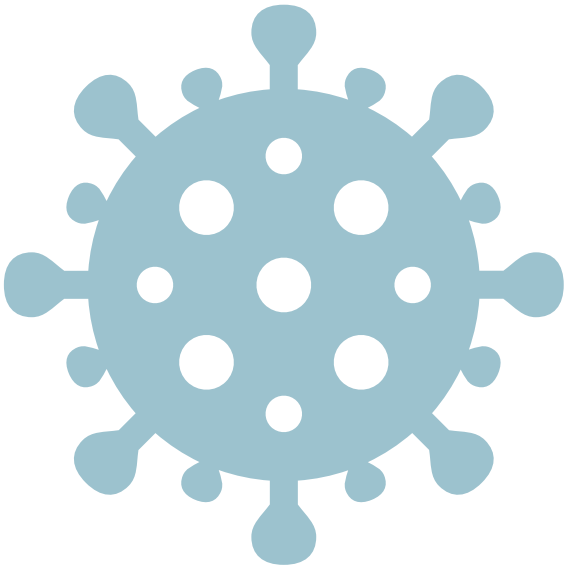

Frequently Asked Questions

Insurance Coverage for Viral Hepatitis Treatment and Preventive Services

October 2022

Contents

PURPOSE

Viral hepatitis screening, testing, vaccination, and treatment are critical components of viral hepatitis elimination plans and care cascades. Lack of insurance coverage, including patient cost-sharing, represents an early and significant patient barrier to preventive care and treatment access. As new and updated recommendations are published, it is important to understand how these recommendations influence insurance coverage decisions to determine whether and when insurance plans will cover the services.

Coverage and subsequent patient costs for these essential services varies by plan type, making it challenging to address patient access barriers and understand the financial and policy impacts of new or updated viral hepatitis recommendations. Insurance plans are not required to cover all the services included in CDC's viral hepatitis screening and testing recommendations; and not all plans have to cover CDC Advisory Committee on Immunization Practices (ACIP) recommended vaccines for adults. Decisions about which screening and vaccination services to cover are at the discretion of the plan administrators. Questions about insurance coverage should be directed to the state Medicaid Director's office, Centers for Medicare & Medicaid Services (CMS), or insurance plan providers.

The purpose of this document is to:

1) provide an introduction to the different insurance plan types covering viral hepatitis screening, testing, vaccination, and treatment services
2) summarize insurance coverage and patient cost-sharing by plan type for viral hepatitis prevention and treatment services

Methods

Information on viral hepatitis preventive services and treatment insurance coverage, as well as drug cost data, were collected through the following strategies:

1) Scanning of federal health agency webpages, namely cms.gov (Medicare, Medicaid, CHIP, private insurance), cdc.gov (317 Vaccine Funding Program), hrsa.gov (340B Drug Pricing Program, safety net programs for the uninsured), healthcare.gov (private insurance), medicaid.gov, and medicare.gov
2) Scanning of Kaiser Family Foundation’s website for available issue briefs and policy analysis reports, followed by review of references
3) Google searches for cost-sharing and coverage of viral hepatitis vaccination, screening/testing and treatment services by insurance plan type
4) Scanning of resources shared by key informants and viral hepatitis partner organizations

[Disclaimer: The information contained in this report does not represent the official views of HHS and its agencies/offices, and the report should not be attributed as an HHS, CDC, or other HHS agency/office report.]

GLOSSARY

Advisory Committee on Immunization Practices (ACIP): a federal advisory committee to the Centers for Disease Control and Prevention consisting of medical and public health experts who develop recommendations on the use of vaccines among the civilian population of the United States. The CDC Director reviews and approves proposed recommendations, which become the official CDC recommendations for vaccination of the U.S. population.

beneficiary: A person covered by or enrolled in a health insurance plan (i.e., patient receiving the plan's benefits).

