MM-101-042920-47

SYLLABUS AND COURSE GUIDE

Live Virtual Symposium: At-Risk Patients Hidden in Plain Sight: Real-World Strategies for Screening and Treating Hepatitis B Virus

Premiere Date: Wednesday, April 29, 2020
6:30 PM - 8:00 PM ET (live)
Credit Expiration Date: Thursday, April 29, 2021

Log-In: www.cmeoutfitters.com/HBVcare
#HBVcare

LIVE FACULTY:
Joseph Ahn, MD, MS, MBA and Amy Shen Tang, MD

CHAIR:
Kris V. Kowdley, MD, FACP, FACG, AGAF, FAASLD

Take advantage of our LIVE Q&A segment during this webcast!

Please click on the **Ask Question** tab and type your question.

Email your question or comment: **questions@cmeoutfitters.com**

All other questions: Call CME Outfitters at 877.CME.PROS

This continuing education activity is provided by

CME Outfitters

INFORMATION FOR PARTICIPANTS

Statement of Need

Chronic hepatitis B virus (HBV) remains a global epidemic, resulting in significant morbidity and mortality. In 2015, there were 257 million people worldwide infected with HBV. In 2016, only 10.5% were diagnosed, with only 16.7% receiving treatment, and without intervention, there are 19 million deaths anticipated by the end of 2020. These numbers are startling as they exist despite the availability of effective treatment, and this is in part due to lack of clinician knowledge on screening and managing patients with HBV as well as lack of ability to foster retention for wrap-around services.

In 2018, The American Association for the Study of Liver Diseases released an updated guidance document for the prevention, diagnosis, and treatment of chronic HBV, including recommendations for screening, testing, counseling, and use of the newest antiviral treatment. Early detection is imperative for prevention and treatment, and this puts internists and primary care clinicians on the front lines to reduce HBV's global disease burden.

In this CME Outfitters virtual symposium, expert faculty will utilize augmented reality to add visualization to their discussion of how to implement routine screening protocols for HBV in primary care settings, how to optimize the efficacy and safety profiles of current agents, and the importance of providing culturally appropriate counseling and support services to patients, which will ensure understanding of their disease and promote retention in care.

Learning Objectives

At the end of this CME/CE activity, participants should be able to:

- Implement routine screening protocols for HBV in primary care settings and utilize results to drive guideline-directed care.
- Optimize efficacy and safety profiles of current agents when initiating or switching treatment in patients with HBV.
- Provide culturally appropriate counseling and support services to patients in order to ensure understanding of their disease and promote retention in care.

The following learning objectives pertain only to those requesting CNE or CPE credit:

- Explain routine screening protocols for HBV in primary care settings and how to utilize results to drive guideline-directed care.
- Describe efficacy and safety profiles of current agents for initiating or switching treatment in patients with HBV.
- Discuss culturally appropriate counseling and support services for patients in order to ensure understanding of their disease and promote retention in care.

Target Audience

Internists, primary care physicians, physician assistants, nurse practitioners, nurses, and pharmacists

Financial Support

Supported by an educational grant from Gilead Sciences, Inc.

CREDIT INFORMATION

CME Credit (Physicians)

CME Outfitters, LLC, is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians. CME Outfitters, LLC, designates this live activity for a maximum of 1.5 *AMA PRA Category 1 Credit(s)™*. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Note to Physician Assistants: AAPA accepts certificates of participation for educational activities certified for *AMA PRA Category 1 Credit™* from organizations accredited by the Accreditation Council for Continuing Medical Education.

CNE Credit (Nurses)

Provider approved by the California Board of Registered Nursing, Provider Number CEP 15510, for 1.5 contact hours.

Note to Nurse Practitioners: Nurse practitioners can apply for *AMA PRA Category 1 Credit™* through the American Academy of Nurse Practitioners (AANP). AANP will accept *AMA PRA Category 1 Credit™* from organizations accredited by the Accreditation Council for Continuing Medical Education. Nurse practitioners can also apply for credit through their state boards.

CPE Credit (Pharmacists)

CME Outfitters, LLC, is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. 1.5 contact hours (0.15 CEUs)

Universal Activity Number: Live: 0376-0000-20-083-L01-P; Enduring: 0376-0000-20-083-H01-P
Type: knowledge-based

ABIM/MOC Credit

Successful completion of this CME activity, which includes participation in the evaluation component, enables the participant to earn up to 1.5 MOC points in the American Board of Internal Medicine's (ABIM) Maintenance of Certification (MOC) program. Participants will earn MOC points equivalent to the amount of CME credits claimed for the activity. It is the CME activity provider's responsibility to submit participant completion information to ACCME for the purpose of granting ABIM MOC credit.

Learning Formats: Live activity. Enduring material.

Royal College MOC

Through an agreement between the Accreditation Council for Continuing Medical Education and the Royal College of Physicians and Surgeons of Canada, medical practitioners participating in the Royal College MOC Program may record completion of accredited activities registered under the ACCME's "CME in Support of MOC" program in Section 3 of the Royal College's MOC Program.

MIPS Improvement Activity

This activity counts towards MIPS Improvement Activity requirements under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). Clinicians should submit their improvement activities by attestation via the CMS Quality Payment Program website.

CREDIT REQUIREMENTS

Post-tests, credit request forms, and activity evaluations must be completed online (requires free account activation), and participants can print their certificate or statement of credit immediately (75% pass rate required). This website supports all browsers except Internet Explorer for Mac. For complete technical requirements and privacy policy, visit https://www.cmeoutfitters.com/privacy-and-confidentiality-policy.

There is no fee for participation in this activity. The estimated time for completion is 90 minutes. Questions? Please call **877.CME.PROS**.

FACULTY BIOS & DISCLOSURES

Kris V. Kowdley, MD, FACP, FACG, AGAF, FAASLD (Chair)

Dr. Kowdley received his BS in Biology and Anthropology as a member of the Dean's List at Columbia University, and his medical degree from Mount Sinai School of Medicine. He completed his internship and residency at Oregon Health Science University and a Fellowship in Gastroenterology and Hepatology at Tufts University School of Medicine.

