Oscar Clinical Guideline: Breast Procedures (CG036, Ver. 12)

Breast Procedures

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

The Plan members with conditions affecting the breast(s) may meet medical necessity for procedures or surgeries, however, benefit coverage is dependent on their plan. Examples of conditions affecting the breast include cancers, trauma or injury, anatomical abnormalities, and complications of prior procedures such as with breast implants. Correction and/or treatment of these conditions is typically surgical, depending on the underlying issue. Expert consensus guidelines and regulations, such as those from MCG, the National Comprehensive Cancer Center, the federal Women's Health and Cancer Rights Act, and other federal or state mandates are used to determine clinical criteria.

This guideline does not discuss medical necessity criteria for gender affirmation procedures. For information on clinical criteria of breast procedures related to sex reassignment, please refer to the Oscar Clinical Guideline: Sex Reassignment Surgery (Gender Affirmation Surgery) and Non-Surgical Services (CG017).

This guideline does not discuss procedures for lymphedema. The Plan considers treatment of lymphedema due to physical complications of mastectomy medically necessary, adhering to the Women's Health and Cancer Rights Act (WHCRA) of 1998.

This guideline does not discuss excision of benign breast conditions (e.g., painful fibroadenomas). Please see The American Society of Breast Surgeons Consensus Guideline on Concordance Assessment of

Image-Guided Breast Biopsies and Management of Borderline or High-Risk Lesions or the MCG General Surgery or Procedure GRG (SG-GS), as needed.

For information on medical necessity criteria of skin and soft tissue substitutes, please refer to the Plan Clinical Guideline: Bioengineered Skin and Soft Tissue Substitutes (CG030).

Definitions

"Mastectomy" is the surgical removal of one or both breasts as part of the treatment for certain types of breast cancer.

"Lumpectomy" or "Breast Conserving Surgery" is the surgical removal of a portion of the cancerous breast tissue without removing the entire breast. It can also be referred to as a "partial mastectomy". Breast conserving surgery is usually followed by radiation therapy.

"Risk-Reduction Mastectomy" or "Prophylactic Mastectomy" is the surgical removal of one or both breasts in the absence of malignant disease with the goal of reducing the risk of breast cancer in members at high-risk.

"Skin-Sparing Mastectomy" is similar to a standard mastectomy in that the nipple-areola complex and the glandular breast tissue is removed, while the skin is left intact. This procedure can only be performed in women when cancer does not affect the skin. It provides superior cosmetic outcomes in most women.

"Nipple-Sparing Mastectomy" is similar to a skin-sparing mastectomy except that the skin AND nipple-areola complex are left intact. This procedure can only be performed in women when cancer does not affect the skin or nipple.

"Reconstructive Breast Surgery" is surgery aimed at restoring the normal anatomical appearance of breasts after an insult, such as trauma, surgical procedure, or cancer.

"Aesthetic Flat Closure" is defined by the National Cancer Institute as "a type of surgery that is done to rebuild the shape of the chest wall after one or both breasts are removed. An aesthetic flat closure may also be done after removal of a breast implant that was used to restore breast shape. During an aesthetic flat closure, extra skin, fat, and other tissue in the breast area are removed. The remaining tissue is then tightened and smoothed out so that the chest wall appears flat."

"Cosmetic Breast Surgery" is surgery aimed at electively improving upon the anatomical appearance of the breasts.

"Mastopexy" is a surgical procedure to elevate the breasts to a normal position

"Augmentation Mammaplasty" or "Breast Augmentation" is a surgical procedure to enlarge one or both breasts.

"Reduction Mammaplasty" or breast reduction, is a surgical procedure to decrease the size of one or both breasts.

"Contracture" is a condition where scar tissue forms at the site of breast implantation and may result in cosmetic deformity, pain, and change in the way the breast feels. The Baker contracture grades are as follows:

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

"Ipsilateral" refers to a procedure or intervention on the same side as the disease

"Contralateral" refers to a procedure or intervention on the side opposite the disease.

"Oncoplastic reconstruction" refers to when an oncologic breast surgery (usually lumpectomy) is followed immediately by a reconstructive plastic surgery procedure during the same operating room time. This is contrasted by a delayed reconstruction approach where the plastic surgery occurs at a later time after the oncologic surgery.

