THE A, B, Cs OF HEPATITIS B AND C

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OBJECTIVES

- Interpret Hepatitis B and Hepatitis C labs from baseline to completion of therapy
- Stage levels of liver fibrosis and how it correlates to follow-up plans
- Select appropriate antiviral therapy for Hepatitis B and C infection based on patient specific factors

ABBREVIATIONS

Abbreviation	Term
HAV HBV HCV	Hepatitis A Hepatitis B Hepatitis C
F0, F1, F2, F3, F4	Fibrosis Score
SVR12	Sustained Virologic Response at 12 weeks
EOT	End of therapy/treatment
CTP	Child-Turcotte-Pugh
PRS	Pegylated-Interferon, Ribavirin, and Sofosbuvir-containing products
HCC	Hepatocellular Carcinoma
DAA	Direct Acting Antivirals

HEPATITIS B

HBV PANEL COMPONENTS

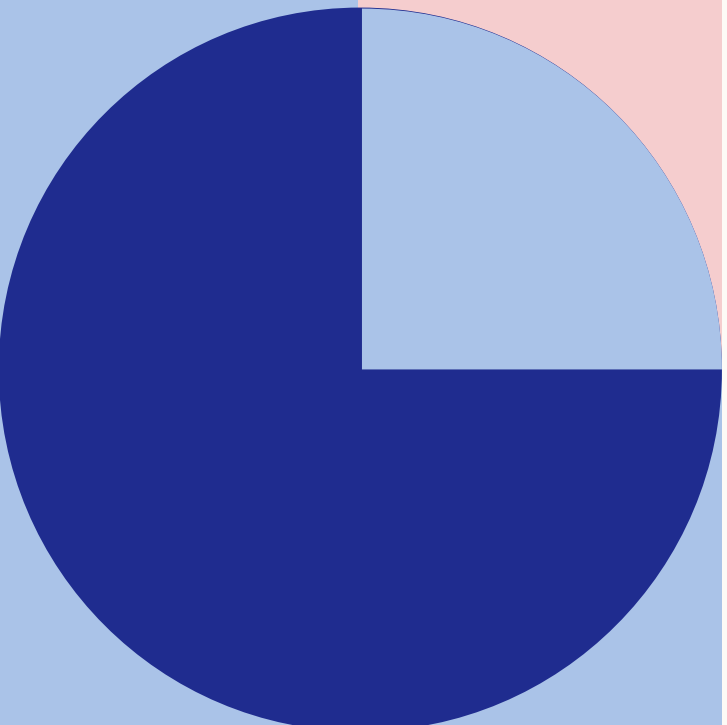
Surface Antigen	Core Antibody	Surface Antibody
HBsAg	Anti-HBc	Anti-HBs

HEPATITIS B

HBV Surface Ag HBV Core Ab HBV Surface Ab	Negative Negative Negative	Susceptible to Hepatitis B

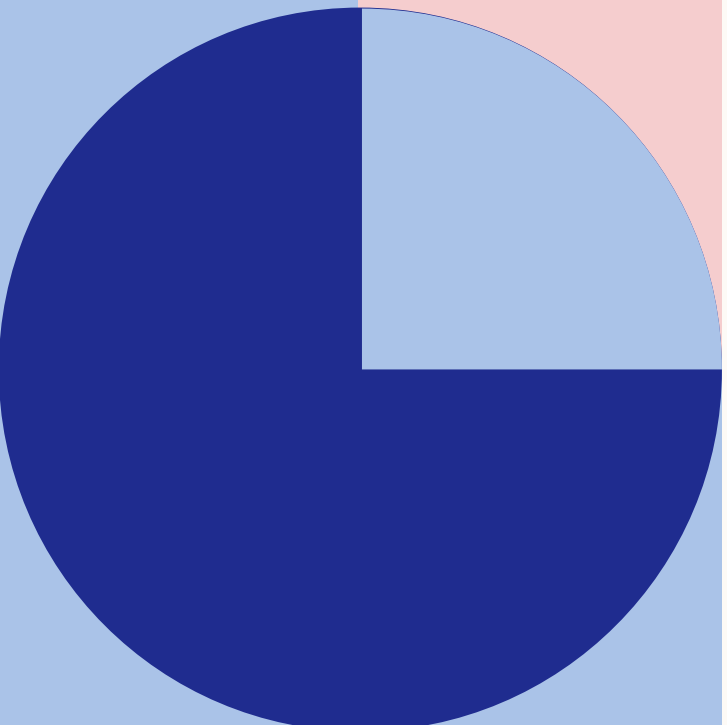
HEPATITIS B

HBV Surface Ag HBV Core Ab HBV Surface Ab	Negative Negative Negative	Susceptible to Hepatitis B
HBV Surface Ag HBV Core Ab HBV Surface Ab	Negative Reactive Reactive	Immune due to natural infection



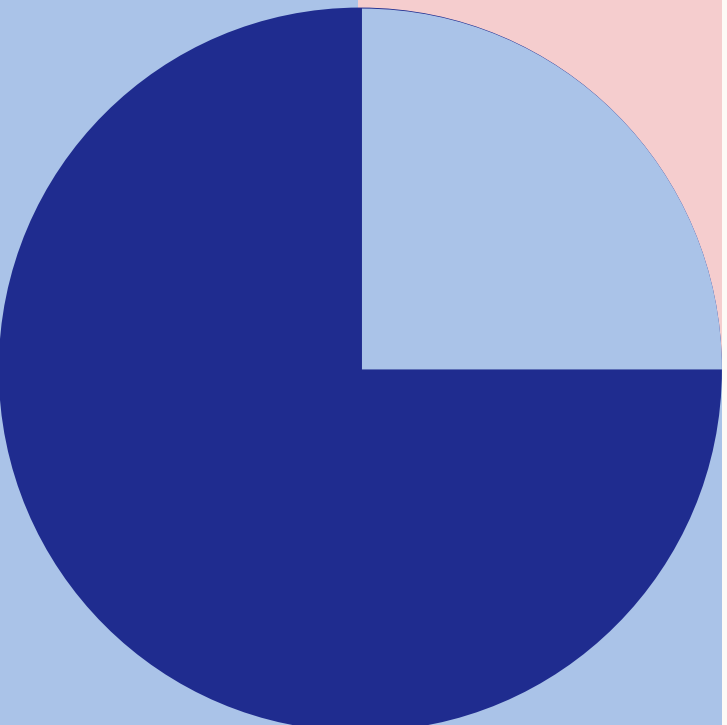
HEPATITIS B

HBV Surface Ag HBV Core Ab HBV Surface Ab	Negative Negative Negative	Susceptible to Hepatitis B
HBV Surface Ag HBV Core Ab HBV Surface Ab	Negative Reactive Reactive	Immune due to natural infection
HBV Surface Ag HBV Core Ab HBV Core IgM Ab HBV Surface Ab	Reactive Reactive Reactive Negative	Acute Infection



