Humira (adalimumab)
Effective 11/26/18

Plan	☐ MassHealth ☒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

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

Moderately to severely active rheumatoid arthritis (RA)

Authorization may be granted for members who have previously received Humira or any other biologic DMARD or targeted synthetic DMARD (e.g., Xeljanz) indicated for moderately to severely active RA.
OR
Authorization may be granted for treatment of moderately to severely active RA when ANY of the following criteria is met, and documentation is provided:

1. Member has experienced an inadequate response to at least a 3-month trial of methotrexate despite adequate dosing (i.e., titrated to 20 mg/week).
2. Member has an intolerance or contraindication to methotrexate (see Appendix A).

Moderately to severely active polyarticular juvenile idiopathic arthritis (pJIA)
Authorization may be granted for members who have previously received Humira or any other biologic DMARD indicated for moderately to severely active pJIA.
OR
Authorization may be granted for treatment of active pJIA when ANY of the following criteria is met, and documentation is provided:

1. Member has experienced an inadequate response to at least a 3-month trial of methotrexate.
2. Member has intolerance or contraindication to methotrexate (see Appendix A).

Active psoriatic arthritis (PsA)
Authorization may be granted for members who have previously received Humira or any other TNF inhibitor indicated for active PsA.
OR
Authorization may be granted for treatment of active PsA when ANY of the following criteria is met, and documentation is provided:

1. Member has had an intolerance to or inadequate response after at least 3 months of treatment with methotrexate OR leflunomide.
2. Member has a contraindication to BOTH methotrexate or leflunomide AND has experienced an inadequate response, intolerance, or contraindication to sulfasalazine.

Active ankylosing spondylitis (AS) and axial spondyloarthritis
Authorizations may be granted for members who have previously received Humira or any other biologic DMARD indicated for active AS.
OR
Authorization may be granted for treatment of active AS and axial spondyloarthritis when ANY of the following criteria is met, and documentation is provided:

1. Member has experienced an inadequate response to at least two non-steroidal anti-inflammatory drugs (NSAIDs).
2. Member has an intolerance or contraindication to two or more NSAIDs.

Moderately to severely active Crohn's disease (CD)
Authorization may be granted for members who have previously received Humira or any other biologic DMARD indicated for moderately to severely active CD.
OR
Authorization may be granted for treatment of moderately to severely active CD if the member has had an inadequate response, intolerance or contraindication to at least one conventional therapy option (see Appendix B).

Moderately to severely active ulcerative colitis (UC)

Authorization may be granted for members who have previously received Humira or any other biologic indicated for moderately to severely active UC.
OR
Authorization may be granted for treatment of moderately to severely active UC if the member has had an inadequate response, intolerance or contraindication to at least one conventional therapy option (see Appendix C).

Moderate to severe chronic plaque psoriasis (PsO)
Authorization may be granted for members who have previously received Humira, Otezla, or any other biologic DMARD indicated for moderate to severe chronic PsO.
OR
Authorization may be granted for treatment of moderate to severe plaque psoriasis when ALL the following criteria are met, and documentation is provided:

1. At least 5% of body surface area (BSA) is affected OR crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
2. Member meets any of the following criteria:
3. Member has had an inadequate response or intolerance to TWO conventional therapies in any of the following combinations:
    a. 1 topical agent + 1 systemic agent
    b. 1 topical agent + 1 phototherapy†
    c. 1 systemic agent + 1 phototherapy
    d. 2 systemic agents
4. Member has a clinical reason to avoid ALL conventional therapies (topical agents, phototherapy, and systemic agents).
5. Member has severe psoriasis that warrants a biologic DMARD as first-line therapy.

Moderate to severe hidradenitis suppurativa
Authorization may be granted for treatment of moderate to severe hidradenitis suppurativa.

Uveitis (non-infectious intermediate, posterior and panuveitis)
Authorization may be granted for treatment of non-infectious intermediate, posterior and panuveitis when ALL the following criteria are met, and documentation is provided:

1. Member is at least 2 years of age.
2. Member has evidence of failure or inadequate response, contraindication, or documented intolerance to conventional therapy such as periocular, intraocular, or systemic corticosteroids OR immunosuppressive drugs (e.g., azathioprine, cyclosporine or methotrexate).

