

Adalimumab Products (Humira[®], Abrilada[™], Amjevita[®], Cyltezo[®], Hadlima[™], Hulio[®], Hyrimoz[®], Idacio[®], Simlandi[®], Yuflyma[®], Yusimry[™], adalimumab)

When requesting an adalimumab product, the individual requiring treatment must be diagnosed with one of the following FDA-approved indications or approved compendial uses and meet the specific coverage guidelines and applicable safety criteria for the covered indications.

FDA-Approved Indications

- Ankylosing spondylitis
- Crohn's disease
- Hidradenitis suppurativa
- Juvenile idiopathic arthritis (JIA)
- Plaque psoriasis,
- Psoriatic arthritis (PsA)
- Rheumatoid arthritis
- Ulcerative colitis
- Uveitis

Approved Off-Label Compendial Uses

- Behcet's Disease
- Pyoderma Gangrenosum
- Sarcoidosis

Coverage Guidelines

Ankylosing Spondylitis.

The individual must meet **all** of the following criteria for initial authorization:

- Is ≥ 18 years of age;
- Medication is prescribed by or in consultation with a rheumatologist.

The individual must meet **all** of the following criteria for reauthorization:

- Has been established on therapy for at least 6 months;
Note: A patient who has received < 6 months of therapy or who is restarting therapy with an adalimumab product is reviewed under initial therapy.
- Meets **one** of the following:
 - o Experienced a beneficial clinical response from baseline when assessed by at least one objective measure; OR

Note: Examples include Ankylosing Spondylitis Disease Activity Score (ASDAS), Ankylosing Spondylitis Quality of Life Scale (ASQoL), Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), Bath Ankylosing Spondylitis Functional Index (BASFI), Bath Ankylosing Spondylitis Global Score (BAS-G), Bath Ankylosing Spondylitis Metrology Index (BASMI), Dougados Functional Index (DFI), Health Assessment Questionnaire for the Spondyloarthropathies (HAQ-S), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).

- o Experienced an improvement in at least one symptom from baseline, such as decreased pain or stiffness, or improvement in function or activities of daily living.

Crohn's Disease

The individual must meet **all** of the following criteria for initial authorization:

- Is ≥ 6 years of age;
- Meets **one** of the following:
 - o Has tried or is currently taking corticosteroids (e.g., prednisone, methylprednisolone), or patient has contraindication to corticosteroids; OR
 - o Has tried one other conventional systemic therapy for Crohn's disease (e.g., azathioprine, 6-mercaptopurine, methotrexate, a biologic. A biosimilar of the requested biologic and mesalamine do not count as conventional systemic therapy); OR
 - o Has enterocutaneous (perianal or abdominal) or rectovaginal fistulas; OR
 - o Had ileocolonic resection (to reduce the chance of Crohn's disease recurrence);
- Medication is prescribed by or in consultation with a gastroenterologist.

The individual must meet **all** of the following criteria for reauthorization:

- Has been established on therapy for at least 6 months;
Note: A patient who has received < 6 months of therapy or who is restarting therapy with an adalimumab product is reviewed under initial therapy.
- Meets at least **one** of the following:
 - o Experienced a beneficial clinical response from baseline when assessed by at least one objective measure; OR
Note: Examples of objective measures include fecal markers (e.g., fecal lactoferrin, fecal calprotectin), serum markers (e.g., C-reactive protein), imaging studies (magnetic resonance enterography [MRE], computed tomography enterography [CTE]), endoscopic assessment, and/or reduced dose of corticosteroids.
 - o Experienced an improvement in at least one symptom from baseline, such as decreased pain, fatigue, stool frequency, and/or blood in stool.

Juvenile Idiopathic Arthritis (JIA) [or juvenile rheumatoid arthritis] {regardless of type of onset}

Note: This includes juvenile spondyloarthropathy/active sacroiliac arthritis.

The individual must meet **all** of the following criteria for initial authorization:

- Is ≥ 2 years of age;
- Meets **one** of the following:
 - o Has tried one other systemic therapy for this condition (e.g., methotrexate, sulfasalazine, leflunomide, or a nonsteroidal anti-inflammatory drug [NSAID: e.g., ibuprofen, naproxen]). (A biosimilar of the requested biologic does not count as conventional systemic therapy); OR
 - o Will be starting on adalimumab concurrently with methotrexate, sulfasalazine, or leflunomide; OR
 - o Has an absolute contraindication to methotrexate, sulfasalazine, or leflunomide; OR

Note: Examples of contraindications to methotrexate include pregnancy, breast feeding, alcoholic liver disease, immunodeficiency syndrome, blood dyscrasias.

