Clinical Policy: Olaratumab (Lartruvo)
Reference Number: CP.PHAR.326
Effective Date: 03.01.17
Last Review Date: 11.18
Line of Business: Medicaid, HIM-Medical Benefit

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

Description
Olaratumab (Lartruvo®) is a platelet-derived growth factor receptor alpha (PDGFR-α) blocking antibody.

FDA Approved Indication(s)
Lartruvo is indicated in combination with doxorubicin for the treatment of adult patients with soft tissue sarcoma (STS) with a histologic subtype for which an anthracycline-containing regimen is appropriate and which is not amenable to curative treatment with radiotherapy or surgery.

Limitation(s) of use: This indication is approved under accelerated approval. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trial.

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 Lartruvo is medically necessary when the following criteria are met:

I. Initial Approval Criteria
   A. Soft Tissue Sarcoma (must meet all):
      1. Diagnosis of STS or uterine sarcoma;
      2. Prescribed by or in consultation with an oncologist;
      3. Age ≥ 18 years;
      4. Prescribed in combination with doxorubicin;
      5. Request meets one of the following (a or b):
         a. Dose does not exceed 15 mg/kg on Days 1 and 8 of each 21-day cycle;
         b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

      Approval duration: 6 months

   B. 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
II. Continued Therapy
   A. Soft Tissue Sarcoma (must meet all):
      1. Currently receiving medication via Centene benefit, or documentation supports that
         member is currently receiving Lartruvo for a covered indication and has received this
         medication for at least 30 days;
      2. Member is responding positively to therapy;
      3. If request is for a dose increase, request meets one of the following (a or b):
         a. New dose does not exceed 15 mg/kg on Days 1 and 8 of each 21-day cycle;
         b. New dose is supported by practice guidelines or peer-reviewed literature for the
            relevant off-label use (prescriber must submit supporting evidence).
   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
   FDA: Food and Drug Administration
   NCCN: National Comprehensive Cancer Network
   PDGFR-α: platelet-derived growth factor receptor alpha
   STS: soft tissue sarcoma

   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>doxorubicin HCL (Adriamycin®)</td>
<td>Labeled dosing regimen for metastatic STS:</td>
<td>Varies</td>
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<tr>
<td></td>
<td>• As a single agent: 60 to 75 mg/m² IV every 21 days.</td>
<td></td>
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</tbody>
</table>
### CLINICAL POLICY

**Olaratumab**

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
<th>Dose Limit/Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• In combination with other chemotherapy drugs: 40 to 75 mg/m² IV every 21 to 28 days. • Consider use of the lower doxorubicin dose in the recommended dose range or longer intervals between cycles for heavily pretreated patients, elderly patients, or obese patients. • Cumulative doses above 550 mg/m² are associated with an increased risk of cardiomyopathy.</td>
<td>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.</td>
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</tbody>
</table>

**Appendix C: Contraindications/Black Box Warnings**

None reported.

**Appendix D: STS Subtypes**

- Sarcomas are divided into STS and sarcomas of bone.
- More than 50 STS histologic subtypes have been identified. Common subtypes include undifferentiated sarcoma, gastrointestinal stromal tumor, liposarcoma, and leiomyosarcoma.
- The most common anatomic STS locations are extremities, trunk, visceral, retroperitoneum, and head and neck. Rhabdomyosarcoma is the most common STS of children and adolescents and is less common in adults.
- NCCN recommends Lartruvo in combination with doxorubicin for use in STS histologies for which an anthracycline-containing regimen is appropriate (e.g., non-specific subtypes, non-pleomorphic rhabdomyosarcoma, desmoid tumors (aggressive fibromatosis)).
- NCCN also recommends Lartruvo in combination with doxorubicin for extremity, superficial trunk, and head/neck STS, retroperitoneal and intra-abdominal STS, angiosarcoma, and uterine sarcoma (e.g., endometrial stromal sarcomas, leiomyosarcoma, adenosarcoma).

**V. Dosage and Administration**

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
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</thead>
<tbody>
<tr>
<td>STS</td>
<td>15 mg/kg IV over 60 minutes on Days 1 and 8 of each 21-day cycle until disease progression or unacceptable toxicity. For first 8 cycles, Lartruvo is administered with doxorubicin. Refer to doxorubicin prescribing information for dosing, and dose modifications.</td>
<td>15 mg/kg per infusion</td>
</tr>
</tbody>
</table>

**VI. Product Availability**

Single-dose vial: 500 mg/50 mL, 190 mg/19 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>
<th>Date</th>
<th>P&amp;T Approval Date</th>
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<tr>
<td>J9285</td>
<td>Injection, olaratumab, 10 mg</td>
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**Reviews, Revisions, and Approvals**

<table>
<thead>
<tr>
<th>Date</th>
<th>P&amp;T Approval Date</th>
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<tbody>
<tr>
<td>02.17</td>
<td>03.17</td>
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<tr>
<td>08.30.17</td>
<td>11.17</td>
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<tr>
<td>08.07.18</td>
<td>11.18</td>
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**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.