AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Humira and Biosimilars	Page:	1 of 23
Effective Date:	11/1/2024	Last Review Date:	10/16/2024
Applies to:	☒New Jersey		

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Humira and biosimilars under the patient's prescription drug benefit.

Description:

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 (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 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 (CD) in adult and pediatric patients 6 years of age and older.
   6. The treatment of moderately to severely active ulcerative colitis (UC) in adults 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.
   7. The 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. (Reference the Biological Response Modifiers (BRMs) in the Treatment of Plaque Psoriasis NJ Protocol)
   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
   1. Non-radiographic axial spondyloarthritis
   2. Behcet's disease
   3. Pyoderma gangrenosum
   4. Oligoarticular juvenile idiopathic arthritis
   5. Immune checkpoint inhibitor-related toxicity- inflammatory arthritis

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

Applicable Drug List:

Preferred Products (*Note: bold products are preferred)*:

Adalimumab-adaz
Adalimumab-fkjp
Hadlima (adalimumab-bwwd)

Non-Preferred Products:

Humira (adalimumab)
Abrilada (adalimumab-afzb)
Amjevita (adalimumab-atto)
Cyltezo (adalimumab-adbm)
Hulio (adalimumab-fkjp)
Hyrimoz (adalimumab-adaz)
Idacio (adalimumab-aacf)
Simlandi (adalimumab-ryvk)
Yuflyma (adalimumab-aaty)
Yusimry (adalimumab-aqvh)
Adalimumab
Adalimumab-aacf
Adalimumab-adbm
Adalimumab-aaty
Adalimumab-ryvk

Policy/Guideline:

Documentation for all indications:
Non-preferred adalimumab products: The patient is unable to take a preferred adalimumab product, where indicated, for the given diagnosis due to a trial and inadequate treatment response or intolerance, or a contraindication. Documentation is required for approval.

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

A. **Rheumatoid arthritis (RA)**
   1. 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. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.

B. **Articular juvenile idiopathic arthritis (JIA)**
   1. Initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy.
   2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.

C. **Ankylosing spondylitis (AS), non-radiographic axial spondyloarthritis (nr-axSpA), psoriatic arthritis (PsA), hidradenitis suppurativa, and uveitis (non-infectious intermediate, posterior and panuveitis) 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.

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

G. **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 Specialty:
This medication must be prescribed by or in consultation with one of the following:

A. Rheumatoid arthritis, articular juvenile idiopathic arthritis, ankylosing spondylitis, non-radiographic 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. Uveitis: ophthalmologist or rheumatologist
E. Immune checkpoint inhibitor-related toxicity: oncologist, hematologist, or rheumatologist

Criteria for Initial Approval:

A. <u>Rheumatoid arthritis (RA)</u>

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 are 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. <u>Articular juvenile idiopathic arthritis (JIA)</u>

1. 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.

2. 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:
   i. 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.
   ii. 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:
      a. Involvement of ankle, wrist, hip, sacroiliac joint, and/or temporomandibular joint (TMJ)
      b. Presence of erosive disease or enthesitis

c. Delay in diagnosis
d. Elevated levels of inflammation markers
e. Symmetric disease

iii. 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:
a. High-risk joints are involved (e.g., cervical spine, wrist, or hip).
b. High disease activity.
c. Is judged to be at high risk for disabling joint disease.

C. <u>Psoriatic arthritis (PsA)</u>

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

D. <u>Ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA)</u>

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 active ankylosing spondylitis or active non-radiographic axial spondyloarthritis.

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

E. <u>Crohn's disease (CD)</u>

Authorization of 12 months may be granted for members 6 years of age or older for treatment of moderately to severely active CD.

F. Ulcerative colitis (UC)

Authorization of 12 months may be granted for members 5 years of age or older for treatment of moderately to severely active ulcerative colitis.

G. 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 member 12 years of age or older for treatment of moderate to severe hidradenitis suppurativa when EITHER of the following is met:
   i. 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).
   ii. Member has an intolerance or contraindication to oral antibiotics used for the treatment of hidradenitis suppurativa.

