

Specialty Guideline Management

Otezla-Otezla XR

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Otezla	apremilast
Otezla XR	apremilast extended-release

Indications

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 Indications¹

Otezla

- Adult patients with plaque psoriasis (PsO) who are candidates for phototherapy or systemic therapy
- Pediatric patients 6 years of age and older and weighing at least 20 kilograms (kg) with moderate to severe plaque psoriasis (PsO) who are candidates for phototherapy or systemic therapy
- Adults and pediatric patients 6 years of age and older and weighing at least 20 kg with active psoriatic arthritis
- Adult patients with oral ulcers associated with Behcet's disease

Otezla XR

- Adult patients with plaque psoriasis who are candidates for phototherapy or systemic therapy

- Pediatric patients 6 years of age and older and weighing at least 50 kg with moderate to severe plaque psoriasis (PsO) who are candidates for phototherapy or systemic therapy
- Adults and pediatric patients 6 years of age and older and weighing at least 50 kg with active psoriatic arthritis
- Adult patients with oral ulcers associated with Behcet's disease

Compendial Use¹¹

Immune checkpoint inhibitor-related toxicity

All other indications are considered experimental/investigational and not medically necessary.

Documentation

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

Plaque psoriasis (PsO) and immune checkpoint inhibitor-related toxicity

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.

Continuation requests

Chart notes or medical record documentation of improvement in signs and symptoms.

Psoriatic arthritis (PsA)

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.

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Behcet's disease

Initial requests

Chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy (if applicable).

Prescriber Specialties

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

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

Coverage Criteria

Plaque Psoriasis (PsO)^{1-3,7-10}

Authorization of 12 months may be granted for members 6 years of age and older who have previously received a biologic or targeted synthetic drug (e.g., Sotyktu) indicated for treatment of plaque psoriasis.

Authorization of 12 months may be granted for members 6 years of age and older for treatment of plaque psoriasis when any of the following criteria is met:

- Member has had an inadequate response or intolerance to ONE of the following:
 - Phototherapy (e.g., UVB, PUVA)
 - Topical therapies (e.g., medium or higher potency topical corticosteroids [see Appendix A], calcineurin inhibitors, vitamin D analogs)
- Member has a contraindication or clinical reason to avoid BOTH of the following:
 - Phototherapy (e.g., UVB, PUVA)
 - Topical therapies (e.g., medium or higher potency topical corticosteroids, calcineurin inhibitors, vitamin D analogs)
- Member has had an inadequate response or intolerance to pharmacological treatment with ONE of the following medications: methotrexate, cyclosporine, or acitretin.
- Member has a clinical reason to avoid pharmacological treatment with ALL of the following medications: methotrexate, cyclosporine, and acitretin (see Appendix B).

Psoriatic Arthritis (PsA)^{1,2,4,5,10}

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

Authorization of 12 months may be granted for members 6 years of age and older for treatment of active psoriatic arthritis when any of the following criteria is met:

- Member has had an inadequate response to methotrexate, leflunomide, or another conventional synthetic drug (e.g., sulfasalazine) administered at an adequate dose and duration.
- Member has an intolerance or contraindication to methotrexate or leflunomide (see Appendix B), or another conventional synthetic drug (e.g., sulfasalazine).
- Member has enthesitis.

Behcet's Disease^{1,6}

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

Authorization of 12 months may be granted for adult members for 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).

Immune checkpoint inhibitor-related toxicity¹¹

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:

- Member has had an inadequate response to high potency topical corticosteroids (see Appendix A).
- Member has an intolerance or contraindication to high potency topical corticosteroids (see Appendix A).

Authorization of 12 months may be granted for treatment of immune checkpoint inhibitor-related toxicity when the member has moderate or severe immunotherapy-related inflammatory arthritis and symptoms are suggestive of psoriatic arthritis or spondyloarthropathies.

Continuation of Therapy

Plaque Psoriasis (PsO)^{1-3,7,8}

Authorization of 12 months may be granted for all members 6 years of age and older (including new members) who are using the requested medication for plaque psoriasis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when either of the following is met:

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

Psoriatic Arthritis (PsA)^{1,2,4,5,10}

Authorization of 12 months may be granted for all members 6 years of age and older (including new members) who are using the requested medication for psoriatic arthritis and who achieve or maintain a 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:

- Number of swollen joints
- Number of tender joints
- Dactylitis
- Enthesitis
- Axial disease
- Skin and/or nail involvement
- Functional status
- C-reactive protein (CRP)

Behcet's Disease^{1,6}

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

Immune checkpoint inhibitor-related toxicity¹¹

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for immune checkpoint inhibitor-related toxicity and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of either of the following conditions:

- Immunotherapy-related psoriasis and psoriasiform diseases

- Immunotherapy-related inflammatory arthritis suggestive of psoriatic arthritis or spondyloarthropathies

Other

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

Dosage and Administration

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

Appendix

Appendix A: Table. Relative Potency of Select Topical Corticosteroid Products⁹

Potency	Drug	Dosage form	Strength
I. Super-high potency (group 1)	Augmented betamethasone dipropionate	Ointment, Lotion, Gel	0.05%
I. Super-high potency (group 1)	Clobetasol propionate	Cream, Gel, Ointment, Solution, Cream (emollient), Lotion, Shampoo, Foam, Spray	0.05%
I. Super-high potency (group 1)	Fluocinonide	Cream	0.1%
I. Super-high potency (group 1)	Flurandrenolide	Tape	4 mcg/cm ²
I. Super-high potency (group 1)	Halobetasol propionate	Cream, Lotion, Ointment, Foam	0.05%
II. High potency (group 2)	Amcinonide	Ointment	0.1%

