Reference number(s)
2008-A

Specialty Guideline Management
Humira and Biosimilars

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Humira	adalimumab
Abrilada	adalimumab-afzb
Amjevita	adalimumab-atto
Cyltezo	adalimumab-adbm
Hadlima	adalimumab-bwwd
Hulio	adalimumab-fkjp
Hyrimoz	adalimumab-adaz
Idacio	adalimumab-aacf
Simlandi	adalimumab-ryvk
Yuflyma	adalimumab-aaty
Yusimry	adalimumab-aqvh
adalimumab (unbranded Humira)	adalimumab
adalimumab-aacf (unbranded Idacio)	adalimumab-aacf
adalimumab-aaty (unbranded Yuflyma)	adalimumab-aaty
adalimumab-adaz (unbranded Hyrimoz)	adalimumab-adaz
adalimumab-adbm (unbranded Cyltezo)	adalimumab-adbm
adalimumab-bwwd (unbranded Hadlima)	adalimumab-bwwd
adalimumab-fkjp (unbranded Hulio)	adalimumab-fkjp
adalimumab-ryvk (unbranded Simlandi)	adalimumab-ryvk

Reference number(s)
2008-A

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.

FDA-approved Indications[1-19]

- 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)
- Reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis (JIA) in patients 2 years of age and older
- Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active psoriatic arthritis (PsA)
- Reducing signs and symptoms in adult patients with active ankylosing spondylitis (AS)
- Treatment of moderately to severely active Crohn's disease (CD) in adult and pediatric patients 6 years of age and older
- Treatment of moderately to severely active ulcerative colitis (UC) in adult and pediatric patients 5 years of age and older
  Limitations of Use: The effectiveness of Humira has not been established in patients who have lost response to or were intolerant to tumor necrosis factor (TNF) blockers
- Treatment of adult patients with moderate to severe chronic plaque psoriasis (PsO) who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate
- Treatment of moderate to severe hidradenitis suppurativa in patients 12 years of age and older
- Treatment of non-infectious intermediate, posterior, and panuveitis in adults and pediatric patients 2 years of age and older

Compendial Uses

- Non-radiographic axial spondyloarthritis[44]
- Behcet's disease[37,44]
- Pyoderma gangrenosum[34-36,45]
- Oligoarticular juvenile idiopathic arthritis[25,57]
- Immune checkpoint inhibitor-related toxicity- inflammatory arthritis[53]

All other indications are considered experimental/investigational and not medically necessary.

Documentation

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

Rheumatoid arthritis (RA)

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.
- 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).

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Articular juvenile idiopathic arthritis (JIA)

Initial requests

Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy.

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Ankylosing spondylitis (AS), non-radiographic axial spondyloarthritis (nr-axSpA), psoriatic arthritis (PsA), hidradenitis suppurativa, uveitis (non-infectious intermediate, posterior and panuveitis), and immune checkpoint inhibitor-related toxicity

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.

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Crohn's disease (CD) and ulcerative colitis (UC)

Continuation requests

Chart notes or medical record documentation supporting positive clinical response to therapy or remission.

Plaque psoriasis (PsO)

Initial requests

- Chart notes or medical record documentation of affected area(s) and body surface area (BSA) affected (if applicable).
- 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.

Continuation requests

Chart notes or medical record documentation of decreased body surface area (BSA) affected and/or improvement in signs and symptoms.

Behcet's disease

Chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy (if applicable).

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.

Prescriber Specialties

This medication must be prescribed by or in consultation with one of the following:

- Rheumatoid arthritis, articular juvenile idiopathic arthritis, ankylosing spondylitis, non-radiographic axial spondyloarthritis, and Behcet's disease: rheumatologist
- Psoriatic arthritis and hidradenitis suppurativa: rheumatologist or dermatologist
- Crohn's disease and ulcerative colitis: gastroenterologist
- Plaque psoriasis and pyoderma gangrenosum: dermatologist
- Uveitis: ophthalmologist or rheumatologist
- Immune checkpoint inhibitor-related toxicity: oncologist, hematologist, or rheumatologist

Coverage Criteria

Rheumatoid arthritis (RA)[1-19,22-24,48,52,55]

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 within the past 120 days.