Children's Health Insurance Program (CHIP): A state administered health insurance program dedicated to covering otherwise uninsured children whose families earn too much to qualify for Medicaid. Similar to Medicaid, each state receives federal funding to administer their own CHIP programs.

co-insurance: A percentage of the health service or prescription drug costs some patients may pay as an out-of-pocket fee required by some health insurance plans. These are typically imposed for more expensive services or drugs.

co-pay: Fixed fees, usually modest, imposed by some insurance plans that patients may pay out-of-pocket for a health service or prescription drug.

cost sharing: A requirement imposed by some insurance plans for all or select services. Patients pay fees out of pocket, such as deductibles, co-pays (fixed fees, usually modest) or a percentage of the health service or prescription drug costs (co-insurance).

deductible: An out-of-pocket amount some insurance plans may require patients to pay for covered health care services or prescription drug costs before the plan starts to pay (i.e., cover the costs).

direct acting antivirals (DAAs): A type of prescription medication recommended and highly effective for treating hepatitis C. Since 2013, a variety of brand and authorized generic DAAs effective against multiple hepatitis C virus (HCV) genotypes (i.e., genetic variants) have become available. They work by blocking certain stages of the HCV replication cycle. Taken by mouth for 8-12 weeks, they can safely cure ≥95% of hepatitis C cases.

expanded Medicaid plans: In states that opted to expand their Medicaid programs under the Affordable Care Act[1], these Medicaid plans cover all non-elderly individuals with annual incomes at or below 133 percent of the federal poverty level). Some of these states may choose to provide the same benefits and coverage to all their beneficiaries as they do through expanded Medicaid plans, which must cover all ACIP and USPSTF recommended preventive services without cost-sharing.

[1] As of June 2022, 39 states (including DC) have adopted Medicaid expansion.

grandfathered insurance plan: An individual health insurance policy purchased on or before March 23, 2010. These plans may not include some rights and protections provided under the Affordable Care Act. More information: here.

Medicaid: A state-administered program that helps cover health care costs for some people with limited income and resources, including adults, children, pregnant women, elderly adults, and persons living with disabilities. Medicaid is jointly funded by the federal government and the state and administered in accordance with federal [Centers for Medicare and Medicaid Services (CMS)] requirements. Eligibility rules and coverage details differ between states (traditional vs. expanded state plans).

Medicare: A federal program that helps cover healthcare costs for adults aged 65 and or older. Part A and Part B of Medicare do not differ between states, but Part D (an optional prescription drug benefit) and other auxiliary plans are managed at the state level. Medicare Advantage (a.k.a. Part C) is a Medicare-approved, private plan alternative that combines Part A, Part B, and (most of the time) Part D coverage.

national coverage determination (NCD) process: Medicare coverage is limited to services that are deemed reasonable and necessary for the diagnosis or treatment of an illness or injury. This process decides what preventive services not specified in the Medicare statutes can and will be covered. More information: here.

non-grandfathered insurance plans: An individual health insurance policy purchased after March 23, 2010, or a policy that was purchased before this date, but lost its grandfathered status at renewal. These plans adhere to rights and protections provided under the Affordable Care Act.

traditional Medicaid plans: Traditional Medicaid plans are those covering patients eligible for Medicaid before it was expanded under the Affordable Care Act (ACA). Traditional Medicaid plans are not required to provide the coverage and benefits mandated under the ACA but may choose to do so.

United States Preventive Services Task Force (USPSTF): an independent volunteer panel that makes evidence-based recommendations about preventive medicine services, such as screening tests, based on peer-reviewed science. The recommendations are intended to guide primary care clinicians and provide accurate patient information on preventing disease onset. The USPSTF assigns letter grades based on the strength of the evidence, without considering the cost of the preventive service. The recommendations only apply to: 1) services offered in or referred by primary care providers, and 2) persons with no signs or symptoms of the disease being assessed.

317 Vaccine Funding Program: Section 317 of the Public Health Service Act authorizes the federal purchase of vaccines to vaccinate children, adolescents, and adults. A Section 317-purchased vaccine has been directed towards meeting the needs of priority populations. Section 317 discretionary funding also supports immunization program operations at the local, state, and national levels. More information: here.

340B Drug Pricing Program: An outpatient medication discount program that allows patients seen by 'covered entities' to receive certain medications at discounted prices; covered entities include safety-net providers that care for uninsured and low-income patients.

FREQUENTLY ASKED QUESTIONS

Vaccination coverage and reimbursement

Is universal hepatitis B adult vaccination covered by insurance?

The Advisory Committee on Immunization Practices (ACIP) currently recommends all adults age 19 to 59 years of age receive hepatitis B vaccination (more detail below). Coverage of adult hepatitis B vaccination depends on plan type.

