**Description**

The use of computer-aided evaluation (CAE) may assist radiologists’ interpretation of contrast-enhanced magnetic resonance imaging (MRI) of the breast and improve the accuracy of diagnosis of malignancy.

**Related Policies**

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

**Policy**

The use of computer-aided evaluation (CAE) is considered investigational for the interpretation of magnetic resonance imaging (MRI) of the breast.

**Policy Guidelines**

There is an add-on CPT category III code for the use of computer-aided evaluation (CAE) with MRI of the breast:

- **0159T**: Computer-aided detection, including computer algorithm analysis of MRI image data for lesion detection/characterization, pharmacokinetic analysis, with further physician review for interpretation, breast MRI (List separately in addition to code for primary procedure)

The above code would be used with the CPT code for breast MRI (77058 or 77059).

**Benefit Application**

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.
Some state or federal mandates (e.g., Federal Employee Program (FEP)) prohibit Plans from denying Food and Drug Administration (FDA) - approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

### Rationale

#### Background

The use of computer-aided evaluation (CAE) is proposed to assist radiologists’ interpretation of contrast-enhanced magnetic resonance imaging (MRI) of the breast. MRI of the breast is suggested as an alternative or adjunct to mammography or other screening and diagnostic tests because of its high sensitivity in detecting breast lesions. However, it has a high false positive rate because of the difficulty in distinguishing between benign and malignant lesions. MRI may be used to screen women at high genetic risk of breast cancer or to look for more extensive disease in women diagnosed with breast cancer who are eligible for breast-conserving surgery; it is also being studied to gauge the impact of cancer treatment (for a discussion of other potential indications, see Blue Shield of California Medical Policy: Magnetic Resonance Imaging of the Breast). The CAE systems reviewed in this policy are intended to improve the specificity of MRI in detecting or measuring malignant tissue, while maintaining the generally high sensitivity of MRI. An improved ability to identify MRI-detected lesions that are almost certainly benign could potentially reduce biopsy rates. There is anecdotal information that MRI also may reduce reoperation rates among patients undergoing breast-conserving surgery by more clearly identifying the tissue that should be removed. CAE also may reduce the time needed to interpret breast MRI images, which currently takes longer than reading mammograms.

CAE systems for MRI essentially provide easier ways of interpreting the patterns of contrast enhancement across a series of images, which in turn may help identify lesions and their likelihood of being malignant. Two key aspects of enhancement (also called kinetics) are examined (Cheng & Li, 2013):

- Within the first minute or so, how quickly does the lesion enhance up to a certain threshold (e.g., 50%, 100% of the initial value; rapid enhancement above 90% in 90 seconds suggests malignancy)?
- What is the subsequent pattern of enhancement (i.e., continues to increase, plateaus, or declines [called washout, which is associated with malignancy])?

In contrast to computer-aided detection (CAD) systems used with mammography, CAE for MRI is not primarily intended to identify lesions for consideration by a radiologist. Unlike the subtle appearance of lesions on mammography, most cancers enhance on MRI. The challenge is determining which lesions are benign and which are malignant. A large number of images are produced during MRI of the breast: images are taken at varying “depths” throughout each breast multiplied by the number of times the breast is imaged to capture different time points in the enhancement process; this can produce hundreds of images. Radiologists view the images to detect suspicious areas, and then pick a region of interest and look at the enhancement pattern. However, there may be variations across radiologists in the regions of interest selected and the precise definition of the region of interest. CAE systems, in contrast, use color-coding and differences in hue to indicate the pattern of enhancement for each pixel in the breast image, thereby allowing radiologists to analyze enhancement patterns systematically. CAE systems for MRI of the breast were initially called CAD (computer-aided detection) systems, the same terminology used for mammography. However, the focus with MRI of
the breast is on improving specificity (distinguishing malignant from benign) rather than increasing sensitivity (i.e., detection), as in mammography. The authors of 2 studies refer to CADstream as a computer-aided evaluation (CAE) program, and that terminology has been adopted in this policy (Lehman et al., 2006; Williams et al., 2007).

