Original Effective Date: 11/2012
Current Effective Date: 11/29/2023
Last P&T Approval/Version: 10/25/2023
Next Review Due By: 10/2024
Policy Number: C10412-A

Humira (adalimumab) and Biosimilars

PRODUCTS AFFECTED

adalimumab-adaz, adalimumab-fkjp, Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hadlima (adalimumab-bwwd), Hulio (adalimumab-fkjp), Humira (adalimumab), Hyrimoz (adalimumab-adaz), Idacio (adalimumab-aacf), Yuflyma (adalimumab-aaty), Yusimry (adalimumab-aqvh)

COVERAGE POLICY

Coverage for services, procedures, medical devices, and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Moderately to severely active rheumatoid arthritis (RA), Juvenile idiopathic arthritis, Psoriatic arthritis, Chronic plaque psoriasis, Moderately to severely active Crohn's disease, Moderately to severely active ulcerative colitis, Moderate to severe ankylosing spondylitis, Hidradenitis suppurativa (acne inversa), Non-infectious uveitis, Pyoderma gangrenosum

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

FOR ALL INDICATIONS:

1. (a) Prescriber attests, or clinical reviewer has found, member has had a negative TB screening* or TB test (if indicated)** result within the last 12 months for initial and continuation of therapy requests
   *MOLINA REVIEWER NOTE: TB SCREENING assesses patient for future or ongoing TB exposure or risk and includes reviewing if they have been exposed to tuberculosis, if they have resided or traveled to areas of endemic tuberculosis, if patient resides or works in a congregate setting (e.g., correctional facilities, long-term care facilities, homeless shelters), etc.
   **MOLINA REVIEWER NOTE: TB SKIN TEST (TST, PPD) AND TB BLOOD TEST (QuantiFERON TB Gold, T-Spot) are not required or recommended in those without risk factors for tuberculosis
   OR
   (b) For members who have a positive test for latent TB, provider documents member has completed a treatment course (a negative chest x-ray is also required every 12 months) OR that member has been cleared by an infectious disease specialist to begin treatment
   AND
2. Prescriber attests member has been evaluated and screened for the presence of hepatitis B virus (HBV) prior to initiating treatment
   AND
3. Member is not on concurrent treatment or will not be used in combination with other TNF-inhibitor, biologic response modifier or other biologic DMARDs, Janus kinase Inhibitors, or Phosphodiesterase 4 inhibitor (i.e., apremilast, tofacitinib, baricitinib) as verified by prescriber attestation, member medication fill history, or submitted documentation
   AND
4. Prescriber attests member does not have an active infection, including clinically important localized infections
   AND
5. (a) IF THIS IS A PHARMACY BENEFIT REQUEST FOR A NON-FORMULARY/NON-PREFERRED PRODUCT: Documentation of trial/failure of or serious side effects to a majority (not more than 3) of the preferred formulary alternatives for the given diagnosis. Documentation of medication(s) tried, dates of trial(s) and reason for treatment failure(s) is required.
   AND
   (b) If request is for a NON-FORMULARY/NON-PREFERRED reference product with a biosimilar available for initial or continuation of therapy requests: Documentation of a trial and failure, serious side effects or contraindication to a majority (not more than 3) biosimilar product(s) is required (unless otherwise specified per applicable state regulations and/or there is data demonstrating clinical superiority of reference drugs over the FDA approved biosimilar drugs).
   [DOCUMENTATION REQUIRED: Document when the preferred biologic product or biosimilar was tried and the length of the trial period. Provide specific clinical documentation of therapeutic failure on the preferred biologic product or biosimilar whenever possible. Describe the medical problem caused by the preferred referenced biologic. Vague and non-descriptive symptoms are not adequate rationale (e.g., stomachache).]
   PREFERRED AGENT: Medicaid: Hadlima (adalimumab-bwwd) and adalimumab-fkjp (unbranded Hulio [Biocon]; Marketplace: Hadlima (adalimumab-bwwd), Humira (adalimumab), Hyrimoz (adalimumab-adaz) [Cordavis]

A. MODERATE TO SEVERE RHEUMATOID ARTHRITIS:

1. Documentation of moderate to severe rheumatoid arthritis diagnosis
   AND
2. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]
   AND
3. (a) Member is currently receiving maximally tolerated dose of methotrexate and is not at goal disease activity
   OR

(b) Member has an FDA labeled contraindication or serious side effects to methotrexate, as determined by the prescribing physician AND Member has tried one additional disease-modifying antirheumatic drug (DMARD) (brand or generic; oral or injectable) for at least 3 months *(NOTE: An exception to the requirement for a trial of one conventional synthetic DMARD can be made if the member has already had a 3-month trial of at least one biologic. These members who have already tried a biologic for RA are not required to "step back" and try a conventional synthetic DMARD*)

B. JUVENILE IDIOPATHIC ARTHRITIS (ACTIVE SYSTEMIC AND POLYARTICULAR):
1. Documented diagnosis of juvenile idiopathic arthritis in a pediatric member
AND
2. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]
AND
3. (a) FOR ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS:
   i. Documentation of treatment failure, serious side effects or clinical contraindication to an adequate trial 12 weeks) of one NSAID or glucocorticoid
   AND
   ii. Documentation of treatment failure, serious side effects or clinical contraindication to an adequate trial (12 weeks) of one of the following: methotrexate, leflunomide, anakinra (Kineret), canakinumab (Ilaris), or tocilizumab (Actemra)

OR

(b) FOR POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS: Documentation of treatment failure, serious side effects or clinical contraindication to an adequate trial (generally ≥12 weeks) of one or more of the following: Methotrexate, hydroxychloroquine, sulfasalazine, leflunomide

C. PSORIATIC ARTHRITIS (PsA):
1. Documentation of active psoriatic arthritis
AND
2. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]
AND
3. (a) Documented treatment failure, serious side effects or clinical contraindication to a minimum 3-month trial of ONE of the following: Leflunomide, Methotrexate, Sulfasalazine, Cyclosporine
OR
(b) Documentation member has severe psoriatic arthritis [erosive disease, elevated markers of inflammation, long term damage that interferes with function, highly active disease that causes a major impairment in quality of life, active PsA at many sites including dactylitis, enthesitis, function-limiting PsA at a few sites or rapidly progressive disease]
OR
(c) Documentation member has severe psoriasis [PASI ≥12, BSA of >5-10%, significant involvement in specific areas (e.g., face, hands or feet, nails, intertriginous areas, scalp), impairment of physical or mental functioning with lower amount of surface area of skin involved]

