MCO POLICY CHANGE

IMMINENT PERIL JUSTIFICATION

DATE: 12/03/19

POLICY NAME: Breast repair/reconstruction not following mastectomy

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POLICY CHANGE: ·Added the following language to the Coverage Rationale:

Removal of a breast implant and capsulectomy is covered, regardless of the indication for the initial implant placement, for the following:

o 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

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JUSTIFICATION: Due to the Allergan BioCell recall for these implants that increase an individual's risk of Anaplastic Lymphoma we felt we needed to include this language immediately for the benefit of our members.

EFFECTIVE DATE: 08/09/19

UnitedHealthcare Community Plan

UnitedHealthcare® Community Plan
Coverage Determination Guideline

BREAST REPAIR/RECONSTRUCTION NOT FOLLOWING MASTECTOMY (FOR LOUISIANA ONLY)

Guideline Number: CS013**LA**.J **Effective Date**: ~~August 9, 2019~~**TBD**

Instructions for Use

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Related Community Plan Policies
- Breast Reconstruction Post Mastectomy
- Breast Reduction Surgery
- Cosmetic and Reconstructive Procedures
- Gender Dysphoria Treatment

Commercial Policy
- Breast Repair/Reconstruction Not Following Mastectomy

APPLICATION

This Medical Policy only applies to the state of Louisiana.

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
    - **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.**
- 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

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- *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 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.

DEFINITIONS

Check the definitions within the member benefit plan document that supersede the definitions below.

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.

Functional or Physical Impairment: A Functional or Physical 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.

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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 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.

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 disorders.

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 policy 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 federal, state or contractual requirements 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

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

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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.

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.

UnitedHealthcare Insurance Company Generic Certificate of Coverage 2018.

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. Accessed March 1, 2019.

GUIDELINE HISTORY/REVISION INFORMATION

Date	Action/Description
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TBD	**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 CS013.I**

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INSTRUCTIONS FOR USE

This Coverage Determination Guideline provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage govern. Before using this guideline, please check the federal, state or contractual requirements for benefit plan coverage. 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.

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

ARCHIVED GUIDELINE VERSIONS

Effective Date	Guideline Number	Guideline Title
06/01/2019 – 08/08/2019	CS013.I	Breast Repair/Reconstruction Not Following Mastectomy
01/01/2019 – 05/31/2019	CS013.H	Breast Repair/Reconstruction Not Following Mastectomy
11/01/2018 – 12/31/2018	CS013.G	Breast Repair/Reconstruction Not Following Mastectomy
09/01/2018 – 10/31/2018	CS013.F	Breast Repair/Reconstruction Not Following Mastectomy
01/01/2018 – 08/31/2018	CS013.E	Breast Repair/Reconstruction Not Following Mastectomy

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Effective Date	Guideline Number	Guideline Title
01/01/2017 – 12/31/2017	CS013.D	Breast Repair/Reconstruction Not Following Mastectomy
01/01/2016 – 12/31/2016	CS013.C	Breast Repair/Reconstruction Not Following Mastectomy
01/01/2015 – 12/31/2015	CS013.B	Breast Repair/Reconstruction Not Following Mastectomy
11/01/2013 – 12/31/2014	CS013.A	Breast Repair/Reconstruction Not Following Mastectomy

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