BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Screening Magnetic Resonance Imaging (MRI) for Evaluation of Breast Implant Integrity in Asymptomatic Individuals

Policy #: 723
Category: Radiology
Latest Review Date: January 2019
Policy Grade: **A**

Background:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

Description of Procedure or Service:

Magnetic resonance imaging (MRI) is a non-invasive test using a multiplanar imaging method based on an interaction between radiofrequency (RF) electromagnetic fields and certain nuclei in the body (usually hydrogen nuclei) after the body has been placed in a strong magnetic field. The magnetic resonance (MR) scanners and intravenous magnetic resonance contrast agents are used to create detailed pictures of areas inside the body.

For individuals who are asymptomatic with silicone breast implants who receive screening with MRI, the evidence includes diagnostic accuracy studies and systematic reviews. Relevant outcomes are test accuracy and validity, morbid events, and treatment-related morbidity. Studies of MRI screening for silent rupture in asymptomatic women with silicone implants have demonstrated reasonably high sensitivity and specificity compared with explantation and these studies reported reasonably high sensitivity and specificity compared with surgical explantation. However, the studies have generally been conducted in select populations (eg, women who want implants removed), and the data lacks screening populations. Moreover, the clinical utility of MRI screening for silent rupture is unclear, ie, complications that may result from asymptomatic leakage of silicone are not well characterized. The evidence is insufficient to determine the effects of the technology on health outcomes.

Policy:

Blue Advantage will treat **Magnetic Resonance Imaging (MRI) of the breast, with or without computer-aided detection**, to evaluate the integrity of silicone gel-filled breast implants when there is no signs or symptoms of rupture as a **non-covered** benefit and as **investigational**.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:

The most recent literature update was performed through October 16, 2018.

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

Leaks of silicone can be contained within the fibrous capsule that commonly forms around the silicone implant (intracapsular); the capsule may also rupture and lead to macroscopic silicone leakage into surrounding tissues (extracapsular; about 10%-20% of ruptures); or 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.

A 2011 meta-analysis by Song et al examined the effect of study design biases on the diagnostic accuracy of MRI imaging for detecting silicone breast implant ruptures. The meta-analysis was initiated because the Food and Drug Administration recommended that women with silicone breast implants undergo MRI screening to detect silent rupture. Sixteen MRI studies were included; reviewers noted that more than 50% of studies used a sample not representative of a screening sample. Only two indicated that study populations were asymptomatic patients. The reference test diagnostic criteria were not specified in 44% of studies, and 44% of studies had partial verification bias. Gel bleeds were addressed inconsistently across studies, because 5 MRI studies did not consider gel bleeds as ruptures and 1 MRI study considered gel bleeds as ruptures. Significant heterogeneity was present across studies for sensitivity and specificity. MRI studies using symptomatic samples had a diagnostic odds ratio that was nearly 14-fold greater than the diagnostic odds ratio of studies with asymptomatic samples. Although pooled summary measures across studies indicated a relatively high accuracy of MRI for detecting breast implant rupture with a pooled sensitivity of 87% and a pooled specificity of 90%, most of the current literature examined only symptomatic patients. The meta-analysis identified many methodologic flaws in the current literature; reported MRI sensitivity and specificity estimates may be high if applied to asymptomatic or screening samples and could result in unnecessary operative exploration based on inaccurate MRI interpretation.

The 2 studies of asymptomatic women, identified in the Song meta-analysis, were published by Scaranelo et al (2004) and by Collis et al (2007). The Collis study reported retrospectively on 149 patients with bilateral silicone implants who underwent MRI. Twenty-three patients were found to have 33 radiologically detected implant ruptures. The study was not designed to evaluate diagnostic accuracy, but to determine longevity of implants, and it did not use a criterion standard for confirming rupture. The Scaranelo study included 44 asymptomatic women with silicone breast implants; all women wanted their implants surgically removed. Thirty-nine women had bilateral implants, and 5 had unilateral implants (total implants, 83). Before surgery, patients underwent mammography and ultrasonography, and 41 also underwent MRI. On surgical removal, 30 (36%) of 83 implants were found to be ruptured. The sensitivities of mammography, ultrasound, and MRI for detecting rupture were 20%, 30%, and 64%, respectively. Specificities were 89%, 81%, and 77%, respectively.

