Adalimumab

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Adalimumab drug policy is to ensure appropriate selection of patients for therapy based on product labeling, clinical guidelines and clinical studies. The adalimumab products in this policy include the following: adalimumab-aacf 40mg pen, adalimumab-aacf 40mg prefilled syringe, adalimumab-adbm 10mg prefilled syringe, adalimumab-adbm 20mg prefilled syringe, Hadlima (adalimumab-bwwd) 40mg/0.8mL PushTouch autoinjector, Hadlima (adalimumab-bwwd) 40mg/0.8mL prefilled syringe, Humira 10mg prefilled syringe, Humira 20mg prefilled syringe, and associated starter packs. For this program, adalimumab-aacf is the preferred product. Coverage for Humira 10mg and 20mg prefilled syringes is provided based on clinical circumstances that would exclude the use of the preferred product. Coverage for non-preferred products, Hadlima (adalimumab-bwwd) 40mg/0.8mL PushTouch autoinjector and Hadlima (adalimumab-bwwd) 40mg/0.8mL prefilled syringe, is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. Submission of medical records documenting relevant history, physician evaluation information, and supporting compendia or current literature (if applicable) will be required for review of these exceptions.

*Note: Requests for adalimumab 10mg and 20mg for the treatment of indications other than pediatric use in hidradenitis suppurativa, uveitis, and ulcerative colitis, adalimumab-adbm (unbranded Cyltezo) 10mg and 20mg are the preferred products.

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. 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 RA.
2. Reducing signs and symptoms of moderately to severely active polyarticular JIA 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 PsA.
4. Reducing signs and symptoms in adult patients with active 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*.
   Limitations of Use: Effectiveness has not been established in patients who have lost response to or were intolerant to TNF blockers.
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*.

*Adalimumab-aacf carries the same labeled indications as Humira except for pediatric use in hidradenitis suppurativa, uveitis, and ulcerative colitis. An exception process may be available to determine situations where a clinical exception can be made for coverage of Humira 40mg.

Compendial Uses
1. Non-radiographic axial spondyloarthritis
2. Behcet's disease
3. Pyoderma gangrenosum
4. Oligoarticular juvenile idiopathic arthritis
5. Immune checkpoint inhibitor-related toxicity

POLICY

Documentation
Submission of the following information is necessary to initiate the prior authorization review:

A. Rheumatoid arthritis (RA)
   1. For initial requests:
      i. Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.
      ii. Laboratory results, chart notes, or medical record documentation of biomarker testing (i.e., rheumatoid factor [RF], anti-cyclic citrullinated peptide [anti-CCP], and C-reactive protein [CRP] and/or erythrocyte sedimentation rate [ESR]) (if applicable).
   2. For continuation requests: Chart notes or medical record documentation supporting positive clinical response.

B. Articular juvenile idiopathic arthritis, ankylosing spondylitis (AS), non-radiographic axial spondyloarthritis (nr-axSpA) and Immune checkpoint inhibitor-related toxicity:

1. Initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.
2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.

C. Psoriatic arthritis (PsA): For continuation requests: Chart notes or medical record documentation supporting positive clinical response.

D. Crohn's disease (CD)
Continuation requests: Chart notes or medical record documentation supporting positive clinical response to therapy or remission.

E. Ulcerative colitis (UC)
Continuation requests: Chart notes or medical record documentation supporting positive clinical response to therapy or remission.

F. Plaque psoriasis (PsO)
1. Initial requests:
    i. Chart notes or medical record documentation of affected area(s) and body surface area (BSA) affected (if applicable).
    ii. Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.
2. Continuation requests: Chart notes or medical record documentation of decreased body surface area (BSA) affected and/or improvement in signs and symptoms.

G. Hidradenitis suppurativa
1. Initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.
2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response to therapy.

H. Uveitis (non-infectious intermediate, posterior and panuveitis)
1. Initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.
2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response to therapy.

I. Behcet's disease (initial requests only): Chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy (if applicable).

J. Pyoderma gangrenosum (initial requests only): Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy

<u>Preferred Drug Plan Design</u>
Member must meet BOTH the Preferred Drug Plan Design and the Criteria for Initial Approval/Continuation of Therapy when both are applicable.

