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Adalimumab Products:
Hadlima (adalimumab-bwwd), adalimumab-adaz, adalimumab-fkjp)

POLICY

I. INDICATIONS

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.

A. FDA-Approved Indications
1. Reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active rheumatoid arthritis (RA)
2. Reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis (pJIA) in patients 2 years of age and older
3. Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active psoriatic arthritis (PsA)
4. Reducing signs and symptoms in adult patients with active ankylosing spondylitis (AS)
5. The treatment of moderately to severely active Crohn's disease in adult and pediatric patients 6 years of age and older
6. The treatment of moderately to severely active ulcerative colitis in adults and pediatric patients 5 years of age and older
7. The treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate
8. The treatment of moderate to severe hidradenitis suppurativa in patients 12 years of age and older
9. The treatment of non-infectious intermediate, posterior, and panuveitis in adults and pediatric patients 2 years of age and older

B. Compendial Uses
Axial spondyloarthritis
Behcet's disease
Pyoderma gangrenosum
Oligoarticular juvenile idiopathic arthritis

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

II. CRITERIA FOR INITIAL APPROVAL

For all indications:

- Submission of the member's chart or medical record is required, documenting medical necessity based on the criteria corresponding to the applicable indication; AND
- Physician has assessed baseline disease severity utilizing an objective measure/tool; AND
- Member is free of any clinically important active infection, including clinically important localized infections; AND
- Member will not receive live vaccines during therapy; AND
- Adalimumab will not be used concomitantly with an injectable biologic response modifier including TNF-inhibitors (e.g., Enbrel (etanercept), Remicade (infliximab), etc.) and IL-inhibitors (e.g., Cosentyx (secukinumab), ustekinumab (e.g., Stelara, Otulfi, Selarsdi, Steqeyma, and Yesintek, etc.), Tremfya (guselkumab), Icotyde (icotrokinra), Ilumya (tildrakizumab), Skyrizi (risankizumab), Bimzelx (bimekizumab), Omvoh (mirikizumab), etc.) or other oral non-biologic agent (e.g., Otezla (apremilast), tofacitinib (Xeljanz), Olumiant (baricitinib), Rinvoq (upadacitinib), Velsipity (etrasimod), etc.); AND
- Member has been evaluated and screened for the presence of latent tuberculosis (TB) infection prior to initiating treatment and will receive ongoing monitoring for the presence of TB during treatment; AND
- Formulary adalimumab biosimilar will pay within the quantity limit if there is at least one paid claim within the last 365 days for a biologic (e.g., Bimzelx, Cosentyx, Otezla, Rinvoq, Skyrizi, Taltz, Tremfya, etc.)

A. **Moderately to severely active rheumatoid arthritis (RA)**
Authorization of 12 months may be granted for treatment of moderately to severely active RA when all of the following criteria are met:

1. Member is 18 years of age or older; AND
2. Prescribed by, or in consultation with, a specialist in rheumatology; AND
3. Documentation has been submitted of one of the following criteria:
    a. Member has been tested for either of the following biomarkers and the test was positive:
        i. Rheumatoid factor (RF)
        ii. Anti-cyclic citrullinated peptide (anti-CCP); OR
    b. Member has been tested for ALL of the following biomarkers:
        i. RF
        ii. Anti-CCP
        iii. C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR); AND
4. Documentation has been submitted that the member has had an inadequate response, intolerance, or contraindication to at least a 3-month trial of methotrexate (see Appendix A) or any other conventional disease-modifying antirheumatic drug (DMARD) at maximum tolerated doses.

B. Moderately to severely active polyarticular juvenile idiopathic arthritis (pJIA)

Authorization of 12 months may be granted for treatment of moderately to severely active polyarticular juvenile idiopathic arthritis when all of the following criteria are met:

1. Member is 2 years of age or older; AND
2. Prescribed by, or in consultation with, a specialist in rheumatology; AND
3. Documentation has been submitted of one of the following:
    a. Member has had an inadequate response, intolerance or contraindication to at least a 1-month trial of either an oral non-steroidal anti-inflammatory drug (NSAID) OR an oral disease-modifying anti-rheumatic agent (DMARD) (e.g., methotrexate, leflunomide, sulfasalazine, etc.) at an adequate dose and duration; OR
    b. Member has risk factors for disease severity and potentially a more refractory disease course (See Appendix E), and also meets one of the following:
        i. High-risk joints are involved (e.g., cervical spine, wrist, or hip)
        ii. High disease activity
        iii. Is judged to be at high risk for disabling joint disease.

