# Hepatitis Delta Testing Rates Remain Low Among Individuals With Chronic Hepatitis B: A US Administrative Claims Analysis



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## Conclusions

- Hepatitis delta virus (HDV) testing rates among those with hepatitis B virus (HBV) were persistently low over the last decade, even among those with recognized risk factors
  - These findings highlight a gap between clinical practice and both risk-based guideline recommendations (AASLD) and universal screening recommendations (European Association for the Study of the Liver [EASL] and the Hepatitis B Foundation) for individuals with HBV[1-3]
- Individuals with HBV who were more likely to be tested for HDV during the study period were older (>34 years); male; Asian, Black, or of missing/unknown race; located in the southern or eastern US; hepatitis B surface antigen positive; or treated for HBV or had hepatic decompensation
  - Contrary to clinical guidelines, those with hepatitis C infection were less likely to be tested for HDV
  - HIV infection and injection drug use were not associated with an increased likelihood of HDV testing
- Although the approval of bulevirtide in the United States provides a treatment option for individuals with HDV infection, efforts are needed to address the unmet need of routine testing and linkage to care

## Plain Language Summary

- Hepatitis delta virus can only grow and spread if hepatitis B virus is present in the body
- This study looked at whether people in the United States who tested positive for hepatitis B virus were likely to be tested for hepatitis delta virus, and what factors influenced their likelihood of being tested
- Among people with chronic hepatitis B, testing for hepatitis delta virus has remained low over the last 10 years; however, there has been a slight upward trend over time among those who tested positive for a part of the virus called the hepatitis B surface antigen and who had other risk factors
  - The likelihood of being tested for hepatitis delta virus during the study period varied depending on age, sex, geographic region, and other factors
  - Individuals with hepatitis C virus were less likely to be tested for hepatitis delta virus than those without, and additional risk factors like HIV infection and injection drug use did not correspond with the likelihood of testing

**References:** **1.** European Association of the Study of the Liver. *J Hepatol.* 2023;79:433-60. **2.** Terrault NA, et al. *Hepatology.* 2018;67(4):1560-99. **3.** Hepatitis B Foundation. 2026. Accessed September 21, 2026. https://www.hepb.org/research-and-programs/hepbetaconnect/testing-and-diagnosis/. **4.** Stockdale AJ, et al. *J Hepatol.* 2020;73:523-32. **5.** Lempp FA, et al. *Nat Rev Gastroenterol Hepatol.* 2016;13:580-89. **6.** Huang C, et al. *World J Gastroenterol.* 2014;20:14589-97. **7.** Da BL, et al. *Gastroenterol Rep.* 2019;7:231-45. **8.** Pan C, et al. *Dig Dis Sci.* 2023;68:3237-48. **9.** Hepcludex. Full prescribing information. US Food and Drug Administration. Gilead Sciences, Inc.; 2026. **10.** Hepcludex (bulevirtide acetate). Australian Register of Therapeutic Goods. Gilead Sciences, Inc.; 2024. **11.** Hepcludex. Product monograph. Gilead Sciences Canada, Inc.; 2025. **12.** Hepcludex (bulevirtide). European Medicines Agency. Gilead Sciences, Inc.; 2024. **13.** Gopalakrishna H, et al. *Curr Hepatol Rep.* 2024;23:32-44. **14.** John BV, et al. *Hepatol Commun.* 2024;8:e0401. **15.** Nathani R, et al. *J Viral Hepat.* 2022;30:195-200. **16.** Wong RJ, et al. *Am J Gastroenterol.* 2022;117:2067-70. **17.** Wong RJ, et al. *Gastro Hep Adv.* 2025;4:100575. **18.** Wong RJ, et al. *Clin Gastroenterol Hepatol.* 2025;23:1954-63.

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## Introduction

- Hepatitis delta virus (HDV) is an incomplete RNA virus that can only propagate in the presence of hepatitis B virus (HBV)[1-4]
- HDV infection causes a severe form of viral hepatitis[5-6] and carries a greater risk of morbidity and mortality compared with HBV alone[7]
- HDV infection remains underdiagnosed in the United States due to limited clinician awareness of the disease and available accurate diagnostic assays, inconsistent screening guidelines, and a lack of approved therapies in the United States until the approval of bulevirtide in 2026[8,9]
  - The AASLD HBV guidelines recommend risk-based screening for HDV in people who are hepatitis B surface antigen (HBsAg) positive, including people with HIV and/or hepatitis C virus (HCV) infection, people from HBV-endemic countries, people who inject drugs, and men who have sex with men[2]
  - By contrast, the European Association for the Study of the Liver (EASL) and the Hepatitis B Foundation guidelines recommend HDV screening in all HBsAg-positive individuals[1,3]
  - Bulevirtide is approved in the United States, the European Economic Area, and other regions for the treatment of chronic hepatitis delta[9-12]
- HDV diagnostic assays have evolved in recent years,[13] but studies evaluating testing trends have been limited to select populations (eg, US veteran populations) and show low testing rates among individuals with chronic hepatitis B (CHB)[14-18]

