Clinical Policy: Certolizumab (Cimzia)
Reference Number: CP.PHAR.247
Effective Date: 08.16
Last Review Date: 05.19
Line of Business: HIM, Medicaid

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

Description
Certolizumab (Cimzia®) 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 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 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 ≥ 18 years;
      4. Member meets one of the following (a or b):
         a. Failure of a ≥ 3 consecutive month trial of at least ONE immunomodulator (e.g., azathioprine, 6-mercaptopurine [6-MP], 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. Failure of a ≥ 3 consecutive month trial of adalimumab (Humira® is preferred) unless contraindicated or clinically significant adverse effects are experienced;

*Prior authorization is required for adalimumab
6. 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;
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 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 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 etanercept (*Enbrel is preferred) and adalimumab (*Humira is preferred), each used for ≥ 3 consecutive months, unless contraindicated or clinically significant adverse effects are experienced;
   *Prior authorization is required for etanercept and adalimumab
6. 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 ≥ 18 years;
4. Failure of etanercept (*Enbrel is preferred) and adalimumab (*Humira is preferred), each used for ≥ 3 consecutive months, unless contraindicated or clinically significant adverse effects are experienced;
   *Prior authorization is required for etanercept and adalimumab
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. Ankylosing Spondylitis (must meet all):
1. Diagnosis of AS;
2. Prescribed by or in consultation with a rheumatologist;
3. Age ≥ 18 years;
4. Failure of at least TWO non-steroidal anti-inflammatory drugs (NSAIDs) at up to maximally indicated doses, each used for ≥ 4 weeks unless contraindicated or clinically significant adverse effects are experienced;
5. Failure of etanercept (*Enbrel is preferred) and adalimumab (*Humira is preferred), each used for ≥ 3 consecutive months, unless contraindicated or clinically significant adverse effects are experienced;
*Prior authorization is required for etanercept and adalimumab

6. 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 ≥ 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, 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 cyclosporine or acitretin at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
   5. Failure of a ≥ 3 consecutive month trial of adalimumab (*Humira is preferred*), unless contraindicated or clinically significant adverse effects are experienced;
   
*Prior authorization is required for adalimumab

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): HIM.PHAR.21 for health insurance marketplace and CP.PMN.53 for Medicaid.

II. **Continued Therapy**
   A. **All Indications in Section I** (must meet all):
      1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
      2. Member is responding positively to therapy;
      3. If request is for a dose increase, new dose does not exceed:
         a. For CD, RA, PsA, AS: 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): HIM.PHAR.21 for health insurance marketplace and CP.PMN.53 for Medicaid.
III. Diagnoses/Indications for which coverage is NOT authorized:
   A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – HIM.PHAR.21 for health insurance marketplace and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
6-MP: 6-mercaptopurine  MTX: methotrexate
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
  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.