Dr. Kowdley is internationally recognized as a clinician, educator, and researcher in the area of liver disease and has presented his research on liver diseases at more than 165 national and international meetings and scientific symposia. He is the author of over 450 articles, book chapters, reviews, and commentaries in this area, with publications in the *Annals of Internal Medicine, Archives of Surgery, Gastroenterology, Hepatology, American Journal of Physiology*, and *New England Journal of Medicine*, among other professional publications.

Dr. Kowdley has extensive experience in clinical trials in all areas of liver disease, including hepatitis C, cholestatic liver disease, primary biliary cirrhosis (PBC), primary sclerosing cholangitis (PSC), nonalcoholic steatohepatitis, and hepatitis B. He has been a principal investigator in several NIDDK-sponsored clinical trials in PBC and PSC and is a member of executive committee of the nonalcoholic steatohepatitis clinical research network (NASH CRN). Dr. Kowdley has also served as the lead investigator of several major international clinical trials in hepatitis C.

Dr. Kowdley's laboratory program is focused on the role of iron as a co-factor in many liver diseases, including hepatitis C, hemochromatosis, and nonalcoholic steatohepatitis (NASH). He has developed murine models for NASH and is currently exploring the contribution of hepatic iron deposition on the severity of NASH.

Dr. Kowdley's research program has been continuously funded by the NIDDK since 1999 in addition to several grants from foundations and scientific societies.

Joseph Ahn, MD, MS, MBA

Dr. Ahn is a transplant hepatologist with Oregon Health & Science University (OHSU) in Portland, Oregon. He is a Professor of Medicine and serves as the Section Chief of Gastroenterology and Director of Clinical Hepatology. Prior to joining OHSU, he was the Medical Director of Liver Transplant and Associate Chief of Hepatology at Loyola University in Chicago, Illinois.

Dr. Ahn is board certified in internal medicine, gastroenterology, and transplant hepatology. He received his medical degree from Northwestern University and completed his residency in internal medicine at the University of Chicago. He trained at Northwestern University as a fellow in hepatology and gastroenterology.

As a transplant hepatologist, Dr. Ahn treats patients with chronic liver diseases as well as liver transplant candidates and recipients. His research interest is focused on hepatitis B, hepatitis C, and liver cancer.

Amy Shen Tang, MD

Amy Shen Tang, MD, is a primary care internist and the new Director of Immigrant Health at North East Medical Services (NEMS) in the San Francisco Bay Area where she oversees clinical programs and community outreach for hepatitis B, latent tuberculosis, and other immigrant health disparities.

Prior to joining NEMS, she served as the Hepatitis B Program Director at Charles B. Wang Community Health Center in New York City where she oversaw hepatitis B clinical care, research, community outreach, and education. She currently serves as Co- Chair for the National Hepatitis B Primary Care Workgroup and Advisor to the National Taskforce on Hepatitis B where she leads a workgroup of hepatitis B experts from the American Association of Study of Liver Diseases, the Center for Disease Control, Project ECHO, and the University of Washington to develop web-based hepatitis B guidance for primary care providers managing chronic hepatitis B. Dr. Tang has also served as a hepatitis B clinical advisor for the CDC Viral Hepatitis Division, National Association of Community Health Centers, New York City Department of Health, and HBV Project ECHO.

She received her medical degree from the University of California San Francisco School of Medicine and completed her primary care internal medicine residency at NYU School of Medicine and Bellevue Hospital.

Disclosure of Relevant Financial Relationships with Commercial Interests

It is the policy of CME Outfitters, LLC, to ensure independence, balance, objectivity, and scientific rigor and integrity in all of their CME/CE activities. Faculty must disclose to the participants any relationships with commercial companies whose products or devices may be mentioned in faculty presentations, or with the commercial supporter of this CE activity. CME Outfitters, LLC, has evaluated, identified, and attempted to resolve any potential conflicts of interest through a rigorous content validation procedure, use of evidence-based data/research, and a multidisciplinary peer review process. The following information is for participant information only. It is not assumed that these relationships will have a negative impact on the presentations.

Dr. Kowdley reports he receives research support from Conatus Pharmaceuticals Inc.; CymaBay Therapeutics.; Enanta Pharmaceuticals, Inc.; Genfit; Gilead Sciences, Inc.; GlaxoSmithKline; HighTide Therapeutics Inc.; Intercept Pharmaceuticals, Inc.; and Zydus Pharmaceuticals, Inc. He serves on the advisory committee for Assembly Biosciences, Inc.; Blade Therapeutics; Boehringer Ingelheim; Merck & Co., Inc.; and Roche. He is on the speakers bureau for AbbVie Inc.; Gilead Sciences, Inc.; and Intercept Pharmaceuticals, Inc.

Dr. Ahn reports he serves on the advisory committee for Gilead Sciences, Inc.

Dr. Tang has no disclosures to report.

Jeffrey Helfand, DO (peer reviewer) has no disclosures to report.

Mae Ochoa, RPh (peer reviewer) has no disclosures to report.

Kashemi D. Rorie, PhD (planning committee) has no disclosures to report.

Susan Perry (planning committee) has no disclosures to report.

Jan Perez (planning committee) has no disclosures to report.

Sharon Tordoff (planning committee) has no disclosures to report.

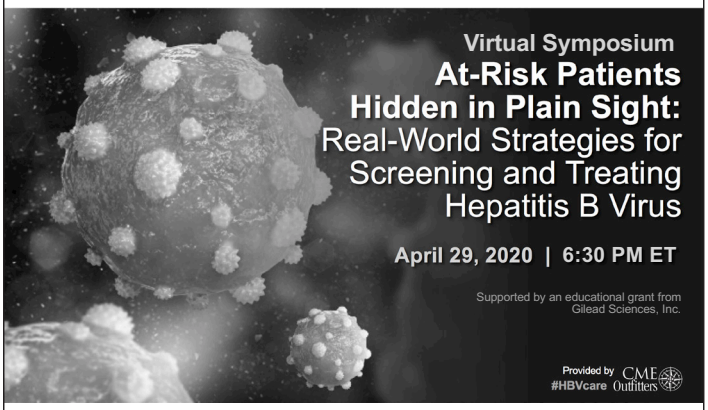
Disclosures were obtained from the CME Outfitters, LLC staff: No disclosures to report.