A. Criteria for initial approval for the non-preferred product, Hadlima (adalimumab-bwwd), will only apply when the member has had a documented intolerable adverse event with the preferred product, adalimumab-aacf, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.
B. Criteria for initial approval for Humira 10mg and Humira 20mg prefilled syringes will only apply when at least ONE of the following criteria are met:
    1. The member had a documented intolerable adverse event with the preferred product, adalimumab-adbm (unbranded Cyltezo) and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.
    2. The member is less than 18 years of age with one of the following conditions:
        a. Uveitis
        b. Hidradenitis Suppurativa
        c. Ulcerative Colitis

Prescriber Specialties (initial approvals only)
This medication must be prescribed by or in consultation with one of the following:

A. Rheumatoid arthritis, articular juvenile idiopathic arthritis, ankylosing spondylitis, axial spondyloarthritis, and Behcet's disease: rheumatologist
B. Psoriatic arthritis and hidradenitis suppurativa: rheumatologist or dermatologist
C. Crohn's disease and ulcerative colitis: gastroenterologist
D. Plaque psoriasis and pyoderma gangrenosum: dermatologist
E. Uveitis: ophthalmologist or rheumatologist
F. Immunotherapy-related inflammatory arthritis: oncologist, hematologist, or rheumatologist

Criteria for Initial Approval

A. Moderately to severely active rheumatoid arthritis (RA)
    1. Authorization of 12 months may be granted for adult members who have previously received a biologic or targeted synthetic drug (e.g., Rinvoq, Xeljanz) indicated for moderately to severely active rheumatoid arthritis.
    2. Authorization of 12 months may be granted for adult members for treatment of moderately to severely active RA when all of the following criteria are met:
        i. Member meets either of the following criteria:
            a. Member has been tested for either of the following biomarkers and the test was positive:
                1. Rheumatoid Factor (RF)
                2. Anti-cyclic citrullinated peptide (anti-CCP)
            b. Member has been tested for ALL of the following biomarkers:
                1. RF
                2. Anti-CCP
                3. C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR)
        ii. Member meets either of the following criteria:
            a. Member has experienced an inadequate response to at least a 3-month trial of methotrexate despite adequate dosing (i.e., titrated to at least 15 mg/week).
            b. Member has an intolerance or contraindication to methotrexate (see Appendix A).

B. Articular juvenile idiopathic arthritis (JIA)
    1. Authorization of 12 months may be granted for members 2 years of age and older who have previously received a biologic or targeted synthetic drug indicated for moderately to severely active articular juvenile idiopathic arthritis.

2. Authorization of 12 months may be granted for members 2 years of age and older for treatment of moderately to severely active articular juvenile idiopathic arthritis when any of the following criteria is met:
    a. The member has had an inadequate response to methotrexate or another conventional synthetic drug (e.g., leflunomide, sulfasalazine, hydroxychloroquine) administered at an adequate dose and duration.
    b. The member has had an inadequate response to a trial of scheduled non-steroidal anti-inflammatory drugs (NSAIDs) and/or intra-articular glucocorticoids (e.g., triamcinolone hexacetonide) and one of the following risk factors for poor outcome:
        i. Involvement of ankle, wrist, hip, sacroiliac joint, and/or temporomandibular joint (TMJ)
        ii. Presence of erosive disease or enthesitis
        iii. Delay in diagnosis
        iv. Elevated levels of inflammation markers
        v. Symmetric disease
    c. The member has risk factors for disease severity and potentially a more refractory disease course (See Appendix B) and the member also meets one of the following:
        i. High-risk joints are involved (e.g., cervical spine, wrist, or hip).
        ii. High disease activity.
        iii. Are judged to be at high risk for disabling joint disease.

C. Psoriatic arthritis (PsA)

1. Authorization of 12 months may be granted for adult members who have previously received a biologic or targeted synthetic drug (e.g., Rinvoq, Otezla) indicated for active psoriatic arthritis.
2. Authorization of 12 months may be granted for adult members for treatment of active psoriatic arthritis when either of the following criteria is met:
    a. Member has mild to moderate disease and meets one of the following criteria:
        i. Member has had an inadequate response to methotrexate, leflunomide, or another conventional synthetic drug (e.g., sulfasalazine) administered at an adequate dose and duration.
        ii. Member has an intolerance or contraindication to methotrexate or leflunomide (see Appendix A), or another conventional synthetic drug (e.g., sulfasalazine).
        iii. Member has enthesitis or predominantly axial disease.
    b. Member has severe disease.

D. Ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA)

1. Authorization of 12 months may be granted for members who have previously received a biologic or targeted synthetic drug (e.g., Rinvoq, Xeljanz) indicated for active ankylosing spondylitis or active non-radiographic axial spondyloarthritis.
2. Authorization of 12 months may be granted for treatment of active ankylosing spondylitis and active non-radiographic axial spondyloarthritis when any of the following criteria is met:
    a. Member has had an inadequate response to at least two non-steroidal anti-inflammatory drugs (NSAIDs).
    b. Member has an intolerance or contraindication to two or more NSAIDs.