"Ptosis" of the breast refers to the weight of the breast tissue causing stretching of the skin allowing the breast to increasingly droop over time. Regnault's classification provides a framework for grading breast ptosis:

- Pseudoptosis: Areola above the mammary crease; loose skin due to hypoplasia
- Partial ptosis: Areola above the crease and gland ptosis
- True ptosis:
    - Grade 1: Areola at the level of the mammary crease and above the contour of the gland
    - Grade 2: Areola below the level of the mammary crease and above the contour of the gland
    - Grade 3: Areola below the level of the mammary crease and below the contour of the gland

"Radiotherapy" or "radiation therapy" refers to the use of therapeutic doses of radiation (usually delivered with high energy photons, electrons, or protons) to kill breast cancer cells. Radiation can be delivered externally (external beam radiotherapy) or internally (brachytherapy).

"Accelerated Partial Breast Irradiation (APBI)" refers to higher doses of radiation delivered over a shorter (e.g. accelerated) period of time and given to smaller areas of the breast (e.g. partial breast) in

comparison to conventionally fractionated whole-breast radiation. APBI can be done using external beam radiation or brachytherapy. For APBI using brachytherapy, a device can be placed inside the breast cancer surgical cavity to allow for radiation to be delivered directly to the tumor bed.

"Brachytherapy"refers to the temporary or permanent placement of radioactive material in the breast tissue for breast cancer treatment and can be applied through interstitial, intracavitary, or intraoperative methods. Brachytherapy is also specified by high-dose-rate and low-dose-rate depending on the radioactive source and approach used.

"Electronic Brachytherapy" refers to a newer technique that delivers low energy photons through miniature x-ray sources (i.e. tubes). This is a different therapy technique than traditional brachytherapy that uses radionuclides to deliver typically high doses of radiation.

"Intraoperative Radiation Therapy (IORT)" refers to radiation given inside or next to the breast tissue where surgery is being performed on the same day in the operating room. It is most often done with electron therapy (external beam radiation) or low energy x-ray therapy.

Medical Necessity Criteria for Clinical Review

Procedures & Length of Stay (Subject to DRG facility)

The Plan considers the following procedures and settings medically necessary when the following criteria are met:

1. Mastectomy
    a. Complete, without reconstruction - Ambulatory, which may include an overnight stay
    b. With immediate insertion of breast implant or tissue expander - Ambulatory, which may include an overnight stay
    c. With tissue flap reconstruction - Subject to DRG for IP stay
2. Lumpectomy - Ambulatory, which may include an overnight stay
3. Breast Reconstructive Surgery (with or without Mastectomy)
    a. With immediate insertion of breast implant or tissue expander - Ambulatory, which may include an overnight stay
    b. With tissue flap reconstruction - Subject to DRG for IP stay
4. Removal of Breast Implants - Ambulatory, which may include an overnight stay

5. Breast Reduction that meets medical necessity - Ambulatory, which may include an overnight stay
6. An inpatient admission for a higher level of care may be considered medically necessary when the member meets MCG Ambulatory Surgery Exception Criteria (CG-AEC)
7. Any ambulatory procedure that requires more than 1 day stay to monitor the blood supply of a flap would qualify for IP level of care. These include, but are not limited to:
    a. Reconstruction with latissimus dorsi myocutaneous (LDM) flap
    b. Rubens flap
    c. Superior or inferior gluteal free flap
    d. Transverse upper gracilis (TUG) flap
    e. Transverse rectus abdominis myocutaneous (TRAM) flap
    f. Deep inferior epigastric perforator (DIEP) flap
    g. Superficial inferior epigastric artery (SIEA) flap
    h. Superior gluteal artery perforator (SGAP) flap
    i. Profunda artery perforator flap

Length of Stay (LOS) Extensions

Subject to medical necessity review, the Plan may consider extensions for inpatient hospital admissions for breast procedures under the following circumstances:

1. In the presence of complex comorbidities (COPD, renal disease, heart failure) anticipated to require extended perioperative treatment and/or monitoring
2. Complications in the peri- or postoperative phases, such as thromboembolic disease (DVT or pulmonary embolism), wound infection, suture line bleeding, or respiratory failure
3. The member meets the extended stay criteria for the procedure as defined by appropriate MCG guidelines
4. Failure to achieve discharge status criteria for the procedure the member received as defined by appropriate MCG guidelines

