Fluarix® Quadrivalent (influenza vaccine) – Expanded indication

- On January 11, 2018, GlaxoSmithKline announced the FDA approval of Fluarix Quadrivalent (influenza vaccine) for active immunization for the prevention of disease caused by influenza A subtype viruses and type B viruses contained in the vaccine in persons aged 6 months and older.
    - Previously, Fluarix Quadrivalent was only approved for use in persons 3 years of age and older.
- The expanded indication was approved based on a clinical study of 1,332 children 6 months through 35 months of age randomized to Fluarix Quadrivalent or a non-influenza control vaccine.
    - Patients in the Fluarix Quadrivalent group demonstrated greater proportions of immune responses as measured by seroconversion rates and antibody titers vs. the control group.
- In children 6 through 35 months of age, the most common (≥ 10%) solicited local adverse reactions were pain (17%) and redness (13%); the most common systemic adverse reactions were irritability (16%), loss of appetite (14%), and drowsiness (13%).
- The recommended dose and schedule for Fluarix Quadrivalent in patients 6 months through 8 years of age not previously vaccinated with an influenza vaccine is two intramuscular injections at least 4 weeks apart. For those who were vaccinated in a previous season, the recommended dose is one or two injections at least 4 weeks apart.
    - The recommended dose for patients ≥ 9 years of age is one injection.