COVERAGE ACCESS GUIDE

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Prepared by Musculoskeletal Clinical Regulatory Advisers, LLC. Ver. 1/19 (V2). ***Disclaimer: The information is for educational purposes only and should not be construed as authoritative. The information is current as of Jan. 2019 and is based upon publicly available source information. Codes and values are subject to frequent change without notice. The entity billing Medicare and/or third party payors is solely responsible for the accuracy of the codes assigned to the services or items in the medical record. When making coding decisions, we encourage you to seek input from the AMA, relevant medical societies, CMS, your local Medicare Administrative Contractor and other health plans to which you submit claims. Items and services that are billed to payors must be medically necessary and supported by appropriate documentation. It is important to remember that while a code may exist describing certain procedures and/or technologies, it does not guarantee payment by the payors.***

Coverage Access Process

Benefits Verification

The initial step in the Coverage Access Process is to perform a Benefits Verification or Benefits Investigation. The goal is to verify both insurance coverage and the covered member's benefits. The following information should be obtained and documented:

- ✓ Insurance coverage effective dates
- ✓ In-Network or out of network coverage
- ✓ Is the service(s) you're seeing the patient for covered?
- ✓ Is pre-authorization for the service(s) required (if a pre-authorization is not required, can a voluntary pre-determination of benefits be requested?)
- ✓ Is a referral from a primary care physician required?
- ✓ Amount of co-pay or deductible for the services, if any
- ✓ Whether the deductible amount has been met

Pre-Authorization/Pre Determination Request

In order to facilitate coverage access for a proposed procedure, the physician may request a pre-authorization from the patient's private insurance carrier. Some health plans require pre-authorization for all surgical procedures. Requesting pre-authorization may only involve a simple contact by the physician's office to verify benefits and acquire an approval number to submit with the claim. Alternatively, pre-authorization may require that the physician provide more substantive information about the case. In the event a payor does not provide pre-authorization, a request for pre-determination can be requested using the same process.

To prepare a pre-authorization request that requires additional information beyond basic coding, the physician's staff must provide technical information about the procedure and the unique technology involved. The treating physician must also establish the medical necessity for the procedure as it applies to the specific patient.

Typically the pre-authorization process and/or appeal process may require submitting some or all of the following documentation:

- ✓ Patient clinical notes, including documentation of prior conservative care;
- ✓ Supportive technical information in the form of the FDA product approval letter, peer-reviewed clinical literature, clinical trial information and other available technical resources;
- ✓ Description of the technology and its use in this patient's case; and
- ✓ Description of medical necessity of the procedure for the specific patient.

Stages of the Pre-Authorization Process:

Initiate Pre-Authorization

- Verify benefits and submit clinical information and literature on product.

Peer to Peer

- Opportunity for the treating physician to discuss the medical necessity of the case with a Medical Director at the health plan.

1st Level Appeal

- Expedited/Standard - Opportunity to request a Medical Director that did not review the initial submission. There may be one or two levels of internal appeals.

2nd Level Appeal

- Expedited/Standard - Opportunity to request a Medical Director that did not review the initial submission as well as the peer to peer.

External Appeal

- Following appeal denial at all available internal levels, the patient should pursue an External Appeal with the applicable State Department of Insurance.

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Advanced Decellularized Dermis

Pre-Authorization Denial Appeal

When a third party health plan denies a procedure in accordance with their medical policy guidelines, there is a process available to appeal that decision. Insurance carriers provide this check and balance to allow for reconsideration of the decision per their plan provisions and applicable state regulations. The process will vary depending on the plan and regulatory requirements, however, there are basic steps that can assist the provider in appealing the initial denial.

To present an effective appeal, follow these steps:

1. Carefully review the denial reason and understand the specific health plan's policy;
2. Write an appeal letter clearly addressing the specific denial reasons;
3. Provide supporting information including product details and FDA clearance; and
4. Submit the appeal on time.

The following additional considerations may be helpful:

1. If the health plan is self-funded (employer based), patients can contact their Human Resources (HR) department to assist in the patient's appeal of the decision. HR departments may have contacts within the health plan that can provide helpful support.

2. The patient can contact the health plan directly. As the policy-holder the patient may have an influence on the decision.

3. There are multiple steps in the appeal process and providers and patients may exercise these rights according to their third party payor and state guidelines.

