Orencia® (abatacept) – Expanded indication

- On October 30, 2023, the FDA approved Bristol Myers Squibb's Orencia (abatacept), for the treatment of patients 2 years of age and older with active psoriatic arthritis (PsA).
    - Orencia was previously approved for this indication in adults only.
- Orencia is also approved for the treatment of adult rheumatoid arthritis (RA) and polyarticular juvenile idiopathic arthritis (pJIA), and prophylaxis for acute graft versus host disease.
- The approval of Orencia for the expanded indication was supported by evidence from adequate and well-controlled studies of Orencia in adults with PsA, pharmacokinetic data from adult patients with RA, adult patients with PsA, and pediatric patients with pJIA, and safety data from clinical studies in pediatric patients 2 to 17 years old with pJIA using the subcutaneous (SC) formulation.
    - The observed pre-dose (trough) concentrations are generally comparable between adults with RA and PsA and pediatric patients with JIA with active polyarthritis, and the pharmacokinetic exposure is expected to be comparable between adult PsA and pediatric patients with PsA.
- The recommended dose of Orencia for the treatment of pediatric patients with PsA is weight based (see table below), and its administered SC weekly.

Body weight of pediatric patient	Dose (once weekly)
10 to less than 25 kg	50 mg
25 to less than 50 kg	87.5 mg
50 kg or more	125 mg

    - Pediatric patients with PsA may self-inject with Orencia or the patient's caregiver may administer Orencia if both the healthcare practitioner and the parent/legal guardian determine it is appropriate.
    - Intravenous administration of Orencia is not approved for pediatric patients with PsA.
    - Refer to the Orencia drug label for dosing for all its other indications.