POLICY Document for TREMFYA (guselkumab)

The overall objective of this policy is to support the appropriate and cost-effective use of the medication, specific to use of preferred medication options, and overall, clinically appropriate use. This document provides specific information to both sections of the overall policy.

Section 1: Preferred Product
- Policy information specific to preferred medications

Section 2: Clinical Criteria
- Policy information specific to the clinical appropriateness for the medication

Section 1: Preferred Product

CAREFIRST: EXCEPTIONS CRITERIA
AUTOIMMUNE CONDITIONS

PRIMARY PREFERRED PRODUCTS: ENTYVIO, SIMPONI ARIA, SKYRIZI, STELARA

Client Requested: The intent of the criteria is to ensure that patients follow selection elements as established by CareFirst.

POLICY
This policy informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

I. PLAN DESIGN SUMMARY

This program applies to the autoimmune drug products specified in this policy. Coverage for targeted product is provided based on clinical circumstances that would exclude the use of the preferred products and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to all members requesting treatment with a targeted product.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Autoimmune Products

	Product(s)
Preferred	• **Entyvio** (vedolizumab) • **Simponi Aria** (golimumab, intravenous) • **Skyrizi** (risankizumab-rzaa) • **Stelara** (ustekinumab)
Targeted	• **Actemra** (tocilizumab) • **Cimzia** (certolizumab pegol) • **Cosentyx** (Secukinumab) • **Ilumya** (tildrakizumab-asmn)

	• **Orencia** (abatacept) • **Tofidence** (Tocilizumab-bavi) • **Tremfya** (guselkumab) • **Tyenne** (Tocilizumab-aazg) • **Tysabri** (natalizumab)

*: Medications considered formulary or preferred on your plan may still require a clinical prior authorization review

II. EXCEPTION CRITERIA

This program applies to members requesting treatment for an indication that is FDA-approved for the preferred products.

Coverage for a targeted product is provided when any of the following criteria is met:

A. For Actemra, Tofidence, or Tyenne when any of the following criteria is met:
   1. When the request is for Systemic Juvenile Idiopathic Arthritis
   2. When the request is for Giant Cell Arteritis
   3. Member is currently receiving treatment with the requested targeted product, excluding when the requested targeted product is obtained as samples or via manufacturer's patient assistance programs.
   4. Member has a documented inadequate response, contraindication, or intolerable adverse event to Simponi Aria.

B. For Cimzia, when any of the following criteria is met:
   1. When the request is for Axial Spondylarthritis
   2. Member is pregnant, breastfeeding, or of childbearing potential
   3. Member suffers from Trypanophobia (needle-phobic) and cannot self-inject
   4. Member is currently receiving treatment with the requested targeted product, excluding when the requested targeted product is obtained as samples or via manufacturer's patient assistance programs.
   5. Member has a documented inadequate response, contraindication, or intolerable adverse event to Simponi Aria, Stelara, Entyvio, and Skyrizi.

C. For Cosentyx, when any of the following criteria is met:
   1. When the request is for Axial Spondylarthritis
   2. Member is currently receiving treatment with the requested targeted product, excluding when the requested targeted product is obtained as samples or via manufacturer's patient assistance programs.
   3. Member has a documented inadequate response, contraindication, or intolerable adverse event to Simponi Aria, Stelara, and Skyrizi.

D. For Ilumya, when any of the following criteria is met:
   1. Member is currently receiving treatment with the requested targeted product, excluding when the requested targeted product is obtained as samples or via manufacturer's patient assistance programs.
   2. Member has a documented inadequate response, contraindication, or intolerable adverse event to Stelara and Skyrizi

E. For Orencia, when any of the following criteria is met:
   1. Member is currently receiving treatment with the requested targeted product, excluding when the requested targeted product is obtained as samples or via manufacturer's patient assistance programs.
   2. Member has a documented inadequate response, contraindication, or intolerable adverse event to Simponi Aria, Stelara, and Skyrizi.

F. For Tremfya, when any of the following criteria is met:
   1. Member is currently receiving treatment with the requested targeted product, excluding when the requested targeted product is obtained as samples or via manufacturer's patient assistance programs.

2. Member has a documented inadequate response, contraindication, or intolerable adverse event to Simponi Aria, Stelara, Entyvio, and Skyrizi.

G. For Tysabri, when any of the following criteria is met:
   1. When the request is for Multiple Sclerosis
   2. Member is currently receiving treatment with the requested targeted product, excluding when the requested targeted product is obtained as samples or via manufacturer's patient assistance programs.
   3. Member has a documented inadequate response, contraindication, or intolerable adverse event to Stelara, Entyvio, and Skyrizi.

Section 2: Clinical Criteria

Speciality Guideline Management Tremfya

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Tremfya	guselkumab

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications[1]

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.

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 Specialties

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

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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.

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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.

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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.

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SECTION 1

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