

MEDICAL POLICY No. 91545-R19

BREAST RELATED PROCEDURES*

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*This policy includes the following previously separate policies: Breast Implants Explantation, Breast MRI, Breast Reconstruction and Revision Following Surgery for Breast Cancer, Male Gynecomastia, and Mastectomy for Intractable Breast Pain and Reduction Mammoplasty. Policy 91478 Breast Ductal Lavage has been retired. For prophylactic mastectomy, please see medical policy Prophylactic Cancer Risk Reduction Surgery 91508.

Summary of Changes

- Clarification: C.1.a. Added criteria for autologous fat transplant (harvesting and grafting) for breast reconstruction.
- Addition: I.G.5 Language from the Breast Specific Gamma Imaging (BSGI) medical policy #91568 was added because the policy has been retired.

I. POLICY/CRITERIA

A. Breast Implant Removal

- 1. Removal of breast implants that were placed for reconstruction after mastectomy, injury, congenital asymmetry, or augmentation mammoplasty is a covered benefit for the following indications:
 - a. Implants with recurrent infection
 - b. Extruded implants
 - c. Baker Class III or IV Contracture, associated with severe pain, or
 - d. Breast cancer, new or recurrent (mastectomy and lumpectomy can be done with an implant in place, however, if a breast malignancy is discovered and the surgeon has requested coverage for removal, it is appropriate to provide coverage).
 - e. Implant rupture
- 2. Replacement/reinsertion of a breast implant is a covered benefit only if the original placement surgery would have been a covered benefit (e.g., if original prosthesis was placed due to cancer surgery, replacement of the prosthesis is a covered benefit; if original surgical indication was cosmetic augmentation, replacement of the prosthesis is not a covered benefit).
- 3. Removal of breast implants for the following conditions has been determined to not be medically necessary, and therefore, not a covered benefit:

- a. Breast malposition/asymmetry
- b. Baker Class I or II Contracture*
- c. Anxiety related to the possibility of developing systemic disease, or anxiety related to the influence of breast implants on a current autoimmune disease. It has not been proven that individuals with breast implants are at an increased risk of developing a systemic disease, or that the implants influence the current status of the systemic disease.
- 4. The requesting physician should supply clinical information related to the degree of contracture (Baker classification*) or describe the etiology of the pain.

* Various systems have been used to classify breast contractures, but the most commonly used is the Baker classification. Four grades are described as follows:

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

B. Reduction Mammoplasty

- 1. Unilateral and bilateral reduction mammoplasty may be considered medically necessary when applicable InterQual® criteria are met.
- 2. The following are not considered medically necessary:
 - a. Mastopexy procedures (e.g., breast ptosis). These procedures are considered to be cosmetic in nature and not performed to relieve pain due to macromastia.
 - b. Reduction mammoplasty for cosmetic purposes (to improve appearance).
 - c. Reduction mammoplasty to treat fibrocystic disease of the breasts.
 - d. Chronic intertrigo, eczema, dermatitis, and/or ulceration in the inframammary fold, in and of itself.
- 3. Coverage is limited to one reduction mammoplasty per member lifetime with Priority Health.
- 4. Photographic documentation must be submitted with prior authorization requests.

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For augmentation mammoplasty for asymmetry that is cancer related see Section C. Breast Reconstruction and Revision below.

C. Breast Reconstruction and Revision

This section applies to reconstruction and revision for breast cancer. It would also apply to women at high risk of breast cancer who require prophylactic mastectomy.

The Women's Health and Cancer Rights Act of 1998 (WHCRA) mandates coverage for all stages of breast reconstruction. Initial reconstruction can occur immediately after a mastectomy or be delayed until a member undergoes radiation or chemotherapy or determines whether she wants breast reconstruction. Some women will opt for immediate breast reconstruction after mastectomy, while some may prefer delayed reconstruction. While some reconstructions can be completed in a single procedure, other techniques may require two or more surgical procedures for completion of the reconstructive process. Breast reconstruction surgery is considered complete when reasonable symmetry is achieved, and when appropriate and desired nipple tattooing and reconstruction.

Further clarification of coverage for breast reconstruction and revision is outlined below.

- 1. Coverage for the breast affected by cancer, as well as for the breast(s) removed prophylactically (including bilateral prophylactic mastectomies). The following are covered benefits:
 - a. Autologous fat harvesting and grafting is considered reconstructive for the diseased/affected breast and non-diseased/unaffected/contralateral breast to produce a symmetrical appearance.
 - i. Due to necrosis or resorption of injected fat cells, transplant is limited to 150 cc per breast per procedure.
 - ii. Fat harvesting (e.g., liposuction) used for body contouring, weight reduction or for the transfer to another body region for alteration of physical appearance is considered cosmetic.
 - b. Treatment for complications of breast reconstruction including cellulitis, other infections, and lymphedema.
 - c. Revisions required by surgical complications including infection, hematoma or seroma, or skin or flap necrosis.
 - d. Capsulotomies/capsulectomies for pain or contractures (see I. A. Breast Implant Removal above) for coverage criteria.
 - e. Prosthesis removal for pain, contractures, rupture, leakage or infection. (See I. A. Breast Implant Removal above) for coverage criteria.
 - f. Scar revisions are only covered if one of the following apply:

