December 2025 ACIP Meeting: Hepatitis B Updates for Health Leaders

On December 4–5, 2025, the Advisory Committee on Immunization Practices (ACIP) voted on changes to the Hepatitis B (Hep B) vaccine recommendations. This document reflects CDC's acceptance of the first recommendation around shared clinical decision-making; CDC is still considering the second recommendation related to serologic testing.

In summary, the evidence continues to support a universal birth dose of Hep B vaccine (part of the infant 3-dose series), as recommended by the American Academy of Pediatrics (AAP). ACIP recommendations diverge from this, but clinicians, hospitals and states can continue with existing (routine) practices for Hep B vaccination without any new administrative restrictions.

What did ACIP recommend for the hepatitis B birth dose?

The recommendation states that infants born to mothers who test positive for hepatitis B infection should continue to receive the birth dose, as should infants whose maternal status is unknown. Infants born to mothers who test negative should receive vaccination based on shared clinical decision-making with their healthcare provider. This represents a shift from universal newborn vaccination to a risk-based and shared clinical decision-making approach, but families can still choose (and providers can still recommend) the standard 3-dose Hep B infant series, regardless of maternal status.

Will the vaccine still be covered?

Coverage is expected to remain in place because federal law requires Medicaid, CHIP, Medicare, most private insurance plans, and the Vaccines for Children (VFC) program to cover ACIP-recommended vaccines without cost sharing, including those recommended under shared clinical decision-making. Additionally, in September 2025, AHIP affirmed that its member plans would continue to cover vaccines recommended by ACIP as of September 1, 2025, without cost sharing vaccines through 2026.

What did ACIP recommend regarding serologic testing?

ACIP voted to approve a statement that parents should consult with clinicians to consider an antibody blood test before dose 2 and/or dose 3 of the hepatitis B vaccine series to help determine whether additional doses are needed. However, parents can still choose for their child to receive the additional doses in line with medical society-recommendations.

Notably, scientists do not know what antibody level guarantees long-term protection for babies, especially after just one dose, so this test cannot reliably tell families whether their child is

protected. Using a blood test to decide on Hep B vaccination requires a separate infant blood draw, additional appointment(s), and added costs.

Additionally, skipping Hep B doses 2 and 3 could disrupt how other routine infant vaccines are given, since many are bundled together (such as DTaP and Hib). Under-immunized babies are at higher risk for preventable chronic liver disease.

Does the ACIP guidance mean that providers will have to use Hep B vaccine "off-label"?

No, the ACIP guidance does not require providers to use the Hepatitis B vaccine "off-label." The Food and Drug Administration's (FDA) role is to determine if a drug or vaccine is safe and effective for a specific use, while ACIP recommends a use schedule for population health, which can inform practice and coverage. There has been no change to the FDA label for Hepatitis B, which authorizes the vaccine's use starting at birth, which would include both a birth dose and doses administered later, such as at the two month mark.

What are the potential implications of these recommendations?

Both risk-based and shared clinical decision-making recommendations often lead to lower vaccine uptake, leaving more babies unprotected from chronic liver disease caused by Hep B. While flexibility remains for vaccines to be provided in line with best practices, clinical workflows would likely need to change and may become more burdensome, including hospitals ensuring maternal Hep B lab results are available at delivery alongside revised newborn order sets, vaccine supply management, and documentation processes. VFC ordering may shift away from hospitals and toward outpatient clinics.

Health insurance coverage for the vaccines should remain intact. Federal law requires Medicaid, CHIP, Medicare, most private insurance, and the VFC program to cover ACIP-recommended vaccines—including those recommended under shared clinical decision-making—without cost sharing. And while the recommendation suggests insurers should cover the serology testing between doses, ACIP does not have authority to require coverage.

What does this mean for state-by-state access?

To avoid confusion for clinicians and patients, states - including those that have diverged from ACIP recommendations - can affirm that hospitals and clinicians can continue offering the birth dose without administrative barriers. States can also help affirm Medicaid and private coverage, and clinical and liability guidance.

For additional vaccine analyses and toolkits, please visit "Vaccine Resources" on the Common Health Coalition website.