

Clinical Policy: Adalimumab (Humira), Adalimumab-atto (Amjevita), Adalimumab-adbm (Cyltezo), Adalimumab-bwvd (Hadlima), Adalimumab-adaz (Hyrimoz)

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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[®]), adalimumab-atto (Amjevita[™]), adalimumab-adbm (Cyltezo[™]), adalimumab-bwvd (Hadlima[™]), and adalimumab-adaz (Hyrimoz[™]) are tumor necrosis factor (TNF) blockers.

FDA Approved Indication(s)

Indications	Description	Humira	Amjevita, Cyltezo, Hadlima, Hyrimoz
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	X	X
Juvenile idiopathic arthritis (JIA)	Reducing signs and symptoms of moderately to severely active polyarticular JIA (PJIA) in patients 2 (Humira, Cyltezo) or 4 (Amjevita) years of age and older	X	X
Psoriatic arthritis (PsA)	Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active PsA	X	X
Ankylosing spondylitis (AS)	Reducing signs and symptoms in adult patients with active AS	X	X
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 (products)	X	X

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Indications	Description	Humira	Amjevita, Cyltezo, Hadlima, Hyrimoz
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)	X	X (Cyltezo only)
Adult 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 adalimumab products has not been established in patients who have lost response to or were intolerant to TNF blockers	X	X
Pediatric UC	Treatment of moderately to severely active UC in pediatric patients 5 years of age and older	X	—
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	X	X
Hidradenitis suppurativa (HS)	The treatment of moderate to severe hidradenitis suppurativa in patients 12 years of age and older	X	—
Uveitis (UV)	The treatment of non-infectious intermediate, posterior and panuveitis in adults and pediatric patients 2 years of age and older	X	—

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, Amjevita, Cyltezo, Hadlima, and Hyrimoz are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Ankylosing Spondylitis (must meet all):

1. Diagnosis of AS;
2. Prescribed by or in consultation with a rheumatologist;
3. Age ≥ 18 years;

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4. Failure of at least TWO NSAIDs at up to maximally indicated doses, each used for \geq 4 weeks unless contraindicated or clinically significant adverse effects are experienced;
5. Failure of ALL of the following, each used for \geq 3 consecutive months, unless clinically significant adverse effects are experienced or all are contraindicated:
Cimzia[®], Enbrel[®], Taltz[®];
**Prior authorization may be required for Cimzia, Enbrel, and Taltz*
6. Dose does not exceed 40 mg every other week.

Approval duration:

Centene – 6 months

Legacy WellCare – 12 months

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

1. Diagnosis of CD;
2. Prescribed by or in consultation with a gastroenterologist;
3. Age \geq 6 years;
4. Member meets one of the following (a or b):
 - a. Failure of a \geq 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 \geq 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:

Centene – 6 months

Legacy WellCare – 12 months

C. 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 at least TWO of the following, each tried for \geq 3 consecutive months from different therapeutic classes, at up to maximally indicated doses, unless clinically significant adverse effects are experienced or all are contraindicated:

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- a. Systemic antibiotic therapy (e.g., clindamycin, minocycline, doxycycline, rifampin);
- b. Oral retinoids (e.g., acitretin, isotretinoin);
- c. Hormonal treatment (e.g., estrogen-containing combined oral contraceptives, spironolactone);
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:

Centene – 6 months

Legacy WellCare – 12 months

D. Plaque Psoriasis (must meet all):

1. Diagnosis of moderate-to-severe PsO as evidenced by involvement of one of the following (a or b):
 - a. $\geq 3\%$ of total body surface area;
 - b. Hands, feet, scalp, face, or genital area;
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 a ≥ 3 consecutive month trial of MTX at up to maximally indicated doses;
 - b. Member has intolerance or contraindication to MTX (*see Appendix D*), and failure of a ≥ 3 consecutive month trial of cyclosporine or acitretin at up to maximally indicated doses, unless clinically significant adverse effects are experienced or both are contraindicated;
5. Failure of a ≥ 3 consecutive month trial of Taltz[®], unless contraindicated or clinically significant adverse effects are experienced;
**Prior authorization may be required for Taltz*
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:

