

Lartruvo (olaratumab) (Intravenous)

Document Number: IC-0287

Last Review Date: 10/30/2018

Date of Origin: 10/25/2016

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

I. Length of Authorization

Coverage will be provided for six months and may be renewed.

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) †

- Patient is 18 years or older; **AND**
- Used in combination with doxorubicin when an anthracycline containing regimen is appropriate; **AND**
 - Disease is not amenable to curative radiotherapy or surgery ‡; **OR**
 - Used for one of the following histologic sub-types of disease ‡:
 - Angiosarcoma
 - Pleomorphic Rhabdomyosarcoma
 - Retro-peritoneal/Intra-Abdominal Sarcoma
 - Primary treatment as chemotherapy or chemoradiation for attempted downstaging of unresectable, recurrent, or metastatic disease; **OR**
 - Used as palliative therapy for unresectable or progressive disease.
 - Extremity/Superficial Trunk/Head-Neck Sarcoma
 - Will not be used as neoadjuvant or adjuvant therapy for Stages II-III disease; **AND**

- Primary treatment as chemotherapy or chemoradiation for stage II-III resectable disease with adverse functional outcomes; **OR**
 - Used as chemotherapy following regional node dissection; **OR**
 - Patient's disease is recurrent or metastatic
- Uterine Sarcoma
- Patient does not have Stage I disease; **AND**
 - May be considered following total hysterectomy with or without bilateral salpingo-oophorectomy (TH ± BSO) for stage II-III disease; **OR**
 - Patient disease is not suitable for primary surgery; **OR**
 - Patient disease is recurrent or metastatic.

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

IV. Renewal Criteria

Authorizations can be renewed based on the following criteria:

- Patient continues to meet criteria identified in Section III; **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 (Effective 1/1/2018)

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; August 2018. Accessed October 2018.

2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for olaratumab. National Comprehensive Cancer Network, 2018. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed October 2018.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C47.0	Malignant neoplasm of peripheral nerves of head, face and neck
C47.10	Malignant neoplasm of peripheral nerves of unspecified upper limb, including shoulder
C47.11	Malignant neoplasm of peripheral nerves of right upper limb, including shoulder
C47.12	Malignant neoplasm of peripheral nerves of left upper limb, including shoulder
C47.20	Malignant neoplasm of peripheral nerves of unspecified lower limb, including hip
C47.21	Malignant neoplasm of peripheral nerves of right lower limb, including hip
C47.22	Malignant neoplasm of peripheral nerves of left lower limb, including hip
C47.3	Malignant neoplasm of peripheral nerves of thorax
C47.4	Malignant neoplasm of peripheral nerves of abdomen
C47.5	Malignant neoplasm of peripheral nerves of pelvis
C47.6	Malignant neoplasm of peripheral nerves of trunk, unspecified
C47.8	Malignant neoplasm of overlapping sites of peripheral nerves and autonomic nervous system
C47.9	Malignant neoplasm of peripheral nerves and autonomic nervous system, unspecified
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
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

ICD-10	ICD-10 Description
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
C78.00	Secondary malignant neoplasm of unspecified lung
C78.01	Secondary malignant neoplasm of right lung
C78.02	Secondary malignant neoplasm of left lung
Z80.49	Family history of malignant neoplasm of other genital organs
Z85.831	Personal history of malignant neoplasm of soft tissue

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)

LARTRUVO (olaratumab) Prior Auth Criteria

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Medicare Part B Administrative Contractor (MAC) Jurisdictions

Jurisdiction	Applicable State/US Territory	Contractor
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
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