Clinical Guideline

Guideline Number: CG036, Ver. 2

Breast Procedures

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Oscar may delegate utilization management decisions of certain services to third-party delegates, who may develop and adopt their own clinical criteria.

The clinical guidelines are applicable to all commercial plans. Services are subject to the terms, conditions, limitations of a member's plan contracts, state laws, and federal laws. Please reference the member's plan contracts (e.g., Certificate/Evidence of Coverage, Summary/Schedule of Benefits) or contact Oscar at 855-672-2755 to confirm coverage and benefit conditions.

Summary

Oscar members with conditions affecting the breast(s) may be eligible for coverage of procedures or surgeries depending 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, such as those from the National Comprehensive Cancer Center, the treating surgeon's expertise, and federal or state mandates are used to determine coverage criteria.

This guideline does not discuss coverage criteria for reduction mammoplasty (see MCG A-0274) or mastectomy for gynecomastia (see MCG A-0273).

This guideline does not discuss coverage criteria for sex reassignment. For information on coverage and criteria of breast procedures related to sex reassignment, please refer to Oscar Clinical Guideline: Sex Reassignment Surgery (CG017).

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. 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.

"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.

Clinical Indications and Coverage

Covered Procedures & Length of Stay

Oscar covers the following procedures and settings when medical necessity criteria are met:

- Mastectomy
    - Complete, without reconstruction - Ambulatory
    - With immediate insertion of breast implant or tissue expander - Ambulatory or 1 day inpatient admission
    - With tissue flap reconstruction - 3 days
- Lumpectomy - Ambulatory
- Breast Reconstructive Surgery (without Mastectomy) - Ambulatory
- Removal of Breast Implants - Ambulatory

Length of Stay (LOS) Extensions

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

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

***Note:** This guideline conforms with the federal Women's Health and Cancer Rights Act, which provisions coverage of breast reconstruction in women undergoing mastectomy for breast cancer.

Mastectomy and Lumpectomy

Oscar covers Mastectomy in women 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 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 following 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***
i. Women with known or suspected genetic predisposition to breast cancer.

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. Mastectomies for complete gender transition must meet the criteria outlined in Oscar Clinical Guideline: Gender Reassignment Surgery (CG017).

Oscar covers Lumpectomy (e.g., breast conserving therapy) in women with breast cancer 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.

Risk-Reduction Mastectomy

Oscar covers Risk-Reduction Mastectomy in women when **ANY** of the following criteria are met:

1. High-risk mutation, defined as any one of the following:
    a. BRCA 1 or 2; ***or***
    b. PTEN; ***or***
    c. P53.
2. Diagnosis 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 history of radiation to chest between 10 and 30 years of age; ***or***
6. 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 same side of family with breast cancer, regardless of age of diagnosis.
7. 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.

Oscar covers prophylactic removal of the contralateral breast tissue in men with a personal history of breast cancer.

Breast Reconstructive Surgery

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

a. Capsulectomy
b. Capsulotomy
c. Mastopexy
d. Insertion of breast implant(s) to restore symmetry
e. Removal of breast implant(s) to restore symmetry
f. Reconstruction with latissimus dorsi myocutaneous (LDM) flap
g. Rubens Flap
h. Tissue expander(s)
i. Superior or inferior gluteal free flap
j. Transverse upper gracilis (TUG) flap
k. Transverse rectus abdominis myocutaneous (TRAM) flap
l. Deep inferior epigastric perforator (DIEP) flap

m. Superficial inferior epigastric artery (SIEA) flap
n. Superior gluteal artery perforator (SGAP) flap
o. Profunda artery perforator flap
p. Fat harvesting and grafting (e.g. liposuction or lipectomy)
q. Nipple and/or areolar reconstruction
r. Tattooing of nipple area for reconstructive purposes
s. External breast prosthesis or mastectomy bras
t. Reduction mammoplasty or augmentation of the unaffected breast for symmetry
u. Covered acellular dermal matrices:
    i. Alloderm
    ii. Alloderm RTU
    iii. Cortiva
    iv. dermACELL
    v. dermaMatrix
    vi. FlexHD

Oscar covers 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 coverage 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 covered reconstructive breast surgery when the initial surgery was inadequate to restore symmetry, or when complications prevented reconstruction.

