

Standard Operating Procedures for use of Skin Substitutes / Advanced Biologics

PMC Wound Care Program

Effective Date: August 1st, 2025

Version: 1.0

Applies to: All participating clinics, physicians, and coordinators within the PMC Wound Care Network

1. Purpose

To ensure standardized, compliant, and clinically appropriate use of advanced wound care therapies, including skin substitutes, under the PMC Wound Care Program. This SOP outlines procedures for authorization, documentation, inventory control, and reporting.

2. Scope

This SOP applies to all PMC-affiliated wound care clinics, physicians, nurse practitioners, and clinic coordinators who participate in the utilization of skin substitutes provided through PMC.

3. Authorized Therapies

Authorized therapies include, but are not limited to:

- **Placental-based grafts** (e.g., Membrane Wrap, MLG Complete, Neostim, Activate)
- **Amniotic or chorionic-based allografts**
- Other PMC-approved advanced wound therapies

Each graft must:

- Be approved by PMC prior to use

- Be used only on eligible patients
- Be applied by credentialed clinicians

4. Clinical Eligibility & Prior Authorization

4.1 Clinician Responsibilities

- Submit a **Prior Authorization Request Form** for each skin substitute treatment
- Document standard of care measures attempted prior to advanced therapy
- Provide a wound staging, diagnosis, and relevant comorbidities (e.g., diabetes, PVD)
- Obtain signed **Patient Consent Form** before initiating treatment

4.2 Clinic Coordinator Responsibilities

- Verify physician credentialing for advanced wound care
- Review requests using the **Skin Substitute Review Checklist**
- Approve or escalate based on appropriateness, wound characteristics, and previous treatments

5. Graft Inventory and Handling

5.1 Storage and Security

- Grafts must be stored per manufacturer instructions
- Maintain a log of **Graft ID / Serial Numbers**
- Ensure grafts are only used for **PMC-approved patients**

5.2 Usage and Waste

- Record usage, patient initials, treatment date, product, and graft serial number in the **Inventory Tracking Sheet**
- Document **any waste** with volume and reason
- Unused or expired grafts must be returned to PMC with tracking

NOTE: Clinics are financially responsible for any grafts not properly returned, misused, or used outside PMC guidelines.

6. Billing and Compliance

- Use only PMC-approved Q codes and ASP (Average Sales Price) values
- Submit **Quarterly Utilization Reports** by the 5th business day of each month
- Maintain full clinical documentation for **medical necessity and audit readiness**
- Report any billing errors, waste, or deviations immediately

7. Compliance Monitoring

PMC will conduct periodic audits and reviews:

- Review of clinical documentation
- Cross-check graft tracking and usage
- Ensure policy adherence for approved providers only

Non-compliance may result in:

- Denial of reimbursement
- Suspension of program privileges
- Full repayment for misused grafts

8. Training and Education

All clinicians and staff must:

- Complete onboarding training
- Review this SOP and acknowledge responsibilities
- Attend refresher sessions annually or when updated protocols are released

9. Contacts and Support

For help with approvals, returns, or technical issues:

 support@pmcwoundcare.com

National Wound Care
Program

Skin Substitutes Advanced
Biologics

PMC Healthcare Network

 (XXX) XXX-XXXX

Acknowledgment:

All participating clinics must sign the **Compliance Acknowledgment Form** and follow this SOP in its entirety.