosbuvir/velpatasvir **(Epclusa®)**	12 weeks	Daily fixed-dose combination of sofosbuvir/velpatasvir **(Epclusa®)**	12 weeks

Treatment Naïve:

Genotype 1 Recommended Treatment Regimens **With Compensated Cirrhosis**

1a Treatment	Duration	1b Treatment	Duration
Daily fixed-dose combination of elbasvir/grazoprevir **(Zepatier®)** for patients without baseline NS5A RASs[b] for elbasvir	12 weeks	Daily fixed-dose combination of elbasvir/grazoprevir **(Zepatier®)**	12 Weeks
Daily fixed-dose combination of ledipasvir/sofosbuvir **(Harvoni®)**	12 weeks	Daily fixed-dose combination of ledipasvir/sofosbuvir **(Harvoni®)**	12 weeks
Daily fixed-dose combination of sofosbuvir /velpatasvir **(Epclusa®)**	12 weeks	Daily fixed-dose combination of sofosbuvir/velpatasvir **(Epclusa®)**	12 weeks

Treatment Naïve:

Genotype 2 Recommended Treatment Regimens

Without Cirrhosis	Duration	With Compensated Cirrhosis	Duration
Daily fixed-dose combination of glecaprevir/pibrentasvir **(Mavyret™)**	8 weeks	Daily fixed-dose combination of sofosbuvir/velpatasvir **(Epclusa®)**	12 Weeks
Daily fixed-dose combination of sofosbuvir/velpatasvir **(Epclusa®)**	12 weeks		

Treatment Naïve:
Genotype 3 Recommended Treatment Regimens

Without Cirrhosis	Duration	With Compensated Cirrhosis	Duration
Daily fixed-dose combination of glecaprevir/pibrentasvir **(Mavyret™)**	8 weeks	Daily fixed-dose combination of sofosbuvir/velpatasvir **(Epclusa®)** for patients without baseline NS5A RAS Y93H for velpatasvir	12 Weeks
Daily fixed-dose combination of sofosbuvir/velpatasvir **(Epclusa®)**	12 weeks		

Treatment Naïve:
Genotype 4 Recommended Treatment Regimens

Without Cirrhosis	Duration	With Compensated Cirrhosis	Duration
Daily fixed-dose combination of elbasvir/grazoprevir **(Zepatier®)**	12 weeks	Daily fixed-dose combination of sofosbuvir/velpatasvir **(Epclusa®)**	12 Weeks
Daily fixed-dose combination of glecaprevir/pibrentasvir **(Mavyret™)**	8 weeks		
Daily fixed-dose combination of ledipasvir/sofosbuvir **(Harvoni®)**	12 weeks		
Daily fixed-dose combination of sofosbuvir/velpatasvir **(Epclusa®)**	12 weeks		

Treatment Naïve:
Genotype 5 or 6 Recommended Treatment Regimens

With & Without Cirrhosis	Duration
Daily fixed-dose combination of glecaprevir/pibrentasvir **(Mavyret™)**	8 weeks

Treatment Experienced:
Specific Treatment Regimen Failures (All Genotypes)

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- Glecaprevir/Pibrentasvir (Mavyret™)

Recommended Treatment	Duration
Daily fixed-dose combination of glecaprevir (300 mg)/pibrentasvir (120 mg)[b] plus daily sofosbuvir (400 mg) and weight-based ribavirin	16 weeks (IIa,B)
Daily fixed-dose combination of sofosbuvir (400 mg)/velpatasvir (100 mg)/voxilaprevir (100 mg)	12 weeks (IIa,B)
For patients with compensated cirrhosis, addition of weight-based ribavirin is recommended.	12 weeks (Iia,C)

- Sofosbuvir/Velpatasvir/Voxilaprevir (Vosevi™)

Recommended Treatment	Duration
Daily fixed-dose combination of glecaprevir (300 mg)/pibrentasvir (120 mg)[b] plus daily sofosbuvir (400 mg) and weight-based ribavirin	16 weeks (IIa,B)
Daily fixed-dose combination of sofosbuvir (400 mg)/velpatasvir (100 mg)/voxilaprevir (100 mg) plus weight-based ribavirin	24 weeks (IIa,B)