**Regulatory Status**

Several CAE systems for use with MRI of the breast have 510(k) marketing clearance from the U.S. Food and Drug Administration (FDA). Some of these systems may have broader uses beyond breast MRI. There also may be some overlap in the functions performed by these devices and other image-processing systems.

- **The 3TP (3 Time Point) Software Option**, manufactured by 3TP LLC (now called CAD Sciences, White Plains, NY), was cleared on June 23, 2003. iCAD acquired CAD Sciences in 2008 and is now marketing a system called SpectraLook with CADVue, which was FDA-cleared on July 20, 2012. According to documents filed with the FDA, the 3TP Software Option is “intended to be used as a postprocessing software package designed to provide a reliable means for visualizing the presence and pattern of contrast-induced enhancement on MR datasets.” It provides a color-coded image that indicates the likelihood that each pixel shows malignant or benign tissue based on the changes in enhancement at 3 points in time, which are defined by the software program.

- **CADstream™**, which is manufactured by Confirma Inc. (Kirkland, WA), was cleared on July 30, 2003; Merger Healthcare (Hartland, WI) subsequently acquired Confirma. CADstream is described as a “Computer Aided Detection (CAD) system 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 postprocessing 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...Patient management should not be based solely on the results of the CADstream analysis.” It also provides automated determination of volumes of interest. In addition, CADstream can be used during MRI-guided biopsies.

- **Aegis™** (Sentinelle Medical Inc., Toronto, Ontario, Canada) received 510(k) marketing clearance from the FDA on February 9, 2007, as substantially equivalent to CADstream Version 4.0. However, in the 510(k) documents, the manufacturer states that the primary goal of Aegis is “to identify where and how deep a biopsy or localization needle should be inserted into an imaged breast.”

- **DynaCAD®** (MRI Devices Corp, Waukesha, WI; now from Invivo Corp, Orlando, FL) was cleared July 21, 2004.

- **z3D Contrast Acuity Software** (Clario Medical Imaging Inc., Seattle, WA) was cleared September 5, 2008 and is apparently used in conjunction with CAE for MRI systems.

To demonstrate the impact of computer-aided evaluation (CAE) in the diagnosis of breast cancer, studies that compare the sensitivity and specificity of magnetic resonance imaging (MRI) with and without the use of CAE systems are needed. Such studies can demonstrate the incremental diagnostic accuracy of CAE compared to no CAE. Ideally, these studies should be prospective and should evaluate a population of patients similar to that presenting for breast cancer screening in a clinical setting.
To demonstrate clinical utility, prospective studies that evaluate whether incremental diagnostic accuracy leads to changes in management and improved outcomes are needed. Changes in management might include changes in the decision to perform biopsies and in subsequent management decisions based on biopsy results.

**Literature Review**

The literature review focuses on studies that compare the diagnostic accuracy of MRI with and without CAE. There are no prospective studies of this type identified in the literature. Retrospective studies generally do not include a population similar to that presenting in clinical care; rather, they utilize an enriched population that includes a greater proportion of patients with cancer than would be expected in consecutive patients presenting for screening. A representative sample of these studies is discussed below.

**What is the incremental improvement in diagnostic accuracy for breast cancer when CAE is added to standard MRI?**

The 2006 Blue Cross Blue Shield Technology Evaluation Center (TEC) Assessment summarized 4 published articles and 4 abstracts that compared the accuracy of MRI with and without CAE. The reviewed studies focused on commercially available CAE systems, but some articles on other systems were included. In addition, studies had to report on cancer detection based on histologic results. Three of the articles reported on development and validation of CAE systems aimed at distinguishing between malignant and benign lesions, and they used information on women with known lesions. The fourth article by Deurloo et al. (2005) provided information on one of the noncommercial systems used to evaluate women with cancer who were eligible for breast-conserving therapy. Additional findings (other lesions or larger lesions) were found in 48 of the 116 women (41%); approximately 80% of these women had further workup; and in 27 of these women, the findings were malignant. The area under the receiver operating characteristic (ROC) curve was 0.91 +/- 0.04 for the radiologist reading and 0.98 +/- 0.04 for the combined radiologist and computerized reading (p = 0.03). However, the ability to generalize these results and the clinical impact of the findings is uncertain.