Centene – 6 months

Legacy WellCare – 12 months

E. Polyarticular Juvenile Idiopathic Arthritis (must meet all):

1. Diagnosis of PJIA as evidenced by ≥ 5 joints with active arthritis;
2. Prescribed by or in consultation with a rheumatologist;
3. Age ≥ 2 years;
4. Documented baseline 10-joint clinical juvenile arthritis disease activity score (cJADAS-10) (*see Appendix J*);
5. Member meets one of the following (a, b, c, or d):
 - a. Failure of a ≥ 3 consecutive month trial of MTX at up to maximally indicated doses;
 - b. Member has intolerance or contraindication to MTX (*see Appendix D*), and failure of a ≥ 3 consecutive month trial of leflunomide or sulfasalazine at up to

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- maximally indicated doses, unless clinically significant adverse effects are experienced or both are contraindicated;
 - c. For sacroiliitis/axial spine involvement (i.e., spine, hip), failure of a ≥ 4 week trial of an NSAID at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
 - d. Documented presence of high disease activity as evidenced by a cJADAS-10 > 8.5 (*see Appendix J*);
 - 6. Failure of both of the following, each used for ≥ 3 consecutive months, unless clinically significant adverse effects are experienced or both are contraindicated (a and b):
 - a. Enbrel[®];
 - b. If member has not responded or is intolerant to one or more TNF blockers, Xeljanz[®]/Xeljanz XR[®], unless member has cardiovascular risk and benefits do not outweigh the risk of treatment;
- *Prior authorization may be required for Enbrel and Xeljanz*
- 7. 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 ≥ 30 kg (66 lbs): 40 mg every other week.

Approval duration:

Centene – 6 months

Legacy WellCare – 12 months

F. Psoriatic Arthritis (must meet all):

- 1. Diagnosis of PsA;
 - 2. Prescribed by or in consultation with a dermatologist or rheumatologist;
 - 3. Age ≥ 18 years;
 - 4. Failure of ALL of the following, each used for ≥ 3 consecutive months, unless clinically significant adverse effects are experienced or all are contraindicated (a and b):
 - a. Enbrel[®], Otezla[®], Taltz[®];
 - b. If member has not responded or is intolerant to one or more TNF blockers, Xeljanz[®]/Xeljanz XR[®], unless member has cardiovascular risk and benefits do not outweigh the risk of treatment;
- *Prior authorization may be required for Enbrel, Otezla, Taltz, Xeljanz/Xeljanz XR*
- 5. Dose does not exceed 40 mg every other week.

Approval duration:

Centene – 6 months

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G. Rheumatoid Arthritis (must meet all):

- 1. Diagnosis of RA per American College of Rheumatology (ACR) criteria (*see Appendix G*);
- 2. Prescribed by or in consultation with a rheumatologist;
- 3. Age ≥ 18 years;
- 4. Member meets one of the following (a or b):

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- a. Failure of a ≥ 3 consecutive month trial of MTX at up to maximally indicated doses;
 - b. Member has intolerance or contraindication to MTX (*see Appendix D*), and failure of a ≥ 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. Failure of at ALL of the following, each used for ≥ 3 consecutive months, unless clinically significant adverse effects are experienced or all are contraindicated (a and b):
 - a. Actemra[®], Enbrel[®], Kevzara[®];
 - b. If member has not responded or is intolerant to one or more TNF blockers, Xeljanz[®]/Xeljanz XR[®], unless member has cardiovascular risk and benefits do not outweigh the risk of treatment;

**Prior authorization may be required for Actemra, Enbrel, Kevzara, and Xeljanz/Xeljanz XR*
6. Documentation of one of the following baseline assessment scores (a or b):
 - a. Clinical disease activity index (CDAI) score (*see Appendix H*);
 - b. Routine assessment of patient index data 3 (RAPID3) score (*see Appendix I*);
7. Dose does not exceed 40 mg every other week.

