Fasenra® (benralizumab) – Expanded indication

- On April 5, 2024, the FDA approved AstraZeneca's Fasenra (benralizumab), as add-on maintenance treatment of patients aged 6 years and older with severe asthma, and with an eosinophilic phenotype.
    - Fasenra was previously approved for this indication in patients aged 12 years and older.
- In addition to the expanded indication, the FDA approved a new Fasenra 10 mg/0.5 mL single-dose prefilled syringe formulation.
    - Fasenra was previously available as a 30 mg/mL single-dose prefilled syringe and a single-dose autoinjector pen.
- The approval of Fasenra for the expanded indication was supported by evidence from adequate and well-controlled trials in adults and adolescents with additional pharmacokinetic, pharmacodynamic, and safety data in pediatric patients aged 6 to 11 years.
    - The effectiveness of Fasenra in pediatric patients 6 to 11 years of age is extrapolated from efficacy in three clinical trials (SIROCCO, CALIMA, and ZONDA) with support from pharmacokinetic analysis and pharmacodynamic response in pediatric patients aged 6 to 11 years compared to adults and adolescents.
- The recommended dose of Fasenra for pediatric patients 6 to 11 years of age is based on body weight:
    - Less than 35 kg: 10 mg (one injection) administered subcutaneously (SC) every 4 weeks for the first 3 doses, and then every 8 weeks thereafter.
    - 35 kg or more: 30 mg (one injection) administered SC every 4 weeks for the first 3 doses, and then every 8 weeks thereafter.
- Refer to the Fasenra drug label for dosing in patients 12 years of age and older.