Indication-Specific Criteria

<u>Mastectomy and Lumpectomy</u>

The Plan considers mastectomy in women medically necessary when ANY of the following criteria are met:

1. Breast conserving surgery (lumpectomy) for biopsy proven breast cancer was unsuccessful; *or*
2. Breast conserving surgery for biopsy proven breast cancer was contraindicated or not indicated, such as, but not limited to the following reasons:
    a. Multicentric disease with two or more primary tumors in separate quadrants of the breast that cannot be excised with a single excision; *or*
    b. Diffuse malignant, indeterminate or suspicious microcalcifications; *or*
    c. History of prior therapeutic radiation therapy including a portion of the breast selected for treatment which result in excessive radiation dose to the chest wall; *or*

    d. Pregnancy, as this is a contraindication to radiation therapy, although in some circumstances the lumpectomy can be performed in the third trimester followed by radiation after birth; *or*
    e. Persistently positive margins after multiple attempts at breast conserving excision; *or*
    f. Homozygous for ATM mutation; *or*
    g. Active connective tissue disease involving the skin (especially scleroderma and lupus); *or*
    h. Tumors >5cm or large tumor-to-breast-size ratio; *or*
    i. Women with known or suspected genetic predisposition to breast cancer; *or*
    j. Inflammatory breast cancer (T4d); *or*
    k. Insufficient response to neoadjuvant chemotherapy or endocrine therapy; *or*
    l. Contraindication to radiation therapy.
3. Member preferred mastectomy for biopsy proven breast cancer (DCIS or invasive, operable breast cancer); *or*
4. Locally recurrent breast cancer after initial treatment with lumpectomy and radiation therapy; *or*
5. Treatment of phyllodes tumor if negative margins cannot be obtained by lumpectomy or partial mastectomy.

The Plan considers lumpectomy (e.g., breast conserving therapy) in women with breast cancer medically necessary meeting ANY of the following criteria:

1. Ductal carcinoma in situ (DCIS) not meeting exclusion criteria or absolute contraindications; *or*
2. Invasive breast cancer (Stage I, IIA, IIB, or T3N1M0) not meeting exclusion criteria or absolute contraindications. (A biopsy proven diagnosis of invasive breast cancer or DCIS clinically assessed as resectable with clear margins).
3. Treatment of phyllodes tumors (which includes benign, borderline, and malignant subtypes) is with local surgical excision with tumor-free margins of 1 cm or greater. *Note*: Lumpectomy or partial mastectomy is the preferred surgical therapy as per NCCN.

<u>Risk-Reduction Mastectomy</u>

The Plan considers risk-reduction mastectomy (including contralateral) in women medically necessary when ANY of the following criteria are met:

1. Carrier for high-penetrance breast cancer susceptibility genes, defined as any one of the following:
    a. BRCA 1 or 2; *or*
    b. CDH1; *or*
    c. PALB2; *or*
    d. PTEN; *or*
    e. STK11; or
    f. TP53 (pP53).
2. Diagnosis of breast cancer at 45 years of age or younger; *or*
3. Multiple primary breast cancers or bilateral breast cancer; *or*

4. Increased risk due to ethnic background (e.g., Ashkenazi Jewish descent) AND 1 or more relatives with breast cancer or epithelial ovarian cancer; *or*
5. Women with a history of radiation to chest between 10 and 30 years of age; *or*
6. History of prior mantle radiation therapy; *or*
7. Women with a family history of ANY of the following:
    a. 1st degree relative who is premenopausal with bilateral breast cancer; *or*
    b. 1st or 2nd degree male relative with breast cancer; *or*
    c. 1st or 2nd degree relative with multiple primary breast cancers or bilateral breast cancer; *or*
    d. 1st or 2nd degree relative with breast cancer AND personal history of epithelial ovarian cancer; *or*
    e. Three or more 1st or 2nd degree relatives on the same side of the family with breast cancer, regardless of age of diagnosis.
8. Atypical hyperplasia of lobular or ductal origin and/or LCIS confirmed on biopsy AND dense, fibronodular breasts that are mammographically or clinically difficult to evaluate.

*Note: Skin-Sparing Risk-Reduction Mastectomy may be considered as an alternative in women meeting the above criteria when there is no cancer involving the skin. Similarly, Nipple-Sparing Risk-Reduction Mastectomy may be considered in women without cancer involving the nipple-areola complex.

