Otezla® START Form for the Specialty Pharmacy (SP)

If you do not e-prescribe, this form can be faxed to your preferred SP to act as a prescription, provided it complies with your state's prescription requirements.
DO NOT SEND to Amgen® SupportPlus, as this form contains the patient's Personal Health Information.

Preferred SP name _____ **Fax #** _____

Please note, if a patient's insurance mandates the use of a specific SP, your preferred SP may need to transfer the prescription.

Patient and Prescriber Information

PATIENT INFORMATION:

Name (First, Middle, Last) _____ Date of birth _____ ☐ Male ☐ Female

Address _____ City _____ State _____ ZIP _____

Home phone _____ Mobile phone _____

Important: Notify your patient that the SP will call them to confirm shipping and patient details. The patient MUST make contact with the pharmacy to receive their Otezla.

INSURANCE INFORMATION: *(Include copies of the front and back of both your patient's insurance and prescription benefit cards.)*

☐ Insurance card attached ☐ Prescription benefit card attached ☐ Patient has no insurance

Primary insurance provider _____ Policy # _____ Group # _____ Insurance phone _____

Policyholder name (First, Middle, Last) _____ Prescription insurance _____

Prescription insurance phone _____ Rx member ID _____ Rx PCN *(if applicable)* _____

Rx group ID _____ Rx BIN *(if applicable)* _____

PRESCRIBER INFORMATION:

Name (First, Last) _____ Facility name _____

Address _____ City _____ State _____ ZIP _____

Phone _____ Fax _____ NPI # *(required)* _____ Office contact _____

Clinical Information for Prior Authorization (PA)

Important: The SP may contact you for additional information required to complete a PA.

PRIMARY DIAGNOSIS/ICD 10 CODE:

☐ L40.0 (Psoriasis vulgaris) %BSA Affected _____
☐ L40.51 (Distal interphalangeal psoriatic arthropathy)
☐ L40.59 (Other psoriatic arthropathy)
☐ L40.8 (Other psoriasis) %BSA Affected _____
☐ L40.9 (Psoriasis, unspecified) %BSA Affected _____
☐ M35.2 (Behçet's Disease)

AFFECTED AREA(S): (For PsO ONLY): ☐ Hands ☐ Arms ☐ Nails ☐ Trunk ☐ Feet ☐ Legs ☐ Scalp ☐ Groin ☐ Other_____

PREVIOUS/CURRENT TREATMENT:

Medication	Duration/Reason for discontinuation	Medication	Duration/Reason for discontinuation
☐ Methotrexate	_____	☐ Phototherapy	_____
☐ Adalimumab	_____	☐ Orals	_____
☐ Sulfasalazine	_____	☐ Topicals	_____
☐ Acitretin	_____	☐ Biologics	_____
☐ Ustekinumab	_____	☐ Other	_____

ADDITIONAL MEDICAL JUSTIFICATION: _____

(Include any clinical notes helpful in documenting diagnosis, Body Surface Area (BSA), and treatment history.)

Prescription Information

Adults and Pediatric Patients 6 Years and Older (for patients weighing at least 50 kg)

☐ 28-Day Treatment Initiation Rx: **Otezla 10 & 20 & 30 mg tablets** (NDC 55513-369-55)
☐ Maintenance Rx: **Otezla 30 mg tablets** (NDC 55513-137-60)
☐ Twice Daily ☐ Once-daily renal dose 30 mg (For patients with severe renal impairment)
☐ 30 Days _____ ☐ 11 Refills ☐ (Other # of refills)_____

Adult XR and Pediatric Patients 6 Years and Older XR (for patients weighing at least 50 kg)

☐ 28-Day Treatment Initiation Rx: **Otezla 10 & 20 & 30 & XR 75 mg tablets** (NDC 55513-516-41)
☐ Maintenance Rx: **Otezla XR 75 mg tablets** (NDC 55513-519-30)
☐ Once Daily
☐ 30 Days _____ ☐ 11 Refills ☐ (Other # of refills)_____

Pediatric Patients 6 Years and Older (for patients weighing 20 kg to less than 50 kg)

☐ 28-Day Treatment Initiation Rx: **Otezla 4 x 10 mg & 51 x 20 mg tablets** (NDC 55513-508-55)
☐ Maintenance Rx: **Otezla 20 mg tablets** (NDC 55513-497-60)
☐ Twice Daily ☐ Once-daily renal dose 20 mg (For patients with severe renal impairment)
☐ 30 Days _____ ☐ 11 Refills ☐ (Other # of refills)_____

