Otezla® SUPPORTPLUS™

Otezla® (apremilast) Telemedicine Prescribing Guide

If you have incorporated telemedicine services into your practice or are considering it, we want to provide you with a few quick steps to help outline the easy process for new and existing patients.

Otezla can be easily prescribed via telemedicine for new and existing patients.

Starting New Patients

- Complete and fax/e-fax the Otezla START Form to Otezla SupportPlus™ (OSP) - **Fax:** 1-855-850-2955
- The START Form is available to download and print on OtezlaPro.com/resources
- Only through OSP, commercially insured patients can receive a free 4-week Starter Pack and Bridge supply. The Otezla Bridge supply can provide continuity of care if there are any delays or coverage denials*
- Your patients' free 4-week Starter Pack will be shipped approximately 2-3 days after the completed START Form is received
- Prescriptions can still be submitted to a specialty pharmacy, but patients will not receive the free 4-week Starter Pack or Bridge Program supply

Existing Patients

- There is no need to change your existing patients' current prescription refill process

$0 co-pay for eligible patients†

Otezla patients can enroll in the $0 Co-pay program at Otezla.com/copay or by calling OSP at **1-844-4OTEZLA** (1-844-468-3952)

*To receive a free Bridge supply of Otezla, commercially insured patients must have an on-label diagnosis and be denied or waiting for coverage. If an in-office Starter Pack (Titration) is not available, please check both the 4-week Starter Pack and Bridge Rx boxes.

†Certain restrictions apply; eligibility not based on income, must be 18 years or older. This offer is not valid for persons eligible for reimbursement of this product, in whole or in part under Medicaid, Medicare, or similar state or federal programs. Offer not valid for cash-paying patients. People who are not eligible can call **1-844-4OTEZLA** to discuss other financial assistance opportunities.

Please refer to the Otezla START Form Guide on pages 2-4 for helpful tips to prevent delays in the prescription-ordering process for your patients.

Please see Important Safety Information on last page and Full Prescribing Information here.

Otezla® (apremilast) 30mg tablets

Completing the Otezla START Form for Telemedicine Patients

To help prevent delays in the prescription process of your patients on Otezla® (apremilast), be sure to fill out the **Otezla START Form** accurately and completely. This guide will help.

FOUR CHECKS FOR SUCCESS

1 **Refer to the guide provided**
We've included detailed tips to help you complete the telemedicine form correctly.

2 **Double-check for common errors**
We've highlighted the fields that are most commonly overlooked. These errors lead to delays in processing. Double-checking may help your patients get their treatment as prescribed and reduce the burden on your office staff.

3 **Make sure you send everything**
Here's a complete list of what to fax to OSP:

- Completed and **signed** Otezla START Form to Otezla SupportPlus™ **(Patient signature is not required during a telemedicine visit.)**
- Copy of **both** sides of patient's insurance and pharmacy benefit card(s)
- Any clinical notes helpful in establishing diagnosis. **Or**, if the patient has been taking Otezla, include updated clinical notes about their progress

4 **Remind your patients they should expect a call**
Make sure your patients know that Otezla SupportPlus™ or their specialty pharmacy will call to confirm their contact and insurance information—and that call may come from an unfamiliar number. They need to answer to avoid delays in processing.

Please see Important Safety Information on last page and Full Prescribing Information here.

