

Clinical Policy Title:	tocilizumab
Policy Number:	RxA.730
Drug(s) Applied:	Actemra®
Original Policy Date:	04/18/2022
Last Review Date:	12/05/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Rheumatoid Arthritis (must meet all):

1. Diagnosis of Rheumatoid Arthritis (RA);
2. Trial and failure of a ≥ 3 months of at least one conventional systemic therapy (methotrexate [MTX], sulfasalazine, leflunomide, hydroxychloroquine) , unless contraindicated or clinically significant adverse effects are experienced;
3. Trial and failure of at least two (2) of the following agents: adalimumab (Abrilada™, Hadlima™, or adalimumab-aaty), Cimzia®, or Enbrel®, Simponi®/ Simponi Aria®, Rinvoq® or Xeljanz/XR® unless contraindicated or clinically significant adverse effects are experienced;

Approval Duration

All Lines of Business (except Medicare): 12 months

B. Giant Cell Arteritis (Temporal Arteritis) (must meet all):

1. Diagnosis of Giant Cell Arteritis (GCA);
2. Trial and failure of a systemic corticosteroid in conjunction with methotrexate (MTX), unless contraindicated or clinically significant adverse effects are experienced;

Approval Duration

All Lines of Business (except Medicare): 12 months

C. Juvenile Idiopathic Arthritis (must meet all):

1. Diagnosis of Polyarticular Juvenile Idiopathic Arthritis (PJIA) or Systemic Juvenile Idiopathic Arthritis (SJIA);
2. Trial and failure of at least one (1) conventional systemic therapy (methotrexate [MTX] or leflunomide [Arava®]) , unless contraindicated or clinically significant adverse effects are experienced;
3. For PJIA: Trial and failure of any two (2) of the following agents: adalimumab (Abrilada™, Hadlima™, or adalimumab-aaty), Enbrel® or Xeljanz®*, unless contraindicated or clinically significant adverse effects experienced;

Approval Duration

All Lines of Business (except Medicare): 12 months

D. Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD) (must meet all):

1. Diagnosis of Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD);

Approval Duration

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. All Indications in Section I (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria.

Approval Duration

All Lines of Business (except Medicare): 12 months

References

1. Aletaha D, Neogi T, Silman AJ, et al. 2010 Rheumatoid Arthritis Classification Criteria. *Arthritis and Rheumatism* September 2010;62(9):2569-2581. Available at: <https://pubmed.ncbi.nlm.nih.gov/20872595/>. Accessed November 22, 2024.
2. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Care Res (Hoboken)*. 2021;73(7):924-939. Available at: <https://pubmed.ncbi.nlm.nih.gov/34101387/>. Accessed November 22, 2024.
3. Maz M, Chung SA, Abril A, et al. 2021 American College of Rheumatology/Vasculitis Foundation Guideline for the Management of Giant Cell Arteritis and Takayasu Arteritis. *Arthritis Care Res (Hoboken)*. 2021;73(8):1071-1087. Available at: <https://pubmed.ncbi.nlm.nih.gov/34235871/>. Accessed November 22, 2024.
4. Onel KB, Horton DB, Lovell DJ, et al. 2021 American College of Rheumatology Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Oligoarthritis, Temporomandibular Joint Arthritis, and Systemic Juvenile Idiopathic Arthritis. *Arthritis Rheumatol*. 2022;74(4):553-569. Available at: [2021 American College of Rheumatology Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Oligoarthritis, Temporomandibular Joint Arthritis, and Systemic Juvenile Idiopathic Arthritis \(nih.gov\)](https://pubmed.ncbi.nlm.nih.gov/39111111/) Accessed November 22, 2024.

Review/Revision History	Review/Revision Date	P&T Approval Date
RxA.592.Biologic_DMARDs was last reviewed and updated on 01/05/2022 and archived on 04/18/2022. For details, please refer to RxA.592.Biologic_DMARDs.	01/05/2022	04/18/2022
Drug specific policy for Actemra® was created based on RxA.592.Biologic_DMARDs <ol style="list-style-type: none"> 1. Dosing Information, Maximum Dose, Actemra: Updated maximum dosing information from general dosing to weight based dosing for indication PJIA and SJIA. 2. Initial Approval Criteria, I.A.5: Updated to remove prior trial and failure criteria "Failure of two (2) of the following, each used for ≥ 3 months, unless contraindicated or clinically significant adverse effects are experienced: Humira®, Cimzia®, Inflectra®, Rinvoq™, Renflexis™, Simponi®, Simponi Aria®, or Xeljanz®/ Xeljanz XR®". 3. Initial Approval Criteria, I.A.5: Updated to include new trial and failure criteria Trial and failure of at least two (2) of the following agents: Cimzia®, Humira®, Simponi®/ Simponi Aria®, Rinvoq® or 	02/10/2022	04/18/2022

