BREAST REPAIR/RECONSTRUCTION NOT FOLLOWING MASTECTOMY

Guideline Number: MMG013.J **Effective Date**: August 9, 2019

Instructions for Use

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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 Medical Management Guideline titled Breast Reconstruction Post Mastectomy for details); or
  - Documented history of chronic nipple discharge, bleeding, scabbing or ductal infection; or
  - For correction of inverted nipple(s) resulting from a Congenital Defect.
- 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 Medical Management 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
- 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 West 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.
- 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 Medical Management 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.

Required Clinical Information
Breast Repair/Reconstruction Not Following Mastectomy
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.

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 Defect: A physical developmental defect that is present at birth, and 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 Services and Surgery (CA only): Cosmetic surgery and cosmetic services are not covered. Cosmetic surgery and cosmetic services are defined as surgery and services performed to alter or reshape normal structures of the body in order to improve appearance. Drugs, devices and procedures related to cosmetic surgery or cosmetic services are not covered. Surgeries or services that would ordinarily be classified as cosmetic will not be reclassified as reconstructive, based on a member's dissatisfaction with his or her appearance.

Cosmetic Services and Surgery (WA, OR, TX and OK only): Cosmetic surgery and cosmetic services are not covered. Cosmetic surgery and cosmetic services are defined as surgery and services performed to alter or reshape normal structures of the body in order to improve appearance. Drugs, devices and procedures related to cosmetic

surgery or cosmetic services are not covered. Surgeries or services that would ordinarily be classified as cosmetic will not be reclassified as reconstructive, based on a member's dissatisfaction with his or her appearance, as influenced by that member's underlying psychological makeup or psychiatric condition.

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, 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 Surgery: Reconstructive surgery is covered to correct or repair abnormal structures of the body caused by Congenital Defects, developmental abnormalities, trauma, infection, tumors or disease. The purpose of Reconstructive Surgery is to correct abnormal structures of the body to improve function or create a normal appearance to the extent possible.

Sickness: Physical illness, disease or Pregnancy. The term Sickness does not include mental illness or substance abuse, regardless of the cause or origin of the mental illness or substance abuse.

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 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 Medical Management Guideline titled Breast Reconstruction Post Mastectomy.

REFERENCES

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.

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

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

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

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

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 MMG013.I

INSTRUCTIONS FOR USE

This Medical Management 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 benefit 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 Medical Management Guideline is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. UnitedHealthcare West Medical Management 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.

Member benefit coverage and limitations may vary based on the member's benefit plan Health Plan coverage provided by or through UnitedHealthcare of California, UnitedHealthcare Benefits Plan of California, UnitedHealthcare of Oklahoma, Inc., UnitedHealthcare of Oregon, Inc., UnitedHealthcare Benefits of Texas, Inc., or UnitedHealthcare of Washington, Inc.