UnitedHealthcare®

UnitedHealthcare® Commercial
Coverage Determination Guideline

BREAST REPAIR/RECONSTRUCTION NOT FOLLOWING MASTECTOMY

Guideline Number: CDG.005.10 **Effective Date**: August 9, 2019

Instructions for Use

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Related Commercial Policies

- Breast Reconstruction Post Mastectomy
- Breast Reduction Surgery
- Cosmetic and Reconstructive Procedures
- Gender Dysphoria Treatment

Community Plan Policy

- Breast Repair/Reconstruction Not Following Mastectomy

COVERAGE RATIONALE

See Benefit Considerations

Indications for Coverage

The following are eligible for coverage as Reconstructive and medically necessary:

- Correction of inverted nipples is considered reconstructive when one of the following criteria are met:
  - Member meets the Women's Health and Cancer Rights Act (WHCRA) criteria (refer to the Coverage Determination Guideline titled Breast Reconstruction Post Mastectomy for details); or
  - Documented history of chronic nipple discharge, bleeding, scabbing or ductal infection; or
  - For correction of an inverted nipple(s) resulting from a Congenital Anomaly.
- Anaplastic Lymphoma of the breast:
  - Removal of a breast implant and capsulectomy is covered, regardless of the indication for the initial implant placement, for:
    - Treatment of Anaplastic Lymphoma of the breast when there is pathologic confirmation of the diagnosis by cytology or biopsy; or
    - Individuals with an increased risk of implant-associated Anaplastic Lymphoma of the breast due to use of Allergan BIOCELL textured breast implants and tissue expanders.
- Removal of a deflated saline breast implant shell when the implants were done post mastectomy (refer to the Coverage Determination Guideline titled Breast Reconstruction Post Mastectomy).
- Removal of a ruptured silicone gel breast implant regardless of the indication for the initial implant placement.
- Treatment of Poland Syndrome with breast reconstruction; this is considered reconstructive surgery although no Functional Impairment may exist.

Removal of breast implants with capsulectomy/capsulotomy for symptomatic capsular contracture is considered reconstructive when the following criteria are met:

- Baker grade III or IV capsular contracture
  Baker Grading System for Capsular Contracture
  - *Grade I* – Breast is soft without palpable thickening
  - *Grade II* – Breast is a little firm but no visible changes in appearance
  - *Grade III* – Breast is firm and has visible distortion in shape
  - *Grade IV* – Breast is hard and has severe distortion or malposition in shape; pain/discomfort may be associated with this level of capsule contracture (ASPS, 2005)
- Limited movement leading to an inability to perform tasks that involve reaching or abduction; examples include retrieving something from overhead, combing one's hair, reaching out or above to grab something to stabilize oneself

The breast reconstruction benefit does not include coverage for any of the following:

- Aspirations

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- Biopsy (open or core)
- Excision of cysts
- Fibroadenomas or other benign or malignant tumors
- Aberrant breast tissue
- Duct lesions
- Nipple or areolar lesions
- Treatment of gynecomastia

Coverage Limitations and Exclusions

UnitedHealthcare excludes Cosmetic Procedures from coverage including but not limited to the following:
- Breast prosthetics or replacement following a cosmetic breast augmentation.
- Breast reduction surgery when done to improve appearance without improving a Functional/Physiologic impairment (unless it is related to coverage required by the Women's Health and Cancer Right's Act).
- Breast surgery only for the purpose of creating symmetrical breasts except when post mastectomy.
- Procedures that correct an anatomical congenital anomaly without improving or restoring physiologic function are considered Cosmetic Procedures. The fact that a Covered Person may suffer psychological consequences or socially avoidant behavior as a result of an Injury, Sickness or Congenital Anomaly does not classify surgery (or other procedures done to relieve such consequences or behavior) as a Reconstructive Procedure.
- Replacement of an existing breast implant if the earlier breast implant was performed as a Cosmetic Procedure. (Replacement of an existing breast implant is considered reconstructive if the initial breast implant followed mastectomy. Refer to the Coverage Determination Guideline titled Breast Reconstruction Post Mastectomy.)
- Revision of a prior reconstructed breast due to normal aging does not meet the definition of a covered reconstructive health service.
- Tissue protruding at the end of a scar ("dog ear"/standing cone), painful scars or donor site scar revisions must meet the definition of a Reconstructive Procedure to be considered for coverage.

DOCUMENTATION REQUIREMENTS

Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The documentation requirements outlined below are used to assess whether the member meets the clinical criteria for coverage but do not guarantee coverage of the service requested.

CPT Codes*	Required Clinical Information
Breast Repair/Reconstruction Not Following Mastectomy	
19328 19330 19370 19371 19380	Medical notes documenting **all** of the following: • History of the medical condition(s) requiring treatment or surgical intervention • Chief complaint, history of the complaint and physical exam • Relevant medical-surgical history including dates • Complications which necessitate the need for removal of the prosthetic **Note**: For Capsular contracture include Baker grade and functional impairment

**For code descriptions, see the Applicable Codes section.*

DEFINITIONS

The following definitions may not apply to all plans. Refer to the member specific benefit plan document for applicable definitions.

Anaplastic Lymphoma: Breast implant–associated (BIA) anaplastic large cell lymphoma (ALCL) is a rare T-cell lymphoma that can present as a delayed fluid collection around a textured implant or surrounding scar capsule.

Congenital Anomaly: A physical developmental defect that is present at the time of birth, and that is identified within the first twelve months of birth.

Cosmetic Procedures: Procedures or services that change or improve appearance without significantly improving physiological function.

Cosmetic Procedures (California only): Procedures or services that are performed to alter or reshape normal structures of the body in order to improve your appearance.

