Mass General Brigham
Health Plan

Humira and Biosimilars (adalimumab)
Effective 04/01/2024

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693 **Non-Specialty Medications** All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	N/A		

Overview
Adalimumab is a recombinant monoclonal antibody that binds to human tumor necrosis factor alpha (TNF-alpha), thereby interfering with binding to TNFα receptor sites and subsequent cytokine-driven inflammatory processes.

Preferred	Non-Preferred*
Humira (Abbvie)	Amjevita
Hadlima	Cyltezo
Adalimumab-adaz	Hyrimoz
Adalimumab-fkjp	Abrilada
	Hulio
	Humira (Cordavis)
	Idacio
	Yuflyma
	Yusimry

*These products are considered non-formulary

Coverage Guidelines
Authorization may be granted for members who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs
OR
Authorizations may be granted for members who meet all diagnosis-specific criteria and documentation has been provided.

1. Moderately to severely active rheumatoid arthritis (RA)

a. The member has a minimum duration of 3-month trial and failure, contraindication, or intolerance to ONE of the following conventional therapies at maximally tolerated doses:
    i. Methotrexate
    ii. Leflunomide
    iii. Sulfasalazine
b. For Amjevita, Cyltezo, Hyrimoz, Abrilada, Hulio, Humira (Cordavis), Idacio, Yuflyma, and Yusimry: Member must have had prior use, intolerance, or contraindication to TWO of the following:
    i. Humira (Abbvie)
    ii. Hadlima
    iii. Adalimumab-adaz
    iv. Adalimumab-fkjp

2. Moderately to severely active polyarticular juvenile idiopathic arthritis (pJIA)

a. The member has a minimum duration of 6-week trial and failure, contraindication, or intolerance to ONE of the following conventional therapies at maximally tolerated doses
    i. Leflunomide
    ii. methotrexate
b. For Amjevita, Cyltezo, Hyrimoz, Abrilada, Hulio, Humira (Cordavis), Idacio, Yuflyma, and Yusimry: Member must have had prior use, intolerance, or contraindication to TWO of the following:
    i. Humira (Abbvie)
    ii. Hadlima
    iii. Adalimumab-adaz
    iv. Adalimumab-fkjp

3. Active psoriatic arthritis (PsA)

a. The member meets ONE of the following:
    i. Actively inflamed joints
    ii. Dactylitis
    iii. Enthesitis
    iv. Axial disease
    v. Active skin and/or nail involvement
b. For Amjevita, Cyltezo, Hyrimoz, Abrilada, Hulio, Humira (Cordavis), Idacio, Yuflyma, and Yusimry: Member must have had prior use, intolerance, or contraindication to TWO of the following:
    i. Humira (Abbvie)
    ii. Hadlima
    iii. Adalimumab-adaz
    iv. Adalimumab-fkjp

4. Active ankylosing spondylitis (AS) or nonradiographic axial spondyloarthritis (nr-axSpA)

a. Member has minimal duration of 1-month trial and failure, contraindication, or intolerance to TWO different non-steroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen) at maximally tolerated doses.
b. For Amjevita, Cyltezo, Hyrimoz, Abrilada, Hulio, Humira (Cordavis), Idacio, Yuflyma, and Yusimry: Member must have had prior use, intolerance, or contraindication to TWO of the following:
    i. Humira (Abbvie)
    ii. Hadlima
    iii. Adalimumab-adaz
    iv. Adalimumab-fkjp

5. **Moderately to severely active Crohn's disease (CD)**
    a. ONE of the following:
        i. Frequent diarrhea and abdominal pain
        ii. At least 10% weight loss
        iii. Complications such as obstruction, fever, abdominal mass
        iv. Abnormal lab values (e.g., C-reactive protein [CRP])
        v. CD Activity Index (CDAI) great than 220
    b. Member has had trial and failure, intolerance, or contraindication to ONE of the following conventional therapies
        i. 6-mercaptopurine
        ii. Azathioprine
        iii. Corticosteroids (e.g., prednisone)
        iv. methotrexate
    c. For Amjevita, Cyltezo, Hyrimoz, Abrilada, Hulio, Humira (Cordavis), Idacio, Yuflyma, and Yusimry: Member must have had prior use, intolerance, or contraindication to TWO of the following:
        i. Humira (Abbvie)
        ii. Hadlima
        iii. Adalimumab-adaz
        iv. Adalimumab-fkjp

