



Wellmark Blue Cross and Blue Shield is an independent licensee of the Blue Cross and Blue Shield Association.

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. Adults with active psoriatic arthritis
3. Adults with oral ulcers associated with Behcet's disease

POLICY

Required Documentation

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

A) Plaque psoriasis

1. Initial requests:
 - a. 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) Psoriatic arthritis: For continuation requests: Chart notes or medical record documentation supporting positive clinical response.

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

Criteria for Initial Approval

A) Plaque psoriasis (PsO)

1. Authorization of 12 months may be granted for treatment of plaque psoriasis in members when one of the following criteria is met:
 - a. Member has previously received a biologic 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 treatment of active psoriatic arthritis.

C) Behcet's disease

1. Authorization of 12 months may be granted for members who have previously received a biologic indicated for the treatment of Behcet's disease.
2. Authorization of 12 months may be granted for the treatment of oral ulcers associated with Behcet's disease when the member has had an inadequate response to at least one nonbiologic medication for Behcet's disease (e.g., colchicine, systemic glucocorticoids, azathioprine).

Continuation of Therapy

A) Plaque psoriasis (PsO)

Authorization of 12 months may be granted for all members (including new members) who are using Otezla 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) Active psoriatic arthritis (PsA)

Authorization of 12 months may be granted for all members (including new members) who are using Otezla for active 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. Skin and/or nail involvement

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.

Other

For all indications: Member cannot use Otezla concomitantly with any other biologic DMARD or targeted synthetic DMARD.

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

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

Medication	Quantity Limit	FDA-recommended dosing
Otezla (apremilast) starter pack	2 packs (110 tablets) per lifetime	Day 1 to day 5 dosage titration schedule 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
Otezla (apremilast) 30 mg tablets	60 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

Potency	Drug	Dosage form	Strength
	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%
		Ointment	0.1%
	Betamethasone valerate	Foam	0.12%
	Desoximetasone	Cream, Ointment	0.05%
	Diflorasone diacetate	Cream	0.05%
	Fluocinonide	Cream, aqueous emollient	0.05%
	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	Cream, 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%

Potency	Drug	Dosage form	Strength
	Triamcinolone acetonide	Cream, lotion	0.025%
VII. Least potent (group 7)	Hydrocortisone (base, less than 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 or Acitretin.

1. Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease
2. Breastfeeding
3. Drug interaction
4. Cannot be used due to 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)

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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POLICY HISTORY

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