

Corporate Medical Policy

Breast Surgeries

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Description of Procedure or Service

Mastectomy is a surgical removal of all or a part of the breast. It is generally performed as treatment for breast cancer or breast disease. When a member certificate covers mastectomy, BCBSNC also covers reconstructive breast surgery resulting from the mastectomy. Procedures or services described in this policy include the following:

Section I -Reconstructive Breast Surgery after Mastectomy

Section II -Surgical Treatment of Gynecomastia

Section III -Reduction Mammoplasty for Breast Related Symptoms

Section IV-Risk-Reducing Mastectomy

Section V -Surgical Management of Breast Implants.

Blue Cross and Blue Shield of North Carolina will not assign specific length of stay for patients having a mastectomy. Whether the surgery is to be inpatient or outpatient and the length of stay are decisions for the attending physician.

Benefits are available for the physical complications related to all stages of mastectomy for breast cancer, including treatment of associated lymphedema.

Related Policies:

Skin and Soft Tissue Substitutes

Cosmetic and Reconstructive Surgery

Gender Affirmation Surgery and Hormone Therapy

Genetic Testing for Breast and Ovarian Cancer

Genetic Testing for PTEN Hamartoma Tumor Syndrome

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

BCBSNC will cover Reconstructive Breast Surgery after Mastectomy, Surgical Treatment of Gynecomastia, Reduction Mammoplasty for Breast Related Symptoms, Risk-Reducing Mastectomy, and Surgical Management of Breast Implants when it is medically necessary because the criteria shown below have been met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

Breast surgeries included in this policy may require prior review.

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SECTION I – Reconstructive Breast Surgery After Mastectomy

Reconstructive breast surgery is defined as a surgical procedure that is designed to restore the normal appearance of the breast after surgery, accidental injury, or trauma. There is a broadening array of surgical approaches to breast reconstruction. The most common is insertion of a breast implant, either a silicone gel-filled or saline-filled prosthesis. The implant is either inserted immediately at the time of mastectomy or sometime afterward in conjunction with the previous use of a tissue expander. The breast may also be reconstructed using autologous tissues, such as a free flap, a latissimus dorsi flap, or more commonly using a transverse rectus abdominis flap (TRAM procedure).

Nipple areola reconstruction or nipple tattooing may also be considered reconstructive breast surgery. Since the purpose of reconstructive breast surgery is to restore the normal appearance of the breast, reconstructive procedures such as mastopexy, reduction mammoplasty, autologous fat transplant (i.e., liposuction) may be performed on the nondiseased/unaffected/contralateral breast to produce a symmetrical appearance. These procedures fall into the category of reconstructive breast surgery when performed in conjunction with a contralateral mastectomy for cancer or other breast disease with associated reconstruction. Except for medically necessary reduction mammoplasty, these procedures are considered cosmetic in other circumstances.

When Reconstructive Breast Surgery is covered

Reconstructive breast surgery post mastectomy will be covered without regard to the time elapsed since a mastectomy. It may be performed at the time of the mastectomy or anytime post-operatively as long as the mastectomy was a medically necessary procedure, i.e., for breast cancer, or medically necessary prophylactic mastectomy, or other breast disease not responsive to conservative measures. Mastectomy refers to radical, modified radical, subcutaneous, simple, complete, or partial (lumpectomy, tylectomy, quadrantectomy, segmentectomy) procedures, with or without axillary lymphadenectomy. Reconstruction may be performed by an implant-based approach or through the use of autologous tissue.

Augmentation mammoplasty, reduction mammoplasty, and/or mastopexy of a non-diseased breast will be covered following medically necessary mastectomy for the purpose of achieving reasonable breast symmetry.

When Reconstructive Breast Surgery is not covered

Reconstructive breast surgery is not covered when the member has a breast removed or reduced in size primarily for cosmetic reasons unrelated to mastectomy for breast cancer, medically necessary risk-reducing mastectomy or breast disease. In this case, both the mastectomy and reconstruction would be excluded from coverage.

Policy Guidelines

Member's attending physician in consultation with the patient will determine the length of the hospital stay following a mastectomy if the member is hospitalized.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: 11920, 11921, 11922, 19316, 19318, 19325, 19328, 19330, 19340, 19342, 19350, 19357, 19361, 19364, 19367, 19368, 19369, L8600, S2066, S2067, S2068.

