Blue Cross Blue Shield Blue Care Network of Michigan

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RETIRED

Effective Date: 02/04/2021

Ervebo® (Ebola Zaire vaccine, live)

FDA approval: December 19, 2019
HCPCS: J3590
Benefit: Medical

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

A. Coverage of the requested drug is provided when all the following are met:
   a. FDA approved age
   b. FDA approved indication

B. Quantity Limitations, Authorization Period and Renewal Criteria
   a. Quantity Limit: FDA approved dosing
   b. Initial Authorization Period: 1 month with no renewal allowed

***Note: Coverage may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at http://www.cms.hhs.gov/. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Therapeutic considerations:

A. **FDA approved indication / Diagnosis**
   a. Indicated for the prevention of disease caused by *Zaire ebolavirus* in individuals 18 years of age and older
   b. Limitations of use
      i. The duration of protection conferred by Ervebo is unknown
      ii. Ervebo does not protect against other species of *Ebolavirus* or *Marburgvirus*
      iii. Effectiveness of the vaccine when administered concurrently with antiviral medication, immune globulin, and/or blood or plasma transfusions is unknown

**Please refer to most recent prescribing information.*

B. **Background Information**
   a. Ebola Virus Disease (EVD) is a rare and deadly disease in people and nonhuman primates found mainly in sub-Saharan Africa
   b. The virus spreads to people initially through direct contact with the blood, body fluids, and tissues of animals and then spreads to other people through direct contact with body fluids of a person who is sick with or has died from EVD
   c. Symptoms may appear anywhere from 2 to 21 days after contact with the virus and include fever, aches and pains, weakness, fatigue, diarrhea, vomiting, abdominal pain, and unexplained hemorrhaging, bleeding, or bruising
   d. In the United States, EVD is very rare and has only occurred because of cases that were acquired in other countries, eventually followed by person-to-person transmission
   e. Prior to approval of Ervebo, prevention of the EVD involved avoiding contact with infected individuals, bats and nonhuman primates, and not eating meat of unknown origin while in areas of outbreaks
   f. After returning from an area affected by Ebola, a person's health should be monitored for 21 days and they should seek medical care immediately if symptoms develop
   g. Symptoms of the virus are treated as they appear and include
      i. Providing intravenous fluids and electrolytes
      ii. Oxygen therapy to maintain oxygen status
      iii. Using medications to support blood pressure, reduce vomiting and diarrhea, and to manage fever and pain
      iv. Treat other infections if they occur

C. **Efficacy**

**Please refer to most recent prescribing information.*

D. **Medication Safety Considerations**

Black Box Warning: No

**Please refer to most recent prescribing information.*

E. **Dosing and administration**
   a. 1 mL given by intramuscular injection

**Please refer to most recent prescribing information.*

F. **How supplied**
   a. 1 mL suspension in single-dose vials

References:

1. Ervebo [package insert]. Whitehouse Station, NJ: Merck and Co., Inc.; December 2019.
2. Henao-Restrepo AM, Camacho A, Longini IM, et al. Efficacy and effectiveness of an rVSV-vectored vaccine in preventing Ebola virus disease: final results from the Guinea ring vaccination, open-label, cluster-randomised trial. Lancet. 2017 Feb 4; 389 (10068): 505 - 18.
3. Centers for Disease Control and Prevention. Ebola (ebola virus disease). 2019 Nov 5. Available at: https://www.cdc.gov/vhf/ebola/index.html. Accessed on December 29, 2019.

4. Lamontagne F, Fowler RA, Adhikari NK, et al. Evidence-based guidelines for supportive care of patients with Ebola virus disease. Lancet. 2018; 391: 700 – 8.

Policy History		
#	Date	Change Description
1.1	Effective Date: 02/04/2021	Retiring policy as drug is not managed with prior authorization
1.0	Effective Date: 02/06/2020	New full drug review

** The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or http://dailymed.nlm.nih.gov/dailymed/index.cfm.*