Sentara Health Plans

Medicaid

Breast Procedures, Surgical 10

Table of Content

Description & Definitions
Criteria
Document History
Coding
Policy Approach and Special Notes
References
Keywords

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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 by 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.*.

Description & Definitions:

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.

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

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.

Criteria:

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

- Breast reconstructive revision surgery (e.g., flap procedures) including areola repigmentation/tattooing and autologous tissue transplant will be approved as inpatient and 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 (**Q4116**)
      - Alloderm-Select RTM (**Q4116**)
      - Alloderm RTU (**Q4116**)
      - AlloMax (**Q4100**)
      - Cortiva (**Q4100**)
      - Dermacell (**Q4122**)
      - DermaMatrix (**Q4100**)
      - FlexHD (**Q4128**)
      - NeoForm (**Q4100**)
      - Strattice (**Q4130**)
      - SurgiMend (**C9358, C9360**)
- Removal or replacement of breast implants is considered medically necessary for indications of **1 or more** of the following and will be approved as ambulatory (outpatient) unless additional criteria are met as noted by MCG's Ambulatory Surgery or Procedure criteria located at the bottom of this section:
  - **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 lobular carcinoma in situ and Breast Cancer susceptibility gene (BRCA) status unknown
    - Biopsy showing atypical hyperplasia and Breast Cancer susceptibility gene (BRCA) status unknown

As noted in MCG's Ambulatory Surgery or Procedure GRG PG-AS (ISC GRG):
This surgery or procedure will be traditionally approved ambulatory (outpatient), but may receive initial approval for Inpatient Care when **1 or more** of the following are met:

- Inpatient care needed for clinically significant disease or condition identified preoperatively, as indicated by **1 or more** of the following:
    - Severe infection
    - Altered mental status
    - Dangerous arrhythmia
    - Hypotension
    - Hypoxemia
- Complex surgical approach or situation anticipated, as indicated by **1 or more** of the following:
    - Prolonged airway monitoring required (eg, severe obstructive sleep apnea, open neck procedure)
    - Other aspect or feature of procedure that indicates a likely need for prolonged postoperative care or monitoring
- High patient risk identified preoperatively, as indicated by **1 or more** of the following:
    - American Society of Anesthesiologists class IV or greater American Society of Anesthesiologists (ASA) Physical Status Classification System
    - Severe frailty
    - Severe valvular disease (eg, severe aortic stenosis)
    - Symptomatic coronary artery disease, or heart failure
    - Symptomatic chronic lung disease (eg, COPD, chronic lung disease of prematurity)
    - Severe renal disease (eg, glomerular filtration rate (GFR) less than 30 mL/min/1.73m^2 (0.5 mL/sec/1.73m^2) or on dialysis) eGFR - Adult Calculator
    - Morbid obesity (eg, body mass index greater than 40 BMI Calculator) with hemodynamic or respiratory problems (eg, severe obstructive sleep apnea, hypoventilation)
    - Complex chronic condition in children (eg, ventilator-dependent, neuromuscular, genetic, or immunologic disease)
    - Other patient condition or finding that places patient at increased anesthetic risk such that prolonged postoperative inpatient monitoring or treatment is anticipated
- Presence of drug-related risk identified preoperatively, as indicated by **1 or more** of the following:
    - Procedure requires discontinuing medication (eg, antiarrhythmic medication, antiseizure or anticoagulant medication), which necessitates preoperative or prolonged postoperative inpatient monitoring or treatment.
    - Preoperative use of drugs that may interact with anesthetic (eg, cocaine, amphetamines, monoamine oxidase inhibitor) such that prolonged postoperative monitoring or treatment is needed

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 (**15777**)

Document History:

Revised Dates:

- 2026: April – Implementation date of August 1, 2026. Complete review removed criteria related to prior auth removal.

- 2025: April – Implementation date of July 1, 2025. Complete review, relaxed auth for Mastectomy (removal of criteria)
- 2025: January – clarified no evidence of breast cancer criteria bullet
- 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

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

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)
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)
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
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
15777	Implantation of biologic implant (eg, acellular dermal matrix, ARTIA) for soft tissue reinforcement (ie, breast, trunk) (List separately in addition to code for primary procedure)
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)

The preceding codes are included above for informational purposes only and may not be all inclusive. Additionally, inclusion or exclusion of a treatment, procedure, or device-code(s) does not constitute or imply member coverage or provider reimbursement.

Policy Approach and Special Notes: *

- Coverage
  - See the appropriate benefir document for specific coverage determination. Member specific benefits take precedence over medical policy.
- Application to products
  - Policy is applicable to Sentara Health Plan Virginia Medicaid Products
- Authorization requirements
  - Precertification required by Plan
  - **Please refer to Prior Authorization List for most up to date requirement <u>Search PAL List: Sentara Health Plans</u>**
  - Prior authorization has been removed from the initial breast reconstruction procedures, revisions remains subject to prior approval.
- 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 by medically necessary to correct or ameliorate the member's condition. EPSDT Supplement B (updated 5.19.22) Final.pdf
- Service authorization requests must be accompanied by sufficient clinical records to support the request. Clinical records must be signed and dated by the requesting provider withing 60 days of the date of service requested.

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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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, 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