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
<th>Dose Limit/Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>acitretin (Soriatane®)</td>
<td>PsO 25 or 50 mg PO QD</td>
<td>50 mg/day</td>
</tr>
<tr>
<td>azathioprine (Azasan®, Imuran®)</td>
<td>RA 1 mg/kg/day PO QD or divided BID</td>
<td>2.5 mg/kg/day</td>
</tr>
<tr>
<td></td>
<td>CD* 1.5 – 2 mg/kg/day PO</td>
<td></td>
</tr>
<tr>
<td>corticosteroids</td>
<td>CD* prednisone 40 mg PO QD for 2 weeks or IV 50 – 100 mg Q6H for 1 week</td>
<td>Various</td>
</tr>
<tr>
<td></td>
<td>budesonide (Entocort EC®) 6 – 9 mg PO QD</td>
<td></td>
</tr>
<tr>
<td>Cuprimine® (d-penicillamine)</td>
<td>RA* Initial dose: 125 or 250 mg PO QD</td>
<td>1,500 mg/day</td>
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<tr>
<td></td>
<td>Maintenance dose: 500 – 750 mg/day PO QD</td>
<td></td>
</tr>
<tr>
<td>cyclosporine (Sandimmune®, Neoral®)</td>
<td>RA, PsO 2.5 – 4 mg/kg/day PO divided BID</td>
<td>4 mg/kg/day</td>
</tr>
<tr>
<td>hydroxychloroquine (Plaquinil®)</td>
<td>RA* Initial dose: 400 – 600 mg/day PO QD</td>
<td>600 mg/day</td>
</tr>
<tr>
<td>Drug Name</td>
<td>Dosing Regimen</td>
<td>Dose Limit/Maximum Dose</td>
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<tr>
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</tr>
<tr>
<td><strong>Certolizumab</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Drug Name</strong></td>
<td><strong>Dosing Regimen</strong></td>
<td><strong>Dose Limit/Maximum Dose</strong></td>
</tr>
<tr>
<td><strong>Maintenance dose:</strong></td>
<td>200 – 400 mg/day PO QD</td>
<td></td>
</tr>
<tr>
<td>leflunomide (Arava®)</td>
<td>RA</td>
<td>20 mg/day</td>
</tr>
<tr>
<td>100 mg PO QD for 3 days, then 20 mg PO QD</td>
<td></td>
<td></td>
</tr>
<tr>
<td>50 mg PO QD or 1 – 2 mg/kg/day PO</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6-mercaptopurine (Purixan®)</td>
<td>CD*</td>
<td>2 mg/kg/day</td>
</tr>
<tr>
<td>methotrexate (Rheumatrex®)</td>
<td>CD*</td>
<td>30 mg/week</td>
</tr>
<tr>
<td>CD*</td>
<td>15 – 25 mg/week IM or SC</td>
<td></td>
</tr>
<tr>
<td>RA</td>
<td>7.5 mg/week PO, SC, or IM or 2.5 mg PO Q12 hr for 3 doses/week</td>
<td></td>
</tr>
<tr>
<td>PsO</td>
<td>10 to 25 mg/week, IM, IV or PO or 2.5 mg PO Q12 hr for 3 doses/week</td>
<td></td>
</tr>
<tr>
<td>NSAIDs (e.g., indomethacin, ibuprofen, naproxen, celecoxib)</td>
<td>AS</td>
<td>Varies</td>
</tr>
<tr>
<td>2 g/day PO in divided doses</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pentasa® (mesalamine)</td>
<td>CD</td>
<td>4 g/day</td>
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<tr>
<td>1,000 mg PO QID</td>
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<tr>
<td>Ridaura® (auranofin)</td>
<td>RA</td>
<td>9 mg/day (3 mg TID)</td>
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<tr>
<td>6 mg PO QD or 3 mg PO BID</td>
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<td></td>
</tr>
<tr>
<td>sulfasalazine (Azulfidine®)</td>
<td>RA</td>
<td>3 g/day</td>
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<tr>
<td>2 g/day PO in divided doses</td>
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<td></td>
</tr>
<tr>
<td>tacrolimus (Prograf®)</td>
<td>CD*</td>
<td>N/A</td>
</tr>
<tr>
<td>0.27 mg/kg/day PO in divided doses or 0.15 – 0.29 mg/kg/day PO</td>
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<tr>
<td>Enbrel® (etanercept)</td>
<td>AS</td>
<td>50 mg/week</td>
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<tr>
<td>50 mg SC once weekly</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PsA, RA</td>
<td>25 mg SC twice weekly or 50 mg SC once weekly</td>
<td></td>
</tr>
<tr>
<td>Humira® (adalimumab)</td>
<td>AS, PsA, PsO</td>
<td>AS, PsA, CD, PsO: 40 mg every other week</td>
</tr>
<tr>
<td>40 mg SC every other week</td>
<td></td>
<td>RA: 40 mg/week</td>
</tr>
<tr>
<td>CD</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Initial dose:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Drug Name</td>
<td>Dosing Regimen</td>
<td>Dose Limit/Maximum Dose</td>
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<tr>
<td></td>
<td>160 mg SC on Day 1, then 80 mg SC on Day 15</td>
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<td></td>
<td>Maintenance dose:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>40 mg SC every other week starting on Day 29</td>
<td></td>
</tr>
<tr>
<td>RA</td>
<td>40 mg SC every other week (may increase to once weekly)</td>
<td></td>
</tr>
</tbody>
</table>

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):
  - 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.

