

|  |   |   |  |
|--|---|---|--|
| <b>POLICY NUMBER</b><br>UM_Onc_1300  | <b>SUBJECT</b><br>Lartruvo™ (olaratumab)  | <b>DEPT/PROGRAM</b><br>UM Dept                                      | <b>PAGE 1 OF 3</b>   |
| <b>DATES COMMITTEE REVIEWED</b><br>11/08/16, 08/10/17, 09/21/18,<br>08/14/19, 12/11/19 | <b>APPROVAL DATE</b><br>December 11, 2019 | <b>EFFECTIVE DATE</b><br>December 11, 2019                          | <b>COMMITTEE APPROVAL DATES</b> (latest<br>version listed last)<br>11/08/16, 08/10/17, 09/21/18, 08/14/19,<br>12/11/19 |
| <b>PRIMARY BUSINESS OWNER: UM</b><br><b>APPROVED BY:</b> Dr. Andrew Hertler            |   | <b>COMMITTEE/BOARD APPROVAL</b><br>Utilization Management Committee |  |
| <b>URAC STANDARDS</b><br>HUM 1   |   | <b>NCQA STANDARDS</b><br>UM 2                                       | <b>ADDITIONAL AREAS OF IMPACT</b>  |
| <b>CMS REQUIREMENTS</b>  | <b>STATE/FEDERAL REQUIREMENTS</b>         |   | <b>APPLICABLE LINES OF BUSINESS</b><br>All   |

## I. PURPOSE

To define and describe the accepted indications for Lartruvo (olaratumab) usage in the treatment of cancer.

## II. DEFINITIONS

**Lartruvo (olaratumab):** is a human antiplatelet-derived growth factor-alpha (PDGFR-alpha) monoclonal antibody that blocks PDGF-AA and -BB ligand binding and prevents PDGF-AA, -BB, and -CC-induced receptor activation and downstream PDGFR-alpha pathway signaling. PDGFR-alpha is a receptor tyrosine kinase expressed on cells of mesenchymal origin; it has been detected on some tumor and stromal cells, including sarcomas. It's signaling results in cancer cell proliferation, metastasis, and maintenance of the tumor microenvironment

Lartruvo (olaratumab) is FDA approved 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.

Lartruvo (olaratumab) is available as an intravenous solution 500 mg/50 mL or 190 mg/19 mL (10 mg/mL) single dose vial.

## III. POLICY

New Century is responsible for processing all medication requests from network ordering providers. Medications not authorized by New Century may be deemed as not approvable and therefore not reimbursable. Treatment request outside the approved FDA manufacturer labeling or CMS approved compendia must follow CMS Medicare Benefit Policy Manual Chapter 15. If references are not produced, delays may occur to the processing of such request.

**Inclusion Criteria:** Lartruvo (olaratumab) may be considered medically necessary when any of the following selection criteria is met:

### 1. Soft Tissue Sarcoma or Uterine Sarcoma

- The member has metastatic soft tissue sarcoma or uterine sarcoma not amenable to curative treatment with radiotherapy or surgery **AND**
- Lartruvo (olaratumab) is given in combination with doxorubicin (excluding liposomal doxorubicin) **AND**
- Member has no prior exposure to an anthracycline (i.e. doxorubicin, daunorubicin, idarubicin) and/or anthracenedione (i.e., mitoxantrone).



# New Century Health

Policy #UM ONC\_1300  
PROPRIETARY & CONFIDENTIAL

**Exclusion Criteria:** Lartruvo (olaratumab) is not considered medically necessary when any of the following selection criteria is met:

1. Lartruvo (olaratumab) is being used after disease progression with the same regimen.
2. Concurrent use with other chemotherapy, immunotherapy, hormonal therapy, radiotherapy, chemo-embolization, or targeted therapy.
3. The member has confirmed Kaposi's sarcoma, untreated central nervous system metastases, prior radiation therapy to the mediastinal/pericardial area, has an uncontrolled intercurrent illness (i.e. active infection, or symptomatic cardiac disease)
4. Dosing exceeds single dose limit of Lartruvo (olaratumab) 15 mg/kg.
5. Treatment exceeds the maximum limit of 8 cycles when used in combination with doxorubicin.
6. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature may be deemed as not approvable and therefore not reimbursable.

## IV. PROCEDURE

Requests for Lartruvo (olaratumab) shall be reviewed for appropriateness per FDA approved product labeling, the National Comprehensive Cancer Network (NCCN) and American Society of Clinical Oncology (ASCO) clinical guidelines, or CMS approved compendia.

1. **Dosage and Administration:** 15 mg/kg IV over 60 minutes on days 1 and 8 repeated every 21 days until disease progression or unacceptable toxicity in combination with doxorubicin 75 mg/m<sup>2</sup> IV on day 1 repeated every 21 days for up to 8 cycles. Premedicate patients with diphenhydramine 25 to 50 mg IV and dexamethasone 10 to 20 mg IV prior to olaratumab on day 1 of cycle 1.
2. **Dosage Adjustments:**
  - a. Grade 4 neutropenia lasting longer than 1 week, neutropenic fever, or infection: Discontinue until absolute neutrophil count is 1000/mcL or greater and then resume at a permanently reduced dose of 12 mg/kg.
  - b. Infusion-related reaction: Interrupt infusion for Grade 1 or 2 event and resume at 50% the initial infusion rate after resolution. Permanently discontinue for a Grade 3 or 4 event
3. **Monitoring**
  - a. Evidence of tumor response may indicate efficacy
  - b. Signs or symptoms of infusion-related reactions; during and after administration.

## V. APPROVAL AUTHORITY

1. Review – UM Department
2. Final Approval – UM Committee



# New Century Health

Policy #UM ONC\_1300  
PROPRIETARY & CONFIDENTIAL

## VI. ATTACHMENTS

None

## VII. REFERENCES

1. Lartruvo prescribing information. Eli Lilly and Company. Indianapolis, IN. 2018.
2. Clinical Pharmacology Elsevier Gold Standard. 2019.
3. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2019.
4. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2019.
5. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD. 2019.