



Otezla[®]

SUPPORT PLUS[™]

Otezla[®] (apremilast) START Form Guide

Helpful tips to prevent delays in the prescription-ordering process for your patients

Be sure to fill out the **Otezla START Form for Specialty Pharmacy** and the **HIPAA Authorization to Share Health Information** accurately and completely

Follow the 4 steps inside to get started

Questions? Call Otezla SupportPlus[™] at **1-844-4OTEZLA** (1-844-468-3952)
8AM–8PM ET, Monday–Friday.

Please see Indications and Important Safety Information on last page and Full Prescribing Information [here](#).



Completing the Otezla START Form

To help prevent delays in the prescription process of your patients on Otezla® (apremilast), be sure to fill out the **Otezla START Form for Specialty Pharmacy** and the **HIPAA Authorization to Share Health Information** 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 and your patients complete both forms 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 the specialty pharmacy. (For a list of enhanced support specialty pharmacies, visit the Resources section of OtezlaPro.com):
 - Completed and **signed** Otezla START Form for Specialty Pharmacy
 - Completed and **signed** HIPAA Authorization to Share Health Information
 - 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 Indications and Important Safety Information on last page and Full Prescribing Information [here](#).




Guide to the Otezla START Form for Specialty Pharmacy

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

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

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).



Section 1: Patient Information

Name (First, MI, Last) _____ Last 4 digits of SS # _____ Date of birth ____/____/____ Male Female
 Address _____ City _____ State _____ ZIP _____
 *Home phone _____ *Mobile phone _____ OK to leave message
 Email address _____ Preferred number: Home Mobile Preferred time: Morning Afternoon Evening Telemed Visit

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) L40.0 (Psoriasis vulgaris) %BSA Affected _____
 L40.51 (Distal interphalangeal psoriatic arthropathy) L40.8 (Other psoriasis) %BSA Affected _____
 L40.52 (Psoriatic arthritis mutilans) L40.9 (Psoriasis, unspecified) %BSA Affected _____
 L40.53 (Psoriatic spondylitis) M35.2 (Behçet's Disease)
 L40.59 (Other psoriatic arthropathy)

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
<input type="checkbox"/> Methotrexate	_____	<input type="checkbox"/> Biologics	_____
<input type="checkbox"/> Cyclosporine	_____	<input type="checkbox"/> Topicals	_____
<input type="checkbox"/> Sulfasalazine	_____	<input type="checkbox"/> Other	_____
<input type="checkbox"/> Acitretin	_____		
<input type="checkbox"/> PUVA or UV	_____		
<input type="checkbox"/> Colchicine	_____		

ADDITIONAL MEDICAL JUSTIFICATION _____

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

1 STEP 1: SELECT TITRATION **2 STEP 2: SELECT MAINTENANCE DOSE** **3 STEP 3: SELECT BRIDGE (IF APPLICABLE)**

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.

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 _____

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 Amgen (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.



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

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

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, including patient/patient representative signature and date.
 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.

Either select the option for your patient to receive a 4-week starter pack from their specialty pharmacy or indicate the date a 2-week starter pack was provided by your office. Be sure to include date.

Bridge supply is only available for commercially insured patients.

Must include NPI number.

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

Please see Indications and Important Safety Information on last page and Full Prescribing Information [here](#).



Sample HIPAA Authorization Form

Always make sure that the completed Otezla START Form is accompanied by a signed HIPAA Authorization, like the one below.

Patient Authorization to Share Health Information



Please present this Authorization to the patient/patient representative and obtain the required signature.

Uses and Disclosure of Personal Information

I authorize Amgen and its contractors and business partners ("Amgen") to use and/or disclose my personal information, including my personal health information, only for the following purposes:

- To operate, administer, enroll me in, and/or continue my participation in Amgen's Otezla SupportPlus™ program or any other Amgen-affiliated patient support services and activities related to my condition or treatment (for example, co-pay card programs, reimbursement assistance programs, drug coverage verification, nurse educator services, adherence program and disease management support);
- To contact, with my permission, my doctor and the rest of my health care team and share with them my health information that may be useful for my care;
- **To provide me with informational and promotional materials relating to Amgen products and services, and/or my condition or treatment;** and/or
- To improve, develop, and evaluate products, services, materials and programs related to my condition or treatment.

In order for Amgen to provide me with the services and/or programs described above, Amgen needs to collect and use my personal information, including my personal health information. I understand that my personal health information may include any information, in electronic or physical form, in the possession of or derived from a health care provider, health care plan, pharmacy, pharmaceutical company, laboratory and/or their contractor ("Health Care Provider"). This may include select information from or about my medical history and general health, my health care plan benefits, payment limits or restrictions covered by my health care plan policy, and/or my adherence to my treatment.

I authorize my Health Care Providers to disclose my personal health information to Amgen, and between themselves, as necessary, but only for the purposes stated above in this Authorization. I understand that certain of my Health Care Providers (such as pharmacies and specialty pharmacies) may receive remuneration from Amgen in exchange for disclosing my personal health information and/or for using my information to contact me with communications about Amgen products which have been prescribed to me (for example medication reminder programs) and other patient support services.

Expiration, Right to Obtain a Copy and Right to Cancel

I understand that by signing this form, I authorize my Health Care Providers or others who might hold my health information to only release it to Amgen employees, as well

as to its contractors and business partners, who are performing the services set forth in this Authorization. I also understand I am authorizing my personal information, including my personal health information, to be used for the purposes described above. I understand and agree that by signing below, I am authorizing those who rely on this Authorization to release my personal health information for the earlier of five (5) years or until my participation in the program ends through my cancellation, unless a shorter time period is required by state law.

I understand that I can obtain a copy of this Authorization or cancel this Authorization at any time by calling Amgen at 1-844-468-3952 or by writing to PO BOX 13185, La Jolla, California, 92039. If I cancel my consent, I will no longer qualify for the services described. I also understand that if a Health Care Provider is disclosing my personal health information to Amgen on an authorized on-going basis, my cancellation with Amgen will be effective with respect to any such Health Care Providers as soon as they receive notice of my cancellation.

No Effect on Treatment

I understand I do not have to sign this Authorization and that my enrollment in any of the services and/or programs described above is entirely voluntary. I understand that Amgen, as well as Health Care Providers, cannot require me, as a condition of having access to medications, prescription drugs, treatment or other care, to sign this Authorization. Federal Law (including HIPAA) requires a signed authorization in order for Amgen to collect this information from my Health Care Providers. I understand I cannot participate in the listed services and/or programs without signing this Authorization or an equivalent authorization with my Health Care Providers.

Information Received from Health Care Providers

I understand that once my personal health information has been disclosed to Amgen, federal privacy laws may no longer apply and protect it from further disclosure. Amgen agrees, however, to protect my personal health information by only using and disclosing it as stated in the Authorization or as otherwise allowed or required by law.

Authorization to Contact

I understand and consent to Amgen contacting me using the contact information provided in this form to enroll me in, operate, and administer Amgen patient support services and/or programs as described above other than promotional communications by telephone or SMS/text (which I can separately opt-in below). I understand that the operation and administration of certain of these services and/or programs may require that Amgen contact me by telephone or SMS/text.

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 $\geq 10\%$ 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 $\geq 5\%$ 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 $\geq 5\%$ 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.



© 2020 Amgen Inc. All rights reserved.
05/20 US-OTZ-20-0684

