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#### 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:**

#### **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

- 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

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- Behcet's disease
- Pyoderma gangrenosum
- Oligoarticular juvenile idiopathic arthritis
- Immune checkpoint inhibitor-related toxicity- inflammatory arthritis

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

## **Applicable Drug List:**

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

Adalimumab-aacf

Adalimumab-adaz

Adalimumab-adbm

Adalimumab-aaty

Adalimumab-fkjp

Adalimumab-ryvk

Note: Reference the Illinois Medicaid Preferred Drug List for preferred and non-preferred products.

## **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.

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#### **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.

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## 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
- Plague psoriasis and pyoderma gangrenosum: dermatologist
- Uveitis: ophthalmologist or rheumatologist
- Immune checkpoint inhibitor-related toxicity: oncologist, hematologist, or rheumatologist

## **Coverage Criteria**

Rheumatoid arthritis (RA)

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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.

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 criteria:
  - 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 either of the following criteria:
  - Member has had an inadequate response to at least a 3-month trial of methotrexate despite adequate dosing (i.e., titrated to at least 15 mg/week).
  - Member has an intolerance or contraindication to methotrexate (see Appendix A).

#### Articular juvenile idiopathic arthritis (JIA)

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)

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- 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)

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)

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 antiinflammatory drugs (NSAIDs).
- Member has an intolerance or contraindication to two or more NSAIDs.

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#### Crohn's disease (CD)

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

## 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.

## Plaque psoriasis (PsO)

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

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.

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## Uveitis (non-infectious intermediate, posterior and panuveitis)

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

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

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

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

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- 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)

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)

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)

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)

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

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)

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.

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:

- 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)

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.

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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:

- 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)

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

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

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#### 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 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

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

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.

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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

- 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

#### **Approval Duration and Quantity Restrictions:**

## **Initial and Renewal Approval: 12 months**

## **Quantity Level Limits:**

Approval quantity level limit will be assessed based on indication and maintenance dose for indication. A quantity level limit request for outside of the FDA dosing will require documentation.

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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)

A. Humira (adalimumab)			
Medication	FDA-recommended dosing		
Humira (adalimumab)  10 mg/0.1 mL single-dose prefilled syringe  Humira (adalimumab)  20 mg/0.2 mL single-dose prefilled syringe  Humira (adalimumab)  40 mg/0.4 mL single-dose prefilled syringe/pen	<ul> <li>RA/PsA/AS</li> <li>40 mg every other week</li> <li>For RA, patients not taking concomitant methotrexate: may increase to 40 mg every week or 80 mg every other week if needed</li> <li>PJIA/Pediatric uveitis (2 years and up)</li> <li>10 kg to &lt; 15 kg: 10 mg every other week</li> </ul>		
Humira (adalimumab) 40 mg/0.8 mL single-dose prefilled syringe/pen Humira (adalimumab) 80 mg/0.8 mL single-dose prefilled pen Humira (adalimumab) 80 mg/0.8 mL syringe Pediatric Crohn's Disease Starter Package	<ul> <li>15 kg to &lt; 30 kg: 20 mg every other week</li> <li>≥ 30 kg: 40 mg every other week</li> <li>Pediatric CD (6 years and up)</li> <li>17 kg to &lt; 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</li> <li>≥ 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</li> </ul>		
Humira (adalimumab) 80 mg/0.8 mL and 40 mg/0.4 mL syringe Pediatric Crohn's Disease Starter Package	starting at week 4 (day 29) of 40 mg every other week  Pediatric UC (5 years and up)		

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	□Michigan	□Pennsylvania Ki	ds □Virgini	ia