Unlabeled Use Disclosure

Faculty of this CME/CE activity may include discussions of products or devices that are not currently labeled for use by the FDA. The faculty have been informed of their responsibility to disclose to the audience if they will be discussing off-label or investigational uses (any uses not approved by the FDA) of products or devices.

Activity Slides

The slides that are presented in this activity will be available to download and print out at the activity details page on the CME Outfitters website: **www.cmeoutfitters.com/HBVcareResources**. Activity slides may also be obtained via fax or email by calling **877.CME.PROS**.



Claim ABIM MOC Credit

3 Things to Do

1. Actively participate in the discussion by **responding to ARS** and/or **asking the faculty questions**
   (It's ok if you miss answering a question or get them wrong, you can still claim MOC)
2. Complete your post-test and evaluation at the conclusion of the webcast
3. Be sure to fill in your **ABIM ID number** and **DOB** (MM/DD) on the evaluation, so we can submit your credit to ABIM.

ABIM CME MOC ACCREDITED

CME Outfitters

CME for MIPS Improvement Activity

How to Claim this Activity as a CME for MIPS Improvement Activity

- Actively participate by responding to ARS questions and/or asking the faculty questions.
- Complete activity posttest and evaluation at the link provided.
- Over the next 90 days, actively work to incorporate improvements in your clinical practice from this presentation.
- Complete the follow-up survey from CME Outfitters in approximately 3 months

CME Outfitters will send you confirmation of your participation to submit to CMS attesting to your completion of a CME for MIPS Improvement Activity.

CME for MIPS IMPROVEMENT ACTIVITY

CME Outfitters

Engage with us via Twitter!

#HBVcare

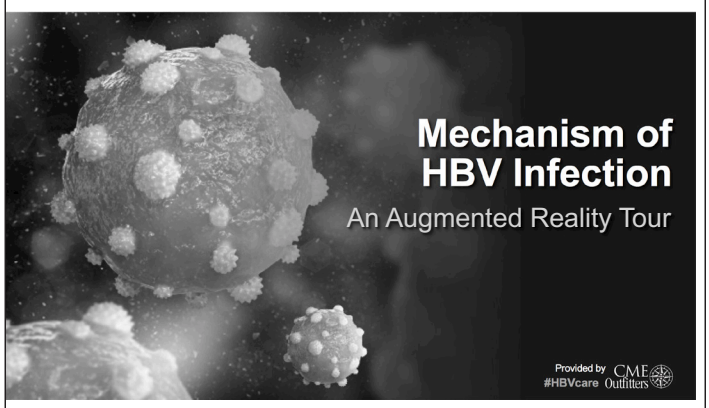
Follow us on Twitter **@cmeoutfitters** for announcements about upcoming CME/CE opportunities, health care news, and more!

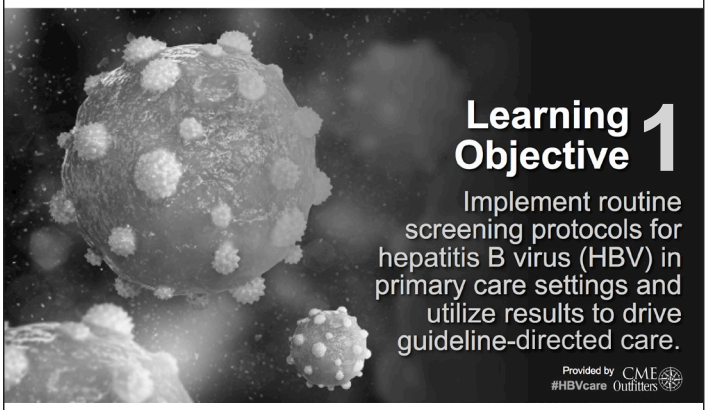
CME Outfitters


Kris V. Kowdley, MD, FACP, FACG, AGAF, FAASLD
Director, Liver Institute Northwest
Clinical Professor,
Elson S. Floyd College of Medicine
Washington State University
Spokane, WA
Provided by CME Outfitters #HBVcare


Joseph Ahn, MD, MS, MBA
Professor of Medicine
Section Chief, Division of Gastroenterology and Hepatology
Director of Clinical Hepatology
Oregon Health & Science University
Portland, OR
Provided by CME Outfitters #HBVcare


Amy Shen Tang, MD
Director of Immigrant Health
North East Medical Services
San Francisco, CA
Provided by CME Outfitters #HBVcare


Mechanism of HBV Infection
An Augmented Reality Tour
Provided by CME Outfitters #HBVcare



The HBV Burden: Call to Action

- Globally, an estimated 292 million persons (3.9% prevalence) are chronically infected with HBV; most are from Africa, Asia, and the Pacific Islands[1]
- Approximately 2 of every 3 persons with chronic HBV are unaware of their infection[2]
- 25% of those without HBV monitoring or treatment will die prematurely of hepatocellular carcinoma, cirrhosis, or liver failure[3,4]
- Current HBV treatment can mitigate this risk but only 10%-15% of treatment candidates are on medication[5]
- HBV is a vaccine-preventable infectious disease, but only about ¼ of adults are fully immunized[6]

[1]Polaris Observatory Collaborators. *Lancet Gastroenterol Hepatol*. 2018;3(6):383-403. [2]Lin SY, et al. *Hepatology*. 2007;46:1034-1040. [3]McMahon BJ. *Hepatology*. 2009;49:S45-S55. [4]McMahon BJ, et al. *Clin Liver Dis*. 2010;14:381-396. [5]Cohen C, et al. *J Viral Hepat*. 2011;18:377-383. [6]Williams WW, et al. *MMWR Surveill Summ*. 2017;66:1-28.

