



**Humira (adalimumab)
Effective 11/26/18**

Plan	<input checked="" type="checkbox"/> MassHealth <input type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit (NLX)		<input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
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

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met, and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

1. Moderately to severely active rheumatoid arthritis (RA)
2. Moderately to severely active polyarticular juvenile idiopathic arthritis (pJIA)
3. Active psoriatic arthritis (PsA)
4. Active ankylosing spondylitis (AS)
5. Moderately to severely active Crohn’s disease (CD)
6. Moderate to severely active ulcerative colitis (UC)
7. Moderate to severe chronic plaque psoriasis (PsO)
8. Moderate to severe Hidradenitis Suppurativa
9. Non-infectious intermediate, posterior and panuveitis

Compendial Uses

1. Axial spondyloarthritis

All other indications are considered experimental/investigational and are not a covered benefit.

Coverage Guidelines

Rheumatoid arthritis (RA), polyarticular juvenile idiopathic arthritis (pJIA), Ankylosing spondylitis (AS) or Psoriatic arthritis (PsA)



Authorization may be granted for members with a diagnosis of RA/pJIA/AS/PsA when ALL the following criteria are met:

1. Prescriber has provided documentation of ONE of the following*:
 - a. Inadequate response, adverse reaction, or contraindication to at least ONE traditional DMARD (hydroxychloroquine, methotrexate, sulfasalazine)
 - b. Inadequate response or adverse reaction to ONE biologic DMARD that is FDA-approved for the requested indication
 - c. Note: * DMARD trial is not required in members with active ankylosing spondylitis or psoriatic arthritis with axial (spine) involvement (including sacroiliitis) whose condition is not sufficiently controlled with NSAIDs.
2. Dosing is appropriate (see appendix A).

Moderate-severe plaque psoriasis

Authorization may be granted for members with a diagnosis of moderate-severe plaque psoriasis when ALL the following criteria are met:

1. Prescriber has provided documentation of ONE of the following*:
 - a. Inadequate response, adverse reaction, or contraindication to at least TWO conventional therapies in any one of the following combinations (combinations DO NOT have to be used concurrently):
 - i. 1 topical agent + 1 systemic agent
 - ii. 1 topical agent + 1 phototherapy (required for diagnosis of guttate psoriasis)
 - iii. 1 systemic agent + 1 phototherapy
 - iv. 2 systemic agents
 - b. Contraindication to ALL conventional therapies
 - i. Topical agents
 - ii. Phototherapy
 - iii. Systemic agents
 - c. Inadequate response or adverse reaction to ONE biologic DMARD that is FDA-approved for plaque psoriasis
2. Dosing is appropriate (see appendix A).

Crohn's disease

Authorization may be granted for members with a diagnosis of Crohn's disease when ALL the following criteria are met:

1. Prescriber has provided documentation of ONE of the following:
 - a. Inadequate response, adverse reaction, or contraindication to ALL the following:
 - i. Aminosalicylate
 - ii. Antibiotic
 - iii. Corticosteroid
 - iv. Immunomodulator (e.g., azathioprine, 6-mercaptopurine or methotrexate)
 1. Note: If a request documents severe disease, a trial of an oral immunomodulator may be bypassed.
 - b. Inadequate response or adverse reaction to ONE biologic DMARD that is FDA-approved for the requested indication.
2. Dosing is appropriate (see appendix A for dosing).

Ulcerative colitis



Authorization may be granted for members with a diagnosis of ulcerative colitis when ALL the following criteria are met:

1. Prescriber has provided documentation of ONE of the following:
 - a. Inadequate response adverse reaction, or contraindication to ALL of the following:
 - i. Aminosalicylate
 - ii. Corticosteroid
 - iii. Immunomodulator (e.g. azathioprine, 6-mercaptopurine or methotrexate)
 1. Note: If a request documents severe disease, a trial of an oral immunomodulator may be bypassed.
 - a. Inadequate response or adverse reaction to ONE biologic DMARD that is FDA-approved for the requested indication.
2. Dosing is appropriate (see appendix A for dosing).

Hidradenitis Suppurativa

Authorization may be granted for members with a diagnosis of moderate to severe hidradenitis suppurativa (Hurley Stage II or Hurley Stage III disease) * when ALL the following criteria are met:

1. Member is at least 18 years of age.
 - a. Note: For mild hidradenitis suppurativa (Hurley Stage I disease), requests for Humira® (adalimumab) may be approvable if the prescriber provides inadequate response or adverse reaction to ONE oral antibiotic or contraindication to ALL oral antibiotics (e.g. rifampin, clindamycin, tetracycline, doxycycline, minocycline)
2. Dosing is appropriate (see appendix A for dosing).
3. Note: * For mild hidradenitis suppurativa (Hurley Stage I disease), requests for Humira® (adalimumab) may be approvable if the prescriber provides inadequate response or adverse reaction to ONE oral antibiotic or contraindication to ALL oral antibiotics (e.g. rifampin, clindamycin, tetracycline, doxycycline, minocycline).

Non-infectious Uveitis

Authorization may be granted for members with a diagnosis of non-infectious Uveitis when ALL the following criteria are met:

1. Member is at least 2 years of age.
2. Prescriber has provided documentation of an inadequate response or adverse reaction to ONE topical or systemic glucocorticoid or a contraindication to ALL topical and systemic glucocorticoids.
3. Prescriber has provided documentation of an inadequate response or adverse reaction to ONE systemic immunosuppressive therapy (e.g., methotrexate, azathioprine, mycophenolate, cyclosporine, tacrolimus, cyclophosphamide) or a contraindication to ALL systemic immunosuppressive therapy.
4. Dosing is appropriate (see appendix A for dosing).

Continuation of Therapy

Reauthorization requires physician documentation of a positive response to therapy to be submitted.

Limitations

1. Initial approvals will be for 6 months except for plaque psoriasis which will be for 3 months.
2. Reauthorizations will be for up to 12 months.

References



N/A

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>

Review History

03/21/05 – Reviewed
 05/15/05 – Effective
 02/27/06 – Reviewed and revised
 02/25/08 – Reviewed and revised
 02/23/09 – Reviewed and revised
 02/22/10 – Reviewed and revised
 02/28/11 – Reviewed
 02/27/12 – Reviewed and revised
 02/25/13 – Reviewed and revised
 02/24/13 – Reviewed and revised
 02/23/15 – Reviewed and revised
 02/2016 – Reviewed in P&T Meeting
 02/2017 – Reviewed and revised (adopted SGM) in P&T Meeting
 03/01/18 – Reviewed and revised (adopted MH RS)
 11/26/18 – Reviewed and revised

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