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| **Clinical Policy Title:** | tocilizumab |
| **Policy Number:** | RxA.730 |
| **Drug(s) Applied:** | Actemra® |
| **Original Policy Date:** | 04/18/2022 |
| **Last Review Date:** | 04/01/2024 |
| **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. Prescribed by or in consultation with a rheumatologist;
3. 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;
4. Trial and failure of at least two (2) of the following agents: adalimumab (adalimumab-adaz, Amjevita™, Hadlima, Humira, Yusimry), 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 Arthritis (GCA);
2. Prescribed by or in consultation with a rheumatologist;
3. 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. Prescribed by or in consultation with a rheumatologist;
3. 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;
4. For PJIA: Trial and failure of any two (2) of the following agents: adalimumab (adalimumab-adaz, Amjevita™, Hadlima, Humira, Yusimry), 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);
2. Prescribed by or in consultation with a pulmonologist;

**Approval Duration**
**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 or has been treated with this medication within the past 90 days, excluding manufacturer samples;

**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 10, 2023.
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. Accessed April 8th, 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. Accessed April 8th, 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. Accessed April 8th, 2024.
5. 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) Accessed April 8th, 2024.
6. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Non-Systemic Polyarthritis, Sacroiliitis, and Enthesitis (nih.gov). Accessed April 8th, 2024.


| Review/Revision History | Review/Revision Date | P&T Approval Date |
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| 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<br>1. Dosing Information, Maximum Dose, Actemra: Updated maximum dosing information from general dosing to weight based dosing for indication PJIA and SJIA.<br>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 | 02/10/2022 | 04/18/2022 |

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| contraindicated or clinically significant adverse effects are experienced: Humira®, Cimzia®, Inflectra®, Rinvoq™, Renflexis™, Simponi®, Simponi Aria®, or Xeljanz®/ Xeljanz XR®".<br>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 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;<br>4. Initial Approval Criteria, I.C: Updated to include new criteria pertaining to indication SJIA.<br>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.<br>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):<br>a. Intravenous: Weight < 30 kg: 12 mg/kg every 2 weeks; ≥ 30 kg: 8 mg/kg every 2 weeks<br>b. Subcutaneous: Weight < 30 kg: 162 mg every 2 weeks; ≥ 30 kg: 162 mg every weeks;<br>7. Initial Approval Criteria, I.D: Updated to remove approval criteria for Juvenile Idiopathic Arthritis.<br>8. Appendix B, Drug Name: Updated to include brand-name therapeutic alternative of other biological DMARDs.<br>9. Disclaimer about contraindications "Contraindications listed reflect statements made in the manufacturer's package insert..." was added to Appendix C.<br>10. Appendix D, General Information: Updated to remove information regarding: (a, b and c )<br>a. Rheumatoid Arthritis;<br>b. Definition of failure of MTX or DMARDs;<br>c. Examples of positive response to therapy.<br>11. References were reviewed and updated. | | |

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| Policy was reviewed:<br>1. 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."<br>2. Initial Approval Criteria, I.A.5 and I.C.5: Updated trial and failure criteria to include drug Enbrel®.<br>3. References were reviewed and updated. | 10/03/2022 | 10/19/2022 |
| Policy was reviewed:<br>1. Initial Approval Criteria I.C.5: Updated to add Xeljanz® in the trial and fail criteria.<br>2. Initial Approval Criteria I.A.5: Updated to add *Trial of Xeljanz/XR®, Rinvoq® requires inadequate response to one or more TNF inhibitors<br>3. Initial Approval Criteria I.C.5: Updated to add *Trial of Xeljanz® requires inadequate response to one or more TNF inhibitors<br>4. References were reviewed and updated. | 01/03/2023 | 01/17/2023 |
| Policy was reviewed:<br>1. Background: Updated to include new indication coronavirus disease 2019 (COVID-19).<br>2. Dosing Information, Indication: Updated to include new indication coronavirus disease 2019 (COVID-19).<br>3. Initial Approval Criteria I.A, I.C: Updated to add Amjevita™ as one of trial and failure criteria alternative drug.<br>4. Initial Approval Criteria, I.F: Updated to include approval criteria for indication, Coronavirus Disease 2019 (COVID-19).<br>5. Continued Therapy Approval Criteria II.B.: Updated to include approval criteria for indication, Coronavirus Disease 2019 (COVID-19).<br>6. Appendix A: Updated to include abbreviations ECMO.<br>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.<br>8. Appendix B, Maximum Dose, methotrexate: Updated maximum dose information from 30 | 03/06/2023 | 04/13/20223 |

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| 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.<br>9. Appendix B, Maximum Dose, methotrexate: Updated maximum dose information from 30 mg/week to 20 mg/week for indication RA.<br>10. References were reviewed and updated. | | |
| Policy was reviewed. | 10/19/2023 | 10/19/2023 |
| Policy was reviewed:<br>1. Updated trial and failure criteria to include Humira biosimilar.<br>2. Removed age criteria.<br>3. Removed dosing criteria.<br>4. Updated Approval duration.<br>5. Removed reauthorization requirement for positive response to therapy.<br>6. References were reviewed and updated. | 11/10/2023 | 02/28/2024 |
| Policy was reviewed:<br>1. I.A.3 Removed up to maximally indicated doses and exception of DMARD use<br>2. I.B. Added “Temporal Arteritis” for completion and correspondence to Micromedex<br>3. I.B.3 Removed up to maximally indicated doses and azathioprine (UpToDate), removed trial of 3 month minimum per guidelines<br>4. I.C.3 Removed up to maximally indicated doses and exception for DMARD use, removed trial of 3 month minimum per guidelines<br>5. Cytokine release syndrome indication was removed. Applies only to IV formulation which is non-formulary.<br>6. COVID indication was removed. Applies only to IV formulation which is nonformulary. | 4/1/2024 | 2/28/2024 |