### V. Dosage and Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>CD</td>
<td>Initial dose: 400 mg SC at 0, 2, and 4 weeks&lt;br&gt;Maintenance dose: 400 mg SC every 4 weeks</td>
<td>400 mg every 4 weeks</td>
</tr>
<tr>
<td>RA</td>
<td>Initial dose: 400 mg SC at 0, 2, and 4 weeks</td>
<td>400 mg every 4 weeks</td>
</tr>
<tr>
<td>PsA</td>
<td>Maintenance dose: 200 mg SC every other week (or 400 mg SC every 4 weeks)</td>
<td>400 mg every 4 weeks</td>
</tr>
<tr>
<td>AS</td>
<td>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.</td>
<td>400 mg every other week</td>
</tr>
<tr>
<td>PsO</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### VI. Product Availability
- Single-use vial: 200 mg
- Single-use prefilled syringe: 200 mg/mL

### VII. References


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.

<table>
<thead>
<tr>
<th>HCPSC Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>J0717</td>
<td>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)</td>
</tr>
</tbody>
</table>
### Reviews, Revisions, and Approvals

<table>
<thead>
<tr>
<th>Event Description</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td>6.16</td>
<td>08.16</td>
</tr>
<tr>
<td>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.</td>
<td>08.17</td>
<td>08.17</td>
</tr>
<tr>
<td>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 trial and failure for RA to at least one conventional DMARD; references reviewed and updated.</td>
<td>02.27.18</td>
<td>05.18</td>
</tr>
<tr>
<td>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.</td>
<td>09.04.18</td>
<td>02.19</td>
</tr>
<tr>
<td>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.</td>
<td>03.05.19</td>
<td>05.19</td>
</tr>
</tbody>
</table>

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program.
approval status; evidence-based guidelines and positions of leading national health professional
organizations; views of physicians practicing in relevant clinical areas affected by this clinical
policy; and other available clinical information. The Health Plan makes no representations and
accepts no liability with respect to the content of any external information used or relied upon in
developing this clinical policy. This clinical policy is consistent with standards of medical
practice current at the time that this clinical policy was approved. “Health Plan” means a health
plan that has adopted this clinical policy and that is operated or administered, in whole or in part,
by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a
component of the guidelines used to assist in making coverage decisions and administering
benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage
decisions and the administration of benefits are subject to all terms, conditions, exclusions and
limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy,
contract of insurance, etc.), as well as to state and federal requirements and applicable Health
Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting
may not be the effective date of this clinical policy. This clinical policy may be subject to
applicable legal and regulatory requirements relating to provider notification. If there is a
discrepancy between the effective date of this clinical policy and any applicable legal or
regulatory requirement, the requirements of law and regulation shall govern. The Health Plan
retains the right to change, amend or withdraw this clinical policy, and additional clinical
policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is
not intended to dictate to providers how to practice medicine. Providers are expected to exercise
professional medical judgment in providing the most appropriate care, and are solely responsible
for the medical advice and treatment of members. This clinical policy is not intended to
recommend treatment for members. Members should consult with their treating physician in
connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent
judgment and over whom the Health Plan has no control or right of control. Providers are not
agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and
distribution of this clinical policy or any information contained herein are strictly prohibited.
Providers, members and their representatives are bound to the terms and conditions expressed
herein through the terms of their contracts. Where no such contract exists, providers, members
and their representatives agree to be bound by such terms and conditions by providing services to
members and/or submitting claims for payment for such services.
Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

For Health Insurance Marketplace members, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the formulary exception policy; HIM.PA.103.

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