Clinical Policy: Adalimumab (Humira)

Reference Number: CP.PHAR.242
Effective Date: 08/16
Last Review Date 08/17
Line of Business: Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Adalimumab (Humira®) is tumor necrosis factor (TNF) blocker.

FDA Approved Indication(s)

Humira is indicated for the treatment of

- Rheumatoid arthritis (RA): 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 RA
- Juvenile idiopathic arthritis (JIA): Reducing signs and symptoms of moderately to severely active polyarticular JIA in patients 2 years of age and older.
- Psoriatic arthritis (PsA): Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active PsA.
- Ankylosing spondylitis (AS): Reducing signs and symptoms in adult patients with active AS.
- Adult Crohn's disease (CD): Reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active CD who have had an inadequate response to conventional therapy. Reducing signs and symptoms and inducing clinical remission in these patients if they have also lost response to or are intolerant to infliximab.
- Pediatric CD: Reducing signs and symptoms and inducing and maintaining clinical remission in patients 6 years of age and older with moderately to severely active CD who have had an inadequate response to corticosteroids or immunomodulators such as azathioprine, 6-mercaptopurine, or methotrexate.
- Ulcerative colitis (UC): 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).
- Plaque psoriasis (PsO): 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.
- Hidradenitis suppurativa (HS): The treatment of moderate to severe hidradenitis suppurativa.
- Uveitis (UV): The treatment of non-infectious intermediate, posterior and panuveitis in adult patients.

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of health plans affiliated with Centene Corporation® that Humira is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Rheumatoid Arthritis (must meet all)**:**

1. Diagnosis of RA per American College of Rheumatology (ACR) criteria (refer to *Appendix B*);
2. Prescribed by or in consultation with a rheumatologist;
3. Age ≥ 18 years;
4. Member meets one of the following (a or b):
   a. Failure of methotrexate (MTX) for ≥ 3 consecutive months unless contraindicated or clinically significant adverse effects are experienced;
   b. If intolerance or contraindication to MTX, failure of sulfasalazine, leflunomide, or hydroxychloroquine for ≥ 3 consecutive months unless contraindicated or clinically significant adverse effects are experienced;
5. Tuberculosis (TB) test within the past 12 months is negative, or if positive, active TB has been ruled out and the patient has received treatment for latent TB infection;
6. Dose does not exceed 40 mg every other week.

Approval duration: 6 months

B. Polyarticular Juvenile Idiopathic Arthritis (must meet all)**:**

1. Diagnosis of PJIA;
2. Prescribed by or in consultation with a rheumatologist;
3. Age ≥ 2 years;
4. Member meets one of the following (a or b):
   a. Failure of MTX for ≥ 3 consecutive months unless contraindicated or clinically significant adverse effects are experienced;
   b. If intolerance or contraindication to MTX, failure of sulfasalazine or leflunomide for ≥ 3 consecutive months unless contraindicated or clinically significant adverse effects are experienced;
5. TB test within the past 12 months is negative, or if positive, active TB has been ruled out and the patient has received treatment for latent TB infection;
6. Dose does not exceed the following:
   a. 10 kg (22 lbs) to <15 kg (33 lbs): 10 mg every other week
   b. 15 kg (33 lbs) to < 30 kg (66 lbs): 20 mg every other week
   c. ≥ 30 kg (66 lbs): 40 mg every other week.

Approval duration: 6 months

C. Psoriatic Arthritis (must meet all)**:**

1. Diagnosis of active PsA;
2. Prescribed by or in consultation with a dermatologist or rheumatologist;

3. Age ≥ 18 years;
4. Member meets one of the following (a or b):
   a. Failure of MTX for ≥ 3 consecutive months unless contraindicated or clinically significant adverse effect are experienced;
   b. If intolerance or contraindication to MTX, failure of sulfasalazine, leflunomide, or cyclosporine for ≥ 3 consecutive months unless contraindicated or clinically significant adverse effect are experienced;
5. TB test within the past 12 months is negative, or if positive, active TB has been ruled out and the patient has received treatment for latent TB infection;
6. Dose does not exceed 40 mg every other week.

