Otezla (apremilast)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Otezla drug policy is to ensure appropriate selection of patients for therapy based on product labeling, clinical guidelines and clinical studies.

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

1. Adult patients with plaque psoriasis who are candidates for phototherapy or systemic therapy
2. Pediatric patients 6 years of age and older and weighing at least 20 kg with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.
3. Adult and pediatric patients 6 years of age and older weighing at least 20 kg with active psoriatic arthritis
4. Adults with oral ulcers associated with Behcet’s disease

Compendial Indications

1. Immune checkpoint inhibitor-related toxicity

POLICY

Required Documentation

Submission of the following information is necessary to initiate the prior authorization review:

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A) Plaque psoriasis (PsO) and psoriatic arthritis (PsA)

1. Initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.
2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response to therapy.

B) Behcet's disease (initial requests only): Chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy (if applicable).

Prescriber Specialties (initial approvals only)

This medication must be prescribed by or in consultation with one of the following:

A. Plaque psoriasis: dermatologist
B. Psoriatic arthritis: rheumatologist or dermatologist
C. Bechet's disease: rheumatologist
D. Immune checkpoint inhibitor-related toxicity: dermatologist, hematologist, or oncologist

Criteria for Initial Approval

A) Plaque psoriasis (PsO)

1. Authorization of 12 months may be granted for treatment of plaque psoriasis in members 6 years of age and older and weighing at least 20 kg when one of the following criteria is met:
   a. Member has previously received a biologic or a targeted synthetic drug (e.g., Sotyktu) indicated for the treatment of plaque psoriasis
   b. Member has had an inadequate response or intolerance to ONE of the following*:
      i. Phototherapy (e.g., UVB, PUVA)
      ii. Topical therapies (e.g., medium or higher potency topical corticosteroids [see Appendix A], calcineurin inhibitors, vitamin D analogs)
   c. Member has a contraindication or clinical reason to avoid BOTH of the following:
      i. Phototherapy (e.g., UVB, PUVA)
      ii. Topical therapies (e.g., medium or higher potency topical corticosteroids [see Appendix A], calcineurin inhibitors, vitamin D analogs)
   d. Member has had an inadequate response to or intolerance to pharmacological treatment with ONE of the following medications: methotrexate, cyclosporine, or acitretin.
   e. Member has a clinical reason to avoid pharmacological treatment with ALL of the following medications: methotrexate, cyclosporine, and acitretin (See Appendix B)

**Note: Defines patients with plaque psoriasis who are candidates for phototherapy or systemic therapy.*

B) Active psoriatic arthritis (PsA)

1. Authorization of 12 months may be granted for adult and pediatric members 6 years of age and older weighing at least 20 kg who have previously received a biologic or targeted synthetic drug (e.g., Rinvoq, Xeljanz) indicated for active psoriatic arthritis.

2. Authorization of 12 months may be granted for adult and pediatric members 6 years of age and older weighing at least 20 kg for treatment of active psoriatic arthritis when one of the following criteria is met:
   a) Member has had an inadequate response to methotrexate, leflunomide, or another conventional synthetic drug (e.g., sulfasalazine) administered at an adequate dose and duration.
   b) Member has an intolerance or contraindication to methotrexate or leflunomide (see Appendix C), or another conventional synthetic drug (e.g., sulfasalazine).

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c) Member has enthesitis.

C) Behcet's disease

1. Authorization of 12 months may be granted for adult members who have previously received a biologic indicated for the treatment of Behcet's disease.

2. Authorization of 12 months may be granted for adult members for the treatment of oral ulcers associated with Behçet's disease when the member has had an inadequate response to at least one nonbiologic medication for Behçet's disease (e.g., colchicine, systemic glucocorticoids, azathioprine).

