



## 5.70.53

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<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	April 1, 2021
<b>Subsection:</b>	Analgesics and Anesthetics	<b>Original Policy Date:</b>	July 1, 2014
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**Last Review Date:** March 12, 2021

## Otezla

### Description

#### Otezla (apremilast)

#### Background

Otezla (apremilast) is an oral treatment that helps regulate inflammation in people with active psoriatic arthritis (PsA), moderate to severe 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 indication: Otezla is indicated for the treatment of adult patients with active psoriatic arthritis (PsA), patients with moderate to severe plaque psoriasis (PsO) who are candidates for phototherapy or systemic therapy, and adult patients with oral ulcers associated with Behçet's Disease (1).

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).

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

Safety and effectiveness of Otezla in pediatric patients less than 18 years of age 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** in patients 18 years of age and older for the treatment of active psoriatic arthritis (PsA), moderate to severe plaque psoriasis (PsO), and oral ulcers associated with Behçet's Disease; and if the conditions indicated below are met.

Otezla may be considered **investigational** for patients less than 18 years of age and 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 response, intolerance or contraindication to a 3-month trial of at least **ONE** conventional DMARD (see Appendix 1)
2. Moderate to severe Plaque Psoriasis (PsO)
  - a. Inadequate response, intolerance, or contraindication to either conventional systemic therapy (see Appendix 1) or phototherapy

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- 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

3. 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)

## Prior – Approval *Renewal* Requirements

**Age** 18 years of age or older

### Diagnoses

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

1. Psoriatic Arthritis (PsA)
2. Plaque Psoriasis (PsO)
3. Oral ulcers associated with Behçet's Disease

**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)

### 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)

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**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 moderate to severe plaque psoriasis (PsO) who are candidates for phototherapy or systemic therapy, for the treatment for active psoriatic arthritis (PsA), and for the treatment of adult patients with oral ulcers associated with Behçet’s Disease. Otezla offers PsA and PsO patients a new treatment option that is taken orally, in pill form. In clinical studies patients on Otezla were allowed to receive stable doses of concomitant DMARDs: methotrexate, sulfasalazine, leflunomide, low dose of oral corticosteroids, and nonsteroidal anti-inflammatory drugs (NSAIDs) (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]. Summit, NJ: Celgene Corporation; June 2020.

## 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

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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.

## Keywords

**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 12, 2021 and is effective on April 1, 2021.**

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### 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
tildrakizumab-asmn	Ilumya
tocilizumab	Actemra
ustekinumab	Stelara
vedolizumab	Entyvio

#### Targeted synthetic disease-modifying antirheumatic drugs (DMARDs)

Generic Name	Brand Name
apremilast	Otezla
baricitinib	Olumiant
tofacitinib	Xeljanz/XR
upadactinib	Rinvoq