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BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

SECTION II – Surgical Treatment of Gynecomastia

Gynecomastia refers to the benign enlargement of the male breast, either due to increased adipose tissue, glandular tissue, fibrous tissue, or a combination of all three. Gynecomastia may be associated with any of the following:

- An underlying hormonal disorder (conditions causing either estrogen excess or testosterone deficiency, such as liver disease or an endocrine disorder)
- A side effect of certain drugs
- Obesity
- Related to specific age groups
 - neonatal gynecomastia related to action of maternal or placental estrogens
 - adolescent gynecomastia consisting of transient, bilateral breast enlargement
 - gynecomastia of aging related to the decreasing levels of testosterone and relative estrogen excess

Treatment of gynecomastia involves consideration of the underlying cause. For example, treatment of the underlying hormonal disorder, cessation of drug therapy or weight loss may all be effective therapies. Gynecomastia may also resolve spontaneously and adolescent gynecomastia may resolve with aging.

Prolonged gynecomastia causes periductal fibrosis and stromal hyalinization which prevents regression of the breast tissue. Surgical removal of the breast tissue, using either surgical excision or liposuction may be considered if the above conservative therapies are not effective or possible and the gynecomastia does not resolve spontaneously or with aging.

When Surgical Treatment of Gynecomastia is covered

Surgical treatment for the condition of gynecomastia is covered when **ALL** of the following conditions are met:

1. Male is over 18 years of age (Male gynecomastia is not uncommon in adolescent males, and generally resolves without treatment.) or male is over 17 years of age with significant breast tissue present for over two years AND
2. Excess breast tissue is glandular and not fatty tissue. (This is confirmed by clinical exam, mammogram and/or tissue pathology.) AND
3. Other causes of gynecomastia have been ruled out, including reversible drug treatments (When drugs can be discontinued). AND
4. Excessive breast development is not due to non-covered therapies or illicit drugs, e.g., anabolic steroids or marijuana AND
5. If gynecomastia is caused by obesity (BMI>30), it is documented to have failed to respond to conservative measures which must include participation in a clinically supervised, comprehensive weight loss and exercise program for at least 6 months, AND
6. The patient has documented and significant medical symptoms not resolved by more conservative treatments.

When Surgical Treatment of Gynecomastia is not covered

Surgical treatment of gynecomastia is not covered when the criteria listed above are not met.

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Policy Guidelines

The evidence for surgical treatment of bilateral gynecomastia in males includes case series. Relevant outcomes are functional status, health status measurements and treatment-related morbidity. There are no randomized controlled trials on surgical treatment of bilateral gynecomastia, therefore it is not possible to determine whether surgical treatment improves symptoms or functional impairment. Conservative therapy should adequately address any physical pain or discomfort and gynecomastia does not typically cause functional impairment. The evidence is insufficient to determine the effect of the technology on health outcomes.

The American Society of Plastic Surgeons (ASPS) issued practice criteria for third-party payers in 2002, which was affirmed in 2015. ASPS classified gynecomastia using the following scale, which was “adapted from the McKinney and Simon, Hoffman and Kohn scales”:

- Grade I: Small breast enlargement with localized button of tissue that is concentrated around the areola.
- Grade II: Moderate breast enlargement exceeding areola boundaries with edges that are indistinct from the chest.
- Grade III: Moderate breast enlargement exceeding areola boundaries with edges that are distinct from the chest with skin redundancy present.
- Grade IV: Marked breast enlargement with skin redundancy and feminization of the breast.

According to ASPS, in adolescents, surgical treatment for “unilateral or bilateral grade II or III gynecomastia” may be appropriate if the gynecomastia “persists for more than 1 year after pathological causation is ruled out” (or 6 months if grade IV) and continues “after 6 months of unsuccessful medical treatment for pathological gynecomastia.” In adults, surgical treatment for “unilateral or bilateral grade III or IV gynecomastia” may be appropriate if the gynecomastia “persists for more than 3 or 4 months after pathological causes ruled out [and continues] after 3 or 4 months of unsuccessful medical treatment for pathological gynecomastia.” ASPS also indicated that surgical treatment of gynecomastia may be appropriate when distention and tightness cause “pain and discomfort.”

Surgical treatment of gynecomastia requires prior review.

Billing/Coding/Physician Documentation Information

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Applicable service codes: 19300

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

SECTION III – Reduction Mammoplasty for Breast Related Symptoms

Macromastia, or gigantomastia, is a condition that describes breast hyperplasia or hypertrophy. Macromastia may result in clinical symptoms such as shoulder, neck, or back pain, or recurrent intertrigo in the mammary folds. Reduction mammoplasty is a surgical procedure designed to remove a variable proportion of breast tissue including skin and underlying glandular tissue to relieve the associated clinical symptoms. It results in a significant reduction in the size of the breast, change in shape and an uplifting effect on the breast tissue. It differs from mastectomy where the entire breast is removed.

