KAISER PERMANENTE® Northwest Region Utilization Review

UR 20.6 Breast Reconstruction Surgery Medical Necessity Criteria: Commercial Members

Department: Surgery	Number: UR 20.6
Section: Plastic Surgery	Effective: 9/14
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MEDICAL NECESSITY CRITERIA AND OTHER REQUIREMENTS FOR BREAST RECONSTRUCTION SURGERY

Medical necessity criteria are applied only after member eligibility and benefit coverage is determined. Questions concerning member eligibility and benefit coverage need to be directed to Membership Services.

DEFINITIONS

See the Evidence of Coverage (EOC) as definitions of *Cosmetic Services* may vary within the Exclusions section of the EOC documents (this exclusion does not apply to 'Reconstructive Surgical Services' or services that are medically necessary).

POLICY AND CRITERIA

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	NCD 140.2 "Breast Reconstruction Following Mastectomy"
Local Coverage Determinations (LCD)	LCD L37020 "Plastic Surgery"
Local Coverage Article	None
Kaiser Permanente Medical Policy	For Medicare lines of business, apply the criteria in the NCD and/or LCD.

For Non-Medicare Members

Patients will be eligible for breast reconstructive surgery under these criteria only 1) after medically necessary mastectomy or lumpectomy related to breast cancer or 2) to correct significant disfigurement resulting from an injury or from medically necessary surgery.

- Reconstructive surgery of the affected side may include any or all of the following:
  - Tissue reconstruction (e.g., flaps)
  - Use of tissue expanders
  - Implantation of FDA-approved internal breast prosthesis. Augmentation may be appropriate only when one of the following conditions is met:
    - Patient has undergone lumpectomy but NOT radiation therapy; OR
    - Patient has undergone mastectomy, with or without radiation therapy

- Areolar and nipple reconstruction
- Areolar and nipple tattooing
- Autologous fat grafting
- Liposuction
- Mastopexy or reduction (e.g. oncoplastic reduction)
- Capsule revision (capsulotomy, capsulectomy, capsulorrhaphy)
- Dermal rearrangement (i.e. “Goldilocks” flaps)

- Reconstructive procedures may be performed on the contralateral (unaffected) side to restore the appearance of the breasts to the level of symmetry present prior to mastectomy or lumpectomy ONLY when mastectomy or lumpectomy has produced significant asymmetry.
    - The patient qualifies as having significant asymmetry when the following criteria are met:
        - There is an absence of breast tissue unilaterally where there is no ability to maintain a normal breast shape using non-surgical methods; AND
        - At least 250 g of tissue were removed OR there is a difference of at least 1 cup size.
    - Reconstructive surgery of the contralateral (unaffected) side may include any of the following when the above criteria are met:
        - Breast reduction by mammoplasty or mastopexy
        - Augmentation mammoplasty
        - Areolar and nipple reconstruction
        - Areolar and nipple tattooing
        - Capsulotomy
        - Capsulectomy
        - Breast implant removal and subsequent re-implantation when original implant was in the unaffected breast prior to disease in the affected breast
        - Liposuction
        - Autologous fat grafting

- Reconstructive procedures are considered medically necessary when performed either at the time of mastectomy (immediate reconstruction) or in a staged manner following mastectomy (delayed reconstruction). Contraindications to immediate reconstruction are:
    - Severe obesity (BMI >40)
    - Uncontrolled diabetes (HbA1c >8.0)
    - Inflammatory breast cancer
    - Members who decline or are non-compliant with standard of care cancer treatment
    - Active or recent use of tobacco and/or tobacco products* (members with a history of tobacco products* use must have a documented “quit” date >6 months prior to referral for consultation OR a negative urine anabasine test (level below 3 ng/dl) within the last 30 days if quit $\leq$6 months prior to referral for consultation. *tobacco products: cigarettes, cigars, pipe tobacco, e-cigarettes, smokeless tobacco (chewing tobacco and snuff))

- Reconstructive surgical revisions may be performed as deemed necessary by a physician board-certified in plastic surgery.

- Revisions will not be covered when performed to correct changes in form or symmetry due to natural processes, such as aging or changes in weight.
- Once the initial sequence of tattoo sessions has been completed, further touch-ups will be considered cosmetic (see Special Group Considerations).

CONTRAINDICATIONS (TO BE DETERMINED BY THE SURGEON)

1. Nicotine use, including tobacco products* and nicotine replacement therapy (NRT) products** within the 30 days prior to surgery.

