Clinical Policy: Olaratumab (Lartruvo)

Reference Number: CP.PHAR.326
Effective Date: 03.01.17
Last Review Date: 11.17
Line of Business: Medicaid

Revision Log

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 (which may include office chart notes and lab results) 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*;
  2. Prescribed in combination with doxorubicin;
  3. Meets a or b:
     a. FDA-approved use (i and ii):
        i. STS histologic subtype** is amenable to an anthracycline-containing regimen (e.g., a regimen containing doxorubicin or epirubicin);
        ii. STS is not amenable to curative treatment with radiation or surgery;
     b. Off-label NCCN recommended use (i, ii, iii, or iv):
        i. Angiosarcoma;
        ii. Pleomorphic rhabdomyosarcoma:
        iii. Retroperitoneal/intraabdominal STS (1, 2, or 3):
           1) As preoperative chemotherapy for resectable disease;

2) As primary chemotherapy or chemoradiation for attempted downstaging of unresectable, recurrent, or metastatic disease;
3) As palliative therapy for unresectable or progressive disease;

iv. Extremity/superficial trunk or head/neck STS (1, 2, or 3):
1) As chemotherapy following regional node dissection;
2) As a treatment before or after metastasectomy for single-organ confined, limited tumor bulk synchronous stage IV or recurrent disease that is amenable to local therapy or for recurrent isolated regional disease or isolated regional lymph nodes;
3) As palliative chemotherapy for synchronous stage IV or recurrent disease with disseminated metastases for which an anthracycline-containing regimen is appropriate;

4. 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*).

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**More than 50 STS histologic subtypes have been identified. Different subtypes have different propensities to spread to different locations. Location, histology and other variables are considerations around which therapy is organized.*

***STS histologic subtypes that may be amenable to anthracycline-containing regimens include, but are not limited to, 1) non-specific histologies, 2) non-pleomorphic rhabdomyosarcoma, 3) desmoid tumors (aggressive fibromatosis).*

Approval duration: 6 months

B. Uterine Sarcoma (off-label) (must meet all)**:**
1. Diagnosis of uterine sarcoma;
2. Use is in combination with doxorubicin for one of the following:
   a. Disease that is not suitable for primary surgery;
   b. Following total hysterectomy for stage II or III disease;
   c. Following total hysterectomy with or without bilateral salpingo-oophorectomy (TH ± BSO) for stage IV disease;
   d. For a radiologically isolated vaginal/pelvic recurrence;
   e. For extrapelvic recurrence with no prior radiation therapy;
   f. For isolated or disseminated metastases;
3. 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

C. Other diagnoses/indications
1. Refer to CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 (e.g., no disease progression, no significant toxicity);
3. If request is for a dose increase, request meets one of the following (a or b):
   a. For STS only: New dose does not exceed 15 mg/kg on Days 1 and 8 of each 21-day cycle;
   b. For STS or uterine sarcoma: 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 CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 policy – CP.PHAR.57 evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration
NCCN: National Comprehensive Cancer Network
STS: soft tissue sarcoma

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
STS	Administer 15 mg/kg IV over 60 minutes on Days 1 and 8 of each 21-day cycle until disease progression or unacceptable toxicity	See dosing regimen

VI. Product Availability

Single-dose vials: 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 August 30, 2017.
2. Olaratumab. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at NCCN.org. Accessed August 30, 2017.

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

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.