Clinical Policy Title:	anakinra
Policy Number:	RxA.739
Drug(s) Applied:	Kineret®
Original Policy Date:	04/18/2022
Last Review Date:	03/15/2024
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 ≥ 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 the following agents, unless contraindicated or clinically significant adverse effects are experienced (a, b, and c):
   a. Two (2) of the following agents: adalimumab (adalimumab-adaz, Amjevita™, Hadlima, Humira, Yusimry), 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);
2. Prescribed by or in consultation with a rheumatologist;

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

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 December 20, 2023.

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 Kineret® was created based on RxA.592.Biologic_DMARDs: 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): a. Trial and failure of at least two (2) of the follwoing agents: Humira®, Cimzia®, Rinvoq®, Simponi® 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; 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
Policy was reviewed: 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	10/03/2022	10/19/2022

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." 3. References were reviewed and updated.		
Policy was reviewed: 1. Initial Approval Criteria, I.A.5.a: Updated trial and failure criteria to include new drug Amjevita™. 2. References were reviewed and updated.	04/04/2023	04/13/2023
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Updated approval duration. 2. References were reviewed and updated.	12/20/2023	01/01/2024
Policy was reviewed.	3/15/2024	3/15/2024