6. **Moderately to severely active ulcerative colitis (UC)**
    a. ONE of the following:
        i. Greater than 6 stools per day
        ii. Frequent blood in stools
        iii. Frequent urgency
        iv. Presence of ulcers
        v. Abnormal lab values (e.g., hemoglobin, ESR, CRP)
        vi. Dependent on, or refractory to, corticosteroids
    b. Member has had trial and failure, intolerance, or contraindication to ONE of the following conventional therapies
        i. 6-mercaptopurine
        ii. Aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine)
        iii. Azathioprine
        iv. Corticosteroids (e.g., prednisone)
    c. For Amjevita, Cyltezo, Hyrimoz, Abrilada, Hulio, Humira (Cordavis), Idacio, Yuflyma, and Yusimry: Member must have had prior use, intolerance, or contraindication to TWO of the following:
        i. Humira (Abbvie)
        ii. Hadlima
        iii. Adalimumab-adaz
        iv. Adalimumab-fkjp

7. **Moderate to severe chronic plaque psoriasis (PsO)**
    a. Member has at least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected
    b. Member meets ONE of the following criteria:
        i. Minimum duration of 4-week trial and failure, contraindication, or intolerance to ONE of the following topical therapies

I. Corticosteroids (e.g., betamethasone, clobetasol)
II. Vitamin D analogs (e.g., calcitriol, calcipotriene)
III. Tazarotene
IV. Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
V. Anthralin
VI. Coal tar

ii. Member has severe psoriasis that warrants a biologic DMARD as first-line therapy.

c. For Amjevita, Cyltezo, Hyrimoz, Abrilada, Hulio, Humira (Cordavis), Idacio, Yuflyma, and Yusimry: Member must have had prior use, intolerance, or contraindication to TWO of the following:
   i. Humira (Abbvie)
   ii. Hadlima
   iii. Adalimumab-adaz
   iv. Adalimumab-fkjp

8. Moderate to severe hidradenitis suppurativa

a. Authorization may be granted for treatment of moderate to severe hidradenitis suppurativa (Hurley state II or III)
b. For Amjevita, Cyltezo, Hyrimoz, Abrilada, Hulio, Humira (Cordavis), Idacio, Yuflyma, and Yusimry: Member must have had prior use, intolerance, or contraindication to TWO of the following:
   i. Humira (Abbvie)
   ii. Hadlima
   iii. Adalimumab-adaz
   iv. Adalimumab-fkjp

9. **Non-infectious Uveitis**

a. Uveitis is classified as ONE of the following:
   i. Intermediate
   ii. Posterior
   iii. Panuveitis
b. For Amjevita, Cyltezo, Hyrimoz, Abrilada, Hulio, Humira (Cordavis), Idacio, Yuflyma, and Yusimry: Member must have had prior use, intolerance, or contraindication to TWO of the following:
   i. Humira (Abbvie)
   ii. Hadlima
   iii. Adalimumab-adaz
   iv. Adalimumab-fkjp

<u>Continuation of Therapy</u>

Reauthorizations for all diagnoses will be granted when documentation is submitted supporting improvement in member's condition as evidenced by low disease activity or improvement in signs and symptoms of the condition.

Limitations

1. Approvals will be granted for 24 months

References

1. Humira (adalimumab) [prescribing information]. North Chicago, IL: AbbVie Inc; March 2020
2. van der Heijde D, Ramiro S, Landewe R, et al. 2016 Update of the international ASAS-EULAR management recommendations for axial spondyloarthritis. Ann Rheum Dis. 2017;0:1-14.