Four abstracts of studies were included in the TEC Assessment because of the small number of studies identified. However, the need to exercise caution in using results from abstracts must be kept in mind as these results are reviewed. Of the 4 abstracts, 2 used CADstream, 1 did not report the system used, and 1 was an excerpt from an article that summarized the results of 3 earlier abstracts on the 3TP system. It is not clear whether the current 3TP system has been modified substantially from the version used in these studies. Once again, these abstracts report on the results of CAE with MRI among women with known lesions.

Finally, DeMartini et al. (2005) reported on the use of CAE with MRI in 15 patients to assess the impact of chemotherapy. This small study found there were a substantial number of false negative results for residual malignancy using CAE—a different type of problem than found with most other uses of MRI (i.e., too many false positive results).

Conclusions of the TEC Assessment were that the literature on CAE with MRI of the breast was sparse overall, and that few studies addressed the specific situations in which CAE with MRI is used in a clinical setting. The few articles and abstracts calculated test characteristics on the basis of lesions and not the number of women or breasts. In a screening population, many women would not have any lesions. Including these women might alter the results. Given MRI’s lower sensitivity in detecting ductal carcinoma in situ (DCIS), the mix of DCIS versus masses would affect the calculations of sensitivity and specificity and might affect the impact of the CAE system.
Since the TEC Assessment was completed in 2006, there have been a number of relevant studies published. All of these have been retrospective analyses that included populations of patients that are not representative of those seen in clinical care.

Two articles were published that were apparently based on one of the retrospective studies presented in an abstract form from the TEC Assessment. The first article, published in 2006 by Lehman et al., reported on 33 consecutive lesions biopsied under MRI guidance at a single institution. The second article, published in 2007 by Williams et al., reported on 155 consecutive lesions that appeared to subsume the 33 lesions included in the 2006 study; the later article is therefore summarized here. The lesions were not palpable or visible on mammography or sonography and were assessed with and without CAE (Lehman et al., 2006). All of these lesions were rated Breast Imaging Reporting and Data Systems (BI-RADS) 4 or 5 (i.e., suspicious or highly suggestive of malignancy). Of these lesions, 64% were in recently diagnosed breast cancer patients, 14% were in high-risk patients being screened, and 14% were for problem solving. Three different MRI protocols were used. CADstream was then retrospectively applied for this study. As expected, increasing the level of enhancement required (to 100%) lowered the number of false positive results. At the 50% enhancement level, no statistically significant difference was found in the positive predictive value between the initial reading and the subsequent application of CAE. At the 100% enhancement level, however, the positive predictive value was significantly higher with CAE than without (30.4% vs 26.6% respectively; p=0.02). Because the radiologists who read each set of images with and without CAE were not necessarily the same, it is possible that some of this difference might be due to a variation across readers rather than to the addition of CAE. There was no significant difference in subsequent enhancement patterns (i.e., washout, persistent, or plateau) between benign and malignant lesions; and many lesions included diverse enhancement patterns.

A 2010 retrospective study by Meeuwis et al. evaluated the use of the CADstream system, using images from a 3.0-T MRI system. Of 426 women imaged consecutively, the final analysis comprised 36 women (42 lesions) with indeterminate mammographic and/or ultrasound results or high-risk screening. Blinded manual reading, by 2 experienced breast radiologists, was followed 6 months later by blinded reading of CAE results, by the same 2 breast radiologists and by 2 residents. For the experienced radiologists, sensitivity and specificity of manual readings were 84.6% and 68.8%, respectively (BI-RADS category 3 considered negative); sensitivity and specificity of CAE readings were 90.4% (p<0.05 vs manual readings) and 81.3% (p<0.05 vs manual readings), respectively. There were no statistically significant differences across CAE readers (residents compared with experienced breast radiologists, or each reader compared individually with the others). Although these results are interesting, this study has several limitations, including its retrospective nature, highly selective sample with a large proportion of cancer cases, and small number of readers. It also is unclear whether the results apply only to a 3.0-T MRI system. Further research is needed with larger, more robust studies to assess these findings.