HEPATITIS B

HBV Surface Ag HBV Core Ab HBV Surface Ab	Negative Negative Negative	Susceptible to Hepatitis B
HBV Surface Ag HBV Core Ab HBV Surface Ab	Negative Reactive Reactive	Immune due to natural infection
HBV Surface Ag HBV Core Ab HBV Core IgM Ab HBV Surface Ab	Reactive Reactive Reactive Negative	Acute Infection
HBV Surface Ag HBV Core Ab HBV Core IgM Ab HBV Surface Ab	Reactive Reactive Negative Negative	Chronic Infection



HEPATITIS B

Immunize

FOCUS

Immunize

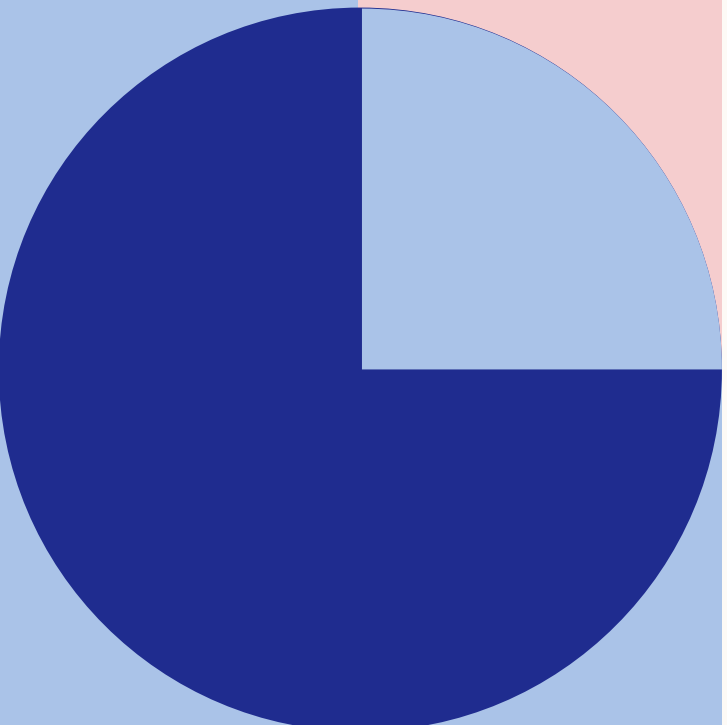
HBV Surface Ag HBV Core Ab HBV Surface Ab	Negative Negative Negative	Susceptible to Hepatitis B
HBV Surface Ag HBV Core Ab HBV Surface Ab	Negative Reactive Reactive	Immune due to natural infection
HBV Surface Ag HBV Core Ab HBV Core IgM Ab HBV Surface Ab	Reactive Reactive Reactive Negative	Acute Infection
HBV Surface Ag HBV Core Ab HBV Core IgM Ab HBV Surface Ab	Reactive Reactive Negative Negative	Chronic Infection
HBV Surface Ag HBV Core Ab HBV Surface Ab	Negative Reactive Negative	1. Resolved infection 2. False positive HBV Core Ab 3. Low level infection 4. Resolving Acute infection

PATIENT CASE 1

AB is a 50 y/o F who recently reported to her PCP to establish care with the below hepatitis panel results.

Hepatitis B Surface Antigen: reactive
Hepatitis B Core Antibody: reactive
Hepatitis B Surface Antibody: non-reactive

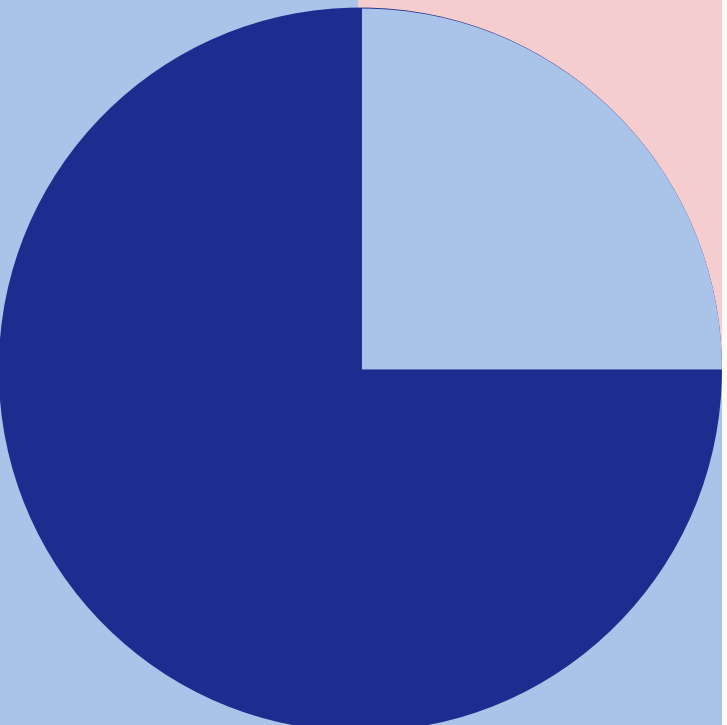
AST: 120 mg/dL
ALT: 130 mg/dL
Alk Phos: 157
Total Bili: 1.7 mg/dL



PATIENT CASE 1

How would you interpret the Hepatitis Panel?

A. Patient immune based on vaccination
B. Unable to determine results
C. Patient immune due to natural infection
D. Patient currently infected (either acutely or chronically)

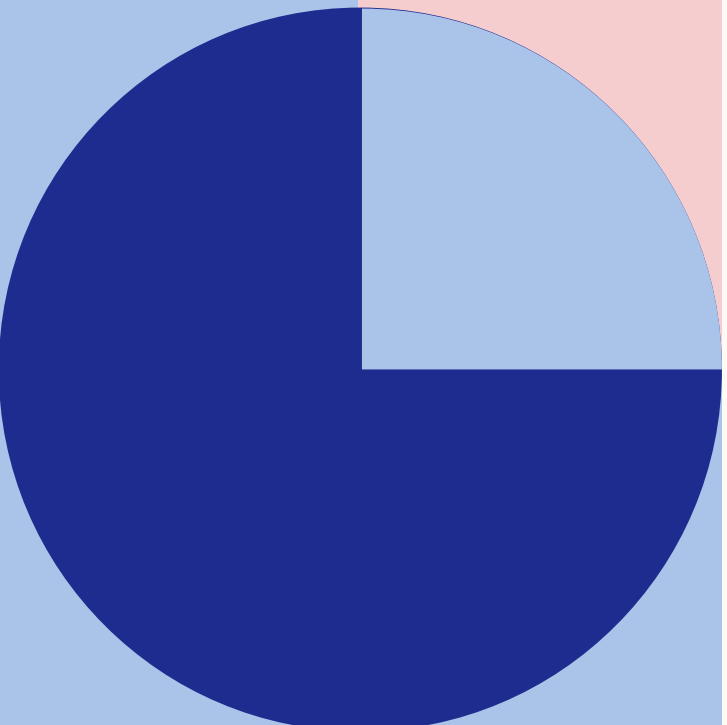


Hepatitis B Surface Antigen: reactive
Hepatitis B Core Antibody: reactive
Hepatitis B Surface Antibody: non-reactive