Approval duration:

Centene – 6 months

Legacy WellCare – 12 months

H. Ulcerative Colitis (must meet all):

1. Diagnosis of UC;
2. Prescribed by or in consultation with a gastroenterologist;
3. Age ≥ 5 years;
4. Documentation of a Mayo Score ≥ 6 (*see Appendix F*);
5. Failure of an 8-week trial of systemic corticosteroids, unless contraindicated or clinically significant adverse effects are experienced;
6. Dose does not exceed one of the following (a, b, or c):
 - a. For 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. For pediatric patients weighing more than 20 kg, but less than 40 kg: 80 mg on Day 1, 40 mg on Day 8 and Day 15, followed by maintenance doses of 40 mg every other week or 20 mg every week
 - c. For pediatric patients weighing more than 40 kg: 160 mg on Day 1 and 80 mg on Day 8 and 15, followed by maintenance doses of 80 mg every other week or 40 mg every week.

Approval duration:

Centene – 6 months

Legacy WellCare – 12 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;

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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:

Centene – 6 months

Legacy WellCare – 12 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): CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Rheumatoid Arthritis (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 as evidenced by one of the following (a or b):
 - a. A decrease in CDAI (*see Appendix H*) or RAPID3 (*see Appendix I*) score from baseline;
 - b. Medical justification stating inability to conduct CDAI re-assessment, and submission of RAPID3 score associated with disease severity that is similar to initial CDAI assessment or improved;
3. If request is for a dose increase, new dose does not exceed one of the following (a or b):*
 - a. 40 mg every other week;
 - b. 40 mg every week and both of the following (i and ii):
 - i. Documentation supports inadequate response to a \geq 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;
 - ii. Failure of ALL of the following, each used for \geq 3 consecutive months, unless contraindicated or clinically significant adverse effects are experienced (a and b):
 - a) Actemra[®], Enbrel[®], Kevzara[®];
 - b) If member has not responded or is intolerant to one or more TNF blockers, Xeljanz[®]/Xeljanz XR[®], unless member has cardiovascular risk and benefits do not outweigh the risk of treatment.

**Prior authorization may be required for Actemra, Enbrel, Kevzara, Xeljanz/Xeljanz XR*

Approval duration: 12 months*

**(If new dosing regimen, approve for 6 months)*

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B. All Other Indications in Section I (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member meets one of the following (a, b, or c):
 - a. For HS, at least a 25% reduction in inflammatory nodules and abscesses;
 - b. For pJIA, member is responding positively to therapy as evidenced by a decrease in cJADAS-10 from baseline (*see Appendix J*)
 - c. For all other indications: 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. PJIA, PsA, AS, CD, PsO, UV: 40 mg every other week;
 - b. HS: 40 mg every week;
 - c. For UC, one of the following (i or ii)
 - i. 40 mg every other week or 20 mg every week;
 - ii. 80 mg every other week or 40 mg every week, and member initiated Humira prior to 18 years of age.

Approval duration: 12 months*

**(If new dosing regimen, approve for 6 months)*

C. 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): 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 – CP.PMN.53 for Medicaid or evidence of coverage documents;
- B. Combination use of biological disease-modifying antirheumatic drugs (bDMARDs), including any tumor necrosis factor (TNF) antagonists [Cimzia[®], Enbrel[®], Simponi[®], Avsola[™], Inflectra[™], Remicade[®], Renflexis[™]], interleukin agents [Arcalyst[®] (IL-1 blocker), Ilaris[®] (IL-1 blocker), Kineret[®] (IL-1RA), Actemra[®] (IL-6RA), Kevzara[®] (IL-6RA), Stelara[®] (IL-12/23 inhibitor), Cosentyx[®] (IL-17A inhibitor), Taltz[®] (IL-17A inhibitor), Siliq[™] (IL-17RA), Ilumya[™] (IL-23 inhibitor), Skyrizi[™] (IL-23 inhibitor), Tremfya[®] (IL-23 inhibitor)], janus kinase inhibitors (JAKi) [Xeljanz[®]/Xeljanz[®] XR, Rinvoq[™]], anti-CD20 monoclonal antibodies [Rituxan[®], Riabni[™], Ruxience[™], Truxima[®], and Rituxan Hycela[®]], selective co-stimulation modulators [Orencia[®]], or integrin receptor antagonists [Entyvio[®]] because of the possibility of increased immunosuppression, neutropenia and increased risk of infection.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