<p>Xeljanz/XR® unless contraindicated or clinically significant adverse effects are experienced; *Exception: If a total of two TNF inhibitors (Humira®, Cimzia®, Simponi®/ Simponi Aria®, Enbrel®) has previously been tried and failed, trial of a third TNF inhibitor is not required;</p> <p>4. Initial Approval Criteria, I.C: Updated to include new criteria pertaining to indication SJIA.</p> <p>5. Initial Approval Criteria, I.C.5: Updated to include new trial and failure criteria Trial and failure of Humira® unless contraindicated or clinically significant adverse effects experienced; *Exception: If a total of two TNF inhibitors (Humira, Simponi Aria, Enbrel®) has previously been tried and failed, trial of a third TNF inhibitor is not required.</p> <p>6. Initial Approval Criteria, I.C.6: Updated dosing criteria from Dose does not exceed maximum dose indicated in dosing information to Dose does not exceed (a or b):</p> <ol style="list-style-type: none"> Intravenous: Weight < 30 kg: 12 mg/kg every 2 weeks; ≥ 30 kg: 8 mg/kg every 2 weeks Subcutaneous: Weight < 30 kg: 162 mg every 2 weeks; ≥ 30 kg: 162 mg every weeks; <p>7. Initial Approval Criteria, I.D: Updated to remove approval criteria for Juvenile Idiopathic Arthritis.</p> <p>8. Appendix B, Drug Name: Updated to include brand-name therapeutic alternative of other biological DMARDs.</p> <p>9. Disclaimer about contraindications "Contraindications listed reflect statements made in the manufacturer's package insert..." was added to Appendix C.</p> <p>10. Appendix D, General Information: Updated to remove information regarding: (a, b and c)</p> <ol style="list-style-type: none"> Rheumatoid Arthritis; Definition of failure of MTX or DMARDs; Examples of positive response to therapy. <p>11. References were reviewed and updated.</p>		
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> Initial Approval Criteria, I.A.5: Updated to remove exception trial and failure criteria "Exception: If a total of two TNF inhibitors (Humira®, Cimzia®, Simponi®/ Simponi Aria®, Enbrel®) has previously been tried and failed, trial of a third TNF inhibitor is not required." Initial Approval Criteria, I.A.5 and I.C.5: Updated 	<p>10/03/2022</p>	<p>10/19/2022</p>

<p>trial and failure criteria to include drug Enbrel®.</p> <p>3. References were reviewed and updated.</p>		
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Initial Approval Criteria I.C.5: Updated to add Xeljanz® in the trial and fail criteria. 2. Initial Approval Criteria I.A.5: Updated to add *Trial of Xeljanz/XR®, Rinvoq® requires inadequate response to one or more TNF inhibitors 3. Initial Approval Criteria I.C.5: Updated to add *Trial of Xeljanz® requires inadequate response to one or more TNF inhibitors 4. References were reviewed and updated. 	01/03/2023	01/17/2023
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Background: Updated to include new indication coronavirus disease 2019 (COVID-19). 2. Dosing Information, Indication: Updated to include new indication coronavirus disease 2019 (COVID-19). 3. Initial Approval Criteria I.A, I.C: Updated to add Amjevita™ as one of trial and failure criteria alternative drug. 4. Initial Approval Criteria, I.F: Updated to include approval criteria for indication, Coronavirus Disease 2019 (COVID-19). 5. Continued Therapy Approval Criteria II.B.: Updated to include approval criteria for indication, Coronavirus Disease 2019 (COVID-19). 6. Appendix A: Updated to include abbreviations ECMO. 7. Appendix B, Dosing Regimen, methotrexate: Updated dosing information from 7.5 mg/week orally, subcutaneous, or intramuscular or 2.5 mg orally every 12 hr for 3 doses/week to 7.5 to 15 mg orally or subcutaneously once weekly, initially. Increase the dose to at least 15 mg/week to achieve optimal response. 8. Appendix B, Maximum Dose, methotrexate: Updated maximum dose information from 30 mg/week to 20 to 30 mg/m2/week (0.65 to 1 mg/kg/week) is a usual maximum dose for indication polyarticular juvenile idiopathic arthritis. 9. Appendix B, Maximum Dose, methotrexate: Updated maximum dose information from 30 mg/week to 20 mg/week for indication RA. 10. References were reviewed and updated. 	03/06/2023	04/13/2023

Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: <ol style="list-style-type: none"> 1. Updated trial and failure criteria to include Humira biosimilar. 2. Removed age criteria. 3. Removed dosing criteria. 4. Updated Approval duration. 5. Removed reauthorization requirement for positive response to therapy. 6. References were reviewed and updated. 	11/10/2023	02/28/2024
Policy was reviewed: <ol style="list-style-type: none"> 1. I.A.3 Removed up to maximally indicated doses and exception of DMARD use 2. I.B. Added “Temporal Arteritis” for completion and correspondence to Micromedex 3. I.B.3 Removed up to maximally indicated doses and azathioprine (UpToDate), removed trial of 3 month minimum per guidelines 4. I.C.3 Removed up to maximally indicated doses and exception for DMARD use, removed trial of 3 month minimum per guidelines 5. Cytokine release syndrome indication was removed. Applies only to IV formulation which is non-formulary. 6. COVID indication was removed. Applies only to IV formulation which is nonformulary. 	4/1/2024	2/28/2024
Policy was reviewed: <ol style="list-style-type: none"> 1. Removed prescriber restrictions. 2. Updated adalimumab biosimilars. 3. Updated Continued therapy approval “Member is currently receiving medication that has been authorized..” 4. References were reviewed and updated. 	11/22/2024	12/05/2024