We Can Do Better

Primary care providers are equipped to **screen**, **vaccinate**, and **monitor** persons at increased risk for HBV

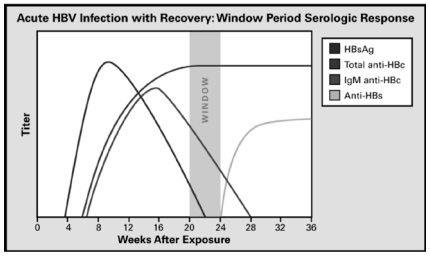
1. Screen and vaccinate as part of routine preventative care
2. Monitor liver enzymes and HBV DNA every 6 months for patients with chronic HBV
3. Screen for liver cancer (HCC) with ultrasound

Real-World Screening of Asian American Patients for Hepatitis B, New York City 1997-2017

Characteristic Subcategory	Ever Infection,* No. (Row %)	Current Infection† No. (Row %)
General Screening Population		
Total	13,326 (52.1)	3,437 (13.4)
Household contacts	544 (70.4)	168 (21.7)
Family history of HBV	326 (75.6)	209 (48.5)
	Sex	
Female	6,986 (48.4)	1,599 (11.1)
Male	6,340 (56.9)	1,838 (16.5)
Preferred Language		
English	619 (17.1)	152 (4.2)
Mandarin	6,644 (60.0)	1,796 (16.2)
Cantonese	2,407 (47.6)	425 (8.4)
Other	92 (24.9)	22 (6.0)
Unknown	3,564 (65.4)	1,042 (19.1)

*All antibody to hepatitis B core antibody (infection. †All hepatitis B surface antigen (HBsAg) positive.
Tang AS, et al. *Am J Public Health*. 2018108(S4):S327-S335.

How to Screen for HBV



- HBsAg (qualitative*) = current infection
- Anti-HBs (qualitative†) = immunity or immune control
- Total (NOT IgM) anti-HBc = ever infected

*Quantitative HBsAg is used for assessing probability of HBsAg seroclearance in patients with inactive chronic HBV and has no role in HBV screening.
†Quantitative anti-HBs is acceptable, too, but does not change management.

CME Outfitters

ACP-CDC Screening Recommendations by HBV Transmission Risk Factors

Vertical Transmission
- Persons born in countries with ≥ 2% HBV prevalence
- Pregnant women
- Infants born to HBV-infected mothers

Blood* Transmission
- Persons who inject drugs
- Incarcerated persons
- Household contacts of HBV-infected persons
- Persons with end-stage renal disease (including hemodialysis patients)
- Blood and tissue donors

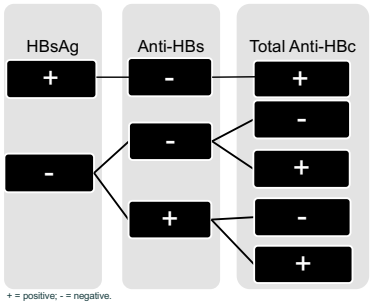
Sexual Transmission
- Men who have sex with men
- Sexual contacts of HBV-infected persons

HBV Reactivation/Liver Complication
- Persons requiring immunosuppressive therapy
- Persons infected with hepatitis C virus (HCV)
- HIV-positive persons
- Persons with elevated ALT levels

*HBV can survive outside the body at least 7 days and still be capable of causing infection.
ACP = American College of Physicians; ALT = alanine aminotransferase; CDC = Centers for Disease Control and Prevention; HIV = human immunodeficiency virus.
Abara WE, et al. *Ann Intern Med*. 2017;167(11):794-804.

CME Outfitters

HBV Serology Interpretation



Current infection > can order immunoglobulin M (IgM) if concern for acute HBV

Susceptible > give complete HBV vaccine series unless non-response to two series

Isolated core > prior infection vs. occult HBV vs. false-positive vs. "window period" of acute infection

Immune from vaccination > reassurance

Prior infection > counsel on reactivation risk

+ = positive; - = negative.

CME Outfitters

Who Should Be Vaccinated for HBV?

Vertical Transmission
- Persons born in countries with ≥ 2% HBV prevalence
- Pregnant women at risk for HBV infection during pregnancy
- Infants born to HBV-infected mothers

Blood Transmission
- Persons who inject drugs
- Incarcerated persons
- Household contacts of HBV-infected persons
- Persons with end-stage renal disease (including hemodialysis patients)
- Blood and tissue donors
- Residents and staff of facilities for developmentally disabled persons
- Public safety workers at risk for exposure to blood or blood-contaminated body fluids
- Adults age < 60 with diabetes mellitus

Sexual Transmission
- Men who have sex with men
- Sexual contacts of HBV-infected persons
- Sexually active persons not in a mutually monogamous relationship
- Persons seeking evaluation or treatment for a sexually transmitted infection

HBV Reactivation/Liver Complication
- Persons requiring immunosuppressive therapy
- Persons infected with hepatitis C virus
- HIV-positive persons
- Persons with elevated ALT levels
- Adults with chronic liver disease

International travelers to regions with high or intermediate levels of endemic HBV infection
Any adult seeking protection from HBV infection

Abara WE, et al. *Ann Intern Med*. 2017;167(11):794-804.

CME Outfitters

Goals of Care

- Impact the natural history of HBV
- Decrease or prevent CHB-related morbidity and mortality, including transmission, cirrhosis, HCC, liver transplant, and death

HBV DNA undetectable (< 12 IU/mL)	ALT "Normal"
HBeAg loss, seroconversion	HBsAg loss, seroconversion

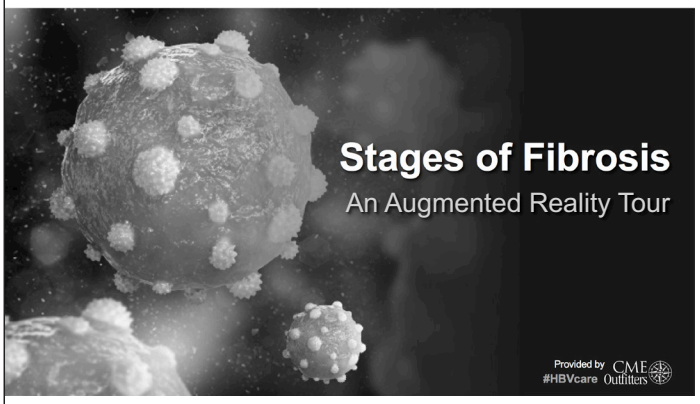
CHB = chronic hepatitis B; HBeAg = hepatitis B e-antigen.
Terrault NA, et al. *Hepatology*. 2018;67(4):1560-1599. Terrault NA, et al. *Hepatology*. 2016;63(1):261-268.

