

Policy #: 139

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Title

Magnetic Resonance Imaging to Monitor Integrity of Gel Filled Breast Implants

For MRI of Breast, please see policy #[106](#).

Description

This policy addresses the use of magnetic resonance imaging (MRI) to monitor the integrity of silicone gel-filled breast implants (hereafter referred to as silicone implants).

On November 16, 2006, the U.S. Food and Drug Administration (FDA) approved the marketing of silicone implants by Allergan Corp. (formerly named Inamed Corp.), Irvine, CA, and Mentor Corp., Santa Barbara, CA. These products were approved for use in breast reconstruction for women of all ages and for breast augmentation among women at least 22 years old. This decision followed 14 years in which silicone implants were not available outside of clinical trials. In 1991, the FDA had decided that premarketing approval (PMA) was required for manufacturers of silicone implants (which had previously been “grandfathered” in to the requirements of the 1976 Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act). In 1992, the agency determined that the PMAs submitted had insufficient evidence on safety and effectiveness to support approval. (See references 1 and 2)

The FDA also required each of the two companies to conduct post-approval studies following up about 40,000 women receiving breast implants for 10 years. These studies will gather information about rates of local complications, connective tissue disease, neurological disease, and related signs and symptoms; potential effects on offspring, reproduction, and lactation; cancer and suicide rates; potential interference with mammography; and magnetic resonance imaging (MRI) compliance and rupture rates. The companies are also required to conduct several other studies (e.g., focus groups to study the patient labeling) and to track each implant so that updated product information can be distributed.

In its announcement of this decision, the FDA cited the Institute of Medicine report (See reference 3), which concluded that there was a lack of evidence on the association between silicone implants and either connective tissue disease or cancer. The labels for these implants indicate that 1) breast implants are not lifetime devices and women are likely to need additional surgeries beyond the initial placement of the implant; 2) changes to the breast following implantation are often irreversible; 3) rupture of a silicone implant is usually silent, with neither the woman nor her surgeon aware of the rupture; and 4) regular screening MRI examinations to detect silent rupture are needed over the patient’s lifetime. The FDA recommends that women have their first MRI 3 years after initial implant surgery and then every 2 years after that. Furthermore, if the MRI indicates implant rupture, the implant should be removed and replaced, if needed.

MRI monitoring apparently is not recommended for women with saline-filled implants. There is less concern about the leakage of saline versus silicone gel, which can migrate to other parts of the body and produce silicone granulomas. 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.

MRI to monitor for the rupture of silicone implants may be performed without contrast and is more sensitive and specific when a dedicated breast coil is used. Silicone-specific sequences are sometimes used.

When services are covered for commercial products and for Medicare HMO Blue, Medicare PPO Blue, and Medicare PFFS PlusRx.

We cover **magnetic resonance imaging (MRI)** to confirm the clinical diagnosis of rupture of silicone breast implants.^{1, 2, 3}

Note: For diagnoses that are considered medically necessary for commercial products and for Medicare HMO Blue, Medicare PPO Blue and Blue Medicare PFFS PlusRx, see footnote 2.

When services are not covered for commercial products or for Medicare HMO Blue, Medicare PPO Blue, and Medicare PFFS PlusRx.

We do not cover **magnetic resonance imaging (MRI)** to monitor the integrity of silicone gel-filled breast implants when there are no signs or symptoms of rupture, since it is considered investigational¹ and does not meet the Blue Cross Blue Shield of Massachusetts Medical Technology Assessment Guidelines, #[350](#).

Individual consideration

All our medical policies are written for the majority of people with a given condition. Each policy is based on medical science. For many of our medical policies, each individual's unique clinical circumstances may be considered in light of current scientific literature. For consideration of an individual patient, physicians may send relevant clinical information to:

For services already billed

Blue Cross Blue Shield of Massachusetts
Provider Appeals
PO Box 986065
Boston, MA 02298

Prior to performance of service

Blue Cross Blue Shield of Massachusetts
Case Creation/Medical Policy
One Enterprise Drive
Quincy, MA 02171
Tel: 1-800-327-6716
Fax: 1-888-641-5330

Authorization Information:

For Managed Care members:

- No authorization is required for this service; *see Managed Care Guidelines for additional requirements.*

For Indemnity and PPO members:

- No authorization is required for this service; *see Indemnity and PPO Guidelines for additional requirements.*

Managed Care Guidelines:

All authorization requirements are determined by the individual's subscriber certificate, explanation of coverage, or summary plan description, however;

- **For Medicare HMO Blue members:** The service must meet the criteria for coverage noted in this policy, be medically necessary, prescribed by a plan physician and provided by a network provider.
- **For Medicare HMO Blue members:** Referrals are required for all visits to a specialist.
- For all other Managed Care plans, any specialist visit requires a referral, except for visits performed by OB/GYN specialists.
- Authorization is required for an inpatient admission.

