Prophylactic Mastectomy

Policy # 00141
Original Effective Date: 09/27/2004
Current Effective Date: 10/18/2017

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Genetic Testing for Hereditary Breast and/or Ovarian Cancer Syndrome (BRCA1 or BRCA2) is addressed separately in medical policy 00047.

Note: Genetic Cancer Susceptibility Panels Using Next Generation Sequencing is addressed separately in medical policy 00382.

Note: Moderate Penetrance Variants Associated With Breast Cancer in Individuals at High Risk Breast Risk is addressed separately in medical policy 00504.

When Services May Be Eligible for Coverage
Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider prophylactic mastectomy (PM) in patients at high risk of breast cancer to be **eligible for coverage**.

Patient Selection Criteria:
Coverage eligibility will be considered for prophylactic mastectomy (PM) in patients at high risk of breast cancer when ANY of the following criteria are met:

- Lobular carcinoma in situ (LCIS); or
- A known *BRCA1* or *BRCA2* mutation; or
- another gene mutation associated with high risk *TP53* (Li-Fraumeni syndrome), *PTEN* (cowden syndrome, Bannayan-Riley-Ruvalcaba syndrome), *CDH1, or STK11* mutation; or
- High risk (lifetime risk about 20% or greater) of developing breast cancer as identified by models that are largely defined by family history; or
- Received radiation therapy to the chest between the ages of 10 and 30 years.

When Services Are Eligible for Coverage
Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
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Based on review of available data, the company considers prophylactic mastectomy (PM) in patients with such extensive mammographic abnormalities (i.e., calcifications) that adequate biopsy or excision is impossible to be **eligible for coverage**.

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

When Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.
Based on review of available data, the Company considers prophylactic mastectomy (PM) for all other indications, including but not limited to contralateral prophylactic mastectomy (CPM) in women with breast cancer who do not meet risk criteria to be **investigational.***

Background/Overview

PM is defined as the removal of the breast in the absence of malignant disease to reduce the risk of breast cancer occurrence. Prophylactic mastectomies may be considered in women thought to be at high risk of developing breast cancer, either due to a family history, presence of genetic mutations such as *BRCA1* or *BRCA2*, having received radiation therapy to the chest, or the presence of lesions associated with an increased cancer risk such as LCIS. LCIS is both a risk factor for all types of cancer, including bilateral cancer, and in some cases, a precursor for 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. Prophylactic mastectomies 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 an invasive cancer (i.e., CPM). The use of CPM has risen in recent years in the United States. An analysis of data from the National Cancer Data Base found that the rate of CPM in women diagnosed with unilateral stage I-III breast cancer increased from approximately 4% in 1998 to 9.4% in 2002.

The appropriateness of a 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, number of breast biopsies, and 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 versus other options.

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FDA or Other Governmental Regulatory Approval

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

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

Rationale/Source

The most recent literature search was performed for the period through January 7, 2016. Following is a summary of key findings.

This policy was initially based on a 1999 Technology Evaluation Center (TEC) Assessment that concluded that PM met the TEC criteria for patients with a family history of breast cancer. The Assessment largely focused on a 1999 retrospective cohort analysis which found that 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 1 occurrence of breast cancer.

As of 2014, the National Comprehensive Cancer Network (NCCN) guideline recommends that PM should only be considered in high-risk women, defined as having a *BRCA1* or *BRCA2* mutation or another gene mutation associated with increased risk (e.g., *PTEN* [Cowden and Bannayan-Riley-Ruvalcaba syndromes], *TP53* [Li-Fraumeni syndrome], *CDH1, STK11*), a compelling family history, and possibly in women with LCIS or prior thoracic radiotherapy before 30 years of age. Additional genetic mutations that have been associated with a high rate of cancer include *TP53* (Li-Fraumeni syndrome) and *PTEN* (Cowden and Bannayan-Riley-Ruvalcaba syndromes). In patients who received prior radiotherapy to the chest between the ages of 10 and 30 years of age, the increased risk of breast cancer can reach almost 30% by age 55 years. Patients with LCIS, which is usually identified incidental to breast biopsy, are also at increased risk of cancer. In 2011, Oppong and King reported that, compared with the general population, women with LCIS face an 8- to 10-fold increased risk of cancer, equaling 26% after 20 years in 1 study.