D. CHRONIC PLAQUE PSORIASIS:
1. Documented diagnosis of moderate to severe psoriasis (BSA ≥ 3%) OR < 3% body surface area with plaque psoriasis that involves sensitive areas of the body or areas that would significantly impact daily function (e.g., face, neck, hands, feet, genitals)
AND
2. (a) Documentation of treatment failure, serious side effects, or clinical contraindication to TWO of the following systemic therapies for ≥3 months: Methotrexate (oral or IM at a minimum dose of 15mg/week), cyclosporine, acitretin, azathioprine, hydroxyurea, leflunomide, mycophenolate mofetil, or tacrolimus
OR
(b) Documentation of treatment failure to Phototherapy for ≥3 months with either psoralens with ultraviolet A (PUVA) or ultraviolet B (UVB) radiation (provider to submit documentation of duration

of treatment, dates of treatment, and number of sessions; contraindications include type 1 or type 2 skin, history of photosensitivity, treatment of facial lesions, presence of premalignant lesions, history of melanoma or squamous cell carcinoma, or physical inability to stand for the required exposure time)
AND
3. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]

E. CROHN'S DISEASE:
1. Documentation of a diagnosis of Crohn's Disease
AND
2. Member has one or more high risk feature:
   i. Diagnosis at a younger age (<30 years old)
   ii. History of active or recent tobacco use
   iii. Elevated C-reactive protein and/or fecal calprotectin levels
   iv. Deep ulcers on colonoscopy
   v. Long segments of small and/or large bowel involvement
   vi. Perianal disease
   vii. Extra-intestinal manifestations
   viii. History of bowel resections
AND
3. (a) Documentation of treatment failure, serious side effects or clinical contraindication to an adequate trial (> 3 months) of ONE immunomodulator (e.g., azathioprine, 6-mercaptopurine, methotrexate) up to maximally indicated doses
OR
(b) Prescriber provides documented medical justification that supports the inability to use immunomodulators
   i. Inability to induce short-term symptomatic remission with a 3-month trial of systemic glucocorticoids
   ii. High-risk factors for intestinal complications may include: Initial extensive ileal, ileocolonic, or proximal GI involvement, Initial extensive perianal/severe rectal disease, Fistulizing disease (e.g., perianal, enterocutaneous, and rectovaginal fistulas), Deep ulcerations, Penetrating, stricturing or stenosis disease and/or phenotype, Intestinal obstruction, or abscess
   iii. High risk factors for postoperative recurrence may include: Less than 10 years duration between time of diagnosis and surgery, Disease location in the ileum and colon, Perianal fistula, Prior history of surgical resection, Use of corticosteroids prior to surgery
AND
4. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]

F. ULCERATIVE COLITIS:
1. Documentation of ulcerative colitis diagnosis with evidence of moderate to severe disease activity
AND
2. (a) Documentation of treatment failure, serious side effects or clinical contraindication to a 2-month trial of one systemic agent (e.g., 6-mercaptopurine, azathioprine, cyclosporine, acrolimus, or a corticosteroid such as prednisone, methylprednisolone) for ulcerative colitis or will continue to take concurrently.
NOTE: A previous trial of a biologic (e.g., an adalimumab product [e.g., Humira], Simponi SC [golimumab SC injection], or Entyvio [vedolizumab IV infusion]) also counts as a trial of one systemic agent for UC
OR
b) The member has pouchitis AND has tried therapy with an antibiotic (e.g., metronidazole, ciprofloxacin), probiotic, corticosteroid enema [for example, Cortenema® (hydrocortisone enema, generics)], or topical mesalamine

AND

3. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]

G. MODERATE TO SEVERE ANKYLOSING SPONDYLITIS:
1. Documented diagnosis of ankylosing spondylitis
AND
2. Documentation of treatment failure, serious side effects or clinical contraindication to TWO NSAIDs (e.g., ibuprofen, naproxen, etodolac, meloxicam, indomethacin) for ≥3 consecutive months at maximal recommended or tolerated anti- inflammatory doses
AND
3. FOR MEMBER WITH PROMINENT PERIPHERAL ARTHRITIS: Documentation of treatment failure, serious side effects or clinical contraindication to a trial (≥3 consecutive months) of methotrexate OR sulfasalazine
AND
4. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]

H. HIDRADENITIS SUPPURATIVA:
1. Documentation of Hurley stage II (moderate recurrent) or stage III (severe diffuse) disease
AND
2. Prescriber attestation that IF member is a smoker, the member has been counseled regarding the benefits of smoking cessation and/or connected with a program to support smoking cessation
AND
3. Documentation indicating the member has been counseled on the use of general supportive measures (e.g., education and support, avoidance of skin trauma, hygiene, dressings, smoking cessation, weight management, diet)
AND
4. (a) Documentation of treatment failure with or a clinical contraindication to a 3-month trial of the following:
(i) Oral tetracycline (e.g., minocycline, doxycycline) AND
(ii) Topical antibiotic (Stage II disease only) AND
(iii) Antiandrogen (e.g., finasteride) OR clindamycin/rifampin
AND
(b) Documentation of treatment failure with or a clinical contraindication to intralesional corticosteroids
Note to reviewer- guideline recommended first line agents are as follows:
Hurley stage I disease: topical clindamycin, oral tetracycline, metformin and antiandrogenic agents; Hurley stage II or III disease: oral tetracycline, oral clindamycin, rifampin, metformin
AND
5. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]

I. NON-INFECTIOUS UVEITIS:
1. Documentation of diagnosis of non-infectious intermediate, posterior, or pan-uveitis
AND
2. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy [DOCUMENTATION REQUIRED]
AND
3. (a) Documentation of treatment failure, serious side effects or clinical contraindication to ONE of the following: (i) an intravitreal steroid (e.g., triamcinolone, dexamethasone) OR (ii) a systemic corticosteroid (e.g., prednisone, methylprednisolone) OR (iii) an anti-metabolite (e.g., methotrexate, azathioprine, mycophenolate) OR (iv) a calcineurin inhibitor (e.g., cyclosporine,

tacrolimus)
OR
(b) Documentation of severe uveitis associated with Behcet's syndrome