Medicare

Medicare generally covers vaccines and their administration under Part D (Medicare prescription drug benefit), which imposes patient cost-sharing that varies by plan. However, Part B specifically covers hepatitis B vaccination without cost-sharing for all beneficiaries (i.e. covered patients) Medicare considers 'medium to high risk' for infection. These risk factors include hemophilia, end stage renal disease, diabetes, living with someone with hepatitis B, health care worker in frequent contact with blood or body fluids. For those without these risk factors, Medicare covers hepatitis B vaccination under Part D with possible cost-sharing. However, the recent enactment of the Inflation Reduction Act of 2022 will eliminate cost-sharing for all ACIP-recommended adult vaccines covered under Part D starting in 2023 (amendment to 42 U.S.C.A. § 1395w-102(b)(8)).

Medicaid

Coverage varies by state and type of plan. In states that have expanded Medicaid, plans covering Medicaid expansion populations (i.e., non-elderly individuals with annual incomes at or below 133 percent of the federal poverty level) cover ACIP-recommended vaccines, including for hepatitis B, without cost sharing (link). Traditional Medicaid plans are those covering patients eligible for Medicaid before expansion under the Affordable Care Act (ACA). Coverage and level of cost-sharing through these plans depends on the state, though the majority of states do cover hepatitis B vaccines (link). Starting in 2023, however, all Medicaid programs will have to cover ACIP-recommended adult vaccines without cost-sharing as part of a provision in the Inflation Reduction Act of 2022 (amendment to 42 U.S.C.A. § 1396o(a)(2)).

Private Insurance

Most private insurance plans (i.e., non-grandfathered plans) are required by the ACA to cover ACIP-recommended vaccinations and their administration costs without imposing cost-sharing. Coverage in accordance with the new universal adult hepatitis B vaccination recommendation will begin in 2023. However, grandfathered plans (those in place before ACA was implemented and adhering to certain regulations), do not have to cover these services and can impose cost-sharing requirements if they do.

Under- or Uninsured Populations

Hepatitis B vaccine, excluding office visit costs and provider fees for administering the shot, can be covered without cost-sharing if a state chooses to use its 317 vaccine program funds to cover adult vaccinations. This varies by state choice/policy.

Is the birth dose for hepatitis B covered by insurance?

CDC recommends that all infants receive the hepatitis B vaccine series as part of the recommended childhood immunization schedule, with the first shot administered the same day or shortly after birth. Coverage of the birth dose for the hepatitis B vaccine depends on plan type.

Medicare

Not applicable. Medicare primarily covers adults 65 years of age and older or certain younger people with disabilities.

Medicaid and Children's Health Insurance Program (CHIP)

Children whose families meet certain eligibility requirements receive insurance coverage through Medicaid (click here for a state-by-state breakdown of income eligibility limits). Medicaid covers all ACIP-recommended childhood vaccines – including the hepatitis B birth dose and subsequent two vaccine doses, as well as the office visits and provider fees for administering the shot – **without imposing cost-sharing**.

Similar to Medicaid, each state receives federal funding to administer their own CHIP programs. However, CHIP specifically covers otherwise uninsured children whose families earn too much to qualify for Medicaid. States have different options for how to create and administer their CHIP programs. They may choose to create and administer their CHIP programs as an expansion of Medicaid (Medicaid-expansion CHIP), as a program entirely separate from Medicaid, or as a combination of both approaches. **ACIP-recommended vaccines for children under age 19 – including the hepatitis B birth dose and subsequent completion of the vaccine series, as well as the office visits and provider fees for administering the shot – are exempt from cost-sharing**, whether the child is covered by Medicaid-expansion CHIP or separate CHIP programs (42 U.S.C. § 1397cc (c), (e)). Funding for children's vaccinations covered by Medicaid-expansion CHIP programs comes from the Vaccines for Children Program (i.e. the 317 vaccine funding program). By contrast, states must use CHIP funds to purchase vaccines for children enrolled in separate CHIP programs.

Private insurance

Most private insurance plans (i.e., non-grandfathered plans) are required by the Affordable Care Act (ACA) to cover ACIP-recommended vaccinations – including the hepatitis B birth dose vaccination – and their administration costs without imposing cost-sharing. However, grandfathered plans (those in place before ACA was implemented and adhering to certain regulations), do not have to cover these services and can impose cost-sharing requirements if they do.

Under- or Uninsured

States can use funding from their 317 vaccine funding program budget to cover the vaccine, excluding office visit costs and provider fees for administering the shot.

Under what circumstances is hepatitis A vaccination covered by insurance?

If a hepatitis A outbreak is actively occurring, states can choose to use the 317 vaccine funding program to supply hepatitis A vaccines to the adult public without cost-sharing. It is up to the state how much funding is put towards these vaccinations. This program applies to several eligible populations:

- Underinsured and uninsured children, adolescents, and adults
- Fully insured children, adolescents, adults affected by disease outbreaks
- Individuals in correctional facilities and jails

Under non-outbreak conditions, coverage of the hepatitis A vaccination depends on plan type.