H. 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 or older for treatment of non-infectious intermediate, posterior and panuveitis when EITHER of the following is met:
   i. Member has experienced an inadequate response to corticosteroids or immunosuppressive therapy (e.g., azathioprine, cyclosporine, methotrexate).
   ii. Member has an intolerance or contraindication to corticosteroids and immunosuppressive therapy (e.g., azathioprine, cyclosporine, methotrexate).

I. 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 non-biologic medication for Behcet's disease (e.g., apremilast, colchicine, systemic glucocorticoids, azathioprine).

J. 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:
   i. Member has experienced an inadequate response to corticosteroids or immunosuppressive therapy (e.g., cyclosporine or mycophenolate mofetil).
   ii. Member has an intolerance or contraindication to corticosteroids and immunosuppressive therapy (e.g., cyclosporine, mycophenolate mofetil).

K. Immune checkpoint inhibitor-related toxicity

1. Authorization of 12 months may be granted for treatment of immune checkpoint inhibitor-related toxicity when the member has severe immunotherapy-related inflammatory arthritis and meets either of the following:
   i. Member has had an inadequate response to corticosteroids or a conventional synthetic drug (e.g., methotrexate, sulfasalazine, leflunomide, hydroxychloroquine).
   ii. Member has an intolerance or contraindication to corticosteroids and a conventional synthetic drug.

Continuation of Therapy:

A. Rheumatoid arthritis (RA)

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.

B. Articular juvenile idiopathic arthritis (JIA)

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:

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 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:

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. <u>Ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA)</u>

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:

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. <u>Crohn's disease (CD)</u>

1. Authorization of 12 months may be granted for all members 6 years of age or older (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 6 years of age or older (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. Ulcerative colitis (UC)

1. Authorization of 12 months may be granted for all members 5 years of age and older (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 5 years of age and older (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. Hidradenitis suppurativa

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:

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

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

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 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

I. 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 with the requested medication as evidenced by low disease activity or improvement in signs and symptoms of the condition.

J. 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 IV 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:

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 6 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.

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. Drug interaction
3. Risk of treatment-related toxicity
4. Pregnancy or currently planning pregnancy
5. Breastfeeding
6. Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension)
7. Hypersensitivity
8. History of intolerance or adverse event

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

Approval Duration and Quantity Restrictions:

Initial and Renewal Approval: 12 months

Quantity Level Limits:

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

Note: The standard limit is designed to allow a quantity sufficient for the most common uses of the medication. The recommended dosing parameters for all FDA-approved indications fall within the standard limits. Coverage of an additional quantity may be reviewed on a case-by-case basis upon request.

A. Humira (adalimumab)

Medication	Standard Limit	FDA-recommended dosing
Humira (adalimumab) 10 mg/0.1 mL single-dose prefilled syringe	2 syringes per 28 days	**RA/PsA/AS** • 40 mg every other week

Medication	Standard Limit	FDA-recommended dosing
Humira (adalimumab) 20 mg/0.2 mL single-dose prefilled syringe	4 syringes per 28 days	• 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 later (day 15); maintenance dose starting at week 4 (day 29) of 40 mg every other week or 20 mg every week • ≥ 40 kg: loading doses of 160 mg on day 1 (single dose or split over
Humira (adalimumab) 40 mg/0.4 mL single-dose prefilled syringe/pen	4 syringes/pens per 28 days	
Humira (adalimumab) 40 mg/0.8 mL single-dose prefilled syringe/pen		
Humira (adalimumab) 80 mg/0.8 mL single-dose prefilled pen	2 pens per 28 days	
Humira (adalimumab) 80 mg/0.8 mL syringe Pediatric Crohn's Disease Starter Package	N/A	
Humira (adalimumab) 80 mg/0.8 mL and 40 mg/0.4 mL syringe Pediatric Crohn's Disease Starter Package	N/A	
Humira (adalimumab) 80 mg/0.8 mL pen Pediatric Ulcerative Colitis Starter Package	N/A	
Humira (adalimumab) 40 mg/0.8 mL pen Crohn's Disease, Ulcerative Colitis, or Hidradenitis Suppurativa Starter Package	N/A	
Humira (adalimumab) 80 mg/0.8 mL pen Crohn's Disease, Ulcerative Colitis, or Hidradenitis Suppurativa Starter Package	N/A	

