# **Polio Vaccine**

· Clinical Policy Bulletins

· Medical Clinical Policy Bulletins

Number: 0402

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### **Policy**

#### Scope of Policy

This Clinical Policy Bulletin addresses polio vaccine.

#### 1. Medical Necessity

- 1. Aetna considers polio vaccine a medically necessary preventive service for members according to the recommendations of the Centers for Disease Control and Prevention's (CDC) Advisory Committee for Immunization Practices (ACIP).
- 2. The ACIP recommends an injectable polio vaccine (IPV) schedule (as opposed to an oral vaccine schedule) for routine childhood polio vaccination in the United States to eliminate the risk for vaccine-associated paralytic polio (VAPP). The schedule recommends that all children should receive 4 doses of IPV at ages 2 months, 4 months, 6 to 18 months, and 4 to 6 years. They recommend the use of oral polio vaccine (OPV) only for the following special circumstances:
  - 1. Children of parents who are not willing to have their child have the recommended injectable form of vaccine. These children may be given OPV only for the 3rd or 4th dose or both. In this situation, health-care providers should administer OPV only after discussing the risk of VAPP with parents or caregivers; *or*
  - 2. Mass vaccination campaigns to control outbreaks of paralytic polio; or
  - 3. Unvaccinated children who will be traveling in less than 4 weeks to areas where polio is endemic.
- 3. Polio vaccine is also recommended for adults (greater than 18 years of age) who are at increased risk of exposure to poliovirus including:
  - 1. Health-care workers in close contact with individuals who may be excreting wild polioviruses\*; or
  - Individuals who are members of specific population groups currently supervening an outbreak of polio caused by wild polioviruses; or
  - 3. Laboratory workers handling specimens which may contain polioviruses\*; or
  - 4. Travelers to areas where poliomyelitis is endemic or epidemic\*.

For adults at increased risk of exposure to poliomyelitis, primary immunization with IPV is recommended. The recommended schedule for adults is 2 doses given at 1 to 2 month intervals, and a 3rd dose given 6 to 12 months later.

#### 2. Policy Limitations and Exclusions

\* **Note:** Some Aetna plans exclude coverage of immunizations required for travel or because of work related risk. Please check benefit plan descriptions for details.

# Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+":

Code Description

#### CPT codes covered if selection criteria are met:

Diphtheria, tetanus toxoids, acellular pertussis vaccine, Haemophilus influenzae type b, and

inactivated poliovirus vaccine (DTaP-IPV/Hib), for intramuscular use

90713 Poliovirus vaccine, inactivated, (IPV), for subcutaneous or intramuscular use

Diphtheria, tetanus toxoids, acellular pertussis vaccine, hepatitis B, and inactivated poliovirus vaccine

(DTaP-HepB-IPV), for intramuscular use

#### ICD-10 codes covered if selection criteria are met:

Z20.89 Contact with and (suspected) exposure to other communicable diseases [poliomyelitis]

Z23 Encounter for immunization [DTP + polio]

## **Background**

Poliomyelitis is a viral disease that causes inflammation of the gray matter of the spinal cord. Infection causes fever, pains, and gastroenteric disturbances in the acute stage, followed by a flaccid paralysis of one or more muscular groups, which is later followed by atrophy. Since 1979, the only indigenous cases of poliomyelitis reported in the United States have been associated with the use of oral polio vaccine (OPV). Oral polio vaccine (OPV) can cause polio (1 case per 2.4 million doses distributed) because it contains live, but weakened, virus. Until recently, the benefits of OPV use (i.e., intestinal immunity, secondary spread) outweighed the risk for vaccine-associated paralytic polio (VAPP). Widespread childhood vaccination has led to the complete eradication of wild-type poliovirus infection in the United States.

Inactivated poliovirus vaccine may be given concurrently with other vaccines. If injectable polio vaccine (IPV) and DTaP or DTP are given at the same time, they should be administered in separate syringes because of possible interference. An investigational, dual-chambered syringe that allows mixing of selective DTP or DTaP and IPV preparations just before injection has been developed.

The Advisory Committee on Immunization Practices (ACIP) updated recommendations for routine poliovirus vaccination (CDC, 2009). These updates aim to

- 1. emphasize the importance of the booster dose at age greater than or equal to 4 years,
- 2. extend the minimum interval from dose 3 to dose 4 from 4 weeks to 6 months,
- 3. add a precaution for the use of minimum intervals in the first 6 months of life, and
- 4. clarify the poliovirus vaccination schedule when specific combination vaccines are used.

Guidelines for preventing infections in hematopoietic cell transplant (HCT) recipients by the Center for International Blood & Marrow Transplant Research, National Marrow Donor Program, European Group for Blood and Marrow Transplantation, American Society for Blood and Marrow Transplantation, Canadian Blood and Marrow Transplant Group, Infectious Diseases Society of America, Society for Healthcare Epidemiology of America, Association of Medical Microbiology and Infectious Disease, and the CDC (Ljungman et al, 2009) indicated that oral poliovirus vaccine (live) should not be given to hematopoietic stem cell recipients since an effective, inactivated alternative exists.