- i. The scar resulted from a serious complication such as infection or wound dehiscence from surgery or post-op period
- ii. The scar revision is an integral (not incidental) part of another covered procedure.
- 2. Additional coverage for the breast(s) removed prophylactically (including bilateral prophylactic mastectomies) *:
 - a. An initial procedure (reduction, augmentation, or mastopexy) on the contralateral breast to produce symmetry between the affected and unaffected breasts.
- * For specific criteria regarding prophylactic mastectomy for cancer risk reduction see policy # 91508 Prophylactic Cancer Surgery
 - 3. Breast reconstruction surgery is also a covered benefit when incidental to disease and/or injury if:
 - a. A functional impairment is established, and surgery is intended to correct the functional impairment OR
 - b. Breast reconstructive surgery is performed to correct asymmetry of a breast when surgery has been performed on the other breast incidental to disease or injury.
 - 4. Coverage is **not** provided for breast reconstruction surgery that is unrelated to disease or trauma. Excluded conditions include, but are not limited to:
 - a. Absence or underdevelopment of chest muscles
 - b. Abnormalities of the chest wall (such as pectus excavatum)
 - c. Congenital underdevelopment or absence of the nipple or breast.
 - 5. WHCRA does not mandate coverage for revision of a previously completed breast reconstruction to improve appearance.
 - a. Reconstruction is not considered "incomplete" if the patient becomes dissatisfied with cosmetic results of reconstruction or where future medical or surgical conditions may alter results. Examples of non-covered conditions include nipple fading, loss of symmetry, for any reason including tissue atrophy after initial symmetry was achieved.
 - b. Revisions for aesthetic/cosmetic reasons beyond the original reconstructive surgery are not covered unless there were surgical complications such as cellulitis, other infections, lymphedema, hematoma, or significant skin or flap necrosis.
 - c. The member's expectations and the limitations of surgical reconstruction must be thoroughly disclosed by the surgeon and understood by the member prior to reconstruction and documented as such in the signed informed consent.

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- 6. Treatment or services to prevent chemotherapy induced hair loss (e.g., cooling therapy or devices during chemotherapy) are considered cosmetic and not covered.
- 7. For procedures that can have both reconstructive and cosmetic indications submission of photographic documentation is required.
- **D.** Microsurgical Lymph Node Transplantation for Post Mastectomy Lymphedema is considered experimental and investigational.

Review for exceptions may be made in the following circumstances:

- 1. Chronic recurrent infection, or
- 2. Clinical functional impairment as defined as a condition which interferes with activities of daily living, and there is reasonable evidence to support that this intervention will correct the condition to which it is being attributed to. Further definition can be located in the Certificate of Coverage.

E. Gynecomastia

- 1. Bilateral Gynecomastia in Adults and Adolescents: Simple mastectomy or reduction mammoplasty for bilateral gynecomastia may be considered medically necessary when applicable InterQual® are met.
- 2. Unilateral Gynecomastia in Adults: Excisional biopsies for adults with unilateral gynecomastia are medically necessary when malignancy is suspected.
- 3. Medicaid members: Prior authorization is required. All of the following documentation should be provided by the requesting physician:
 - a. Patient's age
 - b. Physical description of the enlarged breast including symmetry, mass, induration, and size
 - c. Medical history assessing the differential diagnosis including chronic diseases and medications.
 - d. Previous work-up including mammogram and fine needle aspirate, where appropriate for evaluation of unilateral gynecomastia or masses.
 - e. High-quality original photographs for evaluation of the gynecomastia grade.

For procedures that can have both reconstructive and cosmetic indications submission of photographic documentation is required.

F. Mastectomy for Intractable Breast Pain

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The efficacy and clinical application of mastectomy (simple or total) for intractable breast pain has not been proven to be a medically appropriate treatment and is not a covered benefit.

- G. Screening Mammography, Digital Breast Tomosynthesis, Ultrasound, Electrical Impedance Scanning, Breast MRI, and Breast-specific Gamma Imaging (BSGI)
 - 1. Screening Mammography
 - a. Conventional or digital mammography is considered to be the standard diagnostic method for breast cancer screening. Screening mammograms, conventional or digital, are a covered benefit. Coverage for screening mammography for an average risk woman is provided according to Michigan law. The State of Michigan requires coverage for one mammogram in a five-year period for women at least 35 years of age and less than 40 years of age. For women 40 years of age and older the State requires coverage for one mammogram per year.
 - 2. Digital Breast Tomosynthesis (DBT)
 - a. A screening DBT is considered medically necessary for individuals that have dense breasts.
 - b. A diagnostic DBT is considered medically necessary for individuals that have abnormal mammogram findings that require further imaging.
 - 3. Breast MRI
 - a. eviCore provides prior authorization medical necessity review services on behalf of Priority Health for participating providers. Breast related procedures may be covered when eviCore criteria are met.
 - b. Prior authorization for out-of- network providers must be requested through Priority Health.
 - 4. Ultrasound, thermography, and electrical impedance scans for routine breast cancer screening are considered experimental and investigation because their clinical utility have not been demonstrated.
 - 5. Breast Specific Gamma Imaging (BSGI) is considered experimental and investigational as an adjunct to mammography for imaging of breast tissue, for the detection of axillary metastases, staging the axillary lymph nodes in members with breast cancer, and to assess response to adjuvant chemotherapy in members with breast cancer and for all other indications because its effectiveness has not been established.
 - a. BSGI may be covered when part of an Institutional Review Board (IRB) approved clinical trial designed to assess its clinical utility for individuals with initial abnormal screening mammograms

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compared with other commonly used secondary screening techniques. Individual medical director review required.

H. Bioimpedance (bioelectrical impedance spectroscopy)

- 1. The use of bioimpedance also known as bioelectrical impedance spectroscopy (e.g. SOZO), in the detection, diagnosis, or surveillance of secondary, subclinical (Stage 0 or 1) breast cancer related lymphedema is medically necessary.
- 2. For indications other than cancer related lymphedema, the use of bioimpedance spectroscopy is not medically necessary as conventional measurement methods remain the standard of care. See *Medical Necessity* policy 91447.

II. MEDICAL NECESSITY REVIEW

Prior authorization for certain drug, services, and procedures may or may not be required. In cases where prior authorization is required, providers will submit a request demonstrating that a drug, service, or procedure is medically necessary. For more information, please refer to the <u>Priority Health Provider Manual</u>.

Submission of photographic documentation is required for procedures that can have both reconstructive and cosmetic indications.