Medication	Standard Limit	FDA-recommended dosing
Humira (adalimumab) 40 mg/0.8 mL pen Psoriasis, Uveitis, or Adolescent Hidradenitis Suppurativa Starter Package	N/A	two consecutive days), 80 mg one week later (day 8), and 80 mg one week later (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/Adult uveitis** • 80 mg (day 1), followed by 40 mg every other week starting one week after the initial dose of 80 mg (day 8) **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 (day 22) • ≥ 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 pen Psoriasis, Uveitis, or Adolescent Hidradenitis Suppurativa Starter Package	N/A	
adalimumab 10 mg/0.1 mL single-dose prefilled syringe	2 syringes per 28 days	
adalimumab 20 mg/0.2 mL single-dose prefilled syringe	4 syringes per 28 days	
adalimumab 40 mg/0.4 mL single-dose prefilled syringe/pen	4 syringes/pens per 28 days	
adalimumab 80 mg/0.8 mL single-dose prefilled pen	2 pens per 28 days	

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

B. Abrilada (adalimumab-afzb)

Medication	Standard Limit	FDA-recommended dosing
Abrilada (adalimumab-afzb) 10 mg/0.2 mL single-dose prefilled syringe	2 syringes per 28 days	Refer to Humira (adalimumab)
Abrilada (adalimumab-afzb) 20 mg/0.4 mL single-dose prefilled syringe	4 syringes per 28 days	
Abrilada (adalimumab-afzb) 40 mg/0.8 mL single-dose prefilled syringe/pen autoinjector	4 syringes/pen autoinjectors per 28 days	

C. Amjevita (adalimumab-atto)

Medication	Standard Limit	FDA-recommended dosing
Amjevita (adalimumab-atto) 10 mg/0.2 mL single-dose prefilled syringe	2 syringes per 28 days	Refer to Humira (adalimumab)
Amjevita (adalimumab-atto) 20 mg/0.2 mL single-dose prefilled syringe	4 syringes per 28 days	
Amjevita (adalimumab-atto) 20 mg/0.4 mL single-dose prefilled syringe	4 syringes per 28 days	
Amjevita (adalimumab-atto) 40 mg/0.4 mL single-dose prefilled syringe/SureClick autoinjector	4 syringes/ autoinjectors per 28 days	
Amjevita (adalimumab-atto) 40 mg/0.8 mL single-dose prefilled syringe/SureClick autoinjector	4 syringes/ autoinjectors per 28 days	
Amjevita (adalimumab-atto) 80 mg/0.8 mL single-dose prefilled syringe/SureClick autoinjector	2 syringes/ autoinjectors per 28 days	

D. Cyltezo (adalimumab-adbm)

Medication	Standard Limit	FDA-recommended dosing
Cyltezo (adalimumab-adbm) 10 mg/0.2 mL single-dose prefilled syringe	2 syringes per 28 days	Refer to Humira (adalimumab)
Cyltezo (adalimumab-adbm) 20 mg/0.4 mL single-dose prefilled syringe	4 syringes per 28 days	
Cyltezo (adalimumab-adbm) 40 mg/0.8 mL single-dose prefilled syringe/pen auto-injector	4 syringes/pen autoinjectors per 28 days	
Cyltezo (adalimumab-adbm) 40 mg/0.8 mL pen auto-injector Psoriasis or Uveitis Starter Pack	N/A	
Cyltezo (adalimumab-adbm) 40 mg/0.8 mL pen auto-injector Crohn's Disease, Ulcerative Colitis, or Hidradenitis Suppurativa Starter Pack	N/A	
adalimumab-adbm 10 mg/0.2 mL single-dose prefilled syringe	2 syringes per 28 days	
adalimumab-adbm 20 mg/0.4 mL single-dose prefilled syringe	4 syringes per 28 days	
adalimumab-adbm 40 mg/0.8 mL single-dose prefilled syringe/pen auto-injector	4 syringes/pen autoinjectors per 28 days	
adalimumab-adbm 40 mg/0.8 mL pen auto-injector Psoriasis or Uveitis Starter Pack	N/A	
adalimumab-adbm 40 mg/0.8 mL pen auto-injector Crohn's Disease, Ulcerative Colitis, or Hidradenitis Suppurativa Starter Pack	N/A	

