

Breast Procedures, Surgical 10

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Effective Date 8/1991

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Coverage Policy Surgical 10

Version 6

Member-specific benefits take precedence over medical policy and benefits may vary across plans. Refer to the individual's benefit plan for details *.

Purpose:

This policy addresses Breast procedures including Breast Reduction, Partial Breast Surgery, Complete
mastectomy, Breast reconstruction, Areola repigmentation/areola tattooing and Breast implants removal or
replacement.

Description & Definitions:

Areola repigmentation/areola tattooing, also called medical micropigmentation is the process of tattooing pigment into the breast to recreate the areola or nipple lost to previous medical intervention.

Breast implants removal or replacement involves either removing or replacing a prosthetic made of a flexible sac (containing saline or silicone) that was placed either under the breast or under the breast and muscles for reconstructive or cosmetic purposes.

Breast reconstruction consists of the surgical processes to restore and rebuild the normal contour of the breast after medical interventions.

Types of flap procedures:

- fTRAM free transverse rectus abdominis myocutaneous
- DIEP deep inferior epigastric perforator
- SIEA superficial inferior epigastric perforator (artery) muscle sparing
- GAP flap gluteal artery perforator

Breast Reduction is surgery performed to reduce the size of an individual's breast by removing skin and breast tissue.

Complete mastectomy (e.g., Risk reduction mastectomy (RRM) or Prophylactic) - is the surgical removal of all breast tissue from one (unilateral) both (bilateral) breasts at a time when there is no known breast cancer but breast tissue may become cancerous.

• A first-degree relative is defined as a close blood relative which includes the individual's parents, full siblings, or children

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- A second-degree relative is defined as a blood relative which includes the individual's grandparents, grandchildren, aunts, uncles, nephews, nieces or half-siblings
- A third-degree relative is defined as a blood relative which includes the individual's first-cousins, great-grandparents or great-grandchildren
- Bilateral is defined as the removal of both breasts at the same time.
- Contralateral is defined as the removal of the opposite or undiagnosed (healthy) breast also.

Partial Breast Surgery (e.g., Lumpectomy, breast - conserving surgery or Partial mastectomy) removes the entire tumor and a small amount of surrounding tissue.

Criteria:

Breast procedures are considered medically necessary for 1 or more of the following:

- Breast reconstructive surgery (e.g., flap procedures) including areola repigmentation/tattooing and autologous tissue transplant is considered medically necessary for individuals for 1 or more of the following:
 - Reconstruction post breast cancer treatment including 1 or more of the following:
 - Reduction mammoplasty
 - Augmentation mammoplasty with implants
 - Mastopexy
 - Reconstruction post prophylactic mastectomy (includes bilateral mastectomy)
 - Reconstruction post removal of breast tissue for medical reasons (e.g. breast reduction and breast biopsy)
 - Breast reconstruction with acellular dermal matrices with ALL of the following:
 - Use of FDA-approved product to include 1 or more of the following:
 - Alloderm
 - Alloderm-Select RTM
 - Alloderm RTU
 - AlloMax
 - Cortiva
 - Dermacell
 - DermaMatrix
 - FlexHD
 - NeoForm
 - Strattice
 - SurgiMend
- **Complete Mastectomy** (unilateral or bilateral) (also known as Risk-reduction mastectomy (RRM) is indicated for **1 or more** of the following:
 - Ductal carcinoma in situ not appropriate for partial mastectomy
 - Invasive stage I or II breast cancer not appropriate for partial mastectomy
 - Stage IIIA (T3 N1 M0 stage grouping only) invasive breast cancer and 1 or more of the following:
 - Stage III breast cancer not appropriate for partial mastectomy
 - Individual preference for complete mastectomy rather than partial mastectomy
 - Stage III (other than T3 N1 M0 stage grouping) invasive breast cancer with clinical response to neoadjuvant chemotherapy
 - Angiosarcoma of the breast
 - Risk-reduction mastectomy (RRM), as indicated by ALL of the following:
 - Significantly elevated risk of breast cancer, as indicated by 1 or more of the following:
 - Individual has BRCA1 or BRCA2 genetic mutation, Li-Fraumeni syndrome (TP53 mutation), or Cowden syndrome (PTEN mutation)
 - Lifetime risk of new breast cancer diagnosis estimated to be greater than 20% (eg, based upon models largely dependent on family history such as Claus, Tyrer-Cuzick, or BRCAPRO)

