Clinical Policy: Abatacept (Orencia)
Reference Number: CP.PHAR.241
Effective Date: 08.16
Last Review Date: 02.21
Line of Business: Medicaid

See Important Reminder 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: Orencia should not be administered concomitantly with TNF antagonists. Orencia is not recommended for use concomitantly with other biologic RA therapy, such as anakinra.

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 ≥ 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 ≥ 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 sacroiliitis/axial spine involvement (i.e., spine, hip), failure of a ≥ 4 week trial of an NSAID at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;

d. Documented presence of high disease activity as evidenced by a cJADAS-10 > 8.5 (see Appendix J);

6. Failure of both of the following, each used for ≥ 3 consecutive months, unless clinically significant adverse effects are experienced or both are contraindicated:

   Enbrel, Xeljanz;

   *Prior authorization is required for Enbrel and Xeljanz

7. For members 2 to 5 years of age, prescribed route of administration is SC;

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 < 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 ≥ 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 ≥ 18 years;
   4. Failure of at least THREE of the following, each used for ≥ 3 consecutive months, unless contraindicated or clinically significant adverse effects are experienced:

      Enbrel, Otezla®, Simponi®/Simponi Aria®, Taltz®, Xeljanz/Xeljanz XR;

   *Prior authorization is required for Enbrel, Otezla, Simponi/Simponi Aria, Taltz, Xeljanz/Xeljanz XR

5. 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 ≥ 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
dooses, 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
dooses, unless contraindicated or clinically significant adverse effects are
experienced;
5. Failure of at least TWO of the following, each used for ≥ 3 consecutive months,
   unless contraindicated or clinically significant adverse effects are experienced:
   Enbrel®, Kevzara®, Xeljanz®/Xeljanz XR®;
   *Prior authorization is required for Enbrel, Kevzara, and Xeljanz/Xeljanz XR
6. Documentation of one of the following baseline assessment scores (a or b):
   a. Clinical disease activity index (CDAI) score (see Appendix H);
   b. Routine assessment of patient index data 3 (RAPID3) score (see Appendix I);
7. Dose does not exceed 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;
         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 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 ≥ 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.

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.

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
<th>Dose Limit/Maximum Dose</th>
</tr>
</thead>
<tbody>
<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>
</tbody>
</table>
| Cuprimine® (d-penicillamine)       | RA* Initial dose: 125 or 250 mg PO QD  
                                           Maintenance dose: 500 – 750 mg/day PO QD | 1,500 mg/day           |
| cyclosporine (Sandimmune®, Neoral®) | RA 2.5 – 4 mg/kg/day PO divided BID                  | 4 mg/kg/day             |
| 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            |
| Enbrel® (etanercept)              | PJIA Weight < 63 kg: 0.8 mg/kg SC once weekly  
                                           Weight ≥ 63 kg: 50 mg SC once weekly | 50 mg/week            |
### Drug Name | Dosing Regimen | Dose Limit/Maximum Dose
---|---|---
**PsA, RA**<br>25 mg SC twice weekly or 50 mg SC once weekly | Kevzara®<br>(sarilumab)<br>RA<br>200 mg SC once every two weeks | 200 mg/2 weeks

**PsA**<br>Initial dose:<br>Day 1: 10 mg PO QAM<br>Day 2: 10 mg PO QAM and 10 mg PO QPM<br>Day 3: 10 mg PO QAM and 20 mg PO QPM<br>Day 4: 20 mg PO QAM and 20 mg PO QPM<br>Day 5: 20 mg PO QAM and 30 mg PO QPM<br>Maintenance dose:<br>Day 6 and thereafter: 30 mg PO BID | Otezla®<br>(apremilast)<br>PsA<br>60 mg/day

**PsA**<br>50 mg SC once monthly | Simponi®<br>(golimumab)<br>PsA | 50 mg/month

**PsA**<br>Initial dose:<br>2 mg/kg IV at weeks 0 and 4<br>Maintenance dose:<br>2 mg/kg IV every 8 weeks | Simponi Aria®<br>(golimumab)<br>PsA | 2 mg/kg every 8 weeks

**PsA**<br>Initial dose: 160 mg (two 80 mg injections) SC at week 0<br>Maintenance dose: 80 mg SC every 4 weeks | Taltz | 80 mg every 4 weeks

**PsA, RA**<br>5 mg PO BID | Xeljanz®<br>(tofacitinib) | 10 mg/day

**PsA, RA**<br>11 mg PO QD | Xeljanz XR®<br>(tofacitinib extended-release) | 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:
- Reduction in joint pain/swelling/tenderness
- Improvement in ESR/CRP levels
- Improvements in activities of daily living

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

<table>
<thead>
<tr>
<th>Weight-based Dose Range</th>
<th>Vial Quantity Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤ 262.49 mg</td>
<td>1 vial of 250 mg</td>
</tr>
<tr>
<td>262.50 mg to 524.99 mg</td>
<td>2 vials of 250 mg</td>
</tr>
<tr>
<td>525 to 787.49 mg</td>
<td>3 vials of 250 mg</td>
</tr>
<tr>
<td>787.50 mg to 1,049.99 mg</td>
<td>4 vials of 250 mg</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Weight-based Dose Range</th>
<th>Prefilled Syringe Quantity Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 to 24.99 kg</td>
<td>1 syringe of 50 mg/0.4 mL</td>
</tr>
<tr>
<td>25 to 49.99 kg</td>
<td>1 syringe of 87.5 mg/0.7 mL</td>
</tr>
<tr>
<td>&gt; 50 kg</td>
<td>1 syringe of 125 mg/mL</td>
</tr>
</tbody>
</table>

