Humira (adalimumab)
Effective 01/01/2022

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 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)	**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). **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). **Juvenile Idiopathic Arthritis (≥ 2 years old):** **Weight 10kg to < 15kg:** 10 mg SQ every other week **15kg to < 30kg:** 20 mg SQ every other week **> 30kg:** 40mg every other week

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)

Appendix C: 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 D: Off-Label Indications

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

Pulmonary Sarcoidosis

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

1. Member has an appropriate diagnosis of sarcoidosis with pulmonary involvement
2. Paid claims or physician attestation of inadequate response, adverse reaction or contraindication to **ALL** of the following:

a. Systemic glucocorticoids
b. **ONE** traditional DMARD (methotrexate, azathioprine, leflunomide, or mycophenolate)

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

References

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Review History

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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
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

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