III. APPLICATION TO PRODUCTS

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

- ***** HMO/EPO: This policy applies to insured HMO/EPO plans.
- **OVER UPONE This policy applies to insured POS plans.**
- PPO: This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.
- ASO: For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.
- INDIVIDUAL: For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.
- MEDICARE: Coverage is determined by the Centers for Medicare and Medicaid Services (CMS) and/or the Evidence of Coverage (EOC); if a coverage determination has not been adopted by CMS, this policy applies.
- MEDICAID/HEALTHY MICHIGAN PLAN: For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule located at: <u>http://www.michigan.gov/mdch/0,1607,7-132-2945 42542 42543 42546 42551-159815--,00.html</u>. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual located

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at: <u>http://www.michigan.gov/mdch/0,1607,7-132-2945_5100-87572--,00.html</u>, the Michigan Medicaid Provider Manual will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.

IV. DESCRIPTION/BACKGROUND

Breast Implant Removal

A breast implant is a silicone shell filled with either silicone gel or saline. Some silicone gel may diffuse or "bleed" through the shell of an intact implant into the scar tissue or capsule that surrounds the implant. Rupture of an implant may be related to the length of time it has been in the body or it may also be related to force or trauma. All breast implants, like other medical devices, fail over time and need to be removed or replaced.

Significant local complications of breast implants may require removal of the implant. Contracture is the most common local complication of breast implants. Capsules of tightly-woven collagen fibers form as an immune response around a foreign body (e.g. breast implants, pacemakers, orthopedic joint prosthetics) tending to wall it off. Capsular contracture occurs when the capsule tightens and squeezes the implant. This contracture is a complication that can be very painful and distort the appearance of the implanted breast. The exact cause of contracture is not known. However, some factors include bacterial contamination, silicone rupture or leakage, and hematoma.

When saline breast implants break, they often deflate quickly and can be easily removed. When silicone implants break they rarely deflate, and the silicone from the implant can leak. The differential diagnosis of silicone breast implant rupture includes intracapsular and extracapsular ruptures. If the extruded silicone is contained by this fibrous capsule the rupture is termed intracapsular. If the silicone gel is extruded beyond the capsule, the rupture is termed extracapsular. If intracapsular ruptures are early or focal, extensive gel bleeding has an appearance similar to that of extracapsular rupture by MRI. Extracapsular rupture involves free silicone in the breast parenchyma, which can simulate other breast masses, including breast cancer, at mammography and sonography. An intracapsular rupture can progress to outside of the capsule (extracapsular rupture), and when recognized, both conditions are generally agreed to indicate the need for removal of the implant. Clinically, extracapsular ruptures are often associated with a change in size and consistency of the breast. Extracapsular silicone has the potential to migrate, but most clinical complications have appeared to be limited to the breast and axillae in the form of granulomas (inflammatory nodules) and axillary lymphadenopathy.

Breast Reconstruction and Revision

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Breast reconstruction surgery includes those surgical procedures which are intended to restore the normal appearance of the breast. This restoration occurs after surgery, accidental injury, or trauma.

Mastectomy for cancer is the most common reason women seek breast reconstruction, but other conditions such as severe post radiation changes or congenital deformities are other reasons that a woman may seek breast reconstruction.

Techniques of reconstruction include tissue expansion, flap reconstruction, nipple areola reconstruction with subsequent implantation of a breast prosthesis. The tissue expander is a balloon-like device which is surgically placed under the chest tissue to create a breast-shaped space for the breast implant. Flap reconstruction allows for reconstruction using the patient's own tissues. Donor flap sites include the back, lower abdomen, buttocks, or lateral hip region. For a latissimus flap the latissimus dorsi muscle is used. This muscle is frequently used for reconstruction surgery due to its large size and versatility. For a TRAM flap (transverse rectus abdominus musculocutaneous flap) excess abdominal tissue is tunneled under the skin from the lower abdomen to the chest and used to replace the breast tissue. For a free flap, tissue from other body sites (such as buttock or lateral thigh region) is transferred to the chest.

There are both Federal and Michigan state laws requiring health plans to cover breast reconstruction in certain defined circumstances. The federal and state requirements differ.

Autologous Fat Grafting

High volume fat grafting, otherwise known as autologous fat grafting (AFG), for breast reconstruction is considered investigational. The volume of fat transfer that is generally agreed upon as "high-volume" is >100 cc per breast (Vizcay et al., 2020). Challenges with this procedure include fat necrosis, fat reabsorption, volume retention, and often the need for multiple procedures to achieve the desired outcome. The success of high volume transfer is limited by the size of the skin envelope, which affects the amount of fat that can be injected during one procedure (Mestak et al., 2013). Several external expansion devices, including the Brava® breast enhancement and shaping system, have been proposed as an adjunct to fat transfer procedures to increase the size of the skin envelope, however none of these devices are currently FDA approved for use within the United States. In a recent systematic review by Seth and colleagues (2024), a total of 35 studies comprising 3757 women undergoing autologous fat grafting to the breast were included. The average fat volume injected was 300 mL (range, 134 to 610 mL), and the average volume retention was 58% (range, 44% to 83%). The overall complication rate was 27.8%, with fat necrosis making up 43.7% of all complications. Volume retention was greater with supplementation of fat with platelet-rich plasma and stromal vascular fraction. The most common radiologic changes were fat necrosis (9.4%) and calcification (1.2%). After 1 year of follow-up, patient satisfaction was, on average, 92% (range, 83.2% to

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97.5%). The included studies were of good quality and consisted of a moderate risk of bias.

Medical Society Guidelines

American Society of Plastic Surgeons: *Post-Mastectomy Fat Graft/Fat Transfer ASPS Guiding Principles (2015)* "The quality of evidence to date indicates fat grafting to the post-mastectomy breast with no native breast tissue is a safe and effective modality in breast reconstruction...although there is no standardization for technique, detailed descriptions of fat graft harvest, preparation, storage, and injection have been described in the literature. Overall, autologous fat grafting to the postmastectomy breast with no remaining native tissue yields aesthetic improvement and significant patient satisfaction."

