AETNA BETTER HEALTH®
Coverage Policy/Guideline

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Effective Date:	10/1/2024	Last Review Date:	7/22/2023, 9/2024

Applies to:	☒Illinois	☐Florida	☐Florida Kids
	☐New Jersey	☐Maryland	☐Michigan
	☐Pennsylvania Kids	☐Virginia	☐Kentucky PRMD

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Otezla under the patient's prescription drug benefit.

Description:

FDA-Approved Indications

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

Compendial Use

Immune checkpoint inhibitor-related toxicity

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

Applicable Drug List:

Otezla

Policy/Guideline:

Documentation for all indications:

The patient is unable to take THREE preferred products, where indicated, for the given diagnosis due to a trial and inadequate treatment response or intolerance, or a contraindication. Documentation is required for approval.

Documentation:

A. **Plaque psoriasis (PsO) and immune checkpoint inhibitor-related toxicity**
   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 of improvement in signs and symptoms.

B. **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.

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).

Prescriber Specialty:
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 members 6 years of age and older for treatment of plaque psoriasis when one of the following criteria is met:
      i. Member has previously received a biologic or targeted synthetic drug indicated for treatment of plaque psoriasis.
      ii. Member has had an inadequate response or intolerance to ONE of the following:
         a. Phototherapy (e.g., UVB, PUVA)
         b. Topical therapies (e.g., medium or higher potency topical corticosteroids [see Appendix A], calcineurin inhibitors, vitamin D analogs)
      iii. Member has a contraindication or clinical reason to avoid BOTH of the following:
         a. Phototherapy (e.g., UVB, PUVA)
         b. Topical therapies (e.g., medium or higher potency topical corticosteroids, calcineurin inhibitors, vitamin D analogs)
      iv. Member has had an inadequate response or intolerance to pharmacological treatment with ONE of the following medications: methotrexate, cyclosporine, or acitretin.
      v. Member has a clinical reason to avoid pharmacological treatment with ALL of the following medications: methotrexate, cyclosporine, and acitretin (see Appendix B).

B. Psoriatic arthritis (PsA)

1. Authorization of 12 months may be granted for adult members who have previously received a biologic or targeted synthetic drug indicated for active psoriatic arthritis.
2. Authorization of 12 months may be granted for adult members for treatment of active psoriatic arthritis when one of the following criteria is met:
   i. Member has had an inadequate response to methotrexate, leflunomide, or another conventional synthetic drug (e.g., sulfasalazine) administered at an adequate dose and duration.
   ii. Member has an intolerance or contraindication to methotrexate or leflunomide (see Appendix B), or another conventional synthetic drug (e.g., sulfasalazine).
   iii. 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 treatment of Behcet's disease.
2. 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).

D. Immune checkpoint inhibitor-related toxicity

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:

1. Member has had an inadequate response to medium or higher potency topical corticosteroids (see Appendix A).
2. 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 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:

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 adult members (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:

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 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.

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 Criteria:

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

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%
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%
	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%

Potency	Drug	Dosage form	Strength
	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%
	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%
	Hydrocortisone (base, less than 2%)	Cream, Ointment, Gel, Lotion, Spray, Solution	1%
		Cream, Ointment	0.5%
	Hydrocortisone acetate	Cream	2.5%
		Lotion	2%

Potency	Drug	Dosage form	Strength
		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. Drug interaction
3. Risk of treatment-related toxicity
4. Pregnancy or currently planning pregnancy
5. Breastfeeding
6. Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension)
7. Hypersensitivity
8. History of intolerance or adverse event

Approval Duration and Quantity Restrictions:

Approval:
Initial and Renewal Approval: 12 months

Quantity Level Limit:
Otezla (apremilast) starter pack: 1 pack (55 tablets) per 28 days
Otezla (apremilast) 20 mg and 30 mg tablets: 60 tablets per 30 days

FDA-Recommended Dosing:
Adults PsO/PsA/Behcet's disease:
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

Pediatrics (6-17 years old) PsO weighing at least 20 kg:
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 20 mg in evening

Day 6 and thereafter
20 kg to < 50 kg:

- 20 mg in morning and 20 mg in evening

Greater than or equal to 50 kg:

- 30 mg in morning and 30 mg in evening

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