Medicare Medical Policy

Breast Reconstructive Surgery, Implant Management, and Reduction Mammoplasty

MEDICARE MEDICAL POLICY NUMBER: 523

Effective Date: 5/1/2025

Last Review Date: 4/2025

Next Annual Review: 4/2026

INSTRUCTIONS FOR USE: Company Medicare Medical Policies serve as guidance for the administration of plan benefits and do not constitute medical advice nor a guarantee of coverage. Company Medicare Medical Policies are reviewed annually to guide the coverage or non-coverage decision-making process for services or procedures in accordance with member benefit contracts (otherwise known as Evidence of Coverage or EOCs) and Centers of Medicare and Medicaid Services (CMS) policies, manuals, and other CMS rules and regulations. In the absence of a CMS coverage determination or specific regulation for a requested service, item or procedure, Company policy criteria or applicable utilization management vendor criteria may be applied. These are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

The Company reserves the right to determine the application of Medicare Medical Policies and make revisions to these policies at any time. Any conflict or variance between the EOC and Company Medical Policy will be resolved in favor of the EOC.

SCOPE: Providence Health Plan, Providence Health Assurance, and Providence Plan Partners as applicable (referred to individually as “Company” and collectively as “Companies”).

PRODUCT AND BENEFIT APPLICATION

☒ Medicare Only

MEDICARE COVERAGE CRITERIA

IMPORTANT NOTE: More than one Centers for Medicare and Medicaid Services (CMS) reference may apply to the same health care service, such as when more than one coverage policy is available (e.g., both an NCD and LCD exist). All references listed should be considered for coverage decision-making. The Company uses the most current version of a Medicare reference available at the time of publication; however, these websites are not maintained by the Company, so Medicare references and their corresponding hyperlinks may change at any time. If there is a conflict between the Company Medicare Medical Policy and CMS guidance, the CMS guidance will govern.

Notes:

- This policy does **not** apply to the treatment of male gynecomastia (CPT 19300), which is addressed in the Medicare *Cosmetic and Reconstructive Surgery* medical policy.
- This policy does **not** address breast reconstructive procedures when included in the treatment of gender dysphoria, which is addressed in the *Gender Affirming Surgical Interventions* policy.

Service	Medicare Guidelines
Breast Reconstruction Surgery ***Following Mastectomy*** Includes: • Any breast reconstructive surgical procedure, including but not limited to, a reduction mammoplasty following a mastectomy	National Coverage Determination (NCD) for Breast Reconstruction Following Mastectomy (140.2) **NOTE:** This NCD is not limited to any specific breast reconstruction procedure. Therefore, this NCD will apply to any part of the breast reconstructive process, including but not limited to a mammoplasty when performed following a mastectomy (includes complete mastectomy or partial mastectomy [lumpectomy]) if rendered for any medical reason (i.e., accidental injury, trauma, breast cancer, etc.). This applies to both the affected and contralateral unaffected breast.
Breast Reconstruction Surgery ***Not*** *Following a Mastectomy or Breast Surgery Procedures Performed for Any Other Indication (e.g., cosmetic surgeries)* Includes: • Removal of breast implants • Reduction mammoplasty • Breast augmentation performed for the purpose of enhancing appearance	Local Coverage Determination (LCD) for Plastic Surgery (L37020) *See "Policy Guidelines" below*

Use of Skin Substitutes in the above Procedures	Skin substitutes used in breast reconstruction or surgical procedures may be considered **medically necessary** when **both** of the following are met: 1. The skin/tissue substitute has been approved for use in breast reconstruction procedures (To determine if a product has been approved for use in breast reconstruction procedures, see the Medicare *Skin and Tissue Substitute* medical policy in "Policy Cross References" below, which will then direct you to the Company version of the policy for product-specific information.), **and** 2. The above NCD or LCD criteria for the breast surgery itself are met. **NOTES**: • Medicare does not have criteria for skin or tissue substitute products in either a Medicare manual or a national coverage determination (NCD) manual, for any indication. While LCDs do exist for certain uses of skin and tissue substitute products, as of the most recent policy review, no Medicare Administrative Contractors (MACs) have LCDs for skin/tissue substitute products **used during breast reconstruction surgical procedures**. Therefore, in the absence of **fully established** Medicare coverage criteria in a manual, NCD, LCD, or other regulatory guidance for the health plan's service area, Company criteria are applied for medical necessity decision-making. In this case, Medicare coverage criteria are considered "not fully established" as defined under CFR § 422.101(6)(i)(B) as the available Medicare coverage policies provide flexibility for coverage decisions beyond the NCD and LCD, because the use of these items in this context is outside the scope of the available Medicare coverage policies. • See the "Regulatory Status" section below for more information regarding skin and tissue substitute products used with breast surgeries when such products are not FDA approved for this indication.