DIAGNOSIS

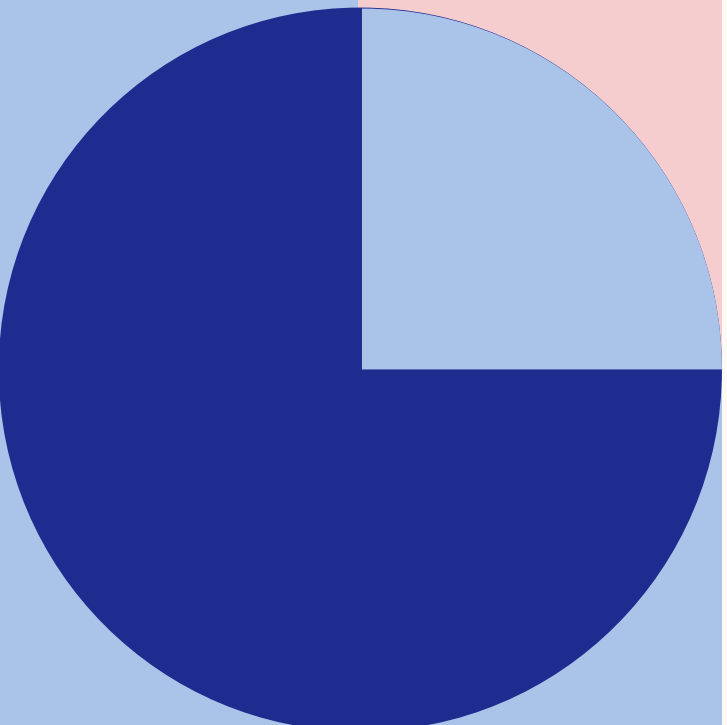
After positive HBsAg further testing required:

- HBV DNA = viral load
- HBeAg-positive : >20,000 IU/mL
- HBeAg-negative: <2,000 IU/mL



CLASSIFICATION
FIBROSIS

- Liver Biopsy – gold standard and most invasive
- Fibroscan (transient elastography)
  - Limited supply
- Fibrosure (lab)



Scoring

F0 – no fibrosis present
F1 – minimal fibrosis
F2 – some fibrosis
F3 – moderate fibrosis
F4 – severe fibrosis

Xiao H. Comparison of diagnostic accuracy of magnetic resonance elastography and Fibroscan for detecting liver fibrosis in chronic hepatitis B patients: A systematic review and meta-analysis. PLoS One. 2017

Carlson JJ. An evaluation of the potential cost-effectiveness of non-invasive testing strategies in the diagnosis of significant liver fibrosis. J Gastroenterol Hepatol. 2009

CLASSIFICATION
GENOTYPE

10 genotypes A through J

- **A, B, and C are the most prevalent**
- **A –** best response to PEG-IFN therapy
- **B** – slower rate of progression, lower rate of HCC, and faster HBeAg seroconversion rate
- **C** – slowest HBeAg seroconversion and higher rate of HCC

Seroconversion:	When HBV is cleared and no longer detected by blood (I.e., HBsAg negative)

Ghany MG. Hepatitis C guidance 2019 update: American Association for the study of liver diseases–infectious diseases society of america recommendations for testing, managing, and treating hepatitis C virus infection. *Hepatology*. 2022

