Reimbursement Guide

PalinGen Membrane

For Skin Replacement Surgery and the Treatment of Chronic Wounds and Burns

July 2015

PalinGen Membrane is a human allograft processed from healthy placental tissue. This human tissue has been tested at multiple points in its processing to insure a healthy, clean, safe membrane that contains collagen substrates, the full range of growth factors and extra cellular matrix. PalinGen Membrane is designated for Human Homologous Allograft use, under FDA under 21 CFR Part 1271 and Section 361 of the Public Health Service Act. Healthy live donors, provide the placental tissue at the time of scheduled caesarian section. Donors are pre-screened through an intensive and complete medical review and pre-natal evaluation. The placental tissue is processed, cleansed, and packaged at an AATB accredited tissue bank. PalinGen Membrane is rich with the basic components necessary for tissue generation. It provides an anti-microbial environment, anti-inflammatory characteristics with anti-adhesion/anti-fibrotic capabilities and is noted in several published studies. PalinGen Membrane is appropriate in the treatment of many clinical conditions where skin regeneration is needed. This Reimbursement Guide focuses only on its use in the treatment of Skin Replacement Surgery, Chronic Wounds and Burns.

HCPCS and CPT™ Coding

HCPCS (Healthcare Common Procedure Code System) and CPT™ (Current Procedural Terminology) codes are broadly used to describe PalinGen Membrane and the manner in which it is used in the treatment of chronic wounds, burns and skin replacement surgery.

Skin Replacement Surgery (CPT codes 15002-15005)

15002 - Surgical preparation or creation of recipient site by excision of open wounds, burn eschar, or scar (including subcutaneous tissues), or incisional release of scar contracture, trunk, arms, legs; first 100 sq. cm or 1% of body area of infants and children
  + 15003 - each additional 100 sq. cm, or part thereof, or each additional 1% of body area of infants and children (List separately in addition to code for primary procedure)
  + Q4100 – Skin substitute, not otherwise specified (report 1 unit of service for each sq. cm of PalinGen)

15004 - Surgical preparation or creation of recipient site by excision of open wounds, burn eschar, or scar (including subcutaneous tissues), or incisional release of scar contracture, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet and/or multiple digits; first 100 sq. cm or 1% of body area of infants and children
  + 15005 - each additional 100 sq. cm, or part thereof, or each additional 1% of body area of infants and children (List separately in addition to code for primary procedure)
  + Q4100 – Skin substitute, not otherwise specified (report 1 unit of service for each sq. cm of PalinGen)
These codes are not intended to be reported for simple graft application alone or application stabilized with dressings (e.g., by simple gauze wrap). The *PalinGen Membrane* graft is anchored using the surgeon’s choice of fixation. When services are performed in the office, the *PalinGen Membrane* product should be reported separately. Routine dressing supplies are not reported separately.

**Treatment of Chronic Wound and Burns (CPT codes 15271 – 15278)**

When used as a Bioengineered Skin Substitute, treatments using *PalinGen Membrane* are reported under CPT code range 15271-15278 for topical application to a wound surface in a) physician office setting, and b) for high cost Bioengineered Skin Substitutes (also referred to as CTPs - Cellular or Tissue Based Products) – those whose cost exceeds $30.00 per sq. cm. This cost threshold is set by Medicare and changes annually. Some, but not all private insurers apply similar criteria.

15271 - Application of skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq. cm; first 25 sq. cm or less wound surface area
   + 15272 - each additional 25 sq. cm wound surface area, or part thereof (List separately in addition to code for primary procedure)
   + Q4100 – Skin substitute, not otherwise specified (report 1 unit of service for each sq. cm of *PalinGen*)

15273 - Application of skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq. cm; first 100 sq. cm wound surface area, or 1% of body area of infants and children
   + 15274 - each additional 100 sq. cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)
   + Q4100 – Skin substitute, not otherwise specified (report 1 unit of service for each sq. cm of *PalinGen*)

15275 - Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq. cm; first 25 sq. cm or less wound surface area
   + 15276 - each additional 25 sq. cm wound surface area, or part thereof (List separately in addition to code for primary procedure)
   + Q4100 – Skin substitute, not otherwise specified (report 1 unit of service for each sq. cm of *PalinGen*)

15277 - Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq. cm; first 100 sq. cm wound surface area, or 1% of body area of infants and children
   + 15278 - each additional 100 sq. cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)
   + Q4100 – Skin substitute, not otherwise specified (report 1 unit of service for each sq. cm of *PalinGen*)

(Note: CPT codes 15040–15261 are for Tissue Cultured Autograft and do not apply to use of *PalinGen Membrane*.)

Medicare assumes that physicians make good faith efforts to minimize the unused portion of *PalinGen Membrane* when ordering, storing and applying the product in their clinical practice. Therefore, Medicare (and most private payers) will cover the amount of product that is discarded along with the amount used to treat the wound. Any discarded material should be documented in the patient medical record with the following: date and location of wound, amount of product used, amount of product discarded, reason for the wastage and manufacturers serial/lot/batch number for the product.

- Some Medicare Administrative Contractors require discarded materials to be reported separately from the medically necessary material. In these instances the Modifier “JW” should be appended to the HCPCS code with the number of sq. cm, and cost of *PalinGen Membrane* that is discarded. Providers should check with their local Medicare administrator.
Hospital and ASC Payment

Medicare employs different payment methodologies and different payment amounts to physicians, hospitals and ambulatory surgery centers (ASCs) for Skin Replacement Surgery and the treatment of Chronic Wounds. Physicians will be paid under the RBRVS system for their professional services. The cost of *PalinGen Membrane* is paid in addition to the professional service when coded and charged as a line item expense. Physicians are to report the amount of product they used.

Under the Hospital Outpatient Prospective Payment System Medicare pays hospitals according to the APC (Ambulatory Payment Classification) methodology. ASCs are paid on based on reported CPT codes. The following chart shows how these provider types are paid for these services. The Medicare allowances cited are national averages (unadjusted for regional variances) for the period beginning July 2015.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Hospital</th>
<th>ASC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin Replacement Surgery</td>
<td>15002/15003</td>
<td>$429.95¹</td>
</tr>
<tr>
<td></td>
<td>15004/15005</td>
<td>$429.95¹</td>
</tr>
<tr>
<td>Chronic Wound Care</td>
<td>15271/15272</td>
<td>$1,406.87²</td>
</tr>
<tr>
<td></td>
<td>15273/15274</td>
<td>$2,300.64³</td>
</tr>
<tr>
<td></td>
<td>15275/15276</td>
<td>$1,406.87²</td>
</tr>
<tr>
<td></td>
<td>15277/15278</td>
<td>$1,406.87²</td>
</tr>
</tbody>
</table>

In each circumstance, Medicare’s allowance for the cost of *PalinGen Membrane* is included in the payments cited above regardless of the size of the wound or the amount of product used.

¹APC #0327 – Level II Skin Procedures
²APC #0328 – Level III Skin Procedures
³APC #0329 – Level IV Skin Procedures

Private insurer payment methodologies and payment levels will vary from Medicare. In most instances the payments are higher and it is not possible to capture all of them in this guide. The coding and billing of these services should be universal. Providers should talk directly with their primary private insurers to understand any unique payment circumstances.

Medicare and Private Payer Coverage

HCPCS and CPT™ coding is universal, however, coverage of medical and surgical services can vary widely among government (Medicare, Medicaid, TRICARE) and private health insurance companies. The procedures described in this Reimbursement Guide are widely covered by third party insurers. Physicians and hospitals, though, are advised to inquire of their major third party payers for any specific coverage protocols or requirements.
**PalinGen Membrane** is a multipurpose, chorion-free cryopreserved amniotic membrane licensed and owned by Amnio Technology, Inc. **PalinGen** is effective in the following clinical applications:

- **Orthopedic Surgery** for the augmentation of tendon, fasciae, ligament and capsule repair, injectable (PalinGen Flow) for use in synovial injuries, injured chondral surfaces, chronic tendinopathies, tendinosis and chronic fasciosis
- **Neuro Surgery** for chronic neuritis and pain
- **Spinal Surgery** for reducing scarring and fibrosis and the reduction of nerve entrapment
- **General Surgery** to reduce scar formation, adhesions and to augment tissue repair
- **Burn Treatment** as a topical wound therapy, anti-microbial, anti-inflammatory and to reduce scarring
- **Wound Care** as an intradermal peri-wound therapy for angiogenesis
- **Plastic Surgery** to reduce scarring, fibrosis and adhesion formation

**PalinGen** does not require fetal sacrifice; the amniotic material is obtained with maternal consent during Cesarian section following a medical prescreening to ensure health tissue.

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**Company Information**
Amnio Technology LLC, Phoenix, AZ is the global leader in developing and supporting research using amnion--derived technology. The company is focused on optimizing the regenerative potential of this unique allograft.

The information in this reimbursement guide is provided to assist hospitals and physicians in understanding the reimbursement process for services involving the use of **PalinGen Membrane**. Providers are responsible for all coding and billing decisions and we strongly recommend you consult your payer organizations with regard to local coverage and payment policies. The information contained in this document is provided for information purposes only and represents no guarantee concerning coverage or levels of payment. Similarly, all CPT™ and ICD-9 CM™ codes reflect consensus opinions of certified professional coders and are supplied for information purposes only. Nothing in this document should be viewed as instructions for selecting any particular code. The information contained herein represents different potential scenarios. Any clinical information contained herein beyond the FDA cleared product indications for use is intended to provide general information.

**Reimbursement Support Contact Information**
This 2015 Reimbursement Guide was created for the benefit of clinicians and hospitals. For providers with coding or payment questions related to this guide, please email info@Reimbursement-Strategies.com or call 651.337.8171. Any five-digit numeric codes, service descriptions, instructions or guidelines from the *Current Procedural Terminology® (CPT)* are copyright of the American Medical Association. The AMA assumes no responsibility for consequences attributable to or related to any use or interpretation of any information or views contained or not contained in this document.