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- History of mantle chest radiation before age 30 years
- Alternative approaches to elevated risk (chemoprophylaxis, close observation) not deemed sufficient by individual
- At least 10-year life expectancy
- Inflammatory breast cancer with response to preoperative chemotherapy
- Breast cancer
- Paget disease without associated cancer elsewhere in breast and individual preference is for complete mastectomy rather than partial mastectomy
- Phyllodes tumor for which negative margins cannot be obtained by partial mastectomy
- o Recurrence of breast cancer in breast previously treated with partial mastectomy
- Stage IV (metastatic) breast cancer with mastectomy needed for palliation of localized breast pain, bleeding, infection, or fungation as indicated by ALL of the following:
 - Signs and symptoms not amenable to or not adequately controlled via other means (eg, topical or systemic therapy)
 - Individual is expected to be able to obtain significant relief from procedure (eg, most or all of the symptomatic tissues can be removed).
 - Individual has sufficient estimated life expectancy so as to allow benefit from procedure (eg, life expectancy of weeks to months or longer, not days).
- A skin-sparing mastectomy is considered an acceptable alternative method of performing a medically necessary prophylactic mastectomy where there is no cancer involving the skin.
- A nipple-sparing mastectomy is considered an acceptable alternative of performing a medically necessary prophylactic mastectomy where there is no cancer involving the nipple-areola complex
- High risk family history of breast cancer with **1 or more** of the following:
 - Untested first degree relative of Breast Cancer susceptibility gene (BRCA) carrier
 - Two or more first degree relatives with breast cancer
 - First degree relative with premenopausal breast cancer
 - First degree relative and other relative with breast cancer
 - Family history of both breast and ovarian cancer
 - Male relative with breast cancer
 - Risk of multigene testing for individual (man or woman) who carry or have a first degree relative who carries a genetic mutation in 1 or more of the following:
 - CDH1
 - STK11
 - TP53
 - PTEN
 - PALB2
- Individual (man or woman) who has a genetic mutation (not a family history) for 1 or more of the following
 - CHEK2
 - NFI
 - RAD51C
 - RAD51D
- Complete mastectomy with reconstruction (insertion of breast prosthesis or tissue expander) for 1 or more of the following:
 - Ductal carcinoma in situ not appropriate for partial mastectomy
 - o Invasive stage I or II breast cancer not appropriate for partial mastectomy
 - Stage IIIA (T3 N1 M0 stage grouping only) invasive breast cancer and 1 or more of the following:
 - Stage III breast cancer not appropriate for partial mastectomy
 - Individual preference for complete mastectomy rather than partial mastectomy
 - Stage III (other than T3 N1 M0 stage grouping) invasive breast cancer with clinical response to neoadjuvant chemotherapy
 - Angiosarcoma of the breast
 - o Risk-reduction mastectomy (RRM), as indicated by **ALL** of the following:

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- Significantly elevated risk of breast cancer, as indicated by 1 or more of the following:
 - Individual has BRCA1 or BRCA2 genetic mutation, Li-Fraumeni syndrome (TP53 mutation), or Cowden syndrome (PTEN mutation)
 - Lifetime risk of new breast cancer diagnosis estimated to be greater than 20% (eg, based upon models largely dependent on family history such as Claus, Tyrer-Cuzick, or BRCAPRO)
 - History of mantle chest radiation before age 30 years
- Alternative approaches to elevated risk (chemoprophylaxis, close observation) not deemed sufficient by individual
- At least 10-year life expectancy
- Paget disease without associated cancer elsewhere in breast and individual preference is for complete mastectomy rather than partial mastectomy
- Phyllodes tumor for which negative margins cannot be obtained by partial mastectomy
- o Recurrence of breast cancer in breast previously treated with partial mastectomy
- A skin-sparing mastectomy is considered an acceptable alternative method of performing a medically necessary prophylactic mastectomy where there is no cancer involving the skin.
- A nipple-sparing mastectomy is considered an acceptable alternative of performing a medically necessary prophylactic mastectomy where there is no cancer involving the nipple-areola complex
- o High risk family history of breast cancer with **1 or more** of the following:
 - Untested first degree relative of Breast Cancer susceptibility gene (BRCA) carrier
 - Two or more first degree relatives with breast cancer
 - First degree relative with premenopausal breast cancer
 - First degree relative and other relative with breast cancer
 - Family history of both breast and ovarian cancer
 - Male relative with breast cancer
 - Risk of multigene testing for individual (man or woman) who carry or have a first degree relative who carries a genetic mutation in 1 or more of the following:
 - CDH1
 - STK11
 - TP53
 - PTEN
 - PALB2
- Individual (man or woman) who has a genetic mutation (not a family history) for 1 or more of the following
 - CHEK2
 - NFI
 - RAD51C
 - RAD51D
- Partial Mastectomy (Lumpectomy) is indicated for 1 or more of the following:
 - Ductal carcinoma in situ (DCIS)
 - Stage I or stage II invasive breast cancer
 - Stage IIIA (T3 N1 M0 stage grouping only) invasive breast cancer
 - Stage III (other than T3 N1 M0 stage grouping) invasive breast cancer with clinical response to neoadjuvant chemotherapy
 - Paget disease without associated cancer elsewhere in breast necessitating complete mastectomy
 - Breast cancer
 - o Phyllodes tumor
 - o Angiosarcoma of the breast
 - Stage IV breast cancer with surgery needed for palliation of localized breast pain, bleeding, infection, or fungation as indicated by ALL of the following:
 - Signs and symptoms are not amenable to or not adequately controlled via other means (eg, topical or systemic therapy).