What Are We Hoping to Accomplish with Treatment?

Decrease the morbidity and mortality related to CHB, particularly:

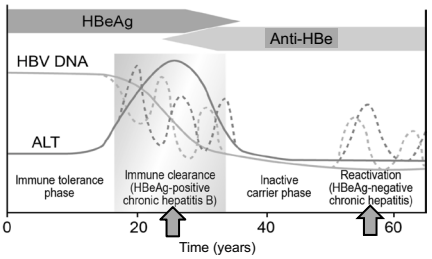
- Achieve sustained suppression of HBV replication
- Reduce the risk of progression to cirrhosis- and liver-related complications, including HCC
- Improve long-term survival

Terrault NA, et al. *Hepatology*. 2018;67(4):1560-1599. Terrault NA, et al. *Hepatology*. 2016;63(1):261-268.



Factors Influencing Treatment Initiation for HBV

Currently, the decision to start antiviral treatment depends on ALT levels, HBV DNA, and fibrosis levels in patients with non-cirrhotic CHB



Terrault NA, et al. *Hepatology*. 2018;67(4):1560-1599. Terrault NA, et al. *Hepatology*. 2016;63:261-283. European Association for the Study of the Liver (EASL). *J Hepatol*. 2017;67:370-398.

AASLD/EASL Guidelines

Guideline	HBeAg Positive			HBeAg Negative		
	HBV DNA, IU/mL	ALT	Liver Disease	HBV DNA, IU/mL	ALT	Liver Disease
AASLD[1,2]	> 20,000	≥ 2 x ULN	N/A	≥ 2,000	≥ 2 x ULN	N/A
	N/A	N/A	Cirrhosis	N/A	N/A	Cirrhosis
EASL[3]	> 2,000	> ULN*	Moderate inflammation or fibrosis*	> 2,000	> ULN*	Moderate inflammation or fibrosis*
	> 20,000	> 2 x ULN	N/A	> 20,000	> 2 x ULN	N/A
	N/A	N/A	Cirrhosis	N/A	N/A	Cirrhosis

Use liver biopsy or transient elastography to detect fibrosis/inflammation in unclear situations

*In patients with HBV DNA > 2,000 IU/mL, treatment indicated if ALT > ULN and/or at least moderate fibrosis.
AASLD = American Association for the Study of Liver Diseases.
[1]Terrault NA, et al. *Hepatology*. 2018;67(4):1560-1599. [2]Terrault NA, et al. *Hepatology*. 2016;63:261-283. [3]EASL. *J Hepatol*. 2017;67:370-398.

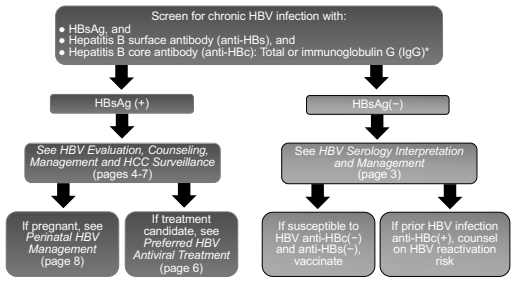
AASLD Guidelines: Initial Treatment

Treatment	Preferred	Notes
ETV	Yes (unless previous history of lamivudine resistance)	High potency, high genetic barrier to resistance
Tenofovir	Yes	High potency, high genetic barrier to resistance
PegIFN	Yes	Less safe in patients with cirrhosis
Adefovir	No	Low genetic barrier to resistance
Lamivudine	No	Low genetic barrier to resistance
Telbivudine	No	Low genetic barrier to resistance

Treatment with antivirals does not eliminate the risk of HCC, and surveillance for HCC should continue in persons who are at risk

ETV = entecavir; PegIFN = peginterferon.
Terrault NA, et al. *Hepatology*. 2018;67(4):1560-1599. Terrault NA, et al. *Hepatology*. 2016;63:261-283.

Chronic Hepatitis B Testing and Management Algorithm for Primary Care Providers (PCPs)



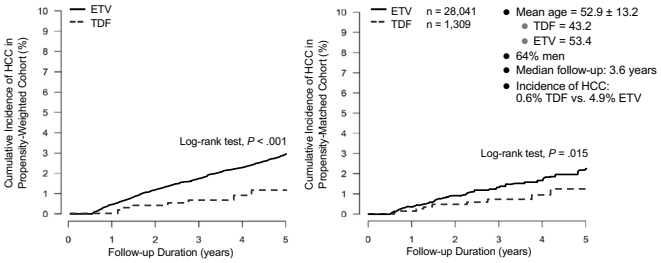
*Do not include anti-HBc IgM in HBV screening panel unless acute HBV is suspected.
Tang AS, et al. Hepatitis B Online Website. 2020. https://www.hepatitisb.uw.edu/page/primary-care-workgroup/guidance.

Management of Patients with HBsAg(+): Tips for PCPs

Cirrhosis	HBV DNA (IU/mL)	ALT (U/L)	Management
YES	Any	Any	• Treat with antiviral medication (page 6) • Monitor HBV DNA and ALT every 6 months • Refer to specialist for screening endoscopy and, if needed, for other cirrhosis-related complications • HCC surveillance (page 7) • All patients with decompensated cirrhosis* should be promptly referred to a hepatologist
NO	> 2,000	Elevated †	• TREAT with antiviral medication (page 6) • Monitor HBV DNA and ALT every 6 months • Monitor HBeAg every 6 months in patients who are HBeAg+ at time of treatment initiation to evaluate for seroconversion HBeAg(+) to HBeAg(-) • Check HBsAg annually if/when HBeAg negative
		Normal	• Monitor HBV DNA and ALT every 6 months • Liver fibrosis assessment every 2-3 years
	< 2,000	Elevated †	• Evaluate other etiologies for elevated ALT • Monitor HBV DNA and ALT every 6 months
		Normal	• Monitor HBV DNA and ALT every 6 months *and* HBsAg every 1 year for seroclearance

*Patients should be considered to have decompensated cirrhosis and promptly referred to a hepatologist if any of the following are present: jaundice, ascites, variceal hemorrhage, hepatic encephalopathy, a Child-Turcotte-Pugh (CTP) score ≥ 7 (CTP calculator LINK), or a Model for End-Stage Liver Disease (MELD) score ≥ 15 (MELD calculator LINK).
†Elevated ALT defined as > 25 U/L in females and > 35 U/L in males that is persistent for at least 3-6 months.
Tang AS, et al. Hepatitis B Online Website. 2020. https://www.hepatitisb.uw.edu/page/primary-care-workgroup/guidance.

