Humira (adalimumab)
Effective 03/01/2023

Plan	☐ MassHealth ☒ MassHealth (PUF) ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ 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 the plan 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:

1. Diagnosis of **ONE** of the following:
    a. Moderate to severe rheumatoid arthritis

b. Moderate to severe polyarticular juvenile idiopathic arthritis

2. **ONE** of the following:
   a. Paid claims or physician attestation of inadequate response or adverse reaction to at least **ONE** traditional DMARD or contraindication to traditional DMARDs (see Appendix B)
   b. Paid claims or physician attestation of inadequate response or adverse reaction to **ONE** biologic DMARD that is FDA-approved for the requested indication
3. Appropriate dosing†

Psoriatic Arthritis (PsA)
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of psoriatic arthritis
2. Appropriate dosing †

Ankylosing spondylitis (AS)
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of ankylosing spondylitis*
2. Paid claims or physician attestation of inadequate response or adverse reaction to **TWO** NSAIDs or contraindication to **ALL** NSAIDs
3. Appropriate dosing †

* 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. Diagnosis of moderate to severe plaque psoriasis
2. **ONE** of the following:
   a. Paid claims or physician attestation of inadequate response or adverse reaction to **ONE** conventional therapy or contraindication to **ALL** conventional therapies (see appendix A)
      i. topical agent
      ii. phototherapy
      iii. systemic agent
   b. Paid claims or physician attestation of 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. Diagnosis of **ONE** of the following:*
   a. Moderate to severe Crohn's disease
   b. Moderate to severe ulcerative colitis
2. Appropriate dosing †

* 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. Diagnosis of non-infectious uveitis

2. Paid claims or physician attestation of inadequate response or adverse reaction to **ONE** or contraindication to **ALL** topical or systemic glucocorticoid
3. Paid claims or physician attestation of inadequate response or adverse reaction to **ONE** or contraindication to **ALL** systemic immunosuppressive therapy (e.g., methotrexate, azathioprine, mycophenolate, cyclosporine, tacrolimus, cyclophosphamide)
4. Appropriate dosing†

Moderate to severe Hidradenitis Suppurativa
Prescriber provides documentation of **ALL** the following:
1. Diagnosis of moderate to severe hidradenitis suppurative (Hurley Stage II or Hurley Stage III disease)*
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)

†Requests for more frequent or higher doses (see appendix C)

Off-Label Indications
Behçet's Disease (BD)
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of Behçet's Disease
2. Paid claims or physician attestation of inadequate response or adverse reaction to **ONE** or contraindication to **ALL** topical corticosteroids
3. Paid claims or physician attestation of inadequate response or adverse reaction to **ONE** or contraindication to **ALL** systemic corticosteroids
4. Paid claims or physician attestation of inadequate response or adverse reaction to **ONE** or contraindication to **ALL** of the following:
    a. azathioprine
    b. colchicine
    c. cyclophosphamide
    d. cyclosporine
    e. methotrexate
    f. Otezla® (apremilast)

Pulmonary Sarcoidosis
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of pulmonary sarcoidosis
2. Paid claims or physician attestation of inadequate response, adverse reaction, or contraindication to **BOTH** of the following:
    a. Systemic glucocorticoids
    b. **ONE** traditional DMARD (methotrexate, azathioprine, leflunomide, or mycophenolate)

Synovitis-acne-pustulosis-hyperostosis-osteitis Syndrome (SAPHO)
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of SAPHO

2. Paid claims or physician attestation of inadequate response or adverse reaction to **ONE** NSAID or contraindication to **ALL** NSAIDs
3. Paid claims or physician attestation of inadequate response or adverse reaction to **ONE** systemic corticosteroid or contraindication to **ALL** systemic corticosteroids

Scleritis
Prescriber provides documentation of **ALL** of the following
1. Diagnosis of scleritis
2. Paid claims or physician attestation of inadequate response, adverse reaction, or contraindication to **BOTH** of the following:
    a. ophthalmic (topical), oral or injectable glucocorticoids
    b. oral or injectable immunosuppressive therapy (e.g., azathioprine, mycophenolate, methotrexate, cyclosporine, tacrolimus, and cyclophosphamide)

Takayasu Arteritis
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of Takayasu arteritis
2. Paid claims or physician attestation of inadequate response, adverse reaction, or contraindication to **BOTH** of the following:
    a. systemic glucocorticoids
    b. **ONE** traditional DMARD (methotrexate, azathioprine, leflunomide, or mycophenolate)

New members currently stable on Humira® can be approved without documentation of failed trials with the conventional therapies.

Continuation of Therapy
Reauthorization requires physician documentation a positive response to therapy.

Limitations
1. Initial approvals will be granted for:
    a. Plaque Psoriasis and off-label indications: 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

Appendix A. 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)

Appendix B. Traditional DMARDS

Traditional DMARDS*	
azathioprine	methotrexate*
cyclosporine	sulfasalazine*
hydroxychloroquine*	thalidomide
Leflunomide	
If a member has a contraindication to **ALL** of the most commonly used traditional DMARDs* (methotrexate, sulfasalazine, and hydroxychloroquine), a trial with a traditional DMARD may be bypassed.	

Appendix C. More frequent/Higher doses

Requests more frequent or higher doses of injectable biologics, may be approved if ALL of the following is provided:

1. Documentation of severe disease
2. Documented partial response to FDA-approved dosing of current biologic therapy
3. Documentation of specialist consult for the requested indication

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Review History

03/21/2005 – Reviewed
05/15/2005 – Effective

02/27/2006 – Reviewed and revised
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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
11/17/2021 – Reviewed and Updated Nov P&T; matched with MH UPPL for implementation 1/1/2022; added appendix with traditional DMARDS and off label indications based on evidence. Effective 01/01/2022
01/11/2023 – Reviewed and updated for Jan P&T. Appropriate diagnosis was replaced with a specific indication throughout. Off-label indications added for: Behcet's disease, pulmonary sarcoidosis, SAPHO, scleritis, TAK. Added language regarding stability of requested medication for new members. Updated Appendix sections by removing off-label indications and dosing information. Effective 3/1/23.

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