 - o Has aggressive disease;
- Medication is prescribed by or in consultation with a rheumatologist.

The individual must meet **all** of the following criteria for reauthorization:

- Has been established on therapy for at least 6 months;

Note: A patient who has received < 6 months of therapy or who is restarting therapy with an adalimumab product is reviewed under initial therapy.
- Meets **one** of the following:
 - o Experienced a beneficial clinical response from baseline when assessed by at least one objective measure; OR

Note: Examples of objective measures include Physician Global Assessment (MD global), Parent/Patient Global Assessment of Overall Well-Being (PGA), Parent/Patient Global Assessment of Disease Activity (PDA), Juvenile Arthritis Disease Activity Score (JDAS), Clinical Juvenile Arthritis Disease Activity Score (cJDAS), Juvenile Spondyloarthritis Disease Activity Index (JSpADA), serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate), and/or reduced dosage of corticosteroids.

 - o Experienced an improvement in at least one symptom from baseline, such as improvement in limitation of motion, less joint pain or tenderness, decreased duration of morning stiffness or fatigue, or improved function or activities of daily living.

Hidradenitis Suppurativa

The individual must meet **all** of the following criteria for initial authorization:

- Is ≥ 12 years of age;
- Has tried at least one other therapy;

Note: Examples include intralesional or oral corticosteroids (such as triamcinolone or prednisone), systemic antibiotics (e.g., clindamycin, dicloxacillin, or erythromycin), or isotretinoin.
- Medication is prescribed by or in consultation with a dermatologist.

The individual must meet **all** of the following criteria for reauthorization:

- Has been established on therapy for at least 3 months;

Note: A patient who has received < 3 months of therapy or who is restarting therapy with an adalimumab product is reviewed under initial therapy.

- Experienced a beneficial clinical response from baseline when assessed by at least one objective measure;

Note: Examples of objective measures include Hurley staging, Sartorius score, Physician Global Assessment, and Hidradenitis Suppurativa Severity Index.

- Experienced an improvement in at least one symptom from baseline, such as decreased pain or drainage of lesions, nodules, or cysts.

Plaque Psoriasis

The individual must meet **all** of the following criteria for initial authorization:

- Is ≥ 18 years of age;
- Meets **one** of the following:
 - o Has tried at least one traditional systemic agent for psoriasis for at least 3 months, unless intolerant; OR
Note: Examples include methotrexate, cyclosporine, or acitretin. A 3-month trial of psoralen plus ultraviolet A light (PUVA) also counts. An exception to the requirement for a trial of one traditional systemic agent for psoriasis can be made if the patient has already had a 3-month trial or previous intolerance to at least one biologic other than the requested medication. A biosimilar of the requested biologic does not count. A patient who has already tried a biologic for psoriasis is not required to “step back” and try a traditional systemic agent for psoriasis.
 - o Has a contraindication to methotrexate;
- Medication is prescribed by or in consultation with a dermatologist.

The individual must meet **all** of the following criteria for reauthorization:

- Has been established on therapy for at least 3 months;
Note: A patient who has received < 3 months of therapy or who is restarting therapy with an adalimumab product is reviewed under Initial therapy.
- Experienced a beneficial clinical response, defined as improvement from baseline in at least one of the following: estimated body surface area affected, erythema, induration/thickness, and/or scale of areas affected by psoriasis;
- Experienced an improvement in at least one symptom from baseline, such as decreased pain, itching, and/or burning.

Psoriatic Arthritis.

The individual must meet **all** of the following criteria for initial authorization:

- Is ≥ 18 years of age;
- Medication is prescribed by or in consultation with a rheumatologist or a dermatologist.

The individual must meet **all** of the following criteria for reauthorization:

- Has been established on therapy for at least 6 months;

Note: A patient who has received < 6 months of therapy or who is restarting therapy with an adalimumab product is reviewed under initial therapy.

