Oscar Clinical Guideline: Tremfya (guselkumab) (PG250, Ver. 2)

Tremfya (guselkumab)

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Plaque psoriasis is a chronic autoimmune condition characterized by the rapid buildup of skin cells, resulting in scaling on the skin's surface. Psoriatic arthritis is a form of inflammatory arthritis that affects some people with psoriasis. Ulcerative colitis is a chronic inflammatory bowel disease that causes inflammation and ulcers in the digestive tract. These conditions are mediated by various inflammatory cytokines, including interleukin-23 (IL-23).

Treatment options for these conditions include topical therapies, phototherapy, conventional systemic agents, and biologic therapies. Biologic therapies target specific components of the immune system and have shown significant efficacy in managing moderate-to-severe cases.

Tremfya (guselkumab) is a human monoclonal antibody that selectively binds to the p19 subunit of IL-23, inhibiting its interaction with the IL-23 receptor. By targeting IL-23, Tremfya reduces inflammation and symptoms associated with plaque psoriasis, psoriatic arthritis, and ulcerative colitis. It is administered

subcutaneously for psoriasis and psoriatic arthritis, and both intravenously and subcutaneously for ulcerative colitis.

Definitions

"**Biologic therapy**" refers to medications created from living organisms or their products, designed to target specific parts of the immune system.

"**Conventional systemic agents**" are traditional oral or injectable medications that affect the entire body and are used to treat widespread psoriasis, psoriatic arthritis, or ulcerative colitis.

"**Enthesitis**" refers to inflammation of the entheses, which are the sites where tendons, ligaments, or joint capsules insert into bone. In psoriatic arthritis, it commonly affects areas such as the heel, the bottom of the foot, and the elbow, causing pain, tenderness, and sometimes swelling at these attachment sites.

"**Interleukin-23 (IL-23)**" is a pro-inflammatory cytokine that plays a crucial role in the pathogenesis of psoriasis, psoriatic arthritis, and ulcerative colitis.

"**Plaque psoriasis**" refers to a chronic autoimmune skin condition characterized by red, raised, scaly patches on the skin.

"**Psoriatic arthritis**" is an inflammatory form of arthritis that affects some individuals with psoriasis, causing joint pain, stiffness, and swelling.

"**Ulcerative colitis**" refers to a chronic inflammatory bowel disease that causes inflammation and ulcers in the lining of the large intestine (colon) and rectum.

Clinical Indications

Tremfya (guselkumab) is approved for the following indications:

A. Moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy.
B. Active psoriatic arthritis in adults.
C. Moderately to severely active ulcerative colitis in adults.

Medical Necessity Criteria for Initial Authorization

The Plan considers **Tremfya (guselkumab)** medically necessary when **ALL** of the following criteria are met and appropriate documentation (*as applicable*) is provided:

1. The member is 18 years of age or older; ***AND***
2. The member has had a documented negative tuberculosis (TB) test (which can include a tuberculosis skin test [TST] or an interferon-release assay [IGRA])[ɳ] within 6 months of initiating therapy for persons who are naïve to biologic drugs or targeted synthetic drugs associated with an increased risk of TB.
    - [ɳ]*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 Tremfya to members with active TB infection. If there is latent disease, TB treatment must be started before initiation of Tremfya.*
3. The member is not receiving Tremfya in combination with any other biologic DMARD or targeted synthetic DMARD for the same indication; ***AND***
4. The member meets the medical necessity criteria for the applicable indication listed below:

Plaque Psoriasis

5. The medication is prescribed by or in consultation with a dermatologist; ***AND***
6. The member has a diagnosis of moderate to severe plaque psoriasis; ***AND***
7. The member meets **ONE** of the following:
    a. Previously received a biologic or targeted synthetic drug (e.g., Sotyktu, Otezla) indicated for the treatment of moderate to severe plaque psoriasis; ***or***
    b. Crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected; ***or***
    c. At least 10% of body surface area (BSA) is affected; ***or***
    d. At least 3% of body surface area (BSA) is affected **AND** the member meets either 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; ***or***
        ii. Member has a clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine, and acitretin (see Appendix); ***AND***
8. Tremfya (guselkumab) is being prescribed at a dose and frequency that is within FDA approved labeling **OR** is supported by compendia or evidence-based published dosing guidelines for the requested indication.
    - *100 mg subcutaneously at Week 0, Week 4, and every 8 weeks thereafter.*

