MRI FOR EVALUATING BREAST IMPLANT INTEGRITY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Medical Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as “Description” defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as “Criteria” defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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Description:

Magnetic resonance imaging (MRI) is a noninvasive diagnostic imaging modality that uses magnetic and radiofrequency fields to image body tissue without radiation.
MRI FOR EVALUATING BREAST IMPLANT INTEGRITY (cont.)

Criteria:

For MRI of the breast, see BCBSAZ Medical Coverage Guideline #O87, “MRI of the Breast”.

- MRI of the breast, with or without computer-aided detection, to evaluate the integrity of silicone breast implants is considered eligible for coverage with documentation that the original indication for implant placement was reconstructive following a mastectomy for breast cancer or fibrocystic disease or related to a complication of a covered medical condition (e.g., abscess, injury, trauma, prior chest surgery with deformity) and ANY of the following:
  1. Mammography and ultrasound are non-diagnostic but the individual is displaying signs and symptoms suggestive of implant rupture, i.e., localized pain/mass, contour irregularity, change in breast size.
  2. Mammography and ultrasound have detected implant rupture and MRI is needed to determine the extent of intra-capsular or extra-capsular leakage.

- 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, is considered experimental or investigational based upon:
  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  4. Insufficient evidence to support improvement outside the investigational setting.

- MRI of the breast, with or without computer-aided detection, to evaluate the integrity of a cosmetic breast implant is considered associated with a cosmetic procedure and, therefore, a non-covered service and not eligible for coverage.

- MRI of the breast, with or without computer-aided detection, for suspected saline implant leakage is considered not medically necessary, as saline implant leakage is not detectable on MRI. Breast ultrasound may be a more appropriate imaging technique.
MRI FOR EVALUATING BREAST IMPLANT INTEGRITY (cont.)

Resources:

Literature reviewed 10/11/16. We do not include marketing materials, poster boards and non-published literature in our review.

The BCBS Association Medical Policy Reference Manual (MPRM) policy is included in our guideline review. References cited in the MPRM policy are not duplicated on this guideline.

Resources prior to 05/14/13 may be requested from the BCBSAZ Medical Policy and Technology Research Department.


FDA 510K Summary for CADSTREAM™:

- FDA-approved indication: Intended for use in analyzing magnetic resonance imaging (MRI) studies. CADstream automatically registers serial patient image acquisitions to minimize the impact of patient motion, segments and labels tissue types based on enhancement characteristics (parametric image maps), and performs other user-defined post-processing functions (image subtractions, multiplanar reformats, maximum intensity projections). When interpreted by a skilled physician, this device provides information that may be useful in screening and diagnosis. CADstream can also be used to provide accurate and reproducible measurements of the longest diameters and volume of segmented tissues. Patient management decisions should not be made based solely on the results of CADstream analysis.

FDA 510K Summary for 3TP Software Option:

- FDA-approved indication: Intended to be used as a post processing software package designed to provide a reliable means for visualizing the presence and pattern of contrast induced enhancement on MR datasets. 3TP supports the evaluation of dynamic h4R data gathered during the injection of a bolus of contrast media. The resulting time course information can be displayed in a variety of formats, including a parametric image overlaid onto source MR images. In the hands of a trained physician the information provided by the 3TP Software Option could yield information that may assist in the interpretation of dynamic contrast enhanced studies.