

Humira (adalimumab)
January 1, 2021

Plan	<input type="checkbox"/> MassHealth <input checked="" type="checkbox"/> MassHealth (PUF) <input type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input checked="" type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit (NLX)		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	Specialty Medications		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview

Humira (adalimumab) is a tumor necrosis factor (TNF) blocker indicated for:

- Treatment of active ankylosing spondylitis
- Treatment of active psoriatic arthritis
- Treatment of moderate to severe plaque psoriasis (PsO)
- Treatment of moderately to severely active rheumatoid arthritis (RA)
- Treatment of moderately to severe polyarticular juvenile idiopathic arthritis (pJIA)
- Treatment of moderate to severe Crohn’s disease (CD)
- Treatment of moderate to severe hidradenitis suppurativa (HS)
- Treatment of moderate to severe ulcerative colitis (UC)
- Treatment of non-infectious uveitis

Coverage Guidelines

Authorization may be reviewed on a case by case basis for members new to AllWays Health Partners who are currently receiving treatment with Humira, excluding when the product is obtained as samples or via manufacturer’s patient assistance programs

OR

Authorization may be granted if the member meets ALL following criteria and documentation has been submitted:

Moderate to Severe Rheumatoid Arthritis (RA) and Polyarticular Juvenile Idiopathic Arthritis (pJIA)

Prescriber provides documentation of ALL of the following:

- Appropriate diagnosis



- **ONE** of the following:
 - a. Paid claims or physician documented inadequate response or adverse reaction to at least **ONE** traditional DMARD (See Appendix B) or contraindication to traditional DMARDs
 - b. Paid claims or physician documented inadequate response or adverse reaction to **ONE** biologic DMARD that is FDA-approved for the requested indication
- Dosing is appropriate

Psoriatic Arthritis (PsA)

Prescriber provides documentation of **ALL** of the following:

1. Appropriate diagnosis
2. Appropriate dosing

Ankylosing spondylitis (AS)

Prescriber provides documentation of **ALL** of the following:

1. Appropriate diagnosis
2. Paid claims or physician documented inadequate response or adverse reaction to **TWO** NSAIDs or contraindication to **ALL** NSAIDs
3. Appropriate dosing (see appendix A)

NOTE: Requests for Humira® in non-radiographic axial spondylarthritis may be approved if all criteria are met.

Moderate to Severe Plaque Psoriasis

Prescriber provides documentation of **ALL** of the following:

1. Appropriate diagnosis
2. **ONE** of the following:
 - a. Paid claims or physician documented inadequate response or adverse reaction to **ONE** conventional therapy (see appendix B)
 - i. topical agent
 - ii. phototherapy
 - iii. systemic agent
 - b. Contraindication to **ALL** conventional therapies:
 - i. topical agents
 - ii. phototherapy
 - iii. systemic agents
 - c. Paid claims or physician documented inadequate response or adverse reaction to **ONE** biologic DMARD that is FDA-approved for plaque psoriasis
3. Appropriate dosing

Moderate to Severe Crohn's Disease (CD) and Moderate to Severe Ulcerative Colitis (UC)

Prescriber provides documentation of **ALL** of the following:

1. Appropriate diagnosis
2. Appropriate dosing

NOTE: Requests for Humira may be approved for fistulizing Crohn's disease if all above criteria are met.

Non-infectious Uveitis

Prescriber provides documentation of **ALL** of the following:



1. Appropriate diagnosis
2. **ONE** of the following:
 - a. Paid claims or physician documented inadequate response or adverse reaction to **ONE** topical or systemic glucocorticoid
 - b. Contraindication to **ALL** topical and systemic glucocorticoids
3. **ONE** of the following:
 - a. Paid claims or physician documented inadequate response or adverse reaction to **ONE** systemic immunosuppressive therapy (e.g., methotrexate, azathioprine, mycophenolate, cyclosporine, tacrolimus, cyclophosphamide)
 - b. Contraindication to **ALL** systemic immunosuppressive therapy (e.g., methotrexate, azathioprine, mycophenolate, cyclosporine, tacrolimus, cyclophosphamide)
4. Appropriate dosing

Moderate to severe Hidradenitis Suppurativa (Hurley Stage II or Hurley Stage III disease)

Prescriber provides documentation of **ALL** the following:

1. Appropriate diagnosis*
2. Appropriate dosing

* For mild hidradenitis suppurativa (Hurley Stage I disease), requests for Humira® (adalimumab) may be approvable if there are paid claims (within the past 6 months) or prescriber provides inadequate response or adverse reaction to ONE oral antibiotic or contraindication to ALL oral antibiotics (e.g. rifampin, clindamycin, tetracycline, doxycycline, minocycline)

Continuation of Therapy

Reauthorization requires physician documentation of continuation of therapy, positive response to therapy, FDA approved indication and appropriate dosing.