	FDA		
Medication	FDA-recommended dosing		
Humira (adalimumab)	• 20 kg to < 40 kg: loading doses of 80 mg on day 1, 40		
80 mg/0.8 mL pen	mg one week later (day 8), and 40 mg one week later		
Pediatric Ulcerative Colitis	(day 15); maintenance dose starting at week 4 (day		
Starter Package	29) of 40 mg every other week or 20 mg every week  • ≥ 40 kg: loading doses of 160 mg on day 1 (single		
Humira (adalimumab)	dose or split over two consecutive days), 80 mg one		
40 mg/0.8 mL pen	week later (day 8), and 80 mg one week later (day 15);		
Crohn's Disease, Ulcerative	maintenance dose starting at week 4 (day 29) of 80		
Colitis, or Hidradenitis	mg every other week or 40 mg every week		
Suppurativa Starter Package	A I. I. OD		
Humira (adalimumab)	<ul> <li>Adult CD and UC</li> <li>Loading doses: 160 mg on day 1 (given in one day or</li> </ul>		
80 mg/0.8 mL pen	split over two consecutive days), followed by 80 mg		
Crohn's Disease, Ulcerative	two weeks later (day 15)		
Colitis, or Hidradenitis	Maintenance dose: two weeks later (day 29), 40 r		
Suppurativa Starter Package	every other week		
Humira (adalimumab)			
40 mg/0.8 mL pen	Plaque psoriasis/Adult uveitis		
Psoriasis, Uveitis, or	80 mg (day 1), followed by 40 mg every other week starting one week after the initial dose of 80 mg (day)		
Adolescent Hidradenitis	8)		
Suppurativa Starter Package	, and the second		
Humira (adalimumab)			
80 mg/0.8 mL and 40 mg/0.4	Adolescent hidradenitis suppurativa (12 years and up)		
mL pen	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)		
Psoriasis, Uveitis, or	≥ 60 kg: Follow adult dosing		
Adolescent Hidradenitis			
Suppurativa Starter Package	Adult hidradenitis suppurativa		
adalimumab	Loading doses: 160 mg on day 1 (given in one day or		
10 mg/0.1 mL single-dose	split over two consecutive days), followed by 80 mg		
prefilled syringe	<ul> <li>two weeks later (day 15)</li> <li>Maintenance dose: begin 40 mg every week or 80 mg</li> </ul>		
adalimumab	every other week two weeks later (day 29)		
20 mg/0.2 mL single-dose	2121, 211121 11211121121121121121121121121121		
prefilled syringe			

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Medication	FDA-recommended dosing
adalimumab	
40 mg/0.4 mL single-dose	
prefilled syringe/pen	
adalimumab	
80 mg/0.8 mL single-dose	
prefilled pen	

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	FDA-recommended dosing
Abrilada (adalimumab-afzb)	
10 mg/0.2 mL single-dose	
prefilled syringe	
Abrilada (adalimumab-afzb)	
20 mg/0.4 mL single-dose	Defends Humaine (adalinannash)
prefilled syringe	Refer to Humira (adalimumab)
Abrilada (adalimumab-afzb)	
40 mg/0.8 mL single-dose	
prefilled syringe/pen	
autoinjector	

C. Amjevita (adalimumab-atto)

Medication	FDA-recommended dosing	
Amjevita (adalimumab-atto) 10 mg/0.2 mL single-dose prefilled syringe	Refer to Humira (adalimumab)	
Amjevita (adalimumab-atto) 20 mg/0.2 mL single-dose prefilled syringe		

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Medication	FDA-recommended dosing
Amjevita (adalimumab-atto)	
20 mg/0.4 mL single-dose	
prefilled syringe	
Amjevita (adalimumab-atto)	
40 mg/0.4 mL single-dose	
prefilled syringe/SureClick	
autoinjector	
Amjevita (adalimumab-atto)	
40 mg/0.8 mL single-dose	
prefilled syringe/SureClick	
autoinjector	
Amjevita (adalimumab-atto)	
80 mg/0.8 mL single-dose	
prefilled syringe/SureClick	
autoinjector	