Providers, please note: *Despite the filing of a pre-authorization request or writing a letter of medical necessity, certain commercial health plans may still elect not to cover or grant pre-authorization for this procedure without further information and clinical evidence supporting its use. Should pre-authorization be denied, the physician requesting coverage should immediately file a written appeal with the health plan and request reconsideration of the coverage decision. When requesting a pre-authorization or denial appeal it is important to remember that payors may require all elements of a procedure to be pre- authorized per their payor guidelines.*

Writing an Appeal Letter

When appealing a denial, the first step is often composing a letter to the health plan that initially reviewed the case. This letter is submitted by the provider on behalf of the patient, with the patient's approval, and should outline the reasons the denial should be overturned.

Detailed information regarding the denial reason should be prepared utilizing the case specific information in the denial, as well as the more general technology specific information and supporting clinical literature.

First, collect all the information required to support the appeal:

- ✓ Denial letter
- ✓ Health plan contracts and provider agreements
- ✓ Applicable medical policy guidelines from the health plan (website access is often a good resource for general policy)
- ✓ Literature supporting the technology
- ✓ FDA establishment registration letter
- ✓ Safety and effectiveness documentation
- ✓ Peer-reviewed literature references

In drafting an appeal letter, consider the following:

- ✓ Did the reviewer miss information about the technology?
- ✓ Did the reviewer overlook a case specific detail?
- ✓ Does the health plan clearly understand the procedure?
- ✓ Was the information provided about the case correctly submitted?
- ✓ Review the plan's official policy online for more detailed understanding of the denial reason

Be mindful of details, including:

- ✓ Patient's name
- ✓ Subscriber's name
- ✓ Policy number
- ✓ Description of exact service denied
- ✓ Date denied

Post-Claim Denial Appeal

Understanding the Appeal Process

Each health plan has an appeal process, however, the general steps are the same: **Internal appeal** (meaning it is appealed directly with the health plan for internal initial resolution), and **External Review**. Internal appeals must occur within a specified time frame as defined by each plan's policies. Health plans must inform patients why their claim was denied and inform them of their rights to an internal appeal, and an external review if the internal appeal upholds the initial claim denial, as well as the availability of a Consumer Assistance Program (CAP) if the patient's state has one. To find out if your patient's state has a CAP, please see: https://www.cms.gov/CCIIO/Resources/Consumer-Assistance-Grants/

First level internal appeal letters should be mailed certified with return receipt requested and addressed to the Appeals Analyst referenced in the denial letter as well as the Director of Claims.

Patients have the right to take their appeal to an independent third party for review, called **External Review.** At this stage, the insurance company no longer makes the final determination as to whether to pay a claim. For more information on how to appeal an insurance company decision, see https://www.healthcare.gov/appeal-insurance-company-decision/appeals/

General Tips:

- Use an appeal letter when reimbursement for a claim is denied
- The appeal letter should come from a treating physician and should be signed by **both** the physician and patient when required
- Refer to the ICD-10 Coding Guidelines regarding certain codes that may be applicable to the patient's diagnosis

Common Reasons for Claims Denials:

1. Not Medically Necessary – the medical provider, and perhaps other medical experts, must provide written documentation explaining why
2. Experimental – experimental treatment may be covered if the medical provider can prove
    a. Medical necessity and considered the standard of care by the medical community
    b. The only or best treatment alternative (showing what was already tried)
    c. More cost effective than the standard treatment
    d. May have been covered by the plan in the past for other patients with the same medical condition

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Sample Template Letters

The following sample letters are not intended to be used for direct submission for case pre-authorizations, pre-authorization denials, special reporting for use with unlisted codes or for post-claim denial appeals. Use of any information contained in these sample letters/templates does not guarantee that the health plan will provide reimbursement and is not intended to be a substitute for or an influence on the independent medical judgement of the physician.

The template and the information provided herein are intended to provide context for the procedure and related coding. Providers should select the procedure, diagnosis, and technology coding that best represents each patient's medical condition and treatment and should reflect the services and products that are medically necessary for the treatment of that patient. Providers must ensure that all statements made to insurance carriers are true and correct.

The following templates/sample letters are included:

1. Pre-Authorization Request
2. Pre-Authorization Denial Appeal
3. Post-Claim Denial Appeal

Physicians should be mindful of the inappropriate use of template documents in place of case-specific language and description of actual procedures performed. Any letters or templates provided are intended to serve as examples of how the submission might be formatted to provide a clear and concise explanation of the actual procedure to be performed and the detail necessary to depict the technology in regard to the patient-specific medical necessity of the procedure as supported with clinical data and case documentation.

