UnitedHealthcare

UnitedHealthcare® Commercial
Coverage Determination Guideline

BREAST RECONSTRUCTION POST MASTECTOMY

Guideline Number: CDG.003.12 **Effective Date**: August 9, 2019

Instructions for Use

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Related Commercial Policies

- Breast Repair/Reconstruction Not Following Mastectomy
- Cosmetic and Reconstructive Procedures
- Durable Medical Equipment, Orthotics, Ostomy Supplies, Medical Supplies and Repairs/ Replacements
- Gender Dysphoria Treatment
- Pneumatic Compression Devices
- Prosthetic Devices, Wigs, Specialized, Microprocessor or Myoelectric Limbs
- Skin and Soft Tissue Substitutes

Community Plan Policy

- Breast Reconstruction Post Mastectomy

COVERAGE RATIONALE

Indications for Coverage

The following are eligible for coverage as reconstructive and medically necessary:
In accordance with Women's Health and Cancer Rights Act of 1998, the following services are covered (with or without a diagnosis of cancer):

- Reconstruction of the breast on which the Mastectomy was performed
- Surgery and reconstruction of the other breast to produce a symmetrical appearance, including nipple tattooing
- Prosthesis (implanted and/or external)
- Treatment of physical complications of Mastectomy, including lymphedema

Note: The Women's Health and Cancer Rights Act of 1998 does not provide a timeframe by which the member is required to have the reconstruction performed post Mastectomy.

Removal, replacement, or revision of an implant may be considered reconstructive in certain circumstances:

- When the original implant or reconstructive surgery was considered reconstructive surgery under the terms of the member's benefit plan, coverage may exist for removal, replacement, and/or reconstruction.
- When the original implant or reconstructive surgery was considered reconstructive surgery under the terms of the member's benefit, then removal of a ruptured prosthesis is treating a "complication arising from a medical or surgical intervention".
- 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.
- Revision of a reconstructed breast (CPT code 19380) when the original reconstruction was performed following Mastectomy or for another covered health service (see Applicable Codes section below for a list of codes that meet the criteria for a reconstructed breast).

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

- Aberrant breast tissue
- Aspirations

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

Breast Reconstruction

The following procedures may be utilized during breast reconstruction:

- A woman's own muscle, fat and skin are repositioned to create a breast mound by one of the following methods:
  - Transverse Rectus Abdominus Myocutaneous (TRAM) Flap – The muscle, fat and skin from the lower abdomen is used to reconstruct the breast
  - Deep Inferior Epigastric Perforator (DIEP) or Superior Gluteal Artery Perforator SGAP Flap – The fat and skin but not muscle is used from the lower abdomen or buttocks to reconstruct the breast
  - Latissimus Dorsi (LD) Flap – The muscle, fat and skin from the back are used to reconstruct the breast – may also need a breast implant
  - Other methods may also be used to move muscle, fat and skin to reconstruct a breast
- Tissue expansion is used to stretch the skin and tissue to provide coverage for a breast implant to create a breast mound. The procedure can be done with or without a dermal matrix including but not limited to Alloderm, Allomax, DermACELL, or FlexHD which are a covered benefit. **Note**: Reconstruction alone may be done with an implant but a tissue expander may be needed.
  - Tissue expansion requires several office visits over 4-6 months to fill the device through an internal valve to expand the skin.
- After the tissue expansion is completed, surgical placement of an FDA approved breast implant (either silicone or saline) is performed. The breast implant may be used with a flap or alone following tissue expansion.
- After the breast implant is completed, creation of a nipple (by various techniques) and areola (tattooing) may be performed.