The Plan considers prophylactic removal of the contralateral breast tissue medically necessary in men with a personal history of breast cancer.

<u>Breast Reconstructive Surgery</u>

The Plan considers reconstructive breast surgeries for ANY of the following indications:

1. Post-mastectomy or lumpectomy reconstruction of both the affected and non-affected breast to restore symmetry, when the original surgery met clinical criteria; *or*
2. Post-traumatic injury with significant anatomical defect; *or*
3. Correction of inverted nipple(s) when ANY of the following criteria are met:
    a. Post-mastectomy; *or*
    b. Documented history of chronic bleeding, discharge, scabbing, or ductal infection that is attributed to inverted nipple.
4. Poland syndrome where there is significant congenital deformity; *or*
5. Revision of a medically necessary reconstructive breast surgery when the initial surgery was inadequate to restore symmetry, or when complications prevented reconstruction; *or*
6. Prophylactic removal (mastectomy) of the non-affected breast, with or without reconstruction, to restore symmetry after ipsilateral mastectomy; *or*
7. Upfront mastopexy or reduction mammoplasty prior to mastectomy in women meeting the above criteria for mastectomy who also have Regnault grade 2 or 3 ptosis of the breast(s).

Associated Breast Procedures

List of reconstructive breast surgeries and associated procedures that may be considered medically necessary when the specific criteria below are met:

a. Aesthetic flat closure for chest wall reconstructive surgery may be considered at the time of mastectomy or delayed after mastectomy for any of the following procedures:
    i. Bilateral mastectomy, unilateral mastectomy, partial mastectomy, or after breast implant removal
b. Autologous fat grafting (lipofilling,lipomodelling) for reconstructive surgery or mastectomy
c. Capsulectomy (indicated except when associated with removal of a saline implant)
d. Capsulotomy
e. Mastopexy
f. Insertion of breast implant(s) to restore symmetry
g. Removal of breast implant(s) to restore symmetry
h. Reconstruction with latissimus dorsi myocutaneous (LDM) flap
i. Rubens Flap
j. Tissue expander(s)
k. Superior or inferior gluteal free flap
l. Transverse upper gracilis (TUG) flap
m. Transverse rectus abdominis myocutaneous (TRAM) flap
n. Deep inferior epigastric perforator (DIEP) flap
o. Superficial inferior epigastric artery (SIEA) flap
p. Superior gluteal artery perforator (SGAP) flap
q. Profunda artery perforator flap
r. Fat harvesting and grafting (e.g. liposuction or lipectomy)
s. Nipple and/or areolar reconstruction
t. Tattooing of nipple area for reconstructive purposes
u. External breast prosthesis or mastectomy bras
v. Reduction mammoplasty or augmentation of the unaffected breast for symmetry
w. Acellular dermal matrices considered medically necessary, please refer to the Plan Clinical Guideline: CG030 Bioengineered Skin and Soft Tissue Substitutes:
    i. Alloderm
    ii. Alloderm RTU
    iii. Cortiva (AlloMax, NeoForm)
    iv. DermACELL
    v. FlexHD

*Note: The reconstructive surgery post-mastectomy or lumpectomy can occur at the same time as the initial procedure (e.g., oncoplastic reconstruction) or anytime thereafter.

Removal of Breast Implants

The Plan considers breast implant removal medically necessary when ANY of the following criteria are met:

1. Implant extrusion through skin; *or*
2. Persistent or recurrent infection (local or systemic) secondary to breast implant that has been refractory to medical management, including the appropriate use of antibiotics; *or*
3. Baker class IV contracture resulting in any one of the following:
    a. Pain; *or*
    b. Persistent infection refractory to medical management; *or*
    c. Interference with standard breast cancer screening.
4. Tissue necrosis secondary to implant; *or*
5. Breast implant associated anaplastic large cell lymphoma; *or*
6. Intra- or extracapsular rupture of a silicone-filled implant WITH documentation of ultrasound, mammographic, or MRI evidence (Capsulectomy or capsulotomy may also be necessary); *or*
7. Removal of a contralateral breast implant to achieve symmetry when medical necessity criteria for removal of the other implant are met; *or*
8. Prior to surgical treatment of breast cancer where the implant would interfere with treatment (*note:* this is usually done at the time of lumpectomy or mastectomy)*; or*
9. Baker class III or IV distortion in a patient with implant placed as part of a medically necessary reconstructive surgery after mastectomy, lumpectomy, or breast cancer treatment; *or*
10. When required to produce a symmetrical appearance after a medically necessary breast cancer surgery on the contralateral breast; *or*
11. Re-insertion of the breast implant after a removal is considered medically necessary in members whose breast implant was originally performed as covered reconstructive surgery.

