Otezla® Prior Authorization Checklist



Your patients may require a Prior Authorization (PA) after being prescribed Otezla. This resource may help you prepare the proper PA documentation to submit to the patient's health insurance plan, also known as the payer:*



PROPER DIAGNOSES

Choose the appropriate diagnoses for your patient out of the response options available on the PA



BODY SURFACE AREA (BSA)

For psoriasis diagnoses, BSA percentage may be required by some health insurance plans



DOCUMENTATION OF TREATMENT HISTORY

If required, it is important to include the current treatment and patient history, including treatment history from other healthcare providers



CONTRAINDICATIONS

If the patient has any contraindications, please specify and provide any additional information. Some health insurance plans might require supporting documentation

FOR PRIMARY CARE OFFICES

A patient's health insurance plan may require documentation that a specialist (eg, dermatologist, rheumatologist) is the prescriber or that the prescriber has consulted with a specialist (generally within the last year) for Otezla approval. If required, document this on the PA form.

TIP: If the patient has a previously approved Otezla PA and the same health insurance plan, make sure to start a PA Renewal or Reauthorization, rather than a new PA.

WHEN SUBMITTING A PRIOR AUTHORIZATION



BE AS THOROUGH AND ACCURATE AS POSSIBLE when completing a PA to help expedite the process for your patient



USE THIS GUIDE to help you prepare information the health insurance plan may require upon submission of the PA



MAKE SURE ALL APPROPRIATE SECTIONS OF THE PA FORM ARE COMPLETED, and take note of any questions that require you to attach documentation

*These examples are informational and provided as a courtesy only. They should not be a substitute for an independent, clinical decision. It is the duty of the healthcare provider to understand individual patient considerations and use their own judgment and clinical decision-making when determining a particular patient's diagnosis and treatment.

INDICATIONS

Otezla® (apremilast) is indicated for the treatment of adult patients with plaque psoriasis who are candidates for phototherapy or systemic therapy.

Otezla is indicated for the treatment of adult patients with active psoriatic arthritis.

Otezla is indicated for the treatment of adult patients with oral ulcers associated with Behçet's Disease.

IMPORTANT SAFETY INFORMATION

Contraindications

• Otezla is contraindicated in patients with a known hypersensitivity to apremilast or to any of the excipients in the formulation

Please see additional Important Safety Information and <u>click here</u> for the full Prescribing Information. This resource is informational only and not intended to be directive or a quarantee of coverage.

Otezla® PA Checklist

Was Otezla prescribed by, or in consultation with, a dermatologist or rheumatologist? • Yes • No



DIAGNOSIS CODES¹

- L40.50 Arthropathic psoriasis, unspecified
- L40.51 Distal interphalangeal psoriatic arthropathy
- L40.52 Psoriatic arthritis mutilans
- L40.53 Psoriatic spondylitis
- L40.59 Other psoriatic arthropathy
- L40.0 Psoriasis vulgaris
- L40.8 Other psoriasis
- L40.9 Psoriasis, unspecified
- M35.2 Behçet's disease



BODY SURFACE AREA (BSA) ASSESSMENT – FOR PLAQUE PSORIASIS²

As a best practice, note the BSA involvement on the PA documentation for specific cases, such as:

- Hands
- Feet
- Nails
- Scalp
- Groin
- Other areas of involvement



TREATMENT HISTORY

PRESCRIPTION TOPICALS³

- Clobetasol
- Triamcinolone
- Fluocinonide
- Desoximetasone
- Halobetasol
- Calcipotriene
- Tacrolimus
- Fluocinolone acetonide
- Betamethasone
- Calcipotriene and betamethasone dipropionate

ORAL SYSTEMICS (INCLUDING DMARDS)^{3,4}

Acitretin

Sulfasalazine

Leflunomide

- Cyclosporine
- Colchicine

NSAIDs

Methotrexate

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and Precautions

- Hypersensitivity: Hypersensitivity reactions, including angioedema and anaphylaxis, have been reported during postmarketing surveillance. If signs or symptoms of serious hypersensitivity reactions occur, discontinue Otezla and institute appropriate therapy
- Diarrhea, Nausea, and Vomiting: Cases of severe diarrhea, nausea, and vomiting were associated with the use of Otezla. Most events occurred within the first few weeks of treatment. In some cases, patients were hospitalized.

Please see additional Important Safety Information and <u>click here</u> for the full Prescribing Information.

Use this checklist as a reference tool when capturing patient diagnosis details, treatment history, and BSA on the health insurance form or payer template: (*Please do not submit this form*)





TREATMENT HISTORY (CONTINUED)

OTHER THERAPIES TO NOTE³

Phototherapy

Biologic therapies

REASONS FOR DISCONTINUATION

Inadequate response

Please specify with additional information

- Trial/failure dates
- Lack of efficacy reasoning
- Photos of the affected area(s)



HISTORY OF INTOLERANCE WITH PRIOR TREATMENTS

Please specify with additional information

- Treatment start and end dates
- Adverse outcomes



REAUTHORIZATIONS OR CONTINUATION OF THERAPY SUBMISSIONS

Positive result notes
 Pictures of improved areas
 Initial BSA % vs current progress

Note: Documentation may be required by your patient's payer. Make sure you read the PA criteria carefully and include all the necessary documents specifically required by your patient's payer. Examples may include medical records, clinical chart notes, and claims histories.