Medicare

Medicare covers hepatitis A vaccination under Part D (the Medicare drug benefit) when it is ordered by a medical professional. Part D prescription plans impose patient cost-sharing that varies by plan. However, the recent enactment of the Inflation Reduction Act of 2022 will eliminate cost-sharing for all ACIP-recommended adult vaccines covered under Part D starting in 2023 (42 U.S.C.A. § 1395w-102(b)(8)).

Medicaid

Coverage varies by state and type of plan. In states that expanded Medicaid, plans covering Medicaid expansion populations (i.e., non-elderly individuals with annual incomes at or below 133 percent of the federal poverty level) cover ACIP-recommended vaccines, including for hepatitis A, without cost sharing (link). In states with traditional Medicaid programs (i.e. those dedicated to covering patients eligible for Medicaid before it was expanded under ACA), coverage and level of cost-sharing depends on the state, though the majority of states do cover hepatitis A vaccines (link). Starting in 2023, however, all Medicaid programs will have to cover ACIP-recommended adult vaccines without cost-sharing as part of a provision in the Inflation Reduction Act of 2022 (amendment to 42 U.S.C.A. § 1396o(a)(2)).

Per the current ACIP recommendations, these plans cover routine hepatitis A vaccination for children, persons at increased risk for infection or severe hepatitis (e.g., persons living with chronic liver disease or human immunodeficiency virus (HIV) infection), persons experiencing homelessness, and any person wishing to obtain immunity. They also cover postexposure prophylaxis (i.e., vaccination immediately following exposure to hepatitis A) for all persons one year and older, as well as preexposure prophylaxis for unvaccinated persons traveling to or working in countries that have high or intermediate hepatitis A virus endemicity.

Private Insurance

Most private insurance plans (i.e., non-grandfathered plans) are required by the Affordable Care Act (ACA) to cover ACIP-recommended vaccinations and their administration costs without imposing cost-sharing. However, grandfathered plans (those in place before ACA was implemented and adhering to certain regulations), do not have to cover these services and can impose cost-sharing requirements if they do.

Under- or Uninsured Populations

The vaccine, excluding office visit costs and provider fees for administering the shot, can be covered without cost-sharing if a state chooses to use its 317 vaccine funding program funds towards adult vaccinations. This varies by state choice/policy.

Screening & testing coverage and reimbursement

Is universal hepatitis C screening covered by insurance?

Since 2020, CDC has recommended hepatitis C screening at least once in a lifetime for all adults aged 18 years and older and during each pregnancy, except in settings where the prevalence of hepatitis C virus infection (HCV) is less than 0.1%. Insurance coverage of hepatitis C screening varies by plan type and, in the case of Medicaid, by state. However, after the passage of the Affordable Care Act (ACA), most insurance plan types must now cover one-time hepatitis C screening for most adults ages 18 to 79 years (including during pregnancy) and periodic testing for persons with continued risk for hepatitis C virus (HCV) infection (e.g., persons with past or current injection drug use), as recommended by the United States Preventive Services Task Force (USPSTF) (grades A and B) without patient cost-sharing.

Medicare

Medicare decided, through their 2014 National Coverage Determination (NCD) process, to cover hepatitis C testing without cost-sharing for beneficiaries considered 'high risk' for HCV infection. Medicare uses the NCD process to make coverage decisions for preventive services with USPSTF recommendation grades A or B. Because Medicare issued their HCV screening NCD before the most recent (2020) update to the USPSTF recommendations, the coverage criteria align with the previous, risk-based USPSTF recommendation from 2013, and include:

- current or past history of illicit injection drug use (repeat screening covered for continued injection drug use since the negative test result)
- history of blood transfusion before 1992 (single screening covered)

If a primary care physician or practitioner orders testing for a patient born between 1945-1965 that does not meet the high risk criteria, Medicare will cover the one-time hepatitis C screening [link]. The public can submit formal NCD requests to Centers for Medicare & Medicaid Services (CMS), including requests to revise/reconsider or initiate new NCDs.

