

Clinical Policy: Abatacept (Orencia)

Reference Number: MDN.CP.PHAR.241

Effective Date: 04.01.22 Last Review Date: 04.22

Line of Business: Meridian IL Medicaid

Coding Implications
Revision Log

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

Description

Abatacept (Orencia®) is a selective T cell costimulation modulator.

FDA Approved Indication(s)

Orencia is indicated for:

- Reducing signs and symptoms, including major clinical response, inhibiting the progression
 of structural damage, and improving physical function in adult patients with moderately to
 severely active rheumatoid arthritis (RA). Orencia may be used as monotherapy or
 concomitantly with disease-modifying antirheumatic drugs (DMARDs) other than tumor
 necrosis factor (TNF) antagonists.
- Reducing signs and symptoms in patients 2 years of age and older with moderately to severely active polyarticular juvenile idiopathic arthritis (PJIA). Orencia may be used as monotherapy or concomitantly with methotrexate (MTX).
- Treatment of adult patients with active psoriatic arthritis (PsA).

Limitation(s) of use: Concomitant use of Orencia with other immunosuppressives [e.g., biologic disease-modifying antirheumatic drugs (bDMARDS), Janus kinase (JAK) inhibitors] is not recommended.

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

I. Initial Approval Criteria

- A. 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 $a \ge 3$ consecutive month trial of MTX at up to maximally indicated doses:



- b. If intolerance or contraindication to MTX (see Appendix D), failure of $a \ge 3$ consecutive month trial of leflunomide or sulfasalazine at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
- c. For sacroilitis/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. **Applies to IL Medicaid only:** Failure of TWO of the following, each used for ≥ 3 consecutive months, unless clinically significant adverse effects are experienced or all are contraindicated (a, b, and c):
 - a. Enbrel®;
 - b. Humira[®];
 - c. Xeljanz[®]/Xeljanz XR[®];

*Prior authorization may be required for Enbrel. Humira, and Xeljanz/Xeljanz XR

- Applies to MI Medicaid only: Failure of Enbrel or Humira, used for ≥ 3 consecutive months, unless clinically significant adverse effects are experienced or both are contraindicated;
- 8. For members 2 to 5 years of age, prescribed route of administration is SC;
- 9. Dose does not exceed one of the following (a or b):
 - a. IV: weight-based dose at weeks 0, 2, and 4, then every 4 weeks (*see Appendix E for dose rounding guidelines*) (i, ii, or iii):
 - i. Weight < 75 kg: 10 mg/kg per dose;
 - ii. Weight 75 kg to 100 kg: 750 mg per dose;
 - iii. Weight > 100 kg: 1,000 mg per dose;
 - b. SC: weight-based dose once weekly (*see Appendix F for dose rounding guidelines*) (i, ii, or iii):
 - i. Weight 10 to <25 kg: 50 mg per dose;
 - ii. Weight 25 to <50 kg: 87.5 mg per dose;
 - iii. Weight \geq 50 kg: 125 mg per dose.

Approval duration: 6 months

- B. 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. **Applies to IL Medicaid only:** Failure of TWO of the following, each used for ≥ 3 consecutive months, unless clinically significant adverse effects are experienced or all are contraindicated (a, b, c, and d):
 - a. Cimzia[®];
 - b. Enbrel[®]:
 - c. Humira®;
 - d. Xelianz[®]/Xelianz XR[®]

^{*}Prior authorization is required for Cimzia, Enbrel, Humira, and Xeljanz/Xeljanz XR



- 5. **Applies to MI Medicaid only:** Failure of one of the following: Enbrel, Humira, or Cosentyx, used for ≥ 3 consecutive months, unless clinically significant adverse effects are experienced or all are contraindicated;
- 6. Dose does not exceed one of the following (a or b):
 - a. IV: weight-based dose at weeks 0, 2, and 4, then every 4 weeks (*see Appendix E for dose rounding guidelines*) (i, ii, or iii):
 - i. Weight < 60 kg: 500 mg per dose;
 - ii. Weight 60 to 100 kg: 750 mg per dose;
 - iii. Weight > 100 kg: 1,000 mg per dose;
 - b. SC: 125 mg once weekly.

Approval duration: 6 months

B. 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 \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 ≥ 3 consecutive month trial of at least ONE conventional DMARD (e.g., sulfasalazine, leflunomide, hydroxychloroquine) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
- 5. **Applies to IL Medicaid only:** Failure of TWO of the following, each used for ≥ 3 consecutive months, unless clinically significant adverse effects are experienced or all are contraindicated (a, b, c, and d):
 - a. Cimzia[®];
 - b. Enbrel[®];
 - c. Humira®;
 - d. Xeljanz[®]/Xeljanz XR[®];
 - *Prior authorization is required for Cimzia, Enbrel, Humira, and Xeljanz/Xeljanz XR
- Applies to MI Medicaid only: Failure of Enbrel or Humira, used for ≥ 3 consecutive months, unless clinically significant adverse effects are experienced or both are contraindicated;
- 7. 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);
- 8. Dose does not exceed one of the following (a or b):
 - a. IV: weight-based dose at weeks 0, 2, and 4, then every 4 weeks (*see Appendix E for dose rounding guidelines*) (i, ii, or iii):
 - i. Weight < 60 kg: 500 mg per dose;
 - ii. Weight 60 to 100 kg: 750 mg per dose;
 - iii. Weight > 100 kg: 1,000 mg per dose;



b. SC: 125 mg once weekly.

