Prophylactic mastectomy may be considered medically necessary in patients at high risk of breast cancer. (For definitions of risk levels, see Policy Guidelines section.)

Prophylactic mastectomy may be considered medically necessary in patients with such extensive mammographic abnormalities (i.e., calcifications) that adequate biopsy or excision is impossible.

Prophylactic mastectomy is considered investigational for all other indications, including but not limited to contralateral prophylactic mastectomy in individuals with breast cancer who do not meet high-risk criteria.

Policy Guidelines

It is strongly recommended that all candidates for prophylactic mastectomy undergo counseling regarding cancer risks from a health professional skilled in assessing cancer risk other than the operating surgeon and discuss the various treatment options, including increased surveillance or chemoprevention with tamoxifen or raloxifene.

There is no standardized method for determining a woman’s risk of breast cancer that incorporates all possible risk factors. There are validated risk prediction models, but they are based primarily on family history.

Some known individual risk factors confer a high risk by themselves. The following list includes factors known to indicate a high risk of breast cancer:

- A known BRCA1 or BRCA2 variant
- Another gene variant associated with high risk, e.g., TP53 (Li-Fraumeni syndrome), PTEN (Cowden syndrome, Bannayan-Riley-Ruvalcaba syndrome), CDH1, and STK11
- Lobular carcinoma in situ
- Received radiotherapy to the chest between 10 and 30 years of age

A number of other factors may increase the risk of breast cancer but do not by themselves indicate high risk, such as ductal carcinoma in-situ (DCIS) and atypical ductal hyperplasia. It is possible that combinations of these factors may be indicative of high risk, but it is not possible to give quantitative estimates of risk. As a result, it may be necessary to individualize the estimate of risk taking into account numerous risk factors. A number of risk factors, not individually indicating high risk, are included in the National Cancer Institute Breast Cancer Risk Assessment Tool, also called the Gail model. Risk factors in the model can be accessed online (http://www.cancer.gov/bcrisktool/Default.aspx). Another tool for risk calculation is the Tyrer-Cuzick Risk Calculator (2017 Revision).

Description

Prophylactic mastectomy is defined as the removal of the breast in the absence of malignant disease to reduce the risk of breast cancer occurrence.

Related Policies

- Genetic Cancer Susceptibility Panels Using Next-Generation Sequencing
- Genetic Testing for Hereditary Breast/Ovarian Cancer Syndrome (BRCA1 or BRCA2)
Moderate Penetrance Variants Associated With Breast Cancer in Individuals at High Breast Cancer Risk

**Benefit Application**

Benefit determinations should be based on 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)] prohibits 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.

**Regulatory Status**

Mastectomy is a surgical procedure and, as such, is not subject to regulation by the U.S. Food and Drug Administration.

**Rationale**

**Background**

Prophylactic mastectomy (PM) may be considered in women thought to be at high risk of developing breast cancer, either due to family history, presence of genetic variants (e.g., BRCA1, BRCA2), having received radiotherapy to the chest, or the presence of lesions associated with an increased cancer risk such as lobular carcinoma in situ. Lobular carcinoma in situ is both a risk factor for all types of cancer, including bilateral cancer and, in some cases, a precursor to invasive lobular cancer. For those who develop invasive cancer, up to 35% may have bilateral cancer. Therefore, bilateral PM may be performed to eliminate the risk of cancer arising elsewhere; chemoprevention and close surveillance are alternative risk-reduction strategies. PMs are typically bilateral but can also describe a unilateral mastectomy in a patient who has previously undergone or is currently undergoing a mastectomy in the opposite breast for invasive cancer (i.e., contralateral PM). Use of contralateral PM has increased in the United States. An analysis of data from the National Cancer Data Base found that the rate of contralateral PM in women diagnosed with unilateral stage I, II, or III breast cancer increased from approximately 4% in 1998 to 9.4% in 2002.

