



Nonprofit corporations and independent licensees
of the Blue Cross and Blue Shield Association

Effective Date: 05/04/2017

Lartruvo™ (olaratumab)

Policy Effective Date:
05/04/2017

FDA approval: October 19th, 2016

HCPCS: J9999

Benefit: Medical

Policy/Criteria:

Note: Requests must be supported by submission of chart notes and patient specific documentation.

- A. Coverage of the requested drug is provided when all the below criteria are met:
 - a. Patient must be 18 years of age or older
 - b. Prescribed by or in consultation with an oncologist or hematologist
 - c. Histologically confirmed diagnosis of locally advanced or metastatic soft-tissue sarcoma NOT previously treated with an anthracycline
 - i. Not amenable to curative treatment with radiotherapy or surgery
 - ii. Histologic subtype for which an anthracycline-containing regimen is appropriate
 - d. Used in combination with doxorubicin for the first eight cycles
- B. Quantity Limitations, Authorization Period and Renewal Criteria
 - a. Quantity Limit: Aligns with FDA recommended dosing
 - b. Initial Authorization Period: 6 months
 - c. Renewal Criteria:
 - 1. Treatment continued until unacceptable toxicity or disease progression occurs
 - d. Renewal Authorization Period: 1 year
- A. Lartruvo is considered investigational when used for all other conditions, including but not limited to:
 - a. STS in combination with docetaxel and gemcitabine
 - b. STS amenable to curative treatment with radiotherapy or chemotherapy
 - c. Any diagnosis other than STS

***Note: Coverage may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at <http://www.cms.hhs.gov/>. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia

Therapeutic considerations:

A. FDA approved indication / Diagnosis

- a. Lartruvo is a platelet-derived growth factor receptor alpha (PDGFR- α) blocking antibody 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.
- b. This indication is approved under accelerated approval. Continued approval for this indication may be contingent upon verification and description of benefit in the confirmatory trial.

**Please refer to most recent prescribing information.*

<https://www.lartruvo.com/>

B. Background Information

- a. STSs are a heterogeneous group of rare malignant tumors originating from mesenchymal precursors, including fibrous connective tissue, fat, smooth or striated muscle, vascular tissue, peripheral neural tissue and visceral tissue. STS accounts for approximately 1% of all new adult malignancies.
- b. PDGFR- α is a tyrosine kinase receptor expressed on cells of mesenchymal origin. Signaling through this receptor plays a role in cell growth, chemotaxis, and mesenchymal stem cell differentiation. It has also been detected on tumor and stromal cells, including sarcomas, where signaling can contribute to cancer cell proliferation, metastasis and maintenance of the tumor microenvironment.
- c. The National Comprehensive Cancer Network (NCCN) guidelines on STS (version 1.2017) have been updated since Lartruvo was approved. It has been given a Category 2A recommendation as part of a combination regimen to treat STS with non-specific histologies.
- d. There are over 50 subtypes of STS and therapy depends on the histologic subtype, tumor characteristics and performance status. Examples of first-line chemotherapy for liposarcoma and leiomyosarcoma (the most common STS) may include anthracycline-based combination regimens or single agent therapy. All first-line STS therapies have been given a Category 2A rating by the NCCN guidelines. Other therapies may include surgical resection or radiation therapy

C. Efficacy

**Please refer to most recent prescribing information.*

D. Medication Safety Considerations

Black Box Warning: No

**Please refer to most recent prescribing information.*

E. Dosing and administration

- a. Dosing:
 - i. 15 mg/kg on Day 1 and 8 of each 21-day cycle (administer with doxorubicin for the first 8 cycles)
 - ii. 190 mg/19ml vial size

**Please refer to most recent prescribing information.*

F. How supplied

- a. 500 mg/50 mL (10mg/ml) single dose vial

References:

1. Lartruvo™ injection for intravenous use [prescribing information]. Indianapolis, IN: Eli Lilly and Company; -October 2016.
2. Tap WD, Jones RL, Van Tine BA, et al. Olaratumab and doxorubicin versus doxorubicin alone for treatment of soft-tissue sarcoma: an open-label phase 1b and randomised phase 2 trial. *Lancet*. 2016;388:488-497.
3. Eli Lilly and Company. A study of doxorubicin plus olaratumab (LY3012207) in participants with advanced or metastatic soft tissue sarcoma (ANNOUNCE). In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000- [cited 2017 Jan 19]. Available from: <https://clinicaltrials.gov/ct2/show/NCT02451943>. NLM Identifier: NCT02451943.
4. US National Institutes of Health. In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000-[cited 2017 Jan 19]. Available from: <https://www.clinicaltrials.gov/ct2/results?term=olaratumab&Search=Search>, and <https://www.clinicaltrials.gov/ct2/results?term=IMC-3G3&Search=Search>. Search terms: olaratumab, IMC-3G3.
5. The NCCN Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology. (Version 1.2017) © 2016 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on January 20, 2017.
6. FDA grants accelerated approval to new treatment for advanced soft tissue sarcoma [press release]. FDA; October 19, 2016. Available at: <http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm525878.htm>. Accessed on October 24, 2016.
7. Highmark® Medication Class Review – Antineoplastics: Monoclonal Antibodies Key Focus: olaratumab (Lartruvo™). December 2016; Completed 12/13/2016. Accessed on January 20, 2017.
8. Express Scripts® Drug Evaluation: Lartruvo™ (olaratumab injection for intravenous use – Eli Lilly and Company. November 2nd, 2016. Accessed on January 20, 2017.

Policy History		
#	Date	Change Description
1.0	SWG: 03/15/2017 P&T: 05/04/2017	

* The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or <http://dailymed.nlm.nih.gov/dailymed/index.cfm>