# POLICY DETERMINATION

Blue Cross Blue Shield Blue Care Network of Michigan

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

***Current Policy Effective Date: 1/1/25**
**(See policy history boxes for previous effective dates)**

## Title: 90689 – FLUAD Quadrivalent Pediatric®

**Brief Description of Service:**

Quadrivalent flu vaccines include an influenza A (H1N1) virus, influenza A (H3N2) virus, and two influenza B viruses. Trivalent flu vaccines only include one influenza B virus. Therefore, they may not offer as much protection against influenza B viruses. Adjuvanted vaccines may provide greater protection against influenza than a non-adjuvanted vaccines when in certain populations.

In a phase III, stratified, randomized, observer blind, controlled, multicenter clinical trial, the safety and efficacy of an adjuvanted quadrivalent subunit influenza virus vaccine was compared to a non-adjuvanted comparator influenza vaccine [Non-adjuvanted Trivalent Influenza Vaccine (TIV) / Quadrivalent Influenza Vaccine (QIV)] in children, ages ≥6 to < 72 months. The study found, relative vaccine efficacy was not different between the adjuvanted quadrivalent inactivated influenza vaccine (aIIV4) and the comparator vaccines in the overall study population. The relative vaccine efficacy in the 6 through 23-month subgroup was significantly greater for aIIV4 than for the comparator vaccine. aIIV4 elicited superior immunogenic response compared with the comparator for all four vaccine strains in participants aged 6 months through 5 years. The highest geometric mean titre ratios were observed in participants aged 6 through 23 months. Safety profiles were similar but more frequent solicited adverse events were reported with aIIV4 than with the comparator vaccines.

At the present time, Fluad Quadrivalent Pediatric®, represented by procedure code 90689 has not received approval from the U.S. Food and Drug Administration and it is not recommended by the Advisory Committee on Immunization Practices. The vaccine is indicated for individuals 6 - 23 months of age. The adjuvant is MF59, a squalene adjuvant. The biological licensing application was submitted in December 2017. The vaccine is pending FDA approval.

**Recommendation:**

The Fluad Quadrivalent Pediatric vaccine is experimental/investigational. The U.S. Food and Drug Administration (FDA) has not approved this vaccine in the pediatric population and it is not currently recommended by the Advisory Committee on Immunization Practices for pediatrics.

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**References:**


1. Sylvester, GC. Adjuvanted Quadrivalent Influenza vaccine (aQIV) in young children. https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2018-06/flu-06-Sylvester-508.pdf. no longer available.
2. Vesikari T, Kirstein J, Devota G et al. Efficacy, immunogenicity, and safety evaluation of an MF59-adjuvanted quadrivalent influenza virus vaccine compared with non-adjuvanted influenza vaccine in children: a multicentre, randomised controlled, observer-blinded, phase 3 trial. Lancet Respir Med. 2018 May;6(5):345-356. doi: 10.1016/S2213-2600(18)30108-5. Epub 2018 Apr 6.
3. Esposito S, Fling J, Chokephaibulkit K, de Bruijn M, Oberye J, Zhang B, Vossen J, Heijnen E, Smolenov I. Immunogenicity and Safety of an MF59-adjuvanted Quadrivalent Seasonal Influenza Vaccine in Young Children at High Risk of Influenza-associated Complications: A Phase III, Randomized, Observer-blind, Multicenter Clinical Trial. Pediatr Infect Dis J. 2020 Aug;39(8):e185-e191. doi: 10.1097/INF.0000000000002727.
4. Centers for Disease Control and Prevention. ACIP Recommended Child and Adolescent Immunization Schedule, United States, 2022-2023. https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html#note-flu. Accessed September 2024.

## Joint BCBSM/BCN Medical Policy History

| Policy Effective Date | BCBSM Signature Date | BCN Signature Date | Comments |
|---|---|---|---|
| 1/1/19 | 2/19/19 | | Joint policy established |
| 1/1/20 | 10/20/20 | | Routine maintenance; no change to policy position |
| 1/1/22 | 10/19/21 | | Routine maintenance; no change to policy position |
| 1/1/23 | 10/18/22 | | Routine policy maintenance, no change to policy status. |
| 1/1/24 | 10/17/23 | | Routine maintenance, no change in policy status. |
| 1/1/25 | 10/15/24 | | This vaccine is no longer available, suggested retirement. (ds) |

Next Review Date: This vaccine is no longer available in the USA and will no longer undergo routine review.