

## **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

[Coding Implications](#)

[Revision Log](#)

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

### **Description**

Olaratumab (Lartruvo<sup>®</sup>) is a platelet-derived growth factor receptor alpha (PDGFR- $\alpha$ ) 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<sup>®</sup> 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  $\geq$  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

NOT authorized): HIM.PHAR.21 for health insurance marketplace and CP.PMN.53 for Medicaid.

**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- $\alpha$ : 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.*

Drug Name	Dosing Regimen	Dose Limit/Maximum Dose
doxorubicin HCL (Adriamycin®)	Labeled dosing regimen for metastatic STS: <ul style="list-style-type: none"> <li>• As a single agent: 60 to 75 mg/m<sup>2</sup> IV every 21 days.</li> </ul>	Varies

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	<ul style="list-style-type: none"> <li>In combination with other chemotherapy drugs: 40 to 75 mg/m<sup>2</sup> IV every 21 to 28 days.</li> <li>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.</li> <li>Cumulative doses above 550 mg/m<sup>2</sup> are associated with an increased risk of cardiomyopathy.</li> </ul>	

*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.*

*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**

Indication	Dosing Regimen	Maximum Dose
STS	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.	15 mg/kg per infusion

**VI. Product Availability**

Single-dose vial: 500 mg/50 mL, 190 mg/19 mL

**VII. References**

1. Lartruvo Prescribing Information. Indianapolis, IN: Eli Lilly and Company; February 2017. Available at <http://pi.lilly.com/us/lartruvo-uspi.pdf>. Accessed July 19, 2018.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: [http://www.nccn.org/professionals/drug\\_compendium](http://www.nccn.org/professionals/drug_compendium). Accessed July 19, 2018.
3. National Comprehensive Cancer Network. Soft tissue sarcoma. Version 2.2018. Available at: [http://www.nccn.org/professionals/physician\\_gls/pdf/nscl.pdf](http://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf). Accessed July 19, 2018.
4. National Comprehensive Cancer Network. Uterine neoplasms. Version 2.2018. Available at: [http://www.nccn.org/professionals/physician\\_gls/pdf/nscl.pdf](http://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf). Accessed July 19, 2018.
5. Doxorubicin Prescribing Information. New York, NY: Pfizer, Inc. October 2013. Available at [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2013/050629s022lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/050629s022lbl.pdf). Accessed July 19, 2018.
6. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2018. Available at: <http://www.clinicalpharmacology-ip.com/>.

**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
J9285	Injection, olaratumab, 10 mg

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy split from CP.PHAR.182 Excellus Oncology. NCCN off-label recommended uses added.	02.17	03.17
Policy converted to new template. Safety criteria was applied according to the safety guidance discussed at CPAC and endorsed by Centene Medical Affairs. Added criteria for NCCN 2A and above recommended off-label use: Uterine sarcoma. Authorization limits extended from 3 and 6 months to 6 and 12 months for initial and continued approval, respectively.	08.30.17	11.17
4Q 2018 annual review: no significant changes; NCCN and FDA-approved uses summarized for improved clarity; specialist involvement in care and continuation of care added; references reviewed and updated.	08.07.18	11.18

**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

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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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