Male Gynecomastia

Gynecomastia is defined as the presence of an abnormal proliferation of breast tissue in males. It is a common breast lesion accounting for more than 65 percent of male breast disorders. Gynecomastia has a broad range of causes that are classified as either physiological or pathological, although in many cases no specific cause can be found (idiopathic). In true gynecomastia, the breast enlargement is due to glandular breast tissue; in pseudo gynecomastia, the breast enlargement is secondary to fat accumulation; and both glandular and fat tissue are present in mixed gynecomastia.

Physiologic gynecomastia occurs most frequently during times of male hormonal changes, resulting from the effect of an altered estrogen/androgen balance on breast tissue or from the increased sensitivity of breast tissue to a normal estrogen level.

Pubertal gynecomastia is a common condition with an overall incidence of 38 percent in males 10 to 16 years of age, increasing to 65 percent at age 14, and dropping to 14 percent in 16-year-old boys. During adolescence, 75 percent of the gynecomastia cases are bilateral but the breasts are often affected to different degrees. Pubertal gynecomastia often regresses spontaneously in six months, 75 percent within two years of onset, and 90 percent resolve within three years of onset.

In adults, gynecomastia is associated with increasing age due to progressive testicular hypofunction, an increase in body far, and an increase in the estrogen/androgen ratio.

Pathological gynecomastia is associated with both androgen deficiency and estrogen excess. Both causes may be due to medications, diseases related to endocrinologic abnormalities, tumors, chronic disease, chromosomal abnormalities, familial disorders, and other miscellaneous conditions. While there is always a concern when a mass is present, breast cancer accounts for only 0.2 percent of all malignancies in male patients. A suspicious mass or lesion requires biopsy.

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Gynecomastia Scale 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.

Causes of Gynecomastia		
Physiologic	Tumor	
Neonatal	Pituitary	
Pubertal	Adrenal	
Age	Testicular	
Pathologic	Breast	
Drugs, including marijuana	Chronic Disease	
Endocrinopathy	Liver disease, cirrhosis	
Primary hypogonadism	Renal failure	
Secondary hypogonadism	Malnutrition	
Hyperthyroidism	Pulmonary	
Adrenal disorders	Nervous system damage	
Familial		
Idiopathic		

Reduction Mammoplasty

Macromastia is the development of abnormally large breasts. Macromastia that may require treatment is distinguished from large, normal breasts by the presence of persistent, painful symptoms and physical signs. These commonly include chronic mechanical upper back and/or neck and/or shoulder pain as the excessive breast weight adversely affects the supporting structures of the shoulders, neck, and trunk. Surgery solely performed to reshape the breasts, in order to improve appearance and self-esteem is considered to be cosmetic surgery.

Excessive breast weight may be reduced through a weight reduction management program or through surgical means. Reduction mammoplasty is the surgical excision of a substantial portion of the breast including the skin and the underlying glandular tissue, until a clinically normal size is obtained.

Inframammary intertrigo can occur where excessive breast tissue opposes the skin. Initiating factors include moisture and friction associated with an absence of air

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circulation in deep skin folds. In addition, candidal or bacterial infection may initiate or aggravate intertrigo (UpToDate, 2024). Reduction mammaplasty has not been established as an effective treatment for this condition. In a systematic review conducted by Mistiaen et al. (2010), 13 databases were sensitively searched for all types of empirical research relating to the prevention or treatment of intertrigo. Sixtyeight studies were identified that fulfilled the inclusion criteria. Only 4 studies were RCTs and these had a considerable risk of bias. Study populations were generally small. No studies were found about the prevention of intertrigo. The therapies concerned mostly the topical application of antimycotics, corticosteroids, antibiotics, antiseptics or a combination of these. Besides these pharmaceutical interventions, surgical breast reduction was also studied. Although most study-authors were positive, the authors could not draw firm conclusions about any of the pharmaceutical interventions. Even patients that received placebo intervention showed improvement. There is weak evidence that reduction mammaplasty may be helpful to treat inframammary intertrigo. All research found had considerable risk of bias, prohibiting firm conclusions.

A breast lift, also known as mastopexy, raises the breasts by removing excess skin and tightening the surrounding tissue to create a more youthful breast contour. This procedure is considered cosmetic in nature. (American Society of Plastic Surgeons, 2024)

Mastectomy for Intractable Breast Pain

Breast pain (mastalgia) is common in women and occasionally occurs in men. Although it is usually mild and self-limited, approximately 15 percent of affected women require treatment. Evaluation of breast pain is important to determine whether the pain is due to normal physiological changes related to hormonal fluctuation or to a pathologic process such as breast cancer. Unfortunately, studies specific to breast pain are limited and often small in number, not well designed, and with limited follow-up. (UpToDate, 2024)

Guidelines do not currently recommend mastectomy as an evidence-based treatment option for intractable breast pain.

Screening Mammography, Breast MRI, Digital Breast Tomosynthesis, Ultrasound, Thermography, Electrical Impedance Scanning, and Breast-specific gamma imaging (BSGI)

Screening Mammography

Screening mammography involves radiographic (X-ray) examination of the breast performed at regular intervals, usually every 1 to 2 years, to detect breast cancer before it displays signs or symptoms. The goals of screening mammography for average risk women without any symptoms are to reduce breast cancer morbidity and mortality (illness and death). This can be accomplished by the accurate detection of the disease before it has metastasized (spread from the breast to another part of the

body), when treatment can be less aggressive, and when the likelihood of long-term remission (decrease in symptoms) or cure is the highest.

According to the State of Michigan Insurance Code, breast cancer screening is defined as mammography using a standard 2-view per breast, low-dose radiographic examination of the breasts, and using equipment designed and dedicated specifically for mammography, in order to detect unsuspected breast cancer.