J. PYODERMA GANGRENOSUM:
1. Documentation of diagnosis of pyoderma gangrenosum
AND
2. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy [DOCUMENTATION REQUIRED]
AND
3. Documentation of a trial (≥ 6 weeks) and failure or labeled contraindication to formulary systemic glucocorticoids AND systemic cyclosporine

CONTINUATION OF THERAPY:

A. ALL INDICATIONS:
1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation
AND
2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity
AND
3. Documentation of positive clinical response as demonstrated by low disease activity and/or improvements in the condition's signs and symptoms. [DOCUMENTATION REQUIRED]
AND
4. (a) Prescriber attests, or clinical reviewer has found, member has had a negative TB screening* or TB test (if indicated)** result within the last 12 months for initial and continuation of therapy requests
*MOLINA REVIEWER NOTE: TB SCREENING assesses patient for future or ongoing TB exposure or risk and includes reviewing if they have been exposed to tuberculosis, if they have resided or traveled to areas of endemic tuberculosis, if patient resides or works in a congregate setting (e.g., correctional facilities, long-term care facilities, homeless shelters), etc.
**MOLINA REVIEWER NOTE: TB SKIN TEST (TST, PPD) AND TB BLOOD TEST (QuantiFERON TB Gold, T-Spot) are not required or recommended in those without risk factors for tuberculosis
OR
(b) For members who have a positive test for latent TB, provider documents member has completed a treatment course (a negative chest x-ray is also required every 12 months) OR that member has been cleared by an infectious disease specialist to begin treatment

DURATION OF APPROVAL:

ULCERATIVE COLITIS: Initial authorization: 2 months *Discontinue therapy in adult patients without evidence of clinical remission by eight weeks of therapy
Continuation of therapy: 6 months

ALL OTHER INDICATIONS:
Initial authorization: 6 months, Continuation of therapy: 6 months

PRESCRIBER REQUIREMENTS:

MODERATE TO SEVERE RHEUMATOID ARTHRITIS, JUVENILE IDIOPATHIC ARTHRITIS, MODERATE TO SEVERE ANKYLOSING SPONDYLITIS: Prescribed by or in consultation with a board- certified rheumatologist

PSORIATIC ARTHRITIS (PsA), CHRONIC PLAQUE PSORIASIS, PYODERMA GANGRENOSUM: Prescribed by or in consultation with a board-certified rheumatologist or dermatologist

MODERATE TO SEVERE CROHN'S DISEASE OR ULCERATIVE COLITIS: Prescribed by or in consultation with a board-certified gastroenterologist or colorectal surgeon

HIDRADENITIS SUPPURATIVA: Prescribed by or in consultation with a board-certified dermatologist

NON-INFECTIOUS UVEITIS: Prescribed by or in consultation with a board-certified ophthalmologist

[If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:
Verify product specific labeling (See FDA Approved uses product chart)
MODERATE TO SEVERE RHEUMATOID ARTHRITIS, PSORIATIC ARTHRITIS (PsA), ANKYLOSING SPONDYLITIS, PYODERMA GANGRENOSUM: 18 years of age and older
JUVENILE IDIOPATHIC ARTHRITIS, UVEITIS: 2 years of age and older
CHRONIC PLAQUE PSORIASIS: 4 years of age and older
CROHN'S DISEASE: 6 years of age and older
ULCERATIVE COLITIS: 5 years of age and older
HIDRADENITIS SUPPURATIVA: 12 years and older

QUANTITY:

Medication	Standard Limit	FDA-recommended dosing
10 mg/0.1 mLsingle-use prefilled syringe	2 syringes per 28 days	**RA/PsA/AS** 40 mg every other week For patients not taking concomitant methotrexate: may increase to 40 mg every week or 80 mg every other week if needed **JIA/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
10 mg/0.2 mLsingle-use prefilled syringe	2 syringes per 28 days	
20 mg/0.2 mLsingle-use prefilled syringe	2 syringes per 28 days	
20 mg/0.4 mLsingle-use prefilled syringe	2 syringes per 28 days	

40 mg/0.4 mL single-use prefilled syringe/pen	4 syringes/pens per 28 days	**Pediatric CD (6 years and up)** 17 kg to < 40 kg: Loading doses of 80 mg on day 1 and 40 mg (on day 15; Maintenance dose of 20 mg every other week starting on day 29
40 mg/0.8 mL single-use prefilled syringe/pen	4 syringes/pens per 28 days	≥ 40 kg: Loading doses of 160 mg on day 1 (single dose or split over two consecutive days) and 80 mg (on day 15; Maintenance dose of 40 mg every other week starting on day 29 **Pediatric plaque psoriasis (off-label dosing)** 0.8 mg/kg (max dose 40mg) at weeks 0 and 1, then every other week
40 mg/0.8 mL Pediatric Crohn's Disease Starter Pack	6 syringes per 28 days	
80 mg/0.8 mL Pediatric Crohn's Disease Starter Pack	3 syringes per 28 days	**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 on day 15 Maintenance dose: 40 mg every other week starting on day 29 **Pediatric UC (5 years and up)** 20 kg to < 40 kg: Loading doses: 80 mg on day 1, 40 mg on days 8 and 15 Maintenance dose: 40 mg every other week or 20 mg every week starting on day 29* ≥ 40 kg: Loading doses: 160 mg on day 1 (single dose or split over two consecutive days), 80mg on days 8 and 15 Maintenance dose: 80 mg every other week or 40 mg every week starting on day 29* *Continue the recommended pediatric dosage in patients who turn 18 years of age and who are well-controlled on their HUMIRA regimen.
80 mg/0.8 mL and 40 mg/0.4 mL Pediatric Crohn's Disease Starter Pack	2 syringes per 28 days	
40 mg/0.8 mL pen Crohn's Disease, Ulcerative Colitis, or Hidradenitis Suppurativa Starter Pack	6 pens per 28 days	**Plaque psoriasis/ Adult Uveitis** 80 mg initial dose, followed by 40 mg every other week starting one week after the initial dose **Adolescent hidradenitis suppurativa (12 years and up)** 30 kg to < 60 kg: 80 mg on day 1, 40 mg on day 8 and subsequent doses 40 mg every other week ≥ 60 kg: Follow adult dosing **Adult hidradenitis suppurativa** Loading doses: 160 mg on day 1 (given in one day or split over two consecutive days), followed by 80mg on day 15 Maintenance dose: 40 mg every week or 80 mg every other week starting on day 29
80 mg/0.8 mL pen Crohn's Disease, Ulcerative Colitis, or Hidradenitis Suppurativa Starter Pack	3 pens per 28 days	
40 mg/0.8 mL pen Psoriasis/Uveitis/Adolescent Hidradenitis Suppurativa Starter Pack	4 pens per 28 days	
80 mg/0.8 mL and 40 mg/0.4 mL Psoriasis/Uveitis/Adolescent Hidradenitis Suppurativa Starter Pack	3 pens per 28 days	**Adult Pyoderma gangrenosum:** SC: 40 to 80 mg every week or every other week