D. Cyltezo (adalimumab-adbm)

Medication	FDA-recommended dosing
Cyltezo (adalimumab-adbm)	
10 mg/0.2 mL single-dose	
prefilled syringe	
Cyltezo (adalimumab-adbm)	
20 mg/0.4 mL single-dose	
prefilled syringe	
Cyltezo (adalimumab-adbm)	Defeate Haming (adelias mach)
40 mg/0.8 mL single-dose	Refer to Humira (adalimumab)
prefilled syringe/pen	
auto-injector	
Cyltezo (adalimumab-adbm)	
40 mg/0.8 mL pen auto-	
injector	
Psoriasis or Uveitis Starter Pack	

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Medication	FDA-recommended dosing
Cyltezo (adalimumab-adbm)	
40 mg/0.8 mL pen auto-	
injector	
Crohn's Disease, Ulcerative	
Colitis, or Hidradenitis	
Suppurativa Starter Pack	
adalimumab-adbm	
10 mg/0.2 mL single-dose	
prefilled syringe	
adalimumab-adbm	
20 mg/0.4 mL single-dose	
prefilled syringe	
adalimumab-adbm	
40 mg/0.8 mL single-dose	
prefilled syringe/pen	
auto-injector	
adalimumab-adbm	
40 mg/0.8 mL pen auto-	
injector	
Psoriasis or Uveitis Starter Pack	
adalimumab-adbm	
40 mg/0.8 mL pen auto-	
injector	
Crohn's Disease, Ulcerative	
Colitis, or Hidradenitis	
Suppurativa Starter Pack	

## E. Hadlima (adalimumab-bwwd)

Medication	FDA-recommended dosing	
Hadlima (adalimumab-bwwd) 40 mg/0.4 mL single-dose	Refer to Humira (adalimumab)	

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	Michigan	□Pennsylvania Kid	ls □Virgini	ia

Medication	FDA-recommended dosing
prefilled syringe/PushTouch	
auto-injector	
Hadlima (adalimumab-bwwd)	
40 mg/0.8 mL single-dose	
prefilled syringe/PushTouch	
auto-injector	

F. Hulio (adalimumab-fkjp)

	EDA recommended desing
Medication	FDA-recommended dosing
Hulio (adalimumab-fkjp)	
20 mg/0.4 mL single-dose	
prefilled syringe	
Hulio (adalimumab-fkjp)	
40 mg/0.8 mL single-dose	
prefilled syringe/pen auto-	
injector	Defer to Humaine (adalies made)
adalimumab-fkjp	Refer to Humira (adalimumab)
20 mg/0.4 mL single-dose	
prefilled syringe	
adalimumab-fkjp	
40 mg/0.8 mL single-dose	
Prefilled syringe/pen auto-	
injector	

G. Hyrimoz (adalimumab-adaz)

Medication	FDA-recommended dosing		
Hyrimoz (adalimumab- adaz) 10 mg/0.1 mL single- dose prefilled syringe	Refer to Humira (adalimumab)		
Hyrimoz (adalimumab-			
adaz) 10 mg/0.2 mL			

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	□Michigan	□Pennsylvania Kids	□Virginia
single-d	dose prefilled		
syringe			
Hyrimo	z (adalimumab-		
adaz) 2	0 mg/0.2 mL		
single-d	dose prefilled		
syringe			
Hyrimo	z (adalimumab-		
adaz) 2	0 mg/0.4 mL		
single-o	dose prefilled		
syringe	•		
	z (adalimumab-		
_	0 mg/0.4 mL		
_	dose prefilled		
syringe	/Sensoready pen		
autoinje	ector Hyrimoz		
(adalim	umab-adaz) 40		
_	3 mL single-dose		
prefilled			
	/Sensoready pen		
autoinje			
_	z (adalimumab-		
_	0 mg/0.8 mL		
_	dose prefilled /Sensoready pen		
	ector Hyrimoz		
_	umab-adaz) 80		
•	mL Sensoready		
	toinjector Crohn's		
	e, Ulcerative Colitis,		
or Hidra	adenitis		
Suppur	ativa Starter		
Packag	je		
Hyrimo	z (adalimumab-		
adaz) 8	0 mg/0.8 mL and		
40 mg/	0.4 mL Sensoready		
pen aut	toinjector Crohn's		
disease	e, Ulcerative Colitis,		

