

Clinical Policy: Adalimumab (Humira)

Reference Number: CP.PHAR.242

Effective Date: 08.16

Last Review Date: 11.18

Line of Business: HIM, Medicaid

[Coding Implications](#)[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

Adalimumab (Humira[®]) is a 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 (PJIA) 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 (MTX).
- 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). The effectiveness of Humira has not been established in patients who have lost response to or were intolerant to TNF blockers.
- 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 in patients 12 years of age and older
- Uveitis (UV): The treatment of non-infectious intermediate, posterior and panuveitis in adults and pediatric patients 2 years of age and older

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) 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;
2. Prescribed by or in consultation with a rheumatologist;
3. Age \geq 18 years;
4. Member meets one of the following (a or b):
 - a. Failure of a \geq 3 consecutive month trial of MTX at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
 - b. If intolerance or contraindication to MTX (*see Appendix D*), failure of a \geq 3 consecutive month trial of at least ONE conventional disease-modifying antirheumatic drug [DMARD] (e.g., sulfasalazine, leflunomide, hydroxychloroquine) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
5. 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 \geq 2 years;
4. Member meets one of the following (a or b):
 - a. Failure of a \geq 3 consecutive month trial of MTX at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
 - b. If intolerance or contraindication to MTX (*see Appendix D*), failure of a \geq 3 consecutive month trial of sulfasalazine or leflunomide at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
5. Dose does not exceed one of the following (a, b, or c):
 - a. Weight 10 kg (22 lbs) to <15 kg (33 lbs): 10 mg every other week;
 - b. Weight 15 kg (33 lbs) to < 30 kg (66 lbs): 20 mg every other week;
 - c. Weight \geq 30 kg (66 lbs): 40 mg every other week.

Approval duration: 6 months

C. Psoriatic Arthritis (must meet all):

1. Diagnosis of PsA;
2. Prescribed by or in consultation with a dermatologist or rheumatologist;
3. Age \geq 18 years;

4. Member meets one of the following (a, b, or c), unless contraindicated or clinically significant adverse effects are experienced:
 - a. Failure of a ≥ 3 consecutive month trial of MTX at up to maximally indicated doses;
 - b. If intolerance or contraindication to MTX (*see Appendix D*), failure of a ≥ 3 consecutive month trial of cyclosporine, sulfasalazine, or leflunomide at up to maximally indicated doses;
 - c. For axial disease, failure of a ≥ 4 week-trial of non-steroidal anti-inflammatory drugs (NSAIDs) at up to maximally indicated doses;
5. Dose does not exceed 40 mg every other week.

Approval duration: 6 months

D. Ankylosing Spondylitis (must meet all):

1. Diagnosis of AS;
2. Prescribed by or in consultation with a rheumatologist;
3. Age ≥ 18 years;
4. Failure of at least TWO NSAIDs at up to maximally indicated doses, each used for ≥ 4 weeks unless contraindicated or clinically significant adverse effects are experienced;
5. Dose does not exceed 40 mg every other week.

Approval duration: 6 months

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

1. Diagnosis of CD;
2. Prescribed by or in consultation with a gastroenterologist;
3. Age ≥ 6 years;
4. Member meets one of the following (a or b):
 - a. Failure of a ≥ 3 consecutive month trial of at least ONE immunomodulator (e.g., azathioprine, 6-mercaptopurine [6-MP], MTX) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
 - b. Medical justification supports inability to use immunomodulators (*see Appendix E*);
5. Dose does not exceed one of the following (a or b):
 - a. Adults: 160 mg on Day 1 and 80 mg on Day 15, followed by maintenance dose of 40 mg every other week starting Day 29;
 - b. Pediatrics (i or ii):
 - i. Weight 17 kg (37 lbs.) to < 40 kg (88 lbs.): 80 mg on Day 1 and 40 mg on Day 15, followed by maintenance dose of 20 mg every other week starting Day 29;
 - ii. Weight ≥ 40 kg (88 lbs): 160 mg on Day 1 and 80 mg on Day 15, followed by maintenance dose of 40 mg every other week starting Day 29.