E. Hadlima (adalimumab-bwwd)

Medication	Standard Limit	FDA-recommended dosing
Hadlima (adalimumab-bwwd) 40 mg/0.4 mL single-dose prefilled syringe/PushTouch auto-injector	4 syringes/ autoinjectors per 28 days	Refer to Humira (adalimumab)
Hadlima (adalimumab-bwwd) 40 mg/0.8 mL single-dose prefilled syringe/PushTouch auto-injector	4 syringes/ autoinjectors per 28 days	

F. Hulio (adalimumab-fkjp)

Medication	Standard Limit	FDA-recommended dosing
Hulio (adalimumab-fkjp) 20 mg/0.4 mL single-dose prefilled syringe	4 syringes per 28 days	Refer to Humira (adalimumab)
Hulio (adalimumab-fkjp) 40 mg/0.8 mL single-dose prefilled syringe/pen auto-injector	4 syringes/pen autoinjectors per 28 days	
adalimumab-fkjp 20 mg/0.4 mL single-dose prefilled syringe	4 syringes per 28 days	
adalimumab-fkjp 40 mg/0.8 mL single-dose Prefilled syringe/pen auto-injector	4 syringes/pen autoinjectors per 28 days	

G. Hyrimoz (adalimumab-adaz)

Medication	Standard Limit	FDA-recommended dosing
Hyrimoz (adalimumab-adaz) 10 mg/0.1 mL single-dose prefilled syringe	2 syringes per 28 days	Refer to Humira (adalimumab)
Hyrimoz (adalimumab-adaz) 10 mg/0.2 mL single-dose prefilled syringe		
Hyrimoz (adalimumab-adaz) 20 mg/0.2 mL single-dose prefilled syringe	4 syringes per 28 days	
Hyrimoz (adalimumab-adaz) 20 mg/0.4 mL single-dose prefilled syringe		
Hyrimoz (adalimumab-adaz) 40 mg/0.4 mL single-dose prefilled syringe/ Sensoready pen auto-injector	4 syringes/ pen autoinjectors per 28 days	
Hyrimoz (adalimumab-adaz) 40 mg/0.8 mL single-dose prefilled syringe/ Sensoready pen auto-injector		
Hyrimoz (adalimumab-adaz) 80 mg/0.8 mL single-dose prefilled syringe/ Sensoready pen auto-injector	2 syringes/ pen autoinjectors per 28 days	
Hyrimoz (adalimumab-adaz) 80 mg/0.8 mL Sensoready pen auto-injector Crohn's disease, Ulcerative Colitis, or Hidradenitis Suppurativa Starter Package	N/A	
Hyrimoz (adalimumab-adaz) 80 mg/0.8 mL and 40 mg/0.4 mL Sensoready pen auto-injector	N/A	

Crohn's disease, Ulcerative Colitis, or Hidradenitis Suppurativa Starter Package		
Hyrimoz (adalimumab-adaz) 80 mg/0.8 mL and 40 mg/0.4 mL Sensoready pen auto-injector Plaque Psoriasis Starter Package	N/A	
Hyrimoz (adalimumab-adaz) 80 mg/0.8 mL prefilled syringe Pediatric Crohn's Disease Starter Pack	N/A	Refer to Humira (adalimumab)
Hyrimoz (adalimumab-adaz) 80 mg/0.8 mL and 40 mg/0.4 mL prefilled syringe Pediatric Crohn's Disease Starter Pack	N/A	
adalimumab-adaz 40 mg/0.4 mL single-dose prefilled syringe/ Sensoready pen auto-injector	4 syringes/ pen autoinjectors per 28 days	