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or Hidradenitis		
Suppurativa Starter		
Package		
Hyrimoz (adalimumab-		
adaz) 80 mg/0.8 mL and		
40 mg/0.4 mL Sensoready		
pen autoinjector Plaque		
Psoriasis or Uveitis Starter		
Package		
Hyrimoz (adalimumab-		
adaz) 80 mg/0.8 mL		
prefilled syringe Pediatric		
Crohn's Disease Starter		
Pack Hyrimoz		
(adalimumab-adaz) 80		
mg/0.8 mL and 40 mg/0.4		
mL prefilled syringe		
Pediatric Crohn's Disease		
Starter Pack		
adalimumab-adaz 10		
mg/0.1 mL single-dose		
prefilled syringe		
adalimumab-adaz 20		
mg/0.2 mL singledose		
prefilled syringe		
adalimumab-adaz 40		
mg/0.4 mL singledose		
prefilled		
syringe/Sensoready pen		
autoinjector		
adalimumab-adaz 80		
mg/0.8 mL singledose		
prefilled		

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	/Sensoready pen				
autoinje	ector				
adalimi	ımab-adaz 80				
	mL Sensoready				
_	oinjector Crohn's				
	, Ulcerative Colitis,				
or Hidra					
Suppur	ativa Starter				
Packag					
adalimu	ımab-adaz 80				
mg/0.8	mL and 40 mg/0.4				
mL Sen	soready pen				
autoinje	ector Crohn's				
disease	, Ulcerative Colitis,				
or Hidra	adenitis				
Suppur	ativa Starter				
Packag	е				
adalimu	ımab-adaz 80				
mg/0.8	mL and 40 mg/0.4				
mL Sen	soready pen				
autoinje	ector Plaque				
Psorias	is or Uveitis Starter				
Packag	е				
adalimu	ımab-adaz 80				
mg/0.8	mL prefilled				
syringe	Pediatric Crohn's				
Disease	Starter Pack				
	ımab-adaz 80				
	mL and 40 mg/0.4				
· ·	filled syringe				
	ic Crohn's Disease				
Starter	Pack	İ			

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	Michigan	□Pennsylvania Kid	s 🗆	Virginia	

Medication	FDA-recommended dosing
Idacio (adalimumab-aacf)	
40 mg/0.8 mL single-dose	
prefilled syringe/pen auto-	
injector	
Idacio (adalimumab-aacf)	
40 mg/0.8 mL pen auto-	
injector	
Plaque Psoriasis Starter	
Package	
	Refer to Humira (adalimumab)
Idacio (adalimumab-aacf)	
40 mg/0.8 mL pen auto-	
injector	
Crohn's Disease or Ulcerative	
Colitis Starter Package	
adalimumab-aacf	
40 mg/0.8 mL single-dose	
pen auto-injector	

I. Simlandi (adalimumab-ryvk)

Medication	FDA-recommended dosing
Simlandi (adalimumab-ryvk)	
20 mg/0.2 mL single-dose	
prefilled syringe	
Simlandi (adalimumab-ryvk)	
40 mg/0.4 mL single-dose	Refer to Humira (adalimumab)
prefilled syringe/autoinjector	
Simlandi (adalimumab-ryvk)	
80 mg/0.8 mL single-dose	
prefilled syringe	

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Applies to: □	New Jersey	□Maryland		□Florida	Kids
	Michigan	□Pennsylvania Kid	s	□Virginia	à

Medication	FDA-recommended dosing
adalimumab-ryvk	
20 mg/0.2 mL single-dose	
prefilled syringe	
adalimumab-ryvk	
40 mg/0.4 mL single-dose	
prefilled syringe/autoinjector	
adalimumab-ryvk	
80 mg/0.8 mL single-dose	
prefilled syringe	

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	□Michigan	□Pennsylvania Kid	s □Virgini	a