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When medically necessary, a reduction mammoplasty is used to relieve symptoms resulting from breast hypertrophy (an increase in the volume and weight of breast tissue in excess of the normal proportion) such as shoulder pain, back pain, and shoulder grooving.

When Reduction Mammoplasty is covered

Reduction mammoplasty for symptomatic breast hypertrophy may be considered medically necessary and eligible for coverage when **ALL** of the following criteria are met (A, B, C, D, and E):

- A.) The patient has significant symptoms that interfere with normal activities, including **at least one** of the following:
 - 1.) symptomatic neck, back or shoulder pain not related to other causes (e.g., poor posture, acute strains, poor lifting techniques). Documentation of evaluation and treatment of neck, back or shoulder pain must be supplied.
 - 2.) clinical, non-seasonal submammary intertrigo

- B.) The patient's physical exam documents **at least two** of the following:
 - 1.) significant shoulder grooving
 - 2.) physical exam indicates obvious breast hypertrophy (pictures are not necessary) that is consistent with symptoms precipitating request for reduction mammoplasty
 - 3.) suprasternal to nipple measurement of greater than 28 cm for individuals greater than or equal to 5' 2" tall, or 25 cm for individuals less than 5' 2" tall.

- C.) Failure of conservative measures including:
 - 1.) for back, neck, or shoulder pain, failure of 6 weeks of conservative treatment, including all of the following:
 - a.) appropriate support bra and
 - b.) NSAIDS (if not contraindicated) and
 - c.) exercises and heat or cold application
 - 2.) For submammary intertrigo, 6 weeks of conservative treatment, including all of the following:
 - a.) appropriate hygiene and
 - b.) appropriate medical/pharmacologic treatment and
 - c.) utilization of an appropriate support bra

- D.) For patients with a Body Mass Index (BMI) greater than 27, a documented and legitimate medically based attempt to reduce and maintain weight. **This requirement relates specifically to patients with low back pain and/or intertrigo, where obesity is a documented risk factor.** In the absence of weight loss to a BMI less than or equal to 27, a legitimate attempt at weight loss includes **all of the following**:
 - 1.) initial consultation with a physician or mid-level practitioner (Nurse Practitioner, Physician's Assistant) regarding weight loss **and**
 - 2.) The weight loss attempt includes all of the following:
 - a.) regular visits with a practitioner, nutritionist, or other recognized weight loss program over 3 months and
 - b.) the weight loss program includes reasonable dietary modifications and appropriate aerobic exercise and
 - c.) the record indicates that the patient has made reasonable attempts to comply with the weight loss program.

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- E.) The weight of breast tissue anticipated to be removed or removed must be greater than the threshold value for a given body surface area (BSA) in order to be considered medically necessary. (See Table I at the end of this policy.)

Body surface area may be calculated by using the following formula:

$$BSA(m^2) = \sqrt{\frac{weight \text{ (kg)} \times height \text{ (cm)}}{3600}}$$

When Reduction Mammoplasty is not covered

Reduction mammoplasty is not covered when the criteria listed above have not been met.

Policy Guidelines

Current literature searches have identified many articles that discuss the surgical technique of reduction mammoplasty and have documented that reduction mammoplasty is associated with relief of physical and psychosocial symptoms. An important issue is whether reduction mammoplasty is a functional need or a cosmetic procedure. This medical policy makes a distinction between a cosmetic procedure, performed primarily to improve the appearance of the breast, or a medically necessary procedure, performed primarily to relieve documented clinical symptoms. Emotional and psychosocial distress associated with body appearance does not constitute a medical rationale for reduction mammoplasty.

Member's attending physician in consultation with the patient will determine length of the hospital stay if member is hospitalized.

Reduction mammoplasty requires prior review.

Billing/Coding/Physician Documentation Information

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Applicable service codes: 19318

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

SECTION IV – Risk-Reducing Mastectomy

Risk-reducing (prophylactic) mastectomy is defined as the removal of the breast in the absence of malignant disease to reduce the risk of breast cancer occurrence.

Risk-reducing mastectomies may be considered in individuals 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 lobular carcinoma in site (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 risk-reducing mastectomy may be performed to eliminate the risk of cancer arising elsewhere; chemoprevention and close surveillance are alternative risk reduction strategies. Risk-reducing mastectomies are typically bilateral but can also describe a unilateral

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mastectomy in a patient who has previously undergone a mastectomy in the opposite breast for an invasive cancer.