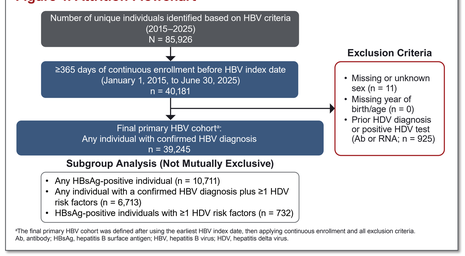
## Objective

- To evaluate HDV testing trends and predictors among individuals with HBV in US commercial and Medicare Advantage claims data

## Methods

- This observational retrospective study used Optum's deidentified ClinFormatics® Data Mart to establish a cohort of individuals with HBV in the United States between January 1, 2015, and June 30, 2025 (**Figure 1**)
- Included individuals had ≥365 days of continuous enrollment before the HBV index date (defined as the earliest confirmed HBV diagnosis); individuals were excluded only if they had prior HDV infection or missing age or sex
- HBV was identified by ≥1 inpatient or ≥2 outpatient *International Classification of Diseases, Ninth/Tenth Revision, Clinical Modification* (*ICD-9/10-CM*) codes ≥30 days apart, laboratory evidence (defined as having ≥2 positive markers for HBV DNA or HBsAg ≥6 months apart or 1 positive HBV DNA or HBsAg test plus 1 positive hepatitis B e antigen test), or HBV treatment with supporting ICD codes and laboratory evidence
- Subgroups included the following:
  - **HBsAg-positive individuals** (individuals were indicated for testing according to EASL and Hepatitis B Foundation guidelines[1-3])
    - If an HDV test result existed, the positive HBsAg test result must have occurred on or before the first HDV test
  - **Individuals with any evidence of HBV plus ≥1 HDV risk factors**
  - **HBsAg-positive individuals with ≥1 HDV risk factors** (indicated for testing according to AASLD guidelines[2])
- HDV risk factors included HIV or HCV coinfection, or a history of injection drug use within 365 days before HBV index
- HDV testing was identified by Current Procedural Terminology (CPT) codes or Logical Observation Identifier Names and Codes (LOINC) on or after the index date
- The proportion of individuals tested and annual testing rates were estimated; temporal trends were evaluated using a Mann-Kendall (MK) test
- Cox proportional hazards models identified predictors of testing, reported as adjusted hazard ratios (HRs) and 95% CIs

### Figure 1. Attrition Flowchart




[a]The final primary HBV cohort was defined after using the earliest HBV index date, then applying continuous enrollment and all exclusion criteria.
Ab, antibody; HBsAg, hepatitis B surface antigen; HBV, hepatitis B virus; HDV, hepatitis delta virus.

## Results

### Table 1. Demographics and Baseline Characteristics Among (A) Overall Individuals With HBV, (B) HBsAg-Positive Individuals, (C) Individuals With HBV Plus HDV Risk Factors, and (D) HBsAg-Positive Individuals With HDV Risk Factors