Limitations

1. Initial approvals will be granted for:
 - a. Plaque Psoriasis: 3 months.
 - b. All other diagnosis: 6 months.
2. Reauthorizations will be granted for 12 months
3. The following quantity limits apply:

Humira Inj 10mg/0.2mL Humira Inj 10mg/0.1mL Humira Inj 20mg/0.2mL Humira Kit 20mg/0.4mL	2 injections per 28 days
Humira Pediatric Inj Crohn's Humira Pen Kit CD/UC/HS Humira Pen Kit PS/UV	3 injections per 28 days
Humira Inj 40mg/0.8mL Humira Inj 40mg/0.4mL Humira Pen Inj 40mg/0.4mL Humira Pen – Psoriasis Starter	4 Injections per 28 days
Humira Pediatric Crohn's Disease	6 syringes per 28 days

Appendices

Appendix A

	Pediatric Dosing
Humira® (adalimumab)	<p>Crohn’s disease (moderate-severe) (≥ 6 years old, weight 17 kg to <40 kg): 80 mg SQ at week 0 (may administer as 4 injections in 1 day or 2 injections daily for 2 consecutive days), 40 mg SQ week 2 (day 15), then 20 mg SQ every other week starting at week 4 (day 29).</p> <p>Crohn’s disease (moderate-severe) (≥ 6 years old, weight ≥ 40 kg): 160 mg SQ at week 0 (may administer as 4 injections in 1 day or 2 injections daily for 2 consecutive days), 80 mg SQ week 2 (day 15), then 40 mg SQ every other week starting at week 4 (day 29).</p> <p>Juvenile Idiopathic Arthritis (≥ 2 years old, weight ≥ 10 kg): 10 mg SQ every other week</p>

Appendix B. Conventional Therapies for Plaque Psoriasis

Conventional Treatment Lines	Agents Used
Topical Agents	emollients, keratolytics, corticosteroids, coal tar, anthralin, calcipotriene, tazarotene, calcitriol, calcineurin inhibitors
Systemic Agents	Traditional DMARDs: methotrexate, apremilast, acitretin,
Phototherapy	ultraviolet A and topical psoralens (topical PUVA), ultraviolet A and oral psoralens (systemic PUVA), narrow band UV-B (NUVB)

References

- Burmester GR, Landewé R, Genovese MC, et al. Adalimumab long-term safety: infections, vaccination response and pregnancy outcomes in patients with rheumatoid arthritis. *Ann Rheum Dis.* 2017;76(2):414-417.[PubMed 27338778]
- Colombel JF, Schwartz DA, Sandborn WJ, et al. Adalimumab for the treatment of fistulas in patients with Crohn's disease. *Gut.* 2009;58(7):940-948. doi: 10.1136/gut.2008.159251.[PubMed 19201775]
- Dassopoulos T, Sultan S, Falck-Ytter YT, et al. American Gastroenterological Association Institute technical review on the use of thiopurines, methotrexate, and anti-TNF-α biologic drugs for the induction and maintenance of remission in inflammatory Crohn's disease. *Gastroenterology.* 2013;145(6):1464-1478.[PubMed 24267475]
- Dommasch E and Gelfand JM, “Is There Truly a Risk of Lymphoma From Biologic Therapies?” *Dermatol Ther,* 2009, 22 (5):418-30.
- Feuerstein JD, Nguyen GC, Kupfer SS, Falck-Ytter Y, Singh S; American Gastroenterological Association Institute Clinical Guidelines Committee. American Gastroenterological Association Institute guideline on therapeutic drug monitoring in inflammatory bowel disease. *Gastroenterology.* 2017;153(3):827-834. doi: 10.1053/j.gastro.2017.07.032.[PubMed 28780013]
- Gordon KB, Langley RG, Leonardi C, et al, “Clinical Response to Adalimumab Treatment in Patients With Moderate to Severe Psoriasis: Double-Blind, Randomized Controlled Trial and Open-Label Extension Study,” *J Am Acad Dermatol,* 2006, 55(4):598-606.[PubMed 17010738]
- Humira (adalimumab) [prescribing information]. North Chicago, IL: AbbVie Inc; March 2020.
- Lichtenstein GR, Loftus EV, Isaacs KL, et al. ACG clinical guideline: management of Crohn's disease in adults. *Am J Gastroenterol.* 2018;113(4):481-517. doi: 10.1038/ajg.2018.27.[PubMed 16618399]