IMPORTANT SAFETY INFORMATION (cont'd)Warnings and Precautions (cont'd)

Patients 65 years of age or older and patients taking medications that can lead to volume depletion or hypotension may be at a higher risk of complications from severe diarrhea, nausea, or vomiting. Monitor patients who are more susceptible to complications of diarrhea or vomiting; advise patients to contact their healthcare provider. Consider Otezla dose reduction or suspension if patients develop severe diarrhea, nausea, or vomiting

Please see additional Important Safety Information and <u>click here</u> for the full Prescribing Information.

Important Safety Information

Warnings and Precautions (cont'd)

- Depression: Carefully weigh the risks and benefits of treatment with Otezla for patients with a history of depression and/or suicidal thoughts/behavior, or in patients who develop such symptoms while on Otezla. Patients, caregivers, and families should be advised of the need to be alert for the emergence or worsening of depression, suicidal thoughts or other mood changes, and they should contact their healthcare provider if such changes occur.
 - <u>Plaque Psoriasis</u>: Treatment with Otezla is associated with an increase in depression. During clinical trials in patients with moderate to severe plaque psoriasis, 1.3% (12/920) of patients reported depression compared to 0.4% (2/506) on placebo. Depression was reported as serious in 0.1% (1/1308) of patients exposed to Otezla, compared to none in placebo-treated patients (0/506). Suicidal behavior was observed in 0.1% (1/1308) of patients on Otezla, compared to 0.2% (1/506) on placebo. One patient treated with Otezla attempted suicide; one patient on placebo committed suicide
 - <u>Psoriatic Arthritis</u>: Treatment with Otezla is associated with an increase in depression. During clinical trials, 1.0% (10/998) reported depression or depressed mood compared to 0.8% (4/495) treated with placebo. Suicidal ideation and behavior was observed in 0.2% (3/1441) of patients on Otezla, compared to none in placebo-treated patients. Depression was reported as serious in 0.2% (3/1441) of patients exposed to Otezla, compared to none in placebo-treated patients (0/495). Two patients who received placebo committed suicide compared to none on Otezla)
 - <u>Behçet's Disease</u>: Treatment with Otezla is associated with an increase in depression. During the clinical trial, 1% (1/104) reported depression or depressed mood compared to 1% (1/103) treated with placebo. No instances of suicidal ideation or behavior were reported in patients treated with Otezla or treated with placebo

- Weight Decrease: Monitor body weight regularly; evaluate unexplained or clinically significant weight loss, and consider discontinuation of Otezla
 - <u>Plaque Psoriasis</u>: Body weight loss of 5-10% occurred in 12% (96/784) of patients with moderate to severe plaque psoriasis treated with Otezla and in 5% (19/382) of patients treated with placebo. Body weight loss of ≥10% occurred in 2% (16/784) of patients treated with Otezla compared to 1% (3/382) of patients treated with placebo
 - <u>Psoriatic Arthritis</u>: Body weight loss of 5-10% was reported in 10% (49/497) of patients taking Otezla and in 3.3% (16/495) of patients taking placebo
 - Behçet's Disease: Body weight loss of >5% was reported in 4.9% (5/103) of patients taking Otezla and in 3.9% (4/102) of patients taking placebo
- Drug Interactions: Apremilast exposure was decreased when Otezla was co-administered with rifampin, a strong CYP450 enzyme inducer; loss of Otezla efficacy may occur. Concomitant use of Otezla with CYP450 enzyme inducers (e.g., rifampin, phenobarbital, carbamazepine, phenytoin) is not recommended

Adverse Reactions

- Plaque Psoriasis: The most common adverse reactions
 (≥ 5%) are diarrhea, nausea, upper respiratory tract
 infection, and headache, including tension headache.
 Overall, the safety profile of Otezla in patients with mild to
 moderate plaque psoriasis was consistent with the safety
 profile previously established in adult patients with
 moderate to severe plaque psoriasis
- Psoriatic Arthritis: The most common adverse reactions (≥ 5%) are diarrhea, nausea, and headache
- <u>Behçet's Disease</u>: The most common adverse reactions (≥ 10%) are diarrhea, nausea, headache, and upper respiratory tract infection

Use in Specific Populations

• Otezla has not been studied in pregnant women. Advise pregnant women of the potential risk of fetal loss

(apremilast) 30 mg tablets

Please <u>click here</u> for the full Prescribing Information.

References: 1. Centers for Medicare & Medicaid Services. ICD-10-CM tabular list of diseases and injuries. https://www.cms.gov/files/zip/2021-code-tables-tabular-and-index-updated-12162020.zip. Accessed September 25, 2023. **2.** Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. *J Am Acad Dermatol.* 2019;80:1029-1072. **3.** Elmets CA, Korman NJ, Prater EF, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. *J Am Acad Dermatol.* 2021;84:432-470. **4.** Menter A, Gelfand JM, Connor C, et al. Joint AAD-NPF guidelines of care for the management of psoriasis with systemic nonbiologic therapies. *J Am Acad Dermatol.* 2020;82:1445-1486.