**A**

| | Overall HBV (N = 39,245) | | | |
|---|---|---|---|---|
| | Total (N = 39,245) | HDV Tested (n = 1,386) | Not Tested (n = 37,859) | *P*-Value |
| **Age, years, mean (SD)** | 57 (17.2) | 56 (15.4) | 57 (17.3) | 0.21 |
| **Age group, years, n (%)** | — | — | — | — |
| <35 | 5,989 (15) | 131 (10) | 5,858 (16) | **<.001** |
| 35–44 | 5,116 (13) | 243 (18) | 4,873 (13) | |
| 45–54 | 5,239 (13) | 251 (18) | 4,988 (13) | |
| 55–64 | 6,317 (16) | 214 (15) | 6,103 (16) | |
| 65–74 | 10,571(27) | 388 (28) | 10,183 (27) | |
| ≥75 | 6,013 (15) | 159 (12) | 5,854 (16) | |
| **Sex, male, n (%)** | 18,747 (48) | 780 (56) | 17,967 (47) | **<.001** |
| **Race or ethnicity, n (%)** | — | — | — | — |
| White | 11,746 (30) | 259 (19) | 11,487 (30) | **<.001** |
| Asian | 8,922 (23) | 499 (36) | 8,423 (22) | |
| Black | 5,411 (14) | 187 (13) | 5,224 (14) | |
| Hispanic | 3,808 (10) | 101 (7) | 3,707 (10) | |
| Missing/ unknown | 9,358 (24) | 340 (25) | 9,018 (24) | |
| **CCI, mean (SD)** | 2.7 (2.9) | 2.0 (2.2) | 2.7 (3.0) | **<.001** |
| **Cirrhosis, n (%)** | 3,014 (8) | 87 (6) | 2,927 (8) | **.046** |
| **HBsAg positive, n (%)** | 10,711 (27) | 508 (37) | 10,203 (27) | **<.001** |
| **HDV risk factors, n (%)** | — | — | — | — |
| HIV | 1,845 (5) | 59 (4) | 1,786 (5) | .426 |
| HCV | 4,052 (10) | 68 (5) | 3,984 (11) | **<.001** |
| Injection drug use | 2,069 (5) | 60 (4) | 2,009 (5) | .110 |
| **Follow-up time, years, mean (SD)** | 3 (2.9) | 2 (2.5) | 3 (2.8) | **<.001** |

**B**

| | HBsAg Positive (n = 10,711) | | | |
|---|---|---|---|---|
| | Total (n = 10,711) | HDV Tested (n = 508) | Not Tested (n = 10,203) | *P*-Value |
| **Age, years, mean (SD)** | 45 (17.8) | 56 (15.5) | 45 (17.7) | **<.001** |
| **Age group, years, n (%)** | — | — | — | — |
| <35 | 4,250 (40) | 47 (9) | 4,203 (41) | **<.001** |
| 35–44 | 2,003 (19) | 91 (18) | 1,912 (19) | |
| 45–54 | 992 (9) | 97 (19) | 895 (9) | |
| 55–64 | 1,012 (9) | 70 (14) | 942 (9) | |
| 65–74 | 1,670 (16) | 143 (28) | 1,527 (15) | |
| ≥75 | 784 (7) | 60 (12) | 724 (7) | |
| **Sex, male, n (%)** | 3,114 (29) | 277 (55) | 2,837 (28) | **<.001** |
| **Race or ethnicity, n (%)** | — | — | — | — |
| White | 2,621 (24) | 74 (15) | 2,547 (25) | **<.001** |
| Asian | 1,962 (18) | 204 (40) | 1,758 (17) | |
| Black | 1,215 (11) | 71 (14) | 1,144 (11) | |
| Hispanic | 1,263 (12) | 35 (7) | 1,228 (12) | |
| Missing/ unknown | 3,650 (34) | 124 (24) | 3,526 (35) | |
| **CCI, mean (SD)** | 1.2 (1.9) | 1.8 (2.1) | 1.1 (1.9) | **<.001** |
| **Cirrhosis, n (%)** | 258 (2) | 32 (6) | 226 (2) | **<.001** |
| **HBsAg positive, n (%)** | 10,711 (100) | 508 (100) | 10,203 (100) | — |
| **HDV risk factors, n (%)** | — | — | — | — |
| HIV | 276 (3) | 20 (4) | 256 (3) | **.047** |
| HCV | 315 (3) | 14 (3) | 301 (3) | .800 |
| Injection drug use | 245 (2) | 15 (3) | 230 (2) | .304 |
| **Follow-up time, years, mean (SD)** | 4 (2.9) | 2 (2.7) | 4 (2.8) | **<.001** |