When requests for off-label dosing, dose escalation, or dose intensification are received, requests will be reviewed for evidence that current or standard dosing is not adequate to produce a therapeutic level of drug (e.g., pharmacokinetic failure), clinical failure or significant loss of response is present, and the requested dosing is established as safe and effective for the condition. There are certain situations where no additional amount of drug is likely to produce or recapture clinical effect because the condition is no longer responsive to the drug (e.g., pharmacodynamic failure) or the drug cannot reach the site of activity at sufficient levels. The following items will assist reviewers in determining if the requested dosing is medically necessary:

- *FDA or compendium-supported dosing and therapeutic monitoring recommendations for the drug*
- *Member claims/adherence history*
- *Clinical documentation of the member's response to current or standard dosing regimens (disease activity indices if commonly used in clinical practice or documentation to approximate them may be necessary to demonstrate the response)*
- *In conjunction with documented clinical failure or loss of response or wearing off of effect, test results that demonstrate failure of current or standard dosing to reach established treatment thresholds (e.g., established therapeutic monitoring recommendations)*
- *If applicable, documentation showing the member does not have conditions which make achieving a therapeutic level of drug unlikely even with dose intensification (eg, dose intensification may be futile due to the presence of anti-drug antibodies, protein losing enteropathy, nephrotic syndrome, severe drug excretion or malabsorption issues, etc.)*

In certain situations, documentation, or peer-to-peer determination that re-induction cannot be tried to recapture response as an alternative to long term dose escalation or intensification

PLACE OF ADMINISTRATION:
The recommendation is that injectable medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Subcutaneous injection

DRUG CLASS:
Anti-TNF-Alpha - Monoclonal Antibodies

FDA-APPROVED USES:
• 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 adults and pediatric patients 6 years of age and older.
• Treatment of moderately to severely active Ulcerative Colitis (UC) in adults and pediatric patients 5 years of age and older. *Limitations of Use: Effectiveness has not been established in patients who have lost response to or were intolerant to TNF blockers.*
• Treatment of adult patients with moderate to severe chronic Plaque Psoriasis (Ps) who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate.

• Treatment of moderate to severe Hidradenitis Suppurativa (HS) 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

Product	Citrate Free?	Interchangeable?	Approved indications
40mg/0.8mL			
Humira	No		
Amjevita	Yes	No	Not indicated for: • Pediatric UC • Adolescent HS • Pediatric UV
Cyltezo	Yes	Yes	Not indicated for: • Pediatric UC • Adolescent HS • Pediatric UV
Hadlima	No	No	Not indicated for: • Pediatric UC • Adolescent HS • Pediatric UV
Hulio Adalimumab-fkjp	Yes	No	Not indicated for: • Pediatric UC • Adolescent HS • UV
Hyrimoz	No	No	Not indicated for: • Pediatric UC • Adolescent HS • UV
Idacio	Yes	No	Not indicated for: • Pediatric UC • Adolescent HS • UV
Yusimry	Yes	No	Not indicated for: • Pediatric UC • Adolescent HS • UV
40mg/0.4mL			
Humira	Yes		
Hadlima HC	Yes	No	Not indicated for: • Pediatric UC • Adolescent HS • Pediatric UV
Hyrimoz HCF Adalimumab-adaz	Yes	No	Not indicated for: • Pediatric UC • Adolescent HS • UV
Yuflyma	Yes	No	Not indicated for: • Pediatric UC • Adolescent HS • UV

COMPENDIAL APPROVED OFF-LABELED USES:
Pyoderma gangrenosum, Systemic juvenile idiopathic arthritis, Moderate to severe psoriasis in children and adolescents

APPENDIX

APPENDIX:
Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*

State Specific Information
State Marketplace
Illinois (Source: Illinois General Assembly)
"(215 ILCS 200/60) Sec. 60. Length of prior authorization approval. *A prior authorization approval shall be valid for the lesser of 6 months after the date the health care professional or health care provider receives the prior authorization approval or the length of treatment as determined* by the patient's health care professional or the renewal of the plan, and the *approval period shall be effective regardless of any changes, including any changes in dosage for a prescription drug* prescribed by the health care professional. All dosage increases must be based on established evidentiary standards and nothing in this Section shall prohibit a health insurance issuer from having safety edits in place. This Section shall not apply to the prescription of benzodiazepines or Schedule II narcotic drugs, such as opioids. Except to the extent required by medical exceptions processes for prescription drugs set forth in Section 45.1 of the Managed Care Reform and Patient Rights Act, nothing in this Section shall require a policy to cover any care, treatment, or services for any health condition that the terms of coverage otherwise completely exclude from the policy's covered benefits without regard for whether the care, treatment, or services are medically necessary. (Source: P.A. 102-409, eff. 1-1-22.)"
"(215 ILCS 200/65) Sec. 65. Length of prior authorization approval for *treatment for chronic or long-term conditions*. If a health insurance issuer requires a prior authorization for a recurring health care service or maintenance medication for the treatment of a chronic or long-term condition, *the approval shall remain valid for the lesser of 12 months from the date the health care professional or health care provider receives the prior authorization approval or the length of the treatment as determined by the patient's health care professional*. This Section shall not apply to the prescription of benzodiazepines or Schedule II narcotic drugs, such as opioids. Except to the extent required by medical exceptions processes for prescription drugs set forth in Section 45.1 of the Managed Care Reform and Patient Rights Act, nothing in this Section shall require a policy to cover any care, treatment, or services for any health condition that the terms of coverage otherwise completely exclude from the policy's covered benefits without regard for whether the care, treatment, or services are medically necessary. (Source: P.A. 102-409, eff. 1-1-22.)"