3. Smolen JS, Landewé R, Billsma J, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2016 update. Ann Rheum Dis. 2017; 0:1-18.
4. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Rheumatol. 2016;68(1)1-26.
5. Saag KG, Teng GG, Patkar NM, et al. American College of Rheumatology 2008 recommendations for the use of nonbiologic and biologic disease-modifying antirheumatic drugs in rheumatoid arthritis. Arthritis Rheum. 2008;59(6):762-784.
6. Beukelman T, Patkar NM, Saag KG, et al. 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: initiation and safety monitoring of therapeutic agents for the treatment of arthritis and systemic features. Arthritis Care Res. 2011;63(4):465-482.
7. Gossec L, Smolen JS, Ramiro S, et al. European League Against Rheumatism (EULAR) recommendations for the management of psoriatic arthritis with pharmacological therapies; 2015 update. Ann Rheum Dis. 2016;75(3):499-510.
8. Gladman DD, Antoni C, P Mease, et al. Psoriatic arthritis: epidemiology, clinical features, course, and outcome. Ann Rheum Dis 2005;64(Suppl II): ii14–ii17.
9. Zouboulis CC, Okun MM, Prens EP, et al. Long-term adalimumab efficacy in patients with moderate-to-severe hidradenitis suppurativa/acne inversa: 3-year results of a phase 3 open-label extension study. J Am Acad Dermatol 2019; 80:60
10. Braun J, van den Berg R, Baraliakos X, et al. 2010 update of the ASAS/EULAR recommendations for the management of ankylosing spondylitis. Ann Rheum Dis 2011; 70:896–904.
11. Landewé R, Sieper J, Mease P, et al. Efficacy and safety of continuing versus withdrawing adalimumab therapy in maintaining remission in patients with non-radiographic axial spondyloarthritis (ABILITY-3): a multicentre, randomised, double-blind study. Lancet 2018; 392:134
12. Talley NJ, Abreu MT, Achkar J, et al. An evidence-based systematic review on medical therapies for inflammatory bowel disease. Am J Gastroenterol. 2011;106(Suppl 1): S2-S25.
13. Jaffe GJ, Dick AD, Brézin AP, et al. Adalimumab in Patients with Active Noninfectious Uveitis. N Engl J Med 2016; 375:932

Review History

03/21/2005 – Reviewed
05/15/2005 – Effective
02/27/2006 – Reviewed and revised
02/25/2008 – Reviewed and revised
02/23/2009 – Reviewed and revised
02/22/2010 – Reviewed and revised
02/28/2011 – Reviewed in P&T Meeting
02/27/2012 – Reviewed and revised
02/25/2013 – Reviewed and revised
02/24/2014 – Reviewed and revised
02/23/2015 – Reviewed and revised
02/22/2016 – Reviewed and revised
02/2017 – Reviewed and revised (switched to SGM)
02/26/2018 – Reviewed and revised
11/26/2018 – Reviewed and revised (switched to Custom) in P&T Meeting
07/22/2020 – Reviewed and updated July P&T Mtg; reworded overview; changed diagnosis of axial spondyloarthritis to nonradiographic axial spondyloarthritis; updated references. Effective 10/01/2020.

11/15/2023 – Reviewed and Updated for Nov P&T; removed TB requirement. Added additional treatment options for conventional therapies for Rheumatoid arthritis. Added additional treatment options for 6-week treatment for PJIA. Psoriatic arthritis – removed conventional therapies and added member meets one of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Plaque psoriasis – changed from 5% BSA to 3% BSA. Removed appendix with contraindications to methotrexate. Consolidated conventional therapies for plaque psoriasis. Removed conventional therapy for uveitis. Added preferred agents: Humira, Hadlima, Adalimumab-adaz, and Adalimumab-fkjp. Non-preferred agents require prior use of TWO preferred agents. Effective 1/1/24
3/13/2024 – Reviewed and Updated for March P&T; Added Humira (Cordavis manufacturer) as a non-preferred agent. Criteria reflects Humira (Abbvie manufacturer) is preferred. Effective ASAP