Pharmacy Drug Policy & Procedure

Policy Name:	Polyarticular Juvenile Idiopathic Arthritis Immunomodulator Therapies	Policy #:	2746P

Purpose of the Policy

The purpose of this policy is to define the criteria for coverage of immunomodulators used in the treatment of Polyarticular Juvenile Idiopathic Arthritis (PJIA) for new starts to therapy.

Statement of the Policy

Health Alliance Medical Plans will approve the use of covered adalimumab biosimilars, Simponi Aria, Cimzia, Xeljanz, Rinvoq, Actemra (Sub-Q only, for IV Actemra, please refer to Tocilizumab Products-Medical policy), Orencia, Enbrel, or Kineret 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 (covered adalimumab biosimilars, Simponi Aria, Enbrel, Cimzia)

1.1 Diagnosis of Polyarticular Juvenile Idiopathic Arthritis
1.2 Ordered by a Rheumatologist (musculoskeletal doctor)
1.3 Age 2 years or older
1.4 Documented failure to respond to a minimum 3-month trial, intolerance, or contraindication to methotrexate

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

2.1 Diagnosis of Polyarticular Juvenile Idiopathic Arthritis
2.2 Ordered by a Rheumatologist (musculoskeletal doctor)
2.3 Age 2 years or older
2.4 Documented failure to respond to a minimum 3-month trial, intolerance, or contraindication to methotrexate
2.5 Documented failure to respond to a minimum 3-month trial, intolerance, or contraindication to one or more TNF inhibitors (e.g. Enbrel)

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

3.1 Diagnosis of Polyarticular Juvenile Idiopathic Arthritis
3.2 Ordered by a Rheumatologist (musculoskeletal doctor)
3.3 Age 2 years or older
3.4 Documented failure to respond to a minimum 3-month trial, intolerance, or contraindication to methotrexate
3.5 Documented failure to respond to a minimum 3-month trial, intolerance, or contraindication to any TWO of the following:
- Covered adalimumab biosimilars

- Enbrel
- Cimzia
- Xeljanz
- Rinvoq

4. Coverage Criteria of Non-Preferred Products with Quadruple Step Edit (Kineret)

4.1 Diagnosis of Polyarticular Juvenile Idiopathic Arthritis
4.2 Ordered by a Rheumatologist (musculoskeletal doctor)
4.3 Age 2 years or older
4.4 Documented failure to respond to a minimum 3-month trial, intolerance, or contraindication to methotrexate
4.5 Documented failure to respond to a minimum 3-month trial, intolerance, or contraindication to Actemra and Orencia and TWO of the following:
- Covered adalimumab biosimilars
- Enbrel
- Cimzia
- Xeljanz
- Rinvoq

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 does not cover more than one 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 Polyarticular Juvenile Idiopathic Arthritis

6.1 Covered adalimumab biosimilars: 10kg to < 15kg: 10mg sub-q every other week; 15kg to < 30kg: 20mg sub-q every other week; ≥ 30kg: 40mg sub-q every other week
6.2 Simponi Aria: 80mg/m^2/dose at weeks 0, 4, and then every 8 weeks thereafter
6.3 Cimzia: 3 loading doses then 10kg to< 20kg: 50mg sub-q every 2 weeks; 20kg to< 40kg: 100mg sub-q every 2 weeks; 2: ≥40kg: 200mg sub-q every 2 weeks
6.4 Xeljanz: 10kg to < 20kg: 3.2mg bid; 20kg to < 40kg: 4mg bid; ≥ 40kg: 5mg bid
6.5 Rinvoq: 10kg to < 20kg: 3mg bid; 20kg to < 30kg: 4mg bid; ≥ 30kg: 6mg bid or 15mg qd ER tablet
6.6 Actemra: <30kg: 162mg sub-q once every 3 weeks; ≥ 30kg: 162mg sub-q once every 2 weeks
6.7 Orencia: 10kg to < 25kg: 50mg sub-q once weekly; ≥ 25kg to < 50kg: 87.5mg sub-q once weekly; ≥ 50kg: 125mg sub-q once weekly
6.8 Enbrel: < 63kg: 0.8mg/kg/dose (up to a maximum of 50mg/dose) su-q once weekly; ≥ 63kg: 50mg sub-q once weekly
6.9 Kineret: 1 to 2 mg/kg/dose once doing; maximum initial dose 100mg; maximum daily dose 200mg

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. Onel KB, Horton DB, Lovell DJ, et al. 2021 American College of Rheumatology Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Oligoarthritis, Temporomandibular Joint Arthritis, and Systemic Juvenile Idiopathic Arthritis. Arthritis Rheumatol. 2022 Apr;74(4):553-569.
2. Ringold S, Weiss PF, Colbert RA, et al. Childhood Arthritis and Rheumatology Research Alliance consensus treatment plans for new-onset polyarticular juvenile idiopathic arthritis. Arthritis Care Res (Hoboken). 2014 Jul;66(7):1063-72.

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