

## **Clinical Policy: Certolizumab (Cimzia)**

Reference Number: CP.PHAR.247

Effective Date: 08.16

Last Review Date: 05.20

Line of Business: Medicaid

[Coding Implications](#)

[Revision Log](#)

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

### **Description**

Certolizumab (Cimzia<sup>®</sup>) is a tumor necrosis factor (TNF) blocker.

### **FDA Approved Indication(s)**

Cimzia is indicated for:

- Reducing signs and symptoms of Crohn's disease (CD) and maintaining clinical response in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy
- Treatment of adults with moderately to severely active rheumatoid arthritis (RA)
- Treatment of adult patients with active psoriatic arthritis (PsA)
- Treatment of adults with active ankylosing spondylitis (AS)
- Treatment of adults with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation
- Treatment of adults with 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<sup>®</sup> that Cimzia is **medically necessary** when the following criteria are met:

#### **I. Initial Approval Criteria**

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

1. Diagnosis of CD;
2. Prescribed by or in consultation with a gastroenterologist;
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 at least ONE immunomodulator (e.g., azathioprine, 6-mercaptopurine [6-MP], methotrexate [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 D*);
5. Dose does not exceed 400 mg at weeks 0, 2, and 4, followed by maintenance dose of 400 mg every 4 weeks.

**Approval duration: 6 months**

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

1. Diagnosis of RA per American College of Rheumatology (ACR) criteria (*see Appendix E*);
2. Prescribed by or in consultation with a rheumatologist;
3. Age  $\geq$  18 years;
4. Member meets one of the following (a or b):
  - a. Failure of a  $\geq$  3 consecutive month trial of MTX at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
  - b. If intolerance or contraindication to MTX (*see Appendix D*), failure of a  $\geq$  3 consecutive month trial of at least ONE conventional disease-modifying anti-rheumatic 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 least TWO of the following, each used for  $\geq$  3 consecutive months, unless contraindicated or clinically significant adverse effects are experienced: Enbrel<sup>®</sup>, Kevzara<sup>®</sup>, Xeljanz<sup>®</sup>/Xeljanz XR<sup>®</sup>;  
*\*Prior authorization is required for Enbrel, Kevzara, and Xeljanz/Xeljanz XR*
6. Documentation of baseline clinical disease activity index (CDAI) score (*see Appendix F*);
7. Dose does not exceed 400 mg at weeks 0, 2, and 4, followed by maintenance dose of 400 mg every 4 weeks.

**Approval duration: 6 months**

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

1. Diagnosis of PsA;
2. Prescribed by or in consultation with a dermatologist or rheumatologist;
3. Age  $\geq$  18 years;
4. Failure of at least THREE of the following, each used for  $\geq$  3 consecutive months, unless contraindicated or clinically significant adverse effects are experienced: Enbrel<sup>®</sup>, Otezla<sup>®</sup>, Simponi<sup>®</sup>/Simponi Aria<sup>®</sup>, Taltz<sup>®</sup>, Xeljanz<sup>®</sup>/Xeljanz XR<sup>®</sup>;  
*\*Prior authorization is required for Enbrel, Otezla, Simponi/Simponi Aria, Taltz, Xeljanz/Xeljanz XR*
5. Dose does not exceed 400 mg at weeks 0, 2, and 4, followed by maintenance dose of 400 mg every 4 weeks.

**Approval duration: 6 months**

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

1. Diagnosis of AS or nr-axSpA;
2. Prescribed by or in consultation with a rheumatologist;
3. Age  $\geq$  18 years;
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 contraindicated or clinically significant adverse effects are experienced;
5. Dose does not exceed 400 mg at weeks 0, 2, and 4, followed by maintenance dose of 400 mg every 4 weeks.

**Approval duration: 6 months**

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

1. Diagnosis of PsO;
2. Prescribed by or in consultation with a dermatologist or rheumatologist;
3. Age  $\geq$  18 years;
4. Member meets one of the following (a or b):
  - a. Failure of a  $\geq$  3 consecutive month trial of MTX at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
  - b. If intolerance or contraindication to MTX (*see Appendix D*), failure of a  $\geq$  3 consecutive month trial of cyclosporine or acitretin at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
5. Failure of a  $\geq$  3 consecutive month trial of Taltz, unless contraindicated or clinically significant adverse effects are experienced;  
*\*Prior authorization is required for Taltz*
6. Dose does not exceed 400 mg every 2 weeks.

