Xofluza® (baloxavir marboxil) – Expanded indication

- On March 1, 2024, the FDA approved Genentech's Xofluza (baloxavir marboxil), for treatment of acute uncomplicated influenza in patients 5 years of age and older who have been symptomatic for no more than 48 hours and who are otherwise healthy or at high risk of developing influenza-related complications.
    - This approval expands the patient population to include the treatment of pediatric patients between the ages of 5 to < 12 years old with acute uncomplicated influenza who are at high risk of developing influenza-related complications.
- Xofluza is also approved for post-exposure prophylaxis of influenza in persons 5 years of age and older following contact with an individual who has influenza.
- The most common adverse reactions (at least 5%) with Xofluza use in pediatric patients between the ages of 5 and < 12 years old were vomiting and diarrhea.
- Refer to the Xofluza drug label for complete dosing and administration recommendations for both the tablet and oral suspension formulations.