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

1. Authorization of 12 months may be granted for treatment of moderately to severely active CD.

F. Moderately to severely active ulcerative colitis (UC)

1. Authorization of 12 months may be granted for treatment of moderately to severely active ulcerative colitis.

G. Plaque psoriasis (PsO)

1. Authorization of 12 months may be granted for adult members who have previously received a biologic or targeted synthetic drug (e.g., Sotyktu, Otezla) indicated for the treatment of moderate to severe plaque psoriasis.
2. Authorization of 12 months may be granted for adult members for treatment of moderate to severe plaque psoriasis in members when any of the following criteria is met:
    a. Crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
    b. At least 10% of the body surface area (BSA) is affected
    c. At least 3% of body surface area (BSA) is affected and the member meets any of the following criteria:
        i. Member has had an inadequate response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine or acitretin.
        ii. Member has a clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine and acitretin (see Appendix A).

H. Moderate to severe hidradenitis suppurativa

1. Authorization of 12 months may be granted for members 12 years of age or older who have previously received a biologic indicated for treatment of moderate to severe hidradenitis suppurativa.
2. Authorization of 12 months may be granted for members 12 years of age or older for treatment of moderate to severe hidradenitis suppurativa when either of the following is met:
    a. Member has had an inadequate response to an oral antibiotic used for the treatment of hidradenitis suppurativa for at least 90 days.
    b. Member has an intolerance or contraindication to oral antibiotics used for the treatment of hidradenitis suppurativa.

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

1. Authorization of 12 months may be granted for members 2 years of age or older who have previously received a biologic indicated for non-infectious intermediate, posterior and panuveitis.
2. Authorization of 12 months may be granted for members 2 years of age and older for treatment of non-infectious intermediate, posterior and panuveitis when either of the following is met:
    a. Member has experienced an inadequate response with corticosteroids or immunosuppressive therapy (e.g., azathioprine, cyclosporine, methotrexate, mycophenolate mofetil).
    b. Member has an intolerance or contraindication to corticosteroids and immunosuppressive therapy (e.g., azathioprine, cyclosporine, methotrexate, mycophenolate mofetil).

J. Behcet’s disease

1. Authorization of 12 months may be granted for members who have previously received Otezla or a biologic indicated for the treatment of Behcet’s disease.
2. Authorization of 12 months may be granted for the treatment of Behcet’s disease when the member has had an inadequate response to at least one nonbiologic medication for Behcet’s disease (e.g., azathioprine, colchicine, cyclosporine, systemic corticosteroids,).

K. Pyoderma gangrenosum

1. Authorization of 12 months may be granted for members who have previously received a biologic indicated for treatment of pyoderma gangrenosum.
2. Authorization of 12 months may be granted for treatment of pyoderma gangrenosum when either of the following is met:
    a. Member has experienced an inadequate response to corticosteroids or immunosuppressive therapy (e.g., cyclosporine or mycophenolate mofetil).

Member has an intolerance or contraindication to corticosteroids and immunosuppressive therapy (e.g., cyclosporine, mycophenolate mofetil).

L. Immune checkpoint inhibitor-related toxicity

Authorization of 12 months may be granted for treatment of immune checkpoint inhibitor-related toxicity when the member has moderate or severe immunotherapy-related inflammatory arthritis and meets either of the following:

1. Member has had an inadequate response to corticosteroids or a conventional synthetic drug (e.g., methotrexate, sulfasalazine, leflunomide, hydroxychloroquine).
2. Member has an intolerance or contraindication to corticosteroids and a conventional synthetic drug (e.g., methotrexate, sulfasalazine, leflunomide, hydroxychloroquine).

Continuation of Therapy

A. Moderately to severely active rheumatoid arthritis (RA)

Authorization of 12 months may be granted for all members (including new members) who are 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. Articular juvenile idiopathic arthritis (JIA)

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active articular 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. Psoriatic arthritis (PsA)

Authorization of 12 months may be granted for all members (including new members) who are 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. Ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA)

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for ankylosing spondylitis or non-radiographic 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

1. 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 who achieve or maintain remission.

2. 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 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:
    i. Abdominal pain or tenderness
    ii. Diarrhea
    iii. Body weight
    iv. Abdominal mass
    v. Hematocrit
    vi. Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound
    vii. Improvement on a disease activity scoring tool (e.g., Crohn's Disease Activity Index [CDAI] score)

F. Moderately to severely active ulcerative colitis

1. 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 who achieve or maintain remission.