D) Immune checkpoint inhibitor-related toxicity

1. Authorization of 12 months may be granted for treatment of immune checkpoint inhibitor-related toxicity when the member has moderate to severe immunotherapy-related psoriasis and psoriasiform diseases and meets either of the following:
   a) Member has had an inadequate response to medium or higher potency topical corticosteroids (see Appendix A).
   b) Member has an intolerance or contraindication to medium or higher potency topical corticosteroids (see Appendix A).

Continuation of Therapy

A) Plaque psoriasis (PsO)

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for plaque psoriasis and who achieve or maintain positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when any of the following is met:

1. Reduction in body surface area (BSA) affected from baseline
2. Improvement in signs and symptoms from baseline (e.g., itching, redness, flaking, scaling, burning, cracking, pain)

B) Psoriatic arthritis (PsA)

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for psoriatic arthritis and who achieve or maintain positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

1. Number of swollen joints
2. Number of tender joints
3. Dactylitis
4. Enthesitis
5. Axial disease
6. Skin and/or nail involvement
7. Functional Status
8. C-reactive protein (CRP)

C) Behcet's disease

Authorization of 12 months may be granted for all members (including new members) who achieve or maintain positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition.

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D) Immune checkpoint inhibitor-related toxicity
Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for immunotherapy-related psoriasis and psoriasiform diseases and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition.

Other
For all indications: Member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication.

Otezla is considered **not medically necessary** for members who do not meet the criteria set forth above.

Members currently receiving the requested medication as samples or via the manufacturer's patient assistance program will be required to meet the criteria for initial approval. This ensures that members are treated equally regardless of their provider's ability to access medication samples.

Dosage and Administration
Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits

<table>
<tr><th>Medication</th><th>Quantity Limit</th><th>FDA-recommended dosing</th></tr>
<tr><td>Otezla (apremilast) starter pack</td><td>2 packs (110 tablets) per lifetime</td><td rowspan="3"><u>Titration schedule</u>
Adult and pediatric patients ≥ 50 kg:
• Day 1: 10 mg in morning
• Day 2: 10 mg in morning and 10 mg in evening
• Day 3: 10 mg in morning and 20 mg in evening
• Day 4: 20 mg in morning and 20 mg in evening
• Day 5: 20 mg in morning and 30 mg in evening
• Day 6 and thereafter: 30 mg in morning and 30 mg in evening
Pediatric patients 20 kg to < 50 kg:
• Day 1: 10 mg in morning
• Day 2: 10 mg in morning and 10 mg in evening
• Day 3: 10 mg in morning and 20 mg in evening
• Day 4 and thereafter: 20 mg in morning and 20 mg in evening</td></tr>
<tr><td>Otezla (apremilast) 20 mg tablets</td><td>60 per 30 days</td></tr>
<tr><td>Otezla (apremilast) 30 mg tablets</td><td>60 per 30 days</td></tr>
</table>

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Medication	Quantity Limit	FDA-recommended dosing
Otezla (apremilast) XR starter pack	1 pack per lifetime	**Otezla XR** • Follow above titration schedule • Day 6 and thereafter: 75 mg once daily
Otezla (apremilast) XR 75 mg tablets	30 per 30 days	

Appendix

Appendix A: Table. Relative potency of select topical corticosteroid products

Potency	Drug	Dosage form	Strength
I. Super-high potency (group 1)	Augmented betamethasone dipropionate	Ointment, Lotion, Gel	0.05%
	Clobetasol propionate	Cream, Gel, Ointment, Solution, Cream (emollient), Lotion, Shampoo, Foam, Spray	0.05%
	Fluocinonide	Cream	0.1%
	Flurandrenolide	Tape	4 mcg/cm^2
	Halobetasol propionate	Cream, Lotion, Ointment, Foam	0.05%
II. High potency (group 2)	Amcinonide	Ointment	0.1%
	Augmented betamethasone dipropionate	Cream	0.05%
	Betamethasone dipropionate	Ointment	0.05%
	Clobetasol propionate	Cream	0.025%
	Desoximetasone	Cream, Ointment, Spray	0.25%
		Gel	0.05%
	Diflorasone diacetate	Ointment, Cream (emollient)	0.05%
	Fluocinonide	Cream, Ointment, Gel, Solution	0.05%
	Halcinonide	Cream, Ointment	0.1%
	Halobetasol propionate	Lotion	0.01%
Potency	**Drug**	**Dosage form**	**Strength**
III. High potency (group 3)	Amcinonide	Cream, Lotion	0.1%
	Betamethasone dipropionate	Cream, hydrophilic emollient	0.05%
	Betamethasone valerate	Ointment	0.1%
		Foam	0.12%
	Desoximetasone	Cream, Ointment	0.05%
	Diflorasone diacetate	Cream	0.05%
	Fluocinonide	Cream, aqueous emollient	0.05%

