Plastic Surgery

1. MCG Criteria Used

Clinical Criteria: MCG Care Guidelines, 30th Edition

- Mastectomy, Complete, with Tissue Flap Reconstruction (MCG ORG: S-864 ISC, 30th Edition)
- Mastectomy, Complete, with Insertion of Breast Prosthesis or Tissue Expander (MCG ORG: S-862 ISC, 30th Edition)

Applicable CPT / HCPCS Codes:

CPT / HCPCS Code	Description
19303	Mastectomy, simple, complete
19361	Breast reconstruction with latissimus dorsi flap
19357	Breast reconstruction, immediate or delayed, with tissue expander, including subsequent expansion
19340, 19342	Insertion of breast implant on the same day as or in a separate procedure after mastectomy
19364, 19367-19369	Breast reconstruction with free flap or transverse rectus abdominis myocutaneous (TRAM) flap, single or double pedicle
19380	Revision of reconstructed breast

2. Statement of Rationale

Akido Labs uses the criteria in MCG Care Guidelines (30th Edition) to supplement the general Medicare criteria regarding breast reconstruction following mastectomy, including reconstruction with autologous tissue flap and reconstruction with breast prosthesis or tissue expander, where Medicare coverage criteria are not fully established or require additional clinical specificity. MCG criteria are used to ensure consistency in reviewing the conditions to be met for coverage of post-mastectomy reconstructive surgery and to determine when such services are medically necessary, including the appropriate level of care. Breast reconstruction following mastectomy is a federally protected benefit under the Women's Health and Cancer Rights Act, and the clinical question for utilization review is rarely whether reconstruction is covered but rather the appropriate timing, technique, and level of care. In the Medicare Advantage population, reconstructive procedures range from prosthesis-based reconstruction with a short recovery to complex autologous free-flap reconstruction requiring inpatient monitoring of flap viability. Absent consistent, evidence-based criteria, there is material risk of both inappropriate denial of medically necessary inpatient care and inappropriate approval of an inpatient stay where a lower level of care would suffice.

Potential Clinical Harms:

Tissue flap reconstruction: Inappropriate denial of inpatient admission after autologous tissue flap reconstruction could result in undetected flap compromise, since free and pedicled flaps

require close postoperative monitoring of perfusion, with failure to detect vascular compromise leading to flap loss and the need for reoperation. Conversely, inappropriate approval of a prolonged inpatient stay beyond the expected recovery course exposes an older patient to avoidable hospitalization risks.

Prosthesis or tissue expander reconstruction: Inappropriate denial of medically necessary prosthesis-based reconstruction or its associated care could compromise the reconstructive outcome and the patient's recovery from cancer treatment. Inappropriate approval of inpatient admission for a routine expander placement that could be managed in an ambulatory or observation setting exposes the patient to unnecessary hospitalization.

Clinical Benefits:

Tissue flap reconstruction: MCG criteria define the indications for autologous tissue flap reconstruction and the clinical factors that justify inpatient admission, including the need for postoperative flap monitoring, and establish the expected recovery course. By tying the inpatient level of care to the documented need for flap monitoring, these criteria directly mitigate the harm of undetected flap compromise identified above while preventing the avoidable hospitalization that follows from admitting patients beyond their clinical need.

Prosthesis or tissue expander reconstruction: MCG criteria define the indications for prosthesis-based reconstruction and the expected recovery course, matching the level of care to the lower postoperative monitoring requirement of expander and implant procedures. This evidence-based selection directly counters both the harm of denying medically necessary reconstruction and the harm of unnecessary inpatient admission described above. The clinical benefits of using MCG Care Guidelines are highly likely to outweigh any clinical harms, including delayed or decreased access to services, because the criteria incorporate evidence-based recovery benchmarks consistent with reconstructive surgery specialty guidance and are unlikely to lead to inappropriate denials.

3. Explanation of Supplementation

Basis for Use: Original Medicare clinical criteria are not fully established and require supplementation to ensure consistent medical necessity and level-of-care determinations for post-mastectomy breast reconstruction. While the Women's Health and Cancer Rights Act and Medicare establish coverage of reconstruction following mastectomy, and Medicare statutes establish the general 'reasonable and necessary' standard, they do not specify the clinical thresholds (e.g., the technique-specific need for inpatient flap monitoring or the expected recovery course) required to determine the appropriate level of care for reconstructive procedures.

