| Effective Date:01/15/2025 |
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| Reviewed: 11/2024<br>Scope: Medicaid |

# Tyenne (Tocilizumab) SC

## POLICY

### I. CRITERIA FOR APPROVAL

**Initial criteria:**

- Patient has been evaluated and screened for the presence of latent TB infection prior to initiating treatment; **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Must not be administered concurrently with live vaccines; **AND**
- Patient is not on concurrent treatment with another biologic therapy (e.g., IL-inhibitor, TNF-inhibitor, integrin receptor antagonist, T cell costimulation modulator, etc.) or targeted synthetic therapy (e.g., Otezla (apremilast), Cibinqo (abrocitinib), Xeljanz/Xeljanz XR (tofacitinib), Rinvoq (Upadacitinib), Jakafi(ruxolitinib), Velsipity (etrasimod), etc.); **AND**

**Rheumatoid Arthritis**

- Patient is 18 years or older; **AND**
- Documentation that the physician has assessed baseline disease severity utilizing an objective measure/tool; **AND**
- Documented moderate to severe active disease; **AND**
    - Documentation that patient has had at least a 3-month trial and failed previous therapy with ONE conventional synthetic disease modifying anti-rheumatic drug (csDMARD) such as methotrexate, azathioprine, hydroxychloroquine, sulfasalazine, leflunomide, etc.; AND has had an inadequate response, intolerance or contraindication to at least a 3-month trial of adalimumab at maximum tolerated doses; OR
    - Documentation that patient is already established on biologic or targeted synthetic therapy for the treatment of RA; AND
- May be used as a single agent or in combination with csDMARD (e.g., methotrexate, hydroxychloroquine, leflunomide, sulfasalazine, etc.); **AND**

**Juvenile Idiopathic Arthritis (sJIA/pJIA)**

- Patient is 2 years or older; **AND**
- Documentation that physician has assessed baseline disease severity utilizing an objective measure/tool; **AND**
- Documentation that patient has active systemic juvenile idiopathic arthritis (sJIA) or polyarticular juvenile idiopathic arthritis (pJIA); **AND**
    - Documentation the patient has had at least a 1-month trial and failure (unless contraindicated or intolerant) of previous therapy with either oral non-steroidal anti-inflammatory drugs (NSAIDs) OR conventional synthetic disease modifying anti-rheumatic drugs (csDMARDS) e.g., methotrexate, hydroxychloroquine, leflunomide, sulfasalazine, etc.; AND has had an inadequate response, intolerance or contraindication to at least a 3-month trial of adalimumab at maximum tolerated doses; OR

  - Documentation that patient is already established on biologic or targeted synthetic therapy for the treatment of SJIA or pJIA; AND
- May be used alone or in combination with methotrexate; **AND**

**Neuromyelitis Optica Spectrum Disorder (NMOSD)**

- Documentation that patient has a confirmed diagnosis based on the following:
  - Patient is seropositive for aquaporin-4 (AQP4) IgG antibodies; **AND**
    - Patient has at least one core clinical characteristic §; **AND**
    - Alternative diagnoses have been excluded (e.g., myelin oligodendrocyte glycoprotein (MOG) antibody disease (MOGAD), multiple sclerosis, sarcoidosis, cancer, chronic infection, etc.); OR
  - Patient is seronegative for AQP-4 IgG antibodies OR has unknown AQP-4-IgG status; **AND**
    - Documentation that patient has at least two core clinical characteristics § occurring as a result of one or more clinical attacks; **AND**
    - Documentation that patient experienced ALL of the following:
      - At least 1 core clinical characteristic must be acute optic neuritis, acute myelitis with, or area postrema syndrome; **AND**
      - Fulfillment of additional typical MRI finding requirements for each area affected, ψ; **AND**
    - Alternative diagnoses have been excluded (e.g., myelin oligodendrocyte glycoprotein (MOG) antibody disease (MOGAD multiple sclerosis, sarcoidosis, cancer, chronic infection, etc.); **AND**
- Used as a single agent or in combination with immunosuppressive therapy (e.g. azathioprine, methotrexate, mycophenolate, etc.)

| **§ Core Clinical Characteristics of NMOSD** [17,29] |
| --- |
| • Acute optic neuritis<br>• Acute myelitis<br>• Area postrema syndrome (APS): episode of otherwise unexplained hiccups and/or nausea and vomiting (lasting for at least 48 hours or with MRI evidence of a dorsal brainstem lesion)<br>• Acute brainstem syndrome other than APS<br>• Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic lesions on MRI **¥**<br>• Acute cerebral syndrome with NMOSD-typical brain lesions on MRI ****** |
| **ψ Typical MRI findings in NMOSD related to clinical presentation (T2 unless noted otherwise)** [29] |
| • Optic neuritis: Normal cerebral MRI (or only nonspecific white matter lesions) OR longitudinally extensive optic nerve lesion (≥ half of the length of the optic nerve or involving optic chiasm; T2 or T1/Gd)<br>• Myelitis: Intramedullary lesion ≥ 3 contiguous VS (LETM) OR focal atrophy ≥ 3 contiguous VS in patients with a history of acute myelitis<br>• Area postrema syndrome (APS): Lesion in the dorsal medulla oblongata/area postrema<br>• Other brainstem syndrome: Periependymal brainstem lesion (4th ventricle)<br>• **¥** Diencephalic syndrome: Periependymal lesion (3rd ventricle) OR hypothalamic/thalamic lesion |