Disclaimer: *This information is for educational/informational purposes only and should not be construed as authoritative. The information presented here is current as of January 2019 and is based upon publicly available source information. Codes and values are subject to frequent change without notice. The entity billing Medicare and/or third party payors is solely responsible for the accuracy of the codes assigned to the services or items in the medical record. When making coding decisions, we encourage you to seek input from the AMA, relevant medical societies, CMS, your local Medicare Administrative Contractor and other health plans to which you submit claims. Items and services that are billed to payors must be medically necessary and supported by appropriate documentation. It is important to remember that while a code may exist describing certain procedures and/or technologies, it does not guarantee payment by payors.*

LIFENET HEALTH - Dermacell AWM® PRE-AUTHORIZATION/LETTER OF MEDICAL NECESSITY

[Site Letterhead]

[DATE]
[NAME OF HEALTH PLAN]
[ADDRESS]
[CITY, STATE, ZIP]
Re: Request for Prior Authorization for **[Dermacell AWM® SKIN SUBSTITUTE GRAFT]**
Patient: **[PATIENT NAME]**
Group/policy number: **[NUMBER]**
Diagnosis: **[CODE & DESCRIPTION]**
Procedure/CPT: **[CODE(S)]**

Dear Utilization Manager:

I am writing on behalf of my patient, **[PATIENT NAME]**, to request prior authorization for the use of **[Dermacell AWM® SKIN SUBSTITUTE GRAFT]** for the treatment of **[INDICATION]**.

Dermacell AWM® is regulated by the U.S. Food and Drug Administration (FDA) as a human skin tissue under its Human Cells, Tissues, and Tissue-Based Products (HCT/P) guidelines, subject to Section 361 of the Public Health Service Act and 21 CFR 1270 and 1271.

Information related to the patient's medical history, prognosis and treatment rationale are summarized below:

[Insert a narrative of the patient's medical history, including: Patient's diagnosis, significant contributory co-morbidities, condition, and treatment history; Previous therapies the patient has undergone for the disease symptoms; Patient's response to past tried and failed therapies including frequency and duration; Brief description of the patient's recent symptoms and conditions, functional impairments]

[Summarize your professional opinion of the patient's likely prognosis or disease progression without treatment with [Dermacell® AWM].

Given **[PATIENT NAME]**'s medical history and the indication for **[Dermacell AWM®]**, I am confident that you will agree that the **[Dermacell AWM®]** is medically necessary for my patient. Please do not hesitate to contact me at **[PHYSICIAN'S TELEPHONE NUMBER]** if you require any further information to approve this request.

Dermacell AWM® is a technologically advanced human acellular dermal matrix. Dermacell AWM® is decellularized using Matracell®, proprietary, patented and validated processing technology that removes cells 97% of donor DNA without compromising the desired biomechanical or biochemical properties of the graft and allowing for rapid cellular infiltration and re-vascularization.

Key features and benefits of **[Dermacell AWM®]:**

- **Dermacell AWM®** demonstrates significantly greater wound healing, larger wound area reduction, and a better capability of keeping healed wounds closed than conventional care in treatment of chronic DFUs. **(Cazzell, 2017)**
- At 16 weeks, **Dermacell AWM®** arm had a significantly higher proportion of completely healed ulcers than the conventional care arm (67.9% vs 48.1%; *P* = .0385) **(Walters, 2016)**

The following evidence will assist you in your evaluation of the technology and indications for **[Dermacell AWM®]**

Peer-reviewed clinical literature:

- Cazzell S, Vayser D, Pham H, Walters J, Reyzelman A, Samsell B, Dorsch K, Moore M. A randomized clinical trial of a human acellular dermal matrix demonstrated superior healing rates for chronic diabetic foot ulcers over conventional care and an active acellular dermal matrix comparator. Wound Repair Regen. 2017 May;25(3):483-497. doi: 10.1111/wrr.12551. Epub 2017 Jun 12.
- Walters, J., Cazzell, S., Pham, H., Vayser, D., & Reyzelman, A. (2016). Healing Rates in a Multicenter Assessment of a Sterile, Room Temperature, Acellular Dermal Matrix Versus Conventional Care Wound Management and an Active Comparator in the Treatment of Full-Thickness Diabetic Foot Ulcers. *Eplasty*, *16*, e10.
- Cole W. DermACELL: Human Acellular Dermal Matrix Allograft A Case Report. J Am Podiatr Med Assoc. 2013; Mar, 106(2):133-7.

