CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Tremfya (guselkumab)
BENEFIT TYPE	Pharmacy or Medical
STATUS	Prior Authorization Required

Tremfya (guselkumab) is an anti-psoriatic agent, interleukin-23 inhibitor, and monoclonal antibody initially approved by the FDA in 2017. It is currently FDA approved for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy, psoriatic arthritis, ulcerative colitis and Crohn's disease in adults.

Tremfya (guselkumab) will be considered for coverage when the following criteria are met:

Plaque Psoriasis (PsO)

For **initial** authorization:

1. Member must be 18 years of age or older; AND
2. Medication must be prescribed by or in consultation with a dermatologist; AND
3. Member has clinical documentation of moderate to severe plaque psoriasis characterized by 3% or more of body surface area (BSA) or disease affecting sensitive areas (e.g., hands, feet, face, genitals, etc.); AND
4. Member has tried and failed to respond to treatment with at least **ONE** of the following:
   a) At least 12 weeks of photochemotherapy (i.e., psoralen plus ultraviolet A therapy);
   b) At least 12 weeks of phototherapy (i.e., UVB light therapy, Excimer laser treatments);
   c) At least a 4-week trial with topical antipsoriatic agents (i.e., anthralin, calcipotriene, coal tar, corticosteroids, tazarotene, tacrolimus, pimecrolimus);
   d) At least a 12-week trial of a systemic conventional DMARD (i.e., cyclosporine, methotrexate, acitretin; AND
5. Member has had a negative tuberculosis test within the past 12 months.
6. **Dosage allowed/Quantity limit:** 100 mg administered by subcutaneous injection at Week 0, Week 4 and every 8 weeks thereafter. Quantity limit:1 syringe every 8 weeks after loading doses.

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:

1. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease such as documented member's BSA improvement, etc.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Psoriatic Arthritis (PsA)

For **initial** authorization:

1. Member must be 18 years of age or older; AND
2. Medication must be prescribed by or in consultation with a rheumatologist or dermatologist; AND
3. Member has a documented diagnosis of active psoriatic arthritis (PsA); AND

4. Member has met a 4-week trial of an NSAID taken at maximally tolerated doses AND a 3-month trial of a conventional DMARD agent (e.g., methotrexate, sulfasalazine, cyclosporine, etc.) unless **ONE** of the following situations is met:
   a) Conventional DMARD is **NOT** required for:
      i) Concomitant axial disease (i.e., involving sacroiliac joint and spine) or enthesitis; OR
   b) NSAID and conventional DMARD are **NOT** required for:
      i) Severe PsA (defined as having at least one of the following: erosive disease, active PsA at many sites including dactylitis or enthesitis, elevated levels of ESR or CRP, joint deformities, or major impairment in quality of life); AND
5. Member has had a negative tuberculosis test within the past 12 months.
6. **Dosage allowed/Quantity limit:** 100 mg administered by subcutaneous injection at Week 0, Week 4 and every 8 weeks thereafter. Quantity limit: 1 syringe every 8 weeks after loading doses.

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:
1. Chart notes have been provided that show improvement of signs and symptoms of disease such as decreased joint swelling and pain, improved skin appearance, improved quality of life, etc.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Ulcerative Colitis (UC)

For **initial** authorization:
1. Member must be 18 years of age or older; AND
2. Medication must be prescribed by or in consultation with a gastroenterologist; AND
3. Member has a documented diagnosis of moderate to severely active UC; AND
4. Member must have a documented trial and inadequate response with **ONE** of the following:
   a) 6-mercaptopurine or azathioprine;
   b) Corticosteroid (e.g., budesonide, prednisone, methylprednisolone);
   c) 5-aminosalicylate (e.g., Asacol HD, Lialda, Pentasa, Delzicol, mesalamine, etc.); AND
5. Member has had a negative tuberculosis test within the past 12 months.
6. **Dosage allowed/Quantity limit:**
   a) 200 mg administered by intravenous infusion at Week 0, Week 4, and Week 8 then 100 mg administered by subcutaneous injection at Week 16, and every 8 weeks thereafter, or 200 mg administered by subcutaneous injection at Week 12, and every 4 weeks thereafter.
   b) Quantity limit:
      i) 100 mg/mL: 1 syringe/injector per 56 days after loading doses.
      ii) 200 mg/mL: 1 pen/syringe per 28 days after loading doses.

If all the above requirements are met, the medication will be approved for 4 months.

For **reauthorization**:
1. Chart notes have been provided that show improvement of signs and symptoms of disease such as clinical remission, reduced rectal bleeding, decreased stool frequency, or endoscopic-histologic mucosal healing, etc.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Crohn's Disease (CD)

For **initial** authorization:

1. Member must be 18 years of age or older; AND
2. Medication must be prescribed by or in consultation with a gastroenterologist; AND
3. Member has a documented diagnosis of moderate to severely active CD; AND
4. Member has had a documented trial and inadequate response, or intolerance to **ONE** of the following conventional therapies:
   a) Corticosteroid;
   b) 6-mercaptopurine, azathioprine, or methotrexate; OR
5. Provider attests member has severe disease that requires immediate use of an advanced therapy (biologic, JAK inhibitor, etc.) agent such as penetrating or fistulizing disease, multiple resections, etc.; AND
6. Member has baseline liver function tests completed or scheduled; AND
7. Member has had a negative tuberculosis test within the past 12 months.
8. **Dosage allowed/Quantity limit:**
   a) Initial dose of 200 mg administered by intravenous infusion over at least one hour at Week 0, Week 4, and Week 8 or 400 mg administered by subcutaneous injection at Week 0, Week 4, and Week 8.
   b) Maintenance dose of 100 mg administered by subcutaneous injection at Week 16, and every 8 weeks thereafter, or 200 mg administered by subcutaneous injection at Week 12, and every 4 weeks thereafter. Quantity limit: for the 100 mg/mL, one patient-controlled injector, pen or syringe per 56 days. For the 200 mg/mL, one pen or syringe per 28 days.

If all the above requirements are met, the medication will be approved for 4 months.

For **reauthorization**:

1. Chart notes have been provided that show improvement of signs and symptoms of disease such as improved endoscopic response, fewer flare-ups of symptoms, improved quality of life, etc.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Tremfya (guselkumab) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
10/19/2017	New policy for Tremfya created.
02/26/2019	Humira was removed from criteria; Cimzia, Cosentyx, Otezla and Siliq added to trial agents list. Initial authorization length increased to 12 months. TB test allowed to be done within 12 months prior to initiation of therapy; chest x-ray option removed. Reauthorization criteria on documented member's PASI score improvement incorporated into general chart noted documentation requirements.
09/23/2020	New indication Psoriatic Arthritis added. For PsO Removed rheumatologist from prescriber. Removed PsO for 6 months or longer. Changed BSA to 3% or sensitive area involvement. Removed PASI score requirement. Removed repeated TB test for reauthorization.
02/22/2022	Transferred policy to new format; Removed initial criteria from reauthorization; Updated wording for biologic DMARDs; Clarified reauth criteria
03/17/2022	Removed preferred biologic trials.
05/15/2024	Added medical benefit option.
09/26/2024	PsO: converted double trial of topicals + systemic therapy to a single trial with both topical and systemic options
10/01/2024	Added UC indication including quantity limit. Simplified TB test requirement.

04/16/2025	Updated references; added Crohn's disease indication
08/19/2025	Updated references. UC: removed trial durations CD: removed trial option of biologic with CD indication and added alternative option of provider attestation that member has severe disease that requires immediate use of advanced therapy PsO and PsA: replaced "non-biologic" with "conventional"

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