9. Lopez-Oilvo MA, Tayar JH, Martinez-Lopez JA, et al, "Risk of Malignancies in Patients With Rheumatoid Arthritis Treated With Biologic Therapy: A Meta-Analysis," *JAMA*, 2012, 308(9): 898-908. [\[PubMed 22948700\]](#)
10. Lovell DJ, Ruperto N, Goodman S, et al. Adalimumab with or without methotrexate in juvenile rheumatoid arthritis. *N Engl J Med*. 2008;359(8):810-820. [\[PubMed 18716298\]](#)
11. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. *J Am Acad Dermatol*. 2019;80(4):1029-1072. [\[PubMed 30772098\]](#)
12. Nguyen GC, Loftus EV Jr, Hirano I, et al; AGA Institute Clinical Guidelines Committee. American Gastroenterological Association Institute guideline on the management of Crohn's disease after surgical resection. *Gastroenterology*. 2017;152(1):271-275. doi: 10.1053/j.gastro.2016.10.038. [\[PubMed 27840074\]](#)
13. Page RL 2nd, O'Bryant CL, Cheng D, et al; American Heart Association Clinical Pharmacology and Heart Failure and Transplantation Committees of the Council on Clinical Cardiology; Council on Cardiovascular Surgery and Anesthesia; Council on Cardiovascular and Stroke Nursing; and Council on Quality of Care and Outcomes Research. Drugs That May Cause or Exacerbate Heart Failure: A Scientific Statement From the American Heart Association [published correction appears in *Circulation*. 2016;134(12):e261]. *Circulation*. 2016;134(6):e32-e69. [\[PubMed 27400984\]](#)
14. Parakkal D, Sifuentes H, Semer R, et al, "Hepatosplenic T-Cell Lymphoma in Patients Receiving TNF- α Inhibitor Therapy: Expanding the Groups at Risk," *Eur J Gastroenterol Hepatol*, 2011, 23(12):1150-6. [\[PubMed 21941193\]](#)
15. Sandborn WJ, Rutgeerts P, Enns R, et al, "Adalimumab Induction Therapy for Crohn Disease Previously Treated With Infliximab: A Randomized Trial.," *Ann Intern Med*, 2007, 146(12):829-38. [\[PubMed 17470824\]](#)
16. Savarino E, Bodini G, Dulbecco P, et al. Adalimumab is more effective than azathioprine and mesalamine at preventing postoperative recurrence of Crohn's disease: a randomized controlled trial. *Am J Gastroenterol*. 2013;108(11):1731-1742. doi: 10.1038/ajg.2013.287. [\[PubMed 24019080\]](#)
17. Singh JA, Furst DE, Bharat A, et al, "2012 Update of the 2008 American College of Rheumatology Recommendations for the Use of Disease-Modifying Antirheumatic Drugs and Biologic Agents in the Treatment of Rheumatoid Arthritis," *Arthritis Care Res (Hoboken)*, 2012, 64(5):625-39. [\[PubMed 22473917\]](#)
18. Singh S, Garg SK, Pardi DS, et al. Comparative efficacy of pharmacologic interventions in preventing relapse of Crohn's disease after surgery: a systematic review and network meta-analysis. *Gastroenterology*. 2015;148(1):64-76.e2. doi: 10.1053/j.gastro.2014.09.031. [\[PubMed 25263803\]](#)
19. Terdiman JP, Gruss CB, Heidelbaugh JJ, et al. American Gastroenterological Association Institute guideline on the use of thiopurines, methotrexate, and anti-TNF- α biologic drugs for the induction and maintenance of remission in inflammatory Crohn's disease. *Gastroenterology*. 2013;145(6):1459-1463. [\[PubMed 24267474\]](#)
20. Weizman AV, Nguyen GC, Seow CH, et al. Appropriateness of biologics in the management of crohn's disease using RAND/UCLA appropriateness methodology. *Inflamm Bowel Dis*. 2019;25(2):328-335. doi: 10.1093/ibd/izy333. [\[PubMed 30346529\]](#)

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
02/27/2012 – Reviewed and revised
02/25/2013 – Reviewed and revised
02/24/2013 – Reviewed and revised
02/23/2015 – Reviewed and revised
02/2016 – Reviewed in P&T Meeting
02/2017 – Reviewed and revised (adopted SGM) in P&T Meeting
03/01/2018 – Reviewed and revised (adopted MH RS)
11/26/2018 – Reviewed and revised
10/21/2020 – Reviewed and Updated; separated out Comm/Exch vs. MassHealth; updated Overview;
Matched MassHealth Preferred Unified Formulary for implementation 1/1/2021

Disclaimer

AllWays Health Partners complies with applicable federal civil rights laws and does not discriminate or exclude people on the basis of race, color, national origin, age, disability, or sex.