
POLICY DETERMINATION



Nonprofit corporations and independent licensees
of the Blue Cross and Blue Shield Association

***Current Policy Effective Date: 5/1/19**
(See policy history boxes for previous effective dates)

Title: Dengue vaccine, quadrivalent, live, 3 dose schedule, for subcutaneous use

Brief Description of Service:

According to the World Health Organization (WHO), dengue is the “fastest spreading vector-borne viral disease and is now endemic in over 100 countries, resulting in over half of the world's population being at risk for Dengue.

Dengvaxia® (CYD-TDV) is a live recombinant tetravalent dengue vaccine developed by Sanofi Pasteur (CYD-TDV), given as a 3-dose series on a 0/6/12-month schedule. To date, the dengue vaccine has been licensed in more than 20 countries. Nearly 3 million vaccine doses have been distributed worldwide since launch.

Sanofi Pasteur (2017) announced that people who receive the vaccine and have not been previously infected with a dengue virus may be at risk of developing severe dengue if they get dengue after being vaccinated. Sanofi proposed that national regulatory agencies update the prescribing information to reflect that vaccination should not be recommended for individuals who have not been previously infected by dengue virus.

WHO (2018) published recommendations stating that countries should consider introduction of the dengue vaccine CYD-TDV (Dengvaxia®) only if the vaccination of seronegative individuals can be avoided. Prevacination screening for past dengue infection is the recommended strategy. Only persons with evidence of a past dengue infection would be vaccinated (based on an antibody test, or on a documented laboratory confirmed dengue infection in the past). If pre-vaccination screening is not feasible, vaccination without individual screening could be considered in carefully selected areas with recent documentation of seroprevalence rates of at least 80% by the age of 9 years old.

The Federal Drug Administration granted approval (2019) of the biological license application (Dengvaxia®) for use in individuals 9 through 16 years of age with laboratory-confirmed previous

dengue infection who are living in endemic areas. Dengvaxia is not approved for use in U.S. travelers who are visiting but not living in an area where dengue is endemic.

The U.S. Advisory Committee on Immunization Practices (2021) recommended use of Dengvaxia to prevent dengue in children aged 9 to 16 years, with laboratory-confirmed previous dengue virus infection and living in areas where dengue is endemic.

Recommendation:

Dengue vaccine, quadrivalent, live, 3-dose schedule, for subcutaneous use is established in individuals 9 through 16 years of age with laboratory-confirmed previous dengue infection who are living in endemic areas.

Effective date: May 1, 2019 (FDA approval)

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

90587

Other codes (investigational, not medically necessary, etc.):

N/A

References:

1. Advisory Committee on Immunization Practices. Dengue for healthcare providers: Prevention. <https://www.cdc.gov/dengue/healthcare-providers/hc-providers-prevention.html>. Accessed 5/24/22.
2. Sanofi Pasteur. Access to vaccines. 2021. <https://www.sanofi.com/-/media/Project/One-Sanofi-Web/Websites/Global/Sanofi-COM/Home/en/our-responsibility/docs/documents-center/factsheets/Access-to-Vaccines.pdf?la=en>. Accessed 5/24/22.
3. United States Food and Drug Administration. BLA approval – Dengue Tetravalent Vaccine. 5/1/19. <https://www.fda.gov/media/124402/download>. Accessed 5/24/22.
4. World Health Organization. Dengue and Severe Dengue: Key Facts. 2022. <https://www.who.int/news-room/fact-sheets/detail/dengue-and-severe-dengue>. Accessed 5/24/22.
5. World Health Organization. Immunizations, Vaccines and Biologicals. Dengue. Last updated: 2022. <https://www.who.int/teams/immunization-vaccines-and-biologicals/diseases/dengue>. Accessed 5/24/22.

6. World Health Organization. Weekly epidemiological record. Dengue vaccine: WHO position paper – September 2018. <https://www.who.int/publications/i/item/WER9335-457-476>. Accessed 5/24/22.

Joint Blue Cross/BCN Medical Policy History

Policy Effective Date	Blue Cross Signature Date	BCN Signature Date	Comments
11/1/21	8/17/21		• Policy determination updated EI to EST • Title changed from: 90587 Dengue vaccine, quadrivalent, live, 3 dose schedule, for subcutaneous use • Effective date for EST cpt backdated to original FDA approval date (5/1/19)
5/1/19	6/21/22		• Recommend retirement • Policy effective date backdated to FDA approval date 5/1/19.

Next Review Date: Policy retired; no longer subject to annual review.