

Clinical Policy Title:	anakinra
Policy Number:	RxA.739
Drug(s) Applied:	Kineret®
Original Policy Date:	04/18/2022
Last Review Date:	12/11/2025
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 ≥ 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 the following agents, unless contraindicated or clinically significant adverse effects are experienced (a, b, and c):
 - a. Two (2) of the following agents: adalimumab (Abrilada™, Hadlima™ or adalimumab-aaty), Cimzia®, Enbrel®, Rinvoq®, Simponi®/ Simponi Aria®, or Xeljanz®/ XR;
 - b. Actemra;
 - c. Orencia.

Approval Duration

All Lines of Business (except Medicare): 12 months

B. Neonatal-Onset Multisystem Inflammatory Disease (must meet all):

1. Diagnosis of neonatal- onset multisystem inflammatory disease (NOMID) or chronic infantile neurological, cutaneous and articular syndrome (CINCA).

Approval duration

All Lines of Business (except Medicare): 12 months

C. Deficiency of Interleukin-1 Receptor Antagonist (DIRA) (must meet all):

1. Diagnosis of Deficiency of Interleukin-1 Receptor Antagonist.

Approval duration

All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. All Indications in Section I:

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

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.

References

1. Aletaha D, Neogi T, Silman AJ, et al. 2010 Rheumatoid Arthritis Classification Criteria: an american college of rheumatology/european league against rheumatism collaborative initiative. Arthritis and Rheumatism September 2010;62(9):2569-2581. Available at: <https://pubmed.ncbi.nlm.nih.gov/20872595/>. Accessed November 25, 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
<p>Drug specific policy for Kineret® was created based on RxA.592.Biologic_DMARDs:</p> <ol style="list-style-type: none"> 1. 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®". 2. Initial Approval Criteria, I.A.5: Updated to include new trial and failure criteria Members meets both (a AND b): <ol style="list-style-type: none"> a. Trial and failure of at least two (2) of the following agents: Humira®, Cimzia®, Rinvoq®, Simponi® or Xeljanz®/ XR unless contraindicated or clinically significant adverse effects are experienced; <ul style="list-style-type: none"> *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; b. Trial and failure of both Actemra® & Orencia® unless contraindicated or clinically significant adverse effects are experienced; 3. References were reviewed and updated. 	02/14/2022	04/18/2022
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Initial Approval Criteria, I.A.5.a: Updated trial and failure criteria to include drug Enbrel® and Simponi Aria®. 2. Initial Approval Criteria, I.A.5.a: Updated to remove exception about trial and failure criteria "*Exception: If a total of two TNF 	10/03/2022	10/19/2022

<p>inhibitors (Humira®, Cimzia®, Simponi®/ Simponi Aria®, Enbrel®) has previously been tried and failed, trial of a third TNF inhibitor is not required."</p> <p>3. References were reviewed and updated.</p>		
<p>Policy was reviewed:</p> <p>1. Initial Approval Criteria, I.A.5.a: Updated trial and failure criteria to include new drug Amjevita™.</p> <p>2. References were reviewed and updated.</p>	04/04/2023	04/13/2023
<p>Policy was reviewed.</p>	10/19/2023	10/19/2023
<p>Policy was reviewed:</p> <p>1. Updated approval duration.</p> <p>2. References were reviewed and updated.</p>	12/20/2023	01/01/2024
<p>Policy was reviewed.</p>	3/15/2024	3/15/2024
<p>Policy was reviewed:</p> <p>1. Removed prescriber restrictions.</p> <p>2. Updated adalimumab biosimilars.</p> <p>3. Updated Continued therapy approval to "Member is currently receiving medication that has been authorized.."</p> <p>4. References were reviewed and updated.</p>	11/25/2024	12/05/2024
<p>Policy reviewed.</p>	12/11/2025	12/11/2025