

Lartruvo (olaratumab) (Intravenous)

Document Number: IC-0287

Last Review Date: 03/04/2019

Date of Origin: 10/25/2016

Dates Reviewed: 10/2016, 10/2017, 10/2018, 03/2019

I. Length of Authorization

Coverage may be renewed every 6 months for patients currently receiving olaratumab who continue to show clinical benefit. Initiating treatment with olaratumab is not supported by Phase 3 data.

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

- Lartruvo 500 mg/50 mL single-dose vial: 8 vials per 21 days
- Lartruvo 190 mg/19 mL single-dose vial: 2 vials per 21 days

B. Max Units (per dose and over time) [Medical Benefit]:

- 400 billable units (4,000 mg) per 21 days

III. Initial Approval Criteria

Soft tissue sarcoma (STS)* †

**Based on the recently completed results of the ANNOUNCE phase 3 soft tissue sarcoma study of Lartruvo in combination with doxorubicin, which did not confirm clinical benefit, specifically improvement in overall survival, the FDA recommends that patients who are currently receiving Lartruvo should consult with their healthcare provider about whether to remain on the treatment. The FDA also recommends that Lartruvo should not be initiated in new patients outside of an investigational study.*

† FDA approved indication(s); ‡ Compendia approved indication(s)

IV. Renewal Criteria

Authorizations can be renewed based on the following criteria:

- Patient has been receiving olaratumab; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe infusion-related reactions, severe neutropenia, etc.

V. Dosage/Administration

Indication	Dose
Soft tissue sarcoma	15 mg/kg by intravenous infusion on Days 1 and 8 of each 21-day cycle until disease progression or unacceptable toxicity. <ul style="list-style-type: none"> • Administer with doxorubicin for the first 8 cycles

VI. Billing Code/Availability Information

HCPCS code:

- J9285 - Injection, olaratumab, 10 mg; 1 billable unit=10 mg

NDC:

- Lartruvo 500 mg/50 mL single-dose vial: 00002-8926-xx
- Lartruvo 190 mg/19 mL single-dose vial: 00002-7190-xx

VII. References

1. Lartruvo [package insert]. Indianapolis, IN; Eli Lilly and Company; October 2018. Accessed February 2019.
2. Lilly Reports Results of Phase 3 Soft Tissue Sarcoma Study of Lartruvo. Press Release. Jan. 2019. Available at: <https://lilly.mediaroom.com/index.php?s=9042&item=137861>
3. FDA grants accelerated approval to new treatment for advanced soft tissue sarcoma. Jan. 2019 Press Announcements Update. Available at: <https://www.fda.gov/Drugs/InformationOnDrugs/ApprovedDrugs/ucm526087.htm>

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C48.0	Malignant neoplasm of retroperitoneum
C48.1	Malignant neoplasm of specified parts of peritoneum
C48.2	Malignant neoplasm of peritoneum, unspecified
C48.8	Malignant neoplasm of overlapping sites of retroperitoneum and peritoneum
C49.0	Malignant neoplasm of connective and soft tissue of head, face and neck
C49.10	Malignant neoplasm of connective and soft tissue of unspecified upper limb, including shoulder
C49.11	Malignant neoplasm of connective and soft tissue of right upper limb, including shoulder
C49.12	Malignant neoplasm of connective and soft tissue of left upper limb, including shoulder
C49.20	Malignant neoplasm of connective and soft tissue of unspecified lower limb, including hip

ICD-10	ICD-10 Description
C49.21	Malignant neoplasm of connective and soft tissue of right lower limb, including hip
C49.22	Malignant neoplasm of connective and soft tissue of left lower limb, including hip
C49.3	Malignant neoplasm of connective and soft tissue of thorax
C49.4	Malignant neoplasm of connective and soft tissue of abdomen
C49.5	Malignant neoplasm of connective and soft tissue of pelvis
C49.6	Malignant neoplasm of connective and soft tissue of trunk, unspecified
C49.8	Malignant neoplasm of overlapping sites of connective and soft tissue
C49.9	Malignant neoplasm of connective and soft tissue, unspecified
C53.0	Malignant neoplasm of endocervix
C54.0	Malignant neoplasm of isthmus uteri
C54.1	Malignant neoplasm of endometrium
C54.2	Malignant neoplasm of myometrium
C54.3	Malignant neoplasm of fundus uteri
C54.8	Malignant neoplasm of overlapping sites of corpus uteri
C54.9	Malignant neoplasm of corpus uteri, unspecified
C55	Malignant neoplasm of uterus, part unspecified

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC

Medicare Part B Administrative Contractor (MAC) Jurisdictions

Jurisdiction	Applicable State/US Territory	Contractor
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC