Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

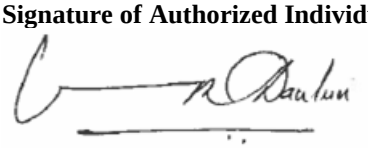
Plan: PA Health & Wellness	**Submission Date: 02/01/2023**
Policy Number: PA.CP.PHAR.562	**Effective Date: 01/2023** **Revision Date: 01/2023**
Policy Name: Allogeneic Cultured Keratinocytes and Dermal Fibroblasts in Murine Collagen-dsat (StrataGraft)	

Type of Submission – Check all that apply:

- ✓ **New Policy**
- ☐ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

Name of Authorized Individual (Please type or print): **Venkateswara R. Davuluri, MD**	**Signature of Authorized Individual:** 

Clinical Policy: Allogeneic Cultured Keratinocytes and Dermal Fibroblasts in Murine Collagen-dsat (StrataGraft)

Reference Number: PA.CP.PHAR.562
Effective Date: 01/2023
Last Review Date: 01/2023

Revision Log

Description
Allogeneic cultured keratinocytes and dermal fibroblasts in murine collagen-dsat (StrataGraft®) is an allogeneic cellularized scaffold product.

FDA Approved Indication(s)
StrataGraft is indicated for the treatment of adults with thermal burns containing intact dermal elements for which surgical intervention is clinically indicated (deep partial-thickness burns).

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of PA Health & Wellness® that StrataGraft is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Thermal Burns (must meet all)**:**

1. Diagnosis of deep partial-thickness thermal burns containing intact dermal elements;
2. Prescribed by or in consultation with a burn specialist;
3. Age ≥ 18 years;
4. Prescriber attestation that surgical intervention is clinically indicated;
5. Member is not allergic to products of bovine or porcine origin;
6. Request meets both of the following (a and b):
   a. Requested number of StrataGraft constructs does not exceed the size of the wound bed (*number of constructs may be rounded up to the nearest whole number*);
   b. Request is for a one-time application only.

Approval duration: 3 months (one time application only)

B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

II. Continued Therapy

A. Thermal Burns

1. Re-authorization is not permitted. Members must meet the initial approval criteria.

Approval duration: Not applicable

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – PA.CP.PMN.53.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): known allergies to murine collagen or products containing ingredients of bovine or porcine origin
- Boxed warning(s): none reported

Appendix D: General information

- Deep partial-thickness burns are complex skin injuries in which the damage extends through the entire epidermis (outermost layer of skin) and into the lower part of the dermis (innermost layer of skin).

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Thermal burns	• Apply topically to a surgically prepared wound bed. The number of StrataGraft constructs applied will vary depending on the size of the wound bed. StrataGraft constructs may be trimmed to accommodate the size and shape of the wound bed. It is not necessary to overlap the edges. Each StrataGraft construct is for application to a single patient only	Not applicable

VI. Product Availability

StrataGraft construct: off-white rectangular sheet of approximately 100 cm^2 (approximately 8 cm by 12.5 cm), consisting of a viable, bioengineered, allogeneic cellularized scaffold product derived from keratinocytes grown on gelled collagen containing dermal fibroblasts

VII. References

1. StrataGraft Prescribing Information. Madison, WI: Stratatech Corporation; June 2021. Available at: www.stratagraft.com. Accessed October 27, 2022.
2. Gibson ALF, Holmes JH, Shupp JW, et al. A phase 3, open-label, controlled, randomized, multicenter trial evaluating the efficacy and safety of StrataGraft construct in patients with deep partial-thickness thermal burns. Burns. 2021; 47: 1024-1037.
3. Holmes JH, Schurr MJ, King BT, et al. An open-label, prospective, randomized, controlled, multicenter, phase 1b study of StrataGraft skin tissue versus autografting in patients with deep partial-thickness thermal burns. Burns. 2019; 45: 1749-1758.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
Q4100	Skin substitute, not otherwise specified

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	01/2023	