6-MP: 6-mercaptopurine

AS: ankylosing spondylitis

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CD: Crohn's disease
 CDAI: clinical disease activity index
 cJADAS: clinical juvenile arthritis disease activity score
 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
 RAPID3: routine assessment of patient index data 3
 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, HS 25 or 50 mg PO QD	50 mg/day
azathioprine (Azasan [®] , Imuran [®])	RA 1 mg/kg/day PO QD or divided BID CD*, 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>	1,500 mg/day

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Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	500 – 750 mg/day PO QD	
cyclophosphamide (Cytoxan [®])	UV* 1 – 2 mg/kg/day PO	N/A
cyclosporine (Sandimmune [®] , Neoral [®])	PsO 2.5 mg/kg/day PO divided BID 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 UV: 5 mg/kg/day
doxycycline (Acticlate [®])	HS* 50 – 100 mg PO BID	300 mg/day
Hormonal agents (e.g., estrogen- containing combined oral contraceptives, spironolactone)	HS varies	varies
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
Isotretinoin (Absorica [®] , Amnesteem [®] , Claravis [®] , Myorisan [®] , Zenatane [®])	HS varies	varies 1.6 to 2 mg/kg/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 RA 100 mg PO QD for 3 days, then 20 mg PO QD	20 mg/day
6-mercaptopurine (Purixan [®])	CD* 50 mg PO QD or 1 – 2 mg/kg/day PO	2 mg/kg/day
methotrexate (Rheumatrex [®])	CD* 15 – 25 mg/week IM or SC PsO 10 – 25 mg/week PO or 2.5 mg PO Q12 hr for 3 doses/week	30 mg/week

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Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	PJIA* 10 – 20 mg/m ² /week PO, SC, or IM RA 7.5 mg/week PO, SC, or IM or 2.5 mg PO Q12 hr for 3 doses/week UV* 7.5 – 20 mg/week PO	
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 Varies	Varies
Pentasa [®] (mesalamine)	CD 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 [®])	PJIA* 30-50 mg/kg/day PO divided BID RA 2 g/day PO in divided doses	PJIA: 2 g/day RA: 3 g/day UC: 4 g/day
tacrolimus (Prograf [®])	CD* 0.27 mg/kg/day PO in divided doses or 0.15 – 0.29 mg/kg/day PO UV* 0.1-0.15 mg/kg/day PO	N/A
Actemra [®] (tocilizumab)	RA IV: 4 mg/kg every 4 weeks followed by an increase to 8 mg/kg every 4 weeks based on clinical response SC: Weight < 100 kg: 162 mg SC every other week, followed by an increase to every week based on clinical response	IV: 800 mg every 4 weeks SC: 162 mg every week

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Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	Weight \geq 100 kg: 162 mg SC every week	
Enbrel [®] (etanercept)	AS 50 mg SC once weekly PJIA Weight < 63 kg: 0.8 mg/kg SC once weekly Weight \geq 63 kg: 50 mg SC once weekly PsA, RA 25 mg SC twice weekly or 50 mg SC once weekly	50 mg/week
Cimzia [®] (certolizumab)	AS <u>Initial dose:</u> 400 mg SC at 0, 2, and 4 weeks <u>Maintenance dose:</u> 200 mg SC every other week (or 400 mg SC every 4 weeks)	400 mg every 4 weeks
Kevzara [®] (sarilumab)	RA 200 mg SC once every two weeks	200 mg/2 weeks
Otezla [®] (apremilast)	PsA <u>Initial dose:</u> Day 1: 10 mg PO QAM Day 2: 10 mg PO QAM and 10 mg PO QPM Day 3: 10 mg PO QAM and 20 mg PO QPM Day 4: 20 mg PO QAM and 20 mg PO QPM Day 5: 20 mg PO QAM and 30 mg PO QPM <u>Maintenance dose:</u> Day 6 and thereafter: 30 mg PO BID	60 mg/day
Taltz [®] (ixekizumab)	AS, PsA <u>Initial dose:</u> 160 mg (two 80 mg injections) SC at week 0 <u>Maintenance dose:</u> 80 mg SC every 4 weeks PsO <u>Initial dose:</u>	80 mg every 4 weeks