G. Idacio (adalimumab-aacf)

Medication	Standard Limit	FDA-recommended dosing
Idacio (adalimumab-aacf) 40 mg/0.8 mL single-dose prefilled syringe/pen auto-injector	4 syringes/pen autoinjectors per 28 days	Refer to Humira (adalimumab)
Idacio (adalimumab-aacf) 40 mg/0.8 mL pen auto-injector Plaque Psoriasis Starter Package	N/A	
Idacio (adalimumab-aacf) 40 mg/0.8 mL pen auto-injector Crohn's Disease or Ulcerative Colitis Starter Package	N/A	
adalimumab-aacf 40 mg/0.8 mL single-dose pen auto-injector	4 pen autoinjectors per 28 days	

I. Simlandi (adalimumab-ryvk)

Medication	Standard Limit	FDA-recommended dosing
Simlandi (adalimumab-ryvk) 20 mg/0.2 mL single-dose prefilled syringe	4 syringes per 28 days	Refer to Humira (adalimumab)
Simlandi (adalimumab-ryvk) 40 mg/0.4 mL single-dose prefilled syringe/autoinjector	4 syringes/ autoinjectors per 28 days	
Simlandi (adalimumab-ryvk) 80 mg/0.8 mL single-dose prefilled syringe	2 syringes per 28 days	
adalimumab-ryvk 20 mg/0.2 mL single-dose prefilled syringe	4 syringes per 28 days	
adalimumab-ryvk 40 mg/0.4 mL single-dose prefilled syringe/autoinjector	4 syringes/ autoinjectors per 28 days	
adalimumab-ryvk 80 mg/0.8 mL single-dose prefilled syringe	2 syringes per 28 days	

J. Yuflyma (adalimumab-aaty)

Medication	Standard Limit	FDA-recommended dosing
Yuflyma (adalimumab-aaty) 20 mg/0.2 mL single-dose prefilled syringe	4 syringes per 28 days	Refer to Humira (adalimumab)
Yuflyma (adalimumab-aaty) 40 mg/0.4 mL single-dose prefilled syringe/pen auto-injector	4 syringes/pen autoinjectors per 28 days	
Yuflyma (adalimumab-aaty) 80 mg/0.8 mL single-dose prefilled syringe/pen auto-injector	2 syringes/pen autoinjectors per 28 days	
Yuflyma (adalimumab-aaty) 40 mg/0.4 mL prefilled pen auto-injector Plaque Psoriasis Starter Package	N/A	
Yuflyma (adalimumab-aaty) 40 mg/0.4 mL prefilled pen auto-injector Crohn's Disease, Pediatric Crohn's Disease, Ulcerative Colitis, or Hidradenitis Suppurativa Starter Package	N/A	
Yuflyma (adalimumab-aaty) 80 mg/0.8 ml and 40 mg/0.4 mL prefilled pen auto-injector Plaque Psoriasis Starter Package	N/A	
Yuflyma (adalimumab-aaty) 80 mg/0.8 ml prefilled pen auto-injector Crohn's Disease, Ulcerative Colitis, or Hidradenitis Suppurativa Starter Package	N/A	
Yuflyma (adalimumab-aaty) 80 mg/0.8 ml and 40 mg/0.4 mL prefilled syringe Pediatric Crohn's Disease Starter Package	N/A	
Yuflyma (adalimumab-aaty)	N/A	

Medication	Standard Limit	FDA-recommended dosing
80 mg/0.8 ml prefilled syringe Pediatric Crohn's Disease Starter Package		
adalimumab-aaty 20 mg/0.2 mL single-dose prefilled syringe	4 syringes per 28 days	
adalimumab-aaty 40 mg/0.4 mL single-dose prefilled syringe/pen auto-injector	4 syringes/pen autoinjectors per 28 days	
adalimumab-aaty 80 mg/0.8 mL single-dose prefilled syringe/pen auto-injector	2 syringes/pen autoinjectors per 28 days	

K. Yusimry (adalimumab-aqvh)

Medication	Standard Limit	FDA-recommended dosing
Yusimry (adalimumab-aqvh) 40 mg/0.8 mL single-dose prefilled syringe/pen	4 syringes/pens per 28 days	Refer to Humira (adalimumab)

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