Mass General Brigham
Health Plan

# Humira and Biosimilars (adalimumab)
# Effective 01/01/2025

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|---|---|---|---|
| **Plan** | ☐ MassHealth UPPL<br>☒Commercial/Exchange | **Program Type** | ☒ Prior Authorization<br>☐ Quantity Limit<br>☐ Step Therapy |
| **Benefit** | ☒ Pharmacy Benefit<br>☐ 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**<br>All Plans \| Phone: 877-519-1908 \| Fax: 855-540-3693<br>**Non-Specialty Medications**<br>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 (Amgen) |
| Hadlima | Adalimumab-aaty |
| Adalimumab-adaz | Adalimumab-adbm |
| Adalimumab-fkjp | Adalimumab-ryvk |
| Amjevita (Nuvaila) | Cyltezo |
| | Hyrimoz |
| | Abrilada |
| | Hulio |
| | Humira (Cordavis) |
| | Idacio |
| | Simlandi |
| | Yuflyma |
| | Yusimry |

**Coverage Guidelines**
Authorization may be granted for members who are new to the plan within the past 90 days 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:

**Moderately to severely active rheumatoid arthritis (RA)**

1. Diagnosis of moderately to severely active rheumatoid arthritis (RA)
2. 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:
    a. Methotrexate
    b. Leflunomide
    c. Sulfasalazine
3. For adalimumab-aaty, adalimumab-adbm, adalimumab-ryvk, Amjevita (Amgen), Cyltezo, Hyrimoz, Abrilada, Hulio, Humira (Cordavis), Idacio, Simlandi, Yuflyma, and Yusimry: Member must have had prior use, intolerance, or contraindication to TWO of the following:
    a. Humira (Abbvie)
    b. Hadlima
    c. Adalimumab-adaz
    d. Adalimumab-fkjp
    e. Amjevita (Nuvaila)

**Moderately to severely active polyarticular juvenile idiopathic arthritis (pJIA)**

1. Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis (pJIA)
2. 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:
    a. Leflunomide
    b. Methotrexate
3. For adalimumab-aaty, adalimumab-adbm, adalimumab-ryvk, Amjevita (Amgen), Cyltezo, Hyrimoz, Abrilada, Hulio, Humira (Cordavis), Idacio, Simlandi, Yuflyma, and Yusimry: Member must have had prior use, intolerance, or contraindication to TWO of the following:
    a. Humira (Abbvie)
    b. Hadlima
    c. Adalimumab-adaz
    d. Adalimumab-fkjp
    e. Amjevita (Nuvaila)

**Active psoriatic arthritis (PsA)**

1. Diagnosis of active psoriatic arthritis
2. The member meets ONE of the following:
    a. Actively inflamed joints
    b. Dactylitis
    c. Enthesitis
    d. Axial disease
    e. Active skin and/or nail involvement
3. For adalimumab-aaty, adalimumab-adbm, adalimumab-ryvk, Amjevita (Amgen), Cyltezo, Hyrimoz, Abrilada, Hulio, Humira (Cordavis), Idacio, Simlandi, Yuflyma, and Yusimry: Member must have had prior use, intolerance, or contraindication to TWO of the following:
    a. Humira (Abbvie)
    b. Hadlima
    c. Adalimumab-adaz
    d. Adalimumab-fkjp
    e. Amjevita (Nuvaila)

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

1. One of the following diagnoses:
    a. Active ankylosing spondylitis
    b. Nonradiographic axial spondyloarthritis (nr-axSpA)
2. 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.
3. For adalimumab-aaty, adalimumab-adbm, adalimumab-ryvk, Amjevita (Amgen), Cyltezo, Hyrimoz, Abrilada, Hulio, Humira (Cordavis), Idacio, Simlandi, Yuflyma, and Yusimry: Member must have had prior use, intolerance, or contraindication to TWO of the following:
    a. Humira (Abbvie)
    b. Hadlima
    c. Adalimumab-adaz
    d. Adalimumab-fkjp
    e. Amjevita (Nuvaila)

**Moderately to severely active Crohn's disease (CD)**

1. Diagnosis of the moderately to severely active Crohn's disease (CD)
2. ONE of the following:
    a. Frequent diarrhea and abdominal pain
    b. At least 10% weight loss
    c. Complications such as obstruction, fever, abdominal mass
    d. Abnormal lab values (e.g., C-reactive protein [CRP])
    e. CD Activity Index (CDAI) greater than 220
3. Member has had trial and failure, intolerance, or contraindication to ONE of the following conventional therapies:
    a. 6-mercaptopurine
    b. Azathioprine
    c. Corticosteroids (e.g., prednisone)
    d. Methotrexate
4. For adalimumab-aaty, adalimumab-adbm, adalimumab-ryvk, Amjevita (Amgen), Cyltezo, Hyrimoz, Abrilada, Hulio, Humira (Cordavis), Idacio, Simlandi, Yuflyma, and Yusimry: Member must have had prior use, intolerance, or contraindication to TWO of the following:
    a. Humira (Abbvie)
    b. Hadlima
    c. Adalimumab-adaz
    d. Adalimumab-fkjp
    e. Amjevita (Nuvaila)