Approval duration: 6 months

D. Ankylosing Spondylitis (must meet all)**:**

1. Diagnosis of active AS;
2. Prescribed by or in consultation with a rheumatologist;
3. Age ≥ 18 years;
4. Failure of at least TWO non-steroidal anti-inflammatory drugs (NSAIDs) each trialed for ≥ 4 weeks unless contraindicated or clinically significant adverse effects are experienced;
5. TB test within the past 12 months is negative, or if positive, active TB has been ruled out and the patient has received treatment for latent TB infection;
6. Dose does not exceed 40 mg every other week.

Approval duration: 6 months

E. Crohn's Disease (must meet all)**:**

1. Diagnosis of CD and (a or b):
   a. Member is identified as moderate/high risk based on one of the following:
      i. Age at initial diagnosis < 30 years;
      ii. Extensive anatomic involvement (e.g., ileocecal disease, continuous ileocolonic disease, small bowel disease);
      iii. Perianal and/or severe rectal disease;
      iv. Deep ulcers;
      v. Prior surgical resection;
      vi. Stricturing and/or penetrating disease;
   b. Failure of an immunomodulator (e.g., azathioprine, mercaptopurine (6MP), methotrexate (MTX)) used for ≥ 3 months; unless contraindicated or clinically significant adverse effects are experienced;
2. Prescribed by or in consultation with a gastroenterologist;
3. Age ≥ 6 years;
4. TB test within the past 12 months is negative, or if positive, active TB has been ruled out and the patient has received treatment for latent TB infection;
5. Dose does not exceed the following (a or b):
   a. Adults:
      i. Initial dose (Day 1): 160 mg
      ii. Second dose (Day 15): 80 mg

iii. Maintenance dose (Day 29): 40 mg every other week

b. Pediatrics:
   i. 17 kg (37 lbs.) to < 40 kg (88 lbs.): initial dose (Day 1): 80 mg; second dose (Day 15): 40 mg; maintenance (Day 29): 20 mg every other week;
   ii. ≥ 40 kg (88 lbs): initial dose (Day 1): 160 mg; second dose (Day 15): 80 mg; maintenance (Day 29): 40 mg every other week.

Approval duration: 6 months

F. Ulcerative Colitis (must meet all)**:**

1. Diagnosis of UC;
2. Prescribed by or in consultation with a gastroenterologist;
3. Age ≥ 18 years;
4. Failure of a thiopurine (e.g., azathioprine, 6MP), used for ≥ 3 months, unless contraindicated or clinically significant adverse effects are experienced;
5. TB test within the past 12 months is negative, or if positive, active TB has been ruled out and the patient has received treatment for latent TB infection;
6. Dose does not exceed the following:
   i. Initial dose (Day 1): 160 mg
   ii. Second dose (Day 15): 80 mg
   iii. Maintenance dose (Day 29): 40 mg every other week

Approval duration: 3 months

G. Plaque Psoriasis (must meet all)**:**

1. Diagnosis of PsO and at least one of the following:
   a. Greater than 5% of body surface area is affected;
   b. Involvement of palms, soles, face/neck, body folds, or genitalia;
2. Prescribed by or in consultation with a dermatologist or rheumatologist;
3. Age ≥ 18 years;
4. Failure of at least one oral systemic therapy for plaque psoriasis (e.g., methotrexate, cyclosporine, acitretin, or thioguanine) in combination with phototherapy or topical therapy (e.g., corticosteroids, calcipotriene, tazarotene) for ≥ 3 consecutive months unless contraindicated or clinically significant adverse effects are experienced;
5. TB test within the past 12 months is negative, or if positive, active TB has been ruled out and the patient has received treatment for latent TB infection;
6. Dose does not exceed 80 mg initial dose, followed by 40 mg every other week starting one week after initial dose.

Approval duration: 6 months

H. Hidradenitis Suppurativa (must meet all)**:**

1. Diagnosis of moderate to severe HS defined as (a or b);
   a. Moderate disease: Hurley stage II (recurrent abscesses, with sinus tracts and scarring, presenting as single or multiple widely separated lesions);
   b. Severe disease: Hurley stage III (diffuse or near-diffuse involvement presenting as multiple interconnected tracts and abscesses across an entire area);
2. Prescribed by or in consultation with a dermatologist;

3. Age ≥ 18 years;
4. Failure of clindamycin or minocycline, in combination with rifampin, for ≥ 10 weeks unless intolerant or contraindicated;
5. TB test within the past 12 months is negative, or if positive, active TB has been ruled out and the patient has received treatment for latent TB infection;
6. Dose does not exceed the following:
   a. Initial dose (Day 1): 160 mg;
   b. Second dose (Day 15): 80 mg;
   c. Maintenance dose (Day 29): 40 mg every week.