***Note:** The reconstructive surgery post-mastectomy or lumpectomy can occur at the same time as the initial procedure or anytime thereafter.

Removal of Breast Implants

Oscar covers breast implant removal 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 covered reconstructive surgery after mastectomy, lumpectomy, or breast cancer treatment; ***or***
10. When required to produce a symmetrical appearance after covered breast cancer surgery on the contralateral breast; ***or***
11. Re-insertion of the breast implant after a covered removal is considered medically necessary in members whose breast implant was originally performed as covered reconstructive surgery.

Oscar requires 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 biopsy of a breast mass that has not proven cancerous; ***or***
3. Implant removal for a covered mastectomy or lumpectomy that can be performed with the implant in place.

Coverage Exclusions

Oscar considers the following indications for Risk-Reduction Mastectomy (e.g., prophylactic mastectomy) experimental, investigational, unproven, and/or not medically necessary:

1. Any indication not included in the covered criteria above
2. Fibrocystic breast disease (unless covered under the Mastectomy criteria above)
    a. *Rationale for non-coverage:* 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 for non-coverage*; 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 for non-coverage:* 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, as highlighted above.

Oscar considers any breast surgery that falls under criteria of cosmetic surgery not medically necessary [except as covered above as reconstructive surgery or when criteria is met in the Oscar Clinical Guideline: Gender Reassignment 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
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)

Oscar considers the following breast implant removal procedures and indications experimental, investigational, unproven, and/or not medically necessary:

1. Any procedure not meeting above criteria
2. Capsulectomy is not covered when associated with removal of a saline implant
    a. *Rationale for non-coverage:* 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 for non-coverage:* 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 covered 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 for non-coverage:* 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 covered indications section
5. Replacement of breast implant after removal is not covered except as mandated for reconstructive purposes in women meeting criteria above per state and/or federal regulation

Oscar considers the following reconstructive procedures and indications experimental, investigational, unproven, and/or not medically necessary:

1. Any procedure not meeting above criteria
2. Body lift perforator flap
    a. *Rationale for non-coverage:* The current evidence is insufficient to support the use of this technique. Further outcomes and evidence of the clinical application are required.[10]
3. Non covered dermal matrices and reconstructive products:
    a. SurgiMend
        i. *Rationale for non-coverage:* In May 2015, the FDA warned the manufacturer of Surgimend that it was not cleared for marketing for use in breast reconstruction.
    b. BioDesign Nipple Reconstruction Cylinder
    c. hMatrix
    d. Permacol
    e. Radiesse
    f. Repriza
    g. Seri Surgical Scaffold
    h. Strattice Reconstructive Tissue Matrix
    i. Veritas Collagen Matrix

Overall Rationale for non-coverage for 'a' through 'i': The evidence on safety and efficacy of the above dermal matrices or reconstructive products is insufficient to support clinical use at this time.

4. Autologous fat transplant with adipose derived stem cells
    a. *Rationale for non-coverage*: The evidence on safety and efficacy of this procedure is limited to case reports and animal models, thus it is insufficient to support clinical use at this time. Furthermore, the American Society of Plastic Surgeons 2009 statement states that fat grafting to the breast is not a strongly recommended procedure.[48]
5. Vascularized lymph node transfer
    a. *Rationale for non-coverage:* Raju et al (2015) conducted a review of the current literature on this procedure for the treatment of lymphedema, which can be seen after breast procedures. They found that, "Although the results with the use of VLNT for treatment of lymphedema have been largely positive, further exploration into standardized protocols for diagnosis, treatment optimization, and patient outcomes assessment is needed." The current literature is limited and further data is required for clinical application.[55]
6. Xenograft cartilage grafting
7. Scar revision after biopsy
8. Removal of cyst(s)
9. Revision of prior reconstructed breast due to normal aging

Oscar considers lumpectomy requiring radiation therapy as non-covered in the following situations:

1. Absolute contraindications per NCCN guidelines:[49]
    a. Multicentric disease with two or more primary tumors in separate quadrants of the breast that cannot be excised with a single excision
    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 following by radiation after birth
    d. Persistently positive margins after multiple attempts at breast conserving excision
    e. Homozygous for ATM mutation
2. Relative contraindications per NCCN guidelines:[49]
    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.