Approval duration: 6 months

C. 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. 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 meets one of the following (a, b, or c):
 - a. For RA member is responding positively to therapy as evidenced by by one of the following (i or ii):
 - i. A decrease in CDAI (*see Appendix H*) or RAPID3 (*see Appendix I*) score from baseline;
 - 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 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 (*see Appendix E and F for dose rounding guidelines*) (a or b):
 - a. RA and PsA (i or ii):
 - i. IV: weight-based dose every 4 weeks (a, b, or c):
 - a) Weight < 60 kg: 500 mg per dose;
 - b) Weight 60 to 100 kg: 750 mg per dose;
 - c) Weight > 100 kg: 1,000 mg per dose;
 - ii. SC: 125 mg once weekly;
 - b. PJIA (i or ii):
 - i. IV: weight-based dose every 4 weeks (a, b, or c):
 - a) Weight < 75 kg: 10 mg/kg per dose;
 - b) Weight 75 kg to 100 kg: 750 mg per dose;
 - c) Weight > 100 kg: 1,000 mg per dose;
 - ii. SC: weight-based dose once weekly (a, b, or c):
 - a) Weight 10 to <25 kg: 50 mg per dose;
 - b) Weight 25 to <50 kg: 87.5 mg per dose;
 - c) Weight \geq 50 kg: 125 mg per dose.

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): 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

CDAI: clinical disease activity index

cJADAS: clinical juvenile arthritis disease

activity score

DMARD: disease-modifying antirheumatic

drug

FDA: Food and Drug Administration

MTX: methotrexate

PJIA: polyarticular juvenile idiopathic

arthritis

PsA: psoriatic arthritis RA: rheumatoid arthritis

RAPID3: 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
azathioprine	RA	2.5 mg/kg/day
(Azasan [®] , Imuran [®])	1 mg/kg/day PO QD or divided BID	
Cuprimine®	RA*	1,500 mg/day
(d-penicillamine)	<u>Initial dose:</u>	
	125 or 250 mg PO QD	
	Maintenance dose:	
	500 – 750 mg/day PO QD	
cyclosporine	RA	4 mg/kg/day
(Sandimmune [®] ,	2.5 – 4 mg/kg/day PO divided BID	
Neoral [®])		



Drug Name	Dosing Regimen	Dose Limit/
		Maximum Dose
hydroxychloroquine (Plaquenil®)	RA* Initial dose: 400 – 600 mg/day PO Maintenance dose: 200 – 400 mg/day PO	600 mg/day
leflunomide (Arava®)	PJIA* Weight 10 mg/1.73 m²/day Or < 20 kg: 10 mg every other day Weight 20 - 40 kg: 10 mg/day Weight > 40 kg: 20 mg/day RA 100 mg PO QD for 3 days, then 20 mg PO QD	20 mg/day
methotrexate (Rheumatrex®)	PJIA* 10 – 20 mg/m²/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
Ridaura® (auranofin)	RA 6 mg PO QD or 3 mg PO BID	9 mg/day (3 mg TID)
sulfasalazine (Azulfidine®)	RA 2 g/day PO in divided doses	RA: 3 g/day
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
Enbrel® (etanercept)	Weight ≥ 100 kg: 162 mg SC every week PJIA Weight < 63 kg: 0.8 mg/kg SC once weekly Weight ≥ 63 kg: 50 mg SC once weekly PsA, RA 25 mg SC twice weekly or 50 mg SC once weekly	50 mg/week



Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Kevzara [®] (sarilumab)	RA 200 mg SC once every two weeks	200 mg/2 weeks
Otezla [®] (apremilast)	PsA Initial dose: 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 Maintenance dose: Day 6 and thereafter: 30 mg PO BID	60 mg/day
Taltz	PsA Initial dose: 160 mg (two 80 mg injections) SC at week 0 Maintenance dose: 80 mg SC every 4 weeks	80 mg every 4 weeks
Xeljanz® (tofacitinib)	PsA, RA 5 mg PO BID	10 mg/day
Xeljanz XR [®] (tofacitinib extended-release)	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 None reported

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:
 - o Reduction in joint pain/swelling/tenderness
 - o Improvement in ESR/CRP levels



o Improvements in activities of daily living

Appendix E: IV Dose Rounding Guidelines for PJIA, PsA, and RA

Weight-based Dose Range	Vial Quantity Recommendation
\leq 262.49 mg	1 vial of 250 mg
262.50 mg to 524.99 mg	2 vials of 250 mg
525 to 787.49 mg	3 vials of 250 mg
787.50 mg to 1,049.99 mg	4 vials of 250 mg