Treatments for Complications Post Mastectomy

- Lymphedema:
  - Complex decongestive physiotherapy (CDP) is covered for the complication of lymphedema post Mastectomy
  - Lymphedema pumps when required are covered (when covered these pumps are covered as Durable Medical Equipment)
  - Compression lymphedema sleeves are covered (when covered, these sleeves are covered as a prosthetic device)
  - Elastic bandages and wraps associated with covered treatments for the complications of lymphedema
- Treatment of a post-operative infection(s)
- Removal of a ruptured breast implant (either silicone or saline) is reconstructive for implants done post Mastectomy; placement of a new breast implant will be covered if the original implantation was done post Mastectomy or for a covered reconstructive health service

Note: A gap exception may be granted if there is not an in-network provider able to provide the requested Reconstructive Procedure. Refer to the member specific benefit plan document for information regarding coverage from out-of-network providers.

Coverage Limitations and Exclusions

UnitedHealthcare excludes Cosmetic Procedures from coverage including but not limited to the following:

- Breast reconstruction has been successfully completed post Mastectomy and the member chooses to enlarge their breasts for cosmetic reasons.
- Breast reconstruction or scar revision after breast biopsy or removal of a cyst with or without a biopsy (Refer to the member specific benefit plan document and applicable state mandates).
- Insertion of breast implants or reinsertion of breast implants for the purpose of improving appearance unless covered under a state or federal mandate.
- Liposuction other than to achieve breast symmetry during post Mastectomy reconstruction.
- 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.
- Removal or replacement of an implant that is not ruptured and unassociated with local breast complications.
- Revision of a prior reconstructed breast due to normal aging.
- 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.

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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.

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.

Deep Inferior Epigastric Perforator (DIEP) Flap: DIEP stands for the deep inferior epigastric perforator artery, which runs through the abdomen. In a DIEP flap reconstruction, fat, skin, and blood vessels are cut from the wall of the lower belly and moved up to the chest to rebuild the breast. The surgeon reattaches the blood vessels of the flap to blood vessels in the chest using microsurgery. DIEP is often referred to as a muscle-sparing or muscle-preserving type of flap, which means that no muscle is taken from the abdomen.

Gluteal Artery Perforator (GAP) Free Flap:
- An SGAP flap (superior gluteal artery perforator), or gluteal perforator hip flap, uses this blood vessel to transfer a section of skin and fat from the upper buttocks/hip to reconstruct the breast.
- The IGAP flap (inferior gluteal artery perforator) uses this blood vessel to transfer a section of skin and fat from the bottom of the buttocks, near the buttock crease to reconstruct the breast.

Latissimus Dorsi (LD) Flap: In a latissimus dorsi flap procedure, an oval flap of skin, fat, muscle, and blood vessels from the upper back is used to reconstruct the breast. This flap is tunneled to the chest to rebuild the breast.

Mastectomy: Mastectomy is the removal of the whole breast. There are five different types of Mastectomy: "simple" or "total" mastectomy, modified radical mastectomy, radical mastectomy, partial mastectomy, and subcutaneous (nipple-sparing) mastectomy.
- Simple or Total Mastectomy – Removes the entire breast and no axillary lymph node dissection.
- Modified Radical Mastectomy – Modified radical mastectomy involves the removal of both breast tissue and axillary lymph nodes.
- Radical Mastectomy – Removes the entire breast, axillary lymph nodes, and the chest wall muscles.
- Partial Mastectomy (Lumpectomy, Tylectomy, Quadrantectomy, and Segmentectomy) – Partial mastectomy is the removal of the cancerous part of the breast tissue and some normal tissue around it. While lumpectomy is technically a form of partial mastectomy, more tissue is removed in partial mastectomy than in lumpectomy.
- Nipple-Sparing Mastectomy – During nipple-sparing mastectomy, all of the breast tissue is removed, however, the nipple is not removed.

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 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.

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

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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.

Transverse Rectus Abdominus Myocutaneous (TRAM) Flap: The surgeon takes muscle and overlying lower abdominal tissue and moves it to the chest area. TRAM flap may be done as either a pedicle flap or a free flap.

