Clinical Policy: Olaratumab (Lartruvo)

Reference Number: CP.PHAR.326
Effective Date: 03/17
Last Review Date: 03/17

Coding Implications
Revision Log

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

Description
The intent of the criteria is to ensure that patients follow selection elements established by Centene® clinical policy for olaratumab for injection (Lartruvo™).

Policy/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 soft tissue sarcoma (STS)*;
2. Meets a or b:
   a. FDA approved use (must meet all):
      i. Prescribed in combination with doxorubicin;
      ii. STS histologic subtype** is amenable to an anthracycline-containing regimen (e.g., a regimen containing doxorubicin or epirubicin);
      iii. STS is not amenable to curative treatment with radiation or surgery;
   b. Off-label NCCN recommended use:
      i. Prescribed in combination with doxorubicin for any of the following STS tumors:
         a) Angiosarcoma;
         b) Pleomorphic rhabdomyosarcoma:
         c) 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;
         d) Extremity/superficial trunk or head/neck STS (1 or 2):
            1) For any stage extending from stage II through stage IV/recurrent disease;
            2) As chemotherapy following regional node dissection.

**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: 3 months

B. Other diagnoses/indications: Refer to CP.PHAR.57 - Global Biopharm Policy.

II. Continued Approval

A. Soft Tissue Sarcoma (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;
2. Member is responding positively to therapy;
3. Member does not have grade 3* (serious) or grade 4* (life-threatening) infusion-related reaction.

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**Grading is based on the Common Terminology Criteria for Adverse Events (CTCAE).*

Approval duration: 6 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy; or
2. Refer to CP.PHAR.57 - Global Biopharm Policy**.**

Background

Description/Mechanism of Action:

Olaratumab is a human immunoglobulin G (IgG)1 antibody that binds platelet-derived growth factor receptor alpha (PDGFR-α). PDGFR-α is a receptor tyrosine kinase expressed on cells of mesenchymal origin. Signaling through this receptor plays a role in cell growth, chemotaxis, and mesenchymal stem cell differentiation. The receptor has also been detected on some tumor and stromal cells, including sarcomas, where signaling can contribute to cancer cell proliferation, metastasis, and maintenance of the tumor microenvironment. The interaction between olaratumab and PDGFR-α prevents binding of the receptor by the PDGF-AA and -BB ligands as well as PDGF-AA, -BB, and -CC-induced receptor activation and downstream PDGFR-α pathway signaling. Olaratumab exhibits in vitro and in vivo anti-tumor activity against selected sarcoma cell lines and disrupted the PDGFR-α signaling pathway in in vivo tumor implant models.

Formulations:

Lartruvo is supplied in single-dose vials as a solution available as a:

- 500 mg/50 mL (10 mg/mL) single-dose vial, individually packaged in a carton.

FDA Approved Indications:

Lartruvo is a platelet-derived growth factor receptor alpha (PDGFR-α) blocking antibody/intravenous formulation 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.
  - 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.

Appendices
Appendix A: Abbreviation Key
CTCAE: Common terminology criteria for adverse events
PDGFR-α: Platelet-derived growth factor receptor alpha
STS: Soft tissue sarcoma
IgG: Immunoglobulin G

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
N/A	

Reviews, Revisions, and Approvals	Date	Approval Date
Policy split from CP.PHAR.182 Excellus Oncology. NCCN off-label recommended uses added.	02/17	03/17

References
1. Lartruvo prescribing information. Indianapolis, IN: Eli Lilly and Company; October 2016. Available at http://pi.lilly.com/us/lartruvo-uspi.pdf. Accessed January 30, 2017.
2. Olaratumab.National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at NCCN.org. Accessed January 30, 2017.
3. Soft tissue sarcoma (Version 1.2017). National Comprehensive Cancer Network Guidelines. Available at NCCN.org. Accessed January 30, 2017.

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.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.