**C**

| | HBV Plus HDV Risk Factors (n = 6,713) | | | |
|---|---|---|---|---|
| | Total (n = 6,713) | HDV Tested (n = 165) | Not Tested (n = 6,548) | *P*-Value |
| **Age, years, mean (SD)** | 61 (12.8) | 59 (12.9) | 61 (12.8) | **.018** |
| **Age group, years, n (%)** | — | — | — | — |
| <35 | 304 (5) | 6 (4) | 298 (5) | .11 |
| 35–44 | 461 (7) | 16 (10) | 445 (7) | |
| 45–54 | 1,013 (15) | 35 (21) | 978 (15) | |
| 55–64 | 1,817 (27) | 45 (27) | 1,772 (27) | |
| 65–74 | 2,349 (35) | 47 (29) | 2,302 (35) | |
| ≥75 | 769 (12) | 16 (10) | 753 (12) | |
| **Sex, male, n (%)** | 4,440 (66) | 118 (72) | 4,322 (66) | .140 |
| **Race or ethnicity, n (%)** | — | — | — | — |
| White or Asian[a] | 2,951 (44) | 59 (36) | 2,892 (44) | **.003** |
| Black | 1,569 (23) | 51 (31) | 1,518 (23) | |
| Hispanic | 805 (12) | 17 (10) | 788 (12) | |
| Missing/ unknown | 958 (14) | 19 (12) | 939 (14) | |
| **CCI, mean (SD)** | 4.8 (3.4) | 3.5 (2.4) | 4.9 (3.4) | **<.001** |
| **Cirrhosis, n (%)** | 1,358 (20) | 17 (10) | 1,341 (20) | **.001** |
| **HBsAg positive, n (%)** | 732 (11) | 43 (26) | 689 (11) | **<.001** |
| **HDV risk factors, n (%)** | — | — | — | **—** |
| HIV | 1,845 (27) | 59 (36) | 1,786 (27) | **.016** |
| HCV | 4,052 (60) | 68 (41) | 3,984 (61) | **<.001** |
| Injection drug use | 2,069 (31) | 60 (36) | 2,009 (31) | .118 |
| **Follow-up time, years, mean (SD)** | 3 (2.6) | 1 (2.4) | 3 (2.6) | **<.001** |

**D**

| | HBsAg Positive Plus HDV Risk Factors (n = 732) | | | |
|---|---|---|---|---|
| | Total (n = 732) | HDV Tested (n = 43) | Not Tested (n = 689) | *P*-Value |
| **Age, years, mean (SD)** | 55 (14.6) | 55 (13.2) | 55 (14.7) | .557 |
| **Age group, years, n (%)** | — | — | — | — |
| <45[b] | 184 (25) | 9 (21) | 175 (25) | .395 |
| 45–54 | 123 (17) | 11 (26) | 112 (16) | |
| 55–64 | 197 (27) | 14 (33) | 183 (27) | |
| ≥65[b] | 228 (31) | 9 (21) | 219 (32) | |
| **Sex, male, n (%)** | 459 (63) | 32 (74) | 427 (62) | .102 |
| **Race or ethnicity, n (%)** | — | — | — | — |
| White or Asian[a] | 302 (41) | 16 (37) | 286 (42) | .943 |
| Black | 204 (28) | 15 (35) | 189 (27) | |
| Hispanic | 109 (15) | 6 (14) | 103 (15) | |
| Missing/ unknown | 117 (16) | 6 (14) | 111 (16) | |
| **CCI, mean (SD)** | 3.8 (2.9) | 3.3 (2.0) | 3.8 (2.9) | .534 |
| **Cirrhosis, n (%)** | 70 (10) | <5 | 66 (10) | .952 |
| **HBsAg positive, n (%)** | 732 (100) | 43 (100) | 689 (100) | — |
| **HDV risk factors, n (%)** | — | — | — | — |
| HIV | 276 (38) | 20 (47) | 256 (37) | .219 |
| HCV | 315 (43) | 14 (33) | 301 (44) | .153 |
| Injection drug use | 245 (33) | 15 (35) | 230 (33) | .840 |
| **Follow-up time, years, mean (SD)** | 4 (2.8) | 2 (3.0) | 4 (2.8) | **<.001** |

**Bold** *P*-values indicate statistical significance. The HBsAg-positive, HBV plus HDV risk factors, and HBsAg-positive plus HDV risk factors groups were not mutually exclusive. The proportions of younger individuals (aged 18–34 years), older individuals (≥65 years), and individuals with cirrhosis and mean CCI differed numerically between the subgroups. For data with n<5, percentages were redacted to protect patient privacy.
[a]To protect patient privacy, selected categories in Table 1D were combined for presentation (<35 and 35–45 years; 65–74 and ≥75 years; White and Asian race), and cells with n<5 were redacted. All categories were analyzed separately.
CCI, Charlson Comorbidity Index; HBsAg, hepatitis B surface antigen; HBV, hepatitis B virus; HCV, hepatitis C virus; HDV, hepatitis delta virus.