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
Mastectomy	
19301	Mastectomy, partial (e.g., lumpectomy, tylectomy, quadrantectomy, segmentectomy)
19302	Mastectomy, partial (e.g., 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 (urban type operation)
19307	Mastectomy, modified radical, including axillary lymph nodes, with or without pectoralis minor muscle, but excluding pectoralis major muscle
Breast Reconstruction Post Mastectomy	
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, or part thereof (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
15271	Application of skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area
15272	Application of skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; each additional 25 sq cm wound surface area, or part thereof (List separately in addition to code for primary procedure)

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CPT Code	Description
Breast Reconstruction Post Mastectomy	
15777	Implantation of biologic implant (e.g., acellular dermal matrix) for soft tissue reinforcement (i.e., breast, trunk) (List separately in addition to code for primary procedure)
19316	Mastopexy
19324	Mammaplasty, augmentation; without prosthetic implant
19325	Mammaplasty, augmentation; with prosthetic 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 abdominis 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
19380	Revision of reconstructed breast
19396	Preparation of moulage for custom breast implant
19499	Unlisted procedure, breast
Covered to Achieve Symmetry of the Contralateral Breast Post Mastectomy Only	
19318	Reduction mammaplasty

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HCPCS Code	Description
L8600	Implantable breast prosthesis, silicone or equal
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
S8950	Complex lymphedema therapy, each 15 minutes

ICD-10 Diagnosis Code	Description
C50.011	Malignant neoplasm of nipple and areola, right female breast
C50.012	Malignant neoplasm of nipple and areola, left female breast
C50.019	Malignant neoplasm of nipple and areola, unspecified female breast
C50.021	Malignant neoplasm of nipple and areola, right male breast

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ICD-10 Diagnosis Code	Description
C50.022	Malignant neoplasm of nipple and areola, left male breast
C50.029	Malignant neoplasm of nipple and areola, unspecified male breast
C50.111	Malignant neoplasm of central portion of right female breast
C50.112	Malignant neoplasm of central portion of left female breast
C50.119	Malignant neoplasm of central portion of unspecified female breast
C50.121	Malignant neoplasm of central portion of right male breast
C50.122	Malignant neoplasm of central portion of left male breast
C50.129	Malignant neoplasm of central portion of unspecified male breast
C50.211	Malignant neoplasm of upper-inner quadrant of right female breast
C50.212	Malignant neoplasm of upper-inner quadrant of left female breast
C50.219	Malignant neoplasm of upper-inner quadrant of unspecified female breast
C50.221	Malignant neoplasm of upper-inner quadrant of right male breast
C50.222	Malignant neoplasm of upper-inner quadrant of left male breast
C50.229	Malignant neoplasm of upper-inner quadrant of unspecified male breast
C50.311	Malignant neoplasm of lower-inner quadrant of right female breast
C50.312	Malignant neoplasm of lower-inner quadrant of left female breast
C50.319	Malignant neoplasm of lower-inner quadrant of unspecified female breast
C50.321	Malignant neoplasm of lower-inner quadrant of right male breast
C50.322	Malignant neoplasm of lower-inner quadrant of left male breast
C50.329	Malignant neoplasm of lower-inner quadrant of unspecified male breast
C50.411	Malignant neoplasm of upper-outer quadrant of right female breast
C50.412	Malignant neoplasm of upper-outer quadrant of left female breast
C50.419	Malignant neoplasm of upper-outer quadrant of unspecified female breast
C50.421	Malignant neoplasm of upper-outer quadrant of right male breast
C50.422	Malignant neoplasm of upper-outer quadrant of left male breast
C50.429	Malignant neoplasm of upper-outer quadrant of unspecified male breast
C50.511	Malignant neoplasm of lower-outer quadrant of right female breast
C50.512	Malignant neoplasm of lower-outer quadrant of left female breast
C50.519	Malignant neoplasm of lower-outer quadrant of unspecified female breast
C50.521	Malignant neoplasm of lower-outer quadrant of right male breast
C50.522	Malignant neoplasm of lower-outer quadrant of left male breast
C50.529	Malignant neoplasm of lower-outer quadrant of unspecified male breast
C50.611	Malignant neoplasm of axillary tail of right female breast
C50.612	Malignant neoplasm of axillary tail of left female breast
C50.619	Malignant neoplasm of axillary tail of unspecified female breast
C50.621	Malignant neoplasm of axillary tail of right male breast
C50.622	Malignant neoplasm of axillary tail of left male breast
C50.629	Malignant neoplasm of axillary tail of unspecified male breast
C50.811	Malignant neoplasm of overlapping sites of right female breast
C50.812	Malignant neoplasm of overlapping sites of left female breast
C50.819	Malignant neoplasm of overlapping sites of unspecified female breast
C50.821	Malignant neoplasm of overlapping sites of right male breast
C50.822	Malignant neoplasm of overlapping sites of left male breast
C50.829	Malignant neoplasm of overlapping sites of unspecified male breast
C50.911	Malignant neoplasm of unspecified site of right female breast
C50.912	Malignant neoplasm of unspecified site of left female breast
C50.919	Malignant neoplasm of unspecified site of unspecified female breast

