

Corporate Medical Policy

BioZorb®

File Name: biozorb
Origination: 5/2019
Last Review: 5/2023

Description of Procedure or Service

Breast conserving surgery and adjuvant radiotherapy is commonly used to treat early-stage breast cancer. A marker may be placed in the tumor bed during the surgery to mark the area for follow-up with subsequent clinical imaging and/or postoperative radiation.

To date, the standard method to mark a tumor bed and define the region targeted for radiation treatment is with individual surgical clips. Studies have shown the effectiveness of surgical clips in localizing the target volume for radiation purposes, with minimal clip movement and ease of identification on various imaging modalities. Other means of identifying a tumor bed postoperatively include use of the surgical scar site or the presence of post-surgical tissue changes or seroma. However, none of these methods produces a standardized target that is reliable during the postoperative period of tissue healing and associated changes to the breast.

A newer technique is BioZorb®, an implantable, three-dimensional (3D), spiral-shaped bioabsorbable tissue marker which contains titanium clips, and is inserted and sutured in the surgical cavity after a lumpectomy.

Biozorb® Tissue Marker has received 510(k) clearance from the FDA.

*****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

BioZorb® three-dimensional (3D) bioabsorbable tissue marker is considered **investigational** for all applications.

BCBSNC does not provide coverage for investigational services or procedures.

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 BioZorb is covered

Not applicable.

When BioZorb is not covered

BioZorb® three-dimensional (3D) bioabsorbable tissue marker is considered investigational for all applications.

Policy Guidelines

The published evidence consists of a review article and cost-effectiveness analysis of surgical clips versus BioZorb, and radiation planning studies.

Rashad and colleagues conducted a comprehensive literature review to compare the traditional placement of surgical clips and the BioZorb marker in the surgical tumor bed in the context of oncoplastic breast surgery. They identified five studies that met their literature inclusion criteria, pooling a total of 359 patients. Clinical outcomes reported included effectiveness in marking the tumor bed and postoperative pain and infection. The authors concluded that there was little clinical data noting any advantage favoring BioZorb over the standard practice of surgical clip placement, and that in the absence of comparative data showing clinical benefit of BioZorb, traditional surgical clips provide a more cost-effective technique.

Weins and colleagues evaluated the effect of BioZorb on radiation boost clinical and planning target volumes (CTV and PTV, respectively), and radiation dose to adjacent organs in early stage breast cancer treated by partial mastectomy. The authors conducted a retrospective cohort study of BioZorb versus no BioZorb placement in 143 patients stratified by age, tumor laterality and cancer stage. The BioZorb arm showed statistically significant reductions in CTV and PTV but not ipsilateral lung or heart radiation. There was a statistically significant increase in the amount of radiation to the ipsilateral lung in the BioZorb arm. The long-term impact of these findings on clinical outcomes is unknown.

Cross and colleagues evaluated the impact of BioZorb on radiation planning in 108 patients undergoing breast conserving surgery. The outcomes measured included post-operative infection rate, impact on ability to perform surgical re-excision and utility for radiation boost planning. No post-operative infections occurred and no impact on surgical margin re-excision was noted. The authors concluded that the marker was easily visible and proved “useful” for radiation planning.

In summary, no prospective, comparative studies of BioZorb versus standard methods of marking a tumor bed were identified nor were studies reporting long-term clinical outcomes such as local tumor recurrence or radiation effects on adjacent organs using BioZorb versus conventional surgical site markers. The evidence is insufficient to determine the effects of BioZorb on health outcomes.

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: 14001, 14301, 19301, C9728

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

Cross MJ, Lebovic GS, Ross J, et al. Impact of a Novel Bioabsorbable Implant on Radiation Treatment Planning for Breast Cancer. *World J Surg.* 2017 Feb;41(2):464-471.

Foster B, Sindhu K, Hepel J, et al. Three-Dimensional Bioabsorbable Tissue Marker Placement is Associated with Decreased Tumor Bed Volume Among Patients Receiving Radiation Therapy for Breast Cancer. *Pract Radiat Oncol.* 2019 Mar;9(2):e134-e141.

Rashad R, Huber K, Chatterjee A. (2018). Cost-Effectiveness of the BioZorb Device for Radiation Planning in Oncoplastic Surgery. 7. 23. 10.5539/cco.v7n2p23.

Wiens N, Torp L, Wolff B, et al. Effect of BioZorb® surgical marker placement on post-operative radiation boost target volume. *J Radiat Oncol.* 2018;7(2):175-179.

U.S. Food and Drug Administration (FDA). Available at:
https://www.accessdata.fda.gov/cdrh_docs/pdf14/K143484.pdf

Medical Director review 6/2019

Specialty Matched Consultant Advisory Panel review 5/2020

Medical Director review 5/2020

Specialty Matched Consultant Advisory Panel review 5/2021

Medical Director review 5/2021

Specialty Matched Consultant Advisory Panel review 5/2022

Medical Director review 5/2022

Specialty Matched Consultant Advisory Panel review 5/2023

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Policy Implementation/Update Information

6/11/19 New policy developed. BioZorb three-dimensional (3D) bioabsorbable tissue marker is considered investigational. References added. Medical Director review 6/2019. Policy noticed 6/11/19 for effective date 8/13/19. (lpr)

6/9/20 Specialty Matched Consultant Advisory Panel review 5/20/2020.No change to policy statement. (lpr)

6/15/21 Specialty Matched Consultant Advisory Panel review 5/19/2021. No change to policy statement. (lpr)

5/31/22 Specialty Matched Consultant Advisory Panel review 5/18/2022. No change to policy statement. (lpr)

6/13/23 Specialty Matched Consultant Advisory Panel review 5/17/2023. No change to policy statement. (lpr)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.