Applicable Medicare References: Social Security Act Section 1862(a)(1): 'Reasonable and necessary' standard Women's Health and Cancer Rights Act of 1998 (coverage of breast reconstruction following mastectomy) Medicare Benefit Policy Manual, Chapter 1: Inpatient Hospital Services Covered Under Part A (CMS IOM Publication 100-02) Medicare Benefit Policy Manual, Chapter 6: Hospital Services Covered Under Part B (CMS IOM Publication 100-02) Medicare Program Integrity Manual, Chapter 6, Section 6.5 (CMS IOM Publication 100-08) Code of Federal Regulations: 42 CFR 412.3; 42 CFR 419.22; 42 CFR 422.101 Medicare Coverage Database: https://www.cms.gov/medicare-coverage-database/search.aspx For post-mastectomy reconstruction, no specific NCD or LCD fully establishes clinical level-of-care thresholds; Original Medicare criteria are not fully established, requiring supplementation. Within the above statutes and regulations, MCG criteria assist in determining the appropriateness of inpatient admission versus observation or outpatient care based on the reconstructive technique and the need for flap monitoring; the expected recovery course and length of stay; and objective discharge readiness.

Use of these criteria helps ensure reconstructive services are not incorrectly denied when medically appropriate, nor incorrectly approved when not reasonable and necessary, and may decrease inappropriate denials by creating a consistent set of evidence-based review criteria.

4. Summary of Clinical Evidence

Note: The following evidence summary is derived directly from MCG Care Guidelines, 30th Edition (guidelines S-864 and S-865). The reference lists below are drawn from those respective MCG guidelines.

Background

Mastectomy with Tissue Flap Reconstruction (MCG ORG: S-864 ISC) Mastectomy with tissue flap reconstruction restores breast form following complete mastectomy using autologous tissue, including pedicled flaps such as the latissimus dorsi or transverse rectus abdominis myocutaneous flap and free flaps. Because flap viability depends on adequate perfusion, the postoperative course requires monitoring of flap perfusion, and inpatient admission may be needed when continued flap monitoring and hospital-based care are required.

Mastectomy with Insertion of Breast Prosthesis or Tissue Expander (MCG ORG: S-862 ISC) Prosthesis-based reconstruction restores breast form using a breast implant or a tissue expander that is gradually inflated before exchange for a permanent implant. Reconstruction may be immediate at the time of mastectomy or delayed. The postoperative monitoring requirement is generally lower than for autologous flap reconstruction, and many procedures are managed with a short recovery course.

Evidence Summary

Mastectomy with Tissue Flap Reconstruction (MCG ORG: S-864 ISC) This guideline (30th Edition) is supported by peer-reviewed articles and oncology and reconstructive surgery specialty society guidance, including NCCN breast cancer guidance, establishing the indications for autologous reconstruction and the postoperative monitoring requirements that inform the level-of-care determination.

Mastectomy with Insertion of Breast Prosthesis or Tissue Expander (MCG ORG: S-862 ISC) This guideline (30th Edition) is supported by peer-reviewed articles and reconstructive surgery specialty guidance establishing the indications for prosthesis-based reconstruction, the role of immediate versus delayed reconstruction, and the expected recovery course.

Rationale (from MCG) Use of these MCG care guidelines helps the clinician identify patient-specific clinical factors that establish the medical necessity and appropriate level of care for post-mastectomy reconstruction, including the necessity of inpatient hospital care for flap monitoring. The evidence-based clinical criteria ensure patients receive the most appropriate reconstructive care for their specific situation, reduce unnecessary risks, and provide a standard that can reduce disparities in care. These guidelines supplement but do not replace, modify, or supersede existing Medicare regulations, the Women's Health and Cancer Rights Act, or applicable NCDs or LCDs.

Related CMS Coverage Guidance (as cited in MCG 30th Edition): Code of Federal Regulations (CFR): 42 CFR 412.3; 42 CFR 419.22; 42 CFR 422.101; CMS IOM Publication 100-02, Medicare Benefit Policy Manual, Chapters 1 and 6; CMS IOM Publication 100-08, Medicare Program Integrity Manual, Chapter 6, Section 6.5; Medicare Coverage Database: https://www.cms.gov/medicare-coverage-database/search.aspx

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