**Approval duration: 6 months**

**F. 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 or b):
  - a. For RA member is responding positively to therapy as evidenced by a decrease in CDAI score since baseline (*see Appendix F*);
  - b. For all other indications: member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed:
  - a. For CD, RA, PsA, AS, nr-axSpA: 400 mg every 4 weeks;
  - b. For PsO: 400 mg every 2 weeks.

**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.

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

6-MP: 6-mercaptopurine	nr-axSpA: non-radiographic axial spondyloarthritis
AS: ankylosing spondylitis	NSAID: non-steroidal anti-inflammatory drug
CD: Crohn’s disease	PsA: psoriatic arthritis
DMARD: disease-modifying antirheumatic drug	PsO: plaque psoriasis
FDA: Food and Drug Administration	RA: rheumatoid arthritis
MTX: methotrexate	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 <sup>®</sup> )	<b>PsO</b> 25 or 50 mg PO QD	50 mg/day
azathioprine (Azasan <sup>®</sup> , Imuran <sup>®</sup> )	<b>RA</b> 1 mg/kg/day PO QD or divided BID  <b>CD*</b> 1.5 – 2 mg/kg/day PO	2.5 mg/kg/day
corticosteroids	<b>CD*</b> prednisone 40 mg PO QD for 2 weeks or IV 50 – 100 mg Q6H for 1 week  budesonide (Entocort EC <sup>®</sup> ) 6 – 9 mg PO QD	Various
Cuprimine <sup>®</sup> (d-penicillamine)	<b>RA*</b> <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 <sup>®</sup> , Neoral <sup>®</sup> )	<b>RA, PsO</b> 2.5 – 4 mg/kg/day PO divided BID	4 mg/kg/day
hydroxychloroquine (Plaquenil <sup>®</sup> )	<b>RA*</b> <u>Initial dose:</u> 400 – 600 mg/day PO QD <u>Maintenance dose:</u> 200 – 400 mg/day PO QD	600 mg/day

<b>Drug Name</b>	<b>Dosing Regimen</b>	<b>Dose Limit/ Maximum Dose</b>
leflunomide (Arava <sup>®</sup> )	<b>RA</b> 100 mg PO QD for 3 days, then 20 mg PO QD	20 mg/day
6-mercaptopurine (Purixan <sup>®</sup> )	<b>CD*</b> 50 mg PO QD or 1 – 2 mg/kg/day PO	2 mg/kg/day
methotrexate (Rheumatrex <sup>®</sup> )	<b>CD*</b> 15 – 25 mg/week IM or SC  <b>RA</b> 7.5 mg/week PO, SC, or IM or 2.5 mg PO Q12 hr for 3 doses/week  <b>PsO</b> 10 to 25 mg/week, IM, IV or PO or 2.5 mg PO Q12 hr for 3 doses/week	30 mg/week
NSAIDs (e.g., indomethacin, ibuprofen, naproxen, celecoxib)	<b>AS, nr-axSpA</b> Varies	Varies
Pentasa <sup>®</sup> (mesalamine)	<b>CD</b> 1,000 mg PO QID	4 g/day
Ridaura <sup>®</sup> (auranofin)	<b>RA</b> 6 mg PO QD or 3 mg PO BID	9 mg/day (3 mg TID)
sulfasalazine (Azulfidine <sup>®</sup> )	<b>RA</b> 2 g/day PO in divided doses	3 g/day
tacrolimus (Prograf <sup>®</sup> )	<b>CD*</b> 0.27 mg/kg/day PO in divided doses or 0.15 – 0.29 mg/kg/day PO	N/A
Enbrel <sup>®</sup> (etanercept)	<b>PsA, RA</b> 25 mg SC twice weekly or 50 mg SC once weekly	50 mg/week
Kevzara <sup>®</sup> (sarilumab)	<b>RA</b> 200 mg SC once every two weeks	<b>200 mg/2 weeks</b>
Otezla <sup>®</sup> (apremilast)	<b>PsA</b> <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	60 mg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	<u>Maintenance dose:</u> Day 6 and thereafter: 30 mg PO BID	
Simponi <sup>®</sup> (golimumab)	<b>PsA</b> 50 mg SC once monthly	50 mg/month
Simponi Aria <sup>®</sup> (golimumab)	<b>PsA</b> <u>Initial dose:</u> 2 mg/kg IV at weeks 0 and 4 <u>Maintenance dose:</u> 2 mg/kg IV every 8 weeks	2 mg/kg every 8 weeks
Taltz <sup>®</sup> (ixekizumab)	<b>PsA</b> <u>Initial dose:</u> 160 mg (two 80 mg injections) SC at week 0 <u>Maintenance dose:</u> 80 mg SC every 4 weeks  <b>PsO</b> <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	80 mg every 4 weeks
Xeljanz <sup>®</sup> (tofacitinib)	<b>PsA, RA</b> 5 mg PO BID	10 mg/day
Xeljanz XR <sup>®</sup> (tofacitinib extended-release)	<b>PsA, RA</b> 11 mg PO QD	11 mg/day

