Pharmacy Drug Policy & Procedure

Policy Name:	Rheumatoid Arthritis Immunomodulator Therapies	Policy #:	2747P

Purpose of the Policy

The purpose of this policy is to define the criteria for coverage of immunomodulators used in the treatment of Rheumatoid Arthritis (RA) for new starts to therapy.

Statement of the Policy

Health Alliance Medical Plans and Health Alliance Northwest will approve the use of Cimzia, covered adalimumab biosimilars, Simponi, Xeljanz/XR, Rinvoq, Actemra (Sub-Q only, for IV Actemra, please refer to Tocilizumab Products-Medical policy), Orencia, Kevzara, Enbrel, Kineret, or Olumiant under the specialty benefit when the following criteria have been met.

Covered adalimumab biosimilars (as of 10/1/2024) include: Amjevita (72511040001, 72511040002, 55513039901, 555130479**, 555130481**, 555130482**), Hadlima (78206018701, 78206018401, 78206018601, and 78206018301), Adalimumab-adaz (61314032720 and 61314032764), and Simlandi (517590402**).

Criteria

1. Coverage Criteria of Preferred Products (Cimzia, Enbrel, covered adalimumab biosimilars, Simponi, Simponi Aria)

1.1 Diagnosis of Rheumatoid Arthritis
1.2 Prescribed by a rheumatologist (musculoskeletal doctor)
1.3 Age 18 years or older
1.4 Documented failure to respond to a minimum 3 month trial, intolerance, or contraindication to a DMARD (Disease Modifying Anti-Rheumatic Drug): methotrexate, Arava (leflunomide), Plaquenil (hydroxychloroquine), or sulfasalazine

2. Coverage Criteria of Preferred Products with Single Step Edit (Rinvoq, Xeljanz/XR)

2.1 Diagnosis of rheumatoid arthritis
2.2 Ordered by a rheumatologist (musculoskeletal doctor)
2.3 Age 18 years or older
2.4 Documented failure to respond to a minimum 3 month trial, intolerance, or contraindication to a DMARD (Disease Modifying Anti-Rheumatic Drug): methotrexate, Arava (leflunomide), Plaquenil (hydroxychloroquine), or sulfasalazine
2.5 Documented failure to respond to a minimum 3 month trial, intolerance, or contraindication to one or more TNF inhibitors (such as Cimzia, Simponi, Enbrel)

3. Coverage Criteria of Non Preferred Products with Double Step Edit (Actemra Sub-Q, Orencia IV or Sub-Q)

3.1 Diagnosis of Rheumatoid Arthritis
3.2 Prescribed by a rheumatologist (musculoskeletal doctor)
3.3 Age 18 years or older

3.4 Documented failure to respond to a minimum 3 month trial, intolerance, or contraindication to a DMARD (Disease Modifying Anti-Rheumatic Drug): methotrexate, Arava (leflunomide), Plaquenil (hydroxychloroquine), or sulfasalazine

3.5 Documented failure to respond to a minimum 3 month trial, intolerance, or contraindication to any TWO of the following:

- Cimzia
- Enbrel
- Covered adalimumab biosimilars
- Simponi
- Xeljanz/XR
- Rinvoq

4. Coverage Criteria of Non Preferred Products with Quadruple Step Edit (Kevzara, Kineret, and Olumiant)

4.1 Diagnosis of Rheumatoid Arthritis

4.2 Prescribed by a rheumatologist (musculoskeletal doctor)

4.3 Age 18 years or older

4.4 Documented failure to respond to a minimum 3 month trial, intolerance, or contraindication to a DMARD (Disease Modifying Anti-Rheumatic Drug): methotrexate, Arava (leflunomide), Plaquenil (hydroxychloroquine), or sulfasalazine

4.5 Documented failure to respond to a minimum 3 month trial, intolerance, or contraindication to any TWO of the following:

- Cimzia
- Enbrel
- Covered adalimumab biosimilars
- Simponi
- Xeljanz/XR
- Rinvoq

4.6 Documented failure to respond to a minimum 3 month trial, intolerance, or contraindication to BOTH of the following:

- Actemra
- Orencia

5. Exclusion Criteria

5.1 Allergic reaction to murine proteins or humanized monoclonal antibody

5.2 Inadequate response to initial or previous therapy with requested immunomodulator

5.3 Patients with active infections, latent tuberculosis, or symptomatic or deteriorating congestive heart failure

5.4 Off-label (non FDA approved) dosing frequencies

5.5 Health Alliance Northwest does not cover more than one biologic immunomodulator at a time because of the possible increased risk for infections and other potential drug interactions

5.6 Only certain NDCs of adalimumab biosimilars will be considered for coverage, please reference statement of policy for covered NDCs

6. FDA Approved Dosages for Rheumatoid Arthritis

6.1 Cimzia: 400mg sub-q at week 0, 2, and 4, then maintenance dose of 200mg sub-q every other week or 400mg sub-q every 4 weeks

6.2 Covered adalimumab biosimilars: 40mg sub-q every other week; may increase to 40mg sub-q every week in patients not on concomitant methotrexate

6.3 Simponi: 50mg sub-q once a month (in combination with methotrexate)

6.4 Xeljanz: 5mg po twice daily
6.5 Xeljanz XR: 11mg po once daily
6.6 Rinvoq: 15mg po once daily
6.7 Actemra: < 100kg: 162mg sub-q once every other week, may be increased to 162mg sub-q once weekly based on clinical response; ≥ 100kg: 162mg sub-q once weekly
6.8 Orencia: 125mg sub-q once weekly
6.9 Kevzara: 200mg sub-q once every 2 weeks
6.10 Enbrel: 50mg sub-q once weekly
6.11 Kineret: 100mg sub-q once daily
6.12 Olumiant: 1mg po once daily

7. Approval Period

7.1 Initial Authorization will be placed for 12 months
7.2 All subsequent authorizations will be placed for 12 months, based upon clinical response to therapy

CPT Codes	
HCPCS Codes	

References

1. 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 Jul;73(7):924- 939.

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