<u>Continuation of Therapy</u>
For all indications except ulcerative colitis
Reauthorization may be granted for all members (including new members) who meet all initial authorization criteria and achieve or maintain positive clinical response after at least 3 months of therapy with Humira as evidenced by low disease activity or improvement in signs and symptoms of the condition.

For ulcerative colitis only

Reauthorization may be granted for all members (including new members) who meet all initial authorization criteria and achieve clinical remission by treatment day 56 (week 8) and maintain positive

clinical response with Humira thereafter as evidenced by low disease activity or improvement in signs and symptoms of ulcerative colitis.

Limitations

1. Approvals will be granted for 24 months
2. **For ALL indications,** member must have a pretreatment tuberculosis (TB) screening with a TB skin test or an interferon gamma release assay (e.g., QFT-GIT, T-SPOT.TB). *
    a. Note: * Members who have received Humira or any other biologic DMARD or targeted synthetic DMARD (e.g., Xeljanz) are exempt from requirements related to TB screening in this Policy.

Appendices

Appendix A: Examples of Contraindications to Methotrexate

1. Alcoholism, alcoholic liver disease or other chronic liver disease
2. Breastfeeding
3. Blood dyscrasias (e.g., thrombocytopenia, leukopenia, significant anemia)
4. Elevated liver transaminases
5. History of intolerance or adverse event
6. Hypersensitivity
7. Interstitial pneumonitis or clinically significant pulmonary fibrosis
8. Myelodysplasia
9. Pregnancy or planning pregnancy (male or female)
10. Renal impairment
11. Significant drug interaction

Appendix B: Examples of Conventional Therapy Options for CD

1. Mild to moderate disease – induction of remission:
    a. Oral mesalamine
2. Mild to moderate disease – maintenance of remission:
    a. Azathioprine, mercaptopurine
    b. Alternatives: methotrexate intramuscularly (IM)
3. Moderate to severe disease – induction of remission:
    a. Methotrexate IM
4. Moderate to severe disease – maintenance of remission:
    a. Azathioprine, mercaptopurine
    b. Alternative: methotrexate IM
5. Perianal and fistulizing disease – maintenance of remission
    a. Azathioprine, mercaptopurine
    b. Alternative: methotrexate IM

Appendix C: Examples of Conventional Therapy Options for UC

1. Mild to moderate disease – induction of remission:
    a. Oral mesalamine (e.g., Asacol, Asacol HD, Lialda, Pentasa)
    b. Rectal mesalamine (e.g., Canasa, Rowasa)
    c. Alternatives: azathioprine, mercaptopurine, sulfasalazine
2. Mild to moderate disease – maintenance of remission:
    a. Oral mesalamine, rectal mesalamine
    b. Alternatives: azathioprine, mercaptopurine, sulfasalazine

3. Severe disease – induction of remission:
    a. Sulfasalazine
4. Severe disease – maintenance of remission:
    a. Azathioprine, mercaptopurine
    b. Alternative: sulfasalazine
5. Pouchitis: rectal mesalamine

Appendix D: Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Cyclosporine or Acitretin.

1. Alcoholism, alcoholic liver disease or other chronic liver disease
2. Breastfeeding
3. Drug interaction
4. Cannot be used due to risk of treatment-related toxicity
5. Pregnancy or planning pregnancy (male or female)
6. Significant comorbidity prohibits use of systemic agents (examples include liver or kidney disease, blood dyscrasias, uncontrolled hypertension)

References

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Review History

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02/23/09 – Reviewed and revised
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02/24/14 – Reviewed and revised
02/23/15 – Reviewed and revised
02/22/16 – Reviewed and revised
02/2017 – Reviewed and revised (switched to SGM)
02/26/18 – Reviewed and revised
11/26/18 – Reviewed and revised (switched to Custom) in P&T Meeting

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