Otezla® (apremilast) Letter Of Medical Necessity

Medical Director		Patient name	
Insurance Company		Policy number	
Address		Date of birth	

Physician's Request for Review:

☐ Peer-to-Peer Review Requested (Same or Like Specialty)

☐ Other

Dear

I am writing to provide additional information to support my request for the treatment of with Otezla® (apremilast) for 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

In brief, treating with Otezla is medically appropriate and necessary and should be covered and reimbursed. Below, this letter outlines the medical history, prognosis and treatment rationale for .

Summary of Patient History:
[Note: Exercise your medical judgment and discretion when providing a diagnosis and characterization of the patient's medical condition.]

Patient's history, diagnosis, and current condition:

Brief description of the patient's recent symptoms and conditions (including BSA% for Plaque Psoriasis patients):

Previous therapies the patient has undergone for the symptoms associated with:

Patient's response to previous therapies. If patient has discontinued, please include reason for discontinuation.

Summary of your professional opinion and the patient's potential prognosis with treatment with Otezla® (apremilast):

Given the patient's history, condition, published data, and information in the Full Prescribing Information (attached) supporting use of Otezla, I believe treatment of with Otezla is warranted, appropriate and medically necessary.

Please call my office at if I can provide you with any additional information to approve my request. I look forward to receiving your timely response and approval of this request.

Sincerely,

INDICATIONS

Otezla® (apremilast) is indicated for the treatment of 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.

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

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

Please see additional Important Safety Information on the next page.

Psoriatic Arthritis: Body weight loss of 5-10% was reported in 10% of patients taking Otezla and in 3.3% 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)

Use in Specific Populations

Pregnancy and Nursing Mothers: Otezla is Pregnancy Category C; it has not been studied in pregnant women. Use during pregnancy only if the potential benefit justifies the potential risk to the fetus. It is not known whether apremilast or its metabolites are present in human milk. Caution should be exercised when Otezla is administered to a nursing woman

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.