Authorization of 12 months may be granted for adult members for treatment of moderately to severely active RA when both of the following criteria are met:

- Member meets either of the following:
  - Member has been tested for either of the following biomarkers and the test was positive:
    - Rheumatoid factor (RF)
    - Anti-cyclic citrullinated peptide (anti-CCP)
  - Member has been tested for ALL of the following biomarkers:
    - RF
    - Anti-CCP
    - C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR)
- Member meets ONE of the following:
  - Member has failed to achieve a low disease activity after a 3-month trial of methotrexate (MTX) monotherapy at a maximum titrated dose of at least 15 mg per week and meets any of the following conditions:
    - Member has had a documented inadequate response to MTX in combination with at least one other conventional synthetic drug (i.e., hydroxychloroquine and/or sulfasalazine) after a 3-month trial at a maximum tolerated dose(s).
    - Member has experienced a documented intolerable adverse event to hydroxychloroquine or sulfasalazine.
    - Member has a documented contraindication to hydroxychloroquine (see Appendix A) and sulfasalazine (e.g., porphyria, intestinal or urinary obstruction).
    - Member has moderate to high disease activity.
  - Member was unable to tolerate a 3-month trial of MTX monotherapy at a maximum titrated dose of at least 15 mg per week and meets any of the following conditions:
    - Member has had a documented inadequate response to MTX in combination with at least one other conventional synthetic drug (i.e., hydroxychloroquine and/or sulfasalazine) after a 3-month trial at a maximum tolerated dose(s).
    - Member has stopped taking MTX and has had a documented inadequate response to another conventional synthetic drug (i.e., leflunomide, hydroxychloroquine, and/or sulfasalazine) alone or in combination after a 3-month trial at a maximum tolerated dose(s).
    - Member has experienced a documented intolerable adverse event to leflunomide, hydroxychloroquine, or sulfasalazine.
    - Member has a documented contraindication to leflunomide, hydroxychloroquine (see Appendix A), and sulfasalazine (e.g., porphyria, intestinal or urinary obstruction).
    - Member has moderate to high disease activity.

- Member has experienced a documented intolerable adverse event or has a documented contraindication to MTX (see Appendix A), discontinues MTX, and meets any of the following conditions:
    - Member has had a documented inadequate response to another conventional synthetic drug (i.e., leflunomide, hydroxychloroquine, and/or sulfasalazine) alone or in combination after a 3-month trial at a maximum tolerated dose(s).
    - Member has experienced a documented intolerable adverse event to leflunomide, hydroxychloroquine, or sulfasalazine.
    - Member has a documented contraindication to leflunomide, hydroxychloroquine (see Appendix A), and sulfasalazine (e.g., porphyria, intestinal or urinary obstruction).
    - Member has moderate to high disease activity.

Articular juvenile idiopathic arthritis (JIA)[1-19,25,57]

Authorization of 12 months may be granted for members 2 years of age or older who have previously received a biologic or targeted synthetic drug (e.g., Xeljanz) indicated for moderately to severely active articular juvenile idiopathic arthritis.

Authorization of 12 months may be granted for members 2 years of age or older for treatment of moderately to severely active articular juvenile idiopathic arthritis when any of the following criteria is met:

- 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.
- 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:
    - Involvement of ankle, wrist, hip, sacroiliac joint, and/or temporomandibular joint (TMJ)
    - Presence of erosive disease or enthesitis
    - Delay in diagnosis
    - Elevated levels of inflammation markers
    - Symmetric disease
- 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:
    - High-risk joints are involved (e.g., cervical spine, wrist, or hip)
    - High disease activity
    - Is judged to be at high risk for disabling joint disease

Psoriatic arthritis (PsA)[1-19,26-29,40]

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.

Authorization of 12 months may be granted for adult members for treatment of active psoriatic arthritis when either of the following criteria is met:

- Member has mild to moderate disease and meets one of the following criteria:
  - Member has had an inadequate response to methotrexate, leflunomide, or another conventional synthetic drug (e.g., sulfasalazine) administered at an adequate dose and duration.
  - Member has an intolerance or contraindication to methotrexate or leflunomide (see Appendix A), or another conventional synthetic drug (e.g., sulfasalazine).
  - Member has enthesitis or predominantly axial disease.
- Member has severe disease.

Ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA)[1-20,30,31]

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 active ankylosing spondylitis or active non-radiographic axial spondyloarthritis.

Authorization of 12 months may be granted for adult members for treatment of active ankylosing spondylitis or active non-radiographic axial spondyloarthritis when either of the following criteria is met:

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

Crohn's disease (CD)[1-19,32,33,54]

Authorization of 12 months may be granted for treatment of moderately to severely active Crohn's disease.

Ulcerative colitis (UC)[1-19,32,41,49]

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

Plaque psoriasis (PsO)[1-19,28,29,38,42,43,56]

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 treatment of moderate to severe plaque psoriasis.

Authorization of 12 months may be granted for adult members for treatment of moderate to severe plaque psoriasis when any of the following criteria is met:

- Crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.

- At least 10% of body surface area (BSA) is affected.
- At least 3% of body surface area (BSA) is affected and the member meets either of the following criteria:
    - Member has had an inadequate response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin.
    - Member has a clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine, and acitretin (see Appendix A).

Hidradenitis suppurativa[1-19,50,51]

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.