Kentucky (Source: Kentucky Revised Statutes)
KY304.17A-167 Time span of authorizations
(Subsection 2) "Unless otherwise provided in subsection (3) of this section or prohibited by state or federal law, if a provider receives a prior authorization for a drug prescribed to a covered person with a condition that requires ongoing medication therapy, and the provider continues to prescribe the drug, and the drug is used for a condition that is within the scope of use approved by the United States Food and Drug Administration or has been proven to be a safe and effective form of treatment for the patient's specific underlying condition based on clinical practice guidelines that are developed from peer-reviewed publications, the prior authorization received shall: (a) Be valid for the lesser of: 1. One (1) year from the date the provider receives the prior authorization; or 2. Until the last day of coverage under the covered person's health benefit plan during a single plan year; and (b) Cover any change in dosage prescribed by the provider during the period of authorization." (Subsection 3) "Except as provided in paragraph (b) of this subsection, the provisions of subsection (2) of this section shall not apply to: 1. Medications that are prescribed for a non-maintenance condition; 2. Medications that have a typical treatment period of less than twelve (12) months; 3. Medications where there is medical or scientific evidence that does not support a twelve (12) month approval; or 4. Medications that are opioid analgesics or benzodiazepines. (b) Paragraph (a) of this subsection shall not

apply to any medication that is prescribed to a patient in a community-based palliative care program."
Re-authorization (approved authorization previously issued by Molina Healthcare) for maintenance medications within this policy shall be approved for a 12 month duration when request meets policy requirements, unless exceptions noted above have been met.

Mississippi (Source: Mississippi Legislature)
"SECTION 13. Length of approvals. (1) A prior authorization approval shall be valid for the lesser of six (6) months after the date the health care professional or health care provider receives the prior authorization approval or the length of treatment as determined by the patient's health care professional or the renewal of the policy or plan, and the approval period shall be effective regardless of any changes, including any changes in dosage for a prescription drug prescribed by the health care professional. Notwithstanding the foregoing, a health insurer and an enrollee or his/her health care professional may extend a prior authorization approval for a longer period, by agreement. All dosage increases must be based on established evidentiary standards, and nothing in this section shall prohibit a health insurance issuer from having safety edits in place. This section shall not apply to the prescription of benzodiazepines or Schedule II narcotic drugs, such as opioids.
(2) Nothing in this section shall require a policy or plan to cover any care, treatment, or services for any health condition that the terms of coverage otherwise completely exclude from the policy's or plan's covered benefits without regard for whether the care, treatment or services are medically necessary.
SECTION 14. Approvals for chronic conditions. (1) If a health insurance issuer requires a prior authorization for a recurring health care service or maintenance medication for the treatment of a chronic or long-term condition, including, but not limited to, chemotherapy for the treatment of cancer, the approval shall remain valid for the lesser of twelve (12) months from the date the health care professional or health care provider receives the prior authorization approval or the length of the treatment as determined by the patient's health care professional. Notwithstanding the foregoing, a health insurer and an enrollee or his or her health care professional may extend a prior authorization approval for a longer period, by agreement. This section shall not apply to the prescription of benzodiazepines or Schedule II narcotic drugs, such as opioids.
(2) Nothing in this section shall require a policy or plan to cover any care, treatment or services for any health condition that the terms of coverage otherwise completely exclude from the policy's or plan's covered benefits without regard for whether the care, treatment, or services are medically necessary."

Ohio (Source: Ohio Revised Code)
Chapter 3923 Sickness And Accident Insurance Section 3923.041 Policies with prior authorization requirement provisions "(B)(6)(a) For policies issued on or after January 1, 2017, *for a prior approval related to a chronic condition*, the insurer or plan shall honor a prior authorization *approval for an approved drug for the lesser of the following from the date of the approval: (i) Twelve months*; (ii) The last day of the covered person's eligibility under the policy or plan. (b) The duration of all other prior authorization approvals shall be dictated by the policy or plan."

State Medicaid
Kentucky (Source: Kentucky Revised Statutes)
KY304.17A-167 Time span of authorizations
(Subsection 2) "Unless otherwise provided in subsection (3) of this section or prohibited by state or federal law, if a provider receives a prior authorization for a drug prescribed to a covered person with a condition that requires ongoing medication therapy, and the provider continues to prescribe the drug, and the drug is used for a condition that is within the scope of use approved by the United States Food and Drug Administration or has been proven to be a safe and effective form of treatment for the patient's specific underlying condition based on clinical practice guidelines that are developed from peer-reviewed publications, the prior authorization received shall: (a) Be valid for the lesser of: 1. One (1) year from the date the provider receives the prior authorization; or 2. Until the last day of coverage under the covered person's health benefit plan during a single plan year; and (b) Cover any change in dosage prescribed by the provider during the period of authorization." (Subsection 3) "Except as provided in paragraph (b) of this

subsection, the provisions of subsection (2) of this section shall not apply to: 1. Medications that are prescribed for a non-maintenance condition; 2. Medications that have a typical treatment period of less than twelve (12) months; 3. Medications where there is medical or scientific evidence that does not support a twelve (12) month approval; or 4. Medications that are opioid analgesics or benzodiazepines. (b) Paragraph (a) of this subsection shall not apply to any medication that is prescribed to a patient in a community-based palliative care program."

Re-authorization (approved authorization previously issued by Molina Healthcare) for maintenance medications within this policy shall be approved for a 12 month duration when request meets policy requirements, unless exceptions noted above have been met.

Appendix A: OBJECTIVE MEASURES FOR RA: [Clinical Disease Activity Index (CDAI), Disease Activity Score with 28-joint counts (erythrocyte sedimentation rate or C-reactive protein), Member Activity Scale (PAS or PAS-II), Routine Assessment of Member Index Data with 3 measures, Simplified Disease Activity Index (SDAI)]
OBJECTIVE MEASURES FOR PJIA: Global Arthritis Score (GAS), Clinical Disease Activity Index (CDAI), Disease Activity Score (DAS), Disease Activity Score based on 28-joint evaluation (DAS28), Simple Disease Activity Index (SDAI), Health Assessment Questionnaire disability index (HAQ-DI), Visual Analogue Scale (VAS), Likert scales of global response or pain by the member or global response by the physician, Joint tenderness and/or swelling counts, Laboratory data

Appendix B:
A biosimilar is highly similar version of a brand name biological drug that meets strict controls for structural, pharmaceutical, and clinical consistency. A biosimilar manufacturer must demonstrate that there are no meaningful clinical differences (i.e., safety and efficacy) between the biosimilar and the reference product. Clinical performance is demonstrated through human pharmacokinetic (exposure) and pharmacodynamic (response) studies, an assessment of clinical immunogenicity, and, if needed, additional clinical studies.1 As costs for biological specialty drugs continue to rise, the growing biosimilar market will benefit providers
and patients by broadening biological treatment options and expanding access to these medications at lower costs. Molina Healthcare, Inc. continues to be committed to continually reevaluating Preferred strategies and applying innovative cost-controls to ensure patients receive safe, effective, and quality healthcare. This commitment includes potentially creating a preference for biosimilars when value can be added without compromising patient satisfaction and safety.