- Meets **one** of the following:
 - Experienced a beneficial clinical response from baseline when assessed by at least one objective measure; OR
Note: Examples of objective measures of disease activity include Disease Activity Index for Psoriatic Arthritis (DAPSA), Composite Psoriatic Disease Activity Index (CPDAI), Psoriatic Arthritis Disease Activity Score (PsA DAS), Grace Index, Leeds Enthesitis Score (LEI), Spondyloarthritis Consortium of Canada (SPARCC) enthesitis score, Leeds Dactylitis Instrument Score, Minimal Disease Activity (MDA), Psoriatic Arthritis Impact of Disease (PsAID-12), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).
 - Experienced an improvement in at least one symptom from baseline, such as less joint pain, morning stiffness, or fatigue; improved function or activities of daily living; or decreased soft tissue swelling in joints or tendon sheaths.

Rheumatoid Arthritis.

The individual must meet **all** of the following criteria for initial authorization:

- Is ≥ 18 years of age;
- Has tried one conventional synthetic disease-modifying antirheumatic drug (DMARD) for at least 3 months;
Note: Examples include methotrexate (oral or injectable), leflunomide, hydroxychloroquine, and sulfasalazine. An exception to the requirement for a trial of one conventional synthetic DMARD can be made if the patient has already had a 3-month trial with at least one biologic other than the requested medication. A biosimilar of the requested biologic does not count. A patient who has already tried a biologic for rheumatoid arthritis is not required to “step back” and try a conventional synthetic DMARD.
- The medication is prescribed by or in consultation with a rheumatologist.

The individual must meet **all** of the following criteria for reauthorization:

- Has been established on therapy for at least 6 months;
Note: A patient who has received < 6 months of therapy or who is restarting therapy with an adalimumab product is reviewed under initial therapy.
- Meets **one** of the following:
 - Experienced a beneficial clinical response when assessed by at least one objective measure; OR
Note: Examples of objective measures of disease activity include Clinical Disease Activity Index (CDAI), Disease Activity Score (DAS) 28 using erythrocyte sedimentation rate or C-reactive protein, Patient Activity Scale (PAS)-II, Rapid Assessment of Patient Index Data 3 (RAPID-3), and/or Simplified Disease Activity Index (SDAI).
 - Experienced an improvement in at least one symptom, such as decreased joint pain, morning stiffness, or fatigue; improved function or activities of daily living; or decreased soft tissue swelling in joints or tendon sheaths.

Ulcerative Colitis

The individual must meet **all** of the following criteria for initial authorization:

- Is ≥ 5 years of age;
- Meets **one** of the following:
 - Has tried one systemic therapy (e.g., 6-mercaptopurine, azathioprine, cyclosporine, tacrolimus, a corticosteroid such as prednisone, methylprednisolone, a biologic; a biosimilar of the requested biologic does not count as conventional systemic therapy); OR
 - Meets **all** of the following:
 - Has pouchitis; AND
 - Has tried an antibiotic (e.g., metronidazole, ciprofloxacin), probiotic, corticosteroid enema (e.g., hydrocortisone enema), or mesalamine enema; AND
- Medication is prescribed by or in consultation with a gastroenterologist.

The individual must meet **all** of the following criteria for reauthorization:

- Has been established on therapy for at least 6 months;
Note: A patient who has received < 6 months of therapy or who is restarting therapy with an adalimumab product is reviewed under initial therapy.
- Meets **one** of the following:
 - Experienced a beneficial clinical response from baseline when assessed by at least one objective measure; OR
Note: Examples of objective measures include fecal markers (e.g., fecal calprotectin), serum markers (e.g., C-reactive protein), endoscopic assessment, and/or reduced dose of corticosteroids.
 - Experienced an improvement in at least one symptom from baseline, such as decreased pain, fatigue, stool frequency, and/or rectal bleeding.

Uveitis (including other posterior uveitides and panuveitis syndromes).

The individual must meet **all** of the following criteria for initial authorization:

- Is ≥ 2 years of age;
- Has tried one of the following therapies: periocular, intraocular, or systemic corticosteroids; immunosuppressives;
Note: Examples of corticosteroids include prednisolone, triamcinolone, betamethasone, methylprednisolone, and prednisone. Examples of immunosuppressive agents include methotrexate, mycophenolate mofetil, azathioprine, and cyclosporine. A trial of one biologic other than the requested medication also counts. A biosimilar of the requested biologic does not count.
- Medication is prescribed by or in consultation with an ophthalmologist.

