Pharmacy Drug Policy & Procedure

Policy Name:	Ankylosing Spondylitis Immunomodulator Therapies	Policy #:	2745P

Purpose of the Policy

The purpose of this policy is to define the criteria for coverage of immunomodulators used in the treatment of ankylosing spondylitis (AS) for new starts to therapy.

Statement of the Policy

Health Alliance Medical Plans will approve the use of Cimzia, covered adalimumab biosimilars, Rinvoq, Simponi, Xeljanz, Taltz, Enbrel, Bimzelx, or Cosentyx under the specialty benefit when the following criteria have been met.

Please refer to most recent formulary file for covered adalimumab biosimilars.

Criteria

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

1.1 Diagnosis of ankylosing spondylitis or other spondyloarthropathy (any of a family of long-term, or chronic diseases of joints)
1.2 Ordered by a Rheumatologist (musculoskeletal doctor)
1.3 Age 18 years or older
1.4 Documented failure, intolerance, or contraindication to at least two formulary anti-inflammatory drugs during a single three month period (celecoxib, diclofenac, others)

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

2.1 Diagnosis of ankylosing spondylitis or other spondyloarthropathy (any of a family of long-term, or chronic diseases of joints)
2.2 Ordered by a Rheumatologist (musculoskeletal doctor)
2.3 Age 18 years or older
2.4 Documented failure, intolerance, or contraindication to at least two formulary anti-inflammatory drugs during a single three month period (celecoxib, diclofenac, others)
2.5 Documented failure to respond to a minimum 3 month trial, intolerance, or contraindication to ONE or more TNF inhibitors (such as Cimzia, Enbrel, Simponi, etc)

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

3.1 Diagnosis of ankylosing spondylitis or other spondyloarthropathy
3.2 Ordered by a Rheumatologist (musculoskeletal doctor)
3.3 Age 18 years or older
3.4 Documented failure, intolerance, or contraindication to at least two formulary anti-inflammatory

drugs during a single three month period.

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
- Rinvoq
- Xeljanz/XR

4. Coverage Criteria of Non-Preferred Products with Triple Step Edit (Bimzelx, Cosentyx IV or Sub-Q)

4.1 Diagnosis of ankylosing spondylitis or other spondyloarthropathy (any of a family of long-term, or chronic diseases of joints)

4.2 Ordered by a Rheumatologist (musculoskeletal doctor)

4.3 Age 18 years or older

4.4 Documented failure, intolerance, or contraindication to at least two formulary anti-inflammatory drugs during a single three month period (celecoxib, diclofenac, others)

4.5 Documented failure to respond to a minimum 3 month trial, intolerance, or contraindication to TWO of the following:
- Cimzia
- Covered adalimumab biosimilars
- Enbrel
- Simponi
- Rinvoq
- Xeljanz/XR

4.6 Documented failure to respond to a minimum 3 month trial, intolerance, or contraindication to Taltz

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 therapy with more than one biologic immunomodulator medication at one time because of the possible increased risk for infections and other drug

5.6 Only certain NDCs of adalimumab biosimilars will be considered for coverage, please reference most recent formulary file for covered NDCs

6. FDA Approved Dosages for Ankylosing Spondylitis

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

6.3 Simponi: 50mg sub-q once a month

6.4 Xeljanz: 5mg orally twice daily

6.5 Xeljanz XR: 11mg orally once daily

6.6 Taltz: 160mg sub-q once, followed by 80mg sub-q every 4 weeks

6.7 Enbrel: 50mg sub-q once weekly

6.8 Bimzelx: 160mg sub-q once every 4 weeks

6.9 Cosentyx:
- 150mg sub-q at week 0, 1, 2, 3, and 4, followed by 150mg sub-q every 4 weeks; dose may be

increased to 300mg sub-q every 4 weeks if needed
- 6mg/kg IV at week 0, followed by 1.75mg/kg every 4 weeks (max 300,g per infusion)

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. Ward MM, Deodhar A, Akl EA, et al. American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network 2015 Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. Arthritis Rheumatol. 2016;68(2):282. Epub 2015 Sep 24.

Created Date: 04/01/20
Effective Date: 04/01/20
Posted to Website: 01/01/22
Revision Date: 04/02/25