Therapeutic alternatives are listed as Brand name<sup>®</sup> (generic) when the drug is available by brand name only and generic (Brand name<sup>®</sup>) when the drug is available by both brand and generic.

\*Off-label

*Appendix C: Contraindications/Boxed Warnings*

- Contraindication(s): none reported
- Boxed warning(s):
  - There is an increased risk of serious infections leading to hospitalization or death including tuberculosis (TB), bacterial sepsis, invasive fungal infections (such as histoplasmosis), and infections due to other opportunistic pathogens.
  - Lymphoma and other malignancies have been observed.
  - Epstein Barr Virus-associated post-transplant lymphoproliferative disorder has been observed.

*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
- Several AS treatment guidelines call for a trial of 2 or 3 NSAIDs prior to use of an anti-TNF agent. A two year trial showed that continuous NSAID use reduced radiographic progression of AS versus on demand use of NSAID.
- 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
- According to the CRADLE, a prospective, postmarketing, multicenter, pharmacokinetic study (n = 17), there were no or minimal certolizumab pegol transfer from the maternal plasma to breast milk, with a relative infant dose of 0.15% of the maternal dose.
- PsA: According to the 2018 American College of Rheumatology and National Psoriasis Foundation guidelines, TNF inhibitors or oral small molecules (e.g., methotrexate, sulfasalazine, cyclosporine, leflunomide, apremilast) are preferred over other biologics (e.g., interleukin-17 inhibitors or interleukin-12/23 inhibitors) for treatment-naïve disease. TNF inhibitors are also generally recommended over oral small molecules as first-line therapy unless disease is not severe, member prefers oral agents, or TNF inhibitor therapy is contraindicated.

*Appendix E: The 2010 ACR Classification Criteria for RA*

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

A	Joint involvement	Score
	1 large joint	0
	2-10 large joints	1
	1-3 small joints (with or without involvement of large joints)	2
	4-10 small joints (with or without involvement of large joints)	3
	> 10 joints (at least one small joint)	5
B	Serology (at least one test result is needed for classification)	
	Negative rheumatoid factor (RF) and negative anti-citrullinated protein antibody (ACPA)	0
	Low positive RF or low positive ACPA * Low: $< 3 \times$ upper limit of normal	2
	High positive RF or high positive ACPA * High: $\geq 3 \times$ upper limit of normal	3
C	Acute phase reactants (at least one test result is needed for classification)	
	Normal C-reactive protein (CRP) and normal erythrocyte sedimentation rate (ESR)	0
	Abnormal CRP or normal ESR	1
D	Duration of symptoms	
	< 6 weeks	0
	$\geq 6$ weeks	1

*Appendix F: 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
$\leq 2.8$	Remission
2.8 to $\leq 10$	Low disease activity
10 to $\leq 22$	Moderate disease activity
$> 22$	High disease activity