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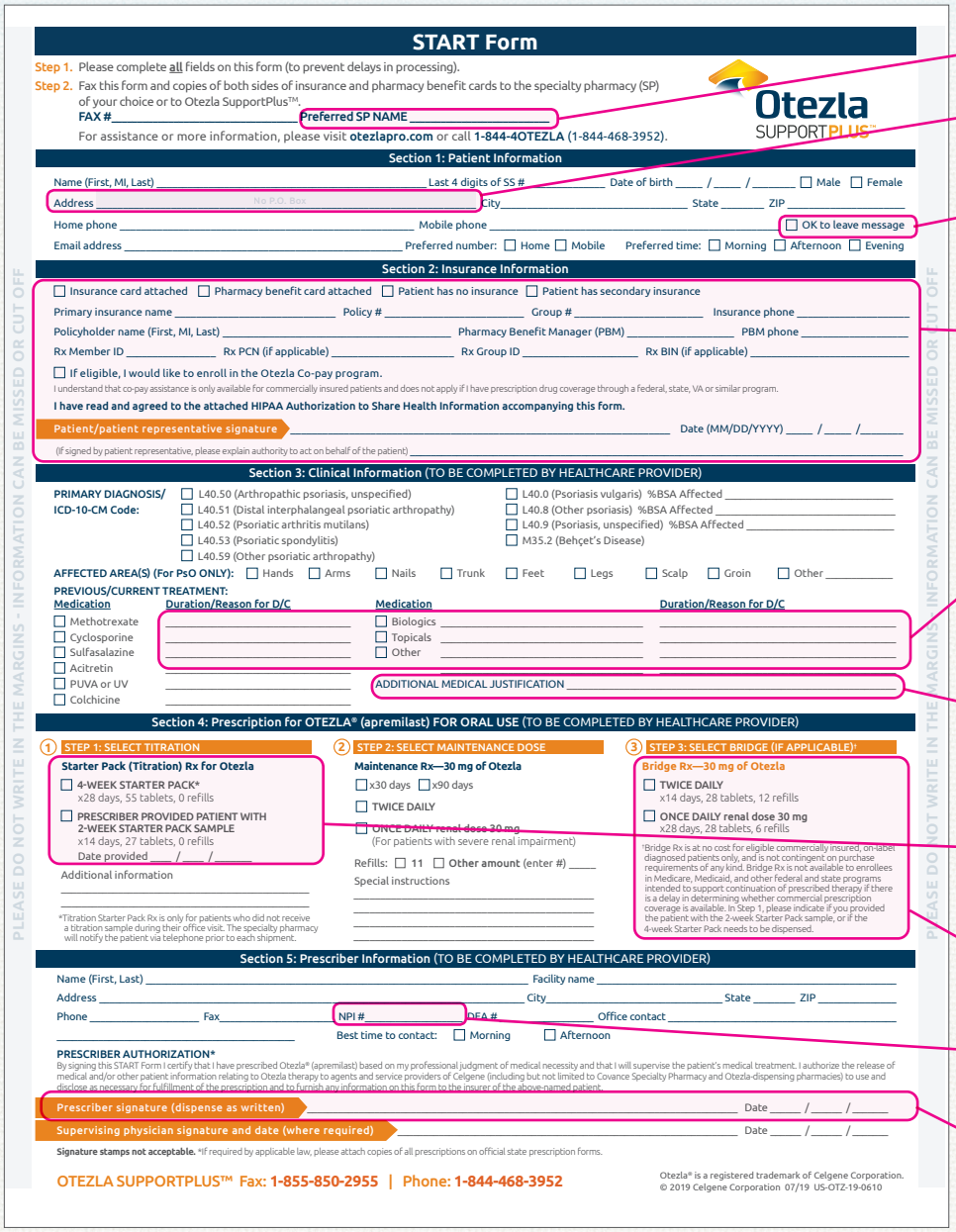
Guide to the Otezla START Form for Telemedicine Patients

Here are some tips for filling out an Otezla® (apremilast) START Form for Telemedicine Patients. Filling out the START Form accurately and completely will help avoid delays in processing. Highlighted areas note fields that are commonly overlooked.



START Form

Step 1. Please complete all fields on this form (to prevent delays in processing).

Step 2. Fax this form and copies of both sides of insurance and pharmacy benefit cards to the specialty pharmacy (SP) of your choice or to Otezla SupportPlus™.

FAX # _____ Preferred SP NAME _____

For assistance or more information, please visit **otezlapro.com** or call **1-844-4OTEZLA** (1-844-468-3952).

Otezla SUPPORTPLUS™

Section 1: Patient Information

Name (First, MI, Last) _____ Last 4 digits of SS # _____ Date of birth ____ / ____ / _____ ☐ Male ☐ Female

Address _____ No P.O. Box City _____ State _____ ZIP _____

Home phone _____ Mobile phone _____ ☐ OK to leave message

Email address _____ Preferred number: ☐ Home ☐ Mobile Preferred time: ☐ Morning ☐ Afternoon ☐ Evening

Section 2: Insurance Information

☐ Insurance card attached ☐ Pharmacy benefit card attached ☐ Patient has no insurance ☐ Patient has secondary insurance

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

Policyholder name (First, MI, Last) _____ Pharmacy Benefit Manager (PBM) _____ PBM phone _____

Rx Member ID _____ Rx PCN (if applicable) _____ Rx Group ID _____ Rx BIN (if applicable) _____

☐ If eligible, I would like to enroll in the Otezla Co-pay program.

I understand that co-pay assistance is only available for commercially insured patients and does not apply if I have prescription drug coverage through a federal, state, VA or similar program.

I have read and agreed to the attached HIPAA Authorization to Share Health Information accompanying this form.

