BlueCross BlueShield of North Carolina

An independent licensee of the Blue Cross and Blue Shield Association

Corporate Medical Policy

Olaratumab (Lartruvo™)

File Name:	olaratumab_lartruvo
Origination:	11/2017
Last CAP Review:	11/2019
Next CAP Review:	11/2020
Last Review:	11/2019

Description of Procedure or Service

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.

****NOTE: As of July 31, 2019, olaratumab (Lartruvo) has been withdrawn from the market.** Based on results from the ANNOUNCE phase 3 STS study of olaratumab in combination with doxorubicin, olaratumab failed to demonstrate clinical benefit through improvement in overall survival. Therefore, the FDA has recommended that patients who are currently receiving olaratumab consult with their healthcare provider whether to remain on this treatment. The FDA has also recommended that olaratumab not be initiated in new patients outside of participation in an ongoing investigational study. See Policy Guidelines for additional information.

****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

BCBSNC will provide coverage for Olaratumab (Lartruvo) when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Olaratumab (Lartruvo) is covered

Olaratumab (Lartruvo) may be medically necessary when the following criteria are met:

- When used 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.

Use of Olaratumab (Lartruvo) may be considered medically necessary for clinical indications not listed above when the drug is prescribed for the treatment of cancer either:

- In accordance with FDA label (when clinical benefit has been established, see Policy Guidelines); **OR**
- In accordance with specific strong endorsement or support by nationally recognized compendia, when such recommendation is based on strong/high levels of evidence, and/or uniform consensus of clinical appropriateness has been reached.

When Olaratumab (Lartruvo) is not covered

Olaratumab (Lartruvo) is considered not medically necessary when criteria under "When Olaratumab (Lartruvo) is covered" are not met.

Olaratumab (Lartruvo) is considered investigational when used for:

1. Non-cancer indications; **OR**
2. When criteria are not met regarding FDA labeling **OR** strong endorsement/support by nationally recognized compendia, as stated under "When Olaratumab (Lartruvo) is covered."

Policy Guidelines

Drugs prescribed for treatment of cancer in accordance with FDA label may be considered medically necessary when clinical benefit has been established, and should not be determined to be investigational as defined in Corporate Medical Policy (CMP), "Investigational (Experimental) Services."

Please refer to CMP "Investigational (Experimental) Services" for a summary of evidence standards from nationally recognized compendia.

Following market withdrawal, all requests for this drug will be handled by the manufacturer through the Lartruvo Patient Access Program. Only patients who are receiving Lartruvo as continuation therapy are eligible for this program, although new patients will be evaluated on a case-by-case basis. Enrollment and access to this drug will be provided free of charge for eligible patients. Following July 31, 2019, further requests will be handled via lartruvopatientaccessprogram@lilly.com. For additional questions regarding the program, the contact information is as follows:

Patient Access Program (for continued access for patients currently receiving commercial olaratumab)
For more information, please contact:
United States/Canada toll-free phone: 1-833-245-8167
Outside US/Canada: 1-917-542-5801
Email: LartruvoPatientAccessProgram@iqvia.com1

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative

Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: J9285, S0353, S0354

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

U.S. Food and Drug Administration (FDA). Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/761038lbl.pdf

Specialty Matched Consultant Advisory Panel 11/2018

Eli Lilly. Lilly to establish an access program for patients as it prepares to withdraw Lartruvo from the global market. April 2019. Available at: https://investor.lilly.com/news-releases/news-release-details/lilly-establish-access-program-patients-it-prepares-withdraw. Last accessed September 2019.

Medical Director review 9/2019

Specialty Matched Consultant Advisory Panel 11/2019

Policy Implementation/Update Information

12/29/17 New policy developed. Olaratumab (Lartruvo) may be medically necessary when used 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. References added. Policy noticed 12/29/17 for effective date 3/29/18. (lpr)

12/14/18 Specialty Matched Consultant Advisory Panel review 11/28/2018. No change to policy intent. (krc)

10/1/19 Added language to reflect market withdrawal on 7/31/2019 and contact information for the Lartruvo Patient Access Program for requests for continued access for patients currently receiving commercial olaratumab. References added. Medical Director review 9/2019. (krc)

12/10/19 Specialty Matched Consultant Advisory Panel review 11/20/2019. No change to policy intent. (krc)