C. Active psoriatic arthritis (PsA)

Authorization of 12 months may be granted for treatment of active psoriatic arthritis when all of the following criteria are met:

1. Member is 18 years of age or older; AND
2. Prescribed by, or in consultation with, a specialist in dermatology or rheumatology; AND
3. Documentation has been submitted indicating one of the following criteria:
    a. Member has mild to moderate disease and meets one of the following criteria:
        i. Member has had an inadequate response, intolerance, or contraindication to methotrexate or another conventional disease-modifying anti-rheumatic agent (DMARD) (e.g., leflunomide, sulfasalazine, etc.) despite adequate dosing; OR
        ii. Member has enthesitis or predominantly axial disease; OR
    b. Member has severe disease.

D. **Active ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA)**

Authorization of 12 months may be granted for treatment of active ankylosing spondylitis or axial spondyloarthritis when all of the following criteria is met:

1. Member is 18 years of age or older; AND
2. Prescribed by, or in consultation with, a specialist in rheumatology; AND
3. Documentation has been submitted that the member has had an inadequate response, intolerance, or contraindication to at least two (2) NSAIDs.

E. Moderately to severely active Crohn's disease (CD)

Authorization of 12 months may be granted for treatment of moderately to severely active CD when all of the following criteria are met:

1. Member is 6 years of age or older; AND
2. Prescribed by, or in consultation with, a specialist in gastroenterology; AND

3. Documentation of moderate to severe Crohn's disease

F. Moderately to severely active ulcerative colitis (UC)

Authorization of 12 months may be granted for treatment of moderately to severely active UC when all of the following criteria are met:

1. Member is 5 years of age or older; AND
2. Prescribed by, or in consultation with, a specialist in gastroenterology; AND
3. Documentation of moderate to severe ulcerative colitis

G. Moderate to severe chronic plaque psoriasis (PsO)

Authorization of 12 months may be granted for treatment of moderate to severe plaque psoriasis when all of the following criteria are met:

1. Member is 18 years of age or older; AND
2. Prescribed by, or in consultation with, a specialist in dermatology; AND
3. Documentation has been submitted of one or more of the following:
    a. BSA affected is at least 10%; OR
    b. Crucial body areas affected (e.g., face, hands, feet, genitals, scalp); OR
    c. Inadequate treatment response to topical therapy (corticosteroids, calcineurin inhibitors (e.g. tacrolimus), vitamin D analogs (e.g. calcipotriene), retinoids (e.g. tazarotene); AND
4. Documentation has been submitted that the member meets any of the following criteria:
    i. Member has had an inadequate response, intolerance, or contraindication to at least a 3-month trial of a conventional oral agent for PsO (e.g., methotrexate, cyclosporine, or acitretin); OR
    ii. Member has had an inadequate response, intolerance, or contraindication to at least a 3-month trial of phototherapy (e.g., UVB, PUVA); OR
    iii. Clinical rationale has been provided indicating member's disease severity warrants a biologic DMARD as first-line therapy.

H. **Moderate to severe hidradenitis suppurativa**

Authorization of 12 months may be granted for treatment of moderate to severe hidradenitis suppurativa when all of the following criteria are met:

1. Member is 12 years of age or older; AND
2. Prescribed by, or in consultation with, a specialist in dermatology or rheumatology; AND
3. Documentation has been submitted that the member has had an inadequate response, intolerance, or contraindication to oral antibiotics for at least 90 days.

I. Uveitis (non-infectious intermediate, posterior and panuveitis)

Authorization of 12 months may be granted for treatment of non-infectious intermediate, posterior, and panuveitis when all of the following criteria are met:

1. Member is 2 years of age or older; AND
2. Prescribed by, or in consultation with, a specialist in ophthalmology or rheumatology; AND

3. Documentation has been submitted that the member has had an inadequate response, intolerance, or contraindication to corticosteroids or immunosuppressive therapy (e.g., azathioprine, cyclosporine, methotrexate).