Functional or Physical Impairment: A physical or functional or physiological impairment causes deviation from the normal function of a tissue or organ. This results in a significantly limited, impaired, or delayed capacity to move,

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coordinate actions, or perform physical activities and is exhibited by difficulties in one or more of the following areas: physical and motor tasks; independent movement; performing basic life functions.

Poland Syndrome: Poland syndrome is a congenital absence of the pectoralis major muscle, usually the sternal component, as well as breast and areolar hypoplasia. This condition can also be associated with absence of the latissimus dorsi and serratus anterior muscles, hand symbrachydactyly, and other extremity deformities.

Reconstructive Procedures: Reconstructive procedures when the primary purpose of the procedure is either of the following:
- Treatment of a medical condition
- Improvement or restoration of physiologic function

Reconstructive procedures include surgery or other procedures which are related to an injury, sickness or congenital anomaly. The primary result of the procedure is not a changed or improved physical appearance. Procedures that correct an anatomical congenital anomaly without improving or restoring physiologic function are considered Cosmetic Procedures. The fact that a you may suffer psychological consequences or socially avoidant behavior as a result of an injury, sickness or congenital anomaly does not classify surgery (or other procedures done to relieve such consequences or behavior) as a Reconstructive Procedure.

Reconstructive Procedures (California only): Reconstructive procedures to correct or repair abnormal structures of the body caused by congenital defects, developmental abnormalities, trauma, infection, tumors, or disease to do either of the following:
- To improve function
- To create a normal appearance, to the extent possible

Reconstructive Procedures include surgery or other procedures which are related to a health condition. The primary result of the procedure is not a changed or improved physical appearance for cosmetic purposes only, but rather to improve function and/or to create a normal appearance, to the extent possible. Covered Health Care Services include dental or orthodontic services that are an integral part of reconstructive surgery for cleft palate procedures.

For the purposes of this section, "cleft palate" means a condition that may include cleft palate, cleft lip, or other craniofacial anomalies associated with cleft palate.

Sickness: Physical illness, disease or Pregnancy. The term sickness includes mental illness or substance-related and addictive disorders, regardless of the cause or origin of the mental illness or substance-related and addictive disorder.

Women's Health and Cancer Rights Act of 1998, § 713 (a): "In general - a group health plan, and a health insurance issuer providing health insurance coverage in connection with a group health plan, that provides medical and surgical benefits with respect to a Mastectomy shall provide, in case of a participant or beneficiary who is receiving benefits in connection with a Mastectomy and who elects breast reconstruction in connection with such Mastectomy, coverage for (1) reconstruction of the breast on which the Mastectomy has been performed; (2) surgery and reconstruction of the other breast to produce symmetrical appearance; and (3) prostheses and physical complications all stages of Mastectomy, including lymphedemas in a manner determined in consultation with the attending physician and the patient."

APPLICABLE CODES

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Coverage Determination Guidelines may apply.

CPT Code	Description
19328	Removal of intact mammary implant
19330	Removal of mammary implant material
19355	Correction of inverted nipples
19370	Open periprosthetic capsulotomy, breast
19371	Periprosthetic capsulectomy, breast
19380	Revision of reconstructed breast

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BENEFIT CONSIDERATIONS

If the member's condition meets the Women's Health and Cancer Rights Act (WHCRA) criteria, refer to the Coverage Determination Guideline titled Breast Reconstruction Post Mastectomy.

REFERENCES

American Society of Plastic Surgeons (ASPS). How to Diagnose and Treat Breast Implant– Associated Anaplastic Large Cell Lymphoma.

American Society of Plastic Surgeons (ASPS). Practice Parameter. Treatment Principles of Silicone Breast Implants. March 2005. Available at: http://www.plasticsurgery.org/Documents/medical-professionals/health-policy/evidence-practice/TreatmentPrinciplesofSiliconeBreastImplants.pdf. Accessed August 29, 2018.

Jones Glyn E. Bostwick's Plastic & Reconstructive Breast Surgery, 3rd ed. Quality Medical Publishing, Inc 2010.

UnitedHealthcare Insurance Company Generic Certificate of Coverage 2018.

United States Food and Drug Administration (FDA), The FDA Takes Action to Protect Patients from Risk of Certain Textured Breast Implants; Requests Allergan Voluntarily Recall Certain Breast Implants and Tissue Expanders from the Market: FDA Safety Communication. Available at: https://www.fda.gov/medical-devices/safety-communications/fda-takes-action-protect-patients-risk-certain-textured-breast-implants-requests-allergan. Accessed August 7, 2019.

Women's Health and Cancer Rights Act of 1998. Available at: https://www.cms.gov/cciio/programs-and-initiatives/other-insurance-protections/whcra_factsheet.html.

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GUIDELINE HISTORY/REVISION INFORMATION

Date	Action/Description
08/09/2019	**Coverage Rationale** • Added language to indicate removal of a breast implant and capsulectomy is covered, regardless of the indication for the initial implant placement, for individuals with an increased risk of implant-associated Anaplastic Lymphoma of the breast due to use of Allergan BIOCELL textured breast implants and tissue expanders **Supporting Information** • Updated *References* section to reflect the most current information • Archived previous policy version CDG.005.09

INSTRUCTIONS FOR USE

This Coverage Determination Guideline provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this guideline, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Coverage Determination Guideline is provided for informational purposes. It does not constitute medical advice.

This Coverage Determination Guideline may also be applied to Medicare Advantage plans in certain instances. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5).

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. UnitedHealthcare Coverage Determination Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

For self-funded plans with SPD language other than fully-insured Generic COC language, please refer to the member specific benefit plan document for coverage.

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