Medicaid

For those with Medicaid, coverage for hepatitis C screening varies by state and type of plan. Traditional Medicaid plans are those covering patients eligible for Medicaid before it was expanded under ACA. These plans do not have to cover USPSTF recommended preventive services and can impose cost-sharing requirements if they do. By contrast, Medicaid plans covering Medicaid expansion populations (i.e., non-elderly individuals with annual incomes at or below 133 percent of the federal poverty level) cover one-time hepatitis C screening for adults ages 18 to 79 and periodic testing for adults at continued increased/higher risk for HCV infection without cost-sharing.

Private Insurance

Most private insurance plans cover one-time hepatitis C screening for all adults age 18-79 years, as well as periodic screening for those with continued risk for HCV infection. However, grandfathered private insurance plans, do not have to cover these services and can impose cost-sharing requirements if they do

Under- or Uninsured populations

Safety net provider facilities may offer hepatitis C screening for free or on a sliding scale.

Is universal hepatitis B screening going to be covered by insurance?

Insurance coverage of hepatitis B screening varies by plan type and, in the case of Medicaid, by state. However, after the passage of the Affordable Care Act (ACA), most insurance plan types must now cover hepatitis B testing for adolescents and adults at increased risk for hepatitis B virus (HBV) infection, as recommended by the United States Preventive Services Task Force (USPSTF) (grades A and B) without patient cost-sharing.

Medicare

Medicare decided, through their National Coverage Determination process, to cover hepatitis B testing without cost-sharing for those considered 'high risk' for infection. Medicare uses the National Coverage Determination process to make coverage decisions for preventive services with USPSTF recommendation grades A or B.

Medicaid

Traditional Medicaid plans are those covering patients eligible for Medicaid before it was expanded under ACA, and these plans do not have to cover these services and can impose cost-sharing requirements if they do. By contrast, Medicaid plans covering Medicaid expansion populations (i.e., non-elderly individuals with annual incomes at or below 133 percent of the federal poverty level) cover hepatitis B testing for adolescents and adults at increased risk for HBV infection without cost-sharing.

Private Insurance

Most private insurance plans cover hepatitis B screening for adolescents and adults at increased risk for HBV infection. However, grandfathered private insurance plans, do not have to cover these services and can impose cost-sharing requirements if they do.

Under- or Uninsured populations

Safety net provider facilities may offer hepatitis B screening for free or on a sliding scale.

Treatment coverage and reimbursement

Is hepatitis C treatment covered by insurance?

Hepatitis C treatment [i.e., direct-acting antiviral (DAA) therapy] coverage and patients' out-of-pocket costs vary by insurance plan and plan type. For example, through a process known as prior authorization, many insurance plans require medical care providers to submit documentation showing that patients meet certain criteria before they will cover the DAA medication costs. The process and criteria vary by insurance plan/payer; the most common criteria include liver damage (i.e., requiring patients to have a certain level of liver damage), abstinence from or counseling for alcohol and other drug use, and having a specialist prescribe the DAA or consult the prescribing provider. The process can delay the start of treatment, and if the patient does not meet all of the prior authorization criteria, their plan can choose not to pay any of the medication costs.

Insurance plans use drug formularies [sometimes referred to as preferred drug lists (PDLs)] to assign medications to cost categories (tiers) that determine how much a patient pays for a drug. Generally, drugs assigned to the lower tiers have lower patient co-pays and those assigned to higher tiers require patients to pay higher fees (often a percentage of the drug cost, i.e., co-insurance). Because of their higher price ['wholesale acquisition costs' (i.e., sticker prices) range from $417 (Mavyret) to $1,125 (Harvoni) per day], DAAs are typically assigned to the highest tier, reserved for specialty medications. However, a plan's formulary may not include every available DAA or assign it to the 'non-preferred' category, meaning the plan would not cover any of the costs, leaving the patient responsible for the entire cost. Patient costs may also vary across plans because insurance providers in the United States each negotiate their own purchase prices with the pharmaceutical manufacturers, often through third party agents called pharmacy benefit managers.

Medicare

Medicare 'Part D' – an optional prescription drug benefit elected by 74% of beneficiaries (as of 2019) and provided through private insurance plans approved by Centers for Medicare and Medicaid Services – covers some of the DAA prescription costs for Medicare enrollees (i.e. beneficiaries). Medicare beneficiaries can receive Part D benefits either through Medicare Advantage (a.k.a. Part C) or standalone prescription drug plans. Medicare Part D plans may impose their own prior authorization requirements that must be met before the plan approves treatment coverage. Currently, Medicare is not allowed to directly negotiate drug prices with pharmaceutical manufacturers that can apply across all Part D plans. Consequently, each Part D plan must negotiate their own drug prices and can decide which DAAs to include in their drug formularies, resulting in different beneficiary costs by plan. However, with the enactment of the Inflation Reduction Act of 2022, the HHS Secretary will have authority to negotiate prices for a limited number of the top 50 most costly, FDA approved, brand or authorized generic drugs covered under Part D and Part B each year, starting in 2026. According to the latest Medicare Part D spending dataset, the only DAA in the top 50 in total Medicare spending during 2020, and therefore potentially eligible for a lower negotiated cost for beneficiaries, was Epclusa (ranked 44). The HHS Secretary will publish their initial list of 10 Part D drugs in September 2023. The amount a Medicare beneficiary pays for