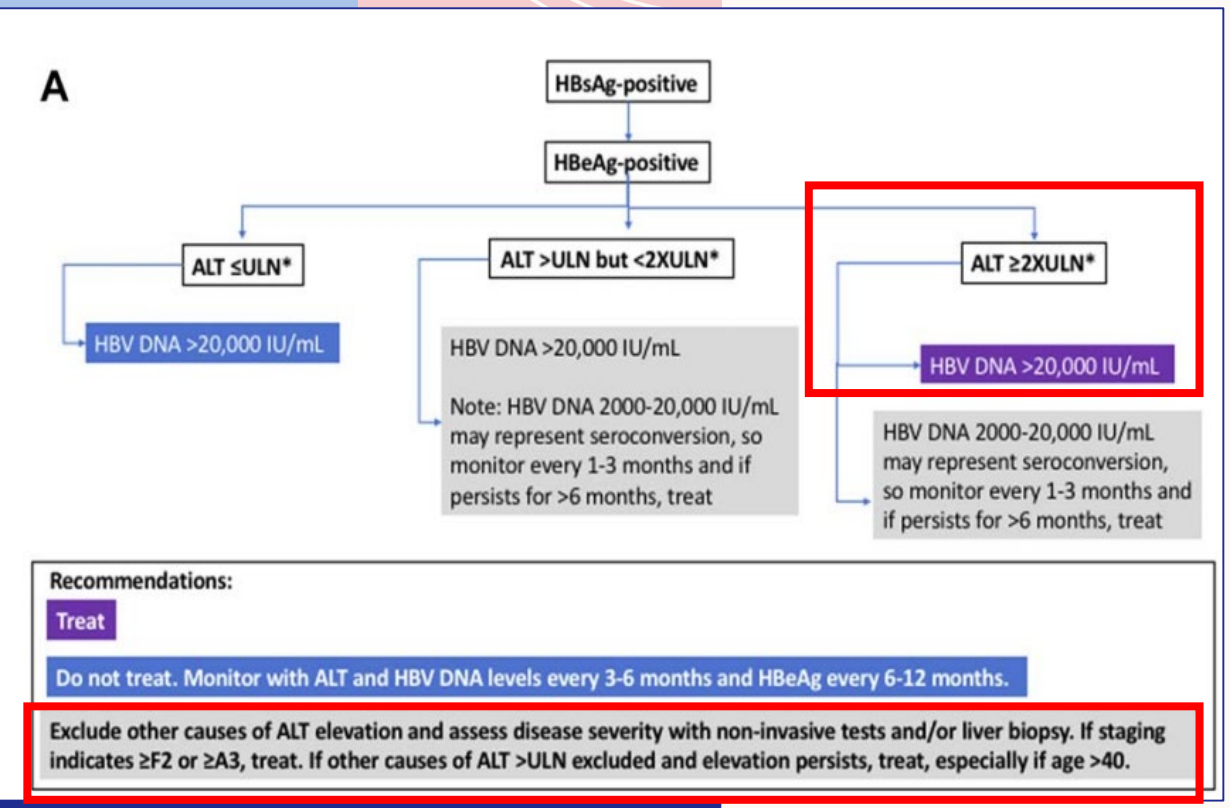
HBV TREATMENT

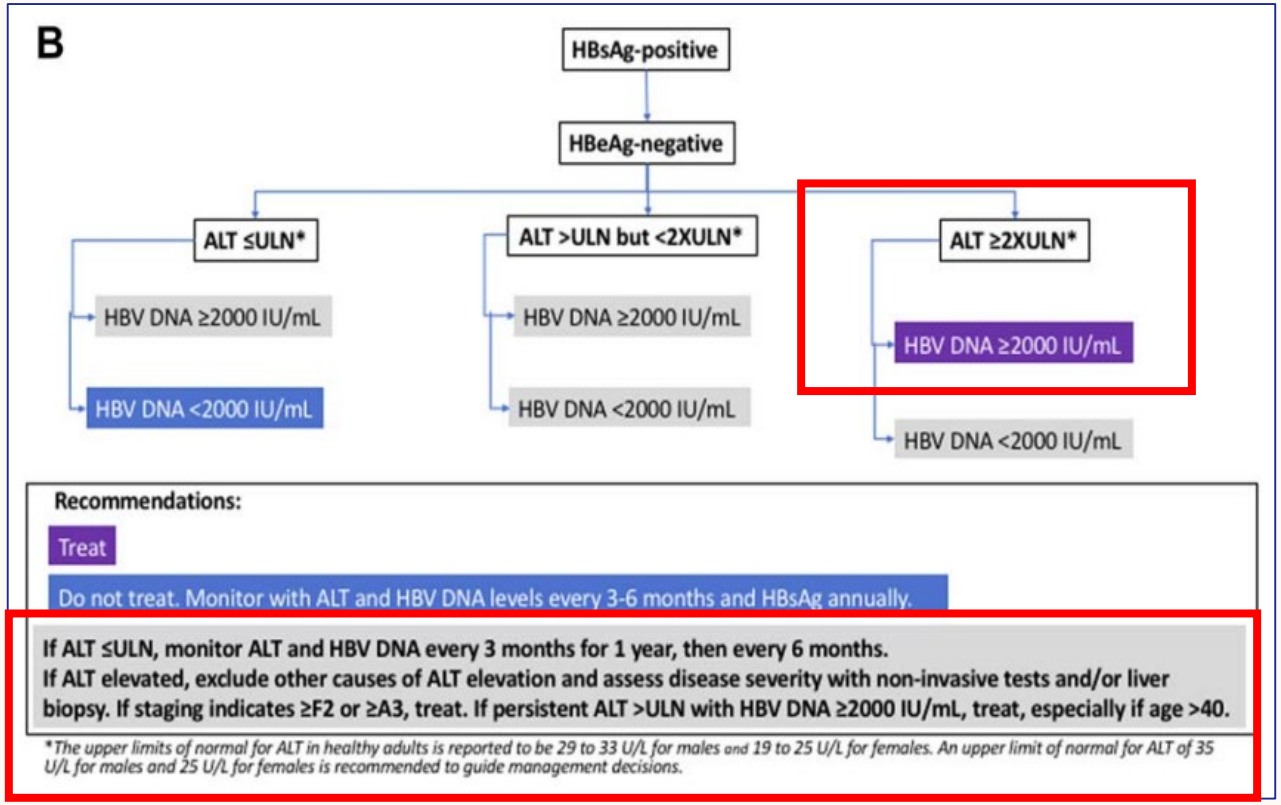
HBV GOALS

- Reduce all-cause mortality and liver-related health adverse consequences
- Reduce progression to end-stage liver disease and hepatocellular carcinoma
- Reduce transmission of active HBV infection
- Control > eradication of HBV

Ghany MG. Hepatitis C guidance 2019 update: American Association for the study of liver diseases–infectious diseases society of america recommendations for testing, managing, and treating hepatitis C virus infection. *Hepatology*. 2022

TO TREAT OR NOT TO TREAT

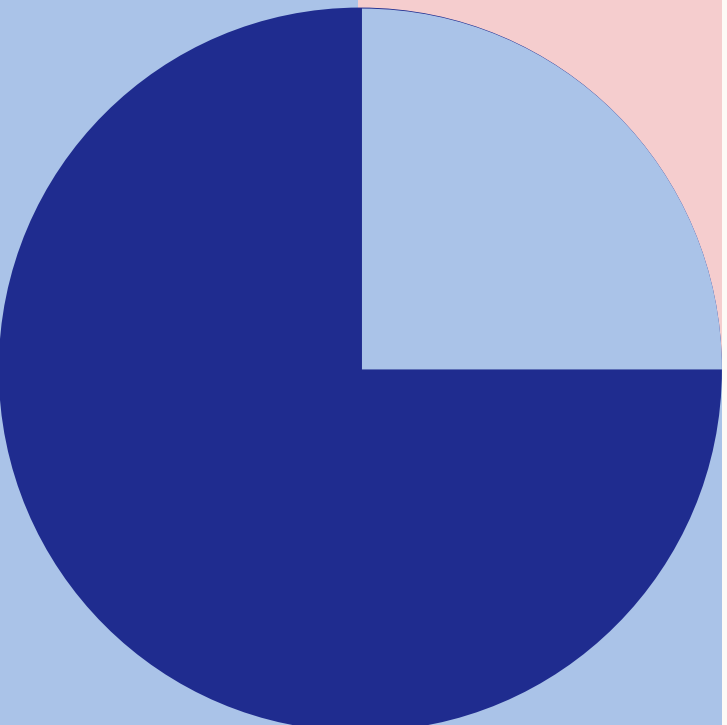




TO TREAT OR NOT TO TREAT

Regardless of lab values:

- Pregnant patients with HBV DNA > 200,000 IU/mL
- HIV/HBV Co-infection
- Chronic HBV receiving HIV PrEP
- Persons at risk for HBV reactivation



HBV TREATMENT
PREFERRED ANTIVIRALS

PEG-IFN

Tenofovir

Entecavir

PEGYLATED INTERFERON

"Finite therapy" for a designated time period of 48 weeks

- **Pegasys (PEG-IFN)**
- **Dosing:** 180 mcg SQ weekly for 48 weeks
- **Side effects:** flu-like symptoms, fatigue, mood disturbances, autoimmune disorders in adults.
- **Hepatic/Renal impairment:** dose adjustment in CrCl <30 mL/min and ALT 5x ULN.
  - Discontinue with ALT > 10 x ULN
- Drug interactions
  - **Theophylline** – increase theophylline concentration (monitor levels more frequently)
  - **Methadone** – increase methadone concentration (monitor for signs of toxicity)
  - **Nucleoside analogues** – concern for neutropenia, hepatic failure, myelotoxicity depending on the agent.