The appropriateness of a risk-reducing mastectomy 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 risk-reducing mastectomy is based on patient tolerance for risk, consideration of changes to appearance and need for additional cosmetic surgery, and the risk reduction offered by risk-reducing mastectomy versus other options.

For reconstructive breast surgery after risk-reducing mastectomy, please refer to Section I of this policy.

When Risk-Reducing Mastectomy is covered

Risk-reducing mastectomy may be considered medically necessary in individuals at high risk of breast cancer. (See Policy Guidelines)

Risk-reducing mastectomy may be considered medically necessary in patients with such extensive mammographic abnormalities (ie, calcifications) that adequate biopsy or excision is impossible.

When Risk-Reducing Mastectomy is not covered

Risk-reducing mastectomy is not covered when the criteria listed above have not been met.

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

Policy Guidelines

There is no standardized method for determining an individual's risk of breast cancer which incorporates all possible risk factors. There are validated risk prediction models, but these are based primarily on family history.

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

- Lobular carcinoma in situ or
- A known BRCA1 or BRCA2 variant,
- Another gene mutation associated with increased risk, e.g., TP53 (Li-Fraumeni syndrome), PTEN (Cowden syndrome, Bannayan-Riley-Ruvalcaba syndrome), CDH1, and STK11 or
- 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 (generally considered to be a lifetime risk of 20% or greater). 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.

Another breast cancer risk assessment tool, using in the Women Informed to Screen Depending on Measures of Risk trial, is the Breast Cancer Surveillance Consortium (BCSC) Risk Calculator a9

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<https://tools.bcsc-scc.org/bc5yearrisk/calculator.htm>). The following information is used in that assessment tool:

- History of breast cancer, ductal carcinoma in situ, breast augmentation, or mastectomy
- Age
- Race/ethnicity
- Number of first-degree relatives diagnosed with breast cancer
- Prior breast biopsies (positive or negative)
- BI-RADS breast density (radiologic assessment of breast tissue density by radiologists who interpret mammograms).

For individuals who have a high risk of breast cancer or extensive mammographic abnormalities precluding incision or biopsy who receive a risk-reducing 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 a risk-reducing mastectomy lowers subsequent breast cancer incidence and increases survival in select high-risk patients. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

The evidence for contralateral risk-reducing mastectomy in individuals with unilateral breast cancer but not otherwise at high risk 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 consistent survival benefit in individuals without high-risk criteria. Moreover, there are potential risks (eg, operative risks) associated with contralateral risk-reducing mastectomy for both the primary surgical and reconstruction procedures. The American Society of Breast Surgeons (ASBrS) endorses the American Board of Internal Medicine's have a Choosing Wisely campaign statement: "Don't routinely perform a double mastectomy in patients who have a single breast with cancer."

National Comprehensive Cancer Network guideline states, "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." American Society of Breast Surgeons states CPM should be 'discouraged' for patients with an average risk of contralateral breast cancer. Therefore, the evidence is insufficient to determine the effects of the technology on health outcomes.

Billing/Coding/Physician Documentation Information

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Applicable codes: 19301, 19302, 19303

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

SECTION V – Surgical Management of Breast Implants

Breast implants are prostheses used for post-surgical mastectomy reconstruction. Breast implants are also used for breast enlargement for primarily cosmetic reasons. They may be internally placed or worn externally in the clothing. For internal use, the breast implant is placed into the breast area once the natural breast tissue has

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been removed. If a patient has adverse reaction to the implants, such as leakage or infection, the implant must be removed.

Breast implants are not lifetime devices. Eventually, most patients will need to undergo at least one or more surgical procedures for routine implant replacement. This may be necessary for reasons ranging from breast implant deflation to medical complications including implant hardening or encapsulation, as well as leaking or frank rupture. Removal of a breast implant may be considered medically necessary depending on the significance of the complication. Capsular contracture is the most common local complication of breast implantation

This policy only addresses internal prosthetic breast implants. For reconstructive breast surgery after risk-reducing mastectomy, please refer to Section I of this policy.

When Surgical Management of Breast Implants is covered

Insertion of breast implants is covered for post surgical mastectomy reconstruction.

Removal of breast implants is covered when it is medically necessary due to complications from an implantation for a covered indication (i.e., not primarily cosmetic).

Removal of breast implants with capsulectomy/capsulotomy is considered medically necessary when the following criteria has been met (See Policy Guidelines):

- Baker Class III contractures (only if the initial implant was for reconstructive purposes)
- Baker Class IV contracture

Removal of a breast implant and capsulectomy is covered, regardless of the indication for the initial implant placement, for:

- Treatment of Anaplastic Lymphoma of the breast when there is pathologic confirmation of the diagnosis by cytology or biopsy; or
- Individuals with an increased risk of implant-associated Anaplastic Lymphoma of the breast due to use of Allergan BIOCELL textured breast implants and tissue expanders.