- Out of 39,245 individuals with HBV, most were White (30%) or Asian (23%) and female (52%), and the mean (SD) age was 57 (17.2; **Table 1A**)
  - The HBsAg-positive group (**Table 1B**) had a higher proportion of younger individuals (aged <35 years) and a lower proportion of older individuals (aged ≥65 years) than the other subgroups
- Several baseline clinical factors differed between those who were tested vs not tested for HDV infection, but these clinical differences were not consistent across subgroups
  - For example, among individuals who were HBsAg positive (**Table 1B**), cirrhosis was more common among those who were tested for HDV (vs not tested; *P* <.001); among individuals with HBV plus HDV risk factors (**Table 1C**), cirrhosis was less common among those who were tested for HDV (*P* = .001)
  - Individuals who were tested for HDV were more likely to have HIV in all subgroups, though not all differences reached statistical significance (**Table 1B**)

### Table 2. Proportion of Individuals With HBV Receiving HDV Testing During Follow-Up by Subgroup

| HBV Group | n | Follow-Up, Years, Median (IQR) | Any HDV Test During Follow-Up, n (%), [95% CI] |
|---|---|---|---|
| **Overall HBV cohort** | 39,245 | 2.6 (1.1, 5.0) | 1,386 (3.5), [3.4, 3.7] |
| **HBsAg positive** | 10,711 | 3.4 (1.8, 5.8) | 508 (4.7), [4.3, 5.2] |
| **HBV + HDV risk factors[a]** | 6,713 | 1.9 (0.8, 4.2) | 165 (2.5), [2.1, 2.9] |
| **HBsAg positive + HDV risk factors[a]** | 732 | 2.6 (1.3, 5.1) | 43 (5.9), [4.3, 7.8] |

The HBsAg-positive, HBV plus HDV risk factors, and HBsAg-positive plus HDV risk factors groups were not mutually exclusive. Any HDV test included antibody and/or RNA tests. Follow-up was calculated from the HBV index date to the censor date and is presented as median (IQR) years among all individuals in each HBV subgroup. For HDV-tested individuals, the censor date was defined as the first HDV test date. Person-time was calculated from an individual's index date until the earliest of their (1) first HDV test, (2) end of enrollment, (3) end of data availability, or (4) death.
[a]HDV risk factors included the presence of HIV or HCV coinfection or a history of injection drug use.
HBsAg, hepatitis B surface antigen; HBV, hepatitis B virus; HCV, hepatitis C virus; HDV, hepatitis delta virus; IQR, interquartile range.

- Only 3.5% of individuals with HBV received HDV tests during follow-up (**Table 2**)
- The overall proportion tested was modestly higher among those with HBsAg positivity (508/10,711; 4.7%) and those with HBsAg positivity plus HDV risk factors (43/732; 5.9%), but generally remained low

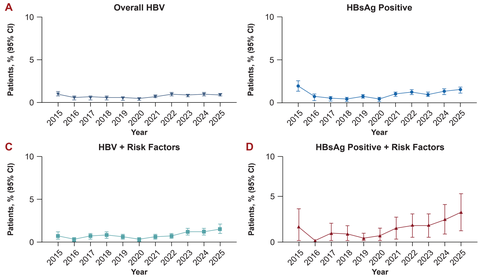
### Table 3. HDV Testing Cascade During Follow-Up Among Individuals in the Overall HBV Cohort Tested for HDV

| Testing Stage | Overall HBV (N = 39,245) n (%), [95% CI] |
|---|---|
| **Any HDV test (antibody and/or RNA)** | |
| Any HDV test ordered and/or completed[a] | 1,267[b] (3.2), [3.1, 3.4] |
| **HDV antibody test** | — |
| ≥1 HDV antibody test ordered and/or completed[a] | 1,163 (3.0), [2.8, 3.1] |
| HDV antibody positive[c] | 25 (2.4), [1.5, 3.5] |
| **Follow-up RNA test** | — |
| HDV RNA test after positive HDV antibody[d] | <5 |
| HDV RNA positive | <5 |

For data with n<5, percentages were redacted to protect patient privacy.
[a]Percentages were based on the number of individuals in the overall HBV group (n = 39,245). [b]Counts used cascade-specific eligibility criteria; 1,267 individuals met the cascade definition for the testing cascade. [c]Percentage was based on the number of individuals who had an HDV antibody test with results (n = 1,056). [d]Percentage was based on the number of individuals with a positive HDV antibody test (n = 25).
HBV, hepatitis B virus; HDV, hepatitis delta virus.