The Insurance Code goes on to define breast cancer diagnostic services as procedures intended to aid in the diagnosis of breast cancer, delivered on an inpatient or outpatient basis, including but not limited to mammogram, mammography, surgical breast biopsy, and pathologic examination and interpretation.

Breast MRI

Screening mammography detects less than half of the breast cancers in mutation carriers, perhaps owing to young age, dense breasts, or pathological features of the tumor. Cancers in mutation carriers grow rapidly; half of them appear in the interval between annual mammograms. Supplementing mammography with other imaging techniques, shorter screening intervals, or both may be valuable in mutation carriers. MRI may be a viable adjunct to mammography for breast cancer screening among carefully selected women at high risk for the disease due to familial or genetic predisposition. Although concerns regarding an increase in invasive follow-up procedures due to the reduced specificity of MRI screening may be warranted, the anxiety level regarding breast cancer among women with familial or genetic predisposition for the disease is already heightened; therefore, it is difficult to determine the clinical implication of additional follow-up procedures. The American Cancer Society does not recommend MRI as a screening test for average risk women.

Digital breast tomosynthesis (DBT)

Breasts are made up of lobules, ducts, and fatty and fibrous connective tissue. Breast tissue may be called dense if there is a lot of fibrous or glandular tissue and not much fat in the breasts. (ACS, 2019). Breast density should be assessed on the standard digital mammogram or on the synthesized mammogram (ACR, 2013). Breast Imaging Reporting and Data System (BI-RADS) outlines four categories of mammographic density: almost entirely fatty, scattered areas of fibroglandular density, heterogeneously dense, and extremely dense. The exact relationship between breast density and breast cancer is still unknown. However, in breasts that are dense, cancer can be hard to see on a mammogram. DBT, also commonly called 3D mammography, provides images of the breast in "slices" from many different angles allowing for improvement in cancer detection, characterization, and localization. DBT reduces the masking effects of superimposed tissue, allowing better visualization of true lesions and decreasing summation shadow. Inclusion of DBT with standard two-dimensional

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digital mammography improves cancer detection while simultaneously reducing the rate of false positive examinations (ACR, 2013).

Ultrasound

Breast ultrasound uses sound waves and their echoes to make computer pictures of the inside of the breast. It can show certain breast changes, like fluid-filled cysts, that can be harder to see on mammograms. Ultrasound is not typically used as a routine screening test for breast cancer. It can be useful for looking at some breast changes, such as lumps (especially those that can be felt but not seen on a mammogram). Ultrasound can be especially helpful in women with dense breast tissue, which can make it hard to see abnormal areas on mammograms. It also can be useful because it can often tell the difference between fluid-filled masses like cysts and solid masses (American Cancer Society, 2024)

According to the American College of Radiology Breast Cancer Screening for Women at Higher-Than-Average Risk: Updated Recommendations (2023), "Although not indicated for the majority of patients at significantly elevated risk, further comparative studies will be crucial to determine if ultrasound is an optimal choice for breast cancer screening for women who have dense breasts as their only risk factor."

Thermography

Thermography uses an infrared camera to detect heat emissions from the targeted body region. Digital infrared thermal imaging is the thermography used to diagnose breast cancer. The concept behind this test is that as cancer cells multiply, they need more oxygen-rich blood for growth. As there is an increase in blood flow to the tumor, the temperature around the tumor also increases. Malignant cells discharge nitric oxide into the bloodstream and cause impairment in the microcirculation. This released nitric oxide, along with the active growth of the cancerous cells, increases blood circulation and temperature in that region. Therefore, evaluating these differences in temperature leads to the detection of the malignant region in the breast. (Rakhunde et al, 2022)

According to National Comprehensive Cancer Network (NCCN) guidelines for Breast Cancer Screening and Diagnosis, "*Current evidence does not support the routine use of thermography as a screening procedure*" (NCCN, 2024)

Electrical Impedance Scanning

Electrical impedance tomography (EIT) is a non-invasive, mobile screening method which does not use ionizing radiation. It is based on the theory that cancer cells display altered local dielectric properties, thus demonstrating measurably higher conductivity values. (Akhtari-Zavare M, et al, 2015) Electrical impedance scanning is not an established modality for breast cancer screening at this time. A large systematic review and meta-analysis conducted by Gatabi and colleagues (2022) using search Page 14 of 32

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terms "EIT" and "Breast Cancer" with the goal of establishing the accuracy of electrical impedance tomography for breast cancer screening found EIT had an overall pooled sensitivity and specificity of 75.88% (95% CI, 61.92% to 85.89%) and 82.04% (95% CI, 69.72% to 90.06%), respectively. The pooled diagnostic odds ratio was 14.37 (95% CI, 6.22% to 33.20%), and the pooled effect of accuracy was 0.79 with 95% CI (0.73, 0.83). The authors concluded that this study showed that EIT can be used as a useful method alongside mammography. EIT sensitivity could not be compared with the sensitivity of MRI, and more large-scale studies will be needed to support these findings.

Breast-specific gamma imaging (BSGI) was developed as a confirmatory test used after mammography and a clinical breast exam. This technique detects abnormal breast tissue based on uptake of technetium-99m sestamibi, a radioactive agent that emits gamma rays and that tends to accumulate in cancerous breast tissue. BSGI is typically performed on an outpatient basis by a nuclear medicine technician with results interpreted by a radiologist or physician specializing in nuclear medicine.

Results of the available studies do not provide conclusive evidence that BSGI can be relied on rather than biopsy in women who have suspicious breast lesions. Studies that compared the sensitivity of BSGI with other techniques showed no statistically significant differences in the sensitivity of BSGI, mammography, ultrasonography, and MRI. Although further studies may indicate that BSGI has greater sensitivity than ultrasonography and MRI, BSGI has the disadvantage that it requires radiation exposure. In addition, unlike biopsy, BSGI does not provide a definitive diagnosis. Further studies are needed to determine the clinical role of BSGI versus MRI and ultrasonography as adjuncts to mammography and clinical breast exams as well as to validate the impact of BSGI on patient survival.