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- Individual is expected to be able to obtain significant relief from procedure (eg, most or all of symptomatic tissues can be removed).
- Partial mastectomy is expected to be sufficient (ie, complete mastectomy not indicated).
- Individual has sufficient estimated life expectancy so as to allow benefit from procedure (eg, life expectancy of weeks to months or longer, not days).
- High risk family history of breast cancer with 1 or more of the following:
 - Untested first degree relative of Breast Cancer susceptibility gene (BRCA) carrier
 - Two or more first degree relatives with breast cancer
 - First degree relative with premenopausal breast cancer
 - First degree relative and other relative with breast cancer
 - Family history of both breast and ovarian cancer
 - Male relative with breast cancer
 - Risk of multigene testing for individual (man or woman) who carry or have a first degree relative who carries a genetic mutation in 1 or more of the following:
 - CDH1
 - STK11
 - TP53
 - PTEN
 - PALB2
- Individual (man or woman) who has a genetic mutation (not a family history) for 1 or more of the following
 - CHEK2
 - NFI
 - RAD51C
 - RAD51D
- Removal or replacement of breast implants is considered medically necessary for indications of 1 or more of the following:
 - Removal of breast implants (Silicone Gel filled, Saline filled, combination or Alternative) is considered medically necessary for individuals with 1 or more of the following:
 - Breast cancer and removal of the implant is required to remove the cancer
 - Recurrent breast infections
 - Implant exposure/extrusion or protrusion through the skin
 - Siliconoma or granuloma
 - Implants causing severe pain due to Baker Class IV contracture
 - Implants that interfere with diagnosis of breast cancer
 - Painful capsular contracture with disfigurement
 - Implants that are silicone gel filled and there is a rupture. Broken or failed implant that is either intracapsular or extracapsular
 - Breast implant-associated Anaplastic large cell lymphoma (BIA-ALCL) that is related to the breast implant
 - Individuals who show skin hypersensitivity-like reactions related to breast implants with ALL of the following:
 - Individual has tried and had unsuccessful conventional treatments including but not limited to antibiotics, oral corticosteroids, and topical corticosteroids
 - After breast reconstruction following a medically necessary mastectomy for indications of 1 or more of the following:
 - Baker Class III contracture
 - An extracapsular rupture of saline implant that jeopardizes the cosmetic character of the implant
 - Implants that have been withdrawn from the market at the request of the Food and Drug Administration (FDA)
 - Replacement of breast implants is considered medically necessary for individuals for indications of 1 or more of the following:

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- When the implant was placed because the affected breast was originally removed due to malignancy and/or implant on contralateral breast was done for symmetry
- When the implant was placed because the breast(s) was/were removed originally due to the individual being a carrier of Breast Cancer susceptibility gene 1 (BRCA1) or Breast Cancer susceptibility gene 2 (BRCA2) mutations
- When the implant was placed because the breast(s) was/were removed originally for 1 or more of the following:
 - High risk of breast cancer because of strong family history
 - Previous cancer in one breast
 - Biopsy showing lobularcarcinoma in situ and Breast Cancer susceptibility gene (BRCA) status unknown
 - Biopsy showing atypical hyperplasia and Breast Cancer susceptibility gene (BRCA) status unknown

Breast Reduction is considered **not medically necessary** for any use other than those indicated in clinical criteria, to include but not limited to:

- Mastopexy procedures
- Reduction mammoplasty for asymptomatic members
- Liposuction (suction lipectomy or ultrasonically-assisted suction lipectomy) to perform breast reduction

