AETNA BETTER HEALTH® Coverage Policy/Guideline					
Name:	Tremfya			Page:	1 of 7
Effective Date:	5/1/2025			Last Review Date:	4/2025
Applies to:	☐Illinois ☐New Jersey ☒Pennsylvania Kids	☐Florida ☒Maryland ☐Virginia		☒Florida Kids ☐Michigan ☒Kentucky PRMD	

Intent:

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

Description:

FDA-Approved Indications

- Treatment of adult patients with moderate to severe plaque psoriasis (PsO) who are candidates for systemic therapy or phototherapy
- Treatment of adult patients with active psoriatic arthritis (PsA)
- Treatment of moderately to severely active ulcerative colitis (UC) in adults
- Treatment of moderately to severely active Crohn's disease (CD) in adults

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

Applicable Drug List:

Non-Preferred: Tremfya

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.
THREE preferred products:

- A preferred ustekinumab product
- TWO additional preferred products
  - A preferred adalimumab product OR Enbrel
  - Rinvoq
  - Otezla

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

Plaque psoriasis (PsO)

Initial requests

- Chart notes or medical record documentation of affected area(s) and body surface area (BSA) affected (if applicable).
- 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 decreased body surface area (BSA) affected and/or 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.

Ulcerative colitis (UC) and Crohn's disease (CD)

Continuation requests

Chart notes or medical record documentation supporting positive clinical response to therapy or remission.

Prescriber Specialty:

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

- Plaque psoriasis: dermatologist
- Psoriatic arthritis: rheumatologist or dermatologist
- Ulcerative colitis and Crohn's disease: gastroenterologist

Coverage Criteria

Plaque psoriasis (PsO)[1-6,10]

Authorization of 12 months may be granted for adult members who have previously received a biologic or targeted synthetic drug (e.g., Sotyktu, Otezla) indicated for the treatment of moderate to severe plaque psoriasis.

Authorization of 12 months may be granted for adult members for treatment of moderate to severe plaque psoriasis when any of the following criteria is met:

- Crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
- At least 10% of body surface area (BSA) is affected.
- At least 3% of body surface area (BSA) is affected and the member meets either of the following criteria:
  - Member has had an inadequate response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin.
  - Member has a clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine, and acitretin (see Appendix).

Psoriatic arthritis (PsA)[1,8-10]

Authorization of 12 months may be granted for adult members who have previously received a biologic or targeted synthetic drug (e.g., Rinvoq, Otezla) indicated for active psoriatic arthritis.

Authorization of 12 months may be granted for adult members for treatment of active psoriatic arthritis when either of the following criteria is met:

- Member has mild to moderate disease and meets any of the following criteria:
  - 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), or another conventional synthetic drug (e.g., sulfasalazine).
  - Member has enthesitis.
- Member has severe disease.

Ulcerative colitis (UC)[1,12-14]

Authorization of 12 months may be granted for treatment of moderately to severely active ulcerative colitis.

Crohn's disease (CD)[1,15,16]

Authorization of 12 months may be granted for treatment of moderately to severely active Crohn's disease.

Continuation of Therapy

Plaque psoriasis (PsO)[1-6]

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for moderate to severe 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)[1,9,10]

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:

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

Ulcerative colitis (UC)[1,12-14]

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active ulcerative colitis and who achieve or maintain remission.

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active ulcerative colitis 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:

- Stool frequency
- Rectal bleeding
- Urgency of defecation
- C-reactive protein (CRP)

- Fecal calprotectin (FC)
- Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound
- Improvement on a disease activity scoring tool (e.g., Ulcerative Colitis Endoscopic Index of Severity [UCEIS], Mayo score)

Crohn's disease (CD)[1,15,16]

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active Crohn's disease and who achieve or maintain remission.

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active Crohn's disease 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:

- Abdominal pain or tenderness
- Diarrhea
- Body weight
- Abdominal mass
- Hematocrit
- Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound
- Improvement on a disease activity scoring tool (e.g., Crohn's Disease Activity Index [CDAI] score)

Other[1,7]

For all indications: Member has had a documented negative tuberculosis (TB) test (which can include a tuberculosis skin test [TST] or an interferon-release assay [IGRA]) within 12 months of initiating therapy for persons who are naïve to biologic drugs or targeted synthetic drugs associated with an increased risk of TB.

If the screening testing for TB is positive, there must be further testing to confirm there is no active disease (e.g., chest x-ray). Do not administer the requested medication to members with active TB infection. If there is latent disease, TB treatment must be started before initiation of the requested medication.

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

Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Cyclosporine, Acitretin, or Leflunomide[11]

- 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.

Approval Duration and Quantity Restrictions:

Approval:

Initial and Renewal Approval: 12 months

Quantity Level Limit:

- Tremfya (guselkumab) 100 mg/mL prefilled syringe/One-press injector:
  - 1 syringe/injector per 56 days
  - Exception limit: 2 syringes/injectors per 28 days
- Tremfya (guselkumab) 200 mg/2 mL prefilled syringe/pen:
  - 1 syringe/pen per 28 days
  - Exception limit: 6 syringes/pens per 56 days
- Tremfya (guselkumab) 200 mg/2 mL prefilled pen Induction Pack for Crohn's Disease:
  - Exception limit: 3 cartons (6 pens) per 56 days

* Coverage up to the exception limits may be provided with prior authorization

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