Microsurgical Lymph Node Transplantation for Post Mastectomy Lymphedema

The vascular lymph node transplant (VLNT) procedure consists of a transfer of lymph node flaps with their vascular supply from a donor site (including the axillary, inguinal, or cervical lymph node basins, or from intra-abdominal donor sites) to the axilla, forearm, or wrist of the lymphedematous upper extremity. The exact physiological response to this procedure has yet to be confirmed. A recent systematic review by Doubblestein et al (2023) investigated which rehabilitation interventions contribute to the highest level of pre- and post-microsurgical outcomes. Thirteen studies met all inclusion criteria and revealed that there is a dearth of high-quality literature leading to a gap in knowledge as to how breast cancer–related lymphedema (BCRL) microsurgical and conservative interventions complement each other. Furthermore, peri-operative outcome measures were inconsistent. The authors concluded that peri-operative guidelines are needed to bridge the knowledge and care gap between lymphedema surgeons and therapists.

MEDICAL POLICY No. 91545-R19

In a consensus conference held in 2017 by the American Association of Plastic Surgeons, an exhaustive review of existing literature was performed to conduct a systematic review and meta-analysis of controlled trials with the goal to examine both the benefits and risks of surgical treatment and surgical prevention of upper and lower extremity lymphedema. Panel members found that there is evidence to support that vascular lymph node transplantation can be effective in reducing severity of lymphedema (grade 1B). Currently, there is no consensus on which procedure (lymphovenous bypass versus vascular lymph node transplantation) is more effective (grade 2C). Ultimately, the authors concluded that many questions remain unanswered and more studies with longer follow-up are required to confirm this benefit (Chang et al, 2021).

Bioimpedance for Lymphedema

Lymphedema (LE) is the accumulation of protein-rich fluids in tissue that has inadequate lymphatic drainage. The cause of this inadequate drainage can be congenital abnormalities of the lymphatic system (primary LE), or, as is more often the case, by acquired damage to the lymphatic system (secondary LE). A common cause of secondary LE is treatment of breast cancer with modalities such as axillary lymph node dissection (ALND), mastectomy, lumpectomy, and radiation therapy. Due to the chronic nature of lymphedema, a preventive approach has the potential to spare patients a great deal of morbidity.

Patients who have lymphedema may present with decreased function due to limbs that are swollen; feel full or heavy; have decreased flexibility; and have skin that feels tight, has changed texture, or developed lesions (National Cancer Institute – Lymphedema PDQ). Pitting edema (in which a dent in the skin is present after it is pressed) indicates swelling is primarily due to lymphatic fluid accumulation in soft tissues. Absence of pitting indicates more progressed lymphedema with swelling primarily due to increased fat deposition and fibrosis. Patients may also present with infections of the limb, such as cellulitis or lymphangitis, due to local immune deficiency caused by lymphatic impairment. Breast cancer treatment–related upper extremity lymphedema usually develops 8 months to 3 years after surgery; lower extremity lymphedema caused by pelvic or inguinal lymph node dissection tends to have a more rapid onset, often occurring 3 to 6 months after surgery.

Bioimpedance analysis (BIA) is a noninvasive method that detects increases in tissue fluid based on increased flow of electricity. This technique is rapid and relies on small electrical currents that do not cause any pain or discomfort. BIA relies on the differing abilities of body tissues to conduct low level (200 to 800 microamperes) alternating electrical currents. Although lymph, blood, and muscle tissue exhibit low impedance (or resistance) to the flow of electricity, fat and bone exhibit high impedance. Changes in bioimpedance can be used to measure changes in body fluid composition due to conditions such as diabetes, cirrhosis of the liver, and lymphedema (LE). BIA can be performed at a single frequency or multiple frequencies ranging from 5000 to 1 million cycles per second. Multiple frequency BIA (MFBIA) is often referred to as Page 16 of 32

bioimpedance spectroscopy (BIS) to distinguish it from the single frequency BIA (SFBIA). NCCN's Survivorship: Lymphedema (2023) recommends survivors at risk for lymphedema be regularly screened for lymphedema by symptom assessment, clinical exam, and, if available, bioimpedance spectroscopy. Early detection/diagnosis and early referral are key for optimal lymphedema management because stages 0 and 1 are reversible, whereas stages 2 and 3 are less responsive to treatment. The stages of lymphedema are defined as (NCI Lymphedema PDQ; International Society of Lymphology, 2016):

- Stage 0 (latent/subclinical): Lymphatic dysfunction without swelling; subtle symptoms, such as a feeling of heaviness or fatigue in the limb, may be present.
- Stage 1 (spontaneously reversible): Accumulation of fluid and protein causing swelling; pitting edema may be evident; increased girth, heaviness, and/or stiffness of affected area. For the limbs, swelling is relieved with elevation.
- Stage 2 (irreversible): Spongy tissue consistency, with pitting edema that becomes less evident as swelling increases; tissue fibrosis causing hardness and increase in size. For the limbs, swelling is not relieved with elevation.
- Stage 3 (lymphostatic elephantiasis): Severe dry, scaly, thickened skin; increased swelling and girth of affected area; can be debilitating. In the limbs, fluid leakage and blisters are common. Fungal infection and papilloma may occur. Pitting can be absent due to progressive deposition of fat and fibrosis, which is the hallmark of later stage lymphedema.