1. Food and Drug Administration. Biosimilar and Interchangeable Products. Retrieved from https://www.fda.gov/drugs/biosimilars/biosimilar-and-interchangeable-products. Accessed October 8, 2019

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Humira (adalimumab) is a monoclonal antibody that binds to tumor necrosis factor alpha. Elevated levels of TNF contribute to pain and joint destruction in immune-mediated arthritis. Humira binds to TNF alpha receptor sites to interfere with the inflammation process. Humira is indicated for 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. It is indicated for reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in pediatric patients 2 years of age and older. Humira is also indicated for reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active psoriatic arthritis. It is indicated for reducing signs and symptoms in adult patients with active ankylosing spondylitis. Humira is indicated for reducing signs and symptoms and

inducing and maintaining clinical remission in adult patients with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy and reducing signs and symptoms and inducing clinical remission in these patients if they have also lost response to or are intolerant to infliximab. Humira is indicated for reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age and older with moderately to severely active Crohn's disease who have had an inadequate response to corticosteroids or immunomodulators such as azathioprine, 6-mercaptopurine, or methotrexate. Humira is also indicated for inducing and sustaining clinical remission in adult patients with moderately to severely active ulcerative colitis who have had an inadequate response to immunosuppressants such as corticosteroids, azathioprine or 6-mercaptopurine (6-MP). Humira is indicated for the treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate. Humira is indicated for the treatment of moderate to severe hidradenitis suppurativa. Finally, Humira is indicated for the treatment of noninfectious intermediate, posterior and panuveitis in adult patients.

Pyoderma Gangrenosum is an inflammatory skin disorder. The exact cause is unknown; however, it is thought to be autoimmune. Approach of treatment depends on severity. Initial treatment for mild cases are typically a high potency or super potent topical steroid or topical tacrolimus. Patients who fail this or have more extensive disease should be treated with systemic treatment such as systemic glucocorticoids, cyclosporine. Humira (adalimumab) has also been noted to be beneficial in members with pyoderma gangrenosum. (Schadt, C)

AGA Guidelines Moderate to Severe Ulcerative Colitis

Recommendations from the recent 2020 guideline update include:

- In adult outpatients with moderate to severe UC who are naïve to biologic agents, the AGA suggests using infliximab or vedolizumab rather than adalimumab, for induction of remission.
- Updated FDA recommendations (July 26, 2019) on indications for use of tofacitinib in UC recommends its use only after failure of or intolerance to TNF-a antagonists.
- In adult outpatients with moderate to severe UC who have previously been exposed to infliximab, particularly those with primary nonresponse, the AGA suggests using ustekinumab or tofacitinib rather than vedolizumab or adalimumab for induction of remission.
- In adult outpatients with moderate to severe UC, the AGA suggests against using methotrexate monotherapy for induction or maintenance of remission
- In adult outpatients with active moderate to severe UC, the AGA suggests using biologic monotherapy (TNF-a antagonists, vedolizumab, or ustekinumab) or tofacitinib rather than thiopurine monotherapy for induction of remission.
- In adult outpatients with moderate to severe UC, the AGA suggests combining TNF-a antagonists, vedolizumab or ustekinumab with thiopurines or methotrexate rather than biologic monotherapy.
- In adult outpatients with moderate to severe UC who have achieved remission with biologic agents and/or immunomodulators or tofacitinib, the AGA suggests against continuing 5-ASA for induction and maintenance of remission.

VARSITY Trial: Ulcerative Colitis in Adults

Entyvio and Humira were compared in adults with moderately to severely active UC in a Phase 3b double-blind, double-dummy, randomized trial. Previous exposure to a tumor necrosis factor inhibitor other than adalimumab was allowed in up to 25% of patients. At week 52, clinical remission was observed in a higher percentage of patients in the Entyvio group than in the Humira group (31.3% vs. 22.5%; difference, 8.8 percentage points; 95% confidence interval [CI], 2.5 to 15.0; P=0.006), as was endoscopic improvement (39.7% vs. 27.7%; difference, 11.9 percentage points; 95% CI, 5.3 to 18.5; P<0.001). This data and the current AGA guidelines that suggest using infliximab or Entyvio rather than adalimumab, for induction of remission, show Entyvio has emerged as a first-line agent for the management of moderately to severely active UC.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Humira (adalimumab) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Humira (adalimumab) include: No labeled contraindications.
Warnings/precautions of Humira (adalimumab) include: Serious infections: Do not start HUMIRA during an active infection. If an infection develops, monitor carefully, and stop HUMIRA if infection becomes serious. Invasive fungal infections: For patients who develop a systemic illness on HUMIRA, consider empiric antifungal therapy for those who reside or travel to regions where mycoses are endemic. Malignancies: Incidence of malignancies was greater in HUMIRA-treated patients than in controls. Anaphylaxis or serious hypersensitivity reactions may occur. Hepatitis B virus reactivation: Monitor HBV carriers during and several months after therapy. If reactivation occurs, stop HUMIRA and begin antiviral therapy. Demyelinating disease: Exacerbation or new onset, may occur.
Cytopenias, pancytopenia: Advise patients to seek immediate medical attention if symptoms develop and consider stopping HUMIRA. Heart failure: Worsening or new onset, may occur. Lupus-like syndrome: Stop HUMIRA if syndrome develops.