The Plan may require medical necessity review for breast implant removal for ANY of the following situations:

1. Baker class III contracture in the absence of prior mastectomy or lumpectomy; *or*
2. Implant removal for removal of a breast mass that has not proven cancerous; *or*
3. Implant removal for a medically necessary mastectomy or lumpectomy that can be performed with the implant in place.

Breast Reduction

The Plan considers the following indications for breast reduction to be medically necessary when ONE of the following criteria are met:

1. Meets MCG A-0274 for reduction mammoplasty; *or*
2. Meets MCG A-0273 for mastectomy for gynecomastia; *or*
3. After mastectomy, breast reduction of the other breast to produce symmetrical appearance as per Women's Health & Cancer Rights Act

Experimental or Investigational / Not Medically Necessary

The Plan considers the following indications for risk-reduction mastectomy (e.g., prophylactic mastectomy) as not medically necessary:

1. Any indication not listed under the Risk-Reduction Mastectomy criteria
2. Fibrocystic breast disease (unless listed under the Mastectomy criteria)
    a. *Rationale:* The data on prophylactic mastectomy for fibrocystic breast disease is limited, and current NCCN guidelines do not include fibrocystic breast disease as a high risk criteria to recommend this treatment option.[20, 49]
3. Pseudoangiomatous stromal hyperplasia (PASH)
    a. *Rationale*: Degmin et al (2010) conducted a study on 9065 excision breast biopsies to examine the correlation between PASH and breast cancer. They found a significantly lower number of breast cancers in women with PASH. Furthermore, NCCN guidelines do not include PASH as a high risk criteria. The current evidence is insufficient to recommend prophylactic mastectomy for patients with PASH.[9, 49]
4. Men with BRCA gene mutations or family history of breast cancer
    a. *Rationale:* Current NCCN guidelines state that there is insufficient evidence for men with BRCA gene mutations and no personal history of breast cancer to guide recommendations regarding prophylactic removal of breast tissue.[49]
5. Women with breast cancer not meeting the high-risk criteria, except when performed for symmetry per the reconstruction criteria, as highlighted above.

The Plan considers any breast surgery that falls under cosmetic surgery to be not medically necessary [except when criteria are met under Breast Reconstructive Surgery or in the Plan Clinical Guideline: Sex Reassignment Surgery (Gender Affirmation Surgery) (CG017)], including, but not limited to the following:

1. Breast augmentation (e.g., breast implants, pectoral implants)
2. Breast lift (mastopexy)
3. Correction of inverted nipple
4. Nipple piercing
5. Removal of supernumerary nipples (polymastia)
6. Surgery to correct tuberous breast deformity
7. Breast reduction for cosmetic purposes
8. Breast augmentation or reduction solely for cosmetic purposes, after a successful post-mastectomy breast reconstruction (e.g., a patient who has undergone breast implants after mastectomy wishes to augment her breasts further)

The Plan considers the following breast implant removal procedures as not medically necessary:

1. Any procedure not meeting the medical necessity criteria
2. Capsulectomy is not considered medically necessary when associated with removal of a saline implant

    a. *Rationale:* Capsulectomy is performed due to complications of silicone implants, which can cause scar tissue and contracture when ruptured. As saline is a non-inflammatory, inert solution, capsular contracture and thus capsulectomy are not indicated for saline implants, whether ruptured or intact.[24]
3. Removal of a ruptured saline-filled or alternative implant
    a. *Rationale:* Saline and alternative implants contain solution that is absorbed into the body in the event of a rupture, unlike silicone which can cause contractures and further complications. Thus, removal of saline and alternative implants is not medically necessary unless meeting criteria above.
4. Removal of any type of breast implant for:
    a. Systemic symptoms thought to be secondary to connective tissue disease, autoimmune disease
        i. *Rationale:* Gabriel et al (1994) conducted a study on 749 women with breast implants and compared them to 1498 community controls, finding no correlation between breast implants and common rheumatologic diseases. Other large-scale studies have demonstrated a lack of evidence for connective tissue or autoimmune disease associated with breast implants.[19, 39, 52]
    b. Anxiety related to breast implant
    c. Pain not meeting the criteria for contracture, rupture, or infection in the clinical indications section
5. Replacement of breast implant after removal is not considered medically necessary except as mandated for reconstructive purposes in women meeting criteria above per state and/or federal regulation

