Cytokine and CAM Antagonists: Interleukin-6 (IL-6) Receptor Antagonist
Utilization Management Criteria

Therapeutic Class:	Cytokine and CAM Antagonists: Interleukin-6 (IL-6) Receptor Antagonist
Non-Preferred Agents:	Actemra (tocilizumab) Avtozma (tocilizumab-anoh) Enspryng (satralizumab-mwge) Kevzara (sarilumab) Tofidence (tocilizumab-bavi)
Preferred Agents:	Tyenne (tocilizumab-aazg)
Implementation Date:	1/1/26
Prepared For:	CT Medicaid
PDL Status:	Non-preferred
Purpose:	The targeted immune modulators, IL-6 inhibitors, are monoclonal antibodies that bind to the IL-6 receptor and inhibit the endogenous activity related to induction of proinflammatory cytokines and acute phase reactants. Both sarilumab and tocilizumab are approved for the treatment of rheumatoid arthritis (RA), either as monotherapy or in combination with methotrexate (MTX) or other non-biologic disease-modifying antirheumatic drugs (DMARDs). Tocilizumab carries additional indications for several other conditions, including various inflammatory and rheumatologic diseases as summarized in Table 1. Sarilumab is also indicated for use in polymyalgia rheumatica and polyarticular juvenile idiopathic arthritis (pJIA) in patients who weigh at least 63 kg. Both agents are administered via subcutaneous injection; tocilizumab is also administered intravenously for certain indications. Satralizumab is approved for the treatment of neuromyelitis optica spectrum disorder (NMOSD). There are 3 biosimilar tocilizumab formulations (tocilizumab-aazg, tocilizumab-anoh, and tocilizumab-bavi). Guidelines for various rheumatic conditions generally do not suggest a preference for specific biologic agents over others. Both sarilumab and tocilizumab carry similar warnings, including a boxed warning regarding increased risks of serious infections. During treatment with sarilumab and tocilizumab, laboratory monitoring should include liver enzymes, neutrophils, platelets, and lipids. Laboratory monitoring for satralizumab should include liver enzymes and neutrophils. Commonly reported adverse events include infection, injection site reactions, and ALT elevations. Sarilumab and tocilizumab carry a risk of bowel perforation.

Table 1. Cytokine and CAM Antagonists: Interleukin-6 (IL-6) Receptor Antagonist

Generic Name	Brand Name	Approved Indications	Route of Administration	Biosimilar Availability
Sarilumab	Kevzara®	PJIA, PMR, RA	SC	No
Satralizumab-mwge	Enspryng®	NMOSD	SC	No
Tocilizumab	Actemra®	COVID-19, CRS, GCA, PJIA, RA, SJIA, SSc-ILD	IV, SC	Yes
Tocilizumab-aazg	Tyenne®	COVID-19, CRS, GCA, PJIA, RA, SJIA	IV, SC	Biosimilar of Actemra®
Tocilizumab-anoh	Avtozma®	COVID-19, CRS, GCA, PJIA, RA, SJIA	IV, SC	Biosimilar of Actemra®
Tocilizumab-bavi	Tofidence™	COVID-19, GCA, PJIA, RA, SJIA	IV	Biosimilar of Actemra®

Abbreviations: COVID-19, coronavirus disease 2019; CRS, cytokine release syndrome; GCA, giant cell arteritis; IV, intravenous; NMOSD, neuromyelitis optica spectrum disorder; PJIA, polyarticular juvenile idiopathic arthritis; PMR, polymyalgia rheumatica; RA, rheumatoid arthritis; SC, subcutaneous; SJIA, systemic juvenile idiopathic arthritis; SSc-ILD, systemic sclerosis-associated interstitial lung disease

All authorizations must be prescribed in accordance with FDA approved labeling. Use of samples to initiate therapy does not meet step therapy and/or continuation of therapy prior authorization requirements. Prior therapies will be verified through pharmacy claims and/or submitted chart notes

General Approval Criteria:

- Claim is for preferred agent (Tyenne) **OR**
- Requested agent is **NOT** used in combination with other targeted immunomodulators **AND**
- Patient does **NOT** have active TB, or other active infection prior to initiation **AND**
- Requested quantity in accordance with FDA approved product labelling