OTHER SPECIAL CONSIDERATIONS:
Humira has a Black Boxed warning for serious infections and malignancy. Increased risk of serious infections leading to hospitalization or death, including tuberculosis (TB), bacterial sepsis, invasive fungal infections (such as histoplasmosis), and infections due to other opportunistic pathogens. Discontinue HUMIRA if a patient develops a serious infection or sepsis during treatment. Perform test for latent TB; if positive, start treatment for TB prior to starting HUMIRA. Monitor all patients for active TB during treatment, even if initial latent TB test is negative. Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers including HUMIRA. Post-marketing cases of hepatosplenic T-cell lymphoma (HSTCL), a rare type of T-cell lymphoma, have occurred in adolescent and young adults with inflammatory bowel disease treated with TNF blockers including HUMIRA.

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
N/A	N/A

AVAILABLE DOSAGE FORMS:

Adalimumab-adaz SOAJ 40MG/0.4ML
Adalimumab-adaz SOSY 40MG/0.4ML
Adalimumab-fkjp AJKT 40MG/0.8ML
Adalimumab-fkjp PSKT 20MG/0.4ML
Adalimumab-fkjp PSKT 40MG/0.8ML
Amjevita SOAJ 40MG/0.8ML
Amjevita SOSY 10MG/0.2ML
Amjevita SOSY 20MG/0.4ML
Amjevita SOSY 40MG/0.8ML
Cyltezo AJKT 40MG/0.8ML
Cyltezo PSKT 10MG/0.2ML
Cyltezo PSKT 20MG/0.4ML
Cyltezo PSKT 40MG/0.8ML
Cyltezo-CD/UC/HS Starter AJKT 40MG/0.8ML
Cyltezo-Psoriasis Starter AJKT 40MG/0.8ML
Hadlima PushTouch SOAJ 40MG/0.4ML
Hadlima PushTouch SOAJ 40MG/0.8ML
Hadlima SOSY 40MG/0.4ML
Hadlima SOSY 40MG/0.8ML
Hulio AJKT 40MG/0.8ML
Hulio PSKT 20MG/0.4ML
Hulio PSKT 40MG/0.8ML
Humira Ped Crohns Start PSKT 80 MG/0.8ML&40MG/0.4M
Humira Pediatric Crohns Start PSKT 80MG/0.8ML
Humira Pen PNKT 40MG/0.4ML
Humira Pen PNKT 40MG/0.8ML
Humira Pen PNKT 80MG/0.8ML
Humira Pen-CD/UC/HS Starter PNKT 40MG/0.8ML
Humira Pen-CD/UC/HS Starter PNKT 80MG/0.8ML
Humira Pen-Pediatric UC Start PNKT 80MG/0.8ML
Humira Pen-Ps/UV/Adol HS Start PNKT 40MG/0.8ML
Humira Pen-Psor/Uveit Start PNKT 80 MG/0.8ML&40MG/
Humira PSKT 10MG/0.1ML
Humira PSKT 10MG/0.2ML
Humira PSKT 20MG/0.2ML
Humira PSKT 20MG/0.4ML
Humira PSKT 40MG/0.4ML
Humira PSKT 40MG/0.8ML
Hyrimoz SOAJ 40MG/0.4ML
Hyrimoz SOAJ 80MG/0.8ML
Hyrimoz SOSY 10MG/0.1 ML
Hyrimoz SOSY 20MG/0.2ML
Hyrimoz SOSY 40MG/0.4ML
Hyrimoz-Crohns/UC Starter Pack SOAJ 80MG/0.8ML
Hyrimoz-Ped Crohns Start SOSY 80 MG/0.8ML&40MG/0.4
Hyrimoz-Ped Crohns Starter SOSY 80MG/0.8ML
Hyrimoz-Plaque Psoriasis Start SOAJ 80 MG/0.8ML&40
Idacio AJKT 40MG/0.8ML
Idacio for Crohns Disease/UC AJKT 40MG/0.8ML
Idacio for Plaque Psoriasis AJKT 40MG/0.8ML
Idacio PSKT 40MG/0.8ML
Yuflyma 1-Pen Kit AJKT 40MG/0.4ML
Yuflyma 2-Pen Kit AJKT 40MG/0.4ML
Yuflyma 2-Syringe Kit PSKT 40MG/0.4ML
Yusimry SOPN 40MG/0.8ML