Appendix F: SC Dose Rounding Guidelines for PJIA, PsA, and RA

Weight-based Dose Range	Prefilled Syringe Quantity Recommendation
10 to 24.99 kg	1 syringe of 50 mg/0.4 mL
25 to 49.99 kg	1 syringe of 87.5 mg/0.7 mL
> 50 kg	1 syringe of 125 mg/mL

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 natient as having definite RA

patiei	it 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
В	Serology (at least one test result is needed for classification)	
	Negative rheumatoid factor (RF) and negative anti-citrullinated protein	0
	antibody (ACPA)	
	Low positive RF <i>or</i> low positive ACPA	2
	*Low: < 3 x upper limit of normal	
	High positive RF or high positive ACPA	3
	* $High: \ge 3 x$ upper limit of normal	
C	Acute phase reactants (at least one test result is needed for classification)	
	Normal C-reactive protein (CRP) and normal erythrocyte sedimentation rate	0
	(ESR)	
	Abnormal CRP or abnormal ESR	1
D	Duration of symptoms	
	< 6 weeks	0
	\geq 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
$> 2.8 \text{ to} \le 10$	Low disease activity
$> 10 \text{ to } \le 22$	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
> 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	IV: weight-based dose at weeks 0, 2, and 4,	IV: 1,000 mg every 4
	followed by every 4 weeks	weeks
	Weight < 60 kg: 500 mg per dose	
	Weight 60 to 100 kg: 750 mg per dose	SC: 125 mg/week
PsA	Weight > 100 kg: 1,000 mg per dose	
	SC: 125 mg once weekly (For RA: if single	
	IV loading dose is given, start first SC	
	injection within one day of IV dose)	



Indication	Dosing Regimen	Maximum Dose
PJIA	IV: weight-based dose at weeks 0, 2, and 4,	IV: 1,000 mg every 4
	followed by every 4 weeks	weeks
	Weight < 75 kg: 10 mg/kg per dose	
	Weight 75 to 100 kg: 750 mg per dose	SC: 125 mg/week
	Weight >100 kg: 1,000 mg per dose	
	SC: weight-based dose once weekly	
	Weight 10 to < 25 kg: 50 mg per dose	
	Weight 25 to < 50 kg: 87.5 mg per dose	
	Weight \geq 50 kg: 125 mg per dose	

VI. Product Availability

- Single-use vial for IV infusion: 250 mg
- Single-dose prefilled syringes for SC injection: 50 mg/0.4 mL, 87.5 mg/0.7 mL, 125 mg/mL
- Single-dose prefilled ClickJectTM autoinjector for SC injection: 125 mg/mL

VII. References

- 1. Orencia Prescribing Information. Princeton, NJ: Bristol-Meyers Squibb Company; June 2020. Available at: http://www.orenciahcp.com/. Accessed January 7, 2021.
- Ringold, S., Weiss, P. F., Beukelman, T., DeWitt, E. M., Ilowite, N. T., Kimura, Y., Laxer, R. M., Lovell, D. J., Nigrovic, P. A., Robinson, A. B. and Vehe, R. K. (2013), 2013 Update of the 2011 American College of Rheumatology Recommendations for the Treatment of Juvenile Idiopathic Arthritis: Recommendations for the Medical Therapy of Children With Systemic Juvenile Idiopathic Arthritis and Tuberculosis Screening Among Children Receiving Biologic Medications. *Arthritis & Rheumatism*. 65: 2499–2512.
- 3. Gossec L, Smolen JS, Ramiro S, et al European League Against Rheumatism (EULAR) recommendations for the management of psoriatic arthritis with pharmacological therapies: 2015 update Annals of the Rheumatic Diseases Published Online First: 07 December 2015. doi: 10.1136/annrheumdis-2015-208337.
- 4. Gottlieb, Alice et al.Guidelines of care for the management of psoriasis and psoriatic arthritis: Journal of the American Academy of Dermatology, Volume 58, Issue 5, 851 864.
- 5. Singh JA, Saag KG, Bridges SL, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Rheumatology*. 2016; 68(1):1-26.
- 6. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the treatment of psoriatic arthritis. *American College of Rheumatology*. 2019; 71(1):5-32. doi: 10.1002/art.40726

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	Description
Codes	
J0129	Injection, abatacept, 10 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
Policy created, adapted from CP.PHAR.241	04.01.22	04.22

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.

©2016 Centene Corporation. All rights reserved. All materials are exclusively owned by Centene Corporation and are protected by United States copyright law and international copyright law. No part of this publication may be reproduced, copied, modified, distributed, displayed, stored in a retrieval system, transmitted in any form or by any means, or otherwise published without the prior written permission of Centene Corporation. You may not alter or remove any trademark, copyright or other notice contained herein. Centene[®] and Centene Corporation. The composition of the composition of the contained herein.