Sincerely,

Signature Treating Physician **[PROVIDER NAME] [DEGREE]** **[PROVIDER IDENTIFICATION NUMBER]**

LIFENET HEALTH - Dermacell AWM® - PRE-AUTHORIZATION DENIAL APPEAL LETTER

[Site Letterhead]

[DATE]
[NAME OF HEALTH PLAN]
[ADDRESS]
[CITY, STATE, ZIP]
Re: Request for Prior Authorization for **[Dermacell AWM® SKIN SUBSTITUTE GRAFT]**
Patient: **[PATIENT NAME]**
Group/policy number: **[NUMBER]**
Diagnosis: **[CODE & DESCRIPTION]**
Procedure/CPT: **[CODE(S)]**

Dear Utilization Manager:

I am writing on behalf of my patient, **[PATIENT NAME]**, to appeal **[HEALTH PLAN NAME]** denial for prior authorization for the use of **[Dermacell AWM®]** for the treatment of **[INDICATION]** given on **[DATE]** because of **[STATE REASON GIVEN IN DENIAL LETTER FOLLOWED BY SUPPORTIVE RATIONALE TO ADDRESS THE DENIAL REASON IF SPECIFIC REASON GIVEN BY PROVIDING CORROBORATING EVIDENCE OR DOCUMENTATION)**.

Since **[DATE OF ONSET]**, **[PATIENT NAME]** has been under my care for **[LIST PERTINENT DIAGNOSES AND INDICATIONS APPROVED FOR/CLEAREDFOR DEVICE USE]**.

Patient's Clinical Need for the Procedure: **[PATIENT NAME]** is a **[AGE] [GENDER]** who presented to me with **[DESCRIBE SYMPTOMS WITH SPECIFICITY]. [DESCRIBE REASON FOR PROCEDURE]**.

[Insert a narrative of the patient's medical history, including: Patient's diagnosis, significant contributory co-morbidities, condition, and treatment history; Previous therapies the patient has undergone for the disease symptoms; Patient's response to past tried and failed therapies including frequency and duration; Brief description of the patient's recent symptoms and conditions, functional impairments]

[Summarize your professional opinion of the patient's likely prognosis or disease progression without treatment with [Dermacell AWM®].

In a discussion with **[INSERT MR/MS]** following an exam, a decision was made to move forward with **[INSERT PROCEDURE]** with the application of **[Dermacell AWM®]**. Please call me at **[PROVIDER'S PHONE NUMBER]** if you require additional information.

Dermacell AWM® is a technologically advanced human acellular dermal matrix. Dermacell AWM® is decellularized using Matracell®, proprietary, patented and validated processing technology that removes cells 97% of donor DNA without compromising the desired biomechanical or biochemical properties of the graft and allowing for rapid cellular infiltration and re-vascularization.

Key features and benefits of **[Dermacell AWM®]**:

- **Dermacell AWM®** demonstrates significantly greater wound healing, larger wound area reduction, and a better capability of keeping healed wounds closed than conventional care in treatment of chronic DFUs. **(Cazzell, 2017)**
- At 16 weeks, **Dermacell AWM®** arm had a significantly higher proportion of completely healed ulcers than the conventional care arm (67.9% vs 48.1%; *P* = .0385) **(Walters, 2016)**

The following evidence will assist you in your evaluation of the technology and indications for **[Dermacell AWM®]**

Peer-reviewed clinical literature:

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- Cole W. DermACELL: Human Acellular Dermal Matrix Allograft A Case Report. *J Am Podiatr Med Assoc.* 2013; Mar, 106(2):133-7. Access at: https://www.ncbi.nlm.nih.gov/pubmed/27031550

- Walters J, Cazzell S. Healing Rates in a Multicenter Assessment of a Sterile, Room Temperature, Acellular Dermal Matrix Versus Conventional Care Wound Management and an Active Comparator in the Treatment of Full-Thickness Diabetic Foot Ulcers. *Open Access Journal of Plastic Surgery.* 2016; 16: e10.
  Access at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4750365/

