

## Breast Procedures, Surgical 10

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**All requests for authorization for the services described by this medical policy will be reviewed per Early and Periodic Screening, Diagnostic and Treatment (EPSDT) guidelines. These services may be authorized under individual consideration for Medicaid members under the age of 21-years if the services are judged to be medically necessary to correct or ameliorate the member’s condition. Department of Medical Assistance Services (DMAS), Supplement B - EPSDT (Early and Periodic Screening, Diagnosis and Treatment) Manual.\*.**

### 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
- 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)
  - 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
- 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
  - 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)
    - 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
- 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
- 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:
  - Angiosarcoma of the breast
  - Breast cancer
  - Ductal carcinoma in situ (DCIS)
  - Paget disease without associated cancer elsewhere in breast necessitating complete mastectomy
  - Phyllodes tumor
  - Stage I or stage II invasive breast cancer

- Stage III (other than T3 N1 M0 stage grouping) invasive breast cancer with clinical response to neoadjuvant chemotherapy
- Stage IIIA (T3 N1 M0 stage grouping only) invasive breast cancer
- 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).
  - 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
    - Breast implant-associated Anaplastic large cell lymphoma (BIA-ALCL) that is related to the breast implant
    - Implant exposure/extrusion or protrusion through the skin
    - Implants causing severe pain due to Baker Class IV contracture
    - Implants that are silicone gel filled and there is a rupture. Broken or failed implant that is either intracapsular or extracapsular
    - Implants that interfere with diagnosis of breast cancer
    - Painful capsular contracture with disfigurement
    - Recurrent breast infections
    - Siliconoma or granuloma
    - 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:
  - 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) |
| 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   |
| 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
- 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)

## References:

Including but not limited to: 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: \*

This medical policy express Sentara Health Plan's determination of medically necessity of services, and they are based upon a review of currently available clinical information. These policies are used when no specific guidelines for coverage are provided by the Department of Medical Assistance Services of Virginia (DMAS). Medical Policies may be superseded by state Medicaid Plan guidelines. Medical policies are not a substitute for clinical judgment or for any prior authorization requirements of the health plan. These policies are not an explanation of benefits.

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.

The Early and Periodic Screening, Diagnostic and Treatment (EPSDT) covers services, products, or procedures for children, if those items are determined to be medically necessary to “correct or ameliorate” (make better) a defect, physical or mental illness, or condition (health problem) identified through routine medical screening or examination, regardless of whether coverage for the same service or support is an optional or limited service under the state plan. Children enrolled in the FAMIS Program are not eligible for all EPSDT treatment services. All requests for authorization for the services described by this medical policy will be reviewed per EPSDT guidelines. These services may be authorized under individual consideration for Medicaid members under the age of 21-years if the services are judged to be medically necessary to correct or ameliorate the member’s condition. *Department of Medical Assistance Services (DMAS), Supplement B - EPSDT (Early and Periodic Screening, Diagnosis and Treatment) Manual.*

## 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 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, Mammoplasty. Includes types (shapes of incisions): Aries-Pitanguy Mammoplasty and Biesenberger, Skoog, McKissock, Goldwyn, and LeJour mammoplasty, 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