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Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	160 mg (two 80 mg injections) SC at week 0, then 80 mg SC at weeks 2, 4, 6, 8, 10, and 12 <u>Maintenance dose:</u> 80 mg SC every 4 weeks	
Xeljanz [®] (tofacitinib)	PsA, RA 5 mg PO BID	PsA, RA 10 mg/day
Xeljanz XR [®] (tofacitinib extended-release)	PsA, RA 11 mg PO QD	PsA, RA 11 mg/day

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.

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- 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: Immunomodulator 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

Appendix F: Mayo Score

- Mayo Score: evaluates ulcerative colitis stage, based on four parameters: stool frequency, rectal bleeding, endoscopic evaluation and Physician's global assessment. Each parameter of the score ranges from zero (normal or inactive disease) to 3 (severe activity) with an overall score of 12.

Score	Decoding
0 – 2	Remission
3 – 5	Mild activity
6 – 10	Moderate activity
>10	Severe activity

- The following may be considered for medical justification supporting inability to use an immunomodulator for ulcerative colitis:
 - Documentation of Mayo Score 6 – 12 indicative of moderate to severe ulcerative colitis.

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Appendix G: 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) <i>and</i> negative anti-citrullinated protein antibody (ACPA)	0
	Low positive RF <i>or</i> low positive ACPA <i>* Low: $< 3 \times$ upper limit of normal</i>	2
	High positive RF <i>or</i> high positive ACPA <i>* High: $\geq 3 \times$ upper limit of normal</i>	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 abnormal ESR	1
D	Duration of symptoms	
	< 6 weeks	0
	≥ 6 weeks	1

Appendix H: Clinical Disease Activity Index (CDAI) Score

The Clinical Disease Activity Index (CDAI) is a composite index for assessing disease activity in RA. CDAI is based on the simple summation of the count of swollen/tender joint count of 28 joints along with patient and physician global assessment on VAS (0–10 cm) Scale for estimating disease activity. The CDAI score ranges from 0 to 76.

CDAI Score	Disease state interpretation
≤ 2.8	Remission
> 2.8 to ≤ 10	Low disease activity
> 10 to ≤ 22	Moderate disease activity
> 22	High disease activity

Appendix I: Routine Assessment of Patient Index Data 3 (RAPID3) Score

The Routine Assessment of Patient Index Data 3 (RAPID3) is a pooled index of the three patient-reported ACR core data set measures: function, pain, and patient global estimate of status. Each of the individual measures is scored 0 – 10, and the maximum achievable score is 30.

RAPID3 Score	Disease state interpretation
≤ 3	Remission
3.1 to 6	Low disease activity
6.1 to 12	Moderate disease activity

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RAPID3 Score	Disease state interpretation
> 12	High disease activity

Appendix J: Clinical Juvenile Arthritis Disease Activity Score based on 10 joints (cJADAS-10)

The cJADAS10 is a continuous disease activity score specific to JIA and consisting of the following three parameters totaling a maximum of 30 points:

- Physician's global assessment of disease activity measured on a 0-10 visual analog scale (VAS), where 0 = no activity and 10 = maximum activity;
- Parent global assessment of well-being measured on a 0-10 VAS, where 0 = very well and 10 = very poor;
- Count of joints with active disease to a maximum count of 10 active joints*

**ACR definition of active joint: presence of swelling (not due to currently inactive synovitis or to bony enlargement) or, if swelling is not present, limitation of motion accompanied by pain, tenderness, or both*

cJADAS-10	Disease state interpretation
≤ 1	Inactive disease
1.1 to 2.5	Low disease activity
2.51 to 8.5	Moderate disease activity
> 8.5	High disease activity

