Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***Current Policy Effective Date: 1/1/24**
(See policy history boxes for previous effective dates)

Title: Magnetic Resonance Imaging to Monitor Integrity of Silicone-Gel-Filled Breast Implants

Description/Background

Silicone or saline breast implants may be used with breast reconstruction or for breast augmentation.

Leaks of silicone can occur at various levels: (1) contained within the fibrous capsule that commonly forms around the silicone implant (intracapsular); (2) outside of the capsule if there is a rupture which leads to macroscopic silicone leakage into surrounding tissues (extracapsular; about 10%-20% of ruptures); or (3) the silicone may “bleed” through the silicone envelope that contains it without any gross holes or tears. Extracapsular ruptures are of particular concern, because silicone may occasionally migrate to different parts of the body (eg, to the axillary lymph nodes, arms, and abdomen) and may form silicone granulomas. Surgery is sometimes needed to remove silicone deposits in other parts of the body. The design of implants has changed over time, with the potential for different rupture rates and rupture patterns with each generation of implants. The age of the implant is a known risk factor for rupture.

Magnetic resonance imaging monitoring is not recommended for women with saline-filled implants. There is less concern about the leakage of saline than silicone gel. Rupture of a saline-filled implant is more obvious to patients and physicians, while silicone implants are more likely to maintain their shape after rupture.

This review does not address the injection of silicone into the breast.

Regulatory Status

Table 1 summarizes select silicone gel−filled breast implants approved by the Food and Drug Administration (FDA).

Table 1. Select Silicone Gel-Filled Breast Implants Approved by FDA

Silicone Implant	Manufacturer	PMA No.	Approval Date
Natrelle	Allergan	P020056	Oct 2021
MemoryGel	Mentor	P030053	Nov 2006
Silicone Gel Breast Implants	Sientra	P070004	Mar 2012
MemoryShape	Mentor	P060028	Jun 2013

FDA: Food and Drug Administration; PMA: premarket approval.
Food and Drug Administration product code: FTR.

Medical Policy Statement

Magnetic resonance imaging (MRI) for the assessment of silicone breast implants may be considered established in specified situations.

Inclusionary and Exclusionary Guidelines

Note: Refer to member's certificate for benefit-specific coverage of screening tests and procedures.

Inclusions:
- To confirm the clinical suspicion of rupture of silicone breast implants

Exclusions:
- Monitoring the integrity of silicone gel-filled breast implants when there are no signs or symptoms of rupture

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure)*

Established codes:

77046 77047

Other codes (investigational, not medically necessary, etc.):

N/A

Rationale

This testing is established and is standard of care for those with silicone-gel-filled breast implants who have symptoms of breast implant rupture.

Refer to radiology vendor guidelines.

American College of Radiology
The American College of Radiology (2018) issued Appropriateness Criteria for breast implant evaluation.[2] Table 2 presents the expert panel recommendations on imaging techniques for patients with suspected silicone implant complications.

Table 2. Imaging Recommendations for Women with Suspected Silicone Implant Complications

Age	Imaging Technique
<30 years	Magnetic resonance imaging without contrast or ultrasound
30 to 39 years	Magnetic resonance imaging without contrast, mammography/digital breast tomosynthesis, or ultrasound
≥40 years	Magnetic resonance imaging without contrast or mammography/digital breast tomosynthesis

Government Regulations

National:

Medicare does not have a specific policy addressing MRI for the assessment of silicone breast implants. According to National Coverage Determination (NCD) for Magnetic Resonance Imaging (220.2), effective 4/10/18, implemented 12/10/2018, “Effective June 3, 2010, all other uses of MRI or MRA for which CMS has not specifically indicated coverage or non-coverage continue to be eligible for coverage through individual local MAC discretion.”

Local:

There is no local coverage determination.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

Magnetic Resonance Imaging (MRI) Detection and Diagnosis of Breast Cancer

References

1. Food and Drug Administration (FDA). FDA Update on the Safety of Silicone Gel-Filled Breast Implants. 2011; https://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/UCM260090.pdf Accessed 8/29/23.
2. Lourenco AP, Moy L, et al. ACR Appropriateness Criteria (R) Breast Implant Evaluation. J Am Coll Radiol. May 2018;15(5S):S13-S25. PMID 29724416
3. Centers for Medicare and Medicaid, National Coverage Determination (NCD) for Magnetic Resonance Imaging (220.2), effective 7/7/11, implemented 9/26/11.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 8/29/23, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
9/1/13	6/18/13	6/26/13	Joint policy established
11/1/14	8/21/14	8/25/14	Routine maintenance
7/1/16	4/19/16	4/19/16	Routine maintenance
1/1/17	10/11/16	10/11/16	Routine maintenance
1/1/18	10/19/17	10/19/17	Routine maintenance
1/1/19	10/16/18	10/16/18	Routine maintenance
1/1/20	10/15/19		Routine maintenance; deleted codes 77058-77059; added 77046-77047
1/1/21	10/20/20		Routine maintenance
3/1/21	12/15/20		Routine maintenance
3/1/22	12/14/21		Routine maintenance Inclusion edited. Rationale section revised.
3/1/23	12/20/22		Routine maintenance (jf) Vendor: NA
1/1/24	10/17/23		Routine maintenance (jf) Vendor Managed: Carelon

Next Review Date: 4th Qtr, 2024

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: MAGNETIC RESONANCE IMAGING TO MONITOR INTEGRITY OF SILICONE-GEL-FILLED BREAST IMPLANTS

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Covered; criteria applies
BCNA (Medicare Advantage)	See Government Regulations section.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.