The individual must meet **all** of the following criteria for reauthorization:

- Has been established on therapy for at least 6 months;
Note: A patient who has received < 6 months of therapy or who is restarting therapy with an adalimumab product is reviewed under initial therapy).
- Meets at least **one** of the following:
 - o Experienced a beneficial clinical response from baseline when assessed by at least one objective measure;
Note: Examples of objective measures include best-corrected visual acuity, assessment of chorioretinal and/or inflammatory retinal vascular lesions, or anterior chamber cell grade or vitreous haze grade.
 - o Experienced an improvement in at least one symptom from baseline, such as decreased eye pain, redness, light sensitivity, and/or blurred vision; or improvement in visual acuity.

Behcet's Disease.

The individual must meet **all** of the following criteria for initial authorization:

- Is ≥ 2 years of age;
- Meets **one** of the following:
 - o Has tried at least one conventional therapy; OR
Note: Examples include systemic corticosteroids (e.g., methylprednisolone), immunosuppressants (e.g., azathioprine, methotrexate, mycophenolate mofetil, cyclosporine, tacrolimus, Leukeran [chlorambucil tablets], cyclophosphamide, interferon alfa). A trial of one biologic other than the requested medication also counts. A patient who has already tried one biologic other than the requested drug for Behcet's disease is not required to "step back" and try a conventional therapy. A biosimilar of the requested biologic does not count.
 - o Has ophthalmic manifestations of Behcet's disease;
- Medication is prescribed by or in consultation with a rheumatologist, dermatologist, ophthalmologist, gastroenterologist, or neurologist.

The individual must meet **all** of the following criteria for reauthorization:

- Has been established on therapy for at least 3 months;
Note: A patient who has received < 3 months of therapy or who is restarting therapy with an adalimumab product is reviewed under initial therapy.
- Experienced a beneficial clinical response from baseline when assessed by at least one objective measure;
Note: Examples of objective measures are dependent upon organ involvement but may include best-corrected visual acuity (if ophthalmic manifestations); serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate); or ulcer depth, number, and/or lesion size.
- Experienced an improvement in at least one symptom from baseline, such as decreased pain or improved visual acuity (if ophthalmic manifestations).

Pyoderma Gangrenosum

The individual must meet **all** of the following criteria for initial authorization:

- Is ≥ 18 years of age;
- Meets **one** of the following:
 - o Has tried one systemic corticosteroid (e.g., prednisone); OR
 - o Has tried one other immunosuppressant for at least 2 months or was intolerant to one of these agents (e.g., mycophenolate mofetil, cyclosporine);
- Medication is prescribed by or in consultation with a dermatologist.

The individual must meet **all** of the following criteria for reauthorization:

- Has been established on therapy for at least 4 months;
Note: A patient who has received < 4 months of therapy or who is restarting therapy with an adalimumab product is reviewed under initial therapy.
- Experienced a beneficial clinical response, defined as improvement from baseline in at least one of the following: size, depth, and/or number of lesions;
- Experienced an improvement in at least one symptom from baseline, such as decreased pain and/or tenderness of affected lesions.

Sarcoidosis

The individual must meet **all** of the following criteria for initial authorization:

- Is ≥ 18 years of age;
- Has tried at least one corticosteroid (e.g., prednisone);
- Has tried at least one immunosuppressive medication (e.g., methotrexate, leflunomide, azathioprine, mycophenolate mofetil, cyclosporine, Leukeran (chlorambucil tablets), cyclophosphamide, Thalomid (thalidomide capsules), an infliximab product, chloroquine)
- Medication is prescribed by or in consultation with a pulmonologist, ophthalmologist, or dermatologist.

The individual must meet **all** of the following criteria for reauthorization:

- Has been established on therapy for at least 3 months;
Note: A patient who has received < 3 months of therapy or who is restarting therapy with an adalimumab product is reviewed under initial therapy.
- Experienced a beneficial clinical response from baseline when assessed by at least one objective measure;
Note: Examples of objective measures are dependent upon organ involvement but may include lung function (e.g., predicted forced vital capacity and/or 6-minute walk distance); serum markers (e.g., C-reactive protein, liver enzymes, N-terminal pro-brain natriuretic peptide [NT-proBNP]); improvement in rash or skin manifestations, neurologic symptoms, or rhythm control; or imaging (e.g., if indicated, chest radiograph, magnetic resonance imaging [MRI], or echocardiography).
- Experienced an improvement in at least one symptom from baseline, such as decreased cough, fatigue, pain, palpitations, neurologic symptoms, and/or shortness of breath.