TENOFOVIR (TDF)

- **Dosing:** 300 mg daily (Viread or TDF) or 25 mg daily (Vemlidy – TAF)
- **Side effects**: nephropathy, lactic acidosis, osteomalacia, Fanconi syndrome
- **Renal impairment**: dose adjustment in CrCl <50 mL/min. Contraindicated in CrCl <10 mL/min or dialysis
  - No hepatic dosing adjustments
  - Dialysis – TAF
- Monitoring:
  - Serum Cr, serum phosphate, urine glucose and protein annually
  - Consider bone density study at baseline and during treatment for high-risk patients.
- Safe to use in pregnancy - TDF
- Preferred in HIV coinfection

TENOFOVIR (TDF)

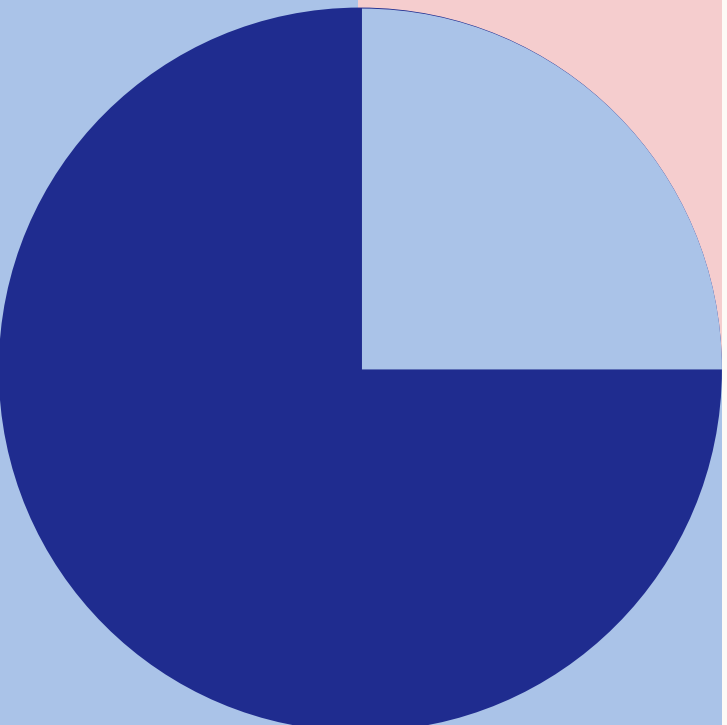
- **Drug interactions**
  - **Didanosine** – increased didanosine concentration can lead to didanosine-associated adverse reactions
    - (i.e., pancreatitis, neuropathy)
  - **Atazanavir** – increase TDF concentration
  - **Lopinavir/Ritonavir** - increase TDF concentration
  - Medications that reduce renal function or compete for tubular secretion can increase concentration TDF
    - Ex: cidofovir, acyclovir, valacyclovir, ganciclovir, and valganciclovir

ENTECAVIR

- **Baraclude (Entecavir)**
- **Dosing:** 0.5 mg daily treatment naïve; 1 mg daily for decompensated
- **Side effects:** lactic acidosis (decompensated cirrhosis only)
- **Hepatic/Renal impairment:** dose adjustment in CrCl <50 mL/min. Contraindicated in CrCl <10 mL/min or dialysis
  - No hepatic dosing adjustments
- Test for HIV at treatment initiation
- Drug interactions:
  - Coadministration **with drugs that reduce renal function** or compete for active tubular secretion **may increase serum concentrations of either entecavir or the coadministered drug.**

FOLLOW-UP/ MONITORING

- Treatment: Continue indefinitely
- Monitor at least every 6 months
- More frequent monitoring (i.e., every 3 months) when ALT levels are elevated



TREATMENT SELECTION

Renal Dysfunction/Dialysis
TAF

HIV Coinfection
TAF TDF

Pregnancy
TDF

Fracture Risk
Entecavir PEG-IFN

Autoimmune Disorder
TAF TDF Entecavir

Decompensated Cirrhosis
TAF TDF Entecavir

PATIENT CASE 1

AB is a 50 y/o F with a PMH of HTN, HLD, osteomalacia (with most recent wrist fracture 1 year ago), and hypothyroidism who was recently diagnosed with Hepatitis B is returning to your clinic for discussing therapy initiation.

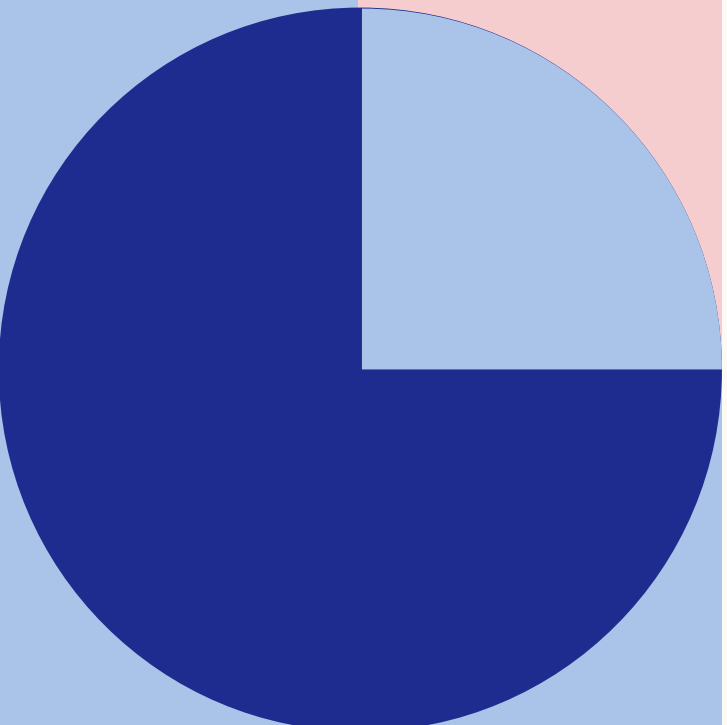
Hepatitis B Surface Antigen: reactive
Hepatitis B Core Antibody: reactive
Hepatitis B Surface Antibody: non-reactive
Hepatitis e-Antigen: positive >20,000
HBV DNA: 400,000 IU/mL

AST: 90 mg/dL
ALT: 120 mg/dL
Alk Phos: 157
Total Bili: 1.7 mg/dL
SCr: 0.89 (CrCl >100 mL/min)
eGFR: 80 mg/dL

PATIENT CASE 1

Considering AB's PMH and labs, what therapy would be preferred to initiate at this time?

A. Initiate Entecavir
B. Initiate TAF
C. Initiate TDF
D. Initiate Lamivudine



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HEPATITIS C

DIAGNOSIS

Positive Hepatitis C Ab on screen

- Qualitative: reactive/non-reactive
- Quantitative : positive if >11
- **HCV RNA = viral load**
  - Non-detectable – cleared virus
  - Elevated – active infection