A 2010 Cochrane review examined the impact of PM on mortality and other health outcomes. The authors did not identify any randomized controlled trials (RCTs). Thirty-nine observational studies with some methodological 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 *BRCA 1/2* mutations. The authors concluded that, while the available observational data suggest that bilateral PM reduces the rate of breast cancer mortality, more rigorous studies (ideally RCTs) are needed, and that bilateral PM should only be considered among patients at very high risk of disease.

Section Summary: Prophylactic Mastectomy
Evidence from systematic reviews found that reduction in breast cancer incidence is reduced and breast cancer survival is increased in women at high risk of breast cancer, especially those with *BRCA1* or *BRCA2* and selected other mutations and those with a compelling family history.

Contralateral Prophylactic Mastectomy
Incidence of Second Primary Breast Cancer
The potential for 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% confidence interval [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 may be attributed at least in part to the increased availability of adjuvant hormone therapies.

Studies were sought on the risk of CBC in women who meet high-risk criteria versus 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* mutations. Twenty studies were included; 12 retrospective cohort studies, 2 prospective cohort studies, and 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* mutation carriers and 3% (95% CI, 2% to 5%) in noncarriers. Cumulative risks of a second primary cancer at 10 years after initial diagnosis was 22% (95% CI, 18% to 27%) in *BRCA1* or *BRCA2* mutation carriers and 5% (95% CI, 3% to 7%) in noncarriers.

Survival
As is the case for bilateral PM, no RCTs 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 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. The authors 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 (relative risk [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). The authors also conducted a subgroup analysis by risk level. Studies in which all patients were *BRCA* mutation 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 in 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, the authors 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 meta-analysis were published between 1997 and 2005. More recent large observational analyses are described below.

Other analyses have also 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. In particular, a 2014 analysis by Kruper et al of a large dataset from the SEER database looked at CBC and survival outcomes. The investigators conducted a case-control analysis including 28,015 CPM patients and 28,015 unilateral mastectomy patients, matched on age group, race/ethnicity, extent of surgery, tumor grade, tumor classification, node classification, estrogen receptor status, and propensity score. The investigators were not able to match for *BRCA* or other mutation 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 (HR) 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 versus 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 was not due to prevention of CBC, but instead to selection bias (e.g., healthier women choosing CBC). A limitation of the analysis was the inability to control for risk factors including gene mutation 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 data from 1450 Commission of Cancer–accredited cancer programs. The analysis included 219,983 women who had 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 mutations. 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 aged 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.

A subsequent study by Pesce et al, published in 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 among 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 versus 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) versus 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 (NSQIP) database. A total of 13,268 (64.7%) women underwent unilateral mastectomy and 7233 (35.3%) had bilateral mastectomy. The analysis did not report on high-risk factors such as *BRCA* mutation status or family history. All women had breast reconstruction; a higher proportion of women who had 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 versus unilateral 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 versus unilateral 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 for unilateral versus bilateral mastectomies.

Several single-center studies have also found significantly higher surgical complication rates after bilateral than 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.15 The difference between groups was not statistically significant (p=0.11), but this study may 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 had 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 improvement in survival after CPM in the general breast cancer population found in some studies is due at least in part to selection bias. Moreover, there are risks (e.g., surgical risks) of CPM.

Ongoing and Unpublished Clinical Trials
A search of ClinicalTrials.gov in January 2016 did not identify any ongoing or unpublished trials that would likely influence this review.

Summary of Evidence
The evidence for PM in women who have high risk of breast cancer or extensive mammographic abnormalities precluding incision or biopsy includes a TEC Assessment and systematic review of observational studies. Relevant outcomes are OS, DSS, functional outcomes, and treatment-related morbidity. The studies found that PM reduces breast cancer incidence and increases survival in select patients. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

The evidence for CPM in women who have unilateral breast cancer but are not otherwise at high risk includes observational studies. Relevant outcomes are OS, DSS, functional outcomes, and treatment-related morbidity. Available studies do not clearly demonstrate a survival benefit in women without high-risk criteria. Moreover, there are potential risks (e.g., surgical risks) associated with CPM. National guidelines, including those from the National Comprehensive Care Network, do not recommend that CPM be considered other than for certain high-risk women. The evidence is insufficient to determine the effects of the technology on health outcomes.

