CVS Caremark®

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| Reference number(s) |
| 2002-A |

# Specialty Guideline Management Otezla

## 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 |

## 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

* 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

### 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, 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 Disease1,6

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 medium or higher potency topical corticosteroids (see Appendix A).
* Member has an intolerance or contraindication to medium or higher potency topical corticosteroids (see Appendix A).

## 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 Disease1,6

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 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.

## 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/cm2 |
| I. Super-high potency (group 1) | Halobetasol propionate | Cream, Lotion, Ointment, Foam | 0.05% |
| II. High potency (group 2) | Amcinonide | Ointment | 0.1% |
| 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, Solution | 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% |
| 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 | Lotion | 0.05% |
| V. Lower-mid potency (group 5) | Hydrocortisone butyrate | Cream, Lotion, Ointment, Solution | 0.1% |
| 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% |
| 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

## References

1. Otezla [package insert]. Thousand Oaks, CA: Amgen Inc.; July 2025.
2. Coates LC, Kavanaugh A, Mease PJ, et al. Group for research and assessment of psoriasis and psoriatic arthritis 2015 treatment recommendation for psoriatic arthritis. Arthritis Rheumatol. 2016 May;68(5):1060-71.
3. Menter A, Gelfand JM, Connor C, et al. Joint AAD-NPF guidelines of care for the management of psoriasis with systemic nonbiologic therapies. J Am Acad Dermatol. 2020;82(6):1445-1486.
4. Gossec L, Baraliakos X, Kerschbaumer A, et al. European League Against Rheumatism (EULAR) recommendations for the management of psoriatic arthritis with pharmacological therapies: 2019 update. Ann Rheum Dis. 2020;79(6):700-712.
5. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis Rheum. 2018;71:5-32.
6. Hatemi G, Christensen R, Bodaghi, et al. 2018 update of the EULAR recommendations for the management of Behcet’s syndrome. Ann Rheum Dis. 2018.; 77: 808-818.
7. Stein Gold L, Papp K, Pariser D, et al. Efficacy and safety of apremilast in patients with mild-to-moderate plaque psoriasis: Results of a phase 3, multicenter, randomized, double-blind, placebo-controlled trial. J Am Acad Dermatol. 2022;86(1):77-85. doi:10.1016/j.jaad.2021.07.040.
8. Elmets CA, Korman NJ, Prater EF, et al. Joint AAD-NPF Guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. J Am Acad Dermatol. 2021;84(2):P432-470.
9. Topical Corticosteroids. Drug Facts and Comparisons. Facts & Comparisons [database online]. St. Louis, MO: Wolters Kluwer Health Inc; September 22, 2023. Accessed January 17, 2025.
10. Coates LC, Soriano ER, Corp N, et al. Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA): updated treatment recommendations for psoriatic arthritis 2021. Nat Rev Rheumatol. 2022;18(8):465-479.
11. NCCN Clinical Practice Guidelines in Oncology® (NCCN Guidelines®). Management of Immunotherapy-Related Toxicities. Version 1.2025. Available at: www.nccn.org. Accessed January 10, 2025.