Approval duration: 6 months

I. Uveitis (must meet all)**:**

1. Diagnosis of non-infectious intermediate, posterior or panuveitis;
2. Prescribed by or in consultation with an ophthalmologist;
3. Age ≥ 18 years;
4. Failure of other local or systemic therapies such as corticosteroids, methotrexate, azathioprine, mycophenolate, cyclosporine, tacrolimus, or cyclophaspamide, or these are inappropriate given disease and/or individual characteristics;
5. TB test within the past 12 months is negative, or if positive, active TB has been ruled out and the patient has received treatment for latent TB infection;
6. Dose does not exceed 80 mg initial dose, followed by 40 mg every other week starting one week after initial dose.

Approval duration: 6 months

J. Other diagnoses/indications

1. Refer to CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy (examples: sign/symptom reduction, no disease progression, no significant toxicity);
3. If request is for a dose increase, new dose does not exceed:
   a. For RA: 40 mg weekly; if request represents a change in regimen from 40 mg every other week to 40 mg weekly, documentation must support all of the following (i and ii):
      i. Member is not a candidate for concurrent methotrexate and Humira due to contraindications or intolerance;
      ii. An inadequate response to adherent use of Humira for ≥ 3 consecutive months at the dose of 40 mg every other week;
   b. For HS: 40 mg every week;
   c. For PJIA, CD, UC, PsA, AS, PsO, uveitis: 40 mg every other week.

Approval duration: 12 months

B. Other diagnoses/indications (1 or 2)**:**
1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.

Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to CP.PHAR.57 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

AS: ankylosing spondylitis
CCP: Crohn's disease
CRP: C-reactive protein
DMARD: disease-modifying antirheumatic drug
ESR: erythrocyte sedimentation rate
MTX: methotrexate
PJIA: polyarticular juvenile idiopathic arthritis
PsA: psoriatic arthritis
PsO: psoriasis
RA: rheumatoid arthritis
SC: subcutaneous
TB: tuberculosis
TNF: tumor necrosis factor
UC: ulcerative colitis

Appendix B: The 2010 ACR Classification Criteria for RA

Add score of categories A through D; a score of ≥ 6 out of 10 is needed for classification of a patient as having definite RA.

A	**Joint involvement**	Score
	1 large joint	0
	2-10 large joints	1
	1-3 small joints (with or without involvement of large joints)	2
	4-10 small joints (with or without involvement of large joints)	3
	> 10 joints (at least one small joint)	5
B	**Serology (at least one test result is needed for classification)**	
	Negative rheumatoid factor (RF) *and* negative anti-citrullinated protein antibody (ACPA)	0
	Low positive RF *or* low positive ACPA * *Low: < 3 x upper limit of normal*	2
	High positive RF *or* high positive ACPA * *High: ≥ 3 x upper limit of normal*	3
C	**Acute phase reactants (at least one test result is needed for classification)**	
	Normal C-reactive protein (CRP) and normal erythrocyte sedimentation rate (ESR)	0
	Abnormal CRP or normal ESR	1

D	Duration of symptoms	
	< 6 weeks	0
	≥ 6 weeks	1

Appendix C: Definition of MTX or DMARD Failure
In RA, failure of MTX or DMARD is defined as ≤ 50% decrease in swollen joint count, ≤ 50% decrease in tender joint count, and ≤ 50% decrease in ESR, or ≤ 50% decrease in CRP.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
RA, PsA, AS	• 40 mg every other week • Some patients with RA not receiving methotrexate may benefit from increasing the frequency to 40 mg every week.	40 mg every week
PJIA	• 10 kg (22 lbs) to <15 kg (33 lbs): 10 mg every other week • 15 kg (33 lbs) to < 30 kg (66 lbs): 20 mg every other week • ≥ 30 kg (66 lbs): 40 mg every other week	40 mg every other week
Adult CD and UC	• Initial dose (Day 1): 160 mg • Second dose two weeks later (Day 15): 80 mg • Two weeks later (Day 29): Begin a maintenance dose of 40 mg every other week • UC only: Only continue Humira in patients who have shown evidence of clinical remission by 8 weeks (Day 57) of therapy.	40 mg every other week
Pediatric CD	17 kg (37 lbs) to < 40 kg (88 lbs): • Initial dose (Day 1): 80 mg • Second dose two weeks later (Day 15): 40 mg. • Two weeks later (Day 29): begin a maintenance dose of 20 mg every other week. ≥ 40 kg (88 lbs): • Initial dose (Day 1): 160 mg • Second dose two weeks later (Day 15): 80 mg. • Two weeks later (Day 29): Begin maintenance dose of 20 mg every other week.	20 mg every other week
PsO or Uveitus	• Initial dose 80 mg, • One week after initial dose, 40 mg every other week	40 mg every other week
HS	• Initial dose (Day 1): 160 mg • Second dose two weeks later (Day 15): 80 mg • Third (Day 29) and subsequent doses: 40 mg every week	40 mg every week

