

Clinical Pharmacy Program Guidelines for Kevzara

Program	Prior Authorization
Medication	Kevzara (sarilumab)
Markets in Scope	California, Hawaii, Maryland, Nevada, New Jersey, New York, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	10/2017
Pharmacy and Therapeutics Approval Date	5/2020
Effective Date	7/2020

1. Background:

Kevzara is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to one or more disease-modifying anti-rheumatic drugs (DMARDs).

2. Coverage Criteria:

<p>A. <u>Initial Authorization</u></p> <p><u>One</u> of the following:</p> <p>(a) <u>All</u> of the following:</p> <ol style="list-style-type: none"> 1. Diagnosis of moderately to severely active rheumatoid arthritis (RA) <p style="text-align: center;">-AND-</p> <ol style="list-style-type: none"> 2. History of failure to a 3 month trial of <u>one</u> non-biologic disease modifying anti-rheumatic drug (DMARD) [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine] at maximally indicated doses within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial) <p style="text-align: center;">-AND-</p> <ol style="list-style-type: none"> 3. Patient is not receiving Kevzara in combination with <u>any</u> of the following: <ol style="list-style-type: none"> a. Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
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- b. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- c. Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

4. Prescribed by or in consultation with a rheumatologist

-OR-

(b) **All** of the following:

1. Patient is currently on Kevzara therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

-AND-

2. Diagnosis of moderately to severely active RA

-AND-

3. Patient is not receiving Kevzara in combination with **any** of the following:

- a. Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- b. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- c. Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

4. Prescribed by or in consultation with a rheumatologist

Authorization will be issued for 12 months.

B. Reauthorization

1. Documentation of positive clinical response to Kevzara therapy

-AND-

2. Patient is not receiving Kevzara in combination with **any** of the following:

- a. Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- b. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- c. Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

3. Prescribed by or in consultation with a rheumatologist

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Kevzara [package insert]. Bridgewater, NJ: Sanofi-Aventis U.S. LLC, April 2018.

Program	Prior Authorization –Kevzara (sarilumab)
Change Control	
Date	Change
10/2017	New program
2/2018	Updated number of trial/fail products from three to two to account for PDL change effective 4/1/18.
7/2018	Updated reference.
3/2019	Removed prescriber check to align with other programs. Minor revisions to the non-biologic DMARD requirement to align with language in other programs.
11/2019	Annual review. Updated reference.
12/2019	Revised prerequisite therapies and added documentation of drug, date, and duration of trials. Separated continuation of therapy requirements for current users.
1/2020	Removed biologic step therapy requirement due to PDL changes.
5/2020	Added prescriber requirement. Minor update to DMARD requirement. Updated references.