Arazi-Kleinman et al. (2009) performed a retrospective study that evaluated the sensitivity and specificity of the MRI CAD software, CAD-Gaea (Sentinelle Medical, Toronto, Canada; commercially released under the name Aegis software). The patients were women at high risk of breast cancer (BRCA1- or BRCA2-mutation-positive, or calculated lifetime risk of being a mutation carrier of >/= 25%). From an initial sample of 1,548 MRI studies on a 1.5-T system, the study sample consisted of 56 lesions in 53 women. Thirty-nine percent of the lesions were malignant, and of those, 59% were DCIS. The relevance of this study for the present policy is limited because it included only BI-RADS 3 to 5 cases that were biopsied and utilized a unilateral diagnostic fat-suppressed MRI protocol.
Readings were performed by 2 experienced breast radiologists looking at different aspects of the CAE results (e.g., different thresholds for initial enhancement and initial enhanced versus delayed pattern or both). The primary finding was that for invasive cancers, sensitivity was 100% using CAE (both initial and delayed enhancement patterns), but when DCIS was included, sensitivity dropped to 73% Overall specificity (i.e., including DCIS) was 56%. Prospective radiologist interpretation (as part of clinical care) was more sensitive than CAE-based interpretation (p=0.05) but less specific (p=0.01); performance values for prospective readings were not reported. The authors concluded that "[t]he breast MRI CAD system could not improve the radiologists' accuracy for distinguishing all malignant from benign lesions, due to the poor sensitivity for DCIS detection."

A 2011 systematic review by Dorius et al. identified 10 CAE studies in women with benign and/or malignant breast lesions (BIRADS category >/= 2), including the 2 studies described above by Meeuwis et al., 2010 and Arazi-Kleinman et al., 2009. In meta-analyses of 3 studies (211 lesions, 55% malignant), 1 of which used 3.0-T MRI (Meeuwis et al.), sensitivity of experienced radiologists' blinded readings was 89% both with and without CAE, but specificity decreased from 86% (95% confidence interval [CI]: 79 to 91) without CAE to 82% (95% CI: 76 to 87) with CAE, a statistically nonsignificant difference. The authors attributed the decrease to a greater reliance by radiologists on the contrast enhancement pattern provided by CAE in the absence of morphology data, which CAE does not provide. For residents with limited breast MRI experience, specificity was approximately 78% with or without CAE, but sensitivity increased from 72% (95% CI: 62 to 81) without CAE to 89% (95% CI: 80 to 94) with CAE, a statistically nonsignificant difference. Statistical heterogeneity was moderate to substantial (56% to 83%) for all results except for the specificity of residents' readings both with and without CAE, which had low to moderate statistical heterogeneity (24% to 33%).

Shimauchi et al. (2011) performed a retrospective analysis in 2011 that was similar to previous studies. In this study, an initial training set of 121 breast lesions (77 malignant and 44 benign) was used to train the CAD system. A sample of 30 malignant breast lesions and 30 benign lesions was used to test the incremental accuracy of computer-aided detection (CAD) when added to conventional MRI. Sensitivity for detection of malignancy was higher for CAD compared to conventional imaging (88% vs 83%; p=0.001), as was the mean area under the curve by ROC analysis (0.84 vs 0.80; p=0.007). Mean specificity was not significantly greater in the CAD group compared to conventional imaging (53% vs 50%; p=0.20).

Cho et al. (2012) reported on a retrospective study that evaluated CAE in detection of contralateral breast cancer lesions in women with breast cancer. There were 23 malignant and 29 benign lesions in 52 consecutive patients. Three experienced radiologists interpreted the images and provided their judgments about the probability of cancer. Sensitivity and specificity was determined with and without CAE for each radiologist. Mean sensitivity improved statistically significantly with CAE, from 76.8% to 92.8% (p value not reported), but specificity decreased by a statistically nonsignificant amount (40.2% to 35.6%; p value not reported). There was an increase in the combined accuracy, as measured by the area under the curve from 0.603 to 0.667, but this difference was not statistically significant (p value not reported).