Removal or replacement of breast implants are considered not medically necessary for any use other than those indicated in clinical criteria, to include but not limited to:

- Prophylactic removal of INTACT silicone implants
- Replacement is for cosmetic reasons
- Removal of ruptured saline-filled breast implants for individuals who have previously undergone cosmetic breast augmentation mammoplasty
- Removal of silicone implants for autoimmune disease (unless individual meets one of the clinical indications for the procedure listed above)
- IgG testing in connection with silicone implants (the development of IgG antibodies is neither specific to silicone implants nor indicative of autoimmune disorders)
- Removal of implant due to personal anxiety
- Removal and replacement of implant due to pain not related to contractures or rupture

Reconstruction breast surgery is considered **not medically necessary** for any use other than those indicated in clinical criteria, to include but not limited to:

- Nerve reimplantation or nerve repair
- ARTIA Reconstructive Tissue Matrix

Coding:

Medically necessary with criteria:

Coding	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, or part thereof (List separately in addition to code for primary procedure)

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15771	Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs; 50 cc or less injectate
15772	Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs; each additional 50 cc injectate, or part thereof (List separately in addition to code for primary procedure)
15777	Implantation of biologic implant (eg, acellular dermal matrix) for soft tissue reinforcement (ie, breast, trunk) (List separately in addition to code for primary procedure)
19301	Mastectomy, partial (eg, lumpectomy, tylectomy, quadrantectomy, segmentectomy)
19302	Mastectomy, partial (eg, lumpectomy, tylectomy, quadrantectomy, segmentectomy); with axillary lymphadenectomy
19303	Mastectomy, simple, complete
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
19316	Mastopexy
19318	Breast reduction
19325	Breast augmentation with implant
19328	Removal of intact breast implant
19330	Removal of ruptured breast implant, including implant contents (eg, saline, silicone gel)
19340	Insertion of breast implant on same day of mastectomy (ie, immediate)
19342	Insertion or replacement of breast implant on separate day from mastectomy
19350	Nipple/areola reconstruction
19355	Correction of inverted nipples
19357	Tissue expander placement in breast reconstruction, including subsequent expansion(s)
19361	Breast reconstruction with latissimus dorsi flap
19364	Breast reconstruction with free flap (eg, fTRAM, DIEP, SIEA, GAP flap)
19367	Breast reconstruction; with single-pedicled transverse rectus abdominis myocutaneous (TRAM) flap

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19368	Breast reconstruction; with single-pedicled transverse rectus abdominis myocutaneous (TRAM) flap, requiring separate microvascular anastomosis (supercharging)
19369	Breast reconstruction; with bipedicled transverse rectus abdominis myocutaneous (TRAM) flap
19370	Revision of peri-implant capsule, breast, including capsulotomy, capsulorrhaphy, and/or partial capsulectomy
19371	Peri-implant capsulectomy, breast, complete, including removal of all intracapsular contents
19380	Revision of reconstructed breast (eg, significant removal of tissue, re-advancement and/or re-inset of flaps in autologous reconstruction or significant capsular revision combined with soft tissue excision in implant-based reconstruction)
C9358	Dermal substitute, native, nondenatured collagen, fetal bovine origin (SurgiMend Collagen Matrix), per 0.5 sq cm
C9360	Dermal substitute, native, non-denatured collagen, neonatal bovine origin (surgimend collagen matrix), per 0.5 square centimeters
Q4100	Skin substitute, not otherwise specified
Q4116	AlloDerm, per sq cm
Q4122	DermACELL, DermACELL AWM or DermACELL AWM Porous, per sq cm
Q4128	FlexHD, AllopatchHD, or Matrix HD, per sq cm
Q4130	Strattice TM, per sq cm

Considered Not Medically Necessary:

Coding	Description
15877	Suction assisted lipectomy; trunk
64912	Nerve repair; with nerve allograft, each nerve, first strand (cable)
64913	Nerve repair; with nerve allograft, each additional strand (List separately in addition to code for primary procedure)

U.S. Food and Drug Administration (FDA) - approved only products only.