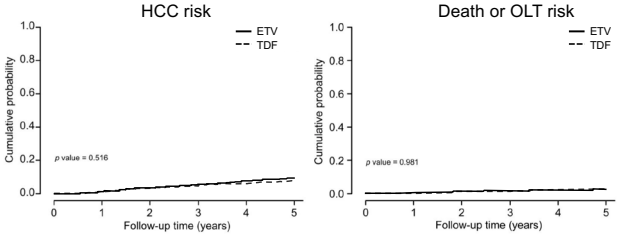
Retrospective Analysis of TDF vs. ETV and Risk of HCC in China, N = 29,350



- Mean age = 52.9 ± 13.2
  - TDF = 43.2
  - ETV = 53.4
- 64% men
- Median follow-up: 3.6 years
- Incidence of HCC: 0.6% TDF vs. 4.9% ETV

Yip TC, et al. *Gastroenterology.* 2020;158(1):215-225.e6.

TDF vs. ETV on Prognosis of Treatment-Naïve CHB in South Korea



N° at risk						
ETV	1,484	1,424	1,317	1,227	1,065	885
TDF	1,413	1,375	1,278	1,196	1,020	593

N° at risk						
ETV	1,484	1,445	1,364	1,284	1,131	942
TDF	1,413	1,393	1,319	1,252	1,095	852

OLT = orthotopic liver transplant.
Kim SU, et al. *J Hepatol.* 2019;71(3):456-464.

Impact on Bone and Renal Parameters in Patients Switching from TDF to TAF at 48 Weeks

Safety Results at Week 48 by Duration of Prior TDF Treatment in Patients with CHB Who Were Switched to TAF

	< 4 Years n = 105	≥ 4 Years n = 138	*P* Value
Renal Parameters			
Albumin/creatinine ratio, mg/g	+5.5 (-24.1, 41.5)	-5.8 (-37.0, 29.7)	.08
Bone Parameters			
Serum bone markers, median (Q1, Q3) % change			
C-type collagen sequence, ng/mL (resorption)	-29.8 (-45.8, -14.0)	-28.8 (-42.8, -15.3)	.57
Procollagen type 1 N-terminal propeptide, ng/mL (formation)	-20.4 (-37.5, -7.4)	-17.7 (-29.6, -8.5)	.16
Parathyroid hormone, pg/mL (metabolism)	-9.4 (-27.6, 16.4)	-13.4 (-32.5, 6.8)	.07
Fasting Lipid Parameters			
Total cholesterol, median (Q1, Q3) change, mg/dL	20 (6, 31)	19 (5, 33)	.93
Total cholesterol/HDL, median (Q1, Q3) change, mg/dL	0.1 (-0.2, 0.4)	0.3 (-0.1, 0.5)	.08

Chan HLY, et al. *Hepatology.* 2019;70(S1):287A.

Efficacy and Safety of Switching from TDF to TAF in Patients with Moderate/Severe Renal Impairment or ESRD

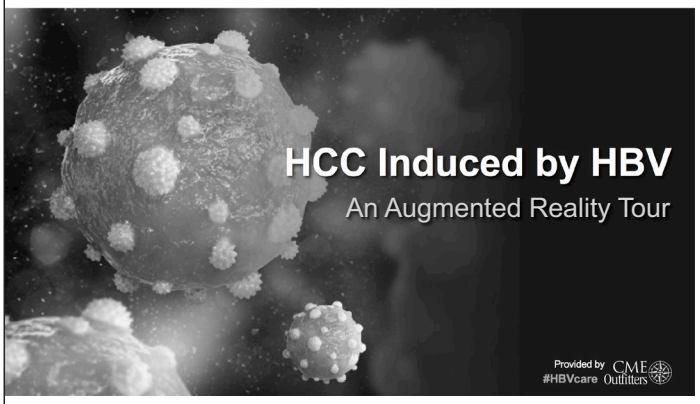
n/N (%) or Median (Q1, Q3)	Moderate-Severe Renal Impairment* (n = 78)	ESRD on HD† (n = 15)
Efficacy		
HBV DNA < 20 IU/mL	76/78 (97)‡	15/15 (100)
ALT normal (2018 AASLD criteria)	68/78 (87)	14/15 (93)
Bone Parameters		
Hip BMD, % change	+0.48 (-0.96, 1.34)	+0.46 (-0.92, 1.60)
Spine BMD, % change	+1.29 (-0.50, 2.84)	+1.34 (-1.25, 2.34)
Renal Parameters		
$eGFR_{CG}$, mL/min	+0.6 (-3.6, 3.6)	---

HBV DNA and ALT assessments are missing equals failure.
$eGFR_{CG}$ = estimated creatinine clearance (Cockcroft-Gault method); ESRD = end-stage renal disease; NA = not applicable.
*Moderate-severe renal impairment: $eGFR_{CG}$ 15 - < 60 mL/min.
†ESRD: $eGFR_{CG}$ < 15 mL/min on hemodialysis.
‡Two patients discontinued study drug early (withdrew consent) with last available HBV DNA < 20 IU/mL.
Janssen HLA, et al. *Hepatology.* 2019;70(S1):306A.

HCC Epidemiology

- Unlike HCV, chronic HBV infection can cause liver cancer in patients without cirrhosis
- Chronic HBV increases the odds of liver cancer 50 to 100 times, hepatitis C 15 to 20 times
- Viral hepatitis has driven the 38% increase in liver cancer in the United States between 2003 and 2012

Bruix J, et al. *Hepatology.* 2011;53(3):1020-1022. National Academies of Sciences, Engineering, and Medicine. 2017. https://www.nap.edu/read/24731.