J. Behcet's disease

Authorization of 12 months may be granted for treatment of Behcet's disease when all of the following criteria are met:

1. Prescribed by, or in consultation with, a specialist in rheumatology; AND
2. Documentation has been submitted that the member has had an inadequate response, intolerance, or contraindication to at least one nonbiologic medication for Behcet's disease (e.g., azathioprine, colchicine, cyclosporine, systemic corticosteroids).

K. Pyoderma gangrenosum

Authorization of 12 months may be granted for treatment of pyoderma gangrenosum when all of the following criteria are met:

1. Prescribed by, or in consultation with, a specialist in dermatology; AND
2. Documentation has been submitted that the member has had an inadequate response, intolerance, or contraindication to corticosteroids or immunosuppressive therapy (e.g., cyclosporine, mycophenolate mofetil).

III. CONTINUATION OF THERAPY

Formulary adalimumab biosimilar will continue to within the quantity limit pay after the initial approval if there is at least one paid claim within the last 365 days for adalimumab or another biologic (e.g., Bimzelx, Cosentyx, Otezla, Rinvoq, Skyrizi, Taltz, Tremfya, etc.).

A. Moderately to severely active rheumatoid arthritis (RA)

Authorization of 12 months may be granted for all members (including new members) with documentation of using the requested medication for moderately to severely active rheumatoid arthritis and who achieve or maintain a positive clinical response as evidenced by disease activity improvement of at least 20% from baseline in tender joint count, swollen joint count, pain, or disability.

B. Moderately to severely active polyarticular juvenile idiopathic arthritis

Authorization of 12 months may be granted for all members (including new members) with documentation of using the requested medication for moderately to severely active polyarticular juvenile idiopathic arthritis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

1. Number of joints with active arthritis (e.g., swelling, pain, limitation of motion)
2. Number of joints with limitation of movement
3. Functional ability

C. Active psoriatic arthritis (PsA)

Authorization of 12 months may be granted for all members (including new members) with documentation of using the requested medication for active psoriatic arthritis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

1. Number of swollen joints
2. Number of tender joints
3. Dactylitis
4. Enthesitis
5. Axial disease
6. Skin and/or nail involvement
7. Functional status
8. C-reactive protein (CRP)

D. Active ankylosing spondylitis (AS) and active axial spondyloarthritis

Authorization of 12 months may be granted for all members (including new members) with documentation of using the requested medication for active ankylosing spondylitis or active axial spondyloarthritis and who achieve or maintain positive clinical response with the requested medication as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

1. Functional status
2. Total spinal pain
3. Inflammation (e.g., morning stiffness)
4. Swollen joints
5. Tender joints
6. C-reactive protein (CRP)

E. Moderately to severely active Crohn's disease

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active Crohn's disease and documentation is submitted indicating one of the following:

1. Member has achieved or maintained remission; OR
2. Member has achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition baseline (e.g., abdominal pain or tenderness, diarrhea, body weight, abdominal mass, hematocrit, endoscopic appearance of the mucosa (e.g., computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound), improvement on a disease activity scoring tool (e.g., Crohn's Disease Activity Index [CDAI] score).

F. Moderately to severely active ulcerative colitis

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active ulcerative colitis and documentation is submitted indicating one of the following:

1. Member has achieved or maintained remission; OR
2. Member has achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition baseline (e.g., stool frequency, rectal bleeding, urgency of defecation, C-reactive protein (CRP), fecal calprotectin (FC), endoscopic appearance of the mucosa (e.g., computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound), improvement on a disease activity scoring tool (e.g., Ulcerative Colitis Endoscopic Index of Severity [UCEIS], Mayo score).

G. Moderate to severe plaque psoriasis

Authorization of 12 months may be granted for all members (including new members) with documentation who are using the requested medication for moderate to severe plaque psoriasis and who achieve or maintain positive clinical response as evidenced by low disease activity (e.g., reduction in BSA from baseline) or improvement in signs and symptoms of the condition (e.g., itching, redness, flaking, scaling, burning, cracking, pain).