VI. Product Availability

- 80 mg/0.8 mL in a single-use prefilled pen (HUMIRA Pen)
- 80 mg/0.8 mL in a single-use prefilled glass syringe
- 40 mg/0.8 mL in a single prefilled pen (HUMIRA Pen)
- 40 mg/0.4 mL in a single-use prefilled pen (HUMIRA Pen)
- 40 mg/0.8 mL in a single-use prefilled glass syringe
- 40 mg/0.4 mL in a single-use prefilled glass syringe
- 20 mg/0.4 mL in a single-use prefilled glass syringe
- 20 mg/0.2 mL in a single-use prefilled glass syringe
- 10 mg/0.2 mL in a single-use prefilled glass syringe
- 10 mg/0.1 mL in a single-use prefilled glass syringe
- 40 mg/0.8 mL in a single-use glass vial for institutional use only

VII. References

1. Humira Prescribing Information. North Chicago, IL: AbbVie, Inc.; May 2017. Available at http://www.rxabbvie.com/pdf/humira.pdf. Accessed August 11, 2017.
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12. Zouboulis CC, Desai N, Emtestam L, et al. European S1 guideline for the treatment of hidradenitis suppurativa/acne inversa. *J Eur Acad Dermatol Venereol*. April 2015; 29(4):619-44. Epub 2015 Jan 30.
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16. 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, vol. 62 (pg. 2569 - 81).

Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J0135	Injection, adalimumab, 20 mg

Reviews, Revisions, and Approvals	Date	Approval Date
Policy split from CP.PHAR.86.ArthritisTreatments, CP.PHAR.85.Psoriasis Treatments, CP.PHAR.87.IBD Treatment_4_ RA, PJIA, PsA, AS, CD, UC, PsO: Removed criteria related to HBV, malignant disease, concomitant use with other biologics, and concurrent administration of live vaccines; added dosing requirement. PJIA: removed question related to number of affected joints; modified criteria to require trial of MTX, unless contraindicated; added sulfasalazine as an alternative to MTX if MTX is contraindicated. RA: changed age requirement to 18 years per PI; modified criteria to require trial of MTX,	08.16	08.16

Reviews, Revisions, and Approvals	Date	Approval Date
unless contraindicated; added sulfasalazine as an alternative to MTX if MTX is contraindicated. PsO: removed duration of trial for topical and phototherapy. Re-auth: combined into All Indications; added dosing and reasons to discontinue; for PsO modified specific efficacy criteria related to Psoriasis Area and Severity Index (PASI)-75 to general efficacy statement. Modified approval duration to 6 months for initial and 12 months for renewal with the exception of UC which is 2 months (time to clinical remission per PI) and 12 months. HS: Added criteria for FDA labeled indication criteria. Uveitis: Added criteria for FDA labeled indication for uveitis. Shortened background section.		
PsO: Removed Otezla from list of therapies to trial per PDL.	11.16	
Added requirement for supportive documentation for dose escalation for Humira for use in rheumatoid arthritis.	03.17	
Converted to new template. RA: Revised criteria for confirmation of RA diagnosis per 2010 ACR Criteria. CD: revised list of poor prognostic indicators per AGA guidelines, added examples of extensive disease. PsO: Trial requirement modified to require the concomitant use of oral and topical or phototherapy. Added initial dosing regimen for all indications where applicable. Safety criteria was applied according to the safety guidance discussed at CPAC and endorsed by Centene Medical Affairs.	08.17	08.17
Added TB requirement for plaque psoriasis for consistency	09.22.17	
Typo removed from AS criteria to ensure prior of first line agent to align with other covered diagnosis	12.08.17	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and

limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.