REFERENCES

1. Amjevita (adalimumab-atto) [prescribing information]. Thousand Oaks, CA: Amgen Inc; April 2023.
2. Cyltezo (adalimumab-adbm) [prescribing information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals Inc; May 2023.
3. Hadlima (adalimumab-bwwd) [prescribing information]. Jersey City, NJ: Organon LLC; July 2023.
4. Hulio (adalimumab-fkjp) [prescribing information]. Morgantown, WV: Mylan Pharmaceuticals Innc.; June 2020.
5. Humira (adalimumab) [prescribing information~~package insert~~]. North Chicago, IL: AbbVie Inc.; February 2021.
6. Hyrimoz (adalimumab-adaz) [prescribing information]. Princeton, NJ: Sandoz Inc.; March 2023.
7. Idacio (adalimumab-aacf) [prescribing information]. Lake Zurick, IL: Fresenius Kabi USA, LLC; December 2022.
8. Yuflyma (adalimumab-aaty) [prescribing information]. Jersey City, NJ: Celltrion USA Inc; May 2023.
9. Yusimry (adalimumab-aqvh) [prescribing information]. Redwood City, CA: Coherus BioSciencesm Inc.; March 2023.
10. van der Heijde D, Sieper J, Maksymowych WP, et al. 2010 Update of the international ASAS recommendations for the use of anti-TNF agents in patients with axial spondyloarthritis. Ann Rheum Dis. 2011;70:905-908.
11. 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 randomized placebo-controlled trial (ABILITY- 1). Ann Rheum Dis. 2013;72(6):815-22.
12. Sotiriou E, Apalla Z, Vakirlis E, et al. Efficacy of adalimumab in recalcitrant hidradenitis suppurativa. Eur J Derm. 2009;19(2):180-181.
13. Smolen JS, Landewé R, Breedveld FC, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2013update. Rheum Dis. 2014;73:492-509.
14. Singh JA, Furst DE, Bharat A, et al. 2012 Update of the 2008 American College of Rheumatology recommendations for the use of disease-modifying antirheumatic drugs and biologic agents in the treatment of rheumatoid arthritis. Arthritis Care Res 2012;64(5):625-639.
15. 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
16. Aletasha 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;62:2569-2581.
17. Anderson J, Caplan L, Yazdany J, et al. Rheumatoid Arthritis Disease Activity Measures: American College of Rheumatology Recommendations for Use in Clinical Practice. ArthritisRheum. 2010;64:640-647.
18. Beukelman T, Patkar NM, Saag KG, et al. 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: initiation and safety monitoring of therapeutic agents for the treatment of arthritis and systemic features. Arthritis Care Res. 2011;63(4):465-482.
19. Gossec L, Smolen JS, Gaujoux-Viala C, et al. European League Against Rheumatism recommendations for the management of psoriatic arthritis with pharmacological therapies. Ann Rheum Dis2012;71:4-12.
20. Gladman DD, Antoni C, P Mease, et al. Psoriatic arthritis: epidemiology, clinical features, course, and outcome. Ann Rheum Dis 2005;64(Suppl II):ii14–ii17.
21. Peluso R, Lervolino S, Vitiello M, et al. Extra-articular manifestations in psoriatic arthritis patients. Clin Rheumatol. 2014 May 8. [Epub ahead of print].
22. Ringold, S., Angeles-Han, S., Beukelman, T., Lovell, D., Cuello, C., Becker, M., Colbert, R., Feldman, B., Ferguson, P., Gewanter, H., Guzman, J., Horonjeff, J., Nigrovic, P., Ombrello, M., Passo, M., Stoll, M., Rabinovich, C., Schneider, R., Halyabar, O., Hays, K., Shah, A., Sullivan, N., Szymanski, A., Turgunbaev, M., Turner, A. and Reston, J., 2019. 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 & Research, 71(6), pp.717-734.
23. Ringold S, Weiss PF, Beukelman T, et al. 2013 update of the 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: recommendations for the medical therapy of children with systemic juvenile idiopathic arthritis and tuberculosis screening among children receiving biologic medications. Arthritis Rheum. 2013;65(10):2499-2512.
24. 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.
25. Braun J, van den Berg R, Baraliakos X, et al. 2010 update of the ASAS/EULA recommendations for the management of ankylosing spondylitis. Ann RheumDis2011;70:896–904.
26. 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.
27. George, C., Deroide, F., & Rustin, M. (2019). Pyoderma gangrenosum - a guide to diagnosis and management. Clinical medicine (London, England), 19(3), 224–228. https://doi.org/10.7861/clinmedicine.19-3-224
28. Pyoderma Gangrenosum - NORD (National Organization for Rare Disorders). NORD (National Organization for Rare Disorders). (2021). Retrieved 20 August 2021, from https://rarediseases.org/rare-diseases/pyoderma-gangrenosum/. from information?search=adalimumab&source=panel_search_result&selectedTitle=1~148&usage_type=panel&kp_tab=drug_general&display_rank=1
29. Onel, K., Horton, D., Lovell, D., Shenoi, S., Cuello, C., & Angeles-Han, S. et al. (2022). 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 & Rheumatology, 74(4), 553-569. doi: 10.1002/art.42037
30. Ringold, S., Angeles-Han, S., Beukelman, T., Lovell, D., Cuello, C., & Becker, M. et al. (2019). 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 & Research, 71(6), 717-734. doi: 10.1002/acr.23870
31. Fraenkel, L., Bathon, J., England, B., St. Clair, E., Arayssi, T., & Carandang, K. et al. (2021). 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care & Research, 73(7), 924-939. doi: 10.1002/acr.24596
32. Singh, J., Guyatt, G., Ogdie, A., Gladman, D., Deal, C., & Deodhar, A. et al. (2018). 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis & Rheumatology, 71(1), 5-32. Doi: 10.1002/art.40726
33. Menter, A., Strober, B., Kaplan, D., Kivelevitch, D., Prater, E., & Stoff, B. et al. (2019). Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. Journal Of The American Academy Of Dermatology, 80(4), 1029-1072. doi: 10.1016/j.jaad.2018.11.057
34. Menter, A., Gelfand, J., Connor, C., Armstrong, A., Cordoro, K., & Davis, D. et al. (2020). Joint American Academy of Dermatology–National Psoriasis Foundation guidelines of care for the management of psoriasis with systemic nonbiologic therapies. Journal Of The American Academy Of Dermatology, 82(6), 1445-1486. doi: 10.1016/j.jaad.2020.02.044
35. Elmets, C., Lim, H., Stoff, B., Connor, C., Cordoro, K., & Lebwohl, M. et al. (2019). Joint American Academy of Dermatology–National Psoriasis Foundation guidelines of care for the management and treatment of psoriasis with phototherapy. Journal Of The American Academy Of Dermatology, 81(3), 775-804. doi: 10.1016/j.jaad.2019.04.042
36. Feuerstein, J., Isaacs, K., Schneider, Y., Siddique, S., Falck-Ytter, Y., & Singh, S. et al. (2020). AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. Gastroenterology, 158(5), 1450-1461. Doi: 10.1053/j.gastro.2020.01.006
37. Sands, B., Peyrin-Biroulet, L., Loftus, E., Danese, S., Colombel, J., & Törüner, M. et al. (2019). Vedolizumab versus Adalimumab for Moderate-to-Severe Ulcerative Colitis. New England Journal Of Medicine, 381(13), 1215-1226. doi: 10.1056/nejmoa1905725
38. Feuerstein, J. D., Ho, E. Y., Shmidt, E., Singh, H., Falck-Ytter, Y., Sultan, S., … Spechler, S. J. (2021). AGA Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal

and Perianal Fistulizing Crohn's Disease. Gastroenterology, 160(7), 2496–2508. https://doi.org/10.1053/j.gastro.2021.04.022
39. Menter, A., Cordoro, K. M., Davis, D. M. R., Kroshinsky, D., Paller, A. S., Armstrong, A. W., … Lim, H. W. (2020). Joint American Academy of Dermatology–National Psoriasis Foundation guidelines of care for the management and treatment of psoriasis in pediatric patients. Journal of the American Academy of Dermatology, 82(1), 161–201. https://doi.org/10.1016/j.jaad.2019.08.049

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Products Affected Required Medical Information Continuation of Therapy Age Restrictions FDA-Approved Uses Compendial Approved Off-Labeled Uses Appendix Other Special Considerations Available Dosage Forms References	Q4 2023
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Duration of Approval Prescriber Requirements Age Restrictions FDA-Approved Uses Background Contraindications/Exclusions/Discontinuation References	Q4 2022
Q2 2022 Established tracking in new format	Historical changes on file