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	40 mg SC every other week	40 mg every other week
AS		
CD	<u>Initial dose:</u> <i>Adults:</i> 160 mg SC on Day 1, then 80 mg SC on Day 15 <i>Pediatrics:</i> 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	40 mg every other week

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Indication	Dosing Regimen	Maximum Dose												
	<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> <i>Adults:</i> 160 mg SC on Day 1, then 80 mg SC on Day 15</p> <p><i>Pediatrics:</i></p> <table><tr><th>Weight</th><th>Days 1 through 15</th></tr><tr><td>20 kg to less than 40 kg</td><td>Day 1: 80 mg Day 8: 40 mg Day 15: 40 mg</td></tr><tr><td>40 kg and greater</td><td>Day 1: 160 mg (single dose or split over two consecutive days) Day 8: 80 mg Day 15: 80 mg</td></tr></table> <p><u>Maintenance dose:</u> <i>Adults:</i> 40 mg SC every other week starting on Day 29</p> <p><i>Pediatrics:</i></p> <table><tr><th>Weight</th><th>Starting on Day 29*</th></tr><tr><td>20 kg to less than 40 kg</td><td>40 mg every other week or 20 mg every week</td></tr><tr><td>40 kg and greater</td><td>80 mg every other week or 40 mg every week</td></tr></table> <p><i>*Continue the recommended pediatric dosage in patients who turn 18 years of age and who are well-controlled on Humira regimen.</i></p>	Weight	Days 1 through 15	20 kg to less than 40 kg	Day 1: 80 mg Day 8: 40 mg Day 15: 40 mg	40 kg and greater	Day 1: 160 mg (single dose or split over two consecutive days) Day 8: 80 mg Day 15: 80 mg	Weight	Starting on Day 29*	20 kg to less than 40 kg	40 mg every other week or 20 mg every week	40 kg and greater	80 mg every other week or 40 mg every week	40 mg every week
Weight	Days 1 through 15													
20 kg to less than 40 kg	Day 1: 80 mg Day 8: 40 mg Day 15: 40 mg													
40 kg and greater	Day 1: 160 mg (single dose or split over two consecutive days) Day 8: 80 mg Day 15: 80 mg													
Weight	Starting on Day 29*													
20 kg to less than 40 kg	40 mg every other week or 20 mg every week													
40 kg and greater	80 mg every other week or 40 mg every 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</p>	40 mg every other week												

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Indication	Dosing Regimen	Maximum Dose
	Weight \geq 30 kg (66 lbs): 40 mg SC every other week <i>Adults:</i> Initial dose of 80 mg SC, followed by 40 mg SC every other week starting one week after the initial dose	
HS	<i>For patients 12 years of age and older weighing at least 30 kg:</i> <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 \geq 60 kg (132 lbs): 160 mg SC on Day 1, then 80 mg SC on Day 15 <u>Maintenance dose:</u> Weight 30 kg (66 lbs) to < 60 kg (132 lbs): 40 mg every other week Weight \geq 60 kg (132 lbs): 40 mg SC once weekly starting on Day 29	40 mg/week

VI. Product Availability

Drug Name	Availability
adalimumab (Humira)	<ul style="list-style-type: none"> 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
Adalimumab-atto (Amjevita)	<ul style="list-style-type: none"> Single-dose prefilled SureClick autoinjector: 40 mg/0.8 mL Single-dose prefilled syringe: 40 mg/0.8 mL, 20 mg/0.4 mL
Adalimumab-adbm (Cyltezo)	<ul style="list-style-type: none"> Single-dose prefilled syringe: 40 mg/0.8 mL, 20 mg/0.4 mL
Adalimumab-bwwd (Hadlima)	<ul style="list-style-type: none"> Single-dose prefilled PushTouch autoinjector: 40 mg/0.8 mL Single-dose prefilled syringe: 40 mg/0.8 mL
Adalimumab-adaz (Hyrimoz)	<ul style="list-style-type: none"> Single-dose prefilled glass syringe (with BD UltraSafe Passive[™] Needle Guard): 40 mg/0.8 mL Single-dose prefilled pen (Sensoready[®] Pen): 40 mg/0.8 mL

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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.

