

# 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 **1-844-40TEZLA** (1-844-468-3952) 8AM–8PM ET, Monday–Friday.



# 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**

- Refer to the guide provided
  We've included detailed tips to help you and your patients complete both forms correctly.
- 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.
- 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
- 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.



# Guide to the Otezla START Form for Specialty Pharmacy

Here are some tips for filling out an Otezla<sup>®</sup> (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.

					Keep a record of the specialty pharmacy to which each form
START Form					submitted. Also include this n in Section 2.
p 1. Please complete	all fields on this form (to prev				in Section 2.
p 2. Fax this form and	copies of both sides of insura	ance and pharmacy benefit cards to the specialty pha	rmacy (SP)		
of your choice or FAX #	to Otezla SupportPlus™.	erred SP NAME	Otezla	1-50 to	P.O. box addresses are not
		visit otezlapro.com or call 1-844-4OTEZLA (1-844			permitted.
Tor assistance of	more informacion, picase	Section 1: Patient Information	100 3332).		permitted.
Name (First, MI, Last)		Last 4 digits of SS #	Date of birth /   Male	do	
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Email address		Section 2: Insurance Information	Morning   Arcentoon   Evening   reterined v	isic	needs to be verified.
				上 能	
Primary insurance name		attached Patient has no insurance Patient has s  Policy # Group #	lnsurance phone		
Primary insurance name Poucy# Group # Insurance pnone Policyholder name (First, MI, Last) Pharmacy Benefit Manager (PBM) PBM phone					In Section 2: All relevant field:
Rx Member ID Rx PCN (if applicable) Rx Group ID Rx BIN (if applicable)					must be completed, including
If eligible, I would like to enroll in the Otezla Co-pay program.					patient/patient representativ
		sy program. Isured patients and does not apply if I have prescription drug coverage th	nrough a federal, state, VA or similar program.	S	signature and date.
I have read and agreed	to the attached HIPAA Authori	zation to Share Health Information accompanying this f	orm.	AIS.	-
Patient/patient repre	sentative signature		Date (MM/DD/YYYY) / /	_ Z	Also include copy of insuranc
(If signed by patient represen	tative, please explain authority to act on	behalf of the patient)		_ ] =	and pharmacy benefit cards
	Section 3: Cli	nical Information (TO BE COMPLETED BY HEALTH	CARE PROVIDER)	A	(both sides).
PRIMARY DIAGNOSIS/	L40.50 (Arthropathic psor		rulgaris) %BSA Affected	Z	
ICD-10-CM Code:	L40.51 (Distal interphalan L40.52 (Psoriatic arthritis	geal psoriatic arthropathy)	riasis) %BSA Affected unspecified) %BSA Affected	0	
	L40.53 (Psoriatic spondyli			A	Be sure to document any
	L40.59 (Other psoriatic ar			S S	previous treatments and reason
		Arms Nails Trunk Feet Le	gs Scalp Groin Other	0	for discontinuation.
PREVIOUS/CURRENT T Medication	REATMENT: Duration/Reason for D/C	Medication	Duration/Reason for D/C	$\equiv$	
☐ Methotrexate		Biologics		$\supset$	
Cyclosporine		Topicals		- Z 🔀	Additional medical justificatio
Acitretin		Ctrier			· ·
☐ PUVA or UV		ADDITIONAL MEDICAL JUSTIFICATION		- X	can help. Also include/attach
Colchicine _				# 1	clinical notes.
Sec	tion 4: Prescription for OT	EZLA® (apremilast) FOR ORAL USE (TO BE COMPL	ETED BY HEALTHCARE PROVIDER)	ı ≓	
STEP 1: SELECT TITE		2 STEP 2: SELECT MAINTENANCE DOSE	3 STEP 3: SELECT BRIDGE (IF APPLICABLE) <sup>†</sup>	Z	
Starter Pack (Titratio		Maintenance Rx—30 mg of Otezla	Bridge Rx—30 mg of Otezla		Either select the option for yo
4-WEEK STARTER I x28 days, 55 tablets	PACK* s. 0 refills	x30 days x90 days	TWICE DAILY x14 days, 28 tablets, 12 refills	WRITI	patient to receive a 4-week
☐ PRESCRIBER PROV	IDED PATIENT WITH	TWICE DAILY	ONCE DAILY renal dose 30 mg	>	starter pack from their specia
2-WEEK STARTER F x14 days, 27 tablets	ACK SAMPLE	(For patients with severe renal impairment)	x28 days, 28 tablets, 6 refills	TON	pharmacy or indicate the date
Date provided	11	Refills:   11 Other amount (enter #)	'Bridge Rx is at no cost for eligible commercially insured, on-labe diagnosed patients only, and is not contingent on purchase requirements of any kind. Bridge Rx is not available to enrollees	0	
Additional information	1	Special instructions			a 2-week starter pack was
			intended to support continuation of prescribed therapy if there is a delay in determining whether commercial prescription	ASE	provided by your office. Be
*Titration Starter Pack Rx is o	only for patients who did not receive eir office visit. The specialty pharmacy		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.	HE SE	sure to include date.
a un ation sample during th will notify the patient via te	lephone prior to each shipment.				
	Section 5: Pres	criber Information (TO BE COMPLETED BY HEALT	HCARE PROVIDER)		
Name (First , Last)		Facility name			Bridge supply is only availab
Address		City	State ZIP	-	for commercially insured
Phone	Fax		Office contact	-	patients.
PRESCRIBER AUTHORI	7ATION*	Best time to contact: Morning Afternoo	A		podicités.
By signing this START Form I	certify that I have prescribed Otezla® (ap	remilast) based on my professional judgment of medical necessity and th	nat I will supervise the patient's medical treatment. I suthorize the release o vance Specialty Pharmacy and Otezla-dispensing pharmacies) to use and	ıf	
medical and/or other patient disclose as necessary for fulfil	inrormation relating to Otezla therapy t lment of the prescription and to furnish	o agents and service providers of Amgen (including but not limited to Co any information on this form to the insurer of the above-named patient.	vance Specialty Pharmacy and Otezla-dispensing pharmacies) to use and		Must include NDI =
	(dispense as written)		Date / /	7	Must include NPI number.
	n signature and date (where	required)	Date / /	$\sim$	
		ease attach copies of all prescriptions on official state prescription forms.			<u> </u>
		50-2955   Phone: 1-844-468-3952	© 2020 Amgen Inc. All rights reserve	d.	Signature required.  Don't forget to sign and date