The appropriateness of PM is a complicated risk-benefit analysis that requires estimates of a patient's risk of breast cancer, typically based on the patient's family history of breast cancer and other factors. Several models are available to assess risk, such as the Claus model and the Gail model. Breast cancer history in first- and second-degree relatives is used to estimate breast cancer risk in the Claus model. The Gail model uses the following 5 risk factors: age at evaluation, age at menarche, age at first live birth, the number of breast biopsies, and the number of first-degree relatives with breast cancer. Moreover, the choice of PM is based on patient tolerance for risk, consideration of changes to appearance and need for additional cosmetic surgery, and the risk-reduction offered by PM vs other options.

**Literature Review**

**Prophylactic Mastectomy**

**Systematic Reviews**

The evidence review was initially based on a 1999 Blue Cross Blue Shield Association Technology Evaluation Center (TEC) Assessment that concluded prophylactic mastectomy (PM) met the TEC
criteria for patients with a family history of breast cancer. The Assessment largely focused on a 1999 retrospective cohort analysis that found approximately 13 moderate-risk women would have to have PM to prevent 1 cancer. For those at high risk of breast cancer, reduction in breast cancer incidence ranged from 90% to 94%. Four to 8 high-risk women would need to undergo PM to prevent a single occurrence of breast cancer.

A 2010 Cochrane review examined the impact of PM on mortality and other health outcomes. Reviewers did not identify any randomized controlled trials. Thirty-nine observational studies with some methodologic limitations were identified in the literature search. The studies presented data on 7384 women with a wide range of risk factors for breast cancer who underwent PM. Studies on the incidence of breast cancer and/or disease-specific mortality reported reductions after bilateral PM, particularly for those with BRCA1 or BRCA2 variants. Reviewers concluded that, while the available observational data suggested bilateral PM reduces the rate of breast cancer mortality, more rigorous studies (ideally randomized controlled trials) were needed, and that bilateral PM should only be considered for patients at very high risk of disease.

Several recent systematic reviews have evaluated the impact of PM on health outcomes in women with BRCA variants. In 2016, Li et al identified 15 controlled studies evaluating the impact of prophylactic surgeries including bilateral PM on women with BRCA1 or BRCA2 variants. In a meta-analysis of 6 studies with 2555 BRCA1 or BRCA2 variant carriers, compared with controls who did not receive PM, there was a significantly lower risk of subsequent breast cancer in women who had bilateral PM (relative risk [RR], 0.11; 95% confidence interval [CI], 0.04 to 0.32). However, in a meta-analysis of 2 studies in BRCA1 or BRCA2 variant carriers with no history of breast cancer, there was no significant effect on breast cancer-specific mortality (hazard ratio [HR], 0.29; 95% CI, 0.03 to 2.61) or on all-cause mortality (HR=0.29; 95% CI, 0.03 to 2.61). Similarly, in 2016 Ludwig et al identified 10 studies on the incidence of breast cancer after bilateral PM in BRCA1 or BRCA2 carriers and found a significant reduction in breast cancer risk ranging from 89.5% to 100%. Ludwig et al did not conduct pooled analyses of studies on the impact of PM on mortality.

Section Summary: Prophylactic Mastectomy
Evidence from systematic reviews has found that the incidence of breast cancer is reduced in women at high risk of breast cancer, especially those with BRCA1, BRCA2, and other pathogenic variants and those with a formal high-risk familial risk assessment. Fewer studies have examined the impact of PM on overall or breast cancer-specific survival.

Contralateral Prophylactic Mastectomy
Incidence of a Second Primary Breast Cancer
The potential for contralateral prophylactic mastectomy (CPM) to impact survival is related to its association with a reduced risk of subsequent primary breast cancer in the other breast (i.e., contralateral breast cancer [CBC]). In general, according to data from the U.S. Surveillance, Epidemiology and End Results (SEER) database, annual rates of CBC were stable between 1975 and 1985, after which rates declined about 3% per year (95% CI, 2.7% to 3.5%). Beginning in 1990, the annual decline in CBC rates was only in women with estrogen receptor-positive cancer, with no decrease in women with estrogen receptor-negative cancer. The investigators suggested that the decrease in CBC rates after estrogen receptor-positive cancer might be attributed at least in part to the increased availability of adjuvant hormone therapies.