Lehman et al. (2013) reported on a multicenter, retrospective study of 9 experienced and 11 inexperienced radiologists who read a set of 70 dynamic contrast-enhanced breast MRIs twice, once with and once without CADstream. Among experienced readers, sensitivity increased from 84% without CAE to 91% with CAE, a statistically significant difference of 7 percentage points (95% CI: 4 to 11). Among inexperienced readers, sensitivity increased from 77% to 83%, a difference of 6 percentage points (95%...
Specificity (BIRADS category 3 considered negative) did not change with the addition of CAE for either group. Similarly, overall diagnostic accuracy did not change statistically for either group: For experienced readers, the area under the ROC curve (AUC) was 0.80 without CAE and 0.83 with CAE (although these values are reversed without subsequent correction in the narrative description of results). For inexperienced readers, the AUC was 0.77 without CAE and 0.79 with CAE. There was no significant difference in overall time to assessment with or without CAE.

Research to improve the ability of CAE systems to provide incremental information and increase diagnostic accuracy continues. Studies use of various metrics (e.g., identification of the “most suspect” enhancement pattern of a lesion or the distribution of different enhancement patterns within a lesion [Baltzer et al., 2009; Ko et al., 2011; Yuan et al., 2010]; textural analysis of lesions [Holli et al., 2010; Huang et al., 2013]; comparison with the contralateral breast [Yang et al., 2013] and determination of the type of breast cancer and presence of metastases [Bhooshan et al., 2010]). These studies did not necessarily use commercially available CAE systems. Further research is needed to evaluate the utility of all of these approaches.

What is the clinical utility of CAE when added to standard MRI of the breast?

There is no direct evidence that evaluates the impact of CAE on health outcomes. There are no prospective studies that examine whether management decisions are changed due to results of CAE. There are also no relevant modeling studies that estimate the impact of CAE on outcomes.

Decisions for biopsies may be changed as a result of CAE; in particular, biopsies may be performed in areas of abnormality identified by CAE that were not seen on standard MRI. This may in turn improve the detection rate for malignancies. It is also possible that the number of false-positive biopsies is increased when CAE is used. Since incremental changes in sensitivity and specificity with CAE are unknown, it is not possible to estimate the number of additional malignancies that would be detected by CAE, nor is it possible to determine the number of additional false positive biopsies that would be performed. As a result, the clinical utility of CAE when added to standard MRI of the breast has yet to be determined.

Summary

Available evidence primarily consists of retrospective studies that compare the accuracy of computer-aided MRI of breast malignancy versus conventional imaging. Populations in these studies are not representative of patients seen in clinical care; rather they include samples of women who are highly selected and usually have far more cases of cancer than would be encountered in a screening population. As a result, the true sensitivity and specificity of computer-aided MRI, and the incremental improvement in accuracy over conventional imaging, cannot be determined with certainty. Larger, well-designed, prospective studies are needed that include relevant clinical populations in order to determine whether computer-aided evaluation results in a clinically significant improvement in diagnostic accuracy. As a result of the deficiencies in the available literature, the use of computer-aided evaluation of malignancy with MRI is considered investigational.

Practice Guidelines and Position Statements

In 2011, the American College of Radiology (ACR) issued a consensus guideline for the use of MRI-guided breast interventional procedures, which acknowledged the potential use of CAE for contrast-enhanced MRI but did not recommend for or against its use.

The European Society of Breast Cancer Specialists (EUSOMA) issued consensus recommendations for MRI of the breast in 2010 by Sardanelli et al. This document states “We recommend the use of standardized interpretation systems such as the above mentioned BI-RADS lexicon, or equivalent. There is some evidence that software for breast MR computer-aided diagnosis (CAD) may be of benefit but insufficient to recommend the routine use of such systems.”

Medicare National Coverage

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

References


Documentation Required for Clinical Review

- No records required

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement.

IE

The following services are considered investigational and therefore not covered for any indication.