- Cole W, Samsell B. Biological Incorporation of Human Acellular Dermal Matrix used in Achilles Tendon Repair. *Cell and Tissue Banking.* 2017; Volume 178, Issue 3, pp 403-411.
  Access at: https://link.springer.com/article/10.1007/s10561-017-9628-3

- Cornwell KG, Landsman A. Extracellular Matrix Biomaterials for Soft Tissue Repair. *Clin Podiatr Med Surg.* 2009; Oct; 26(4): 507-23.
  Access at: https://www.ncbi.nlm.nih.gov/pubmed/19778685

- Capito A, Tholpady S. Evaluation of Host Tissue Integration, Revascularization, and Cellular Infiltration within Various Dermal Substrates. *Annals of Plastic Surgery.* 2012; 68(5): 495-500.
  Access at: https://www.ncbi.nlm.nih.gov/pubmed/22531405

- Yonehiro L. Use of new acellular dermal matrix for treatment of non-healing wounds in the lower extremities of patients and diabetes. *Wounds.* 2013; 25(12):340-4.
  Access at: https://www.ncbi.nlm.nih.gov/pubmed/25867746

- Bertasi G. Case study: Treatment of Diabetic Foot Ulcer with Human Acellular Dermal Matrix (ADM). 68-20-108.
  Access at: https://www.lifenethealth.org/sites/default/files/files/68-20-143%282%29.pdf

- Buchbaum EJ. Case study: Treatment of Plantar Diabetic Ulcer with Human Acellular Dermal Matrix. (ADM).
  Access at: https://www.lifenethealth.org/sites/default/files/files/68-20-143%282%29.pdf

Sincerely,

[Treating Physician Signature]
[PROVIDER NAME] [DEGREE]
[PROVIDER IDENTIFICATION NUMBER]

[Patient/Legal representative Signature]
[PATIENT/LEGAL REPRESENTATIVE NAME]

Enclosures:
Appeal Form (if provided by plan)
Chart notes including test results

LIFENET HEALTH - Dermacell AWM® – POST-CLAIM DENIAL APPEAL LETTER

[Site Letterhead]

[DATE]
[NAME OF INSURANCE COMPANY]
[ATTN:]
[FAX #: AND/OR ADDRESS]

RE: **[PATIENT NAME]** **[INSURANCE IDENTIFICATION NUMBER]**
[PRIOR AUTH OR REFERENCE #:] **[PRIMARY CPT CODE:]**
[PRIMARY DX:] **[CLAIM NUMBER:]**
[DATE OF SERVICE:]

Dear Director of Claims:

I am writing on behalf of my patient, **[PATIENT FULL NAME]**, to request reconsideration of coverage for **[PRIMARY PROCEDURE]** and the application of **[Dermacell AWM®]**, which was performed on **[DATE(S) OF SERVICE]**. Reimbursement was **[DENIED]** because **[STATE REASON GIVEN IN DENIAL LETTER]** as indicated in the enclosed letter dated **[INSERT DENIAL LETTER DATE]**. I will explain why this claim should be reimbursed and **[PROCEDURE WITH Dermacell AWM®]** fully covered for **[PATIENT FULL NAME]**. I have included information about my patient's medical history and diagnosis **[INSERT ICD-10 CODE]**, a statement summarizing my treatment rationale, and other documents that support the medical necessity of **[Dermacell AWM®]** in this clinical case.

Since **[DATE OF ONSET]**, **[PATIENT FULL NAME]** has been under my care for **[INSERT ALL PERTINENT DIAGNOSIS RELATED TO PROCEDURE AND APPLICATION OF Dermacell AWM®]**. Below is a summary of the patient's history:

[TREATMENT HISTORY] [RESPONSE TO PAST THERAPIES] [RECENT SYMPTOMS AND CONDITION]
[SUMMARIZE YOUR PROFESSIONAL OPINION OF THE PATIENT'S LIKELY PROGNOSIS OR DISEASE PROGRESSION WITH AND WITHOUT TREATMENT WITH Dermacell AWM®]

Based on the patient's clinical condition and review of the supporting documentation, I am confident that you will agree that **[Dermacell AWM®]** which is appropriately indicated for this condition and for use in this procedure as an appropriate treatment option. In order for me to provide appropriate care for my patient, it is important that **[HEALTH PLAN NAME]** reimburse our claim and provide adequate coverage for **[Dermacell AWM®]** moving forward. I would appreciate prompt review of this case.

