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Section:	Prescription Drugs	**Effective Date:**	October 1, 2024
Subsection:	Analgesics and Anesthetics	**Original Policy Date:**	July 1, 2014
Subject:	Otezla	**Page:**	1 of 8

Last Review Date: September 6, 2024

Otezla

Description

Otezla (apremilast)

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).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Otezla may be considered **medically necessary** if the conditions indicated below are met.

Otezla may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** the following:

1. Active Psoriatic Arthritis (PsA)
   a. Inadequate treatment response, intolerance, or contraindication to a 3-month trial of at least **ONE** conventional DMARD (see Appendix 1)

2. Active oral ulcers associated with Behçet's Disease (BD)
   a. Previously treated with at least one non-biologic BD medication

AND the following:

a. **NOT** to be used in combination with any other biologic DMARD or targeted synthetic DMARD (see Appendix 1)

Age 6 years of age or older

Diagnosis

Patient must have the following:

1. Plaque Psoriasis (PsO)
    a. 6 to 17 years of age **only**: weight ≥ 20 kg **AND** PsO is considered to be moderate to severe
    b. Inadequate treatment response, intolerance, or contraindication to either conventional systemic therapy (see Appendix 1) or phototherapy
        i. If the patient is intolerant or contraindicated to one therapy then the patient must have an inadequate treatment response, intolerance, or contraindication to the other treatment option
    c. **NOT** to be used in combination with any other biologic DMARD or targeted synthetic DMARD (see Appendix 1)

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Psoriatic Arthritis (PsA)
2. Oral ulcers associated with Behçet's Disease (BD)

AND ALL of the following:

a. Condition has improved or stabilized with therapy

b. **NOT** to be used in combination with any other biologic DMARD or targeted synthetic DMARD (see Appendix 1)

Age 6 years of age or older

Diagnosis

Patient must have the following:

1. Plaque Psoriasis (PsO)
   a. 6 to 17 years of age **only**: weight ≥ 20 kg
   b. Condition has improved or stabilized with therapy
   c. **NOT** to be used in combination with any other biologic DMARD or targeted synthetic DMARD (see Appendix 1)

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 1 two week starter pack (27 tablet titration pack) **OR**
1 month starter pack (55 tablet titration pack)

AND

180 tablets per 90 days

Duration 12 months

Prior – Approval *Renewal* Limits

Quantity 180 tablets per 90 days

Duration 18 months

Rationale

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.

Policy History

Date	Action
June 2014	New addition to PA
September 2014	Annual review Addition of no combination with another biologic agent per SME Addition of new indication- plaque psoriasis
December 2014	Annual review and reference update
March 2015	Addition of a 1 month starter pack to approval limits
June 2015	Annual review
September 2016	Annual editorial review and reference update Addition of not to be used in combination with any other biologic DMARD or targeted synthetic DMARD Policy number change from 5.18.08 to 5.70.53
March 2017	Annual editorial review and reference update Addition of age requirement in renewal section
June 2017	Annual review
December 2017	Annual review
March 2018	Annual editorial review and reference update Addition of Appendix 1

August 2018	Addition of additional requirements to initiation criteria For diagnosis of PsA: inadequate response, intolerance or contraindication to a 3-month trial of at least ONE conventional DMARD For diagnosis of PsO: inadequate response, intolerance or contraindication to a 3-month trial of at least ONE conventional systemic therapy
September 2018	Annual editorial review
March 2019	Annual review
August 2019	Addition of indication: Oral ulcers associated with Behçet's Disease
September 2019	Annual review
March 2020	Annual review
December 2020	Annual editorial review. Changed approval durations to 12 months and 18 months. Revised requirement for plaque psoriasis to t/f conventional systemic therapy or phototherapy. Removed psoriatic arthritis initial requirement for baseline evaluation and changed continuation requirement from reevaluation with tool to "condition has improved or stabilized with therapy"
March 2021	Annual editorial review. Appendix 1 updated.
January 2022	Removed "moderate to severe" requirement from plaque psoriasis per package insert update
March 2022	Annual review
September 2022	Annual review
December 2022	Annual review
September 2023	Annual review and reference update
March 2024	Annual review
May 2024	Per PI update lowered age requirement for plaque psoriasis to 6 and older weighing at least 20 kg
June 2024	Annual review
September 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 6, 2024 and is effective on October 1, 2024.

Appendix 1 - List of DMARDs

Conventional disease-modifying antirheumatic drugs (DMARDs)

Generic Name	Brand Name
azathioprine	Azasan, Imuran
cyclophosphamide	Cytoxan
cyclosporine	Neoral, Gengraf, Sandimmune
hydroxychloroquine	Plaquenil
leflunomide	Arava
methotrexate	Rheumatrex, Trexall,
mycophenolate	Cellcept
sulfasalazine	Azulfidine, Sulfazine

Biological disease-modifying antirheumatic drugs (DMARDs)

Generic Name	Brand Name
abatacept	Orencia
adalimumab	Humira
anakinra	Kineret
brodalumab	Siliq
certolizumab	Cimzia
etanercept	Enbrel
golimumab	Simponi/Simponi Aria
guselkumab	Tremfya
infliximab	Remicade/Avsola/Inflectra/Renflexis
ixekizumab	Taltz
risankizumab-rzaa	Skyrizi
rituximab	Rituxan/Riabni/Ruxience/Truxima
sarilumab	Kevzara
secukinumab	Cosentyx
spesolimab-sbzo	Spevigo
tildrakizumab-asmn	Ilumya
tocilizumab	Actemra
ustekinumab	Stelara
vedolizumab	Entyvio

Targeted synthetic disease-modifying antirheumatic drugs (DMARDs)

Generic Name	Brand Name
apremilast	Otezla
baricitinib	Olumiant

deucravacitinib	Sotyktu
tofacitinib	Xeljanz/XR
upadactinib	Rinvoq