their DAA treatment depends on their income and how much they have spent out-of-pocket that plan year.

The Part D standard benefit has several coverage phases with varying levels of patient out-of-pocket spending responsibility:

1) **deductible**: 100% patient responsibility,
2) **initial coverage phase**: patient pays 25% of drug costs after paying deductible and their plan pays the remaining 75%, until they reach the initial coverage limit ($4,430 in combined patient and plan spending 2022),
3) **coverage gap phase**: a.k.a. the Donut Hole, when patient pays 25% of costs, drug manufacturer covers 70%, and the plan pays the remaining 5%
4) **catastrophic coverage:** after reaching an out-of-pocket spending threshold ($7,050 in 2022), the patient pays the greater of 5% of costs or a co-pay of $3.95 for generics or $9.85 for brand-name drugs. Unlike the initial coverage limit, this threshold does not include spending by the insurance plan. Currently, Medicare does not set a limit on how much patients spend out-of-pocket each plan year. Starting in 2024, as part of a provision in the Inflation Reduction Act of 2022, this 5% co-insurance will be eliminated; an annual out-of-pocket spending threshold of $2,000 will take effect in 2025. More information on what counts towards the out-of-pocket threshold can be found here.

If a patient receiving the standard Part D benefit has not met their deductible, initial coverage limit, or out-of-pocket spending threshold (a.k.a. catastrophic threshold) before starting DAA treatment, they will have to have to pay up to the $7,050 threshold plus 5% of the remaining drug costs in the 2022 plan year. If, on the other hand, the patient has already paid $7,050 in medication costs before starting treatment, they will only pay either 5% of the drug cost or co-pays. Starting in 2024, patients will not have to pay these additional catastrophic coverage fees, and in 2025, patients will only have to pay $2,000 out-of-pocket each year for their medications.

Drug costs are less for certain Medicare beneficiaries with low income. Beneficiaries with income less than 150% of poverty ($19,320 for individuals/$26,130 for married couples in 2021) and modest assets (less than $14,790 for individuals/$29,520 for couples in 2021) can receive financial assistance through the Medicare Savings Program's Low-Income Subsidy (LIS), also called Extra Help. Those enrolled and receiving full LIS benefits pay no Part D deductible and only modest co-pays ($3.95-$9.85 for covered non-generic/preferred medications in 2022) until they reach the catastrophic threshold, after which they pay no cost sharing. Partial LIS benefit recipients (only 3% of all LIS recipients) pay a smaller deductible ($99) and 15% of the drug cost until they reach the catastrophic threshold, when they pay modest co-pays ($3.95-$9.85 for covered non-generic/preferred medications in 2022).

Medicaid

Medicaid plans may choose not to cover all available DAAs. Therefore, if a beneficiary requires a DAA not included in their plan's drug formulary, they would have to pay the full drug costs. In addition, Medicaid

plans may impose prior authorization requirements that must be met before the plan approves treatment coverage. For a state-by-state breakdown of Medicaid prior authorization requirements related to liver damage, sobriety, and prescriber types, refer to HepVu's hepatitis C maps and NVHR's State of Hepatitis C reports.

A Medicaid beneficiary's out-of-pocket costs will vary by plan and DAA prescribed. DAAs generally fall into the specialty drug tier, but there are different classifications within this tier (preferred vs. non-preferred) that affect patient cost-sharing. Fifteen states do not require prescription drug cost-sharing for Medicaid beneficiaries. For other jurisdictions, federal law restricts the amount of cost-sharing Medicaid plans can charge. For beneficiaries with incomes at or below 150% of the federal poverty level (FPL), the maximum allowed co-pay is $4 for preferred drugs and $8 for non-preferred drugs. Beneficiaries with income above 150% FPL could pay a maximum of $4 for preferred drugs and up to 20% of the plan's negotiated drug price for non-preferred drugs. Medicaid plans receive some of the lowest negotiated drug prices from pharmaceutical manufacturers and often negotiate rebates that further reduce that price. Medicaid can also establish different copayments for drugs sold in a pharmacy, but these cannot exceed 5% of a beneficiary's family income.

