We heal and inspire the human spirit.

To: All IPAs

From: IEHP – UM

Date: November 13, 2024

Subject: **Update: Clinical Criteria for UM Decisions and Skin Substitute Documentation Requirements + Attachment**

We have executed a Master Service and License Agreement with Simplr for Hayes Evidence Analysis Software. Hayes, established in 1989, provides real-time clinical evidence research and services designed to inform better, faster and more defensible evidence-based decisions.

We will be implementing an **update to the Clinical Criteria for Utilization Management Decisions**. Hayes Clinical Evidence will be added to the hierarchy.

IEHP and its Delegates shall ensure consistent application of UM criteria by following this specific order:

1. IEHP Member Handbook (Evidence of Coverage); **then**
2. DHCS Medi-Cal Provider Manual **or** Title 22 of California Code of Regulations (CCR); **then**
3. National Comprehensive Cancer Network (NCCN) Drug and Biologics Compendium **or** IBM Watson Health Products: Micromedex; **then**
4. MCG Health Informed Care Strategies Care Guidelines; **then**
5. InterQual Criteria; **then**
6. World Professional Association for Transgender Health standards of care; **then**
7. Hayes Clinical Evidence; **then**
8. Apollo Medical Review Criteria Guidelines for Managing Care; **then**
9. IEHP Utilization Management (UM) Subcommittee Approved Authorization Guidelines **or** Pharmacy and Therapeutics (P&T) Subcommittee Approved Prior Authorization Criteria.

The following policies will be updated to include Hayes Clinical Evidence:

- MC_14A Delegation and Monitoring
- MA_14A Utilization Management – Delegation and Monitoring
- CCA_09A Delegation and Monitoring
- CCA_17F Utilization Management Program Description

IEHP will be reaching out to you the week of November 11 to set up an account with Hayes.

If you are an individual who will have an account created, you will receive a Microsoft Teams invite for a training session that will be held on November 25, 2024 from 3:00-4:00pm.

The implementation date of the new hierarchy shall be effective by January 1, 2025 for all IPA partners.

In addition, we are sending communication to all PCPs and Specialists to request documentation for Skin Substitute authorization requests and encourage IPAs to require the same documentation requirements.

Skin Substitute Documentation Requirements[1]

1. All documentation must be maintained in the patient's medical record and made available to the plan upon request.

2. Every page of the record must be legible and include appropriate patient identification information (e.g., complete name, dates of service[s]). The documentation must include the legible signature of the physician or non-physician practitioner responsible for and providing the care to the patient.

3. Medical record documentation must support the medical necessity of the services as stated in this policy.

4. The documentation must support that the service was performed and must be included in the patient's medical record. This information is normally found in the history and physical, office/progress notes, hospital notes, and/or procedure report.

5. The medical record must clearly show that the criteria listed in the relevant policy have been met, as well as the appropriate diagnosis and response to treatment.

6. The documentation must support the need for skin substitute application and the product used.

7. A description of the wound(s) must be documented at baseline (prior to beginning conservative treatment) relative to size, location, stage, duration, and presence of infection, in addition to type of treatment given and response.
    a. This information must be updated in the medical record throughout treatment.
    b. Wound description must also be documented pre and post treatment with the skin substitute graft being used. Photographs to substantiate wound description may be required by the contractor. High-definition photographs of sufficient quality may be required to substantiate the wound description.
    c. If obvious signs of worsening or lack of treatment response is noted, continuing treatment with the skin substitute would not be considered medically reasonable and necessary without documentation of a reasonable rationale for doing so.

8. Documentation of smoking history, and that the patient has received counseling on the effects of smoking on surgical outcomes and treatment for smoking cessation (if applicable) as well as outcome of counselling must be in the medical record.

9. The amount of utilized and wasted skin substitute must be clearly documented in the procedure note with the following minimum information:
    a. Date, time and location of ulcer treated;
    b. Name of skin substitute and how product supplied;
    c. Amount of product unit used;
    d. Amount of product unity discarded;
    e. Reason for wastage
    f. Manufacturer's serial/lot/batch or other unit identification number of graft material. When manufacturer does not supply unit identification, record must document such

If you have any questions, please contact Juan Ortega Ortega-J2@iehp.org or Jessica Gonzalez Gonzalez-J6@iehp.org

All IEHP communications can be found at: www.providerservices.iehp.org > News and Updates > Notices

[1] Centers for Medicare & Medicaid Services (CMS), LCD - Application of Bioengineered Skin Substitutes to Lower Extremity Chronic Non-Healing Wounds (L35041) (cms.gov), September 29, 2023

Inland Empire Health Plan

Required Documentation for Skin Substitutes

Please ensure the following documentation requirements in Members' medical record when submitting an authorization request for Skin Substitutes:

1. All documentation must be maintained in the Member's medical record and made available to the contractor upon request.

2. Every page of the record must be legible and include appropriate Member's identification information (e.g., complete name, dates of service[s]). The documentation must include the legible signature of the physician or non-physician practitioner responsible for and providing the care to the Members.

3. Medical record documentation must support the medical necessity of the services as stated in this policy.

4. The documentation must support that the service was performed and must be included in the Member's medical record. This information is normally found in the history and physical, office/progress notes, hospital notes, and/or procedure report.

5. The medical record must clearly show that the criteria listed under the Covered Indications and Limitations sections have been met, as well as the appropriate diagnosis and response to treatment.

6. The documentation must support the need for skin substitute application and the product used.

Please provide a response to the following questions:

1. Description of the wound(s):
2. Baseline size of the wound (prior to beginning conservative treatment):
3. Wound location:
4. Stage:
5. Duration:
6. Presence of infection:
    a. Yes / No
7. Type of treatment given:
8. Is there a photo on the wound provided:
    a. Yes / No

Amount of utilized and wasted skin substitute:

1. Date ulcer was treated:
2. Time ulcer was treated:
3. Location of ulcer treated:
4. Amount of product unit used:
5. Amount of product unity discarded:
6. Reason for wastage:
7. Manufacturer's serial/lot/batch or other unit identification number of graft material *(when manufacturer does not supply unit identification, please document 'N/A')*