On behalf of **[PATIENT FULL NAME]**, we appreciate your reconsideration. Please call me at **[PHONE NUMBER]** if I can be of further assistance or if you require additional information. Thank you in advance for your immediate attention to this request.

Sincerely,

[TREATING PHYSICIAN'S SIGNATURE] **[PATIENT/LEGALREPRESENTATIVE SIGNATURE]**
[TREATING PHYSICIAN'S NAME, MD/DO] **[PATIENT/LEGALREPRESENTATIVE NAME]**

Enclosures **(suggested)**: **[APPEAL FORM] [TEST RESULTS] [PATIENT NARRATIVE] [OPERATIVE NOTES]**

Coverage Summaries

Skin Substitute Graft Procedures

The coverage landscape for Skin Substitute Graft Procedures varies by insurance carrier. Please review policies for all payors on a regular basis for updates and changes.

Coverage defines what medical technologies, services and procedures a health plan will reimburse, and generally varies by payor. Private health plans, as well as Medicare, may vary in their consideration of coverage for a particular technology or procedure. Further, the patient's individual benefit plan will delineate what items and services may be covered by the health plan.

Case by case pre-authorization approval should be considered following specific payor guidelines for the pre-authorization and appeal process.

Please check and confirm your insurer's specific medical policies and pre-authorization guidelines to help facilitate the attainment of coverage. It is the provider's and patient's responsibility to verify coverage based upon the patient's health plan and individual plan benefit.

Even where medical policies may deny separate reimbursement for specific Skin Substitute Grafts it may still be possible to obtain reimbursement on a case by case basis through utilization of the health plan's pre-authorization process.

General guidance regarding this pre-authorization process, including documentation required as well as instructions for handling subsequent denials and appeals, is provided in this Resource Guide. Pre-authorization signifies that the health plan has given a general approval of treatment for the patient before the procedure has actually occurred. Final approval and reimbursement is only given after claim submittal and at the time of adjudication by the health plan.

Documentation Support

Documentation of a patient's history, conservative therapies and reason for any service or procedure is the key to a positive reimbursement scenario. When a skin substitute graft procedure is indicated by the physician, the patient's medical record should clearly state the reason for the procedure as well as the outcomes and recommended therapies to follow. This documentation will support claim review and pre-authorization alike. Follow-up or staged procedures will depend on the initial documentation to support medical necessity. The following general documentation guidelines should be followed for all payors.

Clinical notes should contain the following details:

- ☐ Reason for the procedure based on physical exam
- ☐ All conservative therapies previously used in the treatment of the current disease
- ☐ Specific reason why this treatment is indicated for this patient
- ☐ Anticipated outcomes
- ☐ Recommended therapies or treatments

Operational and office visit notes might include the following:

- ☐ History of patient encounters including conservative therapies
- ☐ Current diagnosis or history of disease state
- ☐ Details of findings on exam
- ☐ Reason for procedure relevant to condition
- ☐ Usual details of procedure
- ☐ Explanation of technology specific to ***Dermacell AWM® Skin Substitute Graft***
- ☐ Findings and any anticipated further treatments

A letter of medical necessity (LMN) may be required for pre-authorization of a skin substitute graft procedure or for supporting documentation following a request for a claim review. Details of the LMN should include the items on the checklist above. An example LMN is provided in the previous section of this guide.

Supportive Clinical Literature

The following literature links may provide additional information about the use of Dermacell® acellular dermal matrix to support medical necessity.

- Walters J, Cazzell S. Healing Rates in a Multicenter Assessment of a Sterile, Room Temperature, Acellular Dermal Matrix Versus Conventional Care Wound Management and an Active Comparator in the Treatment of Full-Thickness Diabetic Foot Ulcers. *Open Access Journal of Plastic Surgery.* 2016; 16: e10.
  Access at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4750365/

- Cole W, Samsell B. Biological Incorporation of Human Acellular Dermal Matrix used in Achilles Tendon Repair. *Cell and Tissue Banking.* 2017; Volume 178, Issue 3, pp 403-411.
  Access at: https://link.springer.com/article/10.1007/s10561-017-9628-3

- Cole W. DermACELL: Human Acellular Dermal Matrix Allograft A Case Report. *J Am Podiatr Med Assoc.* 2013; Mar, 106(2):133-7.
  Access at: https://www.ncbi.nlm.nih.gov/pubmed/27031550

