



## **RATIONALE FOR INCLUSION IN PA PROGRAM**

### **Background**

Otezla (apremilast) is an oral treatment that helps regulate inflammation related to psoriatic arthritis (PsA), plaque psoriasis (PsO), and oral ulcers associated with Behçet's Disease by inhibiting an enzyme called phosphodiesterase 4 (PDE4). The inhibition of PDE4 helps control symptoms such as psoriatic skin lesions, stiffness, pain, swelling, and tenderness of the joints, ligaments, and tendons (1).

### **Regulatory Status**

FDA-Approved indications: Otezla is indicated for the treatment of: (1)

- Adult patients with active psoriatic arthritis (PsA)
- Adult patients with plaque psoriasis (PsO) who are candidates for phototherapy or systemic therapy
- 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
- Adult patients with oral ulcers associated with Behçet's Disease (BD)

Otezla should be titrated in initiation of therapy due to gastrointestinal symptoms. Treatment with Otezla is associated with emergence or worsening of depression, suicidal thoughts or other mood changes. Weight should be monitored regularly as unexplained or clinically significant weight loss may occur. Concomitant therapy with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, phenytoin) is not recommended (1).

In clinical studies, patients on Otezla were allowed to receive stable doses of concomitant methotrexate, sulfasalazine, leflunomide, low dose oral corticosteroids, and/or nonsteroidal anti-inflammatory drugs (NSAIDs). Patients with tender and swollen joint counts that were not improved by at least 20% were considered non-responders at Week 16 (1).

The safety and effectiveness of Otezla in pediatric patients less than 6 years of age or weighing less than 20 kg with moderate to severe plaque psoriasis have not been established. The safety and effectiveness of Otezla in pediatric patients less than 18 years of age for all other indications have not been established (1).



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## **OTEZLA** (apremilast)

### **Summary**

Otezla (apremilast) is indicated for the treatment of adult patients with plaque psoriasis (PsO), psoriatic arthritis (PsA), and oral ulcers associated with Behçet's Disease (BD). In clinical studies, patients on Otezla were allowed to receive stable doses of concomitant methotrexate, sulfasalazine, leflunomide, low dose oral corticosteroids, and/or nonsteroidal anti-inflammatory drugs (NSAIDs). The safety and effectiveness of Otezla in pediatric patients less than 6 years of age and older or weighing less than 20 kg with moderate to severe plaque psoriasis have not been established. The safety and effectiveness of Otezla in pediatric patients less than 18 years of age for all other indications have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Otezla while maintaining optimal therapeutic outcomes.

### **References**

1. Otezla [package insert]. Thousand Oaks, CA: Amgen Inc.; April 2024.