Studies were sought assessing the risk of CBC in women who met high-risk and average-risk criteria. In 2014, Molina-Montes et al published a systematic review of studies on the risk of a second primary breast cancer in women with and without BRCA1 or BRCA2 variants. Twenty studies were included (12 retrospective cohort studies, 2 prospective cohort studies, 6 case-control studies). Most studies included only women who had undergone genetic testing; it is likely that even those who tested negative had other risk factors that motivated testing. A meta-analysis found that the cumulative risk of a second primary breast cancer at 5 years after initial diagnosis was 14% (95% CI, 9% to 19%) in BRCA1 or BRCA2 variant carriers and 3% (95% CI, 2% to
5%) in noncarriers. The cumulative risk of a second primary cancer at 10 years after initial diagnosis was 22% (95% CI, 18% to 27%) in BRCA1 or BRCA2 variants and 5% (95% CI, 3% to 7%) in noncarriers.

**Survival after Contralateral Prophylactic Mastectomy**

As is the case for bilateral PM, no randomized controlled trials evaluating the effect of CPM on health outcomes have been published. There are a number of observational studies, including some with large sample sizes, and a systematic review of those observational studies. Observational studies have attempted to control for potential confounders, but not all relevant factors were measured, and the possibility of selection bias remains.

A systematic review and meta-analysis of studies on CPM was published in 2014 by Fayanju et al.8 Reviewers searched for published studies that compared the incidence of CBC in women with unilateral disease who did and did not undergo CPM. Fourteen observational studies met eligibility criteria and were included in the meta-analysis. In a meta-analysis of 4 studies, mortality from breast cancer was lower in the group that had CPM (RR=0.69; 95% CI, 0.56 to 0.85). Moreover, in a meta-analysis of data from 6 studies, overall survival (OS) was significantly higher in patients who underwent CPM (n=10,666) than those who had no CPM (n=145,490; RR=1.09; 95% CI, 1.06 to 1.11). Reviewers also conducted a subgroup analysis by risk level. Studies in which all patients were BRCA variant carriers and studies in which all patients had a family history of breast cancer (4 studies) were categorized as indicating higher familial/genetic risk. Together, the studies included 618 patients who had CPM and 1318 patients who did not. In a meta-analysis limited to these 4 studies, neither OS nor mortality from breast cancer differed significantly among women who had or did not have CPM. The RR of breast cancer mortality with and without CPM was 0.66 (95% CI, 0.27 to 1.64). For OS with and without CPM, the RR was 1.09 (95% CI, 0.97 to 1.24). The absolute reduction in the risk of metachronous breast cancer did not differ between women with and without CPM when data from all 8 studies were analyzed (risk difference [RD], -18.0% 95% CI, -42.0% to 5.9%, but was significantly lower in women with CPM in the 4 studies exclusively enrolling women at increased familial/genetic risk (RD = -24.0% 95% CI, -35.6% to -12.4%). Commenting on the totality of findings, reviewers stated that the improvement in survival after CPM in the general breast cancer population was likely not due to a decreased incidence of CBC, but rather was secondary to selection bias (e.g., CPM recipients may be otherwise healthier and have better access to health care).

Studies in the Fayanju systematic review were published between 1997 and 2005. More recent large observational analyses are described below.

Several analyses of data from the SEER database have been published. In 2017, Wong et al analyzed 496,488 women diagnosed with unilateral invasive breast disease.9 Within this cohort, 58.6% (n=295,860) underwent breast-conserving surgery, 33.4% (n=165,888) had a unilateral mastectomy, and 7% (n=34,740) had CPM. The median age was 50 years in the CPM group and 60 years in the breast conservation group (p<0.001). Patients were followed for a median of 8.25 years. In an analysis adjusting for age and other factors including stage of disease, OS was significantly higher after breast conservation than after CPM (HR=1.08; 95% CI, 1.03 to 1.14). Similarly, breast cancer-specific survival was significantly higher in the breast conservation group than in the CPM group (HR=1.08; 95% CI, 1.01 to 1.16).