J. Yuflyma (adalimumab-aaty)

Medication	FDA-recommended dosing
Yuflyma (adalimumab-aaty)	
20 mg/0.2 mL single-dose	
prefilled syringe	
Yuflyma (adalimumab-aaty)	
40 mg/0.4 mL single-dose	
prefilled syringe/pen	
Yuflyma (adalimumab-aaty)	
80 mg/0.8 mL single-dose	
prefilled syringe/pen	
autoinjector	
Yuflyma (adalimumab-aaty)	
40 mg/0.4 mL prefilled pen	
autoinjector Plaque	
Psoriasis Starter Package	
Yuflyma (adalimumab-aaty)	
40 mg/0.4 mL prefilled pen	Refer to Humira (adalimumab)
autoinjector Crohn's	Refer to Humira (adatimumab)
Disease, Pediatric Crohn's	
Disease, Ulcerative Colitis, or	
Hidradenitis Suppurativa	
Starter Package	
Yuflyma (adalimumab-aaty)	
80 mg/0.8 mL and 40	
mg/0.4 mL prefilled pen	
autoinjector Plaque	
Psoriasis Starter Package	
Yuflyma (adalimumab-aaty)	
80 mg/0.8 mL prefilled pen	
autoinjector Crohn's	
Disease, Ulcerative Colitis, or	
Hidradenitis Suppurativa	
Starter Package	

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Medication	FDA-recommended dosing
Yuflyma (adalimumab-aaty)	
80 mg/0.8 mL and 40	
mg/0.4 mL prefilled syringe	
Pediatric Crohn's Disease	
Starter Package	
Yuflyma (adalimumab-aaty)	
80 mg/0.8 mL prefilled	
syringe Pediatric Crohn's	
Disease Starter Package	
adalimumab-aaty 20	
mg/0.2 mL single-dose	
prefilled syringe	
adalimumab-aaty 40	
mg/0.4 mL singledose	
prefilled syringe/pen	
autoinjector	
adalimumab-aaty 80	
mg/0.8 mL single-dose	
prefilled syringe/pen	
autoinjector	
adalimumab-aaty 80	
mg/0.8 mL prefilled pen	
autoinjector Crohn's	
Disease, Ulcerative Colitis, or	
Hidradenitis Suppurativa	
Starter Package	

# K. Yusimry (adalimumab-aqvh)

Medication	FDA-recommended dosing
Yusimry (adalimumab-aqvh)	
40 mg/0.8 mL single-dose	Refer to Humira (adalimumab)
prefilled syringe/pen	