2. 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 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:
    i. Stool frequency
    ii. Rectal bleeding
    iii. Urgency of defecation
    iv. C-reactive protein (CRP)
    v. Fecal calprotectin (FC)
    vi. Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound
    vii. 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) who are using the requested medication for moderate to severe plaque psoriasis 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 body surface area (BSA) affected from baseline
2. Improvement in signs and symptoms from baseline (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

J. Immune checkpoint inhibitor-related toxicity

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for immunotherapy-related inflammatory 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.

K. 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.

Note: Post Limit Quantity Exception Criteria available for Crohn's disease, Plaque Psoriasis, and Ulcerative Colitis that will allow for dose escalation in patients experiencing a partial response, nonresponse, or a loss of response to the current dosing regimen.

Other

For all indications: Member has had a documented negative TB test (which can include a tuberculosis skin test [TST] or an interferon-release assay [IGRA])* within 12 months of initiating therapy for persons who are naïve to biologic drugs or targeted synthetic drugs associated with an increased risk of TB.

*If the screening testing for TB is positive, there must be further testing to confirm there is no active disease (e.g., chest x-ray). Do not administer adalimumab to members with active TB infection. If there is latent disease, TB treatment must be started before initiation of adalimumab.

For all indications: Member cannot use adalimumab concomitantly with any other biologic drug or targeted synthetic drug for the same indication.

Adalimumab is considered **not medically necessary** for members who do not meet the criteria set forth above.

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. For rheumatoid arthritis, member must initiate treatment with every other week dosing.

Members currently receiving the requested medication as samples or via the manufacturer's patient assistance program will be required to meet the criteria for initial approval. This ensures that members are treated equally regardless of their provider's ability to access medication samples.

Quantity Limits

Medication	Standard Limit	FDA-recommended dosing
Adalimumab-aacf 40 mg/0.8 mL single-use prefilled syringe/pen	4 syringes/pens per 28 days	**RA/PsA/AS** • 40 mg every other week • For RA, patients not taking concomitant methotrexate: may increase to 40 mg every week or 80 mg every other 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 week • ≥ 30 kg: 40 mg every other week **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 **Pediatric UC (5 years and up)** • 20 kg to < 40 kg: loading doses of 80 mg on day 1, 40 mg one week later (day 8) and 40 mg one week after that (day 15); maintenance dose (starting at week 4 (day 29) of 40 mg every other week or 20 mg every week
Adalimumab-adbm 10mg/0.2 mL single-use prefilled syringe	4 syringes per 28 days	
Adalimumab-adbm 20mg/0.4 mL single-use prefilled syringe	4 syringes per 28 days	
Hadlima (adalimumab-bwwd) 40mg/0.8 mL single-use prefilled syringe/pen	4 syringes/pens per 28 days	
Humira (adalimumab) 10 mg/0.1 mL single-use prefilled syringe	4 syringes per 28 days	

Humira (adalimumab) 20 mg/0.2 mL single-use prefilled syringe	4 syringes per 28 days	• ≥ 40 kg: loading doses of 160 mg on day 1 (given in one day or split over two consecutive days), 80 mg one week later (day 8) and 80 mg one week after that (day 15); maintenance dose starting at week 4 (day 29) of 80 mg every other week or 40 mg every 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 or 80 mg every other week two weeks later (day 29)
Humira (adalimumab) 80 mg/0.8 mL and 40 mg/0.4 mL Pediatric Crohn's Disease Starter Pack	1 pack per lifetime	
Humira (adalimumab) 80 mg/0.8 mL and 40 mg/0.4 mL Psoriasis/Uveitis/Adolescent Hidradenitis Suppurativa Starter Pack	1 pack per lifetime	

Abbreviations: RA = rheumatoid arthritis; PsA = psoriatic arthritis; AS = ankylosing spondylitis; PJIA = polyarticular juvenile idiopathic arthritis; CD = Crohn's disease; UC = ulcerative colitis
*Post Limit Quantity Exception Criteria available for CD, plaque psoriasis, and ulcerative colitis

Appendices

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

1. Clinical diagnosis of alcohol use disorder, 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 currently planning pregnancy
10. Renal impairment
11. Significant drug interaction
12. Significant comorbidity prohibits use of systemic agents (examples include liver or kidney disease, blood dyscrasias, uncontrolled hypertension)
13. Risk of treatment-related toxicity

Appendix B: Risk factors for Articular Juvenile Idiopathic Arthritis

1. Positive rheumatoid factor
2. Positive anti-cyclic citrullinated peptide antibodies

3. Pre-existing joint damage

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- N/A

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- Adalimumab-adbm [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; September 2023.
- Hadlima [package insert]. Jersey City, NJ: Organon & Co.; June 2023.
- Humira [package insert]. North Chicago, IL: AbbVie Inc.; February 2021.
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