The Plan considers the following reconstructive procedures and indications as not medically necessary:

1. Any procedure not meeting the medical necessity criteria
2. Scar revision after biopsy
3. Removal of cyst(s)
4. Revision of prior reconstructed breast due to normal aging

The Plan considers the following reconstructive procedures and indications as experimental, investigational, or unproven:

1. Body lift perforator flap
    a. *Rationale:* The current evidence is insufficient to support the use of this technique. Further outcomes and evidence of the clinical application are required.
2. The following dermal matrices and reconstructive products:
    a. SurgiMend
    b. BioDesign Nipple Reconstruction Cylinder
    c. hMatrix
    d. Permacol

e. Radiesse filler
f. Renuva Allograft Adipose Matrix
g. Repriza
h. Strattice Reconstructive Tissue Matrix
i. TIGR Matrix Surgical Mesh
j. Veritas Collagen Matrix
    - *Rationale:* The evidence on the safety and efficacy of the above dermal matrices or reconstructive products is insufficient to support clinical use at this time. Furthermore, as of March 31, 2021, the FDA issued a safety communication stating that it has not approved or cleared any acellular dermal matrix derived from human skin or animal skin for use in implant-based breast reconstruction, and that certain products used for this purpose may have a higher chance for complications.

3. Autologous fat transplant with adipose derived stem cells
    a. *Rationale*: Autologous fat transplant using adipose-derived stem cells (ADSC or ASC) has not yet been fully proven as a safe and effective method of fat grafting. A review of the most recent literature reveals a continued debate over the safety and effectiveness of this technique, especially in patients undergoing oncologic surgery. A 2017 article concluded that ADSC "hold great potential for novel breast reconstruction strategies. However, their use in patients with breast cancer is controversial and their oncological safety, particularly in relation to local disease recurrence, has been questioned." The prospective RESTORE-2 trial found that ADSC fat grafting may be safe and effective, however it was met with much criticism and debate and only consisted of 12 month follow-up. Furthermore, a 2016 review concluded that "with the advent of ASC therapy, autologous fat transfer holds much promise for the future, especially in the realm of soft tissue reconstruction and aesthetic surgery. There remains certain skepticism over the safety of the use of ASCs for post-oncological defects, which needs to be addressed in an ethical and well-conducted human clinical trial."[79-81]
4. Xenograft cartilage grafting

The Plan considers lumpectomy requiring radiation therapy as not medically necessary in the following situations:

1. Absolute contraindications per latest NCCN guidelines for Breast Cancer:
    a. Multicentric disease with any of the following criteria:
        i. Receipt of neoadjuvant chemotherapy or endocrine therapy
        ii. Age ≤ 40
        iii. Triple negative breast cancer (ER-, PR-, and HER2-negative)
        iv. More than 2 lesions involving more than 2 quadrants by MRI evaluation
        v. Any individual lesion ≥5 cm
        vi. BRCA mutation carrier
        vii. Multicentric pure DCIS

viii. Inability to achieve negative margins (defined as no ink on tumor for invasive cancers ± DCIS)
ix. cN2–N3
x. Any reason for precluding the delivery of adjuvant WBRT+ boost

b. Diffuse malignant microcalcifications
c. Pregnancy, as this is a contraindication to radiation therapy, although in some circumstances the lumpectomy can be performed in the third trimester followed by radiation after birth
d. Persistently positive margins after multiple attempts at breast conserving excision
e. Homozygous for ATM mutation
f. Inflammatory breast cancer or invasive breast cancer with extensive skin or dermal lymphatic involvement

2. Relative contraindications per NCCN guidelines:
    a. History of prior therapeutic radiation therapy including a portion of the breast selected for treatment which result in excessive radiation dose to the chest wall
    b. Active connective tissue disease involving the skin (especially scleroderma and lupus)
    c. Tumors > 5 cm
    d. Women with known or suspected genetic predisposition to breast cancer.