Psoriatic Arthritis

The Plan considers **Tremfya (guselkumab)** medically necessary when **ALL** of the following criteria are met:

5. The medication is prescribed by or in consultation with a rheumatologist or dermatologist; ***AND***
6. The member has a diagnosis of active psoriatic arthritis; ***AND***
7. The member meets **ONE** of the following:
    a. Previously received a biologic or targeted synthetic drug (e.g., Rinvoq, Otezla) indicated for the treatment of active psoriatic arthritis; ***or***
    b. Has mild to moderate disease and meets one of the following:
        i. Has had an inadequate response to methotrexate, leflunomide, or another conventional synthetic drug (e.g., sulfasalazine) administered at an adequate dose and duration; ***or***
        ii. Has an intolerance or contraindication to methotrexate or leflunomide (see Appendix), or another conventional synthetic drug (e.g., sulfasalazine); ***or***
        iii. Has enthesitis; ***or***
    b. Has severe disease; ***AND***
8. Tremfya (guselkumab) is being prescribed at a dose and frequency that is within FDA approved labeling **OR** is supported by compendia or evidence-based published dosing guidelines for the requested indication.
    - *100 mg subcutaneously at Week 0, Week 4, and every 8 weeks thereafter.*

Ulcerative Colitis

The Plan considers **Tremfya (guselkumab)** medically necessary when **ALL** of the following criteria are met:

5. The medication is prescribed by or in consultation with a gastroenterologist; ***AND***
6. The member has a diagnosis of moderately to severely active ulcerative colitis; ***AND***
7. Tremfya is being prescribed according to **ONE** of the following FDA-approved regimens:
    a. Standard dosing (preferred):
        i. Induction - 200 mg intravenously at Weeks 0, 4, and 8, followed by
        ii. Maintenance - 100 mg subcutaneously at Week 16 and every 8 weeks thereafter.
    b. Alternative maintenance dosing - 200 mg subcutaneously every 4 weeks, **IF** the member has completed standard induction therapy **AND** meets the Ulcerative Colitis Maintenance Dose Escalation Criteria.

    Note: See "Ulcerative Colitis Maintenance Dose Escalation Criteria" section for requirements.

If the above prior authorization criteria are met, the requested product will be authorized for 12-months.

Medical Necessity Criteria for Reauthorization

Reauthorization for 12 months may be granted for all members (including new members) who meet **BOTH** of the following criteria:

1. The member is not receiving Tremfya in combination with any other biologic DMARD or targeted synthetic DMARD for the same indication; ***AND***
2. The member meets **ONE** of the following:
    a. **For plaque psoriasis** - the member has achieved or maintained 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. Improvement in signs and symptoms (e.g., itching, redness, flaking, scaling, burning, cracking, pain); ***or***
        ii. Reduction in body surface area (BSA) affected; ***or***
    b. **For psoriatic arthritis** - the member has achieved or maintained 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. C-reactive protein (CRP); ***or***
        ii. Dactylitis; ***or***
        iii. Enthesitis; ***or***
        iv. Functional status; ***or***
        v. Number of swollen joints; ***or***
        vi. Number of tender joints; ***or***
        vii. Skin and/or nail involvement; ***or***
    c. **For ulcerative colitis** - the member has achieved or maintained remission OR has achieved or maintained 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. C-reactive protein (CRP); ***or***
        ii. Endoscopic appearance of the mucosa; ***or***
        iii. Fecal calprotectin (FC); ***or***
        iv. Improvement on a disease activity scoring tool (e.g., Ulcerative Colitis Endoscopic Index of Severity [UCEIS], Mayo score); ***or***
        v. Rectal bleeding; ***or***
        vi. Stool frequency; ***or***
        vii. Urgency of defecation.

3. Tremfya (guselkumab) is being prescribed at a dose and frequency that is within FDA approved labeling OR is supported by compendia or evidence-based published dosing guidelines for the requested indication.
    a. Plaque Psoriasis and Psoriatic Arthritis
        i. 100 mg subcutaneously every 8 weeks
        i.e., One 100 mg prefilled syringe/One-Press injector per 56 days
    b. Ulcerative Colitis
        i. 100 mg subcutaneously every 8 weeks
        i.e., One 100 mg prefilled syringe/One-Press injector per 56 days
        ii. 200 mg subcutaneously every 4 weeks, **IF** the member has completed standard induction therapy **AND** meets the Ulcerative Colitis Maintenance Dose Escalation Criteria.
        i.e., with approved exception - One 200 mg prefilled syringe/pen per 28 days
        Note: See "Ulcerative Colitis Maintenance Dose Escalation Criteria" section for requirements.