IMPORTANT NOTICE: While some services or items may appear medically indicated for an individual, they may also be a direct exclusion of Medicare or the member's benefit plan. Such excluded services or items by Medicare and member EOCs include, but are not limited to, services or procedures considered to be cosmetic, not medical in nature, or those considered not medically reasonable or necessary under *Title XVIII of the Social Security Act, §1862(a)(1)(A).* If there is uncertainty regarding coverage of a service or item, please review the member EOC or submit a pre-service organization determination request. Note that the Medicare Advance Beneficiary Notice of Noncoverage (ABN) form **cannot** be used for Medicare Advantage members. *(Medicare Advance Written Notices of Non-coverage. MLN006266 May 2021)*

POLICY CROSS REFERENCES

- Cosmetic and Reconstructive Procedures, MP232
- Skin and Tissue Substitutes, MP16
- Surgical Treatments for Lymphedema, MP341

The full Company portfolio of Medicare Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

COSMETIC SURGERY

According to the Medicare Benefit Policy Manual, Chapter 16, §120:

> "Cosmetic surgery or expenses incurred in connection with such surgery is not covered. Cosmetic surgery includes any surgical procedure directed at improving appearance, except when required for the prompt (i.e., as soon as medically feasible) repair of accidental injury or for the improvement of the functioning of a malformed body member. For example, this exclusion does not apply to surgery in connection with treatment of severe burns or repair of the face following a serious automobile accident, or to surgery for therapeutic purposes which coincidentally also serves some cosmetic purpose."

Therefore, under *Title XVIII of the Social Security Act, Section 1862(a)(1)(P)(10)(4)*, cosmetic procedures or services are excluded from Medicare coverage:

> "Notwithstanding any other provision of this title, no payment may be made under part A or part B for any expenses incurred for items or services where such expenses are for cosmetic surgery or are incurred in connection therewith, except as required for the prompt repair of accidental injury or for improvement of the functioning of a malformed body member."

RECONSTRUCTIVE SURGERY

Reconstructive surgery is performed on abnormal structures of the body caused by congenital defects, developmental abnormalities, trauma, infection, tumors, or disease. While it is generally performed to improve function, it may also be done to approximate a normal appearance. *(Noridian LCD L37020)*

MEDICARE COVERAGE

In order to determine if coverage is available for a procedure, review may be required to determine if the procedure is cosmetic or reconstructive in nature.

REGULATORY STATUS

U.S. FOOD & DRUG ADMINISTRATION (FDA)

While clearance by the Food and Drug Administration (FDA) is a prerequisite for Medicare coverage, the 510(k) premarket clearance process does not in itself establish medical necessity. Medicare payment policy is determined by the interaction of numerous requirements, including but not limited to, the

availability of a Medicare benefit category and other statutory requirements, coding and pricing guidelines, as well as national and local coverage determinations and clinical evidence.

WOMEN'S HEALTH AND CANCER RIGHTS ACT (WHCRA) OF 1998 STATEMENT

The Women's Health and Cancer Rights Act (WHCRA) of 1998 provides protections to individuals who have opted to undergo breast reconstruction in connection with a mastectomy. Under the WHCRA, coverage is provided for all stages of breast reconstruction for both the affected breast (the breast undergoing the mastectomy procedure) and the contralateral breast (for symmetry) and breast prostheses, as well as treatment of complications caused by the mastectomy, such as lymphedema. While the criteria in this policy are primarily based on Medicare guidance, in accordance with the WHCRA, Company coverage may exceed Medicare coverage for items or services required to treat conditions that are the direct result of a mastectomy.

SKIN AND TISSUE SUBSTITUTES

The "FDA has not cleared or approved any surgical mesh for use with breast implants or in breast reconstruction, and thus has not reviewed potential benefits and risks for these uses."[1] The FDA has also released a brief regarding the risk of complications when ADM products are used off-label for breast reconstructive procedures.[2] In the past, the FDA has observed manufacturers of some products, such as LifeCell, marketing their product for use in breast reconstruction procedures and have issued warning letters about this practice, as well as requested "immediately cease activities that result in the misbranding or adulteration" of the product for breast reconstruction.[3,4] Since the FDA approval for many of these products does not include breast reconstruction, then this indication would fall outside of the intended use "because surgical mesh has not been cleared or approved for use in breast reconstructive surgery applications." Therefore, while the plan may approve breast reconstructive procedures, the plan may **not** approve requests for certain products to be used in the context of breast reconstruction procedures. The safety and efficacy of these products have not been adequately evaluated in this context, and thus, due to the potential risks of this, we recommend surgeons use a product with proven efficacy for use in breast reconstruction surgeries.

