



Evolut Clinical Guideline 5047.CC for Tocilizumab Products

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STATEMENT

General Information

- *It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Medical Policy Committee.*
- *If the established criteria are not met, the request is referred to a Medical Director for review, if required for the plan and level of request.*

Purpose

Tocilizumab products are indicated for the treatment of:

- Adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response to one or more DMARDs
- Patients 2 years of age or older with active polyarticular juvenile idiopathic arthritis (PJIA)
- Patients 2 years of age or older with active systemic juvenile idiopathic arthritis (SJIA)
- Patients 2 years of age or older with Chimeric Antigen Receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome (CRS)
- Adult patients with giant cell arteritis (GCA)
- Slowing the rate of decline in pulmonary function in adult patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD)
- Hospitalized adult patients with coronavirus disease 2019 (COVID-19) who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO)

	Actemra	Tofidence	Tyenne
COVID-19	X	X	
CRS	X		
GCA	X	X	X
PJIA	X	X	X
RA	X	X	X
SJIA	X	X	X

	Actemra	Tofidence	Tyenne
SSc-ILD	X		

Scope

This guideline applies to all practitioners who are involved in providing the requested drug. This guideline is specific to the Health Plan's medical benefit.

Special Note

Additional uses are included in this guideline based on being supported by one or more compendia (e.g., Merative Micromedex®, UpToDate® Lexidrug™, Elsevier Clinical Pharmacology).

INITIAL REVIEW CRITERIA

The request must meet all of the criteria listed under the General Criteria **and** diagnosis-specific sections below.

General Criteria

- Must have a negative tuberculosis skin test collected within the last 6 months
 - Example acceptable testing includes the Tuberculin PPD (purified protein derivative) test or Interferon-Gamma Release Assay (IGRA) whole-blood test [such as QuantiFERON®-TB Gold In-Tube test (QFT-GIT) or T-SPOT®.TB test (T-Spot)]
- Must not be used in combination with a biologic disease-modifying antirheumatic drug (DMARD) or a targeted synthetic DMARD (such as Xeljanz (tofacitinib), Olumiant (baracitinib), or Otezla (apremilast))
- Must have no evidence of serious infection (e.g., pneumonia, cellulitis, aspergillosis)*
- Must have the following laboratory values*:
 - AST and ALT laboratory values <1.5x upper limit of normal
 - Absolute neutrophil count >2,000cells/mm³
 - Platelet count >100,000cells/mm³
- Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved labeling

* *Exception:* Use of tocilizumab for COVID-19 management has differing infection and laboratory value recommendations; refer to package insert

Articular Juvenile Idiopathic Arthritis, includes polyarticular juvenile idiopathic arthritis (PJIA):

- Must be prescribed by, or in consultation with, a rheumatologist
 - Must be age 2 years or older
 - Must have a diagnosis of moderately to severely active juvenile idiopathic arthritis
 - Must meet ALL the criteria in at least ONE of the following sections:
 - Must have documentation showing an inadequate response to at least a 3-month trial of methotrexate, leflunomide, sulfasalazine, or hydroxychloroquine OR have an intolerance or contraindication to conventional DMARDs (see **Appendix 1**)
- OR**
- Must have had a trial and failure of scheduled non-steroidal anti-inflammatory drugs (NSAIDs) and/or intra-articular glucocorticoids (e.g., triamcinolone hexacetonide) **AND** has 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
- OR**
- Must have risk factors for disease severity and potentially a more refractory disease course (see **Appendix 2**) and have 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
- Must have an adequate trial (of at least 3 months) and failure of at least two (2) of the following with an inadequate response, or significant side effects/toxicities, or have a contraindication to these therapies:
 - An adalimumab product
 - Cimzia
 - Enbrel
 - Humira

Cytokine Release Syndrome (CRS)

- Must be age 2 years or older (*for CRS related to CAR T-cell ONLY*)
- Must have received CAR T-cell treatment OR blinatumomab

- Must be prescribed by, or in consultation with, an oncologist or hematologist

Giant Cell Arteritis (GCA)

- Must be age 18 years or older
- Must be prescribed by, or in consultation with, a rheumatologist
- Must have a diagnosis of Giant Cell Arteritis confirmed by ONE of the following:
 - Temporal artery biopsy or cross-sectional imaging
 - Acute-phase reactant elevation (i.e., high erythrocyte sedimentation rate [ESR] and/or high serum C-reactive protein [CRP])
- Must submit documentation of baseline disease activity, such as symptoms experienced

