**Utilization Review Policy 171**

**POLICY:** Oncology – Lartruvo™ (olaratumab injection for intravenous use – Eli Lilly and Company)

**EFFECTIVE DATE:** 1/1/2021
**LAST REVISION DATE:** 3/6/2019

**COVERAGE CRITERIA FOR:** All Aspirus Medicare Plans

## OVERVIEW

Lartruvo is a recombinant human IgG1 monoclonal antibody that binds to human platelet-derived growth factor receptor alpha (PDGFR-α).[1] PDGFR-α is a receptor tyrosine kinase that is involved in cell growth, chemotaxis, and mesenchymal stem cell differentiation. The receptor has been found on some tumors, including sarcomas, where signaling can contribute to cell proliferation, metastasis, and maintenance of the tumor microenvironment. Lartruvo prevents binding of PDGFR-α by the PDGF-AA and -BB ligands which prevents receptor activation and downstream PDGFR-α pathway signaling.

Lartruvo, is indicated, in combination with doxorubicin for the treatment of adults with soft tissue sarcoma with a subtype that an anthracycline-containing regimen is appropriate and which is not amenable to curative surgery or radiotherapy.[1]

The FDA granted accelerated approval to Lartruvo in October 2016 with the condition that a larger trial be conducted to confirm the safety and efficacy in patients with soft tissue sarcoma.[2] This study was recently completed and did not meet the primary endpoint of an improvement in overall survival for Lartruvo plus doxorubicin compared with placebo plus doxorubicin (the results are not currently available). In response to these results, the FDA recommends that Lartruvo not be started in new patients outside of a clinical trial and those currently receiving Lartruvo should discuss with their physician whether to remain on treatment.

### Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines on Soft Tissue Sarcoma (Version 2.2019 – February 4, 2019) removed Lartruvo in combination with doxorubicin as a treatment option for soft tissue sarcoma.[3]

The NCCN guidelines on Uterine Neoplasms (Version 3.2019 – February 11, 2019) removed Lartruvo in combination with doxorubicin as a treatment option for uterine sarcoma.[4]

## POLICY STATEMENT

Prior authorization is recommended for medical benefit coverage of Lartruvo. Approval is recommended for those who meet the Criteria and Dosing for the listed indication(s). Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by an Express Scripts clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Lartruvo as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Lartruvo to be prescribed by or in consultation with a physician who specializes in the condition being treated.

## RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Lartruvo is recommended in those who meet one of the following criteria:

**FDA-Approved Indications**

1. **Soft Tissue Sarcoma of Extremity/Superficial Trunk, Head/Neck; Retroperitoneal/Intra-Abdominal; Angiosarcoma; Pleomorphic Rhabdomyosarcoma; and Uterine.**[2,3] Approve for 6 months if the patient meets the following (A and B):
   **A)** The patient is currently receiving Lartruvo; AND
   **B)** Lartruvo is prescribed by or in consultation with an oncologist.

   **Dosing.** Approve the following dosing:
   **A)** Each individual dose must not exceed 15 mg/kg given by intravenous infusion; AND
   **B)** Lartruvo is administered on Days 1 and 8 of each 21-day cycle.[1]

   Note: Dose modifications of Lartruvo are recommended for the management of neutropenia and infusion-related reactions.[1] This may include reducing the dose to 12 mg/kg, withholding the drug until the toxicity is resolved, or discontinuing the drug all together. See the prescribing information for more detail.

## CONDITIONS NOT RECOMMENDED FOR APPROVAL

Lartruvo has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. Rationale for non-coverage for these specific conditions is provided below. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

1. **Initiating therapy on Lartruvo.** The FDA recommends that Lartruvo not be started in new patients outside of a clinical trial.[2]

2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

## REFERENCES

1. Lartruvo™ injection for intravenous use [prescribing information]. Indianapolis, IN: Eli Lilly and Company; October 2016.
2. Olaratumab (Lartruvo) [press release]. Food and Drug Administration; January 24, 2019. Available at: https://www.fda.gov/Drugs/InformationOnDrugs/ApprovedDrugs/ucm526087.htm. Accessed on February 19, 2019.
3. The NCCN Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology (Version 2.2019 – February 4, 2019). © 2019 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on February 19, 2019.
4. The NCCN Uterine Neoplasms Clinical Practice Guidelines in Oncology (Version 1.2019). © 2018 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on February 19, 2019.