Potency	Drug	Dosage form	Strength
II. High potency (group 2)	Augmented betamethasone dipropionate	Cream	0.05%
II. High potency (group 2)	Betamethasone dipropionate	Ointment	0.05%
II. High potency (group 2)	Clobetasol propionate	Cream	0.025%
II. High potency (group 2)	Desoximetasone	Cream, Ointment, Spray	0.25%
II. High potency (group 2)	Desoximetasone	Gel	0.05%
II. High potency (group 2)	Diflorasone diacetate	Ointment, Cream (emollient)	0.05%
II. High potency (group 2)	Fluocinonide	Cream, Ointment, Gel, Solution	0.05%
II. High potency (group 2)	Halcinonide	Cream, Ointment	0.1%
II. High potency (group 2)	Halobetasol propionate	Lotion	0.01%
III. High potency (group 3)	Amcinonide	Cream, Lotion	0.1%
III. High potency (group 3)	Betamethasone dipropionate	Cream, hydrophilic emollient	0.05%
III. High potency (group 3)	Betamethasone valerate	Ointment	0.1%
III. High potency (group 3)	Betamethasone valerate	Foam	0.12%
III. High potency (group 3)	Desoximetasone	Cream, Ointment	0.05%
III. High potency (group 3)	Diflorasone diacetate	Cream	0.05%
III. High potency (group 3)	Fluocinonide	Cream, aqueous emollient	0.05%
III. High potency (group 3)	Fluticasone propionate	Ointment	0.005%
III. High potency (group 3)	Mometasone furoate	Ointment	0.1%
III. High potency (group 3)	Triamcinolone acetonide	Cream, Ointment	0.5%

Potency	Drug	Dosage form	Strength
IV. Medium potency (group 4)	Betamethasone dipropionate	Spray	0.05%
IV. Medium potency (group 4)	Clocortolone pivalate	Cream	0.1%
IV. Medium potency (group 4)	Fluocinolone acetonide	Ointment	0.025%
IV. Medium potency (group 4)	Flurandrenolide	Ointment	0.05%
IV. Medium potency (group 4)	Hydrocortisone valerate	Ointment	0.2%
IV. Medium potency (group 4)	Mometasone furoate	Cream, Lotion, Solution	0.1%
IV. Medium potency (group 4)	Triamcinolone acetonide	Cream	0.1%
IV. Medium potency (group 4)	Triamcinolone acetonide	Ointment	0.05% and 0.1%
IV. Medium potency (group 4)	Triamcinolone acetonide	Aerosol Spray	0.2 mg per 2-second spray
V. Lower-mid potency (group 5)	Betamethasone dipropionate	Lotion	0.05%
V. Lower-mid potency (group 5)	Betamethasone valerate	Cream	0.1%
V. Lower-mid potency (group 5)	Desonide	Ointment, Gel	0.05%
V. Lower-mid potency (group 5)	Fluocinolone acetonide	Cream	0.025%
V. Lower-mid potency (group 5)	Flurandrenolide	Cream, Lotion	0.05%
V. Lower-mid potency (group 5)	Fluticasone propionate	Cream, Lotion	0.05%
V. Lower-mid potency (group 5)	Hydrocortisone butyrate	Cream, Lotion, Ointment, Solution	0.1%

Potency	Drug	Dosage form	Strength
V. Lower-mid potency (group 5)	Hydrocortisone probutate	Cream	0.1%
V. Lower-mid potency (group 5)	Hydrocortisone valerate	Cream	0.2%
V. Lower-mid potency (group 5)	Prednicarbate	Cream (emollient), Ointment	0.1%
V. Lower-mid potency (group 5)	Triamcinolone acetonide	Lotion	0.1%
V. Lower-mid potency (group 5)	Triamcinolone acetonide	Ointment	0.025%
VI. Low potency (group 6)	Alclometasone dipropionate	Cream, Ointment	0.05%
VI. Low potency (group 6)	Betamethasone valerate	Lotion	0.1%
VI. Low potency (group 6)	Desonide	Cream, Lotion, Foam	0.05%
VI. Low potency (group 6)	Fluocinolone acetonide	Cream, Solution, Shampoo, Oil	0.01%
VI. Low potency (group 6)	Triamcinolone acetonide	Cream, Lotion	0.025%
VII. Least potent (group 7)	Hydrocortisone (base, greater than or equal to 2%)	Cream, Ointment, Solution	2.5%
VII. Least potent (group 7)	Hydrocortisone (base, greater than or equal to 2%)	Lotion	2%
VII. Least potent (group 7)	Hydrocortisone (base, less than 2%)	Cream, Ointment, Gel, Lotion, Spray, Solution	1%
VII. Least potent (group 7)	Hydrocortisone (base, less than 2%)	Cream, Ointment	0.5%
VII. Least potent (group 7)	Hydrocortisone acetate	Cream	2.5%
VII. Least potent (group 7)	Hydrocortisone acetate	Lotion	2%

Potency	Drug	Dosage form	Strength
VII. Least potent (group 7)	Hydrocortisone acetate	Cream	1%

Appendix B: Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Cyclosporine, Acitretin, or Leflunomide³

- Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease
- Drug interaction
- Risk of treatment-related toxicity
- Pregnancy or currently planning pregnancy
- Breastfeeding
- Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension)
- Hypersensitivity
- History of intolerance or adverse event

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