Ulcerative Colitis Maintenance Dose Escalation Criteria

Note: Dose escalation is available for ulcerative colitis maintenance therapy only. Standard FDA-approved dosing applies to plaque psoriasis and psoriatic arthritis.

Tremfya 200 mg subcutaneously every 4 weeks may be approved when **ALL** of the following are met:

1. Member has completed induction therapy; ***AND***
2. Documentation of **ONE** of the following:
    a. Inadequate response to standard maintenance dosing after minimum 16 weeks, with evidence of ongoing disease activity, such as:
        i. Continued symptoms (e.g., stool frequency, bleeding); ***and/or***
        ii. Elevated inflammatory markers; ***and/or***
        iii. Endoscopic inflammation; ***and/or***
    b. High-risk features with inadequate response:
        i. Prior biologic/JAK inhibitor failure; ***and/or***
        ii. Severe disease (e.g., Modified Mayo Score ≥7); ***and/or***
        iii. Deep ulcers on endoscopy; ***and/or***
        iv. High inflammatory burden; ***AND***
3. Recent clinical documentation (within the last 90-days) is provided to support the exception request. Examples of supporting documentation include:
    a. Disease activity assessment (e.g., Modified Mayo Score); ***and/or***

b. Recent endoscopy findings; ***and/or***
c. Current lab values (e.g., CRP/calprotectin); ***and/or***
d. Treatment history; ***and/or***
e. Clinical rationale for dose escalation.

Experimental or Investigational / Not Medically Necessary

Tremfya (guselkumab) for any other indication or use is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven. Non-covered indications include, but are not limited to, the following:

- Any other indications not listed in the FDA-approved labeling or recognized compendia, including but not limited to rheumatoid arthritis, ankylosing spondylitis, and Crohn's disease.
- Combination therapy with other biologic agents or targeted synthetic DMARDs, due to lack of sufficient evidence supporting safety and efficacy.
- Doses or dosing schedules outside of those recommended in the FDA approved labeling **OR** is supported by compendia or evidence-based published dosing guidelines for the requested indication.
- Pediatric members (under 18 years of age) for any indication, as safety and efficacy have not been established in this population.

Applicable Billing Codes (HCPCS/CPT Codes)

Service(s) name	
CPT/HCPCS Codes considered medically necessary if criteria are met:	
Code	*Description*
96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular
J1628	Injection, guselkumab, 1 mg
ICD-10 codes considered medically necessary if criteria are met:	
Code	*Description*
K51.00	Ulcerative (Chronic) Pancolitis Without Complications
K51.011	Ulcerative (Chronic) Pancolitis With Rectal Bleeding

K51.012	Ulcerative (Chronic) Pancolitis With Intestinal Obstruction
K51.013	Ulcerative (Chronic) Pancolitis With Fistula
K51.014	Ulcerative (Chronic) Pancolitis With Abscess
K51.018	Ulcerative (Chronic) Pancolitis With Other Complication
K51.019	Ulcerative (Chronic) Pancolitis With Unspecified Complications
K51.20	Ulcerative (Chronic) Proctitis Without Complications
K51.211	Ulcerative (Chronic) Proctitis With Rectal Bleeding
K51.212	Ulcerative (Chronic) Proctitis With Intestinal Obstruction
K51.213	Ulcerative (Chronic) Proctitis With Fistula
K51.214	Ulcerative (Chronic) Proctitis With Abscess
K51.218	Ulcerative (Chronic) Proctitis With Other Complication
K51.219	Ulcerative (Chronic) Proctitis With Unspecified Complications
K51.30	Ulcerative (Chronic) Rectosigmoiditis Without Complications
K51.311	Ulcerative (Chronic) Rectosigmoiditis With Rectal Bleeding
K51.312	Ulcerative (Chronic) Rectosigmoiditis With Intestinal Obstruction
K51.313	Ulcerative (Chronic) Rectosigmoiditis With Fistula
K51.314	Ulcerative (Chronic) Rectosigmoiditis With Abscess
K51.318	Ulcerative (Chronic) Rectosigmoiditis With Other Complication
K51.319	Ulcerative (Chronic) Rectosigmoiditis With Unspecified Complications
K51.40	Inflammatory Polyps Of Colon Without Complications
K51.411	Inflammatory Polyps Of Colon With Rectal Bleeding
K51.412	Inflammatory Polyps Of Colon With Intestinal Obstruction
K51.413	Inflammatory Polyps Of Colon With Fistula
K51.414	Inflammatory Polyps Of Colon With Abscess
K51.418	Inflammatory Polyps Of Colon With Other Complication
K51.419	Inflammatory Polyps Of Colon With Unspecified Complications
K51.50	Left Sided Colitis Without Complications
K51.511	Left Sided Colitis With Rectal Bleeding
K51.512	Left Sided Colitis With Intestinal Obstruction

