Cinryze® (C1 esterase inhibitor [human]) – Expanded indication

- On June 21, 2018 Shire announced the FDA approval of Cinryze (C1 esterase inhibitor [human]) for routine prophylaxis against angioedema attacks in adults, adolescents and pediatric patients (≥ 6 years old) with hereditary angioedema (HAE).
    - Previously, Cinryze was only approved for use in adolescent and adult patients.
- The expanded indication was based on data from a clinical study of 12 patients aged 7 to 11 with HAE who had an average of ≥ 1 angioedema attack per month. Patients received Cinryze 500 Units and Cinryze 1,000 Units every 3 to 4 days for 12 weeks. The primary efficacy measure was the monthly-normalized number of attacks.
    - A greater reduction in the monthly-normalized number of attacks was observed with the 1,000 Units dose vs. the 500 Units dose (0.7 vs. 1.2, respectively, p = 0.03), and both doses achieved greater reductions compared to the mean 3.7 attacks per month during the observation period.
- The recommended dose of Cinryze in pediatric patients 6 to 11 years of age is 500 Units administered intravenously (IV) every 3 or 4 days.
    - The dose may be adjusted according to individual response, up to 1,000 Units every 3 to 4 days.
- The recommended dose of Cinryze in patients ≥ 12 years of age is 1,000 Units administered IV every 3 or 4 days.
    - For patients who have not responded adequately to 1,000 Units of Cinryze every 3 or 4 days, doses up to 2,500 Units (not to exceed 100 Units/kg) every 3 or 4 days may be considered based on individual patient response.