**Moderately to severely active ulcerative colitis (UC)**

1. Diagnosis of moderately to severely active ulcerative colitis
2. ONE of the following:
    a. Greater than 6 stools per day
    b. Frequent blood in stools
    c. Frequent urgency
    d. Presence of ulcers
    e. Abnormal lab values (e.g., hemoglobin, ESR, CRP)
    f. Dependent on, or refractory to, corticosteroids

3. Member has had trial and failure, intolerance, or contraindication to ONE of the following conventional therapies:
    a. 6-mercaptopurine
    b. Aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine)
    c. Azathioprine
    d. Corticosteroids (e.g., prednisone)
4. For adalimumab-aaty, adalimumab-adbm, adalimumab-ryvk, Amjevita (Amgen), Cyltezo, Hyrimoz, Abrilada, Hulio, Humira (Cordavis), Idacio, Simlandi, Yuflyma, and Yusimry: Member must have had prior use, intolerance, or contraindication to TWO of the following:
    a. Humira (Abbvie)
    b. Hadlima
    c. Adalimumab-adaz
    d. Adalimumab-fkjp
    e. Amjevita (Nuvaila)

**Moderate to severe chronic plaque psoriasis (PsO)**

1. Diagnosis of moderate to severe chronic plaque psoriasis
2. 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
3. Member meets ONE of the following criteria:
    a. Minimum duration of 4-week trial and failure, contraindication, or intolerance to ONE of the following topical therapies
        - Corticosteroids (e.g., betamethasone, clobetasol)
        - Vitamin D analogs (e.g., calcitriol, calcipotriene)
        - Tazarotene
        - Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
        - Anthralin
        - Coal tar
    b. Member has severe psoriasis that warrants a biologic DMARD as first-line therapy.
4. For adalimumab-aaty, adalimumab-adbm, adalimumab-ryvk, Amjevita (Amgen), Cyltezo, Hyrimoz, Abrilada, Hulio, Humira (Cordavis), Idacio, Simlandi, Yuflyma, and Yusimry: Member must have had prior use, intolerance, or contraindication to TWO of the following:
    a. Humira (Abbvie)
    b. Hadlima
    c. Adalimumab-adaz
    d. Adalimumab-fkjp
    e. Amjevita (Nuvaila)

**Moderate to severe hidradenitis suppurativa**

1. Diagnosis of moderate to severe hidradenitis suppurativa (Hurley stage II or III)
2. For adalimumab-aaty, adalimumab-adbm, adalimumab-ryvk, Amjevita (Amgen), Cyltezo, Hyrimoz, Abrilada, Hulio, Humira (Cordavis), Idacio, Simlandi, Yuflyma, and Yusimry: Member must have had prior use, intolerance, or contraindication to TWO of the following:
    a. Humira (Abbvie)
    b. Hadlima
    c. Adalimumab-adaz
    d. Adalimumab-fkjp

e. Amjevita (Nuvaila)

**Non-infectious Uveitis**

1. Diagnosis of non-infectious uveitis
2. Uveitis is classified as ONE of the following:
    a. Intermediate
    b. Posterior
    c. Panuveitis
3. For adalimumab-aaty, adalimumab-adbm, adalimumab-ryvk, Amjevita (Amgen), Cyltezo, Hyrimoz, Abrilada, Hulio, Humira (Cordavis), Idacio, Simlandi, Yuflyma, and Yusimry: Member must have had prior use, intolerance, or contraindication to TWO of the following:
    a. Humira (Abbvie)
    b. Hadlima
    c. Adalimumab-adaz
    d. Adalimumab-fkjp
    e. Amjevita (Nuvaila)

**Continuation of Therapy**

Requests for reauthorization for all diagnoses will be approved when the following criteria are met:

1. 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. Amjevita (adalimumab-aato) [prescribing information]. Thousand Oaks, CA: Amgen, Inc; August 2024.
2. 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.
3. 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.
4. 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.
5. 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.
6. Humira (adalimumab) [prescribing information]. North Chicago, IL: AbbVie Inc; February 2024.
7. Jaffe GJ, Dick AD, Brézin AP, et al. Adalimumab in Patients with Active Noninfectious Uveitis. N Engl J Med 2016; 375:932
8. 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
9. 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.
10. 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.

11. 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.
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. 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.
14. 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

**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
08/14/2024 – Reviewed and updated for August P&T. Added adalimumab-aaty, adalimumab-adbm, adalimumab-ryvk, and Simlandi as non-preferred agents. Clarified step therapy language to indicate member must be new to the plan within the past 90 days. Effective 10/1/2024.
10/9/2024 – Reviewed and updated for October P&T. Added Amjevita (Nuvaila) as a preferred adalimumab product. Specified that Amjevita (Amgen) is nonpreferred. Updated policy to include Amjevita (Nuvaila) as a preferred adalimumab step therapy option. Effective 1/1/2025.