

## Xofluza<sup>®</sup> (baloxavir marboxil) – Expanded indication

- On October 17, 2019, [Genentech announced](#) the [FDA approval](#) of [Xofluza \(baloxavir marboxil\)](#), for the treatment of acute uncomplicated influenza in patients 12 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.
  - Xofluza was previously approved for the treatment of acute uncomplicated influenza in patients 12 years of age and older who have been symptomatic for no more than 48 hours.
- The Centers for Disease Control and Prevention defines people at high risk of serious flu complications as those who have conditions such as asthma, chronic lung disease, diabetes, heart disease, morbid obesity or adults 65 years of age or older.
- The approval of Xofluza for the expanded indication was based on a randomized, double-blind study comparing Xofluza vs. placebo or [oseltamivir](#) in adult and adolescent subjects 12 years of age or older with influenza who were at high risk of developing influenza-related complications. A total of 1,158 patients were included in the efficacy analysis. The primary efficacy endpoint was time to improvement of influenza symptoms (cough, sore throat, headache, nasal congestion, feverishness or chills, muscle or joint pain, and fatigue).
  - A statistically significant improvement in the primary endpoint was observed for Xofluza vs. placebo. The median time to improvement of influenza symptoms was 73 hours (95% CI: 67, 85) for Xofluza vs. 102 hours (95% CI: 93, 113) for placebo.
  - There was no statistically significant difference in the median time to improvement of influenza symptoms in the patients who received Xofluza (73 hours) vs. those who received oseltamivir (81 hours).
- The recommended dose of Xofluza for all patients 12 years of age and older is weight-based. Patients with a body weight 40 kg to less than 80 kg should take two 20 mg tablets at the same time for a total single dose of 40 mg. Patients with a body weight at least 80 kg should take two 40 mg tablets at the same time for a total single dose of 80 mg.
- Treatment with Xofluza should be initiated within 48 hours of influenza symptom onset.