- ** Cerebral syndrome: Extensive periependymal lesion (lateral ventricle; often with Gd) OR long (> 1⁄2 length), diffuse, heterogeneous or edematous corpus callosum lesion OR long corticospinal tract lesion (unilateral or bilateral, contiguously involving internal capsule and cerebral peduncle) OR large, confluent (unilateral or bilateral) subcortical or deep white matter lesion
- *LETM = *longitudinally extensive transverse myelitis lesions; VS = vertebral segments*

**Giant Cell Arteritis (GCA)**

- Documentation that the patient has large vessel arteritis that has at some point been verified with biopsy or with imaging of the large vessels (color Doppler ultrasound [CDUS], MRI, PET-CT, or CT angiography); **AND**
- Documentation that the patient has active disease and an elevated c-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR); **AND**
- Documentation that the patient has had an inadequate response, contraindication, or intolerance to glucocorticoid therapy alone; **AND**
- Used in combination with a tapering course of glucocorticoids *(NOTE: tocilizumab can be used alone following discontinuation of glucocorticoids.)*

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

- Will not be used in combination with other treatment modalities (e.g., Ofev (nintedanib), Esbriet (pirfenidone), rituximab, cyclophosphamide, mycophenolate mofetil, etc.); **AND**
- Documentation that patient has a confirmed diagnosis of systemic sclerosis with an American College of Rheumatology (ACR)/European League Against Rheumatism (EULAR) classification criteria score ≥ 9; **AND**
- Onset of disease (first non-Raynaud symptom) of less than or equal to 5 years ago; **AND**
- Documentation of baseline percent forced vital capacity (%FVC) > 55%

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); **Φ** Orphan Drug

## II. CONTINUATION OF THERAPY

- Patient continues to meet initial criteria; AND
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: serious infection, severe neutropenia, severe thrombocytopenia, severe hepatotoxicity, gastrointestinal perforation, immunosuppression, severe hypersensitivity reactions, demyelinating disorders, etc.;

**Rheumatoid arthritis (RA)**

- Documentation of disease response as indicated by improvement in signs and symptoms compared to baseline such as the number of tender and swollen joint counts, reduction of C-reactive protein,

improvement of patient global assessment, and/or an improvement on a disease activity scoring tool [e.g. an improvement on a composite scoring index such as Disease Activity Score-28 (DAS28) of 1.2 points or more or a ≥20% improvement on the American College of Rheumatology-20 (ACR20) criteria, an improvement of disease severity on RAPID3 assessment, etc]

**Juvenile Idiopathic Arthritis (SJIA/PJIA)**

- Documentation of disease response as indicated by improvement in signs and symptoms compared to baseline such as the number of tender and swollen joint counts, reduction of C-reactive protein, improvement of patient global assessment and/or improvement on a disease activity scoring tool [e.g. an improvement on a composite scoring index such as Juvenile Arthritis Disease Activity Score (JADAS) or the American College of Rheumatology (ACR) Pediatric (ACR-Pedi 30) of at least 30% improvement from baseline in three of six variables].

**NMOSD**

- Documentation of disease response as indicated by stabilization/improvement in any of the following: neurologic symptoms as evidenced by a decrease in acute relapses or improvement of stability, reduced hospitalizations, reduction/discontinuation in plasma exchange treatments, and/or reduction/discontinuation of corticosteroids without relapse

**Giant Cell Arteritis (GCA)**

- Documentation of disease response as indicated by improvement in signs and symptoms compared to baseline such as headache, temporal artery tenderness, visual symptoms, inflammatory parameters, (e.g., erythrocyte sedimentation rate [ESR], C-reactive protein), improvement of periodic imaging studies (color Doppler ultrasound [CDUS], MRI, PET-CT, or CT angiography), etc.

**Systemic Sclerosis Associated with Interstitial Lung Disease (SSc-ILD)**

- Documentation that disease response as indicated by a reduction in the rate of decline or stabilization in forced vital capacity (%FVC) or percent predicted FVC (ppFVC) as compared to pre-treatment baseline; AND
- Documentation that patient does not have evidence of disease progression defined as an absolute decline of more than 10% in percent-predicted FVC within any 12-month period

## III. DOSAGE/ADMINISTRATION

| Indication | Dose |
|---|---|
| Adult Rheumatoid Arthritis | <u>Weight < 100 kg</u><br>• 162 mg administered subcutaneously every other week<br>• May increase to every week based on clinical response<br><u>Weight ≥ 100 kg</u><br>• 162 mg administered subcutaneously every week |

| Indication | Dose |
|---|---|
| Polyarticular Juvenile Idiopathic Arthritis | Weight < 30 kg<br>• 162 mg administered subcutaneously every 3 weeks<br>Weight ≥ 30 kg<br>• 162 mg administered subcutaneously every 2 weeks |
| Systemic Juvenile Idiopathic Arthritis | Weight < 30 kg<br>• 162 mg administered subcutaneously every 2 weeks<br>Weight ≥ 30 kg<br>• 162 mg administered subcutaneously every week |
| Giant Cell Arteritis | • 162 mg administered subcutaneously every week (may administer every other week) in combination with a tapering dose of glucocorticoids<br>***NOTE: Tocilizumab SQ can be used alone following discontinuation of glucocorticoids.* |
| NMOSD and SSc-ILD | • 162 mg administered subcutaneously every week |

The following HCPCS/CPT code is:

| HCPCS/CPT Code | Description |
|---|---|
| Q5133 | Injection, tocilizumab-bavi (tofidence), biosimilar, 1 mg |
| Q5135 | Injection, tocilizumab-aazg (tyenne), biosimilar, 1 mg |

## IV. QUANTITY LIMIT

a. Tyenne 162mg 4 syringes/pens per 28 days

## V. COVERAGE DURATION

- Initial: 6 months
- Renewal: 6 months, for GCA can be renewed up to a maximum of 18 months of therapy

## VI. REFERNCES

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