

Clinical Policy: Etanercept (Enbrel)

Reference Number: MDN.CP.PHAR.250

Effective Date: 12.1.23

Last Review Date: 10.4.23

Line of Business: Medicaid

[Coding Implications](#)

[Revision Log](#)

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

Description

Etanercept (Enbrel[®]) is a tumor necrosis factor (TNF) blocker.

FDA Approved Indication(s)

Enbrel is indicated for the treatment of:

- For reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active rheumatoid arthritis (RA). Enbrel can be initiated in combination with methotrexate (MTX) or used alone.
- For reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis (JIA) in patients ages 2 and older
- For reducing signs and symptoms, inhibiting the progression of structural damage of active arthritis, and improving physical function in patients with psoriatic arthritis (PsA). Enbrel can be used with or without methotrexate.
- For reducing signs and symptoms in patients with active ankylosing spondylitis (AS)
- For the treatment of patients 4 years or older with chronic moderate to severe plaque psoriasis (PsO) who are candidates for systemic therapy or phototherapy

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 Enbrel is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Ankylosing Spondylitis (must meet all):

1. Diagnosis of AS;
2. Age \geq 18 years;
3. Prescribed by or in consultation with a rheumatologist;
4. Failure of at least TWO non-steroidal anti-inflammatory drugs (NSAIDs) at up to maximally indicated doses, each used for \geq 4 weeks unless clinically significant adverse effects are experienced or all are contraindicated;
5. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
6. Dose does not exceed 50 mg every week.

Approval duration: 6 months

B. 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 ≥ 4 years;
4. Member meets one of the following (a, b, or c):
 - 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 at up to maximally indicated doses, unless clinically significant adverse effects are experienced or both are contraindicated;
 - c. Member has intolerance or contraindication to MTX and cyclosporine and failure of phototherapy, unless contraindicated or clinically significant adverse effects are experienced;
5. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
6. Dose does not exceed one of the following (a or b):
 - a. Adults: 50 mg twice weekly for 3 months, followed by maintenance dose of 50 mg every week;
 - b. Pediatrics (*see Appendix E for dose rounding guidelines*) (i or ii):
 - i. Weight < 63 kg: 0.8 mg/kg every week;
 - ii. Weight ≥ 63 kg: 50 mg every week.

Approval duration: 6 months

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

1. Diagnosis of PJIA* as evidenced by ≥ 5 joints with active arthritis;
**Overlap of diagnosis exists in children with JIA and non-systemic polyarthritis, which may include children from ILAR JIA categories of enthesitis-related 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 I*);
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 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 I*);
6. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
7. Dose does not exceed one of the following (a or b):
 - a. Adults: 50 mg every week;
 - b. Pediatrics (*see Appendix E for dose rounding guidelines*) (i or ii):
 - i. Weight < 63 kg: 0.8 mg/kg every week;
 - ii. Weight ≥ 63 kg: 50 mg every week.

Approval duration: 6 months

D. 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. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
5. Dose does not exceed 50 mg every week.

Approval duration: 6 months

E. Rheumatoid Arthritis (must meet all):

1. Diagnosis of RA per American College of Rheumatology (ACR) criteria (*see Appendix F*);
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 a ≥ 3 consecutive month trial of methotrexate (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 anti-rheumatic drug [DMARD] (e.g., sulfasalazine, leflunomide, hydroxychloroquine) at up to maximally indicated doses, unless clinically significant adverse effects are experienced or all are contraindicated;
5. Documentation of one of the following baseline assessment scores (a or b):
 - a. Clinical disease activity index (CDAI) score (*see Appendix G*);
 - b. Routine assessment of patient index data 3 (RAPID3) score (*see Appendix H*);
6. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
7. Dose does not exceed 50 mg every week.

Approval duration: 6 months

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

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
 - a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
 - b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

II. Continued Therapy

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

1. Member meets one of the following (a or b):
 - a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
 - b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B*);
2. Member meets one of the following (a, b, or c):
 - a. For RA: member is responding positively to therapy as evidenced by one of the following (i or ii):
 - i. A decrease in CDAI (*see Appendix G*) or RAPID3 (*see Appendix H*) score from baseline;
 - ii. 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;
 - b. For pJIA, member is responding positively to therapy as evidenced by a decrease in cJADAS-10 from baseline (*see Appendix I*);
 - c. For all other indications: member is responding positively to therapy;
3. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
4. If request is for a dose increase, new dose does not exceed 50 mg every week.