K51.513	Left Sided Colitis With Fistula
K51.514	Left Sided Colitis With Abscess
K51.518	Left Sided Colitis With Other Complication
K51.519	Left Sided Colitis With Unspecified Complications
K51.80	Other Ulcerative Colitis Without Complications
K51.811	Other Ulcerative Colitis With Rectal Bleeding
K51.812	Other Ulcerative Colitis With Intestinal Obstruction
K51.813	Other Ulcerative Colitis With Fistula
K51.814	Other Ulcerative Colitis With Abscess
K51.818	Other Ulcerative Colitis With Other Complication
K51.819	Other Ulcerative Colitis With Unspecified Complications
K51.90	Ulcerative Colitis, Unspecified, Without Complications
K51.911	Ulcerative Colitis, Unspecified With Rectal Bleeding
K51.912	Ulcerative Colitis, Unspecified With Intestinal Obstruction
K51.913	Ulcerative Colitis, Unspecified With Fistula
K51.914	Ulcerative Colitis, Unspecified With Abscess
K51.918	Ulcerative Colitis, Unspecified With Other Complication
K51.919	Ulcerative Colitis, Unspecified With Unspecified Complications
L40.0	Psoriasis vulgaris
L40.50	Arthropathic psoriasis, unspecified
L40.51	Distal interphalangeal psoriatic arthropathy
L40.52	Psoriatic arthritis mutilans
L40.53	Psoriatic spondylitis
L40.59	Other psoriatic arthropathy

Appendix

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

1. Alcoholism, alcohol use disorder, alcoholic liver disease, or other chronic liver disease.
2. Blood dyscrasias (e.g., thrombocytopenia, leukopenia, significant anemia).
3. Breastfeeding.
4. Elevated liver transaminases.
5. History of intolerance or adverse events.
6. Hypersensitivity.
7. Interstitial pneumonitis or clinically significant pulmonary fibrosis.
8. Pregnancy or currently planning pregnancy.
9. Renal impairment.
10. Significant drug interaction.
11. Significant comorbidity prohibits use of systemic agents (examples include liver or kidney disease, uncontrolled hypertension).

Table 1: Disease Severity Characteristics by Condition

<table>
<tr><th>Condition Severity</th><th>Psoriatic Arthritis</th><th>Plaque Psoriasis**</th><th>Ulcerative Colitis</th></tr>
<tr><td>Mild</td><td rowspan="2">typically characterized by involvement of fewer than 5 joints, minimal skin involvement, and minimal functional impairment</td><td>< 3% of body surface area (BSA) affected</td><td rowspan="2"></td></tr>
<tr><td>Moderate</td><td>3-10% of BSA affected</td></tr>
<tr><td>Severe</td><td>characterized by involvement of 5 or more joints, especially those in the hands and feet, significant skin involvement, and/or significant functional impairment</td><td>> 10% of BSA affected</td><td>typically characterized by frequent bowel movements (>4 per day), blood in stool, urgency, abdominal pain, and fatigue. May also include elevated inflammatory markers (e.g., C-reactive protein, fecal calprotectin) and endoscopic evidence of inflammation.</td></tr>
<tr><td colspan="4">**Note for Plaque Psoriasis**: The presence of significant symptoms, involvement of crucial areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas), or significant impact on quality of life may classify the disease as moderate to severe regardless of the percentage of BSA affected.</td></tr>
</table>

References

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