

Policy Name:	Psoriatic Arthritis Immunomodulator Therapies	Policy #:	2751P
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Purpose of the Policy

The purpose of this policy is to define the criteria for coverage of immunomodulators used in the treatment of Psoriatic Arthritis (PsA) 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, Skyrizi, Stelara, Tremfya, Otezla, Xeljanz/XR, Rinvoq, Taltz, Orencia, Enbrel, or Cosentyx under the specialty benefit when the following criteria have been met.

Covered adalimumab biosimilars (as of 7/1/2024) include: Amjevita (72511040001, 72511040002, 55513039901, 555130479**, 555130481**, 555130482**), Hadlima (78206018701, 78206018401, 78206018601, and 78206018301), Adalimumab-adaz (61314032720 and 61314032764), and Adalimumab-adbm (005970545**, 00597055580, 00597056520, 005970575**, 00597058589, and 00597059520).

Criteria

1. Coverage Criteria of Preferred Products (Cimzia, covered adalimumab biosimilars, Enbrel, Otezla, Simponi, Simponi Aria, Skyrizi, Stelara IV or Sub-Q, Tremfya)

- 1.1 Diagnosis of Psoriatic Arthritis
- 1.2 Ordered by a rheumatologist (musculoskeletal doctor) or dermatologist (skin doctor)
- 1.3 Age 18 years or older (age 2 years or older for Simponi Aria or Enbrel, age 6 years or older for Stelara)
- 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 Psoriatic Arthritis
- 2.2 Ordered by a rheumatologist (musculoskeletal doctor) or dermatologist (skin doctor)
- 2.3 Age 18 years or older (age 2 years or older for Rinvoq)
- 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 or intolerance to one or more TNF inhibitors (such as Cimzia, Simponi, Enbrel)

3. Coverage Criteria of Non-Preferred Products with Single Step-Edit (Taltz)

- 3.1 Diagnosis of Psoriatic Arthritis
- 3.2 Ordered by a rheumatologist (musculoskeletal doctor) or dermatologist (skin 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 ONE of the following:
- Cimzia
 - Covered adalimumab biosimilars
 - Enbrel
 - Simponi
 - Stelara
 - Tremfya
 - Skyrizi
 - Rinvoq
 - Xeljanz/XR

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

- 4.1 Diagnosis of Psoriatic Arthritis
- 4.2 Ordered by a rheumatologist (musculoskeletal doctor) or dermatologist (skin doctor)
- 4.3 Age 2 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
 - Covered adalimumab biosimilars
 - Enbrel
 - Simponi
 - Stelara
 - Tremfya
 - Skyrizi
 - Rinvoq
 - Xeljanz/XR

5. Coverage Criteria of Non-Preferred Products with Quadruple Step-Edit (Cosentyx IV or Sub-Q)

- 5.1 Diagnosis of Psoriatic Arthritis
- 5.2 Ordered by a rheumatologist (musculoskeletal doctor) or dermatologist (skin doctor)
- 5.3 Age 2 years or older
- 5.4 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
- 5.5 Documented failure to respond to a minimum 3 month trial, intolerance, or contraindication to any TWO of the following:
- Cimzia
 - Covered adalimumab biosimilars
 - Enbrel
 - Simponi

- Skyrizi
- Stelara
- Tremfya
- Xeljanz/XR
- Rinvoq

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

- Taltz
- Orencia

6. Exclusion Criteria

- 6.1 Allergic reaction to murine proteins or humanized monoclonal antibody
- 6.2 Inadequate response to initial or previous therapy with requested immunomodulator
- 6.3 Patients with active infections, latent tuberculosis, or symptomatic or deteriorating congestive heart failure
- 6.4 Off-label (non FDA approved) dosing frequencies
- 6.5 Health Alliance Northwest does not cover more than one biologic immunomodulatory at a time because of possible increased risk for infections and potential drug interactions
- 6.6 Only certain NDCs of adalimumab biosimilars will be considered for coverage, please reference statement of policy for covered NDCs

7. FDA Approved Dosages for Psoriatic Arthritis

- 7.1 Cimzia: 400mg sub-q on weeks 0, 2, and 4, then 200mg sub-q every other week; may consider maintenance dose of 400mg sub-q every 4 weeks
- 7.2 Covered adalimumab biosimilars: 40mg sub-q every other week
- 7.3 Simponi: 50mg sub-q once a month
- 7.4 Stelara: 45mg sub-q at weeks 0, 4, and then every 12 weeks thereafter
- 7.5 Tremfya: 100mg sub-q at weeks 0, 4, and then every 8 weeks thereafter
- 7.6 Otezla: Day 1 – 10mg po in the morning; Day 2 – 10mg po twice daily; Day 3 – 10mg po in the morning and 20mg po in the evening; Day 4 – 20mg po twice daily; Day 5 – 20mg po in the morning and 30mg po in the evening; then maintenance dose of 30mg po twice daily
- 7.7 Xeljanz: 5mg po twice daily
- 7.8 Xeljanz XR: 11mg po once daily
- 7.9 Taltz: 160mg sub-q once, followed by 80mg sub-q every 4 weeks
- 7.10 Orencia: 125mg once weekly
- 7.11 Enbrel: 50mg sub-q once weekly or 25mg sub-q twice weekly
- 7.12 Cosentyx: 150mg to 300mg sub-q every 4 weeks with or without a loading dose. 1.75 mg/kg IV every 4 weeks with or without a loading dose
- 7.13 Rinvoq: 15mg po once daily
- 7.14 Skyrizi: 150mg sub-q at weeks 0, 4, and then every 12 weeks

8. Approval Period

- 8.1 Initial Authorization will be placed for 12 months
- 8.2 All subsequent authorizations will be placed for 12 months, based upon clinical response to therapy

CPT Codes

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HCPCS Codes

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References

1. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. *Arthritis Rheumatol*. 2019 Jan;71(1):5-32.
2. American Academy of Dermatology Work Group, Menter A, Korman NJ, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: section 6. Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. *J Am Acad Dermatol* 2011; 65:137.

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DISCLAIMER

This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.