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DRUG POLICY

Tremfya (guselkumab)

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 Tremfya drug policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

1. Treatment of adults and pediatric patients 6 years of age and older who also weigh at least 40 kg with moderate-to-severe plaque psoriasis (PsO) who are candidates for systemic therapy or phototherapy
2. Treatment of adults and pediatric patients 6 years of age and older who also weigh at least 40 kg with active psoriatic arthritis (PsA)
3. Treatment of adult patients with moderately to severely active ulcerative colitis (UC)
4. Treatment of adult patients with moderately to severely active Crohn's disease (CD)

POLICY

Required Documentation

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

A) Plaque psoriasis (PsO)

1. Initial requests:
 - i. Chart notes or medical record documentation of affected area(s) and body surface area (BSA) affected (if applicable).

- ii. 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 decreased body surface area (BSA) affected and/or 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) Ulcerative Colitis (UC)

- 1. Continuation requests: Chart notes or medical record documentation supporting positive clinical response to therapy or remission.

D) Crohn's disease (CD)

- 1. Continuation requests: Chart notes or medical record documentation supporting positive clinical response to therapy or remission.

Prescriber Specialties (initial approvals only)

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. Crohn's disease and Ulcerative colitis: gastroenterologist

Criteria for Initial Approval

A. Plaque psoriasis (PsO)

- 1. Authorization of 12 months may be granted for members 6 years of age and older weighing at least 40 kg who have previously received a biologic or targeted synthetic drug (e.g., Sotyktu, Otezla) indicated for the treatment of moderate to severe plaque psoriasis.
OR
- 2. Authorization of 12 months may be granted for members 6 years of age and older weighing at least 40 kg for the treatment of moderate to severe plaque psoriasis when any of the following criteria is met:
 - a) Crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
 - b) At least 10% of the body surface area (BSA) is affected.
 - c) At least 3% of the body surface area (BSA) is affected and the member meets any of the following criteria:
 - i. Member has had an inadequate response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin.
 - ii. Member has a clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine, and acitretin (see Appendix).

B. Psoriatic arthritis (PsA)

- 1. Authorization of 12 months may be granted for members 6 years of age and older weighing at least 40 kg who have previously received a biologic or targeted synthetic drug (e.g., Rinvoq, Otezla) indicated for active psoriatic arthritis
OR
- 2. Authorization of 12 months may be granted for members 6 years of age and older weighing at least 40 kg for treatment of active psoriatic arthritis when either of the following criteria are met:

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

C. Ulcerative Colitis (UC)

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

D. Crohn's disease (CD)

- 1. Authorization of 12 months may be granted for members for the treatment of moderately to severely active Crohn's Disease.

Continuation of Therapy

A. Plaque psoriasis (PsO)

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderate to severe 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. Psoriatic arthritis (PsA)

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for 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
- 6. Functional status
- 7. C-reactive protein (CRP)

C. Ulcerative colitis (UC)

- 1. 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.
OR
- 2. 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:
 - i. Stool frequency
 - ii. Rectal bleeding
 - iii. Urgency of defecation
 - iv. C-reactive protein (CRP)

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

D. Crohn's Disease (CD)

1. 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.
OR
2. 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:
 - i. Abdominal pain or tenderness
 - ii. Diarrhea
 - iii. Body weight
 - iv. Abdominal mass
 - v. Hematocrit
 - vi. Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound
 - vii. Improvement on a disease activity scoring tool (e.g., Crohn's Disease Activity Index [CDAI] score)

Other

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.

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

Members currently receiving the requested medication as samples or via the manufacturer's patient assistance program will be required to meet the criteria for initial approval. This ensures that members are treated equally regardless of their provider's ability to access medication samples.

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

Trade Name	Generic Name	Quantity Limit	FDA-recommended dosing
Tremfya®	guselkumab	Plaque Psoriasis and Psoriatic Arthritis Initiation of therapy: 2 x 100 mg syringes/injectors per first 28 days Maintenance: 1 x 100 mg syringe/injector per 56 days	Plaque Psoriasis and Psoriatic Arthritis - Loading doses: 100 mg at week 0 and 4 - Maintenance dose: 100 mg every 8 weeks thereafter
		Ulcerative Colitis and Crohn's Disease Initiation of therapy: 3 x 200 mg vials per first 56 days OR 6 x 200 mg pens Maintenance: 100 mg syringe/injector per 56 days OR 200 mg pen/syringe per 28 days	Ulcerative Colitis and Crohn's Disease - Loading doses: 200 mg by intravenous infusion at weeks 0, 4, and 8 - Loading doses: 400 mg by subcutaneous injection at weeks 0, 4, and 8. - Maintenance dose: 100 mg by subcutaneous injection at week 16 and every 8 weeks thereafter OR 200 mg by subcutaneous injection at week 12 and every 4 weeks thereafter Use the lowest effective recommended dosage to maintain therapeutic response

Appendix

Appendix: 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. Breastfeeding
3. Drug interaction
4. Risk of treatment-related toxicity
5. Pregnancy or currently planning pregnancy
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

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.

- J1628 – Injection, guselkumab, 1 mg

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POLICY HISTORY

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