Otezla® Prior Authorization Checklist

Designed For Rheumatology Healthcare Professionals

The doctor made the decision to prescribe Otezla... now what?

If you are using an electronic prior authorization (ePA) in your electronic health record (EHR), this resource may help you prepare the proper ePA to submit to the patient's health insurance plan.*

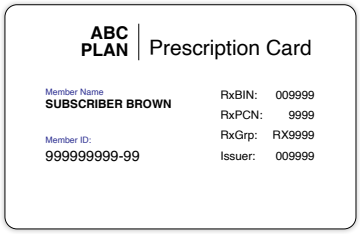
1 HAVE YOU SELECTED THE PRESCRIBED DOSAGE AND FORMULATION IN YOUR ePA-ENABLED ELECTRONIC HEALTH RECORD (EHR) SYSTEM?

Titration Dose: Otezla 10, 20, and 30 mg tablets | **Maintenance Dose:** Otezla 30 mg tablets

2 HAVE YOU SELECTED THE CORRECT HEALTH INSURANCE PLAN AND ePA FORM IN YOUR EHR SYSTEM?

Enter the patient's prescription insurance card information (RxBIN, RxPCN, and RxGroup numbers) or the patient's health insurance plan or pharmacy benefit manager.

Select the appropriate ePA form and select **"Start Request."**



Example insurance card shown

3 DID YOU CHOOSE THE APPROPRIATE PATIENT DIAGNOSES OUT OF THE RESPONSE OPTIONS ON THE ePA?

Sometimes the diagnoses are documented on the ePA using a code. Below is a list of commonly used codes in rheumatology offices:

PSORIATIC ARTHRITIS (PsA) DIAGNOSIS CODES

- L40.50 Arthropathic psoriasis, unspecified
- L40.51 Distal interphalangeal psoriatic arthropathy
- L40.52 Psoriatic arthritis mutilans
- L40.59 Other psoriatic arthropathy
- L40.53 Psoriatic spondylitis

*These examples are informational and provided as a courtesy only. They should not be a substitute for an independent, clinical decision. It is the duty of the healthcare provider to understand individual patient considerations and use their own judgment and clinical decision-making when determining a particular patient's diagnosis and treatment.

See more ePA best practices below

INDICATION

Otezla® (apremilast) is indicated for the treatment of adult patients with active psoriatic arthritis.

IMPORTANT SAFETY INFORMATION

Contraindications

Otezla is contraindicated in patients with a known hypersensitivity to apremilast or to any of the excipients in the formulation

Please see additional Important Safety Information on page 3 and 4.

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4 IS THE ePA AS THOROUGH AND AS ACCURATE AS POSSIBLE?

CONSIDER DOCUMENTING THE FOLLOWING:

A. Patient symptoms mentioned in chart notes

If required, document the current symptoms and patient history, including number of tender joints, number of swollen joints, patient's assessment of pain, Health Assessment Questionnaire-Disability Index (HAQ-DI), enthesitis and dactylitis.

B. Treatment history

You'll likely need to include start date, end date, and duration of each treatment when documenting your patient's treatment history. Examples of prior treatment may include:

Nonsteroidal Anti-Inflammatory Drugs (NSAIDs)	Conventional Synthetic Disease-Modifying Antirheumatic Drugs (csDMARDs)	Biologics
Generic Names: • Aspirin • Ibuprofen • Naproxen	**Generic Names:** • Cyclosporine • Leflunomide • Methotrexate • Sulfasalazine	**Generic Names:** • Adalimumab • Guselkumab • Etanercept • Ixekizumab • Risankizumab • Secukinumab

C. Contraindications: A contraindication is a specific situation in which a medicine should not be used because it may be harmful to the patient. To give the health insurance plan information on a patient's overall health, it can be helpful to include conditions that may be contraindications for some treatments. If the patient has contraindications, please specify and attach any relevant chart notes or medical records to the ePA.

D. Medical exceptions to step therapy requirements: Be sure to review the step therapy requirements in the patient's health insurance plan and document any medical exceptions to the step therapy requirements noted in chart notes or medical records.

E. History of intolerance with prior treatments: An intolerance is a specific situation in which a patient has increased sensitivity to the side effects of a medication. If the patient has a history of intolerance with prior treatments, please specify and attach any relevant chart notes or medical records to the ePA.

You'll likely need to include start date, end date, and adverse outcomes of each treatment when documenting your patient's history of intolerance with prior treatments.

5 DID YOU COMPLETE AND SUBMIT THE ePA REQUEST?

Make sure all appropriate sections of the ePA form are completed and take note of any questions that require you to attach documentation. Select **"Send to Plan."**

Best practices for a streamlined prior authorization (PA) submission process

- Be as thorough and **accurate** as possible
  - Double-check for errors or typos
- **Prepare** information the health insurance plan may require
  - Including the appropriate diagnoses
- Ensure all sections of the PA form are **completed**
- **Attach** necessary documentation
  - Document all previous therapies in the format the health insurance plan requires
- Don't forget to track the status and file the **appeal** if needed

No manual START Forms are needed for Otezla ePAs*

*Does not refer to enrollment in the co-pay program.

IMPORTANT SAFETY INFORMATION (cont'd)

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 and institute appropriate therapy

Please see additional Important Safety Information on next page.

IMPORTANT SAFETY INFORMATION

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and Precautions (cont'd)

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

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

Weight Decrease: Monitor body weight regularly; evaluate unexplained or clinically significant weight loss, and consider discontinuation of Otezla. 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

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

The most common adverse reactions (≥ 5%) are diarrhea, nausea, and headache

Use in Specific Populations

Otezla has not been studied in pregnant women. Advise pregnant women of the potential risk of fetal loss

Please click here for the full Prescribing Information for Otezla.

Reference: Otezla [package insert]. Thousand Oaks, CA: Amgen Inc.