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ICD-10 Diagnosis Code	Description
C50.921	Malignant neoplasm of unspecified site of right male breast
C50.922	Malignant neoplasm of unspecified site of left male breast
C50.929	Malignant neoplasm of unspecified site of unspecified male breast
C79.81	Secondary malignant neoplasm of breast
D05.00	Lobular carcinoma in situ of unspecified breast
D05.01	Lobular carcinoma in situ of right breast
D05.02	Lobular carcinoma in situ of left breast
D05.10	Intraductal carcinoma in situ of unspecified breast
D05.11	Intraductal carcinoma in situ of right breast
D05.12	Intraductal carcinoma in situ of left breast
D05.80	Other specified type of carcinoma in situ of unspecified breast
D05.81	Other specified type of carcinoma in situ of right breast
D05.82	Other specified type of carcinoma in situ of left breast
D05.90	Unspecified type of carcinoma in situ of unspecified breast
D05.91	Unspecified type of carcinoma in situ of right breast
D05.92	Unspecified type of carcinoma in situ of left breast
D48.61	Neoplasm of uncertain behavior of right breast
D48.62	Neoplasm of uncertain behavior of left breast
I97.2	Postmastectomy lymphedema syndrome
N65.0	Deformity of reconstructed breast
N65.1	Disproportion of reconstructed breast
T85.43XA	Leakage of breast prosthesis and implant, initial encounter
T85.43XD	Leakage of breast prosthesis and implant, subsequent encounter
T85.43XS	Leakage of breast prosthesis and implant, sequela
Z42.1	Encounter for breast reconstruction following mastectomy
Z45.811	Encounter for adjustment or removal of right breast implant
Z45.812	Encounter for adjustment or removal of left breast implant
Z45.819	Encounter for adjustment or removal of unspecified breast implant
Z85.3	Personal history of malignant neoplasm of breast
Z90.10	Acquired absence of unspecified breast and nipple
Z90.11	Acquired absence of right breast and nipple
Z90.12	Acquired absence of left breast and nipple
Z90.13	Acquired absence of bilateral breasts and nipples

REFERENCES

American Society of Plastic Surgeons. Breast Reconstruction Procedures Steps. Available at: http://www.plasticsurgery.org./. Accessed August 21, 2018.

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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.html.

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GUIDELINE HISTORY/REVISION INFORMATION

<table>
<tr><th>Date</th><th>Action/Description</th></tr>
<tr><td>08/09/2019</td><td>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:
Treatment of Anaplastic Lymphoma of the breast when there is pathologic confirmation of the diagnosis by cytology or biopsy
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
Definitions
Added definition of “Anaplastic Lymphoma”
Supporting Information
Updated References section to reflect the most current information
Archived previous policy version CDG.003.11</td></tr>
</table>

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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