See also policy titled “Gender Confirmation Surgery and Hormone Treatment.”

When Surgical Management of Breast Implants is not covered

Insertion of the implant is not covered for primarily cosmetic enhancement of the breast in the absence of mastectomy for breast cancer, medically necessary risk-reducing mastectomy or other breast disease.

Removal of the implant is not covered for asymptomatic patients desiring removal.

Removal of the implant is not covered when the original implant surgery was primarily for cosmetic reasons or other non-covered indications.

Removal of breast implants with capsulectomy/capsulotomy is not covered for Baker Class III contractures in patients with implants for cosmetic purposes.

Policy Guidelines

Insertion and Removal of Breast Implants may require prior review.

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Screening for possible leakage of breast implants would initially involve mammography. If negative, the next diagnostic tool would be ultrasound or MRI of the breast.

Baker Classification system:

- Class I Augmented breast feels as soft as a normal breast.
- Class II Breast is less soft and the implant can be palpated, but is not visible.
- Class III Breast is firm, the implant is palpable and the implant (or its distortion) is visible.
- Class IV Breast is hard, painful, cold, tender and distorted

Billing/Coding/Physician Documentation Information

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Applicable codes: 19325, 19328, 19330, 19340, 19342, 19370, 19371, L8600

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

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North Carolina Senate Bill 714, July 10, 1997

Federal Provisions in the Omnibus Appropriation Bill of 1998

Policy entitled: Mastectomy for Gynecomastia

National Association - 12/95

Policy entitled: Mammoplasty, Reduction

1995 Manual 60-1A, BCBSNC 1995 Prior Authorization Criteria

North Carolina Senate Bill 714, Provision of coverage for Reconstructive Breast Surgery resulting from mastectomy, July 10, 1997.

Policy entitled Subcutaneous and Prophylactic Mastectomy

Independent Review; Corporate and ADS Medical Directors

Physician Advisory Group, February 21, 1991

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Policy entitled: Insertion and Removal of Silicone Breast Implants

Information - Food and Drug Administration, April 1992

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Policy entitled: Mastectomy, Length of Stay

North Carolina Senate Bill 273, Ratified August 19, 1997

New policy created entitled: Breast Surgeries

Specialty Matched Consultant Advisory Panel - 11/99

Medical Policy Advisory Group - 12/2/1999

Consultant review - 3/7/2000

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Medical Director review 8/2022

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Policy Implementation/Update Information

Policy entitled: Reconstructive Breast Surgery Post Mastectomy

11/97 Original policy issued.

3/98 Revised: Removed statement under policy section “Reconstruction of the non-diseased breast should occur at the same time as reconstruction on the diseased breast.

11/98 Added statement, “Benefits are available for the physical complications related to all stages of the mastectomy, including treatment of associated lymphedema”.

Policy entitled: Mastectomy for Gynecomastia

6/96 Original policy issued

7/97 Reaffirmed

Policy entitled: Reduction Mammoplasty

1/96 Original policy issued

5/96 Revised: Updated patient criteria

8/97 Revised: Change statement under Policy section from "Revision of remaining non-diseased breast as part of a post unilateral mastectomy reconstruction [is for cosmetic effect and is not covered]." to "is eligible for benefits when necessary to achieve symmetry between the two breasts," based on North Carolina Senate Bill 714.

Policy entitled: Prophylactic Mastectomy

5/91 Original policy issued

8/96 Reaffirmed

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1/99 Reaffirmed: Medical Policy Advisory Group

Policy entitled: Insertion and Removal of Breast Implants

5/92 Original policy issued

7/93 Revised: Policy revised and effective date reinstated 7/28/93

8/96 Reaffirmed

9/98 Reviewed: Added information related to MRI not indicated to detect breast cancer in patients with implants and appropriate diagnostic tools to detect implant leakage.

Policy entitled: Mastectomy, Length of Stay

1/98 Original Policy issued

New policy created entitled: Breast Surgery

5/99 Combined Reconstructive breast surgery post mastectomy, Mastectomy for gynecomastia, Reduction mammoplasty, Prophylactic Mastectomy, and Insertion and Removal of Breast Implants. Mastectomy Length of Stay policy incorporated throughout the policy. No separate section dedicated to this policy. Reformatted and added medical term definitions.

12/99 Approved, Medical Policy Advisory Group

2/00 Typographical errors corrected. System coding changes.