An analysis of SEER data by Kruper et al suggested that the association between CPM and reduced mortality identified in some data analyses can be attributed at least in part to selection of a healthier cohort of women for CPM.10 In 2014, Kruper et al conducted a case-control analysis including 28,015 CPM patients and 28,015 unilateral mastectomy patients in the SEER database, matched by age group, race/ethnicity, extent of surgery, tumor grade, tumor classification, node classification, estrogen receptor status, and propensity score. The investigators were unable to match for BRCA or other genetic variant status. When all matched patients were included, disease-specific survival (DSS) and OS were significantly lower in women who underwent unilateral mastectomy compared with CPM. For DSS, the hazard ratio was 0.83.
(95% CI, 0.77 to 0.90); for OS, it was 0.77 (95% CI, 0.73 to 0.82). Presumably, CPM would increase survival by lowering the risk of CBC. The authors conducted another analysis excluding women diagnosed with CBC; the remaining sample was still large (25,924 women with unilateral mastectomy and 26,299 women with CPM). In the analysis excluding women with CBC, DSS, and OS remained significantly lower in women who had unilateral mastectomy vs CPM. For DSS, the HR was 0.87 (95% CI, 0.80 to 0.94); for OS, it was 0.76 (95% CI, 0.71 to 0.81). The investigators suggested that the survival benefits found in CBC patients were not due to prevention of CBC, but to selection bias (e.g., healthier women choosing CBC). A limitation of the analysis was the inability to control for risk factors including gene variant status, family history, and a history of radiotherapy to the chest between ages 10 and 30 years.

In 2013, Yao et al evaluated OS after CPM by analyzing data from the National Cancer Data Base. The database collects information from 1450 Commission of Cancer–accredited cancer programs. The analysis included 219,983 women who had a mastectomy for unilateral breast cancer; 14,994 (7%) of these women underwent CPM at the time of their mastectomy surgery. The investigators did not report risk factors such as known genetic variants. The 5-year OS rate was 80%. In an analysis adjusting for confounding factors, the risk of death was significantly lower in women who had CPM than in women who did not. The adjusted HR for OS was 0.88 (95% CI, 0.83 to 0.93). The absolute risk of death over 5 years with CPM was 2.0% lower than without CPM. In subgroup analyses, there was a survival benefit after CPM for individuals ages 18 to 49 years and ages 50 to 69 years, but not for those 70 years or older. There was also a survival benefit for women with stage I and II tumors, but not stage III tumors.

In a subsequent study, Pesce et al (2014) focused on the subgroup of patients who were young (<45 years old) with stage I or II breast cancer. A total of 4338 (29.7%) of 14,627 women in this subgroup had CPM at the time of mastectomy surgery. Median follow-up was 6.1 years. In a multivariate analysis controlling for potentially confounding factors, OS did not differ significantly between patients who underwent unilateral mastectomy and those who also had CPM (HR=0.93; 95% CI, 0.79 to 1.09). Moreover, among women younger than 45 years with estrogen receptor–negative cancer, there was no significant improvement in OS in those who had CPM or unilateral mastectomy (HR=1.13; 95% CI, 0.90 to 1.42).

There are risks and benefits associated with CPM. In particular, several analyses have found higher rates of surgical complications in women undergoing CPM (bilateral mastectomy) or unilateral mastectomy. Besides morbidity associated with these complications, surgical complications may delay receiving adjuvant therapy.

In 2015, Silva et al published a large multicenter study including 20,501 women with unilateral breast cancer from the American College of Surgeons National Surgery Quality Improvement Program database. A total of 13,268 (64.7%) women underwent a unilateral mastectomy, and 7233 (35.3%) had a bilateral mastectomy. The analysis did not report on high-risk factors such as BRCA variant status or family history. All women had breast reconstruction; a higher proportion of women who had a unilateral mastectomy (19.5%) than bilateral mastectomy (8.9%) had autologous reconstruction; the remainder had implant-based reconstruction. The authors conducted analyses controlling for confounding variables (i.e. age, race smoking, diabetes, chronic pulmonary disease, hypertension) and stratifying by type of implant. The rate of overall complications was significantly higher for women who had a bilateral mastectomy, regardless of reconstruction type. Among women with implant reconstructions, overall complication rates were 10.1% after bilateral mastectomy and 8.8% after unilateral mastectomy (adjusted odd ratio [OR], 1.20; 95% CI, 1.08 to 1.33). In women with autologous reconstructions, overall complication rates were 21.2% after bilateral mastectomy and 14.7% after unilateral mastectomy (adjusted OR=1.60; 95% CI, 1.28 to 1.99). The most common complication was reoperation within 30 days, followed by surgical site complications. Transfusion rates were also significantly higher (p<0.001) in women with bilateral mastectomies who had either type of reconstruction. The rates of medical complications were relatively low—approximately 1% of women who had implant reconstructions and 3% of women who had autologous reconstructions experienced a medical
complication (i.e., pneumonia, renal insufficiency or failure, sepsis, urinary tract infection, venous thromboembolism)—and did not differ significantly between unilateral and bilateral mastectomies.