HCC Surveillance: Additional Risk Factors

- BCP/PC mutations
- Genotype C
- Coinfection with HCV, HIV, HDV
- Persistently high HBV DNA
- Late HBeAg loss (40+ years)
- Persistent elevation of liver function tests (> 1.5 ULN*)
- Alcohol use, smoking
- Cirrhosis

*Abnormal ALT: male ≥ 35 U/L, female ≥ 25 U/L.
Terrault NA, et al. *Hepatology*. 2018;67(4):1560-1599. Bruix J, et al. *Hepatology*. 2005;42:1208-1236. Chan HL, et al. *Gut*. 2004;53(10):1494-1498.

HCC Surveillance Methods

- Liver ultrasound every 6 months
- +/- serum alpha-fetoprotein
- Follow-up MRI or CT of abdomen with and without contrast may be indicated to evaluate suspicious lesions identified on ultrasound
- HCC can be diagnosed by imaging alone

CT = computed tomography; MRI = magnetic resonance imaging.
Heimbach JK, et al. *Hepatology*. 2018;67(1):358-380. Bruix J, et al. *Hepatology*. 2011;53:1020-1022.

Impact of Monitoring on HCC Mortality in 414,074 Korean Patients with HBV

- 44% reduction in risk of death from liver cancer with regular vs. no follow-up
- Significantly higher rate of curative treatment with regular vs. no or irregular follow-up

Outcome, n (%)	No Follow-up (n = 79,333)	Irregular Follow-up (n = 239,960)	Regular Follow-up (n = 94,781)
New liver cancer	1258 (14.3)	3834 (43.6)	3707 (42.1)
Liver cancer death	488 (38.8)	1211 (31.6)	856 (23.1)
HR for liver cancer death (95% CI)	Ref	0.869* (0.780-0.968)	0.561† (0.500-0.631)
Curative treatment	190 (15.1)‡	595 (15.5)‡	855 (23.1)

*$P < .05$.
†$P < .0001$.
‡$P < .001$ vs. regular follow-up.
Shim J-J, et al. *Hepaology*. 2019;70(S1):105A.

Impact of Monitoring on HCC Mortality in 414,074 Korean Patients with HBV (continued)

- Patients with cirrhosis had much higher incidence of HCC than those without cirrhosis
- Among patients without cirrhosis, HCC incidence was highest for those with regular follow-up

	Total (N = 414,074)		Cirrhosis (n = 26,086)		No Cirrhosis (n = 387,988)	
Patient Group	HCC, n (%)	HCC Incidence/ 1,000 PY	HCC, n (%)	HCC Incidence/ 1,000 PY	HCC, n (%)	HCC, Incidence/ 1,000 PY
All	8,799 (100)	3.19	3,959 (100)	25.00	4,840 (100)	1.86
No follow-up	1,258 (14.3)	2.34	367 (9.3)	27.82	891 (18.4)	1.70
Irregular follow-up	3,834 (43.6)	2.39	1298 (32.8)	26.61	2,536 (52.4)	1.63
Regular follow-up	3,707 (42.1)	6.02	2294 (57.9)	23.79	1,413 (29.2)	2.72

PY = patient years.
Shim J-J, et al. *Hepaology*. 2019;70(S1):105A.

Counseling the HBsAg(+) Patient: Tips for PCPs

1. Give a plan for follow-up care; patients will need regular (minimum every 6 months) follow-up and monitoring for disease progression
2. Educate and counsel on the long-term implications of chronic HBV infection (e.g., cirrhosis and hepatocellular carcinoma)
3. Advise patient to inform all current and future medical providers of their HBsAg-positive status, especially if they ever need treatment for cancer or any immunologic condition such as rheumatoid arthritis or other immune disorders
4. Counsel to avoid or limit alcohol use
5. Advise to optimize body weight and address metabolic complications, including control of diabetes and dyslipidemia (to prevent concurrent development of metabolic syndrome and fatty liver)
6. Provide education on how to prevent transmission of HBV to others

Tang AS, et al. Hepatitis B Online Website. 2020. https://www.hepatitisb.uw.edu/page/primary-care-workgroup/guidance.

CME Outfitters

When to Refer to a Specialist

- All PCPs must screen and vaccinate individuals at increased risk for HBV
- Patients identified with chronic HBV infection must be counseled, monitored, and evaluated for treatment
  - Chronic HBV is a dynamic disease and requires lifelong monitoring by a PCP or a specialist
- All patients identified with HCC or cirrhosis should be referred to a specialist

CME Outfitters

The Cultural Divide in CHB

Adapted from hepBMD Website. 2020. https://hepbmd.com/hepatitis-b-resources/?utm_source=google&utm_medium=cpc&utm_campaign=2020+Health+Concern_Broad&utm_content=Condition+Information_Hep+B-KW&utm_term=%2Bhep+%2Bb&gclid=EAIaIQobChMItuvO29786AIVgYjICh1LWQ8TEAMYAyAAEgJSkfD_BwE&gclsrc=aw.ds.

CME Outfitters

Cultural Considerations in CHB Management

- Language barriers
- Stigma
- Denial of disease
- Limited knowledge of disease
- Lack of trust in health care systems / underutilization of health care resources
- Immigration status precluding insurance and access to care

Vijayan T, et al. *J Immigr Minor Health*. 2015;17(1):112–117. Shankar H, et al. *Clin Infect Dis*. 2016; 62(Suppl 4):S289-S297. Djofack R, et al. *World J Gastroenterol*. 2017;23(42):7626-7634.

CME Outfitters

Management Considerations for HBV in the COVID-19 Era: The Role of Telehealth

- Emergency funding legislation waived many of the long-standing restrictions to the use of telehealth for Medicare recipients:
  - Allowing a patient's home to be an eligible originating site;
  - Allowing phones with two-way, real-time interactive audio and visual capabilities to be used;
  - And allowing the provider to conduct a telehealth encounter from his/her home
- Medicare (and some Medicaid programs) will currently reimburse telephone and telehealth visits for both new and established patients
- Providers can bill for telehealth visits at the same rate as in-person visits
- The Centers for Medicare & Medicaid Services (CMS) has temporarily waived the Medicare and Medicaid requirements that physicians and non-physician practitioners be licensed in the state where they are providing services
- Benefits:
  - Lab evaluation/monitoring play greater role in HBV management than physical exam
  - Patients are receptive to telehealth

AASLD. 2020. https://www.aasld.org/sites/default/files/2020-04/AASLD-COVID19-ClinicalInsights-April162020-FINAL.pdf.

