INTERLEUKIN-6 RECEPTOR ANTAGONISTS

Included Products: Actemra (tocilizumab), Tyenne prefilled syringe and autoinjector (tocilizumab-aazg)

Created: 01/18/2023 Revised: 09/12/2024 *Reviewed*: 09/12/2024 *Updated*: 10/01/2024

All Diagnoses			
Initial Criteria: All Diagnoses		**If yes**	**If no**
1.	Is the requested agent indicated for or supported for use in the submitted diagnosis for the member's age?	Continue to #2.	Do not approve.
2.	Is the request for maintenance of remission in a patient who already achieved remission with the requested product or has already initiated therapy?	Continue to renewal criteria for the submitted diagnosis.	Continue to #3.
3.	Has the risk of infections been addressed by the following? a. Initial testing for latent TB and treatment, if necessary, before starting therapy b. No current active infection at initiation of therapy c. Risks and benefits documented in cases of chronic or recurrent infection	Continue to #4	Do not approve.
4.	Does the member have medical record documentation of all of the following? a. absolute neutrophil count (ANC) above 2000/mm3, and b. platelet count above 100,000/mm, and c. ALT or AST below 1.5 times the upper limit of normal (ULN)	Continue to #5	Do not approve.
5.	Has the treatment been initiated by or is an appropriate specialist currently supervising it?	Continue to #6.	Do not approve.
6.	Is the requested agent to be used in combination with another biologic?	Do not approve	Continue to #7.

7.	Continue to diagnosis.		

Giant Cell Arteritis

Initial Criteria		If yes	If no
1.	Does the member have a diagnosis of giant cell arteritis diagnosed by temporal artery biopsy or imaging?	Continue to #2.	Do not approve.
2.	Has the member tried high dose steroids (starting with prednisone 60mg per day) to induce remission?	Continue to #3.	Do not approve.
3.	Is the member currently on steroids and has failed to respond or failed to maintain remission during a taper according to schedule?	Continue to #4.	Do not approve.
4.	Will the requested product be initiated in conjunction with a steroid taper?	Continue to #5.	Do not approve.
5.	Approve for 6 months.		
Renewal Criteria		**If yes**	**If no**
1.	Is there medical record documentation of laboratory monitoring of neutrophils, platelets, liver function tests, and lipids?	Continue to #2.	Do not approve.
2.	Has the member achieved clinical response, including normalization of erythrocyte sedimentation rate and c-reactive protein, successful steroid taper, or sustained absence of signs and symptoms?	Continue to #3.	Do not approve.
3.	Approve for 12 months.		

Juvenile Idiopathic Arthritis

Initial Criteria		If yes	If no
1.	Does the member have juvenile idiopathic arthritis with active systemic features of JIA, with a physician global assessment of 5 or higher (or any systemic activity in the absence of active joint involvement)?	Continue to #3.	Continue to #2.
2.	Does the member have juvenile idiopathic arthritis without active systemic features of JIA?	Continue to #4.	Do not approve.
3.	Has the member tried and failed systemic	Continue to #4.	Do not approve.

	corticosteroids?		
4.	Has the member tried and failed methotrexate or leflunomide for at least 3 months (or have a contraindication to both)?	Continue to #5.	Do not approve.
5.	Approve for 6 months.		
Renewal Criteria		If yes	If no
1.	Has the member experienced 20% or greater improvement in tender joint count and swollen joint count or stabilization of active systemic activity?	Continue to #2.	Do not approve.
2.	Approve for 12 months.		

Rheumatoid Arthritis

Initial Criteria		If yes	If no
1.	Does the member have a baseline of moderate to high disease activity of rheumatoid arthritis measured as such by an accepted assessment instrument (PAS, PASII, RAPID3, CDAI, DAS28, SDAI)?	Continue to #2.	Do not approve.
2.	Is the member transitioning to the requested treatment from a different biologic product?	Continue to #5.	Continue to #3.
3.	Has the member tried and failed or have contraindications to methotrexate dosed at least 20mg per week for at least 8 weeks?	Continue to #4.	Do not approve.
4.	Has the member tried and failed or have contraindications to the following: leflunomide, hydroxychloroquine, or sulfasalazine?	Continue to #5.	Do not approve.
5.	Has the member tried and failed or have a contraindication to infliximab?	Continue to #6.	Do not approve.
6.	Approve for 6 months		
Renewal Criteria		If yes	If no
1.	Is there medical record documentation of laboratory monitoring of neutrophils, platelets, liver function tests, and lipids?	Continue to #2.	Do not approve.
2.	Has the member experienced 20% or greater improvement in tender joint count and swollen joint?	Continue to #3.	Do not approve.
3.	Approve for 12 months.		

Systemic Sclerosis-Associated Interstitial Lung Disease (SSC-ILD)

Initial Criteria		If yes	If no
1.	Does the member have a confirmed diagnosis of SSc-ILD?	Continue to #2.	Do not approve.
2.	Has the member failed mycophenolate mofetil (or cyclophosphamide if unable to take mycophenolate)?	Continue to #3.	Do not Approve
3.	Approve for 6 months		
Renewal Criteria		**If yes**	**If no**
1.	Has the provider documented a decrease in decline in lung function?	Continue to #2.	Do not approve.
2.	Approve for 12 months.		

Thyroid Eye Disease

Initial Criteria		If yes	If no
1.	Does the member have a diagnosis of Graves' Disease?	Continue to #2	Do not approve. Use is investigational.
2.	Is the patient pregnant?	Do not approve.	Continue to #3.
3.	Has the patient been assessed by a specialized ophthalmologist (neuro-ophthalmologist or ocular facial plastic surgeon??	Continue to #4.	Do not approve.
4.	Does the patient have immediate sight-threatening disease?	Do not approve.	Continue to #5.
5.	Is the patient euthyroid?	Continue to #6.	Do not approve.
6.	Does the member have active thyroid eye disease defined as a CAS of 4 or higher within the past 3 months?	Continue to #7.	Do not approve.
7.	Does the patient have moderate to severe TED?	Continue to #8.	Do not approve.
8.	Does the patient have diabetes and an HbA1C% of over 9%?	Do not approve.	Continue to #9.
9.	Has the member failed or the provider submitted an acceptable statement to avoid 3 weeks of high dose corticosteroids?	Continue to #10	Do not approve.
10.	Approve for requested dose and duration.		

REFERENCES

- British Society for Rheumatology guideline on diagnosis and treatment of giant cell arteritis
- 2013 update of the 2011 ACR Recommendations for the treatment of juvenile idiopathic arthritis
- 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Non-Systemic Polyarthritis, Sacroiliitis, and Enthesitis
- 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis
- 2021 European Guidelines for the Treatment of Graves' Orbitopathy (EUGOGO)