Rheumatoid Arthritis (RA)

- Must be prescribed by, or in consultation with, a rheumatologist
- Must be age 18 years or older
- Must have a diagnosis of moderate to severely active rheumatoid arthritis
- Must have documentation of testing of the following:
 - Rheumatoid factor (RF)
 - Anti-cyclic citrullinated peptide (anti-CCP)
 - C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR) – *not required if RF & anti-CCP are positive*
- Must submit documentation of baseline activity, such as tender joint count, swollen joint count, pain, or disability
- Must have an adequate trial (of at least 3 months) and failure of at least two (2) of the following with an inadequate response, or significant side effects/toxicities, or have a contraindication to these therapies:
 - An adalimumab product
 - Cimzia
 - Enbrel
 - Xeljanz

Systemic Juvenile Idiopathic Arthritis (SJIA) / Still's Disease

- Must be prescribed by, or in consultation with, a rheumatologist
- Must be age 2 years or older
- Must submit chart note documentation showing active systemic juvenile idiopathic arthritis, including work-up to rule out other diagnoses
- Must submit chart documentation showing ALL the following:

- Fever $\geq 39^{\circ}\text{C}$ (102.2°F) for at least 7 days
- Transient rash often coinciding with fever spikes, preferentially involving trunk.
 - Rash is typically erythematous (salmon pink), but other rashes (e.g., urticarial) may be accepted
- Musculoskeletal involvement is present with arthralgia/myalgia
- High levels of inflammation (typically identified by neutrophilic leucocytosis, increased serum CRP and ferritin)

Systemic Sclerosis – Associated Interstitial Lung Disease (SSc-ILD)

- Must be age 18 years or older
- Must be prescribed by, or in consultation with, a pulmonologist or a rheumatologist
- Must have SSc-ILD confirmed by a high-resolution computed tomography (HRCT) study of the chest

Acute Graft Versus Host Disease (*off-label supported indication*)

- Must be prescribed by, or in consultation with, an oncologist or hematologist
- Must have had an inadequate response to systemic corticosteroids or have an intolerance or contraindication to this therapy

Immune Checkpoint Inhibitor-Related Toxicity (*off-label supported indication*)

- Must be prescribed by, or in consultation with, a gastroenterologist, hematologist, or oncologist
- Must have had an inadequate response to corticosteroids or a conventional synthetic drug (e.g., methotrexate, sulfasalazine, leflunomide, hydroxychloroquine)

Multicentric Castleman Disease (*off-label supported indication*)

- Must be prescribed by, or in consultation with, an oncologist or hematologist
- Must have documentation or an attestation from the provider that the requested medication will be used as a single agent
- Must have been previously treated for Castleman disease and is now progressing following treatment

Polymyalgia Rheumatic (PMR) (*off-label supported indication*)

- Must be prescribed by, or in consultation with, a rheumatologist
- Must submit documentation of baseline disease activity, such as stiffness and pain experienced, range of motion, or baseline inflammation levels

- Must meet ONE of the following:
 - Has had an inadequate response to systemic corticosteroids
 - Has experienced a disease flare during a taper with systemic corticosteroids
 - Has experienced an inadequate response to methotrexate
 - Has experienced an intolerance or has contraindication to both systemic corticosteroids and methotrexate (see **Appendix 1**)

Unicentric Castleman Disease (*off-label supported indication*)

- Must be prescribed by, or in consultation with, an oncologist or hematologist
- Must have documentation showing the member is negative for human immunodeficiency virus (HIV) & human herpesvirus-8
- Must have documentation or an attestation from the provider that the requested medication will be used as a single agent
- Must have been previously treated for Castleman disease and is now progressing following treatment

REAUTHORIZATION CRITERIA

Reauthorization requests for CRS and GVHD must meet initial criteria at each review.

For all other diagnoses (if applicable): all prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon meeting general reauthorization criteria **and** diagnosis-specific criteria.