Prescriber signature (dispense as written) _____ Date _____

Supervising physician signature and date (where required) _____ Date _____

THIS FORM SHOULD BE SUBMITTED TO THE SP. If sent to Amgen® SupportPlus, by completing and faxing this form, you represent that your patient has requested and authorized the disclosure of their personal health information to Amgen and its agents for the limited purpose of enabling Amgen to facilitate delivery of the form to the preferred Specialty Pharmacy. You represent that you have explained to the patient, and the patient indicated they understand and have consented to, the disclosure of their personal health information to Amgen for this purpose, that the patient may withdraw their consent at any time by contacting Amgen at 1-833-442-6436 or visiting www.amgen.com/DataSubjectRights, and that the patient can view additional information about Amgen's privacy practices at www.amgen.com/privacy.

Please see the below page for Indications and Important Safety Information.
Please click here for the full Prescribing Information for Otezla.

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PLEASE DO NOT WRITE IN THE MARGINS – INFORMATION CAN BE MISSED OR CUT OFF
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INDICATIONS AND IMPORTANT SAFETY INFORMATION

INDICATIONS

Active Psoriatic Arthritis:

- OTEZLA is indicated for the treatment of adult patients and pediatric patients 6 years of age and older and weighing at least 20 kg with active psoriatic arthritis.
- OTEZLA XR is indicated for the treatment of adult patients and pediatric patients 6 years of age and older and weighing at least 50 kg with active psoriatic arthritis.

Plaque Psoriasis:

- OTEZLA/OTEZLA XR 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 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.
- OTEZLA XR is indicated for the treatment of pediatric patients 6 years of age and older and weighing at least 50 kg with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.

Oral Ulcers Associated with Behçet's Disease:

- OTEZLA/OTEZLA XR is indicated for the treatment of adult patients with oral ulcers associated with Behçet's Disease.

IMPORTANT SAFETY INFORMATION

Contraindications

- Otezla/OTEZLA XR is contraindicated in patients with a known hypersensitivity to apremilast or to any of the excipients in the formulation.

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/OTEZLA XR 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. 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/OTEZLA XR dose reduction or suspension if patients develop severe diarrhea, nausea, or vomiting.
- Depression: Carefully weigh the risks and benefits of treatment with Otezla/OTEZLA XR for patients with a history of depression and/or suicidal thoughts/behavior, or in patients who develop such symptoms while on Otezla/OTEZLA XR. 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.
  - Plaque Psoriasis: Treatment with Otezla is associated with an increase in depression. During clinical trials in adult 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.
  - Psoriatic Arthritis: Treatment with Otezla is associated with an increase in depression. During clinical trials in adult patients, 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/OTEZLA XR.
  - Plaque Psoriasis: Body weight loss of 5-10% occurred in 12% (96/784) of adult 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 adult patients treated with Otezla compared to 1% (3/382) of patients treated with placebo. Body weight loss of 5%-10% occurred in 12% (19/163) of pediatric patients with moderate to severe plaque psoriasis treated with Otezla compared to 2.5% (2/80) with placebo. Body weight loss of ≥ 10% occurred in 1% (1/163) of pediatric patients treated with Otezla twice daily compared to 0% (0/80) of patients with placebo. Closely monitor growth (height and weight) in Otezla/OTEZLA XR -treated pediatric patients. Pediatric patients who are not growing or gaining weight as expected may need to have their treatment interrupted.
  - Psoriatic Arthritis: Body weight loss of 5-10% was reported in 10% (49/497) of adult 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 co-administered with rifampin, a strong CYP450 enzyme inducer; loss of Otezla/OTEZLA XR efficacy may occur. Concomitant use of Otezla/OTEZLA XR 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 adult patients with mild to moderate plaque psoriasis and pediatric patients with moderate to severe plaque psoriasis was consistent with the safety profile established in adult patients with moderate to severe plaque psoriasis.
- Psoriatic Arthritis: The most common adverse reactions (≥ 5%) are diarrhea, nausea, and headache.
- Behçet's Disease: The most common adverse reactions (≥ 10%) are diarrhea, nausea, headache, and upper respiratory tract infection.

Use in Specific Populations

- Advise pregnant women of the potential risk of fetal loss.

Please click here for the full Prescribing Information for Otezla.

Otezla® (apremilast) 30mg tablets

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