Approval duration: 12 months

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

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):

- a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
 - b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: 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 with biological disease-modifying antirheumatic drugs (bDMARDs) or potent immunosuppressants, including but not limited to any tumor necrosis factor (TNF) antagonists [e.g., Cimzia[®], Enbrel[®], Humira[®] and its biosimilars, Simponi[®], Avsola[™], Inflectra[™], Remicade[®], Renflexis[™]], interleukin agents [e.g., 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) [e.g., Xeljanz[®]/Xeljanz[®] XR, Cibinqo[™], Olumiant[™], Rinvoq[™]], anti-CD20 monoclonal antibodies [Rituxan[®], Riabni[™], Ruxience[™], Truxima[®], Rituxan Hycela[®]], selective co-stimulation modulators [Orencia[®]], and integrin receptor antagonists [Entyvio[®]] because of the additive immunosuppression, increased risk of neutropenia, as well as increased risk of serious infections.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

AS: ankylosing spondylitis

CDAI: clinical disease activity index

cJADAS: clinical juvenile arthritis disease activity score

DMARD: disease-modifying anti rheumatic drug

FDA: Food and Drug Administration

GI: gastrointestinal

JAKi: Janus kinase inhibitors

MTX: methotrexate

NSAID: non-steroidal anti-inflammatory drug

PsO: plaque psoriasis

PJIA: polyarticular juvenile idiopathic arthritis

PsA: psoriatic arthritis

RA: rheumatoid arthritis

RAPDI3: routine assessment of patient index data 3

TNF: tumor necrosis factor

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	2.5 mg/kg/day
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
cyclosporine (Sandimmune [®] , Neoral [®])	PsO 2.5 – 4 mg/kg/day PO divided BID RA 2.5 – 4 mg/kg/day PO divided BID	4 mg/kg/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 Weight 20 - 40 kg: 10 mg/day Weight > 40 kg: 20 mg/day RA <u>Initial dose (for low risk hepatotoxicity or myelosuppression):</u> 100 mg PO QD for 3 days <u>Maintenance dose:</u> 20 mg PO QD	20 mg/day
methotrexate (Trexall [®] , Otrexup [™] , Rasuvo [®] , RediTrex [®] , Rheumatrex [®])	PsO 10 to 25 mg/week IM, SC or PO or 2.5 mg PO Q12 hr for 3 doses/week 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	30 mg/week
NSAIDs (e.g., indomethacin, ibuprofen,	AS Varies	Varies

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
naproxen, celecoxib)		
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 <u>Initial dose:</u> 500 mg to 1,000 mg PO QD for the first week. Increase the daily dose by 500 mg each week up to a maintenance dose of 2 g/day. <u>Maintenance dose:</u> 2 g/day PO in divided doses	PJIA: 2 g/day RA: 3 g/day
Actemra [®] (tocilizumab)	pJIA • Weight < 30 kg: 10 mg/kg IV every 4 weeks or 162 mg SC every 3 weeks • Weight ≥ 30 kg: 8 mg/kg IV every 4 weeks or 162 mg SC every 2 weeks 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 Weight ≥ 100 kg: 162 mg SC every week	PJIA: • IV: 10 mg/kg every 4 weeks • SC: 162 mg every 2 weeks RA: IV: 800 mg every 4 weeks SC: 162 mg every week
Hadlima (adalimumab-bwwd), Yusimry (adalimumab-aqvh), adalimumab-adaz (Hyrimoz [®]), adalimumab-fkjp (Hulio [®])	RA, AS, PsA 40 mg SC every other week PsO <u>Initial dose:</u> 80 mg SC <u>Maintenance dose:</u> 40 mg SC every other week starting one week after initial dose pJIA	40 mg every other week