The Plan considers radiation therapy given while in the operating room as not medically necessary:

1. Intraoperative Radiation Therapy such as a radiation-generating device placed into breast surgery cavity for single-fraction electron therapy or x-ray therapy; *or*
    a. Accelerated Partial Breast Irradiation when billed as IORT, such as when the first dose is given in the operating room at time of surgery and balloon/catheter is placed.
    b. Rationale: In 2018, American Brachytherapy Society issued their consensus statement that intraoperative radiation therapy is not recommended for breast cancer treatment. In 2016, according to the American Society for Radiation Oncology (ASTRO) Coverage with Evidence Development (CED) statement, low-energy x-ray IORT for partial breast irradiation should be used within the context of a prospective registry or clinical trial. When used, it should be restricted to women with invasive cancer considered "suitable" for partial breast irradiation (recommendation is weak). There is a higher risk of ipsilateral breast tumor recurrence with IORT compared with whole breast irradiation.
2. Electronic Brachytherapy such as a portable linear accelerator intraoperatively to deliver radiation to the breast (e.g., AccuBoost Technique, Xoft Axxent Electronic Brachytherapy System, Esteya EBT system and the INTRABEAM system). Electronic brachytherapy are typically low energy photons through miniature x-ray sources (i.e. tubes). This is a different therapy technique than traditional brachytherapy that uses radionuclides to deliver typically high doses of radiation:
    a. *Rationale*: In 2018, American Brachytherapy Society issued their consensus statement that electronic brachytherapy is not recommended for breast cancer treatment. In 2016,

according to the American Society for Radiation Oncology (ASTRO) Coverage with Evidence Development (CED) statement, electron beam IORT should be restricted to women with invasive cancer considered "suitable" for partial breast irradiation based on the results of a multivariate analysis with median follow-up of 5.8 years (recommendation is strong).

Applicable Billing Codes

Table 1	
Mastectomy and Lumpectomy	
CPT/HCPCS codes considered medically necessary if criteria are met:	
Code	*Description*
15771	Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs; 50 cc or less injectate
15772	Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs; each additional 50 cc injectate, or part thereof (List separately in addition to code for primary procedure)
19301	Mastectomy, partial (eg, lumpectomy, tylectomy, quadrantectomy, segmentectomy)
19302	Mastectomy, partial (eg, 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; excluding pectoralis major muscle

Table 2	
ICD-10 codes considered medically necessary with Table 1 codes if criteria are met:	
Code	*Description*
C50.011 - C50.929	Malignant neoplasm of breast
C79.81	Secondary malignant neoplasm of breast

D05.00 - D05.92	Carcinoma in situ of breast
Z85.3	Personal history of malignant neoplasm of breast
Z92.3	Personal history of irradiation

Table 3	
Breast Implant Removal	
CPT/HCPCS codes considered medically necessary if criteria are met:	
Code	*Description*
19328	Removal of breast implant
19330	Removal of ruptured breast implant, including implant contents (eg, saline, silicone gel)
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

Table 4	
ICD-10 codes considered medically necessary with Table 3 codes if criteria are met:	
Code	*Description*
C50.011 - C50.929	Malignant neoplasm of breast
C84.60 - C84.69	Anaplastic large cell lymphoma, ALK-positive
C84.70 - C84.79	Anaplastic large cell lymphoma, ALK-negative
N64.4	Mastodynia
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, or grafts

Table 5	
Breast Reconstruction	
CPT/HCPCS codes considered medically necessary if criteria are met:	
Code	*Description*
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
15771	Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs; 50 cc or less injectate
15772	Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs; each additional 50 cc injectate, or part thereof (List separately in addition to code for primary procedure)
15777	Implantation of biologic implant (eg, acellular dermal matrix) for soft tissue reinforcement (ie, breast, trunk) (List separately in addition to code for primary procedure)
15839	Excision, excessive skin and subcutaneous tissue (includes lipectomy); other area
15877	Suction assisted lipectomy; trunk
19316	Mastopexy
19318	Breast reduction
19325	Breast augmentation with implant
19328	Removal of breast implant
19330	Removal of ruptured breast implant, including implant contents (eg, saline, silicone gel)
19340	Insertion of breast implant on same day of mastectomy (ie, immediate)
19342	Insertion or replacement of breast implant on separate day from mastectomy
19350	Nipple/areola reconstruction
19355	Correction of inverted nipples
19357	Tissue expander placement in breast reconstruction, including subsequent expansion(s)
19361	Breast reconstruction with latissimus dorsi flap
19364	Breast reconstruction with free flap (eg, fTRAM, DIEP, SIEA, GAP flap)
19367	Breast reconstruction; with single-pedicled transverse rectus abdominis myocutaneous (TRAM) flap