Acute v. Chronic HCV Infection

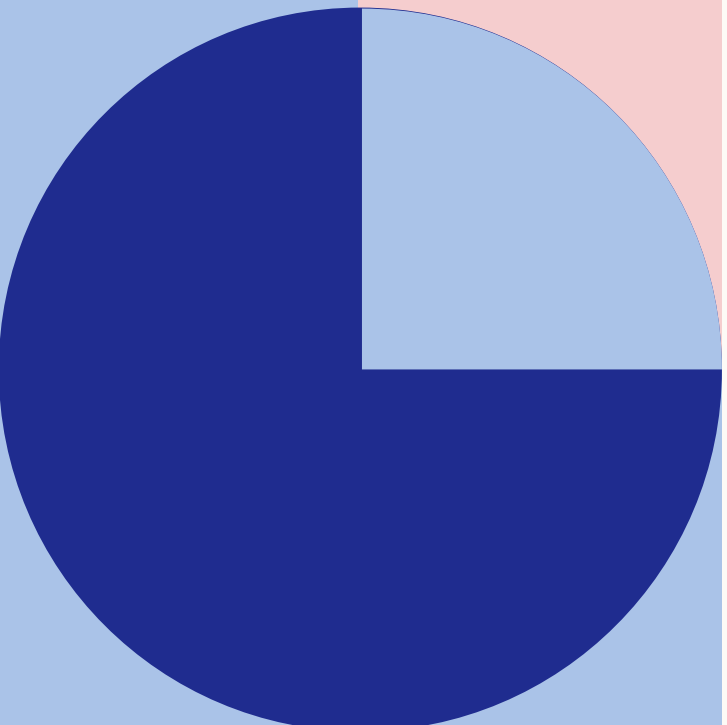
- 30-40% acute HCV infections
  - Spontaneous Resolution
- 2019 AASLD Guidelines: Test and Treat

Ghany MG. Hepatitis C guidance 2019 update: American Association for the study of liver diseases–infectious diseases society of america recommendations for testing, managing, and treating hepatitis C virus infection. *Hepatology*. 2022

CLASSIFICATION
GENOTYPE

6 genotypes

- **1a /1b** – Most common genotype and most data to treat
- **2a/2b**
- **3** – Most difficult to treat and fastest progression
- **4** – 1-2% of all HCV infections
- **5** – Uncommon in US and
  - Most common in South Africa
- **6** – Uncommon in US and
  - Most common in Southeast Asia



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HCV TREATMENT

HCV GOALS

- Reduce all-cause mortality and liver-related health adverse consequences
- Reduce progression to end-stage liver disease and hepatocellular carcinoma
- Achieve virologic cure as evidenced by a sustained virologic response (SVR)
- Reduce transmission of active HCV infection

Ghany MG. Hepatitis C guidance 2019 update: American Association for the study of liver diseases–infectious diseases society of america recommendations for testing, managing, and treating hepatitis C virus infection. *Hepatology*. 2022

HCV TREATMENT
DIRECT-ACTING ANTIVIRALS

Mavyret

Epclusa

Harvoni

Vosevi

MAVYRET

Glecaprevir **Pibrentasvir**

- **Dosing:** 3 tablets once daily
- **Side effects**: headache and fatigue and nausea (take with food)
- **Contraindications:** Co-administration with atazanavir and rifampin
- **Hepatic impairment**: CONTRAINDICATED in Child-Pugh B and C

Mavyret [prescribing information]. North Chicago, IL: AbbVie Inc.; June 2021.

MAVYRET

Glecaprevir | **Pibrentasvir**

Treatment-naïve:

- Genotypes 1 thru 6
  - w/ or w/o compensated (Child-Pugh A) cirrhosis x 8 weeks

Treatment-experienced:

- Genotypes 1,2,4,5,6
  - Previous use with with IFN, ribavirin and/or SOF regimens, but NOT NS3/4a or NS5a regimens : x 16 weeks
  - PRS: w/o cirrhosis x 8 weeks
  - PRS: w/ compensated cirrhosis (Child-Pugh A) x 12 weeks
- Genotype 3
  - w/o or w/ cirrhosis x 16 weeks

Mavyret [prescribing information]. North Chicago, IL: AbbVie Inc.; June 2021.

MAVYRET

Glecaprevir **Pibrentasvir**

Drug interactions:

- ↑ Digoxin – routine monitoring on concomitant therapy
- Anticonvulsants – check; hold if possible or switch
- Rifampin
- Ethinyl-estradiol containing contraceptive
- St. John's Wort – hold
- Statins - monitor LFT elevation; hold if possible
  - rosuvastatin 10 mg qd (do not exceed)
  - ↓ pravastatin 50%

Mavyret [prescribing information]. North Chicago, IL: AbbVie Inc.; June 2021.

EPCLUSA

Sofosbuvir **Velpatasvir**

- **Dosing:** 1 tablet once daily w/ or w/o food
- **Side effects**: headache and fatigue and weakness
- **No renal or hepatic dose adjustments**
- **Pangenotypic**

Treatment-naïve:

- w/o cirrhosis and with compensated cirrhosis (Child-Pugh A)
  - EPCLUSA x12 weeks
- w/ decompensated cirrhosis (Child Pugh B and C)
  - + **Ribavirin** x12 weeks
  - If ribavirin ineligible: x 24 weeks

Treatment-experienced:

- Previous PEG+RBV: x12 weeks

EPCLUSA [prescribing information]. Foster City, CA: Gilead Sciences, Inc; April 2022

EPCLUSA

Sofosbuvir **Velpatasvir**

Drug interactions:

- Bradycardia with **amiodarone** and **beta blocker** co-administration
- ↑ Digoxin – routine monitoring on concomitant therapy
- Acid reducing agents (PPI/H2A/antacids)
  - **Antacids** : separate by 4 hours
  - **H2RA**: switch to famotidine
    - Max: 40 mg bid
    - either take with Epclusa OR separate by 12 hours
  - **PPI**: switch to omeprazole take Epclusa 4 hours before
    - Max 20 mg once daily
- Anticonvulsants – check; hold if possible or switch
- Statins - monitor LFT elevation
  - Hold or transition to rosuvastatin 10 mg qd (do not exceed)
- St. John's Wort – hold

EPCLUSA [prescribing information]. Foster City, CA: Gilead Sciences, Inc; April 2022

HARVONI

Sofosbuvir **Ledipasvir**

- **Dosing:** 1 tablet once daily w/ or w/o food
- **Side effects:** headache and fatigue and weakness
- **No adjustment in renal or hepatic impairment**
- **Genotypes:** 1,4,5,6 only

Treatment-naïve:

- w/ or w/o cirrhosis: x12 weeks
- **8 weeks of therapy if:**
  - Genotype 1 (a or b)
  - < 6 mill viral load at baseline
  - Not of African descent
  - No cirrhosis

Treatment-experienced:

- Treatment-experienced PEG +RBV w/o cirrhosis: 12 weeks
- Treatment-experienced w/ cirrhosis + ribavirin (600 mg): 12 weeks
  - If ribavirin ineligible x 24 weeks

HARVONI [prescribing information]. Foster City, CA: Gilead Sciences, Inc; March 2020

HARVONI

Sofosbuvir | **Ledipasvir**

Drug interactions:

- Bradycardia with **amiodarone** and **beta blocker** co-administration
- ↑ Digoxin – routine monitoring on concomitant therapy
- Acid reducing agents (PPI/H2A/antacids)
  - **Antacids** : separate by 4 hours
  - **H2RA**: either with Harvoni OR separate by 12 hours
    - Max: famotidine 40 mg bid or equivalent
  - **PPI**: switch to Omeprazole
    - Take with Harvoni on empty stomach
- Anticonvulsants – check; hold if possible or switch
- Statins - monitor LFT elevation
  - Hold or transition to pravastatin dose equivalent
  - Atorvastatin: monitor for myopathy and rhabdomyolysis
- St. John's Wort – hold

