Humira® (adalimumab) – Expanded orphan indication

- On September 28, 2018, the FDA approved AbbVie's Humira (adalimumab) for the treatment of non-infectious intermediate, posterior, and panuveitis in adults and pediatric patients 2 years of age and older.
    - Previously, Humira was approved for use in adults for this indication.
- Humira is also FDA-approved for the following conditions: rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, adult and pediatric Crohn's disease, ulcerative colitis, plaque psoriasis, and hidradenitis suppurativa.
- The safety and efficacy of Humira for the treatment of pediatric uveitis were assessed in a placebo-controlled study of 90 patients from 2 to < 18 years of age with active juvenile idiopathic arthritis-associated non-infectious uveitis. The primary endpoint was time to treatment failure, defined as worsening or sustained non-improvement in ocular inflammation, or worsening of ocular co-morbidities.
    - Humira significantly decreased the risk of treatment failure by 75% relative to placebo (hazard ratio = 0.25 [95% CI: 0.12, 0.49]).
- Humira carries a boxed warning for serious infections and malignancy.
- The recommended dose of Humira for patients ≥ 2 years of age with pediatric uveitis is weight-based:
    - 10 kg (22 lbs) to < 15 kg (33 lbs): 10 mg every other week (10 mg prefilled syringe)
    - 15 kg (33 lbs) to < 30 kg (66 lbs): 20 mg every other week (20 mg prefilled syringe)
    - ≥ 30 kg (66 lbs): 40 mg every other week (Humira pen or 40 mg prefilled syringe)
- Refer to the Humira drug label for dosing recommendations for all other indications.