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	<p>Hadlima, Hyrimoz: Weight 10 kg (22 lbs) to < 15 kg (33 lbs): 10 mg SC every other week</p> <p>Hadlima, Hulio: Weight 15 kg (33 lbs) to < 30 kg (66 lbs): 20 mg SC every other week</p> <p>Hadlima, Hulio, Hyrimoz, Yusimry: Weight ≥ 30 kg (66 lbs): 40 mg SC every other week</p>	
Kevzara [®] (sarilumab)	<p>RA 200 mg SC once every two weeks</p>	200 mg/2 weeks
Oluminat [®] (baricitinib)	<p>RA 2 mg PO QD</p>	2 mg/day
Otezla [®] (apremilast)	<p>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</p> <p><u>Maintenance dose:</u> Day 6 and thereafter: 30 mg PO BID</p>	60 mg/day
Taltz [®] (ixekizumab)	<p>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</p> <p>PsO <u>Initial dose:</u> 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</p>	80 mg every 4 weeks

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Xeljanz [®] (tofacitinib)	AS, PsA, RA 5 mg PO BID pJIA <ul style="list-style-type: none"> • 10 kg ≤ body weight < 20 kg: 3.2 mg (3.2 mL oral solution) PO BID • 20 kg ≤ body weight < 40 kg: 4 mg (4 mL oral solution) PO BID Body weight ≥ 40 kg: 5 mg PO BID	10 mg/day
Xeljanz XR [®] (tofacitinib extended-release)	AS, PsA, RA 11 mg PO QD	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): patients with sepsis
- Boxed warning(s):
 - Serious infections
 - Malignancies

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."
 - Per the 2019 North American guidelines for HS, the limited available evidence does not support use of etanercept for HS. One randomized, double-blind, placebo-controlled study (n = 20) demonstrated no statistically significant improvement in patient or physician-reported outcomes. Other studies demonstrated either mixed

- evidence or the limited efficacy was determined using incompletely validated outcome measures.
- TNF blockers:
 - Etanercept (Enbrel[®]), adalimumab (Humira[®]) and its biosimilars, infliximab (Remicade[®]) and its biosimilars (Avsola[™], Renflexis[™], Inflectra[®]), certolizumab pegol (Cimzia[®]), and golimumab (Simponi[®], Simponi Aria[®]).

Appendix E: Dose Rounding Guidelines for PJIA and Pediatric PsO

Weight-based Dose Range	Vial Quantity Recommendation
≤ 25.99 mg	1 vial of 25 mg/0.5 mL
26 to 52.49 mg	1 vial of 50 mg/mL

Appendix F: 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 <i>* Low: < 3 x upper limit of normal</i>	2
	High positive RF or high positive ACPA <i>* High: ≥ 3 x 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 G: 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

CDAI Score	Disease state interpretation
> 22	High disease activity

Appendix H: 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
> 12	High disease activity

Appendix I: 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	25 mg SC twice weekly or 50 mg SC once weekly	50 mg/week
PsA		
AS	50 mg SC once weekly	50 mg/week
PJIA	Weight < 63 kg: 0.8 mg/kg SC once weekly Weight ≥ 63 kg: 50 mg SC once weekly	50 mg/week
PsO	<i>Adults:</i> <u>Initial dose:</u> 50 mg SC twice weekly for 3 months <u>Maintenance dose:</u> 50 mg SC once weekly <i>Pediatrics:</i>	50 mg/week

Indication	Dosing Regimen	Maximum Dose
	Weight < 63 kg: 0.8 mg/kg SC once weekly Weight ≥ 63 kg: 50 mg SC once weekly	

VI. Product Availability

- Single-dose prefilled syringe: 25 mg/0.5 mL, 50 mg/mL
- Single-dose prefilled SureClick[®] autoinjector: 50 mg/ml
- Single-dose vial: 25 mg/0.5 mL
- Multi-dose vial for reconstitution: 25 mg
- Enbrel Mini[™] single-dose prefilled cartridge for use with AutoTouch[™] reusable autoinjector: 50 mg/mL

VII. References

1. Enbrel Prescribing Information. Thousand Oaks, CA: Immunex Corporation: June 2022. Available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/103795s5591lbl.pdf. Accessed January 10, 2023.
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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
J1438	Injection, etanercept, 25 mg (code may be used for Medicare when drug administered under the direct supervision of a physician, not for use when drug is self-administered)

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Criteria adapted from CP.PHAR.250 to align with HFS PDL	10.4.23	

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.

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