Otezla® (apremilast) 30mg tablets

Composing a Letter of Medical Necessity

This guide is for informational purposes only. It is not intended to provide reimbursement or legal advice. Individual health plans' policies concerning reimbursement are complex and frequently revised. Therefore, please contact third-party payers for specific information on coverage policies. For more information, please call Otezla SupportPlus™ at 1-844-4OTEZLA (1-844-468-3952).

Many plans require a Letter of Medical Necessity to accompany an Appeal Letter supporting the choice of Otezla® (apremilast) over other agents that are on the formulary. The purpose of the letter is to explain the rationale for the drug.* The following resource provides information to help in the process of writing a Letter of Medical Necessity, including the checklist below and a sample letter.

Checklist

This checklist can help ensure all relevant information is included in the Letter of Medical Necessity:

- ☐ Patient's name, policy number, and date of birth
- ☐ Support for recommending Otezla (patient history, diagnosis, and current condition; include relevant medical records and history of infections, allergies, and existing comorbidities)
- ☐ Documentation of severity of condition (include photos)
- ☐ List of previous therapies and duration of treatment, including explanation of why each therapy was discontinued
- ☐ Explanation of why formulary-preferred agents are not appropriate and clinical support for your recommendation (this clinical trial data can be from the Otezla package insert)

*For Medicare beneficiaries, there are specific requirements that need to be met for the HCP to be considered a legal representative of the patient in an appeal. For additional information, please visit: https://www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG/Downloads/Parts-C-and-D-Enrollee-Grievances-Organization-Coverage-Determinations-and-Appeals-Guidance.pdf.

Please see the last three pages for Important Safety Information.

Sample Letter of Medical Necessity

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
- ☐ M35.2 (Behçet's Disease)

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:

STEP 1.

Include the patient information

STEP 2.

Provide the information relevant to the primary diagnosis

STEP 3.

Describe the patient history and current condition (include copies of relevant medical records)

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Sample Letter of Medical Necessity

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,

STEP 4.

Outline the severity of symptoms (include pictures, as appropriate)

STEP 5.

List previous therapies

STEP 6.

Include patient's clinical response to prior therapy

STEP 7.

Insert your recommendation here. Include clinical rationale and your professional opinion of the patient's likely prognosis or disease progression

STEP 8.

Provide a phone number should any additional information be required

STEP 9.

Please sign your name to complete the letter

Please be sure that ALL relevant sections of the letter are completely and correctly filled out

Celgene

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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.

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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.

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

Please see additional Important Safety Information on the next page.

- Depression (cont'd):

  — 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 at least ≥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/

Please see additional Important Safety Information on the next page.

- 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.

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