HARVONI [prescribing information]. Foster City, CA: Gilead Sciences, Inc; March 2020

VOSEVI

Sofosbuvir **Velpatasvir** **Voxilaprevir**

SALVAGE THERAPY
(only used in treatment-experienced)

- **Dosing:** 1 tablet once daily w/ food
- **Side effects:** headache, fatigue, diarrhea, and nausea
- **Hepatic Impairment:** CONTRAINDICATED in Child Pugh B and C

Treatment-experienced: 12 weeks of therapy

- Previous treatment: 1a and 3 infection that previously treated with HCV regimen containing SOF w/o an NS5A inhibitor ("-asvir")
- Previous treatment genotype 1 thru 6 with an NS5a inhibitor ("-asvir")

VOSEVI [prescribing information]. Foster City, CA: Gilead Sciences, Inc; July 2017

VOSEVI

Sofosbuvir **Velpatasvir** **Voxilaprevir**

Drug interactions:

- Bradycardia with **amiodarone** and **beta blocker** co-administration
- ↑ Digoxin – routine monitoring on concomitant therapy
- Acid reducing agents (PPI/H2A/antacids)
  - **Antacids** : separate by 4 hours
  - **H2RA**: either taken with Vosevi or staggered
    - MAX: famotidine 40 mg bid
  - **PPI**: transition to omeprazole with Vosevi
- Anticonvulsants – check; hold if possible or switch
- Statins - monitor LFT elevation
  - Do not exceed pravastatin 40 mg

VOSEVI [prescribing information]. Foster City, CA: Gilead Sciences, Inc; July 2017

HCV TREATMENT

Ribavirin

- Weight based dosing taken with DAA
  - <75 kg: 500 mg bid
  - ≥ 75 kg: 600 mg bid
- Side Effects:
  - Hemolytic anemia
  - Fatigue/asthenia
  - Headache
  - Rigors
  - Fevers
  - Nausea
  - Myalgia
  - Anxiety
- Teratogenic 6 months following cessation

WHICH TO CHOOSE?!

Therapy	Trials	SVR12
Mavyret	EXPEDITION (III)	98%
Epclusa	SIMPLIFY (III)	94%
Harvoni	LONESTAR Trial (II) ION-3 (III)	95-100% 93-94%
Vosevi	POLARIS (III)	95%

Jacobson IM. Efficacy of 8 Weeks of Sofosbuvir, Velpatasvir, and Voxilaprevir in Patients With Chronic HCV Infection: 2 Phase 3 Randomized Trials. Gastroenterology. 2017

Grebely JSIMPLIFY Study Group. Sofosbuvir and velpatasvir for hepatitis C virus infection in people with recent injection drug use (SIMPLIFY): an open-label, single-arm, phase 4, multicentre trial. Lancet Gastroenterol Hepatol. 2018 Mar

Jacobson IM. Efficacy of 8 Weeks of Sofosbuvir, Velpatasvir, and Voxilaprevir in Patients With Chronic HCV Infection: 2 Phase 3 Randomized Trials. Gastroenterology. 2017

Kowdley KVION-3 Investigators. Ledipasvir and sofosbuvir for 8 or 12 weeks for chronic HCV without cirrhosis. N Engl J Med. 2014

DRUG INTERACTION RESOURCES

1. **Liverpool Hepatitis B and C Drug Interactions**
   a. https://www.hep-druginteractions.org/checker

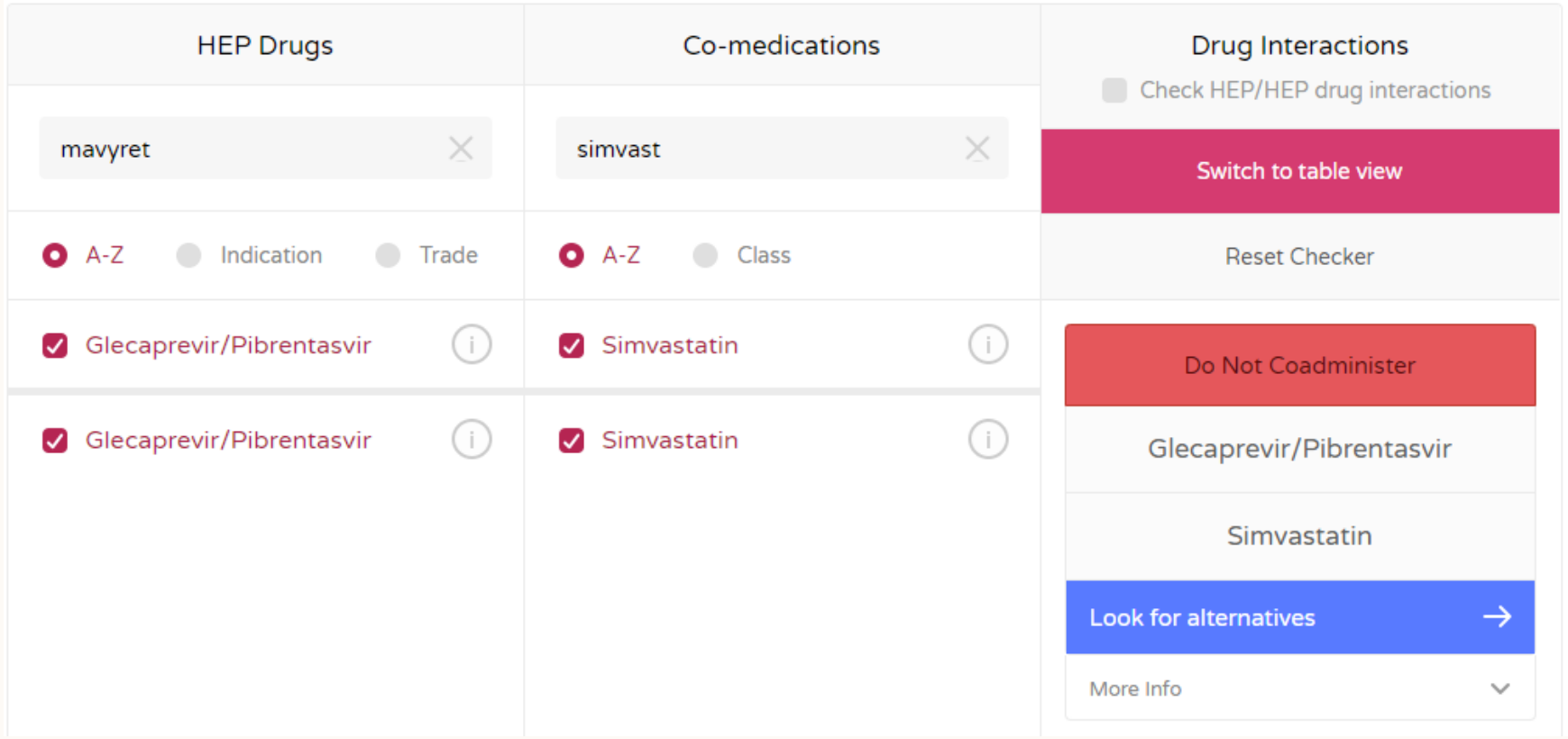
2. **Package Insert**
   a. Mavyret: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/209394s000lbl.pdf
   b. Epclusa: https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/208341s000lbl.pdf
   c. Harvoni: https://www.gilead.com/~/media/files/pdfs/medicines/liver-disease/harvoni/harvoni_pi.pdf
   d. Vosevi: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/209195s000lbl.pdf

