POLICY Document for CIMZIA (certolizumab pegol)

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

Specialty Guideline Management
Cimzia

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
Cimzia	certolizumab pegol

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 Indication[1]

- Reducing signs and symptoms of Crohn's disease and maintaining clinical response in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy.
- Treatment of adults with moderately to severely active rheumatoid arthritis.
- Treatment of active polyarticular juvenile idiopathic arthritis (pJIA) in patients 2 years of age and older.
- Treatment of adult patients with active psoriatic arthritis.
- Treatment of adults with active ankylosing spondylitis.

- Treatment of adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation.
- Treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

Compendial Use[25]

Immune checkpoint inhibitor-related toxicity - inflammatory arthritis

Documentation

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

Rheumatoid Arthritis (RA)

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.

Laboratory results, chart notes, or medical record documentation of biomarker testing (i.e., rheumatoid factor [RF], anti-cyclic citrullinated peptide [anti-CCP], and C-reactive protein [CRP] and/or erythrocyte sedimentation rate [ESR]) (if applicable).

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Polyarticular Juvenile Idiopathic Arthritis (pJIA)

Initial requests

Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy.

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Ankylosing Spondylitis (AS), Non-Radiographic Axial Spondyloarthritis (nr-axSpA), Psoriatic Arthritis (PsA), and Immune Checkpoint Inhibitor-Related Toxicity

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.

Crohn's Disease (CD)

Continuation requests

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

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.

Prescriber Specialties

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

- Rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, ankylosing spondylitis, or non-radiographic axial spondyloarthritis: rheumatologist
- Psoriatic arthritis: rheumatologist or dermatologist
- Crohn's disease: gastroenterologist
- Plaque psoriasis: dermatologist
- Immune checkpoint inhibitor-related toxicity: oncologist, hematologist, or rheumatologist

Coverage Criteria

Rheumatoid Arthritis (RA)[1,3-5,20,21,24]

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

Authorization of 12 months may be granted for adult members for treatment of moderately to severely active RA when both of the following criteria are met:

- Member meets either of the following criteria:
  - Member has been tested for either of the following biomarkers and the test was positive:
    - Rheumatoid Factor (RF)
    - Anti-cyclic citrullinated peptide (anti-CCP)
  - Member has been tested for ALL of the following biomarkers:
    - RF
    - Anti-CCP
    - C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR)
- Member meets either of the following criteria:
  - Member has had an inadequate response to at least a 3-month trial of methotrexate despite adequate dosing (i.e., titrated to at least 15 mg/week).
  - Member has an intolerance or contraindication to methotrexate (see Appendix A).

Polyarticular Juvenile Idiopathic Arthritis (pJIA)[1,26,27]

Authorization of 12 months may be granted for members 2 years of age or older who have previously received a biologic or targeted synthetic drug (e.g., Xeljanz) indicated for moderately to severely active polyarticular juvenile idiopathic arthritis.

Authorization of 12 months may be granted for members 2 years of age or older for treatment of moderately to severely active polyarticular juvenile idiopathic arthritis when any of the following criteria is met:

- Member has had an inadequate response to methotrexate or another conventional synthetic drug (e.g., leflunomide, sulfasalazine, hydroxychloroquine) administered at an adequate dose and duration.
- Member has had an inadequate response to a trial of scheduled non-steroidal anti-inflammatory drugs (NSAIDs) and/or intra-articular glucocorticoids (e.g., triamcinolone hexacetonide) and one of the following risk factors for poor outcome:
  - Involvement of ankle, wrist, hip, sacroiliac joint, and/or temporomandibular joint (TMJ)
  - Presence of erosive disease or enthesitis
  - Delay in diagnosis
  - Elevated levels of inflammation markers
  - Symmetric disease
- Member has risk factors for disease severity and potentially a more refractory disease course (see Appendix B) and meets one of the following:
  - High-risk joints are involved (e.g., cervical spine, wrist, or hip)
  - High disease activity
  - Is judged to be at high risk for disabling joint disease

Psoriatic Arthritis (PsA)[1,6-9,17]

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 one 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 A), or another conventional synthetic drug (e.g., sulfasalazine).
  - Member has enthesitis or predominantly axial disease.
- Member has severe disease.

Ankylosing Spondylitis (AS) and Non-Radiographic Axial Spondyloarthritis (nr-axSpA)[1,2,10-12]

Authorization of 12 months may be granted for adult members who have previously received a biologic or targeted synthetic drug (e.g., Rinvoq, Xeljanz) indicated for active ankylosing spondylitis or active non-radiographic axial spondyloarthritis.

Authorization of 12 months may be granted for adult members for treatment of active ankylosing spondylitis or active non-radiographic axial spondyloarthritis when either of the following criteria is met:

- Member has had an inadequate response to at least two non-steroidal anti-inflammatory drugs (NSAIDs).
- Member has an intolerance or contraindication to two or more NSAIDs.

Crohn's Disease (CD)[1,13,14,22]

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

Plaque Psoriasis (PsO)[1,6,9,15,18,19,23]

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 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 A).

Immune Checkpoint Inhibitor-Related Toxicity[25]

Authorization of 12 months may be granted for treatment of immune checkpoint inhibitor-related toxicity when the member has moderate or severe immunotherapy-related inflammatory arthritis and meets either of the following:

- Member has had an inadequate response to corticosteroids or a conventional synthetic drug (e.g., methotrexate, sulfasalazine, leflunomide, hydroxychloroquine).
- Member has an intolerance or contraindication to corticosteroids and a conventional synthetic drug (e.g., methotrexate, sulfasalazine, leflunomide, hydroxychloroquine).

Continuation of Therapy

Rheumatoid Arthritis (RA)[1,3-5,20,21,24]

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for moderately to severely active rheumatoid arthritis and who achieve or maintain a positive clinical response as evidenced by disease activity improvement of at least 20% from baseline in tender joint count, swollen joint count, pain, or disability.

Polyarticular Juvenile Idiopathic Arthritis (pJIA)[1,26]

Authorization of 12 months may be granted for all members 2 years of age or older (including new members) who are using the requested medication for moderately to severely active polyarticular juvenile idiopathic 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 joints with active arthritis (e.g., swelling, pain, limitation of motion)
Number of joints with limitation of movement
Functional ability

Psoriatic Arthritis (PsA)[1,6-9,17]

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

Axial disease
Skin and/or nail involvement
Functional status
C-reactive protein (CRP)

Ankylosing Spondylitis (AS) and Non-Radiographic Axial Spondyloarthritis (nr-axSpA)[1,2,10-12]

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for ankylosing spondylitis or non-radiographic axial spondyloarthritis 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:

Functional status
Total spinal pain
Inflammation (e.g., morning stiffness)
Swollen joints
Tender joints
C-reactive protein (CRP)

Crohn's Disease (CD)[1,13,14,22]

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)

Plaque Psoriasis (PsO)[1,6,15,18,19,23]

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)

Immune Checkpoint Inhibitor-Related Toxicity

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for immunotherapy-related inflammatory 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.

Other[1,16]

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

Appendix A: Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Cyclosporine, Acitretin, or Leflunomide[19]

- 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

Appendix B: Risk factors for polyarticular juvenile idiopathic arthritis

Positive rheumatoid factor
Positive anti-cyclic citrullinated peptide antibodies
Pre-existing joint damage

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SECTION 1

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SECTION 2

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