Several studies were published after the 2011 meta-analysis. In 2014, Maijers et al reported on 2 studies from a prospective cohort of 112 women with 224 recalled implants. Patients had the breast implants for 10 years on average before explantation. Review of magnetic resonance images before explantation correctly detected 154 intact and 35 ruptured implants; sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) were 80%, 91%, 69%, and 95%, respectively. In a subsequent blinded evaluation of available MRI results, 2 radiologists independently agreed on the condition of 208 of 214 explanted implants. Agreement also was also reached in five additional patients where the radiologists initially disagreed on the implant condition; sensitivity, specificity, PPV, and NPV were 93%, 93%, 77%, and 98%, respectively. The κ value of interobserver agreement was 0.92.

Rietjens et al (2014) prospectively studied 102 consecutive women with 130 implants who were undergoing breast implant replacement for aesthetic improvement. The median duration of implantation was 57 months (range, 6-166 months). Intraoperative evaluation identified 36 ruptured implants (prevalence, 28%). Preoperative magnetic resonance images were evaluated by 1 experienced MRI reader. MRI sensitivity, specificity, PPV, and NPV were 83% (95% CI, 66% to 93%), 98% (95% CI, 92% to 100%), 94% (95% CI, 79% to 99%), and 94% (95% CI, 88% to 97%), respectively. Although patients did not present with symptoms of implant rupture or history of trauma, patients presenting for "aesthetic" improvement may not represent a typical screening population.

Clinical Utility
There is no direct evidence of the clinical utility of MRI for screening asymptomatic women with silicone breast implants for silent rupture. Moreover, the complications that may result from asymptomatic leakage of silicone are not well-characterized, limiting the potential clinical benefit of early detection.

Section Summary
There are fewer studies of MRI screening for silent rupture in asymptomatic women with silicone breast implants compared with MRI studies in symptomatic patients. No systematic review reported pooled diagnostic accuracy estimates of studies in asymptomatic women. In the available studies reporting diagnostic accuracy, sensitivity of MRI compared with surgical explantation ranged from 64% to 93% and specificity ranged from 77% to 98%. The evidence base is limited because studies of asymptomatic women have generally been conducted in select populations (eg, women who want their implants removed), and data are lacking in screening populations. Moreover, the clinical utility of MRI screening for silent rupture is unclear (eg, complications that may result from asymptomatic leakage of silicone are not well-characterized). The evidence is insufficient to determine the effects of the technology on health outcomes.

Practice Guidelines and Position Statements
American Society of Breast Surgeons
The American Society of Breast Surgeons (2017) updated its guidelines on diagnostic and screening magnetic resonance imaging (MRI) of the breast. The guidelines stated that MRI may be used "for evaluation of suspected breast implant rupture, especially in patients with silicone implants, if the MRI findings will aid the decision-making for implant removal or aid the diagnostic evaluation of indeterminate clinical or conventional imaging findings". However, the

Society did not recommend routine MRI screening in asymptomatic patients with silicone or saline implants.

European Society of Breast Imaging
The European Society of Breast Imaging (2015) published recommendations for communicating information about breast MRI to women. The recommendations stated: "MRI is the most sensitive technique to detect breast implant ruptures when an appropriate protocol is performed.... In the absence of symptoms, breast implants do not need to be screened for integrity with breast MRI."

Key Words:
Magnetic resonance imaging (MRI), Breast, Screening silicone breast implants

Benefit Application:
Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

Coding:
CPT Codes:

77046	Magnetic resonance imaging, breast, without contrast material; unilateral
77047	Magnetic resonance imaging, breast, without contrast material; bilateral
77048	Magnetic resonance imaging, breast, without and with contrast material(s), including computer-aided detection (CAD real-time lesion detection, characterization and pharmacokinetic analysis), when performed; unilateral
77049	Magnetic resonance imaging, breast, without and with contrast material(s), including computer-aided detection (CAD real-time lesion detection, characterization and pharmacokinetic analysis), when performed; bilateral

References:

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Policy History:

Adopted for Blue Advantage, January 2019
Medical Policy Group, January 2019