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#### **References:**

- 1. Humira [package insert]. North Chicago, IL: AbbVie Inc.; February 2024.
- 2. Abrilada [package insert]. New York, NY: Pfizer Inc.; April 2024.
- 3. adalimumab [package insert]. North Chicago, IL: AbbVie Inc.; November 2023.
- 4. adalimumab-aacf [package insert]. Lake Zurich, IL: Fresenius Kabi USA, LLC; June 2024.
- 5. adalimumab-aaty [package insert]. Jersey City, NJ: Celltrion USA, Inc.; December 2023.
- 6. adalimumab-adaz [package insert]. Princeton, NJ: Sandoz Inc.; June 2024.
- 7. adalimumab-adbm [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; April 2024.
- 8. adalimumab-fkjp [package insert]. Cambridge, MA: Biocon Biologics Inc.; December 2023.
- 9. adalimumab-ryvk [package insert]. Leesburg, VA: Alvotech USA Inc.; July 2024.
- 10. Amjevita [package insert]. Thousand Oaks, CA: Amgen Inc.; August 2023.
- 11. Cyltezo [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; April 2024.
- 12. Hadlima [package insert]. Jersey City, NJ: Organon & Co.; June 2024.
- 13. Hulio [package insert]. Morgantown, WV: Mylan Specialty L.P.; August 2023.
- 14. Hyrimoz [package insert]. Princeton, NJ: Sandoz Inc.; April 2024.
- 15. Idacio [package insert]. Lake Zurich, IL: Fresenius Kabi USA, LLC; January 2024.
- 16. Simlandi [package insert]. Leesburg, VA: Alvotech USA Inc.; July 2024.
- 17. Yuflyma [package insert]. Jersey City, NJ: Celltrion USA, Inc.; January 2024.
- 18. Yusimry [package insert]. Redwood City, CA: Coherus BioSciences, Inc.; September 2023.
- 19. van der Heijde D, Ramiro S, Landewe R, et al. 2016 Update of the international ASAS-EULAR management recommendations for axial spondyloarthritis. Ann Rheum Dis. 2017;0:1-14.
- 20. Sieper J, van der Heijde D, Dougados M, et al. Efficacy and safety of adalimumab in patients with non-radiographic axial spondyloarthritis: results of a randomised placebo-controlled trial (ABILITY-1). Ann Rheum Dis. 2013;72(6):815-22.
- 21. Smolen JS, Landewé R, Billsma J, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2016 update. Ann Rheum Dis. 2017;0:1-18.
- 22. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Rheumatol. 2016;68(1):1-26.
- 23. Saag KG, Teng GG, Patkar NM, et al. American College of Rheumatology 2008 recommendations for the use of nonbiologic and biologic disease-modifying antirheumatic drugs in rheumatoid arthritis. Arthritis Rheum. 2008;59(6):762-784.
- 24. Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Non-Systemic Polyarthritis, Sacroiliitis, and Enthesitis. Arthritis Care Res. 2019;71(6):717-734.
- 25. Gossec L, Baraliakos X, Kerschbaumer A, et al. European League Against Rheumatism (EULAR) recommendations for the management of psoriatic arthritis with pharmacological therapies; 2019 update. Ann Rheum Dis. 2020;79(6):700-712.
- 26. Gladman DD, Antoni C, Mease P, et al. Psoriatic arthritis: epidemiology, clinical features, course, and outcome. Ann Rheum Dis 2005;64(Suppl II):ii14-ii17.

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	□Michigan	□Pennsylvania Kid	ls □Virgin	ia

- 27. Coates LC, Soriano ER, Corp N, et al. Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA): updated treatment recommendations for psoriatic arthritis 2021. Nat Rev Rheumatol. 2022;18(8):465-479.
- 28. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 6: Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. J Am Acad Dermatol. 2011;65(1):137-174.
- 29. Braun J, van den Berg R, Baraliakos X, et al. 2010 update of the ASAS/EULAR recommendations for the management of ankylosing spondylitis. Ann Rheum Dis 2011;70:896–904.
- 30. Ward MM, Deodhar A, Gensler LS, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. Arthritis Rheumatol. 2019;71(10):1599-1613.
- 31. Talley NJ, Abreu MT, Achkar J, et al. An evidence-based systematic review on medical therapies for inflammatory bowel disease. Am J Gastroenterol. 2011;106(Suppl 1):S2-S25.
- 32. Lichtenstein GR, Loftus Jr EV, Isaacs KI, et al. ACG Clinical Guideline: Management of Crohn's Disease in Adults. Am J Gastroenterol. 2018;113:481-517.
- 33. Agarwal A, Andrews JM. Systematic review: IBD-associated pyoderma gangrenosum in the biologic era, the response to therapy. Aliment Pharmacol Ther. 2013;38(6):563-572.
- 34. Arguelles-Arias F, Castro-Laria L, Lobaton T, et al. Characteristics and treatment of pyoderma gangrenosum in inflammatory bowel disease. Dig Dis Sci. 2013;58(10):2949-2954.
- 35. Marzano AV, Ishak RS, Saibeni S, et al. Autoinflammatory skin disorders in inflammatory bowel diseases, pyoderma gangrenosum and Sweet's syndrome: A comprehensive review and disease classification criteria. Clin Rev Allergy Immunol. 2013;45(2):202-210.
- 36. Hatemi G, Christensen R, Bodaghi, et al. 2018 update of the EULAR recommendations for the management of Behcet's syndrome. Ann Rheum Dis. 2018.; 77: 808-818.
- 37. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol. 2019;80(4):1029-1072.
- 38. Testing for TB Infection. Centers for Disease Control and Prevention. Retrieved on August 5, 2024 from: https://www.cdc.gov/tb/testing/index.html.
- 39. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis Rheumatol. 2019;71(1):5-32.
- 40. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. Gastroenterology. 2020; 158:1450.
- 41. Menter, A, Cordero, KM, Davis, DM, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis in pediatric patients. J Am Acad Dermatol. 2020;82(1):161-201.
- 42. Menter A, Gelfand JM, Connor C, et al. Joint AAD-NPF guidelines of care for the management of psoriasis with systemic nonbiologic therapies. J Am Acad Dermatol. 2020;82(6):1445-86.
- 43. Micromedex® (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com. Accessed August 6, 2024.
- 44. George C, Deroide F, Rustin M. Pyoderma gangrenosum a guide to diagnosis and management. Clin Med. 2019;19(3): 224-8.
- 45. Jaffe G, Dick A, Brezin A, et al. Adalimumab in Patients with Active Noninfectious Uveitis. N Engl J Med. 2016; 375: 932-943.

