FluLaval® Quadrivalent (influenza vaccine) – Expanded Indication

- On November 18, 2016, GlaxoSmithKline announced the FDA approval of FluLaval 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. FluLaval Quadrivalent is approved for use in persons ≥ 6 months of age.
    - Previously, FluLaval Quadrivalent was approved for use in patients ≥ 3 years of age.
- Fluzone® Quadrivalent (influenza vaccine) is another currently available quadrivalent influenza vaccine approved for use in persons ≥ 6 months of age.
- The efficacy of FluLaval Quadrivalent in children aged 6 through 35 months was demonstrated in a clinical study of 2,424 patients randomized to receive FluLaval Quadrivalent or Fluzone Quadrivalent. FluLaval Quadrivalent demonstrated non-inferiority to Fluzone Quadrivalent for all vaccine strains based on adjusted geometric mean antibody titers and seroconversion rates.
- In children aged 6 through 35 months, the most common (≥ 10%) solicited local adverse reaction was pain. The most common solicited systemic adverse events were irritability, drowsiness, and loss of appetite.
- The recommended dose for persons ≥ 6 months of age of FluLaval is one or two doses (0.5 mL each) depending on vaccination history per the annual Advisory Committee on Immunization Practices recommendation on the prevention and control of influenza with vaccines.
    - If two doses are needed, each dose should be administered at least 4 weeks apart.