Several single-center studies have also found significantly higher surgical complication rates after bilateral than a unilateral mastectomy. For example, in a 2013 study by Miller et al, which included 600 women with unilateral breast cancer, CPM remained associated with a significantly higher risk of any complication (OR=1.53; 95% CI, 1.04 to 2.25) and a significantly higher risk of major complications (OR=2.66; 95% CI, 1.37 to 5.19) than unilateral mastectomy. Moreover, in a 2014 study by Eck et al, which assessed 352 women with unilateral breast cancer, 94 (27%) women had complications, 48 (14%) in the unilateral mastectomy group, and 46 (13%) in the bilateral mastectomy group. The difference between groups was not statistically significant (p=0.11), but this study might have been underpowered. Moreover, the Eck study found a significant delay in adjuvant therapy after surgical complications: women with complications waited longer before receiving adjuvant therapy than those without complications (49 days vs 40 days, p<0.001).

Section Summary: Contralateral Prophylactic Mastectomy
Large observational studies have reported mixed findings on the survival benefit of CPM in women with unilateral breast cancer who do not otherwise meet high-risk criteria. Researchers have suggested that improvements in survival after CPM in the general breast cancer population found in some studies are due at least in part to selection bias. Moreover, there are risks of CPM associated with both the surgical and the reconstruction procedures.

Summary of Evidence
For individuals who have a high risk of breast cancer or extensive mammographic abnormalities precluding excision or biopsy who receive a prophylactic mastectomy, the evidence includes systematic reviews and observational studies. Relevant outcomes are overall survival, disease-specific survival, functional outcomes, and treatment-related morbidity. The studies found that prophylactic mastectomy reduces breast cancer incidence and increases survival in select patients. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have unilateral breast cancer but are not otherwise at high risk who receive a contralateral prophylactic mastectomy, the evidence includes systematic reviews and observational studies. Relevant outcomes are overall survival, disease-specific survival, functional outcomes, and treatment-related morbidity. Available studies do not demonstrate a survival benefit in women without high-risk criteria. Moreover, there are risks of contralateral prophylactic mastectomy associated with the surgical procedure itself, as well as associated reconstruction procedures. The evidence is insufficient to determine the effects of the technology on health outcomes.

Supplemental Information
Clinical Input from Physician Specialty Societies and Academic Medical Centers
While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests from Blue Cross Blue Shield Association, focused clinical input was received from 1 specialty society and 6 academic medical centers in 2016. Input addressed use of contralateral prophylactic mastectomy in women with unilateral breast cancer who are not otherwise at high risk for developing breast cancer in the contralateral breast. Clinical input was mixed. Clinicians offered suggestions for modifying high-risk criteria, but there was no consensus on potential additional risk factors.
Practice Guidelines and Position Statements
Society of Surgical Oncology
The Society of Surgical Oncology published an updated position statement on prophylactic mastectomy in 2017. The position statement concluded the following about prophylactic mastectomy:

“There is no single-risk threshold above which risk-reducing mastectomy is clearly indicated, and it is important for treating physicians and surgeons to explain to individuals not only the risk assessment but also all available treatment strategies to facilitate a shared decision-making process.”

“The available data suggest that BMP [bilateral prophylactic mastectomy] confers a survival advantage in women with the highest risk who undergo the procedure at a relatively early age ... the impact of CPM [contralateral prophylactic mastectomy] in women with invasive breast cancer is more difficult to assess ... however, CPM does not appear to confer a survival advantage.”