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 \geq 18 years;
4. Failure of a \geq 3 consecutive month trial of azathioprine, 6-MP, or an aminosalicylate (e.g., sulfasalazine) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
5. Dose does not exceed 160 mg on Day 1 and 80 mg on Day 15, followed by maintenance dose of 40 mg every other week starting Day 29.

Approval duration: 6 months

G. Plaque Psoriasis (must meet all):

1. Diagnosis of PsO;
2. Prescribed by or in consultation with a dermatologist or rheumatologist;
3. Age \geq 18 years;
4. Member meets one of the following (a or b):
 - a. Failure of a \geq 3 consecutive month trial of MTX at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
 - b. If intolerance or contraindication to MTX (*see Appendix D*), failure of a \geq 3 consecutive month trial of cyclosporine or acitretin at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
5. Dose does not exceed 80 mg initial dose, followed by maintenance dose of 40 mg every other week starting one week after initial dose.

Approval duration: 6 months

H. Hidradenitis Suppurativa (must meet all):

1. Diagnosis of HS;
2. Prescribed by or in consultation with a dermatologist, rheumatologist, or gastroenterologist;
3. Age \geq 12 years;
4. Documentation of Hurley stage II or stage III (*see Appendix D*);
5. Failure of a \geq 3 consecutive month trial of systemic antibiotic therapy (e.g., clindamycin, minocycline, doxycycline, rifampin) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
6. Dose does not exceed 160 mg on Day 1 and 80 mg on Day 15, followed by maintenance dose of 40 mg every week starting Day 29.

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 or rheumatologist;
3. Age \geq 2 years;
4. Failure of a \geq 2 week trial of a systemic corticosteroid (e.g., prednisone) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;

5. Failure of a trial of a non-biologic immunosuppressive therapy (e.g., azathioprine, methotrexate, mycophenolate mofetil, cyclosporine, tacrolimus, cyclophosphamide, chlorambucil) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
6. Dose does not exceed 80 mg initial dose, followed by maintenance dose of 40 mg every other week starting one week after initial dose.

Approval duration: 6 months

J. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

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;
3. If request is for a dose increase, new dose does not exceed one of the following (a, b, or c):
 - a. RA (i or ii):
 - i. 40 mg every other week;
 - ii. 40 mg every week, if documentation supports inadequate response to a ≥ 3 month trial of 40 mg every other week or member is not a candidate for concurrent methotrexate and Humira due to contraindications or intolerance;
 - b. PJA, PsA, AS, CD, UC, PsO, UV: 40 mg every other week;
 - c. HS: 40 mg every week.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

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 the off label use policies – HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

6-MP: 6-mercaptopurine
AS: ankylosing spondylitis
CD: Crohn’s disease
DMARD: disease-modifying
antirheumatic drug
FDA: Food and Drug Administration
GI: gastrointestinal
HS: hidradenitis suppurative
MTX: methotrexate

NSAIDs: nonsteroidal anti-inflammatory
drugs
PJIA: polyarticular juvenile idiopathic
arthritis
PsA: psoriatic arthritis
PsO: psoriasis
RA: rheumatoid arthritis
TNF: tumor necrosis factor
UC: ulcerative colitis
UV: uveitis