Table 5	
Breast Reconstruction	
CPT/HCPCS codes considered medically necessary if criteria are met:	
Code	*Description*
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, re-advancement and/or re-inset of flaps in autologous reconstruction or significant capsular revision combined with soft tissue excision in implant-based reconstruction)
19396	Preparation of moulage for custom breast implant
C1781	Mesh (implantable)
C1789	Prosthesis, breast (implantable)
L8020	Breast prosthesis, mastectomy form
L8030	Breast prosthesis, silicone or equal, without integral adhesive
L8031	Breast prosthesis, silicone or equal, with integral adhesive
L8032	Nipple prosthesis, prefabricated, reusable, any type, each
L8033	Nipple prosthesis, custom fabricated, reusable, any material, any type, each
L8035	Custom breast prosthesis, post mastectomy, molded to patient model
L8039	Breast prosthesis, not otherwise specified
L8600	Implantable breast prosthesis, silicone or equal
Q4100	Skin substitute, not otherwise specified
Q4116	Alloderm, per square centimeter
Q4122	Dermacell, dermacell awm or dermacell awm porous, per square centimeter
Q4128	Flex hd, or allopatch hd, per square centimeter
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
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

Table 5	
Breast Reconstruction	
CPT/HCPCS codes considered medically necessary if criteria are met:	
Code	*Description*
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

Table 6	
ICD-10 codes considered medically necessary with Table 5 codes if criteria are met:	
Code	*Description*
C50.011 - C50.929	Malignant neoplasm of breast
C79.81	Secondary malignant neoplasm of breast
D05.00 - D05.92	Carcinoma in situ of breast
N64.53	Retraction of nipple
N65.0	Deformity of reconstructed breast
N65.1	Disproportion of reconstructed breast
Q79.8	Other congenital malformations of musculoskeletal system [Poland Syndrome]
Z42.1	Encounter for breast reconstruction following mastectomy
Z85.3	Personal history of malignant neoplasm of breast
Z90.10 - Z90.13	Acquired absence of breast and nipple

Table 7	
CPT/HCPCS codes considered experimental, investigational, or unproven for indications listed in this guideline:	
Code	*Description*
19350	Nipple/areola reconstruction ● Due to multiple procedure techniques represented by this CPT code, specific exclusions are indicated: ● When this code is billed for BioDesign Nipple Reconstruction Cylinder, it is considered experimental, investigational, or unproven
Q2026	Injection, Radiesse, 0.1 ml

J3590	Unclassified biologics • Due to multiple products represented by this CPT code, specific exclusions are indicated: • When this code is billed for Renuva Allograft Adipose Matrix, it is considered experimental, investigational, or unproven
No specific code - may be billed as generalized skin tissue or mesh	• Due to multiple products represented by this CPT code, specific exclusions are indicated: • When this code is billed for TIGR Matrix Surgical Mesh, it is considered experimental, investigational, or unproven

Table 8	
Intraoperative Radiation Therapy, Electronic Brachytherapy	
CPT/HCPCS codes not considered medically necessary:	
Code	*Description*
0394T	High dose rate electronic brachytherapy, skin surface application, per fraction, includes basic dosimetry, when performed
0395T	High dose rate electronic brachytherapy, interstitial or intracavitary treatment, per fraction, includes basic dosimetry, when performed
19294	Preparation of tumor cavity, with placement of a radiation therapy applicator for intraoperative radiation therapy (IORT) concurrent with partial mastectomy (List separately in addition to code for primary procedure)
77424	Intraoperative radiation treatment delivery, x-ray, single treatment session
77425	Intraoperative radiation treatment delivery, electrons, single treatment session
77469	Intraoperative radiation treatment management
C9726	Placement and removal (if performed) of applicator into breast for intraoperative radiation therapy, add-on to primary breast procedure

Table 9	
ICD-10 codes not considered medically necessary with Table 8 codes:	
Code	*Description*
C50.011-C50.929	Malignant neoplasm of breast
C79.81	Secondary malignant neoplasm of breast
D05.00 - D05.92	Carcinoma in situ of breast

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