

NEW 2-DOSE HEPATITIS B VACCINE FOR ADULTS

Last November, the Food and Drug Administration approved a new Hepatitis B vaccine, HEPLISAV-B, from Dynavax Technologies Corp. In February, the Advisory Committee on Immunization Practices (ACIP) voted to recommend HEPLISAV-B for adults 18 years and older.

HEPLISAV-B is the first two-dose vaccine against hepatitis B infection, with doses administered one month apart. All other hepatitis B vaccines are available only as three-shot series over six months.

Pre-licensure data indicates that the recombinant, adjuvanted vaccine appears to be as effective as existing vaccines with a similar safety profile. Prelicensure studies only assessed seroprotection; no studies looked at hepatitis B as an outcome. Mild and serious adverse events were generally similar to other hepatitis B vaccines. One study showed an increased risk of serious cardiac events, but evidence did not support a causal relationship. Post marketing data will be collected to confirm that there is no link.

In 2015, the number of new cases of hepatitis B in the U.S. increased 20%. The opioid epidemic is playing a role, with the largest increase in those 30-39 years. From 2009–2013, the combined incidence of acute HBV infection in three states (Kentucky, Tennessee, and West Virginia) increased 114% and was associated with increasing injection-drug use.*

In 1991, the ACIP recommended universal HepB vaccination of infants and routine vaccination of unimmunized children and adolescents. ACIP recommends vaccination of adults at risk for HepB infection, including universal vaccination of adults in settings in which a high proportion have risk factors for HepB infection, and vaccination of adults requesting protection from HepB without acknowledgment of a specific risk factor. However, less than 30% of all U.S. adults have been fully immunized against hepatitis B. A contributing factor is that many adults don't complete the three-shot series previously needed to be fully protected from hepatitis B.

If HEPLISAV-B is used to complete a series started with Recombivax HB or Energix B, a three-dose series must be completed. A 2-dose series is only indicated when HEPLISAV-B is used exclusively.

Availability to VFA Providers

When multiple vaccines are FDA approved for one disease, and made available on the Federal contract for purchase, the Immunization Program reviews data on indications, effectiveness, adverse events and cost before offering them to participating practices. VFC/VFA enrolled providers may choose one of those vaccines by completing the annual Vaccine Choice survey in July.

VFA providers interested in using HEPLISAV-B as their primary adult hepatitis B vaccine will need to complete the Vaccine Choice Survey in July and may begin ordering it in October. Katie Martinez will work with practices as they transition from a 3-dose to a 2-dose hepatitis B vaccine. When reporting to the Immunization Registry, it is important to ensure the vaccine administered is correctly recorded.

*Schillie S, Vellozzi C, Reingold A, et al. Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices. MMWR Recomm Rep 2018;67(No. RR-1):1–31. DOI: <http://dx.doi.org/10.15585/mmwr.rr6701a1>