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
acitretin (Soriatane [®])	PsO 25 or 50 mg PO QD	50 mg/day
azathioprine (Azasan [®] , Imuran [®])	RA 1 mg/kg/day PO QD or divided BID CD*, UC*, UV* 1.5 – 2 mg/kg/day PO	2.5 mg/kg/day
chlorambucil (Leukeran [®])	UV* 0.2 mg/kg PO QD, then taper to 0.1 mg/kg PO QD or less	0.2 mg/kg/day
clindamycin (Cleocin [®]) + rifampin (Rifadin [®])	HS* clindamycin 300 mg PO BID and rifampin 300 mg PO BID	clindamycin: 1,800 mg/day rifampin: 600 mg/day
corticosteroids	CD* prednisone 40 mg PO QD for 2 weeks or IV 50 – 100 mg Q6H for 1 week budesonide (Entocort EC [®]) 6 – 9 mg PO QD UV* prednisone 5 – 60 mg/day PO in 1 – 4 divided doses	Various
Cuprimine [®] (d-penicillamine)	RA* <u>Initial dose:</u> 125 or 250 mg PO QD <u>Maintenance dose:</u> 500 – 750 mg/day PO QD	1,500 mg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
cyclophosphamide (Cytoxan [®])	UV* 1 – 2 mg/kg/day PO	N/A
cyclosporine (Sandimmune [®] , Neoral [®])	PsO 2.5 mg/kg/day PO divided BID PsA* 2.5 – 3 mg/kg/day PO QD RA 2.5 – 4 mg/kg/day PO divided BID UV* 2.5 – 5 mg/kg/day PO in divided doses	PsO, RA: 4 mg/kg/day PsA: 3 mg/kg/day UV: 5 mg/kg/day
doxycycline (Acticlate [®])	HS* 50 – 100 mg PO BID	300 mg/day
hydroxychloroquine (Plaquenil [®])	RA* <u>Initial dose:</u> 400 – 600 mg/day PO QD <u>Maintenance dose:</u> 200 – 400 mg/day PO QD	600 mg/day
leflunomide (Arava [®])	PJIA* Weight < 20 kg: 10 mg every other day PO Weight 20 - 40 kg: 10 mg/day PO Weight > 40 kg: 20 mg/day PO PsA* 100 mg/day PO loading dose for 3 days followed by 20 mg/day PO QD RA 100 mg PO QD for 3 days, then 20 mg PO QD	20 mg/day
6-mercaptopurine (Purixan [®])	CD*, UC* 50 mg PO QD or 1 – 2 mg/kg/day PO	2 mg/kg/day
methotrexate (Rheumatrex [®])	CD*, UC* 15 – 25 mg/week IM or SC PsO 10 – 25 mg/week PO or 2.5 mg PO Q12 hr for 3 doses/week PJIA* 10 – 20 mg/m ² /week PO, SC, or IM	30 mg/week

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	<p>PsA* 7.5 – 15 mg/week PO</p> <p>RA 7.5 mg/week PO, SC, or IM or 2.5 mg PO Q12 hr for 3 doses/week</p> <p>UV* 7.5 – 20 mg/week PO</p>	
minocycline (Minocin [®])	HS* 50 – 100 mg PO BID	200 mg/day
mycophenolate mofetil (Cellcept [®])	UV* 500 – 1,000 mg PO BID	3 g/day
NSAIDs (e.g., indomethacin, ibuprofen, naproxen, celecoxib)	AS, PsA Varies	Varies
Pentasa [®] (mesalamine)	CD, UC 1,000 mg PO QID	4 g/day
Ridaura [®] (auranofin)	RA 6 mg PO QD or 3 mg PO BID	9 mg/day (3 mg TID)
sulfasalazine (Azulfidine [®])	<p>PJIA* 30-50 mg/kg/day PO divided BID</p> <p>PsA* 2 g/day PO QD</p> <p>RA 2 g/day PO in divided doses</p> <p>UC <u>Initial dose:</u> 3 – 4 g/day PO in divided doses (not to exceed Q8 hrs)</p> <p><u>Maintenance dose:</u> 2 g PO daily</p>	<p>PJIA: 2 g/day</p> <p>PsA: 5 g/day</p> <p>RA: 3 g/day</p> <p>UC: 4 g/day</p>
tacrolimus (Prograf [®])	CD* 0.27 mg/kg/day PO in divided doses or 0.15 – 0.29 mg/kg/day PO	N/A

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	UV* 0.1-0.15 mg/kg/day PO	

Therapeutic alternatives are listed as Brand name[®] (generic) when the drug is available by brand name only and generic (Brand name[®]) when the drug is available by both brand and generic.