Peginterferon/Ribavirin-Experienced

Genotype 1 Recommended Treatment Regimens **Without Cirrhosis**

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1a Treatment	Duration	1b Treatment	Duration
Daily fixed-dose combination of elbasvir/grazoprevir **(Zepatier®)** for patients without baseline NS5A RASs for elbasvir	12 weeks	Daily fixed-dose combination of elbasvir/grazoprevir **(Zepatier®)**	12 Weeks
Daily fixed-dose combination of glecaprevir/pibrentasvir **(Mavyret™)**	8 weeks	Daily fixed-dose combination of glecaprevir/pibrentasvir **(Mavyret™)**	8 weeks
Daily fixed-dose combination of ledipasvir/sofosbuvir **(Harvoni®)**	12 weeks	Daily fixed-dose combination of ledipasvir/sofosbuvir **(Harvoni®)**	12 weeks
Daily fixed-dose combination of sofosbuvir/velpatasvir **(Epclusa®)**	12 weeks	Daily fixed-dose combination of sofosbuvir/velpatasvir **(Epclusa®)**	12 weeks

Peginterferon/Ribavirin-Experienced

Genotype 1 Recommended Treatment Regimens **With Cirrhosis**

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1a Treatment	Duration	1b Treatment	Duration
Daily fixed-dose combination of elbasvir/grazoprevir **(Zepatier®)** for patients without baseline NS5A RASs for elbasvir	12 weeks	Daily fixed-dose combination of elbasvir/grazoprevir **(Zepatier®)**	12 Weeks
Daily fixed-dose combination of sofosbuvir/velpatasvir **(Epclusa®)**	12 weeks	Daily fixed-dose combination of sofosbuvir/velpatasvir **(Epclusa®)**	12 weeks

NS3/4A Protease Inhibitor (Telaprevir, Boceprevir, or Simeprevir) + Peginterferon/Ribavirin Treatment-Experienced:

Genotype 1 Recommended Treatment Regimens **Without Cirrhosis**

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Without Cirrhosis	Duration	With Compensated Cirrhosis	Duration
Daily fixed-dose combination of ledipasvir/sofosbuvir **(Harvoni®)**	12 weeks	Daily fixed-dose combination of sofosbuvir/velpatasvir **(Epclusa®)**	12 Weeks
Daily fixed-dose combination of sofosbuvir/velpatasvir **(Epclusa®)**	12 weeks		

Non-NS5A Inhibitor (NS5B), Sofosbuvir-Containing Regimen-Experienced:

Genotype 1 Recommended Treatment Regimens **Without Cirrhosis**

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Without Cirrhosis	Duration	With Compensated Cirrhosis	Duration
Daily fixed-dose combination of sofosbuvir/velpatasvir /voxilaprevir **(Vosevi™)** for genotype 1a patients	12 weeks	Daily fixed-dose combination of sofosbuvir/velpatasvir /voxilaprevir **(Vosevi™)** for genotype 1a patients	12 Weeks

NS5A Inhibitor DAA-Experienced (Excluding Glecaprevir/Pibrentasvir Failures):

Genotype 1 Recommended Treatment Regimens **With or Without Cirrhosis**

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Treatment	Duration
Daily fixed-dose combination of sofosbuvir /velpatasvir /voxilaprevir **(Vosevi™)**	12 weeks

Peginterferon/Ribavirin-Experienced

Genotype 2 Recommended Treatment Regimens

Without Cirrhosis	Duration	With Compensated Cirrhosis	Duration
Daily fixed-dose combination of glecaprevir/pibrentasvir **(Mavyret™)**	8 weeks	Daily fixed-dose combination of sofosbuvir/velpatasvir **(Epclusa®)**	12 Weeks
Daily fixed-dose combination of sofosbuvir/velpatasvir **(Epclusa®)**	12 weeks		

DAA-Experienced (Including NS5A Inhibitors Except Glecaprevir/Pibrentasvir Failures):
Genotype 2 Recommended Treatment Regimens **With or Without Compensated Cirrhosis**

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Sofosbuvir + Ribavirin-Experienced, Genotype 2 Patients, With or Without Compensated Cirrhosis	Duration	Sofosbuvir + NS5A Inhibitor-Experienced (Excluding Glecaprevir/Pibrentasvir Failures)	Duration
Daily fixed-dose combination of sofosbuvir/velpatasvir **(Epclusa®)**	12 weeks	Daily fixed-dose combination of sofosbuvir/velpatasvir /voxilaprevir **(Vosevi™)**	12 Weeks