<table>
<thead>
<tr>
<th>Type</th>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT®</td>
<td>0159T</td>
<td>Computer-aided detection, including computer algorithm analysis of MRI image data for lesion detection/characterization, pharmacokinetic analysis, with further physician review for interpretation, breast MRI (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>HCPCS</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>ICD-9 Procedure</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>ICD-10 Procedure</td>
<td>BH30Y0Z</td>
<td>Magnetic Resonance Imaging (MRI) of Right Breast using Other Contrast, Unenhanced and Enhanced</td>
</tr>
<tr>
<td></td>
<td>BH30YZ</td>
<td>Magnetic Resonance Imaging (MRI) of Right Breast using Other Contrast</td>
</tr>
<tr>
<td></td>
<td>BH30ZZ</td>
<td>Magnetic Resonance Imaging (MRI) of Right Breast</td>
</tr>
<tr>
<td></td>
<td>BH31Y0Z</td>
<td>Magnetic Resonance Imaging (MRI) of Left Breast using Other Contrast, Unenhanced and Enhanced</td>
</tr>
<tr>
<td></td>
<td>BH31YZ</td>
<td>Magnetic Resonance Imaging (MRI) of Left Breast using Other Contrast</td>
</tr>
<tr>
<td></td>
<td>BH31ZZ</td>
<td>Magnetic Resonance Imaging (MRI) of Left Breast</td>
</tr>
<tr>
<td></td>
<td>BH32Y0Z</td>
<td>Magnetic Resonance Imaging (MRI) of Bilateral Breasts using Other Contrast, Unenhanced and Enhanced</td>
</tr>
</tbody>
</table>
### ICD-9 Diagnosis

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>174.0</td>
<td>Malignant neoplasm of nipple and areola of female breast</td>
</tr>
<tr>
<td>174.1</td>
<td>Malignant neoplasm of nipple and areola of female breast</td>
</tr>
<tr>
<td>175.0</td>
<td>Malignant neoplasm of nipple and areola of male breast</td>
</tr>
<tr>
<td>175.1</td>
<td>Malignant neoplasm of nipple and areola of male breast</td>
</tr>
<tr>
<td>198.81</td>
<td>Secondary malignant neoplasm of breast</td>
</tr>
<tr>
<td>233.0</td>
<td>Carcinoma in situ of breast</td>
</tr>
<tr>
<td>611.72</td>
<td>Lump or mass in breast</td>
</tr>
<tr>
<td>V10.3</td>
<td>Personal history of malignant neoplasm of breast</td>
</tr>
<tr>
<td>V16.3</td>
<td>Family history of malignant neoplasm of breast</td>
</tr>
</tbody>
</table>

**For dates of service on or after 10/01/2015**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C50.01</td>
<td>Malignant neoplasm of female/male breast</td>
</tr>
<tr>
<td>C50.929</td>
<td>Secondary malignant neoplasm of breast</td>
</tr>
<tr>
<td>C79.81</td>
<td>Secondary malignant neoplasm of breast</td>
</tr>
<tr>
<td>D05.01</td>
<td>Lobular carcinoma in situ of right breast</td>
</tr>
<tr>
<td>D05.99</td>
<td>Lobular carcinoma in situ of right breast</td>
</tr>
<tr>
<td>N63</td>
<td>Unspecified lump in breast</td>
</tr>
<tr>
<td>Z80.3</td>
<td>Family history of malignant neoplasm of breast</td>
</tr>
<tr>
<td>Z85.3</td>
<td>Personal history of malignant neoplasm of breast</td>
</tr>
</tbody>
</table>

### Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

<table>
<thead>
<tr>
<th>Effective Date</th>
<th>Action</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>8/29/2014</td>
<td>BCBSA Medical Policy adoption</td>
<td>Medical Policy Committee</td>
</tr>
</tbody>
</table>

### Definitions of Decision Determinations
**Medical Policy**

**Medically Necessary:** A treatment, procedure or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

**Investigational/Experimental:** A treatment, procedure or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California / Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a Split Evaluation, where a treatment, procedure or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

**Prior Authorization Requirements**

This service (or procedure) is considered **medically necessary** in certain instances and **investigational** in others (refer to policy for details).

For instances when the indication is **medically necessary**, clinical evidence is required to determine **medical necessity**.

For instances when the indication is **investigational**, you may submit additional information to the Prior Authorization Department.

Within five days before the actual date of service, the Provider MUST confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should also be directed to the Prior Authorization Department. Please call 1-800-541-6652 or visit the Provider Portal www.blueshieldca.com/provider.

The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.