
POLICY DETERMINATION



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

***Current Policy Effective Date: 3/1/24**
(See policy history boxes for previous effective dates)

Title: 90589-Chikungunya Virus Vaccine

Brief Description of Service:

Chikungunya is a mosquito-borne viral disease caused by the chikungunya virus (CHIKV), an RNA virus in the alphavirus genus of the family *Togaviridae*. The name chikungunya derives from a word in the Kimakonde language, meaning “to become contorted”. CHIKV was first identified in the United Republic of Tanzania in 1952 and subsequently in other countries Africa and Asia. Urban outbreaks were first recorded in Thailand in 1967 and in India in the 1970s. Since 2004, outbreaks of CHIKV have become more frequent and widespread, caused partly due to viral adaptations allowing the virus to be spread more easily by *Aedes albopictus* mosquitoes.¹

In symptomatic patients, CHIKV disease onset is typically 4–8 days (range 2–12 days) after the bite of an infected mosquito. It is characterized by an abrupt onset of fever, frequently accompanied by severe joint pain. The joint pain is often debilitating and usually lasts for a few days but may be prolonged, lasting for weeks, months or even years. Other common signs and symptoms include joint swelling, muscle pain, headache, nausea, fatigue and rash. Most patients recover fully from the infection; however, occasional cases of eye, heart, and neurological complications have been reported with CHIKV infections.¹

VLA1553 is currently the only chikungunya vaccine candidate worldwide for which regulatory review processes are underway. It targets long-term protection following vaccination with a single dose. A Biologic License Application (BLA) is currently under priority review by the U.S. Food and Drug Administration (FDA) with a Prescription Drug User Fee Act (PDUFA) review goal date at the end of November 2023. Valneva is seeking approval of its investigational chikungunya vaccine in persons aged 18 years and above. A regulatory application has also been filed with Health Canada.

These regulatory submissions follow final pivotal Phase 3 data in March 2022, final lot-to-lot consistency results in May 2022 and positive twelve-month persistence data in December 2022.²

The FDA extended the review period for Valneva's chikungunya vaccine candidate by 3 months while the design of a phase 4 study is finalized.³

The U.S. Food and Drug Administration approved this vaccine November 9, 2023. ACIP is scheduled to review this vaccine in February of 2024. It is uncertain when ACIP will publish their recommendations.

The CPT code for this vaccine is effective 01/01/2024.

Recommendation:

The Chikungunya virus vaccine is experimental/investigational. Although it has been approved by the U.S. Food and Drug Administration, ACIP has not yet reviewed or published any recommendations regarding the vaccine.

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:

N/A

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

90589

References:

1. World Health Organization. Chikungunya, Key Facts. Available at: <https://www.who.int>. Accessed November 2023.
2. Valneva Press Release. Chikungunya-VLA1553. Available at: <https://valneva.com>. Accessed November 2023.
3. Valneva Press Release. Valneva announces PDUFA date extension for chikungunya virus candidate. Available at: <https://valneva.com/press-release/valneva-announces-pdufa-date-extension-for-chikungunya-virus-vaccine-candidate/>. Accessed November 2023.
4. Lentschner AJ, McAllister N, Griswold KA, et al. Chikungunya virus vaccine candidate incorporating synergistic mutations is attenuated and protects against virulent virus challenge. J Infect Dis. Feb 2023;227(3):457-465.
5. Weaver SC, Osorio JE, Livengood JA, et al. Chikungunya virus and prospects for a vaccine. Expert Rev Vaccines. Sept 2012;11(9):1087-1101.

Joint Blue Cross/BCN Medical Policy History

Policy Effective Date	Blue Cross Signature Date	BCN Signature Date	Comments
3/1/24	12/19/23		Joint policy established

Next Review Date: 4th Qtr., 2024