- Cornwell KG, Landsman A. Extracellular Matrix Biomaterials for Soft Tissue Repair. *Clin Podiatr Med Surg.* 2009; Oct; 26(4): 507-23.
  Access at: https://www.ncbi.nlm.nih.gov/pubmed/19778685

- Capito A, Tholpady S. Evaluation of Host Tissue Integration, Revascularization, and Cellular Infiltration within Various Dermal Substrates. *Annals of Plastic Surgery.* 2012; 68(5): 495-500.
  Access at: https://www.ncbi.nlm.nih.gov/pubmed/22531405

- Yonehiro L. Use of new acellular dermal matrix for treatment of non-healing wounds in the lower extremities of patients and diabetes. *Wounds.* 2013; 25(12):340-4.
  Access at: https://www.ncbi.nlm.nih.gov/pubmed/25867746

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  Access at: https://www.lifenethealth.org/sites/default/files/files/68-20-143%282%29.pdf

- Buchbaum EJ. Case study: Treatment of Plantar Diabetic Ulcer with Human Acellular Dermal Matrix. (ADM).
  Access at: https://www.lifenethealth.org/sites/default/files/files/68-20-143%282%29.pdf

- Cazzell S, Vayser D. A Randomized Clinical Trial of a Human Acellular Dermal Matrix Demonstrated Superior Healing Rates for Chronic Diabetic Foot Ulcers Over Conventional Care
  Access at: Access at: https://www.ncbi.nlm.nih.gov/pubmed/28544150

- Mulder G. Tissue Augmentation and Replacement of a Heel Fat Pad with a Decellularized Sterile Human Dermal Matrix. *Wounds.* 2012; 24(7):185-9.
  Access at: https://www.ncbi.nlm.nih.gov/pubmed/25874540

- Roussalis J. Novel Use of an Acellular Dermal Matrix Allograft to Treat a Chronic Scalp Wound with Bone Exposure: A case study. *Int J Burn Trauma.* 2014;4(2):49-52.
  Access at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4212880/

- Shitrit SB. Use of a Novel Acellular Dermal Matrix allograft to Treat Complex Trauma Wound: a case study. *Int J Burn Trauma.* 2014;4(2):62-5.
  Access at: https://www.ncbi.nlm.nih.gov/pubmed/25356372

- Cazzell S, Vayser D. A Multicenter, Randomized Study to Access a Sterile, Hydrated Acellular Dermal Matrix Versus Conventional Care Wound Management in Subjects with Venous Stasis Ulcers: A Interim Analysis. (CR-006) *SAWC* April 29-May 3, 2015.
  Access at: https://www.lifenethealth.org/sites/default/files/files/68-20-143%282%29.pdf

- Deanesi W. Case Report: Treatment of a Venous Leg Ulcer Using DermACELL®, a Human Acellular Dermal Matrix (ADM).
  Access at: https://www.lifenethealth.org/sites/default/files/files/68-20-143%282%29.pdf

- Chen SG, Tzeng YS. Case Report: Treatment of a Severe Burn with DermACELL®, an Acellular Dermal Matrix. *Int J Burn Trauma.* 2012;2(2):105-9.
  Access at: https://pdfs.semanticscholar.org/9911/283883f2cf5a2a22d0ecad80f43d35e21741.pdf

Coding & Reimbursement Support Call Center

To assist your office or facility, LifeNet Health, provides experienced coding assistance and Coverage Access© Services for ***Dermacell AWM® Skin Substitute Graft*** procedures through our consulting partner, Musculoskeletal Clinical Regulatory Advisers, LLC (MCRA).

The staff at MCRA is experienced in working with URAC Standards and Patient Protection and Affordable Care Act Criteria. They are available in real-time to assist with product specific coding options guidance.

MCRA's Certified Professional Coders are provided by LifeNet Health to assist you with the following:

- Answering questions related to CPT and ICD-10 codes
- Claim submission guidance
- Benefits Verification
- Pre-Authorization and Pre-Determination requests
- Pre-Authorization denial appeals

Professional Coders are available **Monday through Friday from 8:30 AM until 7:00 PM EST.**

Your dedicated **Dermacell AWM®– LifeNet Health**

Call Center phone number is:

866-562-6349

Please email the Support Call Center at:

DermACELL@mcra.com

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