V. CODING INFORMATION

A. Breast Implant Removal

ICD-10 Codes that <u>may</u> apply:

I I	
N64.9	Disorder of breast, unspecified
T85.44xA - T85.44xS	Capsular contracture of breast implant
T85.828A - T85.828S	Fibrosis due to internal prosthetic devices, implants and grafts
T85.848A -T85.848S	Pain due to internal prosthetic devices, implants and grafts
T85.898A - T85.89S	Other specified complication of internal prosthetic devices, implants and grafts

CPT/HCPCS Codes

- 19328 Removal of intact breast implant
- 19330 Removal of ruptured breast implant, including implant contents (eg saline, silicone gel)

B. Reduction Mammoplasty

ICD-10 Codes that <u>may</u> apply:

N62 Hypertrophy of breast



CPT/HCPCS Code

19318 Reduction Mammoplasty

C. Breast Reconstruction and Revision

ICD-10 Codes that support medical necessity:

C50.011 - C50.929	Malignant neoplasm of breast
C79.81	Secondary malignant neoplasm of breast
D05.00 - D05.92	Lobular carcinoma in situ of breast
D07.30	Carcinoma in situ of unspecified female genital organs
Z40.01	Encounter for prophylactic removal of breast
Z42.1	Encounter for breast reconstruction following mastectomy
Z42.8	Encounter for other plastic and reconstructive surgery
	following medical procedure or healed injury
Z85.3	Personal history of malignant neoplasm of breast
Z90.10 - Z90.13	Acquired absence of breast and nipple
Z98.82	Breast implant status

N64.89	Other specified disorders of breast
T85.44xA - T85.44xS	Capsular contracture of breast implant,
T85.41xA - T85.49xS	Mechanical complication of breast prosthesis and implant
T85.79xA - T85.79xS	Infection and inflammatory reaction due to other internal
	prosthetic devices, implants and grafts
T85.828A-T85.828S	Fibrosis due to other internal prosthetic devices, implants
	and grafts
T85.848A-T85.848S	Pain due to other internal prosthetic devices, implants and
	grafts
T85.898A-T85.898S	Other specified complication of other internal prosthetic
	devices, implants and grafts

CPT/HCPCS Codes

The above diagnoses support medical necessity for the following procedures. <u>*All other indications must be prior authorized.*</u>

- 11920 Tattooing, intradermal introduction of insoluble opaque pigments to correct color defects of skin, including micropigmentation; 6.0 sq cm or less
- 11921 Tattooing, intradermal introduction of insoluble opaque pigments to correct color defects of skin, including micropigmentation; 6.1 to 20.0 sq cm
- 11922 Tattooing, intradermal introduction of insoluble opaque pigments to correct color defects of skin, including micropigmentation; each additional 20.0 sq cm (List separately in addition to code for primary procedure)
- 11970 Replacement of tissue expander with permanent implant
- 11971 Removal of tissue expander(s) without insertion of implant
- 19316 Mastopexy
- 19318 Breast Reduction
- 19325 Breast augmentation; with implant
- 19340 Insertion or replacement of breast implant on the same day of mastectomy (ie, immediate)
- 19342 Insertion or replacement of breast implant on separate day from mastectomy
- 19350 Nipple/areola reconstruction

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- 19357 Tissue expander or placement in breast reconstruction, including subsequent expansion (s)
- 19361 Breast reconstruction with latissimus dorsi flap,
- 19364 Breast reconstruction with free flap (ex fTram, DIEP, SIEA, GAP flap)
- 19367 Breast reconstruction with with single pedicled transverse rectus abdominis myocutaneous (TRAM) flap
- 19368 Breast reconstruction with single pedicled transverse rectus abdominis myocutaneous (TRAM) flap requiring separate microvascular anastomosis (supercharging)
- 19369 Breast reconstruction with bipedicled transverse rectus abdominis myocutaneous (TRAM) flap
- 19370 Revision of peri-implant capsule, breast, including capsulotomy, capsulorrhaphy, and/or partial capsulectomy
- 19371 Peri-implant capsulectomy, breast, complete, including removal of all intracapsular contents
- 19380 Revision of reconstructed breast (eg, significant removal of tissue, readvancement and/or re-inset of flaps in autologous reconstruction or significant capsular revision combined with soft tissue excision in implantbased reconstruction)
- 19396 Preparation of moulage for custom breast implant
- C1789 Prosthesis, breast (implantable) Bill with Revenue Code 0272 Sterile supply (not separately payable for Priority Health Medicaid)
- L8039 Breast prosthesis, not otherwise specified Billed with Revenue Code 0274 Prosthetic/orthotic devicesd (not separately payable for Priority Health Medicaid)
- L8600 Implantable breast prosthesis, silicone or equal Billed with Revenue Code 0278 Other implants (Not separately payable for Priority Health Medicaid)
- S2066 Breast reconstruction with gluteal artery perforator (GAP) flap, including harvesting of the flap, microvascular transfer, closure of donor site and shaping the flap into a breast, unilateral *(S Code is not covered for Priority Health Medicaid and Priority Health Medicare)*
- S2067 Breast reconstruction of a single breast with "stacked" deep inferior epigastric perforator (DIEP) flap(s) and/or gluteal artery perforator (GAP) flap(s), including harvesting of the flap(s), microvascular transfer, closure of donor site(s) and shaping the flap into a breast, unilateral *(S Code is not covered for Priority Health Medicaid and Priority Health Medicare)*
- S2068 Breast reconstruction with deep inferior epigastric perforator (DIEP) flap or superficial inferior epigastric artery (SIEA) flap, including harvesting of the flap, microvascular transfer, closure of donor site and shaping the flap into a breast, unilateral *(S Code is not covered for Priority Health Medicaid and Priority Health Medicare)*

Not Covered

0662T Scalp cooling, mechanical; initial measurement and calibration of cap

MEDICAL POLICY No. 91545-R19

- 0663T Scalp cooling, mechanical; placement of device, monitoring, and removal of device (List separately in addition to code for primary procedure)
- 0694T 3-dimensional volumetric imaging and reconstruction of breast or axillary lymph node tissue, each excised specimen, 3-dimensional automatic specimen reorientation, interpretation and report, real-time intraoperative
- 0857T Opto-acoustic imaging, breast, unilateral, including axilla when performed, real-time with image documentation, augmentative analysis and report (List separately in addition to code for primary procedure)
- 0945T Intraoperative assessment for abnormal (tumor) tissue, in-vivo, following partial mastectomy (e.g., lumpectomy) using computer-aided fluorescence imaging (List separately in addition to code for primary procedure)