*Off-label

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): none reported
- Boxed warning(s):
 - Serious infections
 - Malignancy

Appendix D: General Information

- Definition of failure of MTX or DMARDs
 - Child-bearing age is not considered a contraindication for use of MTX. Each drug has risks in pregnancy. An educated patient and family planning would allow use of MTX in patients who have no intention of immediate pregnancy.
 - Social use of alcohol is not considered a contraindication for use of MTX. MTX may only be contraindicated if patients choose to drink over 14 units of alcohol per week. However, excessive alcohol drinking can lead to worsening of the condition, so patients who are serious about clinical response to therapy should refrain from excessive alcohol consumption.
- Examples of positive response to therapy may include, but are not limited to:
 - Reduction in joint pain/swelling/tenderness
 - Improvement in ESR/CRP levels
 - Improvements in activities of daily living
- Hidradenitis suppurativa:
 - HS is sometimes referred to as: "acne inversa, acne conglobata, apocrine acne, apocrinitis, Fox-den disease, hidradenitis axillaris, HS, pyoderma sinifica fistulans, Velpeau's disease, and Verneuil's disease."
 - In HS, Hurley stages are used to determine severity of disease. Hurley stage II indicates moderate disease, and is characterized by recurrent abscesses, with sinus tracts and scarring, presenting as single or multiple widely separated lesions. Hurley stage III indicates severe disease, and is characterized by diffuse or near-diffuse involvement presenting as multiple interconnected tracts and abscesses across an entire area.
- Ulcerative colitis: there is insufficient evidence to support the off-label weekly dosing of Humira for the treatment of moderate-to-severe UC. It is the position of Centene Corporation[®] that the off-label weekly dosing of Humira for the treatment of moderate-to-severe UC is investigational and not medically necessary at this time.
 - The evidence from the *post hoc* study of the Humira pivotal trial suggests further studies are needed to confirm the benefit of weekly Humira dosing for the treatment of UC in patients with inadequate or loss of therapeutic response to treatment with Humira every other week. No large, randomized or prospective studies have been

published to support the efficacy of the higher frequency of dosing, while national and international treatment guidelines also do not strongly support dose escalation of Humira for UC. The current market consensus is that weekly dosing of Humira is not medically necessary due to lack of evidence to support its benefit.

Appendix E: Medical Justification

- The following may be considered for medical justification supporting inability to use an immunomodulator for Crohn’s disease:
 - Inability to induce short-term symptomatic remission with a 3-month trial of systemic glucocorticoids
 - 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
 - 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

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
RA	40 mg SC every other week Some patients with RA not receiving concomitant methotrexate may benefit from increasing the frequency to 40 mg every week.	40 mg/week
PJIA	Weight 10 kg (22 lbs) to < 15 kg (33 lbs): 10 mg SC every other week Weight 15 kg (33 lbs) to < 30 kg (66 lbs): 20 mg SC every other week Weight ≥ 30 kg (66 lbs): 40 mg SC every other week	40 mg every other week
PsA AS	40 mg SC every other week	40 mg every other week
CD	<u>Initial dose:</u> <i>Adults:</i> 160 mg SC on Day 1, then 80 mg SC on Day 15 <i>Pediatrics:</i>	40 mg every other week