Patient/patient representative signature _____ Date (MM/DD/YYYY) ____ / ____ / _____

(If signed by patient representative, please explain authority to act on behalf of the patient) _____

Section 3: Clinical Information (TO BE COMPLETED BY HEALTHCARE PROVIDER)

PRIMARY DIAGNOSIS/ ICD-10-CM 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) %BSA Affected _____
☐ 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 D/C	Medication	Duration/Reason for D/C
☐ Methotrexate		☐ Biologics	
☐ Cyclosporine		☐ Topicals	
☐ Sulfasalazine		☐ Other	
☐ Acitretin			
☐ PUVA or UV			
☐ Colchicine			

ADDITIONAL MEDICAL JUSTIFICATION _____

Section 4: Prescription for OTEZLA® (apremilast) FOR ORAL USE (TO BE COMPLETED BY HEALTHCARE PROVIDER)

① STEP 1: SELECT TITRATION

Starter Pack (Titration) Rx for Otezla

☐ 4-WEEK STARTER PACK*
x28 days, 55 tablets, 0 refills

☐ PRESCRIBER PROVIDED PATIENT WITH 2-WEEK STARTER PACK SAMPLE
x14 days, 27 tablets, 0 refills
Date provided ___ / ___ / _____

Additional information _____

*Titration Starter Pack Rx is only for patients who did not receive a titration sample during their office visit. The specialty pharmacy will notify the patient via telephone prior to each shipment.

② STEP 2: SELECT MAINTENANCE DOSE

Maintenance Rx—30 mg of Otezla

☐ x30 days ☐ x90 days

☐ TWICE DAILY

☐ ~~ONCE DAILY renal dose 30 mg~~
(For patients with severe renal impairment)

Refills: ☐ 11 ☐ Other amount (enter #) ____

Special instructions _____

③ STEP 3: SELECT BRIDGE (IF APPLICABLE)†

Bridge Rx—30 mg of Otezla

☐ TWICE DAILY
x14 days, 28 tablets, 12 refills

☐ ONCE DAILY renal dose 30 mg
x28 days, 28 tablets, 6 refills

†Bridge Rx is at no cost for eligible commercially insured, on-label diagnosed patients only, and is not contingent on purchase requirements of any kind. Bridge Rx is not available to enrollees in Medicare, Medicaid, and other federal and state programs intended to support continuation of prescribed therapy if there is a delay in determining whether commercial prescription coverage is available. In Step 1, please indicate if you provided the patient with the 2-week Starter Pack sample, or if the 4-week Starter Pack needs to be dispensed.

Section 5: Prescriber Information (TO BE COMPLETED BY HEALTHCARE PROVIDER)

Name (First, Last) _____ Facility name _____

Address _____ City _____ State _____ ZIP _____

Phone _____ Fax _____ NPI # _____ DEA # _____ Office contact _____

Best time to contact: ☐ Morning ☐ Afternoon

PRESCRIBER AUTHORIZATION*

By signing this START Form I certify that I have prescribed Otezla® (apremilast) based on my professional judgment of medical necessity and that I will supervise the patient's medical treatment. I authorize the release of medical and/or other patient information relating to Otezla therapy to agents and service providers of Celgene (including but not limited to Covance Specialty Pharmacy and Otezla-dispensing pharmacies) to use and disclose as necessary for fulfillment of the prescription and to furnish any information on this form to the insurer of the above-named patient.

Prescriber signature (dispense as written) _____ Date ____ / ____ / _____

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

Signature stamps not acceptable. *If required by applicable law, please attach copies of all prescriptions on official state prescription forms.

OTEZLA SUPPORTPLUS™ Fax: **1-855-850-2955** | Phone: **1-844-468-3952**

PLEASE DO NOT WRITE IN THE MARGINS - INFORMATION CAN BE MISSED OR CUT OFF

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Keep a record of the specialty pharmacy to which each form is submitted. Also include this name in Section 2.

P.O. box addresses are not permitted.

If left unchecked, orders may be delayed when information needs to be verified.

In Section 2: All relevant fields must be completed, except patient/patient representative signature and date as they are not required for telemedicine.

Also include copy of insurance and pharmacy benefit cards (both sides).

Be sure to document any previous treatments and reasons for discontinuation.

Additional medical justification can help. Also include/attach all clinical notes.

Select the option for your patient to receive a 4-week Starter Pack from Otezla Support Plus™.

Select Bridge supply (if eligible) to provide continuity of care if there are any delays or coverage denials.

Must include NPI number.

Signature required.
Don't forget to sign and date!

Please see Important Safety Information on last page and Full Prescribing Information here.

Otezla® (apremilast) 30mg tablets

Indications and Important Safety Information

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

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.

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