**V. Dosage and Administration**

Indication	Dosing Regimen	Maximum Dose
CD	<u>Initial dose:</u> 400 mg SC at 0, 2, and 4 weeks <u>Maintenance dose:</u> 400 mg SC every 4 weeks	400 mg every 4 weeks
RA, PsA, AS, nr-axSpA	<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



Indication	Dosing Regimen	Maximum Dose
PsO	400 mg SC every other week. For some patients (with body weight ≤ 90 kg), a dose of 400 mg SC at 0, 2 and 4 weeks, followed by 200 mg SC every other week may be considered.	400 mg every other week

## VI. Product Availability

- Single-use vial: 200 mg
- Single-use prefilled syringe: 200 mg/mL

## VII. References

1. Cimzia Prescribing Information. Smyrna, GA: UCB, Inc.; September 2019. Available at [http://www.cimzia.com/assets/pdf/Prescribing\\_Information.pdf](http://www.cimzia.com/assets/pdf/Prescribing_Information.pdf). Accessed February 28, 2020.
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11. Singh JA, Saag KG, Bridges SL, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Care and Research.* 2015; 1-25. DOI 10.1002/acr.22783.
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pharmacokinetic study. *Ann Rheum Dis* 2017;76:1980-1896. doi:10.1136/annrheumdis-2017-211384.

13. 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 Codes	Description
J0717	Injection, certolizumab pegol, 1 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 split from CP.PHAR.86.ArthritisTreatments, CP.PHAR.85 Psoriasis Treatment, CP.PHAR.87 IBD Treatment. CD, RA, PsA, AS: Removed criteria related to HBV, malignant disease, concomitant use with other biologics, and concurrent administration of live vaccines; added dosing requirement; added requirement for trial and failure of PDL Enbrel and Humira, unless contraindicated (just Humira for CD). PsA: required trial of MTX and added requirement for the following agents as an alternative if MTX cannot be used: leflunomide, cyclosporine, sulfasalazine, azathioprine. CD: removed aminosalicylate as an option for initial therapy. RA: changed age requirement to 18 years; modified criteria to require trial of MTX, unless contraindicated; added sulfasalazine and hydroxychloroquine as an alternative to MTX if MTX is contraindicated. Re-auth: combined into All Indications; added criteria for dosing and reasons to discontinue. Modified approval duration to 6 months for initial and 12 months for renewal. Shortened background section.	6.16	08.16
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; examples of extensive disease added. Safety criteria was applied according to the safety guidance discussed at CPAC and endorsed by Centene Medical Affairs.	08.17	08.17
2Q 2018 annual review: added HIM; removed specific diagnosis requirements for CD; modified specialist requirement to any GI specialist for CD; removed TB testing for all indications; modified	02.27.18	05.18

Reviews, Revisions, and Approvals	Date	P&T Approval Date
trial and failure for RA to at least one conventional DMARD; references reviewed and updated.		
4Q 2018 annual review: criteria added for new FDA indication: plaque psoriasis; modified prescriber specialist from GI specialist to gastroenterologist for CD; 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	02.19
2Q 2019 annual review: removed trial and failure requirement of conventional DMARDs (e.g., MTX)/NSAIDs for biologic DMARDs for PsA per ACR/NPF 2018 guidelines; references reviewed and updated.	03.05.19	05.19
Criteria added for new FDA indication: non-radiographic axial spondyloarthritis; references reviewed and updated.	05.21.19	08.19
Removed HIM line of business; updated preferred redirections based on SDC recommendation and prior clinical guidance: for RA: removed redirection to adalimumab, added redirection to 2 of 3 (Enbrel, Kevzara and Xeljanz/Xeljanz XR); for PsA, changed redirection from 2 agents (adalimumab and etanercept) to 3 of 5 (Enbrel, Simponi, Taltz, Otezla, Xeljanz/Xeljanz XR); for PsO, removed redirection to adalimumab and added redirection to Taltz; for CD, removed redirection to adalimumab; for AS, removed redirection to etanercept and adalimumab.	12.13.19	
2Q 2020 annual review: for RA, added specific diagnostic criteria for definite RA, baseline CDAI score requirement, and decrease in CDAI score as positive response to therapy; references reviewed and updated.	04.23.20	05.20

**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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