Applicable Billing Codes (HCPCS/CPT Codes)

Mastectomy and Lumpectomy	
CPT/HCPCS Codes covered if criteria are met:	
Code	*Description*
19301	Mastectomy, partial (eg, lumpectomy, tylectomy, quadrantectomy, segmentectomy);
19302	Mastectomy, partial (eg, lumpectomy, tylectomy, quadrantectomy, segmentectomy); with axillary lymphadenectomy
19303	Mastectomy, simple, complete
19304	Mastectomy, subcutaneous
19305	Mastectomy, radical, including pectoral muscles, axillary lymph nodes
19306	Mastectomy, radical, including pectoral muscles, axillary and internal mammary lymph nodes
19307	Mastectomy, modified radical, including axillary lymph nodes, with or without pectoralis minor; excluding pectoralis major muscle
ICD-10 codes covered 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 [when specified to chest]

Breast Implant Removal	
CPT/HCPCS Codes covered if criteria are met:	
Code	*Description*
19328	Removal of intact mammary implant
19330	Removal of mammary implant material
19370	Open periprosthetic capsulotomy, breast
19371	Periprosthetic capsulectomy, breast
ICD-10 codes covered 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
T85.41x+ - T85.49x+	Mechanical complication of breast prosthesis and implant
T85.79x+	Infection and inflammatory reaction due to other internal prosthetic devices, implants, or grafts

Breast Reconstruction	
CPT/HCPCS Codes covered 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 prosthesis
11971	Removal of tissue expander(s) without insertion of prosthesis
15877	Suction assisted lipectomy; trunk
19316	Mastopexy
19318	Reduction mammaplasty
19324	Mammaplasty, augmentation; without prosthetic implant
19325	Mammaplasty, augmentation; with prosthetic implant
19328	Removal of intact mammary implant
19330	Removal of mammary implant material
19340	Immediate insertion of breast prosthesis following mastopexy, mastectomy or in reconstruction
19342	Delayed insertion of breast prosthesis following mastopexy, mastectomy or in reconstruction
19350	Nipple/areola reconstruction
19355	Correction of inverted nipples
19357	Breast reconstruction, immediate or delayed, with tissue expander, including subsequent expansion
19361	Breast reconstruction with latissimus dorsi flap, without prosthetic implant
19364	Breast reconstruction with free flap
19366	Breast reconstruction with other technique
19367	Breast reconstruction with transverse rectus abdominus myocutaneous flap (TRAM), single pedicle, including closure of donor site;
19368	Breast reconstruction with transverse rectus abdominis myocutaneous flap (TRAM), single pedicle, including closure of donor site; with microvascular anastomosis (supercharging)
19369	Breast reconstruction with transverse rectus abdominis myocutaneous flap (TRAM), double pedicle, including closure of donor site
19370	Open periprosthetic capsulotomy, breast
19371	Periprosthetic capsulectomy, breast
19380	Revision of reconstructed breast
19396	Preparation of moulage for custom breast implant
21740 - 21743	Reconstructive repair of pectus excavatum or carinatum
C1781	Mesh (implantable) [Cortiva]
C1789	Prosthesis, breast (implantable)

L8020 - L8039	Breast prostheses
L8600	Implantable breast prosthesis, silicone or equal
Q4116	Alloderm, per square centimeter
Q4128	Flex HD, Allopatch HD, or Matrix HD, per square centimeter
Q4122	DermACELL, per sq cm
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
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
ICD-10 codes covered 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	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 [following medically necessary mastectomy or lumpectomy resulting in significant deformity]

CPT/HCPCS codes *not* covered:	
Code	*Description*
19350	Nipple reconstruction [when billed as BioDesign Nipple Reconstruction Cylinder]

Q2026	Injection, Radiesse, 0.1 ml
Q4130	Strattice TM, per sq cm

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Clinical Guideline Revision/History Information

Original: Review/Revise Dates	**Approval Signature/Title**
Original Date: Reviewed/Revised: Signed:	7/31/2017 1/18/2018 Sean Martin, MD