The American Academy of Pediatrics (2011) stated that despite marked progress in global polio eradication, the threat of polio importation into the United States remains; therefore, all children should be protected against the disease. The standard schedule for poliovirus immunization remains 4 doses of inactivated poliovirus vaccine at 2, 4, and 6 through 18 months and 4 through 6 years of age. The minimum interval between doses 1 and 2 and between doses 2 and 3 is 4 weeks, and the minimum interval between doses 3 and 4 is 6 months. The minimum age for dose 1 is 6 weeks. Minimal age and intervals should be used when there is imminent threat of exposure, such as travel to an area in which polio is endemic or epidemic. The final dose in the inactivated poliovirus vaccine series should be administered at 4 through 6 years of age, regardless of the previous number of doses administered before the 4th birthday, and at least 6 months since the last dose was received.

Nelson et al (2012) stated that OPV will likely be insufficient to completely eradicate polio due to its propensity to mutate into neurovirulent forms and its inability to produce adequate immunity in certain areas of the world. Inactivated polio vaccine, a killed vaccine that therefore cannot mutate, may be more effective than OPV in certain populations, and will likely be required for global polio eradication. However, the high cost of inactivated polio vaccine is prohibitive in many areas of the world.

Intradermal administration has the potential to lower the dose, and thus the cost, of inactivated polio vaccine. These investigators reviewed the clinical studies to date on intradermal fractional dose polio vaccination. They concluded that intradermal IPV vaccination shows potential as a means to reduce the cost and increase the ease of administration of inactivated polio vaccine, but that additional research is needed to determine the optimal fractional dose, timing, and role of adjuvants in intradermal inactivated polio vaccine vaccination as well as the clinical significance of different antibody titers above the threshold for sero-conversion.

Zaman et al (2023) noted that type 2 circulating vaccine-derived polioviruses (cVDPV2) from Sabin oral poliovirus vaccines (OPVs) are the leading cause of poliomyelitis. A novel type 2 OPV (nOPV2) has been developed to be more genetically stable with similar tolerability and immunogenicity to that of Sabin type 2 vaccines to mitigate the risk of cVDPV2. In a randomized, controlled, double-blind, phase-II clinical trial, these researchers examined these aspects of nOPV2 in poliovirus vaccine-naive newborn infants. They enrolled newborn infants at the Matlab Health Research Centre, Chandour, Bangladesh, This trial included infants who were healthy and were a single birth after at least 37 weeks' gestation. Infants were randomly assigned (2:1) to receive either 2 doses of nOPV2 or placebo, administered at age 0 to 3 days and at 4 weeks. Exclusion criteria included receipt of rotavirus or any other poliovirus vaccine, any infection or illness at the time of enrolment (vomiting, diarrhea, or intolerance to liquids), diagnosis or suspicion of any immunodeficiency disorder in the infant or a close family member, or any contraindication for venipuncture. The primary safety outcome was safety and tolerability after 1 and 2 doses of nOPV2, given 4 weeks apart in poliovirus vaccine-naive newborn infants and the primary immunogenicity outcome was the seroconversion rate for neutralizing antibodies against type 2 poliovirus, measured 28 days after the 1st and 2nd vaccinations with nOPV2. Study staff recorded solicited and unsolicited adverse events (AEs) after each dose during daily home visits for 7 days. Poliovirus neutralizing antibody responses were measured in sera drawn at birth and at age 4 weeks and 8 weeks. Between September 21, 2020, and August 16, 2021, these researchers screened 334 newborn infants, of whom 3 (less than 1 %) were found to be ineligible and 1 (less than 1 %) was withdrawn by the parents; the remaining 330 (99 %) infants were assigned to receive nOPV2 (n = 220 [67 %]) or placebo (n = 110 [33 %]). nOPV2 was well-tolerated; 154 (70 %) of 220 newborn infants in the nOPV2 group and 78 (71 %) of 110 in the placebo group had solicited AEs, which were all mild or moderate in severity. Severe unsolicited AEs in 11 (5 %) vaccine recipients and 5 (5 %) placebo recipients were considered unrelated to vaccination. A total of 306 (93 %) of 330 infants had seroprotective maternal antibodies against type 2 poliovirus at birth, decreasing to 58 (56 %) of 104 in the placebo group at 8 weeks. In the nOPV2 group 196 (90 %) of 217 infants seroconverted by week 8 after 2 doses, when 214 (99 %) had seroprotective antibodies. The authors concluded that nOPV2 was well-tolerated and immunogenic in newborn infants, with 2 doses, at birth and 4 weeks, resulting in almost 99 % of infants having protective neutralizing antibodies.

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The above policy is based on the following references:

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# **Policy History**

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- Review History
- Definitions

#### **Additional Information**

Clinical Policy Bulletin Notes