Peginterferon/Ribavirin-Experienced

Genotype 3 Recommended Treatment Regimens

Without Cirrhosis	Duration	With Compensated Cirrhosis	Duration
Daily fixed-dose combination of sofosbuvir/velpatasvir **(Epclusa®)** for patients without baseline Y93H RAS to velpatasvir	12 weeks, I A	Daily fixed-dose combination of glecaprevir/pibrentasvir **(Mavyret™)**	16 Weeks, IIa, B

DAA-Experienced (Including NS5A Inhibitors Except Glecaprevir/Pibrentasvir Failures):
Genotype 3 Recommended Treatment Regimens **With or Without Compensated Cirrhosis**

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Sofosbuvir + Ribavirin-Experienced (± Peginterferon)	Duration	DAA-Experienced (Including NS5A Inhibitors Except Glecaprevir/Pibrentasvir Failures)	Duration
Daily fixed-dose combination of sofosbuvir/velpatasvir /voxilaprevir **(Vosevi™)**	12 weeks I, B	Daily fixed-dose combination of sofosbuvir/velpatasvir /voxilaprevir **(Vosevi™)**	12 Weeks I, A

Peginterferon/Ribavirin-Experienced

Genotype 4 Recommended Treatment Regimens **With & Without Cirrhosis**

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Without Cirrhosis	Duration	With Cirrhosis	Duration
Daily fixed-dose combination of sofosbuvir/velpatasvir **(Epclusa®)**	12 weeks	Daily fixed-dose combination of sofosbuvir/velpatasvir **(Epclusa®)**	12 Weeks

DAA-Experienced (Including NS5A Inhibitors Except Glecaprevir/Pibrentasvir Failures):

Genotype 4 Recommended Treatment Regimens **With or Without Compensated Cirrhosis**

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Treatment	Duration
Daily fixed-dose combination of sofosbuvir/velpatasvir /voxilaprevir **(Vosevi™)**	12 weeks

Peginterferon/Ribavirin-Experienced

Genotype 5 or 6 Recommended Treatment Regimens **With or Without Cirrhosis**

Without Cirrhosis	Duration	With Cirrhosis	Duration
Daily fixed-dose combination of glecaprevir/pibrentasvir **(MAVYRET™)** for patients without cirrhosis	8 weeks (IIa,B)	Daily fixed-dose combination of glecaprevir /pibrentasvir **(MAVYRET™)** for patients with compensated cirrhosis	12 Weeks (I,B)

Treatment	Duration
Daily fixed-dose combination ledipasvir /sofosbuvir **(HARVONI®)**	8 weeks (IIa, B)
Daily fixed-dose combination of sofosbuvir//velpatasvir **(EPCLUSA®)**	8 weeks (IIa, B)

DAA-Experienced (Including NS5A Inhibitors Except MAVYRET™ Failures):

Genotype 5 or 6 Recommended Treatment Regimens With or Without Compensated Cirrhosis

Treatment	Duration
Daily fixed-dose combination of sofosbuvir /velpatasvir/voxilaprevir **(VOSEVI™)**	12 weeks (IIa,B)

Special populations

- Pediatric patients
- HIV/HCV coinfection patients
- Decompensated cirrhosis
- HCV post liver transplantation
- Severe renal impairment
- Post kidney transplantation

Conclusion

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- New testing recommendations will increase the spectrum of individuals screened for HCV, enabling the systems ability to detect and treat patients in a timely fashion to reduce the incidence & prevalence of HCV transmission.
- HCV has proven to be a burdensome disease on both patient and health care system, with the new therapies and intent of treatment to cure, a vast decrease in the clinical and economic of strain both parties will occur.
- Medication Adherence rates amongst HCV individuals in real world scenarios may vary in comparison to the expected SVR as approximately 10-20% of patients are lost to follow-up visits and in a few amount of cases re-treatment is needed to achieve the desired SVR
- Through thorough patient profile reviews community pharmacist play a major role in patient safety and adherence as many of the new DAAs interact with various other medication regimens which could influence compliance rates amongst those experiencing undesired side effects.
- The increase of substance abuse programs play a major role in assisting with the decrease in the number of re-infection cases amongst those likely to be re-infected through the use of injectable drugs.

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Thank you!

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Questions?