CME Outfitters

Telehealth AASLD Recommendations

- Consider phone visits or telehealth as appropriate and available to replace in-person visits
- Conduct patient education as well as social work, dietitian, and financial consultations by video conference, telehealth, or telephone for liver transplant evaluations
- Consider telehealth alternatives in place of outreach clinics
- Minimize in-person visits for posttransplant patients by maximizing use of telehealth

AASLD. 2020. https://www.aasld.org/sites/default/files/2020-04/AASLD-COVID19-ClinicalInsights-April162020-FINAL.pdf.

CME Outfitters

SMART Goals

Specific, **M**easurable, **A**ttainable, **R**elevant, **T**imely

- Employ culturally-sensitive strategies to improve the detection and management of HBV
- Screen 100% of your patients at-risk for HBV using appropriate serologic markers (i.e., HBsAg, anti-HBs, and anti-HBc)
- Use recent clinical trial data to drive safe, effective treatment selection when initiating HBV treatment or switching when initial treatment fails
- Monitor all patients with HBV for progression to HCC

CME Outfitters

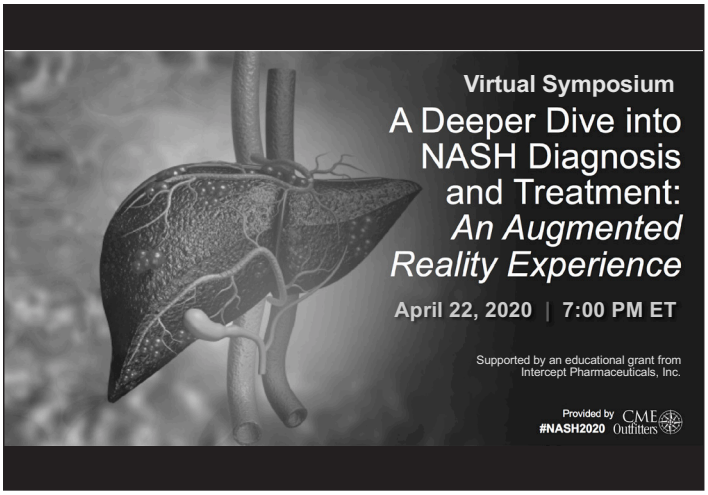
How to Collect Credit for this Activity

To receive CME/CE credit, click on the link to complete the post-test and evaluation online.

www.cmeoutfitters.com/TST36646

Participants can print their certificate or statement of credit immediately.

CME Outfitters



Claim ABIM MOC Credit

3 Things to Do

1. Actively participate in the discussion by **responding to ARS** and/or **asking the faculty questions**
   (It's ok if you miss answering a question or get them wrong, you can still claim MOC)
2. Complete your post-test and evaluation at the conclusion of the webcast
3. Be sure to fill in your **ABIM ID number** and **DOB** (MM/DD) on the evaluation, so we can submit your credit to ABIM.

ABIM CME MOC ACCREDITED

CME Outfitters

CME for MIPS Improvement Activity

How to Claim this Activity as a CME for MIPS Improvement Activity

- Actively participate by responding to ARS questions and/or asking the faculty questions.
- Complete activity posttest and evaluation at the link provided.
- Over the next 90 days, actively work to incorporate improvements in your clinical practice from this presentation.
- Complete the follow-up survey from CME Outfitters in approximately 3 months

CME Outfitters will send you confirmation of your participation to submit to CMS attesting to your completion of a CME for MIPS Improvement Activity.

CME for MIPS IMPROVEMENT ACTIVITY

CME Outfitters

Engage with us via Twitter! #NASH2020

Follow us on Twitter @cmeoutfitters for announcements about upcoming CME/CE opportunities, health care news, and more!

CME Outfitters

This continuing education activity is provided by CME Outfitters

MM-101-042920-47

Attendance Form for Groups

Please complete and FAX to **614.929.3600**

Activity Title and Faculty:

Live Virtual Symposium: At-Risk Patients Hidden in Plain Sight: Real-World Strategies for Screening and Treating Hepatitis B Virus

with Kris V. Kowdley, MD, FACP, FACG, FASGE, AGAF, FAASLD (Chair); Joseph Ahn, MD, MS, MBA; Amy Shen Tang, MD

Site/Institution Name: ______________________________

Practice Setting: ❑ Office-based ❑ Hospital ❑ Clinic ❑ Managed Care ❑ Small Group Practice (less than 5) ❑ Large Group Practice (more than 5) ❑ Other: ______________________________

Address: ______________________________

City: ______________________________ State: ________ ZIP: ______________

Site Coordinator: ______________________ Phone: ______________________

Fax: ______________________ Email: ______________________

Completion Date: ____________ We participated in: ______________________

Attendee Name (please print)	Please Circle Discipline						
______________________	MD	DO	PA	NP	RN	Pharm	Other: __________
______________________	MD	DO	PA	NP	RN	Pharm	Other: __________
______________________	MD	DO	PA	NP	RN	Pharm	Other: __________
______________________	MD	DO	PA	NP	RN	Pharm	Other: __________
______________________	MD	DO	PA	NP	RN	Pharm	Other: __________
______________________	MD	DO	PA	NP	RN	Pharm	Other: __________
______________________	MD	DO	PA	NP	RN	Pharm	Other: __________
______________________	MD	DO	PA	NP	RN	Pharm	Other: __________
______________________	MD	DO	PA	NP	RN	Pharm	Other: __________
______________________	MD	DO	PA	NP	RN	Pharm	Other: __________
______________________	MD	DO	PA	NP	RN	Pharm	Other: __________
______________________	MD	DO	PA	NP	RN	Pharm	Other: __________
______________________	MD	DO	PA	NP	RN	Pharm	Other: __________
______________________	MD	DO	PA	NP	RN	Pharm	Other: __________
______________________	MD	DO	PA	NP	RN	Pharm	Other: __________

Please FAX completed form to 614.929.3600 and use additional sheets as necessary.
Questions? Call 877.CME.PROS. Thank you for participating in this continuing education activity!