Indication	Dosing Regimen	Maximum Dose
	<p>Weight 17 kg (37 lbs) to < 40 kg (88 lbs): 80 mg SC on Day 1, then 40 mg SC on Day 15 Weight ≥ 40 kg (88 lbs): 160 mg SC on Day 1, then 80 mg SC on Day 15</p> <p><u>Maintenance dose:</u> <i>Adults:</i> 40 mg SC every other week starting on Day 29</p> <p><i>Pediatrics:</i> Weight 17 kg (37 lbs) to < 40 kg (88 lbs): 20 mg SC every other week starting on Day 29 Weight ≥ 40 kg (88 lbs): 40 mg SC every other week starting on Day 29</p>	
UC	<p><u>Initial dose:</u> 160 mg SC on Day 1, then 80 mg SC on Day 15</p> <p><u>Maintenance dose:</u> 40 mg SC every other week starting on Day 29</p>	40 mg every other week
PsO	<p><u>Initial dose:</u> 80 mg SC</p> <p><u>Maintenance dose:</u> 40 mg SC every other week starting one week after initial dose</p>	40 mg every other week
UV	<p><i>Pediatrics:</i> Weight 10 kg (22 lbs) to < 15 kg (33 lbs): 10 mg SC every other week Weight 15 kg (33 lbs) to < 30 kg (66 lbs): 20 mg SC every other week Weight ≥ 30 kg (66 lbs): 40 mg SC every other week</p> <p><i>Adults:</i> Initial dose of 80 mg SC, followed by 40 mg SC every other week starting one week after the initial dose</p>	40 mg every other week
HS	<p><i>For patients 12 years of age and older weighing at least 30 kg:</i></p> <p><u>Initial dose:</u> Weight 30 kg (66 lbs) to < 60 kg (132 lbs): 80 mg SC on Day 1, then 40 mg on Day 8 Weight ≥ 60 kg (132 lbs): 160 mg SC on Day 1, then 80 mg SC on Day 15</p> <p><u>Maintenance dose:</u> Weight 30 kg (66 lbs) to < 60 kg (132 lbs): 40 mg every other week</p>	40 mg/week

Indication	Dosing Regimen	Maximum Dose
	Weight ≥ 60 kg (132 lbs): 40 mg SC once weekly starting on Day 29	

VI. Product Availability

- Single-dose prefilled pen: 80 mg/0.8 mL, 40 mg/0.8 mL, 40 mg/0.4 mL
- Single-dose prefilled syringe: 80 mg/0.8 mL, 40 mg/0.8 mL, 40 mg/0.4 mL, 20 mg/0.4 mL, 20 mg/0.2 mL, 10 mg/0.2 mL, 10 mg/0.1 mL
- Single-use vial for institutional use only: 40 mg/0.8 mL

VII. References

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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.

	Description
J0135	Injection, adalimumab, 20 mg

Reviews, Revisions, and Approvals	Date	P&T 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, 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	08.16	08.16

Reviews, Revisions, and Approvals	Date	P&T Approval Date
<p>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.</p>		
<p>PsO: Removed Otezla from list of therapies to trial per PDL.</p>	11.16	
<p>Added requirement for supportive documentation for dose escalation for Humira for use in rheumatoid arthritis.</p>	03.17	
<p>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.</p>	08.17	08.17
<p>Added TB requirement for plaque psoriasis for consistency</p>	09.22.17	
<p>Typo removed from AS criteria to ensure prior of first line agent to align with other covered diagnosis</p>	12.08.17	
<p>2Q 2018 annual review: policies combined for HIM and Medicaid lines of business; Medicaid and HIM: removed TB testing requirement from all criteria, modified trial and failure for RA to at least one conventional DMARD, removed requirements for specific criteria relating to diagnosis for CD and PsO, modified gastroenterologist specialty requirement to gastrointestinal specialist for CD/UC, added aminosalicylate as an option for trial and failure for UC, removed trial and failure of phototherapy and topical therapy for PsO, modified trial and failure for PsO to require methotrexate (or another agent if methotrexate is not tolerated or contraindicated, generalized trial of failure of systemic antibiotics for HS, added rheumatologist as an option for specialist requirement for UV, modified trial and failure for UV to require both systemic corticosteroid and immunosuppressive therapy; modified initial approval duration for UC from 3 months to 6 months; references reviewed and updated.</p>	02.27.18	05.18
<p>4Q 2018 annual review: updated pediatric indication expansion for uveitis and adolescent indication expansion for hidradenitis suppurativa; modified prescriber specialist from GI specialist to gastroenterologist for CD, UC, and HS; added trial and failure of immunosuppressants, or medical necessity for use of biologics in</p>	09.04.18	11.18

Reviews, Revisions, and Approvals	Date	P&T Approval Date
CD; allowed bypassing conventional DMARDs for axial PsA and required trial of NSAIDs; references reviewed and updated.		

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.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

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.

For Health Insurance Marketplace members, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the formulary exception policy.

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