

Clinical Policy Title:	sarilumab
Policy Number:	RxA.738
Drug(s) Applied:	Kevzara®
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) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
3. Trial and failure of the following, 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. Polymyalgia rheumatica (PMR) (must meet all):

1. Diagnosis of Polymyalgia rheumatica (PMR);
2. Trial and failure of corticosteroids at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced.

Approval Duration

All Lines of Business (except Medicare): 12 months

C. Polyarticular Juvenile Idiopathic Arthritis (pJIA) (must meet all):

1. Diagnosis of Polyarticular Juvenile Idiopathic Arthritis (pJIA) who weigh 63 kg or greater.

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 medication that has been authorized by RxAdvance or the member has met initial approval criteria.

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

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.Biologics_DMARDs	01/05/2022	04/18/2022
<p>Drug specific policy for Kevzara® 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 trial and failure prior criteria Failure of two of the following, each used for ≥ 3 months, unless contraindicated or clinically significant adverse effects are experienced: Cimzia®, Humira®, Inflectra®, Otezla®, Renflexis™, Skyrizi™, Stelara®, Taltz®; 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®/ Simponi Aria®, or Xeljanz®/ XR unless contraindicated or clinically significant adverse effects are experienced; <p>*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> <ol style="list-style-type: none"> b. Trial and failure of both Actemra® & Orencia® unless contraindicated or clinically significant adverse effects are experienced; 3. References were reviewed and updated. 	02/11/2022	04/18/2022
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Removed Exception criteria from trial and failure for Rheumatoid Arthritis. 2. References were reviewed and updated. 	12/20/2023	01/01/2024

<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Removed prescriber restrictions. 2. Updated adalimumab biosimilars. 3. Updated Continued therapy approval to “Member is currently receiving medication that has been authorized..” 4. New Indication added, Polyarticular Juvenile Idiopathic Arthritis (pJIA). 5. References were reviewed and updated. 	<p>11/25/2024</p>	<p>12/05/2024</p>
<p>Policy reviewed.</p>	<p>12/11/2025</p>	<p>12/11/2025</p>