D. Microsurgical Lymph Node Transplantation for Post mastectomy Lymphedema

ICD-10 Codes that <u>may</u> apply:

I97.2 Post mastectomy lymphedema syndrome

CPT/HCPCS Codes:

38999 Unlisted procedure, hemic or lymphatic system (Explanatory notes must accompany claim)

E. Gynecomastia

ICD-10 Codes that support medical necessity:

N62 Hypertrophy of breast

CPT/HCPCS Codes

- 19300 Mastectomy for gynecomastia
- 19303 Mastectomy, simple, complete
- 19318 Reduction Mammoplasty
- *Special Note:* Most benefit plans have a 50% co-pay on professional fees effective 1/1/2003. A rider allowing coverage at a higher level is available to employers.

F. Mastectomy for Intractable Breast Pain (Not covered)

ICD-10 Codes that apply:

N64.4 Mastodynia

CPT/HCPCS Codes

- 19301 Mastectomy, partial; (e.g., lumpectomy, tylectomy, quadrantectomy, segmentectomy)
- 19302 Mastectomy, partial; with axillary lymphadenectomy (e.g., lumpectomy, tylectomy, quadrantectomy, segmentectomy); with axillary lymphadenectomy
- 19303 Mastectomy, simple, complete
- 19305 Mastectomy, radical, including pectoral muscles, axillary lymph nodes
- 19306 Mastectomy, radical, including pectoral muscles, axillary and internal mammary lymph nodes (Urban type operation)

19307 Mastectomy, modified radical, including axillary lymph nodes, with or without pectoralis minor muscle, but excluding pectoralis major muscle

G. Mammography, Digital Breast Tomosynthesis (DBT), Breast MRI and Breast Specific Gamma Imaging (BSGI)

Diagnostic Procedures:

- 76641 Ultrasound, breast, unilateral, real time with image documentation, including axilla when performed; complete
- 76642 Ultrasound, breast, unilateral, real time with image documentation, including axilla when performed; limited
- 77046 Magnetic resonance imaging, breast, without contrast material; unilateral
- 77047 Magnetic resonance imaging, breast, without contrast material; bilateral
- 77048 Magnetic resonance imaging, breast, without and with contrast material(s), including computer-aided detection (CAD real-time lesion detection, characterization and pharmacokinetic analysis), when performed; unilateral
- 77049 Magnetic resonance imaging, breast, without and with contrast material(s), including computer-aided detection (CAD real-time lesion detection, characterization and pharmacokinetic analysis), when performed, bilateral
- 77065 Diagnostic mammography, including computer-aided detection (CAD) when performed; unilateral
- 77066 Diagnostic mammography, including computer-aided detection (CAD) when performed; bilateral
- 77061 Digital breast tomosynthesis; unilateral
- 77062 Digital breast tomosynthesis; bilateral
- G0279 Diagnostic digital breast tomosynthesis, unilateral or bilateral (list separately in addition to 77065 or 77066)

Screening Procedures:

- 77067 Screening mammography, bilateral (2-view study of each breast), including computer-aided detection (CAD) when performed
- 77063 Screening digital breast tomosynthesis, bilateral (List separately in addition to code for primary procedure)

ICD-10 Codes that support preventive benefit for the following diagnostic

- procedures if performed for screening indication and converted to diagnostic
- Z12.31 Encounter for screening mammogram for malignant neoplasm of breast
- Z12.39 Encounter for other screening for malignant neoplasm of breast
- Z80.3 Family history of malignant neoplasm of breast
- Z85.3 Personal history of malignant neoplasm of breast

CPT/HCPCS Codes

- 77065 Diagnostic mammography, including computer-aided detection (CAD) when performed; unilateral
- 77066 Diagnostic mammography, including computer-aided detection (CAD) when performed; bilateral
- 77061 Diagnostic digital breast tomosynthesis; unilateral
- 77062 Diagnostic digital breast tomosynthesis; bilateral
- G0279 Diagnostic digital breast tomosynthesis, unilateral or bilateral (list separately in addition to 77065 or 77066)

<u>BSGI</u>

ICD-10 Codes that are <u>not covered</u> :		
C50.011 - C50.929	Malignant neoplasm of breast	
D05.00 - D05.92	Carcinoma in situ of breast	
R92.0 - R92.8	Abnormal and inconclusive findings on diagnostic imaging of breast	
Z12.31	Encounter for screening mammogram for malignant neoplasm of breast	
Z12.39	Encounter for other screening for malignant neoplasm of breast	
Z40.01	Encounter for prophylactic removal of breast	
Z80.3	Family history of malignant neoplasm of breast	
Z85.3	Personal history of malignant neoplasm of breast	

CPT/HCPCS Codes:

Not covered for any indication

S8080 Scintimammography (radioimmunoscintigraphy of the breast), unilateral, including supply of radiopharmaceutical

Not covered for the diagnoses listed above

- 78800 Radiopharmaceutical localization of tumor or distribution of radiopharmaceutical agent(s); limited area
- 78801 Radiopharmaceutical localization of tumor or distribution of radiopharmaceutical agent(s); multiple areas

H. Bioimpedance (bioelectrical impedance spectroscopy)

ICD-10 Codes that <u>support medical necessity</u>: C50-C50.929 Malignant neoplasm of breast D05-D05.92 Carcinoma in situ of breast

CPT/HCPCS Codes

93702 Bioimpedance spectroscopy (BIS), extracellular fluid analysis for lymphedema assessment(s)

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