Otezla® (apremilast) – Expanded indication

- On April 25, 2024, the FDA approved Amgen's Otezla (apremilast), for the treatment of pediatric patients 6 years of age and older and weighing at least 20 kg with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.
    - Otezla was previously approved for treatment of adult patients with plaque psoriasis who are candidates for phototherapy or systemic therapy.
- In addition to plaque psoriasis, Otezla is also approved for adult patients with psoriatic arthritis and oral ulcers associated with Behçet's disease.
- The approval of Otezla for the expanded indication was based on a randomized, double-blind, placebo-controlled study (PSOR-6) in 245 pediatric patients 6 to 17 years of age with moderate to severe plaque psoriasis who were candidates for phototherapy or systemic therapy. Patients were randomized to receive either Otezla or placebo for 16 weeks. The primary endpoint was the proportion of patients who achieved a static Physician Global Assessment (sPGA) response at week 16. The key secondary endpoint was the proportion of patients who achieved a Psoriasis Area and Severity Index (PASI)-75 response (at least a 75% reduction in PASI score from baseline) at week 16.
    - sPGA response was achieved in 33.1% with Otezla vs. 10.8% with placebo (treatment difference 22.3, 95% CI: 12.2, 32.4).
    - PASI-75 response was achieved in 45.7% with Otezla vs. 16.0% with placebo (treatment difference 29.7, 95% CI: 17.9, 41.6).
- The recommended dosage of Otezla for pediatric patients with plaque psoriasis is based on body weight. Following the appropriate initial titration schedule (see Otezla drug label for complete details), the recommended maintenance dosage of Otezla taken orally is 30 mg twice daily for pediatric patients who weigh at least 50 kg and 20 mg twice daily for pediatric patients who weigh from 20 kg to less than 50 kg.
- Refer to the Otezla drug label for dosing for its other indications.