3/00 Consultant review. Medical criteria modifications include: 1.) Mastectomy for Gynecomastia - phrase added "when drugs can be discontinued"; 2.) Reduction Mammoplasty - added suprasternal to nipple measurement for individuals equal to or over 5' 2" tall, and for under 5' 2" tall; added criteria detailing weight loss attempt under when it is covered.

4/00 Added Medical Policy Advisory Group reference to the Scientific Background and Reference Source section of the policy.

10/00 System coding changes.

12/00 Specialty Matched Consultant Advisory panel review. Changes to criteria for gynecomastia stating, "...male is over 17 years of age with significant breast tissue present for over two years." Also added information stating that glandular breast tissue can be confirmed by clinical exam, mammogram and/or tissue pathology. Medical Policy Advisory Group review. No further changes to policy.

04/01 Changes in formatting. Typographical errors corrected.

5/01 Revised. Under what is covered for Prophylactic Mastectomies, the term "normal" was changed to "hormonal". Commas removed.

10/01 Coding format changes.

6/02 Policy reformatted for clarity. Definition of Intertrigo changed from "irritation" to "inflammation". Definition added for Body Mass Index (BMI). Removed the statement, "inability to sleep in a reclined position due to shortness of breath." from the When Reduction Mammoplasty is covered section of the policy. Added code L8600 to the policy.

10/02 Specialty Matched Consultant Advisory Panel review. No change in policy. System coding changes.

11/02 New Source added. Revised "When Mastectomy for Gynecomastia is Covered" section revised to be consistent with certificate language.

1/04 Benefits Application and Billing/Coding sections updated for consistency.

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- 2/04 Section III - Reduction Mammoplasty - "When covered" - D. second sentence now reads "This requirement relates specifically to patients with low back pain and/or intertrigo, where obesity is a documented risk factor." Typos corrected.
- 4/22/04 Changes made for Section III-Reduction Mammoplasty: "When covered", E. criteria revised "The weight of breast tissue to be removed or removed must be greater than the threshold value for a given BSA in order to be considered medically necessary." Also added body surface area formula. Under "Policy Guidelines", added Table 1: Schnur Sliding Scale. Reference sources added. Notification given 4/22/04. Effective date 7/1/04.
- 10/28/04 Specialty Matched Consultant Advisory Panel review - 8/27/04. Under Benefits Application; added "Breast surgeries included in this policy may require prior plan approval." Under Section II - Mastectomy for Gynecomastia; Expanded "Description" section, under "When it is Covered" pulled obesity out of #3 and added as a separate entity with guidelines - "If gynecomastia is caused by obesity (BMI>30), it is documented to have failed to respond to conservative measures which must include participation in a clinically supervised, comprehensive weight loss and exercise program for at least 6 months, **AND**....." Under Section III - Reduction Mammoplasty; "Policy Guidelines", Table I: Schnur Sliding Scale, added "from each breast" to the end of "Threshold of breast tissue to be removed (in grams). Under Section V - Insertion and Removal of Breast Implants; removed "MRI has not been established as a screening modality for breast cancer even in the presence of breast implants." based on MRI of The Breast policy #RAD5105. Reference sources added. Notification given 10/28/04. Effective date 1/6/05.
- 1/6/05 Removed CPT codes 19160, 19162, 19180, 19182, 19200, 19220, 19240, L8030 and L8039 from Section I, Reconstructive Breast Surgery - After Mastectomy, Billing/Coding section. Section I is for reconstruction, not the actual mastectomy so the mastectomy codes were removed. Codes 19328 and 19330 added to section I. Codes L8030 and L8039 are for the type of prosthesis that can be worn in a bra, not implanted (removed these two codes from Section I and V). Appropriate additions and removals indicated in final Billing/Coding section that includes all codes in each section.
- 2/2/06 Added 2006 HCPCS code S2068 to Section I, Reconstructive Breast Surgery, Billing/Coding section and in the final Billing/Coding section that includes all codes in the policy.
- 12/11/06 Policy status changed to "Active policy, no longer scheduled for routine literature review."
- 1/3/07 CPT codes 19300, 19301, 19302, 19303 and 19304 effective January 1, 2007 added to Billing/Coding section. Removed deleted CPT codes 19140, 19160, 19162, 19180 and 19182.
- 1/7/07 HCPCS codes S2066 and S2067, effective July 1, 2007 added to appropriate Billing/Coding
- 6/22/10 Policy Number(s) removed (amw)
- 6/29/12 Policy revised and status changed to active. Policy will undergo yearly scheduled review. Revisions of Section I titled "Reconstructive Breast Surgery after Mastectomy" include: Description section updated. Following statement added to "When Covered" section: "Reconstruction may be performed by an implant based approach or through the use of autologous tissue." Section II re-titled from "Mastectomy for Gynecomastia" to "Surgical Treatment of Gynecomastia." Description section updated, otherwise no changes to policy statements. Section III re-titled from "Reduction Mammoplasty" to "Reduction Mammoplasty for Breast Related Symptoms." "When Covered" section revised. B#2 rephrased to state: "physical exam indicates obvious breast hypertrophy (pictures are not necessary) that is consistent with symptoms precipitating request for reduction mammoplasty." B#4 statement deleted. Revisions to Section IV titled "Prophylactic Mastectomy" include Description section update, "When Covered" section revised to allow coverage when **one or more** criteria are met. New clinical criteria for Prophylactic Mastectomy are: "Two or more first-degree relatives with breast cancer or ovarian cancer, One first-degree relative and two or more second-degree or third-degree relatives with breast cancer, One first-degree relative with breast cancer before the age of 45 years and one other relative with breast cancer, One first-degree relative with breast cancer and one or more relatives with ovarian cancer, Two second-degree or third-degree relatives with breast cancer and one or