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:

- Member has had an inadequate response to an oral antibiotic used for the treatment of hidradenitis suppurativa for at least 90 days (e.g., clindamycin, metronidazole, moxifloxacin, rifampin, tetracyclines).
- Member has an intolerance or contraindication to oral antibiotics used for the treatment of hidradenitis suppurativa.

Uveitis (non-infectious intermediate, posterior and panuveitis)[1-19,46,47,58]

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.

Authorization of 12 months may be granted for members 2 years of age or older for treatment of non-infectious intermediate, posterior and panuveitis when either of the following is met:

- Member has had an inadequate response to corticosteroids or immunosuppressive therapy (e.g., azathioprine, cyclosporine, methotrexate, mycophenolate mofetil).
- Member has an intolerance or contraindication to corticosteroids and immunosuppressive therapy (e.g., azathioprine, cyclosporine, methotrexate, mycophenolate mofetil).

Behcet's disease[37,44]

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.

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 non-biologic medication for Behcet's disease (e.g., azathioprine, colchicine, cyclosporine, systemic corticosteroids).

Pyoderma gangrenosum[34-36,45,59]

Authorization of 12 months may be granted for members who have previously received a biologic indicated for treatment of pyoderma gangrenosum.

Authorization of 12 months may be granted for treatment of pyoderma gangrenosum when either of the following is met:

- Member has had 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).

Immune checkpoint inhibitor-related toxicity[53]

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:

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

Continuation of Therapy

Rheumatoid arthritis (RA)[1-19,22-24,48,52,55]

Authorization of 12 months may be granted for all adult 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.

Articular juvenile idiopathic arthritis (JIA)[1-19,25]

Authorization of 12 months may be granted for all members 2 years of age or older (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:

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

Psoriatic arthritis (PsA)[1-19,26-29,40]

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for 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:

- Number of swollen joints
- Number of tender joints
- Dactylitis
- Enthesitis
- Axial disease
- Skin and/or nail involvement
- Functional status
- C-reactive protein (CRP)

Ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA)[1-20,30,31]

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

- Functional status
- Total spinal pain
- Inflammation (e.g., morning stiffness)
- Swollen joints
- Tender joints
- C-reactive protein (CRP)

Crohn's disease (CD)[1-19,32,33,54]

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.

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:

- Abdominal pain or tenderness
- Diarrhea
- Body weight
- Abdominal mass
- Hematocrit

- Appearance of the mucosa on endoscopy, 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)

Ulcerative colitis (UC)[1-19,32,41,49]

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.

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:

- Stool frequency
- Rectal bleeding
- Urgency of defecation
- C-reactive protein (CRP)
- Fecal calprotectin (FC)
- Appearance of the mucosa on endoscopy, 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)

Plaque psoriasis (PsO)[1-19,29,38,42,43]

Authorization of 12 months may be granted for all adult 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 either of the following is met:

- Reduction in body surface area (BSA) affected from baseline
- Improvement in signs and symptoms from baseline (e.g., itching, redness, flaking, scaling, burning, cracking, pain)

Hidradenitis suppurativa[1-19,50,51]

Authorization of 12 months may be granted for all members 12 years of age and older (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:

- Reduction in abscess and inflammatory nodule count from baseline
- Reduced formation of new sinus tracts and scarring

- Decrease in frequency of inflammatory lesions from baseline
- Reduction in pain from baseline
- Reduction in suppuration from baseline
- Improvement in frequency of relapses from baseline
- Improvement in quality of life from baseline
- Improvement on a disease severity assessment tool from baseline

Uveitis (non-infectious intermediate, posterior and panuveitis)[1-19,46,47]

Authorization of 12 months may be granted for all members 2 years of age and older (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 any of the following is met:

- Reduced frequency of disease flares compared to baseline
- Stability or improvement in anterior chamber (AC) cell grade compared to baseline
- Stability or improvement in vitreous haze (VH) grade compared to baseline
- Stability or improvement in visual acuity compared to baseline
- Reduction in glucocorticoid requirements from baseline
- No new active inflammatory chorioretinal and/or inflammatory retinal vascular lesions relative to baseline

Immune checkpoint inhibitor-related toxicity[53]

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.

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 the coverage criteria section and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition.

Other[1-19,39]

For all indications: Member has had a documented negative tuberculosis (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 the requested medication to members with active TB infection. If there is latent disease, TB treatment must be started before initiation of the requested medication.

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

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.

Appendix

Appendix A: Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Cyclosporine, Acitretin, or Leflunomide[43]

- Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease
- Drug interaction
- Risk of treatment-related toxicity
- Pregnancy or currently planning pregnancy
- Breastfeeding
- Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension)
- Hypersensitivity
- History of intolerance or adverse event

Appendix B: Risk Factors for Articular Juvenile Idiopathic Arthritis

- Positive rheumatoid factor
- Positive anti-cyclic citrullinated peptide antibodies
- Pre-existing joint damage

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