Scleritis or Sterile Corneal Ulceration

The individual must meet **all** of the following criteria for initial authorization:

- Is ≥ 18 years of age;
- Has tried one other therapy for this condition (e.g., oral nonsteroidal anti-inflammatory drugs [NSAIDs]: e.g., indomethacin, naproxen, ibuprofen; oral, topical [ophthalmic], or intravenous corticosteroids [e.g., prednisone, prednisolone, methylprednisolone]; methotrexate; cyclosporine; other immunosuppressants);
- Medication is prescribed by or in consultation with an ophthalmologist.

The individual must meet **all** of the following criteria for reauthorization:

- Has been established on therapy for at least 6 months;
- *Note: A patient who has received < 6 months of therapy or who is restarting therapy with an adalimumab product is reviewed under initial therapy.*
- Meets **one** of the following:
 - o Experienced a beneficial clinical response from baseline when assessed by at least one objective measure (e.g., serum markers: C-reactive protein, erythrocyte sedimentation rate); OR
 - o Experienced an improvement in at least one symptom from baseline, such as decreased eye pain, redness, light sensitivity, tearing, and/or improvement in visual acuity.

Spondyloarthritis, Other Subtypes:

Note: This includes undifferentiated arthritis, non-radiographic axial spondyloarthritis, reactive arthritis (Reiter's Disease), arthritis associated with inflammatory bowel disease.

The individual must meet **all** of the following criteria for initial authorization:

- Is ≥ 18 years of age;
- Meets **one** of the following:
 - o Meets all of the following:
 - Has arthritis primarily in the knees, ankles, elbows, wrists, hands, and/or feet; AND
 - Has tried at least one conventional synthetic disease-modifying antirheumatic drug (DMARD) (e.g., methotrexate, leflunomide, or sulfasalazine); OR
 - o Has axial spondyloarthritis and has objective signs of inflammation, defined as one of the following:
 - C-reactive protein elevated beyond the upper limit of normal for the reporting laboratory; OR
 - Sacroiliitis reported on magnetic resonance imaging (MRI);
- Medication is prescribed by or in consultation with a rheumatologist.

The individual must meet **all** of the following criteria for reauthorization:

- Has been established on therapy for at least 6 months;
Note: A patient who has received < 6 months of therapy or who is restarting therapy with an adalimumab product is reviewed under initial therapy).
- Meets **one** of the following:
 - o Experienced a beneficial clinical response from baseline when assessed by at least one objective measure; OR
Note: Examples of objective measures include Ankylosing Spondylitis Disease Activity Score (ASDAS) and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).
 - o Experienced an improvement in at least one symptom from baseline, such as decreased pain or stiffness, or improvement in function or activities of daily living.

Approval duration (initial):

- Hidradentitis suppurativa/Plaque psoriasis/Behcet's disease/Sarcoidosis: 3 months
- Pyoderma gangrenosum: 4 months
- All others: 6 months

Approval duration (renewal): 12 months

Dosing Recommendations

Administer adalimumab by subcutaneous injection.

- **Ankylosing spondylitis**
40 mg every other week
- **Crohn's disease**
160 mg day 1, then 80 mg 2 weeks later on day 15, and 40 mg every other week thereafter starting on day 29
- **Hidradenitis suppurativa**
160 mg, followed by 80 mg 2 weeks later on day 15, and then 40 mg every week or 80 mg every other week starting 2 weeks later on day 29
- **Juvenile idiopathic arthritis (JIA)**

Pediatric weight 2 yrs of age and older	Recommended Dosage
10 kg (22 lbs) to less than 15 kg (33 lbs)	10 mg every other week
15 kg (33 lbs) to less than 30 kg (66 lbs)	20 mg every other week
30 kg (66 lbs) and greater	40 mg every other week

- **Plaque psoriasis**
Initial, 80 mg once, followed by 40 mg every other week starting 1 week after the initial dose
- **Psoriatic arthritis (PsA)**
40 mg every other week
- **Rheumatoid arthritis**
40 mg every other week; may increase to 40 mg every week or 80 mg every other week in patients not receiving concomitant methotrexate
- **Ulcerative colitis**
160 mg on day 1, then 80 mg on day 15, and 40 mg every other week starting on day 29
- **Uveitis**
80 mg once, followed by 40 mg every other week starting 1 week after the initial dose

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