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- more with ovarian cancer, One second-degree or third-degree relative with breast cancer and two or more with ovarian cancer, Three or more second-degree or third-degree relatives with breast cancer, One first-degree relative with bilateral breast cancer, Presence of a BRCA1 or BRCA2 mutation in the patient consistent with a BRCA1 or 2 mutation in a family member with breast or ovarian cancer, Presence of a TP53 or PTEN mutation, Received radiation therapy to the chest between the ages of 10 and 30 years. Moderately increased risk based on family history with or without breast lesions associated with an increased risk, including, but not limited to, atypical hyperplasia or breast cancer diagnosed in the opposite breast, Patients with such extensive mammographic abnormalities (i.e., calcifications) that adequate biopsy or excision is impossible.” Policy Guidelines updated. Section V re-titled from “Insertion and Removal of Breast Implants” to “Surgical Management of Breast Implants.” The following statement added to Description section: “This policy only addresses internal prosthetic breast implants. For information regarding external breast prosthetics see policy titled, “Prosthetic Appliances.” Otherwise, no changes to Policy Statements. References updated. Medical Director review 6/2012. (mco)
- 10/16/12 Specialty Matched Consultant Advisory Panel review 9/2012. No changes to Policy Statements. (mco)
- 1/29/13 References updated. No changes to Policy Statements. (mco)
- 2/26/13 Added the following statement to the “When not Covered” section: “Autologous fat grafting using liposuction technique for breast reconstruction is not covered. Please see policy titled, “Autologous Fat Grafting to the Breast.” Added Related Policy to the Description section. (mco)
- 10/15/13 Added related policies to Description section. Added the following syndromes associated with TP53 and PTEN mutations: (Li-Fraumeni syndrome, Cowden syndrome, Bannayan-Riley-Ruvalcaba syndrome) to the “Prophylactic Mastectomy” section. References updated. Specialty Matched Consultant Advisory Panel review 9/2013. Medical Director review 9/2013. (mco)
- 1/14/14 References updated. No changes to Policy Statements. (mco)
- 4/29/14 References updated. No changes to Policy Statements. (mco)
- 8/26/14 Deleted the following Related Policy from Description section: “Autologous Fat Grafting to the Breast.” Removed the following statement from the section “When Breast Reconstruction is Not Covered”: “Autologous fat grafting using liposuction technique for breast reconstruction is not covered. Please see policy titled, “Autologous Fat Grafting to the Breast.” (mco).
- 12/9/14 References updated. Specialty Matched Consultant Advisory Panel review 9/2014. Senior Medical Director Review 11/2014. Added definition of mastectomy and “or medically necessary prophylactic mastectomy,” statement to Section I under When Reconstructive Breast Surgery is covered section. Related Policy added to Description section. No changes to Policy Intent. (td)
- 12/30/14 References updated. No change to policy statement. (td)
- 7/1/15 References updated. Policy Statement unchanged. (td)
- 10/30/15 References updated. Specialty Matched Consultant Advisory Panel review 9/30/2015. Senior Medical Director Review 9/2015. Policy Statement remains unchanged. (td)
- 11/22/16 Updated the Policy Guidelines for gynecomastia and reduction mammoplasty. Extensive revisions to section regarding prophylactic mastectomy. Prophylactic mastectomy may be considered medically necessary in individuals at high risk of breast cancer. While there is no standardized method for determining an individual’s risk of breast cancer which incorporates all possible risk factors, there are validated risk prediction models, but these are based primarily on family history. There are some known individual risk factors which confer a high risk by themselves. The following list includes the factors that are known to indicate a high risk of breast cancer: lobular carcinoma in situ, known BRCA1 or BRCA2 mutation or another gene mutation associated with increased risk, family history or radiotherapy to the chest between 10 and 13 years of age.

