Sample letter of medical necessity

A letter of medical necessity can be submitted to a health plan by a physician to demonstrate why a patient needs treatment with StrataGraft® (allogeneic cultured keratinocytes and dermal fibroblasts in murine collagen-dsat). The sample letter and checklist below include some information you may want to provide to the health plan.

The sample letter and checklist are provided for your consideration and reference only, and any letter of medical necessity should align to the appropriate patient's clinical records, treatment history, and medical needs as determined by the treating physician in their independent medical judgment. The sample letter and checklist do not represent any statement, promise, or guarantee, whether express or implied, by Mallinckrodt concerning coverage by any health plan or insurance plan.

Things to keep in mind when writing a letter of medical necessity

- Provide relevant information regarding your patient's diagnosis and medical history
- Describe the recommended treatment plan details
- Please note that variable information in the sample letter is identified with brackets; patient details should be updated as appropriate, and irrelevant fields should be removed

Checklist

Patient information

- ☐ Full name
- ☐ Date of birth
- ☐ Insurance ID
- ☐ Insurance group number
- ☐ Case ID number (if applicable)

Clinical rationale

- ☐ Patient's diagnosis and the Indication, such as an adult with thermal burns containing intact dermal elements for which surgical intervention is clinically indicated (deep partial-thickness burns), for the treatment being prescribed
- ☐ Patient's medical condition, including relevant data to demonstrate current condition
- ☐ Summary of the patient's pertinent medical history, including previous treatments/procedures for the condition
- ☐ The clinical rationale for StrataGraft treatment, including trial data supporting the FDA approval, administration, and procedural information, along with an explanation of how elimination of donor site wounds for autografting may lead to better patient outcomes

Additional enclosures

- ☐ Prescribing Information
- ☐ FDA approval information
- ☐ Clinical notes/medical records

INDICATION

StrataGraft® is an allogeneic cellularized scaffold product indicated for the treatment of adults with thermal burns containing intact dermal elements for which surgical intervention is clinically indicated (deep partial-thickness burns).

SELECT IMPORTANT SAFETY INFORMATION

Contraindications

- Do not use in patients with known allergies to murine collagen or products containing ingredients of bovine or porcine origin.

Please see additional Important Safety Information on page 2 and full Prescribing Information.

Sample letter of medical necessity

SELECT IMPORTANT SAFETY INFORMATION

Warnings and Precautions

- StrataGraft® (allogeneic cultured keratinocytes and dermal fibroblasts in murine collagen-dsat) contains glycerin. Avoid glycerin in patients with known sensitivity (irritant reaction) to glycerin.
- Severe hypersensitivity reactions may occur. Monitor for both early and late symptoms and signs of hypersensitivity reaction following StrataGraft application, and treat according to standard medical practice.
- StrataGraft contains cells from human donors and may transmit infectious diseases or infectious agents, eg, viruses, bacteria, or other pathogens, including the agent that causes transmissible spongiform encephalopathy (TSE, also known as Creutzfeldt-Jakob disease [CJD or variant CJD]).

  StrataGraft is a xenotransplantation product because of an historic exposure of the keratinocyte cells to well-characterized mouse cells. The cell banks have been tested and found to be free of detectable adventitious agents, and mouse cells are not used in the manufacture of StrataGraft; however, these measures do not entirely eliminate the risk of transmitting infectious diseases and disease agents.

  Transmission of infectious diseases or agents by StrataGraft has not been reported.
- Because StrataGraft is a xenotransplantation product, StrataGraft recipients should not donate whole blood, blood components, plasma, leukocytes, tissues, breast milk, ova, sperm, or other body parts for use in humans.

Adverse Reactions

- The most common adverse reactions (incidence ≥2%) were itching (pruritus), blisters, hypertrophic scar, and impaired healing. Other adverse events reported are included in the full Prescribing Information.

Pediatric Use

- The safety and effectiveness of StrataGraft in pediatric patients (<18 years) have not been established.

Please see additional Important Safety Information on page 1 and full Prescribing Information.

For more information, visit StrataGraft.com or call 1-877-647-2239 for additional support

Sample letter of medical necessity

[Treating physician's letterhead]

[Date]
[Payer name]
[Payer street address]
[Payer city, state, and zip code]

Patient name: [patient full name]
Date of birth: [patient birth date]
Member ID: [patient member ID number]
Policy or group number: [patient policy or group number]
Case ID number: [case ID number (if available)]

To whom it may concern,

I am writing on behalf of my patient, [patient full name], to provide information supporting medical necessity for treatment with StrataGraft® (allogeneic cultured keratinocytes and dermal fibroblasts in murine collagen-dsat). In this letter, I am providing my patient's medical history and diagnosis as well as a summary of their treatment plan. I have also provided a clinically based treatment rationale supporting the medical necessity for StrataGraft.

Patient's clinical/medical history

- [Patient's diagnosis (ICD-10-CM codes), date of diagnosis]
- [Patient's admission date and/or date of referral to burn center]
- [Detailed description and medical history necessitating the use of StrataGraft]
- [Additional factors affecting treatment selection]

Treatment plan

On June 15, 2021, the FDA approved StrataGraft for the treatment of adults with thermal burns containing intact dermal elements for which surgical intervention is clinically indicated (deep partial-thickness burns).

- [Include plan of treatment (eg, procedure, anticipated outcomes)]
- [Provide a clinical rationale for the prescription of StrataGraft]

Summary

Based on the provided explanation, I believe that StrataGraft is medically necessary for [patient full name]. Please find enclosed additional documents, including [list any attachments, such as relevant peer-reviewed literature and clinical practice guidelines], that support my clinical decision. Please contact my office at [phone number] if any additional information is needed.

Sincerely,
[Physician name]
[Physician address]
[Physician phone]

Enclosures: [List any applicable enclosures, such as Prescribing Information, clinical notes/medical records, diagnostic test results, relevant peer-reviewed articles, clinical practice guidelines, FDA approval letter, etc]

StrataGraft®
allogeneic cultured keratinocytes and dermal fibroblasts in murine collagen - dsat