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	□New Jersey	□Maryland	□Florida	a Kids
	□Michigan	□Pennsylvania Kid	s □Virgini	a

- 46. Nguyen QD, Merrill P, Jaffe G, et al. Adalimumab for prevention of uveitic flare in patients with inactive non-infectious uveitis controlled by corticosteroids (VISUAL II): a multicentre, double-masked, randomized, placebo-controlled phase 3 trial. Lancet. 2016; 388(10050):1183-92.
- 47. Aletaha D, Neogi T, Silman AJ, et al. 2010 Rheumatoid arthritis classification criteria: an American College of Rheumatology/European League Against Rheumatism collaborative initiative. Arthritis Rheum. 2010;62(9):2569-81.
- 48. Rubin DT, Ananthakrishnan AN, et al. 2019 ACG Clinical Guideline: Ulcerative Colitis in Adults. Am J Gastroenterol. 2019;114:384-413.
- 49. Alikhan A, Sayed C, Alavi A, et al. North American clinical management guidelines for hidradenitis suppurativa: A publication from the United States and Canadian Hidradenitis Suppurativa Foundations Part I: Diagnosis, evaluation, and the use of complementary and procedural management. J Am Acad Dermatol. 2019; 81(1): 76-90.
- 50. Alikhan A, Sayed C, Alavi A, et al. North American clinical management guidelines for hidradenitis suppurativa: A publication from the United States and Canadian Hidradenitis Suppurativa Foundations Part II: Topical, intralesional, and systemic medical management. J Am Acad Dermatol. 2019; 81(1): 91-101.
- 51. Smolen JS, Aletaha D. Assessment of rheumatoid arthritis disease activity and physical function. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Available with subscription. URL: www.uptodate.com. Accessed November 29, 2023.
- 52. The NCCN Drugs & Biologics Compendium 2024 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed August 20, 2024.
- 53. Feuerstein J, Ho E, Shmidt E, et al. AGA Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease. Gastroenterology. 2021; 160:2496-2508.
- 54. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. Arthrit Care Res. 2021;0:1-16.
- 55. Elmets C, Korman N, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. J Am Acad Dermatol. 2021; 84(2):432-470.
- 56. Onel KB, Horton DB, Lovell DJ, et al. 2021 American College of Rheumatology guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for oligoarthritis, temporomandibular joint arthritis, and systemic juvenile idiopathic arthritis. Arthritis Rheumatol. 2022;74(4):553-569.
- 57. Angeles-Han ST, Ringold S, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation guideline for the screening, monitoring, and treatment of juvenile idiopathic arthritis-associated uveitis. Arthritis Care Res. 2019; 71(6):703-716.
- 58. Maronese CA, Pimentel MA, et al. Pyoderma Gangrenosum: An Updated Literature Review on Established and Emerging Pharmacological Treatments. Am J Clin Dermatol. 2022;23(5):615-634.