Document History:

Revised Dates:

- 2022: April, June, October
- 2021: March, August, October, December
- 2020: January, February, May, July, September
- 2019: November, December
- 2016: April, May
- 2015: February, March, July, October
- 2014: July, August, October, November
- 2013: February, July, August
- 2012: February, April, May, August, September
- 2011: March, November

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- 2008: March, August, September
- 2005: August
- 2004: April, July, September, November
- 2003: February, May, October
- 2001: September, November
- 1999: February, May, July, November
- 1998: November
- 1996: June, August
- 1994: February

Reviewed Dates:

- 2024: August no changes references updated
- 2023: October
- 2021: April, June, October
- 2020: October, December
- 2019: April, October
- 2018: April, May, September, November
- 2017: January, November
- 2016: March
- 2015: March
- 2014: April
- 2013: March
- 2012: March
- 2011: August, September
- 2010 March, August, September
- 2009: March, August, September
- 2007: June, December
- 2005: May, July, October, November
- 2004: May, February, September, October
- 2003: May, June, September
- 2002: June, September, October
- 2001: May, September
- 2000: March, September, October, November
- 1999: March
- 1998: October, November
- 1996: June
- 1994: February, August

Effective Date:

 August 1991 (Reconstruction Breast), October 1991 (Breast Reduction), July 1992 (Breast Implant Removal or Replacement), February 1996 (Prophylactic Mastectomy)

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Specialty Association Guidelines; Government Regulations; Winifred S. Hayes, Inc; UpToDate; Literature Review; Specialty Advisors; National Coverage Determination (NCD); Local Coverage Determination (LCD).

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Special Notes: *

Medical policies can be highly technical and complex and are provided here for informational purposes. These medical policies are intended for use by health care professionals. The medical policies do not constitute medical advice or medical care. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Sentara Health Plan members should discuss the information in the medical policies with their treating health care professionals. Medical technology is constantly evolving, and these medical policies are subject to change without notice, although Sentara Health Plan will notify providers as required in advance of changes that could have a negative impact on benefits.

Services mean both medical and behavioral health (mental health) services and supplies unless We specifically tell You otherwise. We do not cover any services that are not listed in the Covered Services section unless required to be covered under state or federal laws and regulations. We do not cover any services that are not Medically Necessary. We sometimes give examples of specific services that are not covered but that does not mean that other similar services are covered. Some services are covered only if We authorize them. When We say You or Your We mean You and any of Your family members covered under the Plan. Call Member Services if You have questions.

Keywords:

Breast Procedures, Breast reconstruction, Areola Tattoo, Areola repigmentation, Breast surgery, Acellular dermal matrix, SHP Surgical 10, SurgiMend, DermaMatrix, FlexHD, AlloMax, Alloderm, Alloderm-Select RTM, Silicone Gel-filled Implants, Saline filled implants, Alternative Implants, Combination Implants, implant infection, Implant exposure, implant extrusion, capsular contracture, Baker Class IV, Baker class III contracture, implant rupture, breast cancer, Autologous tissue transplant, Breast Tissue, breast biopsy, breast reduction, pedicled TRAM flap, fat grafting, various microsurgical flaps, lipoinjection, lipofilling, lipomodeling, latissimus dorsi flaps, Dermacell, Neoform, Prophylactic, breast, cancerous, mastectomy, BRCA, cancer, carcinoma, ductal, hyperplasia, Prophylactic Mastectomy, breast cancer, Ductal carcinoma in situ, Lobular carcinoma in situ, Atypical lobular hyperplasia, Atypical ductal hyperplasia, Breast Cancer susceptibility gene 1, BRCA1, Breast Cancer susceptibility gene 2, BRCA2, CDH1, STK11, TP53, PTEN, Risk-reduction mastectomy, Cowden syndrome, Li-Fraumeni syndrome, Reduction, breast, mammoplasty, mammoplasty, Breast Reduction, brachial

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plexus compression syndrome, breast size, breast growth, Chronic skin problems, breast tissue, Shoulder grooves from bra straps, Skin irritation under breasts, Ulceration in the infra-mammary fold, Reduction Mammoplasty, Mammaplasty. Includes types (shapes of incisions): Aries-Pitanguy Mammaplasty and Biesenberger, Skoog, McKissock, Goldwyn, and LeJour mammaplasty, Breast, implant, saline, silicone, mammoplasty, augmentation, reconstruction, mammary, BRCA, malignancy, contracture, rupture, removal, replacement, breast cancer, Breast Implant Removal or Replacement, implants, extrusion, Baker Class IV, mammography, Breast Cancer susceptibility gene, Partial Breast Surgery, Complete mastectomy, Mastopexy, INTACT silicone implants, Partial Mastectomy, Lumpectomy, Paget disease, Phyllodes tumor, Angiosarcoma of the breast, nipple-sparing mastectomy, skin-sparing mastectomy, insertion of breast prosthesis or tissue expander

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