Enbrel® (etanercept) – Expanded Indication

- On November 4, 2016, Amgen announced the FDA approval of Enbrel (etanercept) for the treatment of patients 4 years or older with chronic moderate to severe plaque psoriasis (PsO) who are candidates for systemic therapy or phototherapy.
    - Previously, Enbrel was not indicated in pediatric patients with PsO.
- Enbrel is also indicated for the following:
    - Reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active rheumatoid arthritis. Enbrel can be initiated in combination with methotrexate (MTX) or used alone.
    - Reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis (JIA) in patients ages 2 and older.
    - Reducing signs and symptoms, inhibiting the progression of structural damage of active arthritis, and improving physical function in patients with psoriatic arthritis. Enbrel can be used with or without MTX.
    - Reducing signs and symptoms in patients with active ankylosing spondylitis.
- The expanded indication for Enbrel was approved based on a 48-week double-blind, placebo-controlled study conducted in 211 children (4 – 17 years of age) with moderate to severe PsO. Response to treatment was assessed after 12 weeks of therapy and was defined as the proportion of subjects who achieved a reduction in psoriasis area and severity index (PASI) score of at least 75% from baseline. Other evaluated outcomes included the proportion of subjects who achieved a score of "clear" or "almost clear" by the static physician global assessment (sPGA) and the proportion of subjects with a reduction in PASI score of at least 90% from baseline.
    - The PASI 75 for placebo patients was 11% vs. 57% for Enbrel patients.
    - The PASI 90 for placebo patients was 7% vs. 27% for Enbrel patients.
    - The sPGA of clear or almost clear was 13% for placebo patients vs. 52% for Enbrel patients.
    - The proportion of placebo patients who maintained PASI 75 response at week 48 was 49% vs. 65% for Enbrel patients.
- Enbrel carries a boxed warning regarding serious infections and malignancies.
- The recommended dose of Enbrel for pediatric patients with PsO or JIA is 50 mg subcutaneously (SC) once weekly for those $\geq$ 63 kg and 0.8 mg/kg SC weekly for those < 63 kg.
- Refer to the prescribing information for the recommended doses of Enbrel for adults.