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- Prophylactic mastectomy may be considered medically necessary in patients with such extensive mammographic abnormalities (ie, 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. Specialty Matched Consultant Advisory Panel review 9/28/16. (an)
- 5/26/17 Updated Description Section regarding gynecomastia and reduction mammoplasty. Formatting for section on prophylactic mastectomy revised and Guidelines section updated. No change to policy statements or coverage criteria. (an)
- 7/28/17 Clarified the statement in Section I Reconstructive Breast Surgery after Mastectomy to read: Since the purpose of reconstructive breast surgery is to restore the normal appearance of the breast, reconstructive procedures such as mastopexy, reduction mammoplasty, autologous fat transplant (i.e., liposuction) may be performed on the nondiseased/ unaffected/contralateral breast to produce a symmetrical appearance. These procedures fall into the category of reconstructive breast surgery only when performed in conjunction with a contralateral mastectomy for cancer with associated reconstruction. (an)
- 9/15/17 In Description section for Section 1: Reconstructive Breast Surgery after Mastectomy, added wording “or other breast disease.” Policy Guidelines for Section 4: Prophylactic Mastectomy updated. Reference added. Specialty Matched Consultant Advisory Panel review 8/30/2017. (an)
- 9/7/18 Statement from the American Society of Plastic Surgeons added to Policy Guidelines section for Gynecomastia. Name of “prophylactic mastectomy” changed to “risk-reducing mastectomy” throughout. Policy Guidelines for Risk-Reducing Mastectomy updated. References added. Specialty Matched Consultant Advisory Panel review 8/22/2018. (an)
- 9/10/19 Clarifying statement added to “When not covered” in Sections 1 and 5. Added wording “medically necessary risk-reducing mastectomy.” Society guidelines added to section IV and references added. No change to policy intent. Specialty Matched Consultant Advisory Panel 8/20/2019. (eel)
- 9/8/20 Removed reference to related archived policy. Specialty Matched Consultant Advisory Panel review 8/19/2020. No change to policy statement. (eel)
- 12/31/20 Removed deleted codes 19366 and 19324 from Section I, Reconstructive Breast Surgery, Billing/Coding/Physician Documentation Information section. (bb)
- 4/6/21 Updated SECTION IV – Risk-Reducing Mastectomy Policy Guidelines for clarity. No change to policy statement. (bb)
- 9/7/21 Updated Related Policies section. References updated. Specialty Matched Consultant Advisory Panel review 8/2021. Medical Director review 8/2021. (jd)
- 9/13/22 Section V Surgical Management of Breast Implants description updated. Section V When Covered section updated to include the following statement: “Removal of breast implants with capsulectomy/capsulotomy is considered medically necessary when the following criteria has been met (See Policy Guidelines): Baker Class III contractures (only if the initial implant was for reconstructive purposes), Baker Class IV contracture.” And “Removal of a breast implant and capsulectomy is covered, regardless of the indication for the initial implant placement, for: Treatment of Anaplastic Lymphoma of the breast when there is pathologic confirmation of the diagnosis by cytology or biopsy; or Individuals with an increased risk of implant-associated Anaplastic Lymphoma of the breast due to use of Allergan BIOCELL textured breast implants and tissue expanders.” Section V When not Covered section updated to include the following statement: “Removal of breast implants with capsulectomy/capsulotomy is not covered for Baker Class III contractures in patients with implants for cosmetic purposes.” Section V Policy Guidelines Updated to include Baker Classification System. Added codes 19370 and 19371 to Section V Billing/Coding Section, References updated. Medical Director Review 8/2022.

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Specialty Matched Consultant Advisory Panel review 8/2022. **Notification given 9/13/2022 for effective date 11/15/2022.** (tt)

12/13/22 Removed 19304 from Billing/Coding section. (tt)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.

Table 1: Schnur Sliding Scale

Body Surface Area (m²)	Average grams of tissue per breast to be removed
1.35	199
1.40	218
1.45	238
1.50	260
1.55	284
1.60	310
1.65	338
1.70	370
1.75	404
1.80	441
1.85	482
1.90	527
1.95	575
2.00	628
2.05	687
2.10	750
2.15	819
2.20	895
2.25	978
2.30	1068
2.35	1167
2.40	1275
2.45	1393
2.50	1522
2.55	1662