

Enbrel[®] (etanercept) – New indication

- On October 18, 2023, the [FDA approved](#) Amgen's [Enbrel \(etanercept\)](#), for the treatment of active juvenile psoriatic arthritis (JPsA) in pediatric patients 2 years of age and older.
- Enbrel is also approved for rheumatoid arthritis (RA), polyarticular juvenile idiopathic arthritis (JIA), psoriatic arthritis (PsA), ankylosing spondylitis, and plaque psoriasis (PsO).
- The approval of Enbrel for the new indication was supported by evidence from adequate and well controlled studies of Enbrel in adults with PsA; pharmacokinetic data from adult patients with PsA, RA, and PsO; and pharmacokinetic data from pediatric patients with active JIA and PsO. Safety of Enbrel in JPsA is supported by a clinical study in 69 pediatric patients with moderately to severely active JIA aged 2 to 17 years; a clinical study in 211 pediatric patients with moderate to severe PsO aged 4 to 17 years; and an open-label extension study in 182 pediatric patients with moderate to severe PsO aged 4 to 17 years.
- Enbrel carries a boxed warning for serious infections and malignancies.
- The recommended dose of Enbrel for the treatment of JPsA in patients 63 kg (138 pounds) or more is 50 mg subcutaneously (SC) weekly and in patients less than 63 kg (138 pounds) the dose is 0.8 mg/kg SC weekly.
 - Refer to the Enbrel drug label for dosing for all its other indications.