*tobacco products: cigarettes, cigars, pipe tobacco, e-cigarettes, smokeless tobacco (chewing tobacco and snuff)
**NRT products: nicotine gum, lozenges, sublingual tablets, transdermal patch, nasal spray, inhaler.

2. Uncontrolled diabetes as indicated by a HbA1c of 8.0 or higher. Members with a HbA1c in the 7-8 range may be assessed for relative contraindications on a case-by-case basis.
3. Obesity is also a risk factor for poor surgical outcome. Members who are obese but otherwise meet the above medical necessity criteria will be assessed on a case-by-case basis.
4. Any other surgical contraindications will be determined by the surgeon.

SPECIAL GROUP CONSIDERATIONS

Medicare- This policy does not apply to Medicare. See NCD 140.2: Breast Reconstruction Following Mastectomy and LCD 37020: Plastic Surgery.

Senior Advantage EOC states:

- We cover reconstructive surgery to correct or repair abnormal structures of the body caused by congenital defect, developmental abnormalities, accidental injury, trauma, infection, tumors, or disease, if a network physician determines that it is necessary to improve function, or create a normal appearance, to the extent possible. However, reconstructive surgery that offers only a minimal improvement in appearance or is performed to alter or reshape normal structures of the body in order to improve appearance are not covered.
- Cosmetic Surgery or Procedures are covered in cases of an accidental injury or for improvement of the functioning of a malformed body member; and for all stages of reconstruction for a breast after a mastectomy, as well as for the unaffected breast to produce a symmetrical appearance.

Tattooing is covered when performed in conjunction with breast reconstruction. If the tattooing is done by the operating surgeon and within the 90-days after the reconstruction surgery, it is included in the global fee for breast reconstruction CPT codes (19350, 19357-19369) and not separately reported. If the tattooing is not done by the operating surgeon and/or not done within the 90-days after the reconstruction surgery, it may be billed separately.

The touch up tattooing after one year is separately reportable and is covered indefinitely for Medicare members when associated with a covered breast reconstruction (Medicare does not have a NCD (National Coverage Determination) for tattooing to correct color defects of the skin nor does Noridian have a LCD (Local Coverage Determination)).

RATIONALE

EVIDENCE BASIS

A 2021 Agency for Healthcare Research and Quality (AHRQ) systematic review of surgical breast reconstruction options after mastectomy for breast cancer compared implant-based reconstruction (IBR) vs. autologous reconstruction (AR), assessed evidence about the timing of IBR and AR in relation to chemotherapy and radiation therapy, compared implant materials for IBR, compared anatomic planes of implant placement during IBR, evaluated the used of acellular dermal matrices (ADMs) during IBR, and compared flap types for AR.[1] The overall conclusions of this review are as follows:

> "Our analysis of all surgical choices examined as KQs in this review finds no clear winners when all outcomes are considered. We encourage clinicians to inform patients about the limitations of existing research and to help patients make decisions regarding options for breast reconstruction based on their values and preferences, together with the clinician's expertise and experience. Research is needed to address various questions related to breast reconstruction, particularly the timing of IBR and AR in relation to chemotherapy and radiation therapy, and the choices of implant materials, anatomic planes of implant placement during IBR, and flaps used for AR. Future studies should either randomize patients or adequately account for important confounders and evaluate key outcomes, especially those in the existing core outcome set for breast reconstruction after mastectomy."[1]

Tobacco Use:

A 2018 systematic review of the effect of smoking on post-operative outcomes in patients who had common elective procedures in plastic surgery reports that tobacco use was associated with a significant increase in the total number of post-operative complications following breast reconstruction.[2] These complications include donor site complications, infection, and fat necrosis, all of which were significantly more common among smokers compared to non-smokers.[2] A 2015 systematic review of the association between smoking status and outcomes of plastic surgery reports significantly increased odds of surgical site infections, delayed wound healing, and cutaneous necrosis among patients who were smokers compared to non-smokers.[3]

REFERENCES

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4. WHCRA (Women's Health and Cancer Rights Act)
5. ORS 743A.110 Mastectomy-related Services
6. Oregon House Bill 3616 amending ORS 743A.110- defines "mastectomy" for purposes of statute requiring health benefit plan coverage
7. Xu, Z., Norwich-Cavanaugh, A., Hsia, HC (2019), Can Nicotine Replacement Decrease Complications in Plastic Surgery? *Annals of Plastic Surgery*. 83: S55-S58.