### Appendix G: The 2010 ACR Classification Criteria for RA

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

<table>
<thead>
<tr>
<th>A Joint involvement</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 large joint</td>
<td>0</td>
</tr>
<tr>
<td>2-10 large joints</td>
<td>1</td>
</tr>
<tr>
<td>1-3 small joints (with or without involvement of large joints)</td>
<td>2</td>
</tr>
<tr>
<td>4-10 small joints (with or without involvement of large joints)</td>
<td>3</td>
</tr>
<tr>
<td>&gt; 10 joints (at least one small joint)</td>
<td>5</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>B Serology (at least one test result is needed for classification)</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative rheumatoid factor (RF) and negative anti-citrullinated protein antibody (ACPA)</td>
<td>0</td>
</tr>
<tr>
<td>Low positive RF or low positive ACPA *Low: &lt; 3 x upper limit of normal</td>
<td>2</td>
</tr>
<tr>
<td>High positive RF or high positive ACPA *High: ≥ 3 x upper limit of normal</td>
<td>3</td>
</tr>
</tbody>
</table>
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.

<table>
<thead>
<tr>
<th>CDAI Score</th>
<th>Disease state interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤ 2.8</td>
<td>Remission</td>
</tr>
<tr>
<td>2.8 to ≤ 10</td>
<td>Low disease activity</td>
</tr>
<tr>
<td>10 to ≤ 22</td>
<td>Moderate disease activity</td>
</tr>
<tr>
<td>&gt; 22</td>
<td>High disease activity</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>RAPID3 Score</th>
<th>Disease state interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤ 3</td>
<td>Remission</td>
</tr>
<tr>
<td>3.1 to 6</td>
<td>Low disease activity</td>
</tr>
<tr>
<td>6.1 to 12</td>
<td>Moderate disease activity</td>
</tr>
<tr>
<td>&gt; 12</td>
<td>High disease activity</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>cJADAS-10</th>
<th>Disease state interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤ 1</td>
<td>Inactive disease</td>
</tr>
<tr>
<td>1.1 to 2.5</td>
<td>Low disease activity</td>
</tr>
<tr>
<td>2.51 to 8.5</td>
<td>Moderate disease activity</td>
</tr>
</tbody>
</table>
V. Dosage and Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
</tr>
</thead>
</table>
| RA         | IV: weight-based dose at weeks 0, 2, and 4, followed by every 4 weeks  
Weight < 60 kg: 500 mg per dose  
Weight 60 to 100 kg: 750 mg per dose  
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) | IV: 1,000 mg every 4 weeks  
SC: 125 mg/week |
| PsA        | IV: weight-based dose at weeks 0, 2, and 4, followed by every 4 weeks  
Weight < 75 kg: 10 mg/kg per dose  
Weight 75 to 100 kg: 750 mg per dose  
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 ≥ 50 kg: 125 mg per dose | IV: 1,000 mg every 4 weeks  
SC: 125 mg/week |
| PJIA       | IV: weight-based dose at weeks 0, 2, and 4, followed by every 4 weeks  
Weight < 60 kg: 500 mg per dose  
Weight 60 to 100 kg: 750 mg per dose  
Weight > 100 kg: 1,000 mg per dose  
SC: 125 mg/week | SC: 125 mg/week |

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 ClickJect™ autoinjector for SC injection: 125 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>HCPCS Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>J0129</td>
<td>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)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Reviews, Revisions, and Approvals</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Added new indication for PsA&lt;br&gt;Revised criteria for confirmation of RA diagnosis per 2010 ACR Criteria. Removed safety requirements per updated CPAC Safety Precaution in PA Policies approach.</td>
<td>07.17</td>
<td>11.17</td>
</tr>
<tr>
<td>2Q 2018 annual review: added HIM; added rheumatologist specialist requirement for RA; removed TB testing from RA and PJIA; revised dosing in initial and continuation approval criteria for PJIA per package insert; references reviewed and updated.</td>
<td>02.27.18</td>
<td>05.18</td>
</tr>
<tr>
<td>4Q 2018 annual review: allowed bypassing conventional DMARDs for axial PsA and required trial of NSAIDs; references reviewed and updated.</td>
<td>08.28.18</td>
<td>11.18</td>
</tr>
<tr>
<td>2Q 2019 annual review: removed trial and failure requirement of conventional DMARDs (e.g., MTX)/NSAIDs for PsA per ACR/NPF 2018 guidelines; references reviewed and updated.</td>
<td>03.05.19</td>
<td>05.19</td>
</tr>
<tr>
<td>Removed HIM line of business; updated preferred redirections based on SDC recommendation and prior clinical guidance: for PJIA, removed adalimumab; 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, Talktz, Otezla, Xeljanz/Xeljanz XR).</td>
<td>12.13.19</td>
<td></td>
</tr>
<tr>
<td>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; added rounding guidelines for weight-based dosing for all indications; references reviewed and updated.</td>
<td>04.23.20</td>
<td>05.20</td>
</tr>
</tbody>
</table>
### Reviews, Revisions, and Approvals

| Revised typo in Appendix E from “normal ESR” to “abnormal ESR” for a point gained for ACR Classification Criteria. | 11.22.20 |
| Updated pJIA criteria to require diagnosis as evidenced by ≥ 5 joints, cJADAS assessment, and redirection to Enbrel and Xeljanz per SDC. Additionally, updated criteria to allow tiered redirection or bypass of MTX in the event of sacroiliitis or high disease activity. Added criteria for RAPID3 assessment for RA given limited in-person visits during COVID-19 pandemic, updated appendices. | 11.24.20 02.21 |

### 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.