Otezla SUPPORTPLUS™

FAX COMPLETED FORM TO 1-844-269-3053

**Thank you for your interest in the Amgen Patient Assistance Program for Otezla® (apremilast).**

The Amgen Patient Assistance Program for Otezla provides no-cost medication to patients who meet specific program eligibility requirements. Please complete, sign, and submit this application form in order to begin the evaluation process for enrollment.

**To prevent processing delays, all fields of this application must be completed and submitted with copies of all required financial documents. Do not send original documents as they will not be returned.**

| No Prescription Coverage for Otezla | Medicare Part D Coverage |
|---|---|
| If you do not have prescription drug coverage, or Otezla is not covered by your plan, you may be eligible for the Amgen Patient Assistance Program for Otezla. If eligible, your enrollment will expire after twelve (12) months. | If you have Medicare Part D, you may be eligible for the Amgen Patient Assistance Program for Otezla. If eligible, your enrollment will expire on December 31st. |

**Program eligibility criteria**

To be eligible, uninsured or underinsured patients must meet the following criteria:

- o FDA-approved diagnosis
- o Be a permanent resident of the United States
- o Medicare-eligible beneficiaries must have enrolled in a Medicare Part D plan or other creditable coverage
- o Annual family gross income is equal to or less than the Annual Income Guidelines (adjusted gross income is not accepted)

| 2020 Poverty Guidelines* | | | |
|---|---|---|---|
| **Persons in Family/Household** | **All States and DC** | **Hawaii** | **Alaska** |
| 1 | $51,040 | $58,720 | $63,800 |
| 2 | $68,960 | $79,320 | $86,200 |
| 3 | $86,880 | $99,920 | $108,600 |
| 4 | $104,800 | $120,520 | $131,000 |
| 5 | $122,720 | $141,120 | $153,400 |
| 6 | $140,640 | $161,720 | $175,800 |

*Please note: The income limits are 400 percent of the 2019 Federal Poverty Level (FPL). You may visit https://aspe.hhs.gov/poverty-guidelines for information on Federal Poverty Level guidelines. 2020 Federal Poverty Level may change yearly.

**In order to begin the application process, please complete the following steps:**

**Provider:**

- o Complete Section B of this application, including the required signature

**Patient:**

- o Complete and sign Section A of this application
- o Provide a copy of the front and back of your insurance card(s), if applicable
- o Proof of household income is required to determine eligibility for assistance. Proof of income should include a copy of your most recent federal tax return documents (1040, 1040A, 1040EZ, or 1099s), W-2 form(s), Social Security Disability Income (SSDI), and Social Security Income (SSI) for all household members who contribute to your family's income
- o If you have $0 income, you must provide a written letter of explanation on how you are being supported
- o Fax the completed application and required financial documents to Amgen Patient Assistance Program for Otezla at **1-844-269-3053**. If you do not have access to a fax machine, please mail documents to the Amgen Patient Assistance Program for Otezla at P.O. box 503227, San Diego, CA 92150

If you have any questions regarding this application, please call us at **1-855-554-9168**, Monday–Friday, 8:00AM–8:00PM ET.

**Please see Indications and Important Safety Information starting on page 3, and Full Prescribing Information here.**





05/20 US-OTZ-20-0682

Otezla SUPPORTPLUS™

FAX COMPLETED FORM TO 1-844-269-3053

☐ New ☐ Renewal

## Section A: Patient Information ▶ TO BE COMPLETED BY PATIENT OR PATIENT REPRESENTATIVE

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

Address (P.O. box not accepted)_____ City_____ State_____ ZIP _____

Phone number_____ Email_____

Marital Status: ☐ Single ☐ Married ☐ Widowed Do you permanently reside in the U.S. or a U.S. territory? ☐ Yes ☐ No

Do you give Amgen Patient Assistance Program for Otezla consent to leave you detailed voice messages? ☐ Yes ☐ No

## Patient Insurance Information

If the patient has insurance, please check all that apply (include copies of front & back of insurance cards): ☐ Part D ☐ Medicare Advantage ☐ Private Insurance ☐ Patient has **no** insurance ☐ Patient has secondary insurance

**Medicaid:** ☐ **Denied/Not Eligible (Please provide copy of denial letter)** ☐ **Not applied** ☐ **Pending Coverage**

Primary insurance name_____ Policy # _____

Group # _____

Insurance phone number_____ Policyholder name (First, MI, Last) _____

Pharmacy Benefit Manager (PBM) _____ PBM phone _____

Rx Member ID _____ Rx Group ID _____

## Patient Household Income

Total Annual Gross Household Income*_____ Household Size†_____

*Remember to include proof of household income (1040, 1040A, 1040EZ, 1099, W-2 form(s) SSI/SSDI, etc). If you have $0 income, you must provide a written letter of explanation on how you are being supported.

†Number of people who contribute to or are dependent on your household income (household size must be reflected on your tax forms).