Initial Therapy – All the following must be met:

For Coronavirus Disease 2019 (Actemra, Avtozma, Tyenne, Tofidence)

- Limited to inpatient use. Not payable for outpatient use for this indication

For Cytokine Release Syndrome (Actemra, Avtozma)

- Documentation of diagnosis (listed above)
- Patient aged 2 years and older
- Medical reason preferred agent (Tyenne) cannot be used
- *Initial therapy requirements apply to both new starts and continued therapy requests for non-preferred tocilizumab formulations*

For Giant Cell Arteritis (GCA) (Actemra, Avtozma, Tofidence)

- Prescribed by or in consultation with a rheumatologist, neurologist, ophthalmologist or any other specialist familiar with the treated disease state
- Documentation of diagnosis (listed above)
- Trial and failure of preferred agent Tyenne (30 days) or documented adverse drug event or adverse drug reaction (ADE/ADR) to Tyenne
- Patient aged 18 years and older
- *Initial therapy requirements apply to both new starts and continued therapy requests for non-preferred tocilizumab formulations*

For Polymyalgia Rheumatica (PMR) (Kevzara)

- Prescribed by or in consultation with a rheumatologist
- Documentation of diagnosis (listed above)
- Trial of corticosteroids (30 days) **AND** cannot tolerate corticosteroid taper **OR** contraindication to corticosteroids or documented adverse drug event or adverse drug reaction (ADE/ADR) to corticosteroids
- Patient aged 18 years and older

For Active Polyarticular Juvenile Idiopathic Arthritis (PJIA) (Actemra, Avtozma, Kevzara, Tofidence)

- Prescribed by or in consultation with a rheumatologist
- Documentation of diagnosis (listed above)
- Trial and failure of preferred agent Tyenne (30 days) or documented adverse drug event or adverse drug reaction (ADE/ADR) to Tyenne
- Patient aged 2 years and older (Actemra, Avtozma, and Tofidence only)
- Patient weighs 63 kg or greater (Kevzara only)
- *Initial therapy requirements apply to both new starts and continued therapy requests for non-preferred tocilizumab formulations*

For Moderate to Severe Rheumatoid Arthritis (RA) (Actemra, Avtozma, Kevzara, Tofidence)

- Prescribed by or in consultation with a rheumatologist
- Documentation of diagnosis (listed above)
- Trial and failure of preferred agent Tyenne (30 days) or documented adverse drug event or adverse drug reaction (ADE/ADR) to Tyenne
- Patient aged 18 years and older
- *Initial therapy requirements apply to both new starts and continued therapy requests for non-preferred tocilizumab formulations*

For Active Systemic Juvenile Idiopathic Arthritis (SJIA) (Actemra, Avtozma, Tofidence)

- Prescribed by or in consultation with a rheumatologist
- Documentation of diagnosis (listed above)
- Trial and failure of preferred agent Tyenne (30 days) or documented adverse drug event or adverse drug reaction (ADE/ADR) to Tyenne
- Patient aged 2 years and older
- *Initial therapy requirements apply to both new starts and continued therapy requests for non-preferred tocilizumab formulations*

For Systemic Sclerosis-associated Interstitial Lung Disease (SSc-ILD) (Actemra)

- Prescribed by or in consultation with a pulmonologist or rheumatologist
- Documentation of diagnosis (listed above)
- Patient aged 18 years and older

For Neuro-myelitis Optica Spectrum Disorder NMOSD (Enspryng):

- Prescribed by or in consultation with a neurologist or any other specialist familiar with the treated disease state
- Documentation of diagnosis (listed above)
- Documented positive lab results for anti-aquaporin-4 (AQP4) antibody
- Additional coverage criteria

- Patient does not have active hepatitis B
- Patient aged 18 years and older

Initial PA length: 1 year

Exclusion Criteria: Approval criteria not met

Continuation Therapy: Documentation of continued clinical benefit **AND** Documented compliance on current therapy regimen *(exceptions apply as noted in initial therapy section)*

Continuation Length: 1 year

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Revision History

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