National Cancer Institute
The National Cancer Institute updated its fact sheet in 2013 on risk-reducing surgery for breast cancer. The fact sheet stated women with the following characteristics may consider bilateral prophylactic mastectomy:
- Deleterious variant in BRCA1 or BRCA2
- Strong family history of breast cancer
- Lobular carcinoma in situ and family history of breast cancer
- Radiotherapy to the chest before the age of 50 years.

American Society of Breast Surgeons
A 2016 consensus statement from the American Society of Breast Surgeons made the following recommendations on contralateral prophylactic mastectomy (CPM):

CPM should be considered for the following individuals at significant risk of contralateral breast cancer:
- Documented BRCA1 or BRCA2 carrier
- Strong family history in the absence of genetic testing
- History of chest radiation before age 30

CPM can be considered for the following individuals at lower risk of contralateral breast cancer:
- Carrier of CHEK2, PALB2, TP53, or CDH1
- Strong family history in BRCA-negative patients without known BRCA family member

CPM may be considered for other reasons:
- “To limit contralateral breast surveillance (dense breasts, failed surveillance, recall fatigue).
- To improve breast symmetry in reconstruction.
- To manage risk aversion ... [or] extreme anxiety.” (note: anxiety may better be measured through psychological support.)

CPM should be discouraged in the following situations:
- “Average-risk women with unilateral breast cancer
- Women with advanced stage index cancer....
- Women at high risk of surgical complications (e.g., ... comorbidities, obesity, smoking, diabetes)”
- BRCA-negative, with BRCA-positive family members
- “Males with breast cancer, including BRCA carriers.”
National Comprehensive Cancer Network
NCCN has made recommendations on several cancers relevant to this evidence review. On breast cancer risk-reduction (v.1.2017), NCCN recommends:

“Risk-reduction mastectomy should generally be considered only in women with a genetic mutation conferring a high risk history for breast cancer..., compelling family history, or possibly with LCIS [lobular carcinoma in situ] or prior thoracic radiation therapy at <30 years of age.... The value of risk-reduction mastectomy in women with deleterious mutations in other genes associated with a 2-fold or greater risk for breast cancer ... in the absence of a compelling family history of breast cancer is unknown.”

For invasive breast cancer (v.2.2017) NCCN has discouraged CPM, except for certain high-risk situations (noted in the risk-reduction guideline previously discussed). The guidelines state:

“the small benefits from contralateral prophylactic mastectomy for women with unilateral breast cancer must be balanced with the risk of recurrent disease from the known ipsilateral breast cancer, psychological and social issues of bilateral mastectomy, and the risks of contralateral mastectomy. The use of a prophylactic mastectomy contralateral to a breast treated with breast-conserving therapy is very strongly discouraged.”

As part of genetic/familial high-risk assessment for breast and ovarian cancer (v.2.2017), NCCN recommends that the option of risk-reduction mastectomy be discussed in women with BRCA-related breast and/or ovarian syndrome, Li-Fraumeni syndrome, and Cowden syndrome or PTEN hamartoma tumor syndrome. In addition, NCCN guidelines recommend that risk-reducing mastectomy be considered based on family history in women with certain genetic variants including CHEK2, STK11, and CDH1.

U.S. Preventive Services Task Force Recommendations
No U.S. Preventive Services Task Force recommendations for prophylactic mastectomy have been identified.

Medicare National Coverage
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials
A search of ClinicalTrials.gov in May 2017 did not identify any ongoing or unpublished trials that would likely influence this review.

References


### Documentation for Clinical Review

Please provide the following documentation (if/when requested):

- History and physical and/or consultation notes including:
  - High-risk of breast cancers
  - Familial history as it relates to high-risk breast cancer
  - Previous radiotherapy to the chest
Post Service
- Operative report(s)

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of codes does not constitute or imply member coverage or provider reimbursement.

MN/IE

The following services may be considered medically necessary in certain instances and investigational in others. Services may be considered medically necessary when policy criteria are met. Services may be considered investigational when the policy criteria are not met or when the code describes application of a product in the position statement that is investigational.

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Policy History

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

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Definitions of Decision Determinations

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 (as applicable to your plan)

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 be directed to the Prior Authorization Department. Please call (800) 541-6652 or visit the provider portal at www.blueshieldca.com/provider.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.