## Patient Consent and Attestation

**To the extent necessary to process and administer my Amgen Patient Assistance Program for Otezla® (apremilast) application, in connection with all Amgen Patient Assistance Program for Otezla services, I hereby agree:**

By completing this application you are providing authorization to Amgen and its agents* engaged in providing services under the Amgen Patient Assistance Program for Otezla (collectively, "Amgen") for the collection of certain information that is necessary in order to evaluate your enrollment into the Amgen Patient Assistance Program for Otezla, and if enrolled, to provide you with Otezla at no cost to you. This personal information may be shared with physicians and health insurers in order to provide you with program services. By completing this application you are agreeing that the information you provide is accurate and you have made no misrepresentations regarding your residency, insurance status, or income. You are required to notify the program of insurance changes or financial changes that may impact your eligibility for the program. You will promptly provide to the Amgen Patient Assistance Program for Otezla all documentation and information requested by the program to verify the accuracy of your eligibility, including any and all documentation requested by the Amgen Patient Assistance Program for Otezla pertaining to your income level, financial situation, insurance status and medical condition. The Amgen Patient Assistance Program for Otezla may terminate your enrollment in the program if you fail to comply with our request for any documentation.

I understand that the Amgen Patient Assistance Program for Otezla and its agents will request only that information needed to process and administer this application, and that they will not disclose the information they obtain, except as needed for this purpose or as required by applicable law.

*Agents may include third-party reimbursement service providers.

I hereby represent, covenant and certify as follows: (a) the medical and insurance information in this form is provided with my consent; (b) the information contained in this application is complete and accurate to the best of my knowledge; (c) I understand that if my prescription drug plan coverage changes or if my financial status changes, I may no longer be eligible under this program, and I will promptly notify Amgen Patient Assistance Program for Otezla of any such changes; (d) in the event that I become eligible for a benefit through a federal, state or private program which may reimburse for the medication requested I will notify Amgen Patient Assistance Program for Otezla and understand that I may no longer be eligible for assistance; (e) upon the request of Amgen Patient Assistance Program for Otezla and/or its agents/representatives, I will provide documentation—including but not limited to personal financial records—to verify the information contained in this application; (f) I understand that if there is a determination at any time that I am no longer eligible for this program, Amgen may immediately stop any assistance provided under this program; and (g) I will notify Amgen Patient Assistance Program for Otezla of any errors regarding the foregoing and will make every effort to correct those errors.

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

Patient Representative (PLEASE PRINT)_____ Date (MM/DD/YYYY) ____/____/____

(If signed by Patient Representative, please fax documentation of Power of Attorney)





05/20 US-OTZ-20-0682

Otezla SUPPORTPLUS™

FAX COMPLETED FORM TO 1-844-269-3053

☐ New ☐ Renewal

## Section B: Patient Diagnosis and Prescriber Information ▶ TO BE COMPLETED BY HEALTHCARE PROVIDER

Patient name (First, Last) _____ Date of birth ____/____/____

Primary insurance _____ Policy number _____

Primary Diagnosis/ICD-10-CM:

- ☐ 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)

Physician Name (First, Last) _____ NPI # _____ Tax ID # _____

Address _____ City _____ State _____ ZIP _____

Office Contact Name _____ Email _____

Phone & Ext. # _____ Fax # _____

Best time to contact: ☐ Morning ☐ Afternoon ☐ Evening

## Prescription Information ▶ TO BE COMPLETED BY HEALTHCARE PROVIDER

**PRESCRIPTION FOR OTEZLA® (apremilast) FOR ORAL USE: SELECT ALL THAT APPLY**

**Starter Pack (Titration) Rx for Otezla***

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

OR

☐ **PRESCRIBER PROVIDED 2-WEEK STARTER PACK SAMPLE TO PATIENT** 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.

**Maintenance Rx – 30 mg of Otezla Covance Specialty Pharmacy will notify the patient via telephone prior to each shipment.**

☐ **x90 DAYS TWICE DAILY** (Recommended daily dose) OR ☐ **x90 DAYS ONCE DAILY** (For patients with severe renal impairment)

REFILLS: ☐ **3** ☐ **Other amount** (enter #) _____ Special instructions _____

**PRESCRIBER AUTHORIZATION***

By signing this START Form I certify that I have prescribed Otezla 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 Amgen and its agents† engaged in providing services under the Amgen Patient Assistance Program for Otezla (collectively, "Amgen"), 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 furnish any information on this form to the insurer of the above-named patient.

I hereby represent, covenant, and certify as follows: (a) I have obtained from my patient all required authorization to release to Amgen Patient Assistance Program for Otezla and its representatives/agents all patient information needed for this application, including, without limitation, my patient's financial and medical information; (b) I understand that this information is for the sole use of Amgen to assess the patient's eligibility for participation in Amgen Patient Assistance Program for Otezla; (c) I have not received, nor will I seek or accept, reimbursement for any drug provided for my patient in Amgen Patient Assistance Program for Otezla; (d) I understand that if my patient's insurance or financial status changes, the patient may no longer be eligible under this program, and I will notify Amgen Patient Assistance Program for Otezla if I become aware of any such changes; (e) I understand that I am under no obligation to prescribe any Amgen drug and I have not received and will not receive any benefit from Amgen for prescribing an Amgen drug; (f) the information contained in this form is complete and accurate to the best of my knowledge; and (g) I will notify Amgen Patient Assistance Program for Otezla of any errors regarding the foregoing and will make every effort to correct those errors.

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.
†Agents may include third-party reimbursement service providers.

## 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





05/20 US-OTZ-20-0682

Otezla SUPPORTPLUS™

**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.**





05/20 US-OTZ-20-0682