# Otezla Prior Authorization (PA) Checklist

Otezla® (apremilast) 30mg tablets

A resource to help organize PA information and potential documentation requirements

Patient name _____ Date of birth ___/___/___

Patient insurance plan _____
Please make a copy of the patient's insurance card for the submission process

Healthcare provider name _____

Was Otezla® (apremilast) prescribed by, or in consultation with, a Dermatologist or Rheumatologist?

☐ Yes _____ ☐ No
Name of specialist

Do you plan on submitting the PA to Otezla SupportPlus™ or to a preferred Specialty Pharmacy?

☐ Otezla SupportPlus™ ☐ Specialty Pharmacy _____
Name of the pharmacy

## Diagnosis Code:

- ☐ 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)

## Treatment History:

Prescription Topicals

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

Oral Systemics

- ☐ Acitretin
- ☐ Cyclosporine
- ☐ Methotrexate
- ☐ Leflunomide
- ☐ Sulfasalazine
- ☐ Colchicine
- ☐ NSAIDs

Other Therapies to Note

- ☐ Phototherapy
- ☐ Biologic therapies

**Questions? Call 1-844-4OTEZLA or visit OtezlaPro.com for additional resources**

## INDICATIONS

Otezla® (apremilast) is indicated for the treatment of adult patients with moderate to severe 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® (apremilast) 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 throughout and click here to view Full Prescribing Information**

This resource is informational only and not intended to be directive or a guarantee of coverage.

# Important Safety Information

## IMPORTANT SAFETY INFORMATION (cont'd)

### Warnings and Precautions

- 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. 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
- 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
  - Psoriasis: Treatment with Otezla is associated with an increase in depression. During clinical trials, 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
  - Psoriatic Arthritis: 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
  - Behçet's Disease: 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
  - Psoriasis: Body weight loss of 5-10% occurred in 12% (96/784) of patients 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
  - Psoriatic Arthritis: 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

- Psoriasis: Adverse reactions reported in ≥5% of patients were (Otezla%, placebo%): diarrhea (17, 6), nausea (17, 7), upper respiratory tract infection (9, 6), tension headache (8, 4), and headache (6, 4)
- Psoriatic Arthritis: Adverse reactions reported in at least 2% of patients taking Otezla, that occurred at a frequency at least 1% higher than that observed in patients taking placebo, for up to 16 weeks (after the initial 5-day titration), were (Otezla%, placebo%): diarrhea (7.7, 1.6); nausea (8.9, 3.1); headache (5.9, 2.2); upper respiratory tract infection (3.9, 1.8); vomiting (3.2, 0.4); nasopharyngitis (2.6, 1.6); upper abdominal pain (2.0, 0.2)
- Behçet's Disease: Adverse reactions reported in ≥5% of patients taking Otezla, that occurred at a frequency at least 1% higher than that observed in patients taking placebo, for up to 12 weeks, were (Otezla%, placebo%): diarrhea (41.3, 20.4); nausea (19.2, 10.7); headache (14.4, 10.7); upper respiratory tract infection (11.5, 4.9); upper abdominal pain (8.7, 1.9); vomiting (8.7, 1.9); back pain (7.7, 5.8); viral upper respiratory tract infection (6.7, 4.9); arthralgia (5.8, 2.9)

### Use in Specific Populations

- Pregnancy: Otezla has not been studied in pregnant women. Advise pregnant women of the potential risk of fetal loss. Consider pregnancy planning and prevention for females of reproductive potential. There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to Otezla during pregnancy. Information about the registry can be obtained by calling 1-877-311-8972 or visiting https://mothertobaby.org/ongoing-study/otezla/
- Lactation: There are no data on the presence of apremilast or its metabolites in human milk, the effects of apremilast on the breastfed infant, or the effects of the drug on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Otezla and any potential adverse effects on the breastfed child from Otezla or from the underlying maternal condition
- Renal Impairment: Otezla dosage should be reduced in patients with severe renal impairment (creatinine clearance less than 30 mL/min); for details, see Dosage and Administration, Section 2, in the Full Prescribing Information

**Please click here for Full Prescribing Information.**

This resource is informational only and not intended to be directive or a guarantee of coverage.



Otezla® (apremilast) 30mg tablets