**Bioengineered Skin and Soft Tissue Substitutes**

**Policy Number: 7.01.113**

**Effective Date: March 1, 2019**

| **Patient Name:** askdfjasdflkjasdfkljalkjsdf | **CLQ System ID:** | | **Sub ID #:** |
| --- | --- | --- | --- |
| **Policy Title:** | **Bioengineered Skin and Soft Tissue Substitutes**  **Billed Descriptor or Procedure for review:** **ALLOMEND** | | |
| **Effective Date:** | **March 1, 2019** | | |
| **MD Determination:** | | APPROVE  MODIFY DENY  UPHOLD  **(Explanation for MD if approved):** | |

***Not Medically Necessary* FACETS (AJW-claim, JLP-line)**

A Blue Shield of California Medical Director has reviewed the medical documentation sent and has determined the service is not medically necessary as established in Blue Shield of California Medical Policy.

***Investigational/Experimental* FACETS (AJK-claim, JHR-line)**

A Blue Shield of California Medical Director has determined that the service or item is identified in Blue Shield of California Medical Policy as investigational or experimental and therefore, is not covered.

A Blue Shield of California Medical Director has reviewed the submitted medical documentation and has determined the service is not a covered benefit per your Evidence of Coverage (EOC).

|  |  |  |  |
| --- | --- | --- | --- |
| **Policy Name or Drug Name** | **Subcategory** | **Type of Denial** | **Rationale for Subcategory** |

|  |  |  |  |
| --- | --- | --- | --- |
| Bioengineered Skin and Soft Tissue Substitutes | IE - Reconstructive breast surgery | **I & E**  **Med Nec**  **Benefit** | A request has been made for coverage of , which is a man-made (bioengineered) skin or tissue product. This is to be used to make your breast appear more normal after breast cancer treatment (reconstructive breast surgery). After a review of the medical records sent in, we cannot approve this for payment. There are not enough quality medical studies showing better results or safety than standard treatments for your medical problem, which are covered. Please talk to your doctor to see if one of the Blue Shield of California preferred bioengineered products listed below is suitable for your medical problem.  For use in reconstructive breast surgery, Blue Shield of California covers the following bioengineered products when medically necessary:   * AlloDerm® * AlloMend® * Cortiva® [AlloMax™] * DermACELL™ * DermaMatrix™ * FlexHD® * FlexHD® Pliable™ * Graftjacket® |
| Bioengineered Skin and Soft Tissue Substitutes | IE - Diabetic lower-extremity ulcers | **I & E**  **Med Nec**  **Benefit** | A request has been made for coverage of , which is a man-made (bioengineered) skin or tissue product. This is to be used for treating your leg sores (ulcers) caused by high sugar in your blood (diabetes). After a review of the medical records sent in, we cannot approve this for payment. There are not enough quality medical studies showing better results or safety than standard treatments for your medical problem, which are covered. Please talk to your doctor to see if one of the Blue Shield of California preferred bioengineered products listed below is suitable for your medical problem.  To treat diabetic leg ulcers, Blue Shield of California covers the following bioengineered products when medically necessary:   * AlloPatch® * Apligraf® * Dermagraft® * Integra® Omnigraft™ Dermal Regeneration Matrix (also known as Omnigraft™) and Integra Flowable Wound Matrix |
| Bioengineered Skin and Soft Tissue Substitutes | IE - Venous insufficiency lower-extremity ulcers | **I & E**  **Med Nec**  **Benefit** | A request has been made for coverage of , which is a man-made (bioengineered) skin or tissue product. This is to be used for treating your leg sores (ulcers) caused by poor blood flow in your veins (venous insufficiency). After a review of the medical records sent in, we cannot approve this for payment. There are not enough quality medical studies showing better results or safety than standard treatments for your medical problem, which are covered. Please talk to your doctor to see if one of the Blue Shield of California preferred bioengineered products listed below is suitable for your medical problem.  To treat leg ulcers due to venous insufficiency, Blue Shield of California covers the following bioengineered products when medically necessary:   * Apligraf® * Oasis™ Wound Matrix |
| Bioengineered Skin and Soft Tissue Substitutes | IE - Dystrophic epidermolysis bullosa | **I & E**  **Med Nec**  **Benefit** | A request has been made for coverage of , which is a man-made (bioengineered) skin or tissue product. This is to be used for treating your skin that blisters easily (dystrophic epidermolysis bullosa). After a review of the medical records sent in, we cannot approve this for payment. There are not enough quality medical studies showing better results or safety than standard treatments for your medical problem, which are covered. Please talk to your doctor to see if the Blue Shield of California preferred bioengineered product listed below is suitable for your medical problem.  To treat dystrophic epidermolysis bullosa, Blue Shield of California covers the following bioengineered product when medically necessary:   * OrCel™ |
| Bioengineered Skin and Soft Tissue Substitutes | IE - Second and third-degree burns | **I & E**  **Med Nec**  **Benefit** | A request has been made for coverage of , which is a man-made (bioengineered) skin or tissue product. This is to be used for treating severe burns (second or third-degree). After a review of the medical records sent in, we cannot approve this for payment. There are not enough quality medical studies showing better results or safety than standard treatments for your medical problem, which are covered. Please talk to your doctor to see if one of the Blue Shield of California preferred bioengineered products listed below is suitable for your medical problem.  To treat second- or third-degree burns, Blue Shield of California covers the following bioengineered products when medically necessary:   * Epicel® * Integra Dermal Regeneration Template™ |
| Bioengineered Skin and Soft Tissue Substitutes | IE - Non-approved indication | **I & E**  **Med Nec**  **Benefit** | A request has been made for coverage of , which is a man-made (bioengineered) skin or tissue product for . After a review of the medical records sent in, we cannot approve this for payment. There are not enough quality medical studies showing better results or safety than standard treatments for your medical problem, which are covered. |