Indemnity and PPO Guidelines:

All authorization requirements are determined by the individual's subscriber certificate, explanation of coverage, or summary plan description, however;

- Authorization is required for an inpatient admission.
- Authorizations are not required for most outpatient services as determined by the individual's subscriber certificate.
- Referrals to a specialist are not required.

Other information

For our Medical Technology Assessment Guidelines, see document #[350](#).

Coding information

Procedure codes are from current CPT, HCPCS Level II, Revenue Code, and/or ICD-9-CM manuals, as recommended by the American Medical Association, Centers for Medicare and Medicaid Services and American Hospital Associations. Blue Cross Blue Shield Association national codes may be developed when appropriate.

The following codes are included below for informational purposes. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

CPT codes:

- **77058:** magnetic resonance imaging, breast, without and/or with contrast material(s); unilateral
- **77059:** magnetic resonance imaging, breast, without and/or with contrast material(s); bilateral

Note: For diagnoses that are considered medically necessary for commercial products and for Medicare HMO Blue, Medicare PPO Blue and Blue Medicare PFFS PlusRx, see footnote 2.

Policy update history

Updated 11/02 to include coverage guidelines for MRI of the breast, effective 4/1/03. Updated 2/05 to include rationale and references pertaining to Breast MRI based on the BCBSA national policy (6.01.29) footnote #38. Updated 4/07 based on a completed comparative review of BCBSA National policy MRI of the Breast- no change in policy statement; footnote #38 edited to align w/ BCBSA policy rationale due to reference re-sequencing; references added. Updated 3/08 based on a comparison review of BCBSA medical policy- MR of the Breast completed; BCBSA coverage unchanged; BCBSMA benchmarks the BCBSA policy as noted in this medical policy document. Updated 6/09 based on the comparison review of the BCBSA new National medical policy, Use of Magnetic Resonance Imaging to Monitor Silicone Gel-Filled Breast Implants; BCBSMA covered and non-covered language clarified; footnote 42 created to identify BCBSA policy references. New policy document #139, issued 11/1/2009. Magnetic resonance imaging for breast implants was previously addressed on BCBSMA medical policy #106, Magnetic Resonance Imaging.

References

References for footnote 1:

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2. U.S. Food and Drug Administration. FDA approves silicone gel-filled breast implants after in-depth evaluation: Agency requiring 10 years of patient follow-up. 2006. Available online at: www.fda.gov/bbs/topics/NEWS/2006/NEW01512.html . Last accessed March 2009.
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http://www.plasticsurgery.org/medical_professionals/health_policy/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=18812 . Last accessed March 2009.
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15. Quinn SF, Neubauer NM, Sheley RC et al. MR imaging of silicone breast implants: Evaluation of prospective and retrospective interpretations and interobserver agreement. *J Magn Reson Imaging* 1996; 6(1):213-8.
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This document is designed for informational purposes only and is not an authorization, or an explanation of benefits, or a contract. Receipt of benefits is subject to satisfaction of all terms and conditions of the coverage. Medical technology is constantly changing, and we reserve the right to review and update our policies periodically.

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Footnotes

¹ Based on the BCBSA national medical policy 6.01.50, Use of Magnetic Resonance Imaging to Monitor Integrity of Silicone Gel Filled Breast Implants, issued 3/2009.

² **ICD-9-CM** diagnosis codes that support medical necessity:

- 996.54: mechanical complication of other specified prosthetic device, implant, and graft; due to breast prosthesis
- 996.69: infection and inflammatory reaction due to internal prosthetic device, implant, and graft; due to other internal prosthetic device, implant, and graft- breast prosthesis
- 996.79: other complications of internal (biological) (synthetic) prosthetic device, implant, and graft; due to other internal prosthetic device, implant, and graft

³ Coverage based on recommendation from local physician radiologist experts and a breast surgeon specialist at the 2002 Medical Policy Group meeting – Obstetrics and Gynecology.