Mass General Brigham
Health Plan

Adalimumab Products:
Adalimumab-aaty
Adalimumab-adaz
Hadlima
Effective 01/01/2027

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 Benefit** **Pharmacy Benefit**	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Exceptions	N/A		

Overview

Adalimumab a tumor necrosis factor (TNF) blocker indicated for:

- **Rheumatoid arthritis:** Reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active rheumatoid arthritis
- **Polyarticular juvenile idiopathic arthritis:** Reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients 2 years of age and older
- **Psoriatic Arthritis:** Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active psoriatic arthritis
- **Ankylosing Spondylitis:** Reducing signs and symptoms in adult patients with active ankylosing spondylitis
- **Crohn's Disease:** Treatment of moderately to severely active Crohn's disease in adults and pediatric patients 6 years of age and older
- **Ulcerative Colitis:** Treatment of moderately to severely active ulcerative colitis in adults and pediatric patients 5 years of age and older
- **Plaque Psoriasis:** Treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate
- **Hidradenitis Suppurativa:** Treatment of moderate to severe hidradenitis suppurativa in patients 12 years of age and older
- **Uveitis:** Treatment of non-infectious intermediate, posterior, and panuveitis in adults and pediatric patients 2 years of age and older

Adalimumab-aaty, adalimumab-adaz and Hadlima are the Plan's preferred adalimumab products. All other adalimumab products are nonformulary.

Coverage Guidelines
If member is new to the plan (as evidenced by coverage effective date of less than or equal to 90 days), submission of medical records documenting that the member is currently receiving treatment with the requested drug, 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 of the following diagnosis-specific criteria:

Moderately to severely active rheumatoid arthritis (RA)
1. Diagnosis of moderately to severely active rheumatoid arthritis (RA)
2. 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

Moderately to severely active polyarticular juvenile idiopathic arthritis (pJIA)
1. Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis (pJIA)
2. 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

Active psoriatic arthritis (PsA)
1. Diagnosis of active psoriatic arthritis
2. ONE of the following:
    a. Actively inflamed joints
    b. Dactylitis
    c. Enthesitis
    d. Axial disease
    e. Active skin and/or nail involvement

Active ankylosing spondylitis (AS)
1. Diagnosis of active ankylosing spondylitis
2. Minimum 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.

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. Trial and failure, contraindication, or intolerance to ONE of the following conventional therapies:
        i. 6-mercaptopurine
        ii. Azathioprine
        iii. Corticosteroids (e.g., prednisone)
        iv. Methotrexate
    b. Disease severity warrants systemic biologic or targeted synthetic therapy as first-line therapy

Moderately to severely active ulcerative colitis (UC)

1. Diagnosis of moderately to severely active ulcerative colitis
2. ONE of the following:
    a. Trial and failure, contraindication, or intolerance to ONE of the following conventional therapies:
        i. 6-mercaptopurine
        ii. Aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine)
        iii. Azathioprine
        iv. Corticosteroids (e.g., prednisone)
    b. Disease severity warrants systemic biologic or targeted synthetic therapy as first-line therapy

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:
        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
    b. Member has severe psoriasis that warrants a biologic DMARD or targeted synthetic therapy as first-line therapy.

Moderate to severe hidradenitis suppurativa

1. Diagnosis of moderate to severe hidradenitis suppurativa (Hurley stage II or III)

Non-infectious Uveitis

1. Diagnosis of non-infectious uveitis
2. Uveitis is classified as ONE of the following:
    a. Intermediate
    b. Posterior
    c. Panuveitis

<u>Continuation of Therapy</u>

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

1. Submission of medical records (e.g., chart notes) documenting an improvement in the member's condition, as evidenced by low disease activity or improvement in signs and symptoms of the condition.

Limitations

1. Initial approval and reauthorizations will be granted for 24 months
2. The following quantity limits apply:

Dosage	Quantity Limit
Starter Packs	1 pack per 365 days
10 mg injection	2 injections per 28 days
20 mg injection	4 injections per 28 days

40 mg injection	4 injections per 28 days
80 mg injection	2 injections per 28 days

References

1. 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.
2. 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.
3. 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.
4. 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.
5. Humira (adalimumab) [prescribing information]. North Chicago, IL: AbbVie Inc; February 2024.
6. Jaffe GJ, Dick AD, Brézin AP, et al. Adalimumab in Patients with Active Noninfectious Uveitis. N Engl J Med 2016; 375:932
7. 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
8. 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.
9. 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.
10. 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.
11. 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.
12. 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.
13. 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.
11/13/2024 – Reviewed and updated for November P&T. Added adalimumab-aacf as a nonpreferred product. Effective 02/01/2025.
12/11/2024 – Reviewed and updated for December P&T. Removed diagnosis of nonradiographic axial spondyloarthritis. Effective 3/1/2025.
05/14/2025 – Reviewed and updated for May P&T. Updated criteria for Crohn's disease and ulcerative colitis to remove disease characteristic requirement and allow for approval if disease severity warrants systemic biologic as first-line therapy. Effective 07/01/2025.
10/08/2025 – Reviewed and updated for October P&T. Updated verbiage for nonpreferred agents and trial language for ankylosing spondylitis. Updated policy to reflect updated preferred adalimumab products. Effective 01/01/2026.
11/12/2025 – Reviewed and updated for November P&T. Administrative update – added quantity limits to the policy. Effective 01/01/2026.
03/11/2026 – Reviewed and updated for March P&T. Effective 04/01/2026: administrative update - changing verbiage in reauthorization criteria from “documentation is submitted” to “submission of medical records (e.g., chart notes…” and updating language for members who are new to the Plan. Effective 05/01/2025: Adding adalimumab-bwwd to the policy as a nonpreferred adalimumab product. Administrative update made to remove examples of nonpreferred adalimumab products throughout the criteria and instead replaced with “nonpreferred adalimumab products.”
04/15/2026 – Reviewed and updated at April P&T. Updated previous trial language for plaque psoriasis, ulcerative colitis and Crohn’s disease, allowing for bypassing conventional therapy if member has severe psoriasis that warrants a systemic biologic or targeted synthetic therapy as first-line therapy. Effective 08/16/2026.
09/09/2026 – Reviewed and updated at September P&T. Renamed policy to “Adalimumab Products.” Updating policy to reflect that adalimumab-aaty, adalimumab-adaz and Hadlima will be the preferred adalimumab products and that all other adalimumab products will be nonformulary. Effective 01/01/2027.