# Sample HIPAA Authorization Form

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

### HIPAA Authorization to Share Health Information



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

By signing this Authorization (on the signature line in Section 2 on the front of this START Form),

I authorize my healthcare providers, my health insurance company, and my pharmacy providers to disclose to Amgen and companies working on its behalf (collectively, "Amgen") health information relating to my medical condition, treatment, and insurance coverage so that Amgen may use the information to (1) provide me with treatment support services through Otezla SupportPlus™ and marketing or educational information or materials related to such services; (2) ask me about my experience with or thoughts about Otezla and Otezla SupportPlus™; (3) analyze the usage patterns and the effectiveness of Otezla and Otezla SupportPlus™; (4) help develop new products, services, and programs; (5) conduct Amgen general business and administrative activities, and (6) communicate with me by mail, email, phone, fax, or otherwise about my prescription for Otezla, including through product adherence and refill reminder messages.

I understand that my pharmacy providers may receive remuneration from Amgen for disclosing my health information to Amgen and for using my health information to contact me with communications about Otezla and Otezla SupportPlus™.

I understand that once my health information has been disclosed to Amgen, federal privacy laws may no longer protect the information. However, I understand that Amgen plans to use and disclose the health information it receives pursuant to this Authorization only for purposes authorized herein or as required by law or regulation.

I understand that I may refuse to sign this
Authorization, but that if I do, Otezla SupportPlus™
may not have full access to my prescription status.

I further understand that my treatment, insurance enrollment, and eligibility for insurance benefits are not conditioned upon my signing this Authorization.

I may cancel this Authorization at any time by mailing a letter to Otezla SupportPlus™ at PO BOX 13185, La Jolla, California 92039 or by sending an email to privacyoffice@amgen.com. I understand that if I do cancel this Authorization, that will not invalidate reliance on the Authorization to use or disclose my information before Amgen receives the revocation. This Authorization expires ten [10] years from the date on which I sign it (ie, the date next to my signature on the front of this START Form), unless I cancel the Authorization earlier. I understand that I am entitled to receive a copy of this Authorization after I sign on the front of this START Form.

### \$0 Co-pay Eligibility

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 **1-844-40TEZLA** to discuss other financial assistance opportunities.

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



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# **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
- <u>Psoriasis</u>: 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
- <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
- 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
- <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**

- 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 <u>click here</u> for Full Prescribing Information.