H. Moderate to severe hidradenitis suppurativa

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderate to severe hidradenitis suppurativa and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when any of the following is met:

1. Reduction in abscess and inflammatory nodule count from baseline
2. Reduced formation of new sinus tracts and scarring
3. Decrease in frequency of inflammatory lesions from baseline
4. Reduction in pain from baseline
5. Reduction in suppuration from baseline
6. Improvement in frequency of relapses from baseline
7. Improvement in quality of life from baseline
8. Improvement on a disease severity assessment tool from baseline

I. Uveitis (non-infectious intermediate, posterior and panuveitis)

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for non-infectious intermediate, posterior, and panuveitis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when the patient meets any of the following:

1. Reduced frequency of disease flares compared to baseline
2. Stability or improvement in anterior chamber (AC) cell grade compared to baseline
3. Stability or improvement in vitreous haze (VH) grade compared to baseline
4. Stability or improvement in visual acuity compared to baseline
5. Reduction in glucocorticoid requirements from baseline

6. No new active inflammatory chorioretinal and/or inflammatory retinal vascular lesions relative to baseline

All other indications

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for an indication outlined in Section III and who achieve or maintain a positive clinical response with the requested medication as evidenced by low disease activity or improvement in signs and symptoms of the condition.

IV. QUANITY LIMIT

Drug Name	Quantity Limit	Daily Dose Quantity Limit
Hadlima (adalimumab-bwwd) 40mg/0.4 ml	1.6 ml per 28 days (4 per 28 days)	0.06
Hadlima (adalimumab-bwwd) 40mg/0.8 ml	3.2 ml per 28 days (4 per 28 days)	0.12
adalimumab-adaz 40mg/0.4 ml	1.6 ml per 28 days (4 per 28 days)	0.06
adalimumab-adaz 80mg/0.8 ml	1.6 ml per 28 days (2 per 28 days)	0.06
adalimumab-fkjp 20mg/0.4 ml	2 per 28 days	0.072
adalimumab-fkjp 40mg/0.8 ml	4 per 28 days	0.15

V. DOSING

The prescribed dose and quantity fall within the FDA-approved labeling or within compendia supported dosing guidelines

FDA-recommended dosing
RA/PsA/AS • 40 mg every other week • For patients not taking concomitant methotrexate: may increase to 40 mg every week if needed **PJIA/Pediatric uveitis (2 years and up)** • 10 kg to < 15 kg: 10 mg every other week • 15 kg to < 30 kg: 20 mg every other weeks • ≥ 30 kg: 40 mg every other week

FDA-recommended dosing
Pediatric CD (6 years and up) • 17 kg to < 40 kg: loading doses of 80 mg on day 1 and 40 mg two weeks later (day 15); maintenance dose (starting at week 4 (day 29) of 20 mg every other week • ≥ 40 kg: loading doses of 160 mg on day 1 (given in one day or split over two consecutive days) and 80 mg two weeks later (day 15); maintenance dose starting at week 4 (day 29) of 40 mg every other week **Adult CD and UC** • Loading doses: 160 mg on day 1 (given in one day or split over two consecutive days), followed by 80 mg two weeks later (day 15) • Maintenance dose: two weeks later (day 29), 40 mg every other week **Plaque psoriasis/ uveitis** • 80 mg, followed by 40 mg every other week starting one week after the initial dose of 80 mg **Adolescent hidradenitis suppurativa (12 years and up)** • 30 kg to < 60 kg: 80 mg on day 1, 40 mg on day 8 and subsequent doses 40 mg every other week • ≥ 60 kg: Follow adult dosing **Adult hidradenitis suppurativa** • Loading doses: 160 mg on day 1 (given in one day or split over two consecutive days), followed by 80 mg two weeks later (day 15) Maintenance dose: begin 40 mg every week two weeks later (day 29)

Abbreviations: RA = rheumatoid arthritis; PsA = psoriatic arthritis; AS = ankylosing spondylitis; PJIA = polyarticular juvenile idiopathic arthritis; CD = Crohn's disease; UC = ulcerative colitis

VI. 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
10. Renal impairment
11. Significant drug interaction

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
6. Significant comorbidity prohibits use of systemic agents (examples include liver or kidney disease, blood dyscrasias, uncontrolled hypertension)

APPENDIX E: Risk factors for Articular Juvenile Idiopathic Arthritis

1. Positive rheumatoid factor
2. Positive anti-cyclic citrullinated peptide antibodies
3. Pre-existing joint damage

VII. REFERENCES

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