BILLING GUIDELINES AND CODING

GENERAL

See associated local coverage articles (LCAs) for related billing and coding guidance:

- LCA: Billing and Coding: Plastic Surgery (A57222)

FREE FLAP BREAST RECONSTRUCTION

According to CPT Guidelines, "Code 19364 describes a microsurgical free tissue transfer of skin and subcutaneous fat and/or muscle for breast reconstruction. This code includes the flap harvest, microsurgical anastomosis of one artery and two veins with use of an operating microscope, flap inset as a breast mound, and donor-site closure. Typical free flaps include free transverse rectus abdominis myocutaneous (fTRAM), deep inferior epigastric perforator (DIEP), superficial inferior epigastric artery (SIEA), or gluteal artery perforator (GAP) flaps."

Like all S-codes, the *National Physician Fee Schedule Relative Value File (NPFSRVF)*, which is published by Medicare[5], indicates HCPCS codes S2066-S2068 have been assigned a Status Indicator of "I." This is defined as "Not valid for Medicare purposes." In addition, all S-codes codes, including S2066-S2068, are not recognized as valid codes for claim submission as indicated in the relevant Company Coding Policy *(HCPCS S-Codes and H-Codes,* 22.0*).* Providers need to use alternate available CPT or HCPCS codes to report for the service. If no specific CPT or HCPCS code is available, then an unlisted code may be used. Unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level and should only be used if no other CPT or HCPCS code is available. CPT code 19364 is the appropriate code to use for these procedures and HCPCS codes S2066-S2068 are not accepted.

CODES*		
CPT	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 implant
	11971	Removal of tissue expander(s) without insertion of implant
	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)
	19396	Preparation of moulage for custom breast implant
HCPCS	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 *(CMS-assigned Status "I" code – See above billing guidelines)*
	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 *(CMS-assigned Status "I" code – See above billing guidelines)*
	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 *(CMS-assigned Status "I" code – See above billing guidelines)*

***Coding Notes:**

- The code list above is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit. According to Medicare, "presence of a payment amount in the MPFS and the Medicare physician fee schedule database (MPFSDB) does not imply that CMS has determined that the service may be covered by Medicare." The issuance of a CPT or HCPCS code or the provision of a payment or fee amount by Medicare does **not** make a procedure medically reasonable or necessary or a covered benefit by Medicare. *(Medicare Claims Processing Manual, Chapter 23 - Fee Schedule Administration and Coding Requirements, §30 - Services Paid Under the Medicare Physician's Fee Schedule, A. Physician's Services)*
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- **See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

REFERENCES

1. Food and Drug Administration (FDA). Breast Implant Surgery. 2023. https://www.fda.gov/medical-devices/breast-implants/breast-implant-surgery#:~:text=Related%20Links-,Surgical%20Mesh%20and%20Breast%20Surgery,with%20their%20health%20care%20providers. Accessed 11/4/2024.
2. FDA Brief. 2021. https://www.fda.gov/news-events/fda-brief/fda-brief-fda-warns-about-differing-complication-rates-acellular-dermal-matrix-type-surgical-mesh#:~:text=%E2%80%9CThe%20FDA%20has%20issued%20a,in%20implant%2Dbased%20breast%20reconstruction. Accessed 11/4/2024.
3. FDA Warning Letter to LifeCell. 2011. https://www.circare.org/fdawls2/lifecell_fdawl_20110511.pdf. Accessed 11/4/2024.
4. FDA Warning Letters. June 2015. https://www.fdaweb.com/default.php?ea=fv&aid=D5132386&cate=

5. Medicare Physician Fee Schedule (PFS) Relative Value Files; Available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Relative-Value-Files

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
7/2022	Interim update (converted to new format 2/2023)
6/2023	Annual review. No criteria changes. Updated code descriptions for many CPT codes and not accepted by the plan, added S2066-S2068 as relevant codes
5/2024	Annual review. No changes to criteria, update title
9/2024	Interim update; Add clarification regarding applicable medical policy for skin substitutes used for breast reconstruction procedures
5/2025	Annual review. No changes to criteria, add information about skin substitute products used for breast surgeries