3. **Micromedex or Lexicomp**

HEP Drug Interactions

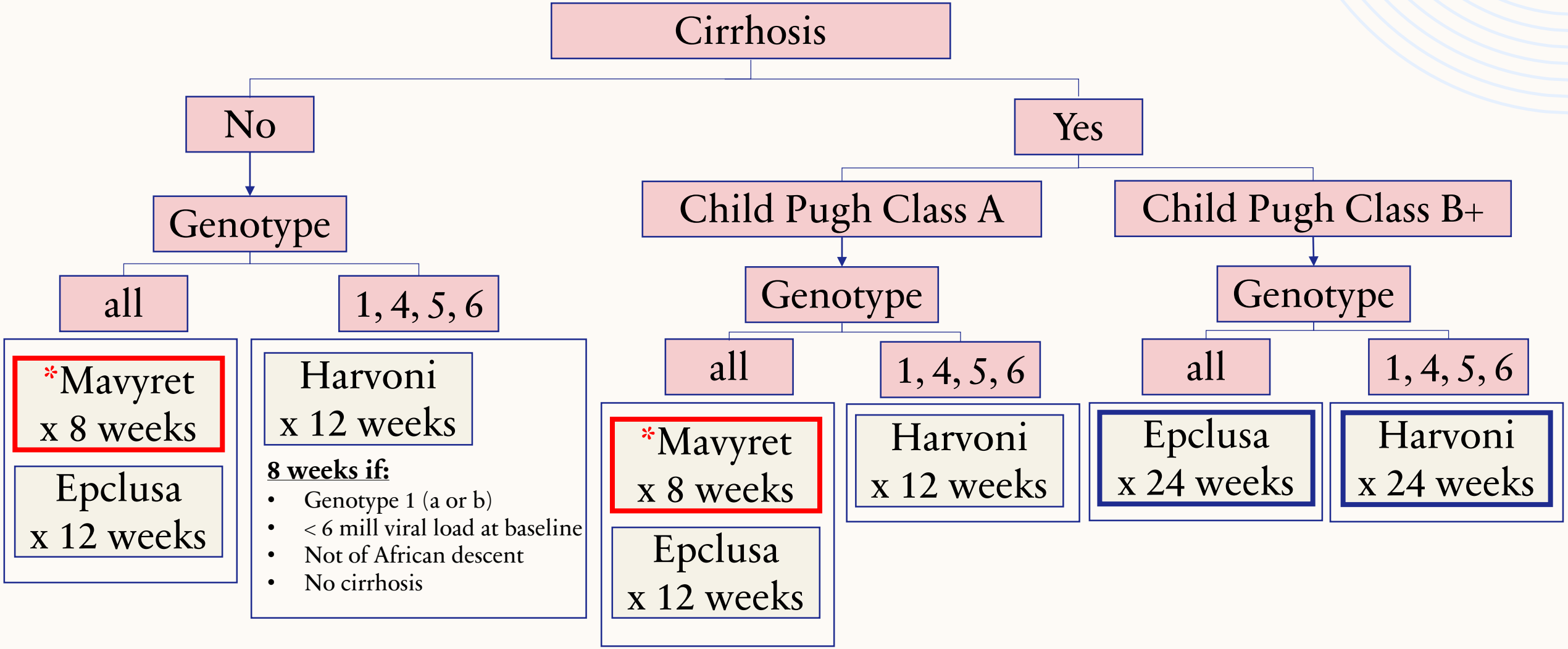
UNIVERSITY OF LIVERPOOL

DRUG INTERACTION RESOURCES



- Based on United Kingdom
- Be mindful of medication name differences
  - i.e., Acetaminophen : Paracetamol (UK) v Tylenol (US)

TREATMENT ALGORITHM
Treatment-Naive



*Medicaid Preferred *12 weeks with ribavirin

FOLLOW-UP/ MONITORING

- Recommendation to test HCV RNA (viral load) at start of therapy and at SVR12 date
- SVR12 = 12 weeks following last dose of therapy
  - Measure HCV RNA (viral load) at that time
    - Non-detectable – cleared virus
    - Elevated – active infection
- Monitor annually for patients with high risk for recontraction of Hepatitis C
  - All persons who inject drugs
  - HIV or HBV coinfection
  - Taking PrEP
  - Hemodialysis

PATIENT CASE

KS is a 31 y/o F with a past medical history of T1DM, HLD, MDD, ADHD, who was recently diagnosed with Hepatitis C in her first trimester of pregnancy and is currently 6 months post-partum. She has not been started on any hepatitis C medications since the birth of her son and is interested in starting now.

Insurance: Molina Medicaid

Baseline Labs: 8/2/2020

AST: 73	HCV Ab: positive
ALT: 79	HCV VL: 3.7 million
INR: 0.9	HCV Genotype: 3
Plts: 320	Fibrosure: F0
Total bilirubin: 0.6	HAV: reactive
LDL, direct: 192	HBV Surface Ab: reactive
HDL: 60	HBV Core Ab: non-reactive
TC: 290	HBV Surface Ag: non-reactive
TG: 230	hCG: negative

PATIENT CASE

Considering what you know about KS, her fibrosis score and her insurance, what HCV therapy would you recommend?

A. Epclusa for 36 weeks

B. Mavyret for 12 weeks

C. Mavyret for 8 weeks

D. Harvoni for 16 weeks

Baseline Labs: 8/2/2020

AST: 73
ALT: 79
INR: 0.9
Plts: 320
Total bilirubin: 0.6
LDL, direct: 192
HDL: 60
TC: 290
TG: 230

HCV Ab: positive
HCV VL: 3.7 million
HCV Genotype: 3
Fibrosure: F0
HAV: reactive
HBV Surface Ab: reactive
HBV Core Ab: non-reactive
HBV Surface Ag: non-reactive
hCG: negative

COMPARISON

HBV

- Genotype A thru J
- Can vaccinate against
- No cure
- Certain criteria met to treat

HCV

- Genotype 1 thru 6
- Cannot vaccinate against
- There's a cure
- Can treat all

QUESTIONS?

THE A, B, Cs OF HEPATITIS B AND C

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