Private Insurance

Private insurance plans may choose not to cover all available DAAs. Therefore, if a patient requires a DAA not included in their plan's drug formulary, they would pay the full drug costs. In addition, private insurance plans may impose prior authorization requirements that must be met before the plan approves treatment coverage. Prior authorization requirements also vary by plan.

A private insurance beneficiary's out-of-pocket costs will vary by plan and DAA prescribed; DAAs generally fall into the specialty drug tier, which can translate to higher co-pays and/or co-insurance fees. However, those covered by private insurance may be eligible for financial aid through drug manufacturer patient assistance programs and cost-sharing assistance programs.

Under- or uninsured populations

Safety net providers – such as federal qualified health centers, public and community hospitals, community health centers, rural health centers, and local health departments – participating in the 340B Drug Pricing Program may be able to provide free or sliding-scale health care and discounted DAAs to under- or uninsured populations. Some patients may also qualify for co-pay assistance or no-cost medication through DAA manufacturer payment assistance programs.

Is medication for managing chronic hepatitis B covered by insurance?

The American Association for the Study of Liver Diseases recommends treatment with one of the following preferred antiviral therapies for chronic hepatitis B: tenofovir disoproxil fumarate (TDF, brand name: Viread), tenofovir alafenamide (TAF, brand name: Vemlidy), entecavir (brand name: Baraclude), and peginterferon (brand name: Pegasys). Non-preferred therapies include adefovir (brand name: Hepsera), lamivudine (brand name: Epivir-HBV), telbivudine (brand name: Tyzeka).

Insurance coverage and patients' out-of-pocket costs vary by insurance plan and plan type. Insurance plans use drug formularies [sometimes referred to as preferred drug lists (PDLs)] to assign medications to cost categories (tiers) that determine how much a patient pays for a drug. Generally, drugs assigned to the lower tiers have lower patient co-pays and those assigned to higher tiers require patients to pay higher fees (i.e. co-insurance). Within these tiers, plans may classify medications as preferred (requiring lower cost-sharing) or non-preferred. Because TAF is a relatively more expensive medication (average $2,037 per 30-day bottle, as of July 2022) without a generic option (i.e. only available as brand-name drug), plans may choose to assign it to one of the non-preferred drug formulary tiers, which would incur higher patient costs (up to the full cost of the medication, depending on the type of insurance plan).

Medicare

Medicare 'Part D' – an optional prescription drug benefit elected by 74% of beneficiaries (as of 2019) and provided through private insurance plans approved by Centers for Medicare and Medicaid Services – covers some of the chronic hepatitis B prescription costs for Medicare enrollees (i.e. beneficiaries). Medicare beneficiaries can receive Part D benefits either through Medicare Advantage (a.k.a. Part C) or standalone prescription drug plans. Medicare is not allowed to directly negotiate with pharmaceutical manufacturers on drug prices that can apply across all Part D plans. Consequently, each Part D plan must negotiate their own drug prices and can decide which DAAs to include in their drug formularies, resulting in different beneficiary costs by plan. The amount a Medicare beneficiary pays for their medications depends on their income and how much they have spent out-of-pocket that plan year.

The Part D standard benefit has several coverage phases with varying levels of patient out-of-pocket spending responsibility:

1) **deductible**: 100% patient responsibility,
2) **initial coverage phase**: patient pays 25% of drug costs after paying deductible and their plan pays the remaining 75%, until they reach the initial coverage limit ($4,430 in combined patient and plan spending 2022),
3) **coverage gap phase**: a.k.a. the Donut Hole, when patient pays 25% of costs, drug manufacturer covers 70%, and the plan pays the remaining 5%
4) **catastrophic coverage:** after reaching an out-of-pocket spending threshold ($7,050 in 2022), the patient pays the greater of 5% of costs or a co-pay of $3.95 for generics or $9.85 for brand-name drugs. Unlike the initial coverage limit, this threshold does not include spending by the insurance plan. Currently, Medicare does not set a limit on how much patients spend out-of-pocket each plan year. Starting in 2024, as part of a provision in the Inflation Reduction Act of 2022, this 5% co-insurance will be eliminated; an annual out-of-pocket spending threshold of $2,000 will take effect in 2025. More information on what counts towards the out-of-pocket threshold can be found here.