General Criteria

- Must have the following laboratory values:
 - AST and ALT laboratory values <5x upper limit of normal
 - Absolute neutrophil count >500cells/mm³
 - Platelet count >50,000cells/mm³
- Member must be prescribed a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved labeling
- Must not be used in combination with a biologic disease-modifying antirheumatic drug (DMARD) or a targeted synthetic DMARD [such as Xeljanz (tofacitinib), Olumiant (baricitinib), or Otezla (apremilast)]

Articular Juvenile Idiopathic Arthritis, includes polyarticular juvenile idiopathic arthritis (PJIA):

- Must have recent chart note documentation showing achievement or maintenance of a

positive clinical response as evidenced by low disease activity OR improvement in at least ONE 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

Giant Cell Arteritis (GCA)

- Must have recent chart note documentation showing achievement or maintenance of a positive clinical response as evidenced by low disease activity OR improvement in at least ONE of the following from baseline:
 - Headaches
 - Scalp tenderness
 - Tenderness and/or thickening of superficial temporal arteries
 - Constitutional symptoms (e.g., weight loss, fever, fatigue, night sweats)
 - Jaw and/or tongue claudication
 - Acute visual symptoms (e.g., amaurosis fugax, acute visual loss, diplopia)
 - Symptoms of polymyalgia rheumatica (e.g., shoulder and/or hip girdle pain)
 - Limb claudication

Rheumatoid Arthritis (RA)

- Must have recent chart note documentation showing achievement or maintenance of 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.

Systemic Juvenile Idiopathic Arthritis (SJIA) / Still's Disease

- Must have recent chart note documentation showing achievement or maintenance of a positive clinical response as evidenced by low disease activity OR improvement in at least ONE 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
 - Systemic features (e.g., fever, evanescent rash, lymphadenopathy, hepatomegaly, splenomegaly, serositis)

Immune Checkpoint Inhibitor-Related Toxicity (*off-label supported indication*)

- Must have recent chart note documentation showing achievement or maintenance of a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms.

Multicentric Castleman Disease (*off-label supported indication*)

- Must have recent chart note documentation showing the following
 - No evidence of unacceptable toxicity
 - No evidence of disease progression while on current regimen

Polymyalgia Rheumatic (PMR) (*off-label supported indication*)

- Must have recent chart note documentation showing achievement or maintenance of a positive clinical response as evidenced by low disease activity OR improvement in at least ONE of the following from baseline:
 - Morning stiffness
 - Hip or shoulder pain
 - Hip or shoulder range of motion
 - C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR)

Unicentric Castleman Disease (*off-label supported indication*)

- Must have recent chart note documentation showing the following
 - No evidence of unacceptable toxicity
 - No evidence of disease progression while on current regimen

APPROVAL DURATIONS

If the above criteria are met, the request will be approved for up to the duration of time dictated below:

Initial Authorization	<ul style="list-style-type: none"> ● CRS: Up to 1 month ● SSc-ILD: Up to indefinite ● All other diagnoses: Up to 1 year
Reauthorization	<ul style="list-style-type: none"> ● Same as initial

APPENDICES

Appendix 1 – Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Cyclosporine, Acitretin, or Leflunomide

- 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

Appendix 2: Risk Factors for Articular Juvenile Idiopathic Arthritis

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

CODING AND STANDARDS

Codes

Code	Brand	Description
J3262	Actemra	Injection, Tocilizumab 1mg
Q5133	Tovidence	Injection, Tocilizumab-bavi (Tovidence), biosimilar, 1mg
Q5135	Tyenne	Injection, Tocilizumab-aazg (Tyenne), biosimilar, 1mg

Applicable Lines of Business

<input type="checkbox"/>	CHIP (Children’s Health Insurance Program)
<input type="checkbox"/>	Commercial
<input type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input type="checkbox"/>	Medicare Advantage

BACKGROUND

Definitions

ALT – alanine aminotransferase

AST – aspartate aminotransferase

DMARDs – Disease-Modifying Anti-Rheumatic Drugs

TNF – Tumor Necrosis Factor

POLICY HISTORY

Date	Summary
March 2025	<ul style="list-style-type: none"> Renamed policy to Tocilizumab Products Added Tofidence and Tyenne Select revisions to existing diagnoses to match pharmacy benefit criteria Added 5 new indications – Unicentric Castleman Disease, Multicentric Castleman Disease, Immune Checkpoint Inhibitor-Related Toxicity, Acute GVHD, PMR
March 2022	<ul style="list-style-type: none"> New Guideline

LEGAL AND COMPLIANCE

Guideline Approval



Committee

Reviewed / Approved by Evolent Administrative Services Medical Policy Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

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