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Potency	Drug	Dosage form	Strength
	Fluticasone propionate	Ointment	0.005%
	Mometasone furoate	Ointment	0.1%
	Triamcinolone acetonide	Cream, Ointment	0.5%
IV. Medium potency (group 4)	Betamethasone dipropionate	Spray	0.05%
	Clocortolone pivalate	Cream	0.1%
	Fluocinolone acetonide	Ointment	0.025%
	Flurandrenolide	Ointment	0.05%
	Hydrocortisone valerate	Ointment	0.2%
	Mometasone furoate	Cream, Lotion, Solution	0.1%
	Triamcinolone acetonide	Cream	0.1%
		Ointment	0.05% and 0.1%
		Aerosol Spray	0.2 mg per 2-second spray
V. Lower-mid potency (group 5)	Betamethasone dipropionate	Lotion	0.05%
	Betamethasone valerate	Cream	0.1%
	Desonide	Ointment, Gel	0.05%
	Fluocinolone acetonide	Cream	0.025%
	Flurandrenolide	Cream, Lotion	0.05%
	Fluticasone propionate	Lotion	0.05%
	Hydrocortisone butyrate	Cream, Lotion, Ointment, Solution	0.1%
	Hydrocortisone probutate	Cream	0.1%
	Hydrocortisone valerate	Cream	0.2%
	Prednicarbate	Cream (emollient), Ointment	0.1%
	Triamcinolone acetonide	Lotion	0.1%
		Ointment	0.025%
VI. Low potency (group 6)	Alclometasone dipropionate	Cream, Ointment	0.05%
	Betamethasone valerate	Lotion	0.1%
	Desonide	Cream, Lotion, Foam	0.05%
	Fluocinolone acetonide	Cream, Solution, Shampoo, Oil	0.01%
	Triamcinolone acetonide	Cream, lotion	0.025%
VII. Least potent (group 7)	Hydrocortisone (base, greater than or equal to 2%)	Cream, Ointment, Solution	2.5%
		Lotion	2%
		Cream, Ointment, Gel, Lotion, Spray, Solution	1%
		Cream, Ointment	0.5%
	Hydrocortisone acetate	Cream	2.5%
		Lotion	2%
		Cream	1%

Appendix B: Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Cyclosporine, Acitretin, or Leflunomide.

1. Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease
2. Breastfeeding
3. Drug interaction
4. Risk of treatment-related toxicity
5. Pregnancy or currently planning pregnancy
6. Significant comorbidity prohibits use of systemic agents (examples include liver or kidney disease, blood dyscrasias, uncontrolled hypertension)

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Appendix C: Examples of Contraindications to Methotrexate or Leflunomide

1. Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease
2. Breastfeeding
3. Blood dyscrasias (e.g., thrombocytopenia, leukopenia, significant anemia)
4. Elevated liver transaminases
5. History of intolerance or adverse event
6. Hypersensitivity
7. Interstitial pneumonitis or clinically significant pulmonary fibrosis
8. Myelodysplasia
9. Pregnancy or currently planning pregnancy
10. Renal impairment
11. Significant drug interaction

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- N/A

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*Some content reprinted from CVSHealth

POLICY HISTORY

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