HCPCS Codes	Description
J0135	Injection, adalimumab, 20 mg

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Reviews, Revisions, and Approvals	Date	P&T Approval Date
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	
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.	02.27.18	05.18
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 CD; allowed bypassing conventional DMARDs for axial PsA and required trial of NSAIDs; references reviewed and updated.	09.04.18	11.18
2Q 2019 annual review: removed trial and failure of conventional DMARDs (e.g., MTX)/NSAIDs for PsA per 2018 ACR/NPF guidelines; revised approval duration to 6 months if request is for continuation of therapy with a new (e.g., increased dose/frequency) regimen; references reviewed and updated.	03.05.19	05.19

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Reviews, Revisions, and Approvals	Date	P&T Approval Date
RT4: no significant change; added biosimilar Amjevita to policy.	06.18.19	
RT4: no significant change; added biosimilars Cyltezo and Hadlima to policy.	09.23.19	
Removed HIM line of business; updated preferred redirections based on SDC recommendation and prior clinical guidance: for PsA, added redirection to 3 of 5 (Enbrel, Simponi, Taltz, Otezla, Xeljanz/Xeljanz XR); for PsO, added redirection to Taltz; for AS, added redirection to 2 of 3 (Enbrel, Cimzia, Taltz); for PJIA, added redirection to etanercept; for RA, added redirection to 2 of 3 (Enbrel, Kevzara, Xeljanz/Xeljanz XR) for initial therapy and 3 of 3 (Enbrel, Kevzara, Xeljanz/Xeljanz XR) for continued therapy at weekly dosing interval.	12.16.19	
2Q 2020 annual review: added Hyrimoz to the policy; for UC, revised redirection from AZA, 6-MP, and ASA to corticosteroids and added requirement of Mayoscore of at least 6; for RA, added specific diagnostic criteria for definite RA, baseline CDAI score requirement, and decrease in CDAI score as positive response to therapy; for HS, revised requirement from systemic antibiotics to additionally require oral retinoids or hormonal therapy, and required at least a 25% reduction in inflammatory nodules and abscesses for reauthorization; references reviewed and updated.	04.23.20	05.20
Revised typo in Appendix E from “normal ESR” to “abnormal ESR” for a point gained for ACR Classification Criteria.	11.22.20	
Updated pJIA criteria to require diagnosis as evidenced by ≥ 5 joints, cJADAS assessment, and redirection to Enbrel and Xeljanz per SDC. Additionally, updated criteria to allow tiered redirection or bypass of MTX in the event of sacroiliitis or high disease activity. Added criteria for RAPID3 assessment for RA given limited in-person visits during COVID-19 pandemic, updated appendices.	11.24.20	02.21
2Q 2021 annual review: added additional criteria related to diagnosis of moderate-to-severe PsO per 2019 AAD/NPF guidelines specifying at least 3% BSA involvement or involvement of areas that severely impact daily function; added combination of bDMARDs under Section III; updated CDAI table with “>” to prevent overlap in classification of severity; clarified that different therapeutic classes must be tried for HS, each for 3 months; references reviewed and updated. RT4: updated criteria to reflect pediatric extension for UC to include patients 5 years of age and older.	05.04.21	05.21
Per August SDC and prior clinical guidance, for RA added Actemra to redirect options and modified to require a trial of all; For PsA removed Simponi as a redirect option and modified to require a trial of all; for AS modified from trial of two to trial of all; for Xeljanz	08.25.21	11.21

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Reviews, Revisions, and Approvals	Date	P&T Approval Date
redirection requirements added bypass for members with cardiovascular risk and qualified redirection to apply only for member that has not responded or is intolerant to one or more TNF blockers; added Legacy WellCare line of business to policy (WCG.CP.PHAR.242 to be retired).		
RT4: updated FDA approved indications to reflect pediatric extensions for Cyltezo in JIA and CD.	11.01.21	

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.

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