If a patient receiving the standard Part D benefit has not met their deductible, initial coverage limit, or out-of-pocket spending threshold (a.k.a. catastrophic threshold) before starting treatment, they will have to pay up to the $7,050 threshold plus 5% of the remaining drug costs in the 2022 plan year. If, on the other hand, the patient has already paid $7,050 in medication costs before starting treatment, they will only pay either 5% of the drug cost or co-pays. Starting in 2024, patients will not have to pay these additional catastrophic coverage fees, and in 2025, patients will only have to pay $2,000 out-of-pocket each year for their medications.

Drug costs are less for certain Medicare beneficiaries with low income. Beneficiaries with income less than 150% of poverty ($19,320 for individuals/$26,130 for married couples in 2021) and modest assets (less than $14,790 for individuals/$29,520 for couples in 2021) can receive financial assistance through the Medicare Savings Program's Low-Income Subsidy (LIS), also called Extra Help. Those enrolled and receiving full LIS benefits pay no Part D deductible and only modest co-pays ($3.95-$9.85 for covered non-generic/preferred medications in 2022) until they reach the catastrophic threshold, after which they pay no cost sharing. Partial LIS benefit recipients (only 3% of all LIS recipients) pay a smaller deductible ($99) and 15% of the drug cost until they reach the catastrophic threshold, when they pay modest co-pays ($3.95-$9.85 for covered non-generic/preferred medications in 2022).

Medicaid

Medicaid plans may choose not to cover all available chronic hepatitis B treatments. Therefore, if a beneficiary requires a medication not included in their plan's drug formulary, they would pay the full drug costs. In addition, Medicaid plans may impose prior authorization requirements that must be met before the plan approves treatment coverage. For chronic hepatitis B, this generally applies to medications classified as non-preferred in the drug formulary. For example, the plan may require the medication to be prescribed by a specialist or, in the case of TAF, only approve it for patients living with or at risk for bone or kidney disease. Prior authorization requirements vary by plan.

A Medicaid beneficiary's out-of-pocket costs will vary by plan and hepatitis B treatment prescribed. Brand-name hepatitis B treatments, such as Vemlidy and Baraclude, may fall into the more expensive non-preferred or Tier 2 drug tier because of their higher cost. Generic options, such as entecavir and TDF, are more likely to fall into the preferred or Tier 1 drug tier. Fifteen states do not require prescription drug cost-sharing for Medicaid beneficiaries. For other jurisdictions, federal law restricts the amount of cost-sharing Medicaid plans can charge. For beneficiaries with incomes at or below 150% of the federal poverty level (FPL), the maximum allowed co-pay is $4 for preferred drugs and $8 for non-preferred drugs. Beneficiaries with income above 150% FPL could pay a maximum of $4 for preferred drugs and up to 20% of the plan's negotiated drug price for non-preferred drugs. Medicaid plans receive some of the lowest negotiated drug prices from pharmaceutical manufacturers and often negotiate rebates that further reduce that price. Medicaid can also establish different copayments for drugs sold in a pharmacy, but these cannot exceed 5% of a beneficiary's family income.

Private Insurance

Private insurance plans may choose not to cover all available chronic hepatitis B treatments. Therefore, if a patient requires a treatment not included in their plan's drug formulary, they would pay the full drug costs.

In addition, private insurance plans may impose prior authorization requirements that must be met before the plan approves treatment coverage. Prior authorization requirements also vary by plan.

A private insurance beneficiary's out-of-pocket costs will vary by plan and hepatitis B treatment prescribed; brand-name hepatitis B treatments, such as Vemlidy and Baraclude, may fall into the more expensive non-preferred or Tier 2 drug tiers because of their higher cost. Generic options, such as entecavir and TDF, are more likely to fall into the lower cost preferred or Tier 1 drug tier. However, those covered by private insurance may be eligible for financial aid through drug manufacturer cost-sharing assistance programs.

Under- or Uninsured populations

Safety net providers – such as federal qualified health centers, public and community hospitals, community health centers, rural health centers, and local health departments – participating in the 340B Drug Pricing Program may be able to provide free or sliding-scale health care and discounted hepatitis B treatments to under- or uninsured populations. Some patients may also qualify for low or no-cost medication through drug manufacturer payment assistance programs.

ADDITIONAL RESOURCES

Policy briefs and other reference material

Medicare

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Private insurance

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Patient and provider resources

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Co-pay assistance programs and other financial assistance resources

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