Practice Guidelines and Position Statements
National Comprehensive Cancer Network

- Breast Cancer Risk Reduction (v.2.2015): “Risk-reduction mastectomy should generally be considered only in women with a genetic mutation conferring a high risk history for breast cancer (See NCCN guidelines for Genetic/Familial High-Risk Assessment: Breast and Ovarian, Table on GENE-2*), compelling family history, or possibly with LCIS 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 (based on large epidemiologic studies) in the absence of a compelling family history of breast cancer is unknown.”
- Breast cancer (v.2.2015): Except for certain high-risk situations (noted in the risk reduction guideline previously discussed), CPM is discouraged. The guideline states: “the small benefits

from contralateral PM 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 PM contralateral to a breast treated with breast-conserving therapy is very strongly discouraged."

* Genes that confer more than 20% risk of breast cancer include *BRAC1, BRCA2, ATM, CDH1, CHEK2, PALB2, PTEN, STK11,* and *TP53.*

Society of Surgical Oncology
The Society of Surgical Oncology developed a position statement on PM in 1993 and updated it in 2007.

The position statement states that bilateral PM is potentially indicated in patients with:

- known *BRCA* 1 or 2 mutations or other genes that strongly predispose susceptibility to breast cancer,
- a history of multiple first-degree relatives with breast cancer history or multiple successive generations of breast and/or ovarian cancer, or
- biopsy-confirmed, high-risk histology such as atypical ductal or lobular hyperplasia or LCIS.

The position statement also stated that CPM may be potentially indicated in patients:

- with high risk (as defined above) of CBC,
- in whom surveillance would be difficult such as with dense breast tissue or diffuse indeterminate microcalcifications, or to improve symmetry.

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Policy History

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08/31/2004	Medical Director review
09/21/2004	Medical Policy Committee review
09/27/2004	Managed Care Advisory Council approval
09/07/2005	Medical Director review
09/20/2005	Medical Policy Committee review Coverage eligibility unchanged
09/22/2005	Quality Care Advisory Council approval
07/07/2006	Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.
10/04/2006	Medical Director review
10/18/2006	Medical Policy Committee approval. Policy statement unchanged. Addition of FDA and or other governmental regulatory approval. References added.
10/10/2007	Medical Director review
10/17/2007	Medical Policy Committee approval. No change to coverage eligibility.
10/01/2008	Medical Director review
10/22/2008	Medical Policy Committee approval. No change to coverage eligibility.
10/01/2009	Medical Policy Committee approval
10/14/2009	Medical Policy Implementation Committee approval. Added moderately increased risk for breast cancer to be eligible for coverage with criteria. Added last two criteria bullets for high risk breast cancer.
10/14/2010	Medical Policy Committee review
10/20/2010	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
10/06/2011	Medical Policy Committee review
10/19/2011	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
10/11/2012	Medical Policy Committee review

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10/31/2012	Medical Policy Implementation Committee approval. The term “p53” was updated to the more current “TP53” terminology in the Patient Selection Criteria.
10/03/2013	Medical Policy Committee review
10/16/2013	Medical Policy Implementation Committee approval. High risk criteria revised to track BCBSA. Investigational statement reworded to track BCBSA.
10/02/2014	Medical Policy Committee review
10/15/2014	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
10/08/2015	Medical Policy Committee review
10/21/2015	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
10/06/2016	Medical Policy Committee review
10/19/2016	Medical Policy Implementation Committee approval. Removed coverage statement on lobular carcinoma in situ and added LCIS to criteria for high risk. *CDH1*, or *STK11*mutation added to high risk criteria. Removed moderate risk from policy statement and a coverage statement for extensive abnormalities.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
10/05/2017	Medical Policy Committee review
10/18/2017	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 10/2018

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2016 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	19301, 19302, 19303, 19304, 19305, 19306, 19307
HCPCS	No codes
ICD-10 Diagnosis	D05.00-D05.92, Z15.01, Z40.01, Z80.3

*****Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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