Pharmacy Drug Policy & Procedure

Policy Name:	Adalimumab Products	Policy #:	1843P

Purpose of the Policy

The purpose of this policy is to establish the criteria for coverage of formulary adalimumab biosimilars.

Statement of the Policy

Health Alliance Medical Plans will approve the use of formulary adalimumab biosimilars under the specialty pharmacy benefit when the criteria below have been met. Please see most recent formulary file for the most accurate list of covered biosimilars.

Brand Humira products are excluded from coverage as of 7/1/2024 due to the availability of adalimumab biosimilars. Biosimilars do not have any clinically meaningful differences in efficacy. Patients who have switched to a biosimilar and are experiencing side effects should be routed to a different formulary biosimilar product.

Criteria

1. Coverage Criteria for Pediatric Crohn's Disease and Active Adult Crohn's Disease

1.1 See Crohn's Disease Immunomodulator Therapies policy

2. Coverage Criteria for Rheumatoid Arthritis

2.1 See Rheumatoid Arthritis Immunomodulator Therapies policy

3. Coverage Criteria for Juvenile Idiopathic Arthritis

3.1 See Polyarticular Juvenile Idiopathic Arthritis Immunomodulator policy

4. Coverage Criteria for Plaque Psoriasis

4.1 See Plaque Psoriasis Immunomodulator Therapies policy

5. Coverage Criteria for Active Psoriatic Arthritis

5.1 See Psoriatic Arthritis Immunomodulator Therapies policy

6. Coverage Criteria for Ankylosing Spondylitis and Other Spondyloarthropathies

6.1 See Ankylosing Spondylitis Immunomodulator Therapies policy

7. Coverage Criteria for Ulcerative Colitis

7.1 See Ulcerative Colitis Immunomodulator Therapies policy

8. Coverage Criteria for Hidradenitis Suppurativa

8.1 See Hidradenitis Suppurativa Immunomodulator Therapies policy

9. Coverage Criteria for Arthritis Associated with Hidradenitis Suppurativa

9.1 Diagnosis of Arthritis associated with Hidradenitis Suppurativa

9.2 Prescribed by a rheumatologist (musculoskeletal doctor)

9.3 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

10. Coverage Criteria for Uveitis

10.1 Diagnosis of Uveitis

10.2 Prescribed by an ophthalmologist (eye doctor) or a specialist in the treatment of uveitis
10.3 Documented failure to respond to topical glucocorticoids (such as prednisolone eye drops)
10.4 Documented failure to respond to systemic glucocorticoids or immunosuppressive agents (such as prednisone or methotrexate)

11. Coverage Criteria for Pyoderma Gangrenosum

11.1 Ordered by a specialist
11.2 Diagnosis of refractory pyoderma gangrenosum not responding to standard therapy (such as prednisone or cyclosporine)

12. Exclusion Criteria

12.1 Allergic reaction to murine proteins or humanized monoclonal antibody
12.2 Inadequate response to initial or previous adalimumab therapy
12.3 Patients with active infections, latent tuberculosis, or symptomatic or deteriorating congestive heart failure
12.4 Health Alliance does not cover more than one immunomodulator at a time because of the possible increased risk for infections and potential drug interactions
12.5 Off-label (non-FDA-Approved) dosing frequencies
12.6 Only certain NDCs of adalimumab biosimilars will be considered for coverage, please reference statement of policy for covered NDCs

13. FDA Approved Dosages

13.1 Ankylosing spondylitis/psoriatic arthritis/juvenile idiopathic arthritis: 40 mg every other week
13.2 Crohn's: 160 mg day 1, 80 mg at week 2, and 40 mg every other week starting week 4, can go up to every week for maintenance therapy
13.3 Pediatric Crohn's: 80 mg (17kg to <40kg) or 160 mg (>40 kg) day 1, 80 mg at week 2, and 40 mg every other week starting week 4, can go up to every week for maintenance therapy
13.4 Ulcerative Colitis: 160 mg day 1, 80 mg at week 2, and 40 mg every other week starting week 4
13.5 Plaque psoriasis: 80 mg initial dose, 40 mg every other week starting 1 week after initial dose
13.6 Psoriatic arthritis: 40 mg every other week
13.7 Rheumatoid arthritis: 40 mg every other week; may increase to 40 mg every week in patients not on concomitant methotrexate
13.8 Hidradenitis suppurativa: 160mg given on day 1 or split and given over 2 consecutive days, then 80 mg 2 weeks later, then 40mg every week or 80mg every other week beginning on day 29
13.9 Pyoderma gangrenosum: 40 to 80mg every week or every other week
13.10 Uveitis: 80mg as a single dose, then 40mg every other week beginning one week after initial dose
13.11 Juvenile idiopathic arthritis: 10kg to <15kg: 10mg every other week; 15kg to < 30kg: 20mg every other week; ≥ 30kg: 40kg every other week

14. Approval Time

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

CPT Codes	

HCPCS Codes	

References

1. Alexander KL, Dul MW, Lalle PA, et al. Optometric Clinical Practice Guideline: Care of the Patient with Anterior Uveitis. American Optometric Association. 2010.
2. Janowska A, Oranges T, Fissi A, et al. PG-TIME: A practical approach to the clinical management of pyoderma gangrenosum. Dermatol Ther. 2020 May;33(3):e13412.

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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.