- Among 1,267 (3.2%) individuals with HBV who were tested for HDV according to cascade-specific eligibility criteria, the majority (1,163) received an HDV antibody test (**Table 3**)
  - Of those with a positive antibody test, fewer than 5 proceeded to be tested for HDV RNA

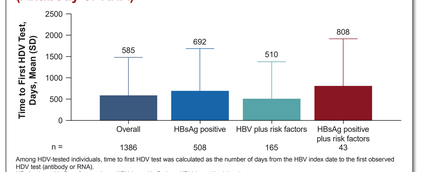
### Figure 2. Temporal Trends in HDV Testing Among (A) Overall Individuals With HBV, (B) HBsAg-Positive Individuals, (C) Individuals with HBV Plus HDV Risk Factors, and (D) HBsAg-Positive Individuals With HDV Risk Factors Between 2015 and 2025




MK test statistics for the overall HBV group: s-statistic, 9; z-statistic, 0.623, *P* = .533. MK test statistics for the HBsAg-positive group: s-statistic, 17; z-statistic, 1.246; *P* = .213. MK test statistics for the HBV + HDV risk factors group: s-statistic, 23; z-statistic, 1.713; *P* = .087. MK test statistics for the HBsAg-positive + HDV risk factors group: s-statistic, 33; z-statistic, 2.491; *P* = .013. The reference year was 2015.
For individuals with HDV testing, follow-up was censored at the first HDV test date; for individuals without HDV testing, follow-up was censored at the earliest of the enrollment end date, death date, or study end date.
HBsAg, hepatitis B surface antigen; HBV, hepatitis B virus; HDV, hepatitis delta virus; MK, Mann-Kendall.

- HDV testing rates remained low, with only 1% of individuals with HDV receiving testing in 2025 vs 0.6% to 1% annually from 2015 to 2024 (**Figure 2**)
  - The proportions tested in the HBsAg-positive, HBV plus risk factors, and HBsAg-positive plus risk factors subgroups increased slightly from 2020 to 2025
- The MK test indicated an upward trend in testing among the HBsAg-positive plus risk factors group (*P* = .013) but remained low overall (3% tested in 2025)

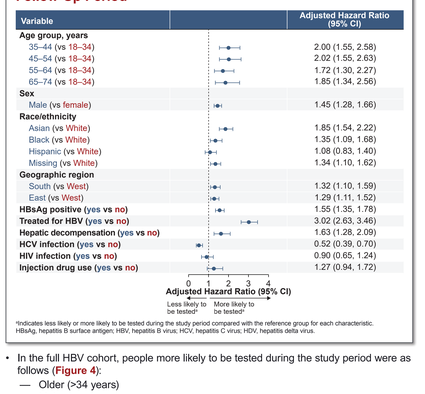
### Figure 3. Time From HBV Index Date to First HDV Test (Antibody or RNA)




Among HDV-tested individuals, time to first HDV test was calculated as the number of days from the HBV index date to the first observed HDV test (antibody or RNA).
HBsAg, hepatitis B surface antigen; HBV, hepatitis B virus; HDV, hepatitis delta virus.

- Overall, the mean time to the first HDV test was 585 days in individuals with HBV and was similar across the subgroups (**Figure 3**)
  - The mean time to the first HDV test was longest in the HBsAg-positive plus HDV risk factors group (808 days)

### Figure 4. Predictors of Receiving an HDV Test During the Follow-Up Period




[a]Indicates less likely or more likely to be tested during the study period compared with the reference group for each characteristic.
HBsAg, hepatitis B surface antigen; HBV, hepatitis B virus; HCV, hepatitis C virus; HDV, hepatitis delta virus.

- In the full HBV cohort, people more likely to be tested during the study period were as follows (**Figure 4**):
  - Older (>34 years)
  - Male
  - Asian, Black, or of unknown/missing race (vs White)
  - Located in the southern or eastern United States (vs western)
  - HBsAg positive
  - Treated for HBV
  - Had hepatic decompensation
- Of note, those with HBV plus HCV coinfection were less likely to be tested for HDV during the study period (adjusted HR, 0.52; 95% CI, 0.39, 0.70), and HIV infection and injection drug use were not associated with an increased likelihood of testing

## Limitations

- Interpretations from these results are constrained by limitations associated with administrative claims and electronic medical record datasets, including limited follow-up and laboratory or clinical measures
- As with any retrospective claims analysis, outcomes defined with *ICD-9/10-CM* codes are susceptible to miscoding and consequently to misclassification bias
- Some groups with risk factors indicated for testing cannot be identified in claims data (eg, individuals from HBV-endemic regions and men who have sex with men)