As a contractor, TrailBlazer oversees LCD development and reconsideration. More information is available on the LCD Development Process and the steps involved in the LCD Reconsideration Process at these links.

Instructions for Accessing LCDs

Providers may submit questions or comments concerning Local Coverage Determinations via e-mail at policy@trailblazerhealth.com.

LCD/LM Article | Comment Summary | Additional Information | Add Comments/Feedback

Application of Bioengineered Skin Substitutes: Ulcers (of Lower Extremities) (DRAFT POLICY)

Search LCDs/LMRPs

Effective: 3/1/2008
Status: Draft Final

Revision Date: 11/30/2007

LCD Title

Application of Bioengineered Skin Substitutes: Ulcers (of Lower Extremities) - 4S-134AB

Contractor's Determination Number

4S-134AB (L26731)

Contractor Name

TrailBlazer Health Enterprises, LLC

Contractor Number

- 04001.
- 04002.

Contractor Type

- MAC – Part A.
- MAC – Part B.

AMA CPT / ADA CDT Copyright Statement

CMS National Coverage Policy

- *Medicare Benefit Policy Manual* – Pub. 100-02.
- *Medicare National Coverage Determinations Manual* – Pub. 100-03.
- *Medicare Claims Processing Manual* – Pub. 100-04, Chapter 17, Section 40.

- Correct Coding Initiative – *Medicare Contractor Beneficiary and Provider Communications Manual* – Pub. 100-09, Chapter 5.
- Social Security Act (Title XVIII) Standard References, Sections:
  - 1862(a)(1)(A) Medically Reasonable & Necessary.
  - 1862(a)(1)(D) Investigational or Experimental.
  - 1862(a)(6) Personal Comfort Items.
  - 1862(a)(10) Cosmetic Surgery.
  - 1833(e) Incomplete Claim.

Primary Geographic Jurisdiction

- CO – 04101.
- NM – 04201.
- OK – 04301.
- TX – 04401.
  - Indian Health Service.
  - End Stage Renal Disease (ESRD) facilities.
  - Skilled Nursing Facilities (SNFs).
  - Rural Health Clinics (RHCs).
- CO – 04102.
- NM – 04202.
- OK – 04302.
- TX – 04402.
  - Indian Health Service.

Secondary Geographic Jurisdiction

N/A

Oversight Region

- Region VI.

Original Determination Effective Date

03/01/2008

03/21/2008

06/13/2008

Original Determination Ending Date

N/A

Revision Effective Date

N/A

Revision Ending Date

N/A

Indications and Limitations of Coverage and/or Medical Necessity

Application of bioengineered skin substitutes will be covered when the following conditions are met and documented **as appropriate for the individual patient:**

- Presence of neuropathic diabetic foot ulcers for greater than four (4) weeks' duration.
- Presence of venous stasis ulcers of greater than three (3) months' duration that have failed to respond to documented conservative measures for greater than two (2) months' duration.
- Neuropathic diabetic foot ulcers that have failed to respond to documented conservative measures for greater than one (1) month's duration.
- Presence of partial or full-thickness ulcers.
- There **must** be measurements of the initial ulcer size, the size following cessation of conservative management and the size at the beginning of skin substitute treatment.
- For neuropathic diabetic foot ulcers, appropriate steps to off-load pressure during treatment must be taken.

In addition, the ulcer must be free of infection and underlying osteomyelitis. Following successful treatment of either of these underlying diseases/conditions, documentation must be provided to that effect prior to instituting skin substitute treatment.

Coverage and Frequency Limitations

- Use of the skin substitute is limited to three (3) separate applications to any given ulcer, or more **only** when utilized with adherence to specific FDA labeling instructions and criteria.
- Absent specific medical record documentation of the reasons for

more frequent application, there should be no fewer than two (2) weeks between applications for venous stasis ulcers and there should be no fewer than three (3) weeks between applications for neuropathic diabetic foot ulcers, except when more frequent applications are part of the FDA labeling instructions.

- For venous stasis ulcers, two (2) applications of the skin substitute are indicated, or more only if provided for in the FDA labeling. If after twelve (12) weeks of compression treatment and the appropriate number of applications of the skin substitute, a 50 percent or greater improvement is noted and documented, then one or more subsequent reapplications of the skin substitute will be considered for Medicare coverage. Otherwise, reapplication of the skin substitute is not recommended and will not be reimbursed, and other treatment modalities should be considered.
- For neuropathic diabetic foot ulcers, if after nine (9) weeks of treatment and three (3) applications of the skin substitute, satisfactory healing progress is not noted, then reapplication of the skin substitute is not recommended and other treatment modalities should be considered.
- Coverage will not be provided for any wound treatment that does not meet the definition of J7340, J7341 or J7342. All other such products, unless they are FDA-labeled for use in the types of ulcers considered in this LCD, will be considered to be, at most, “biologic wound dressings” and will be considered to be part of the relevant Evaluation and Management (E/M) service provided and not separately payable. Furthermore, even in those instances where the labeled indications include venous stasis or neuropathic diabetic ulcers, if the product is not biologically active as noted in the CPT descriptors for J7340, J7341 and J7342, J7347 and J7349 it will still be considered as not covered. As examples of such non-covered wound dressing products, Biovance™ (Biovance™ is described in its FDA-labeling as “wound covering”), Primatrix™ (J7349) and Integra®–(J7347)–are considered wound dressings, not skin substitutes, and are not separately payable by Medicare. Use of these products is included within the appropriate level of E/M service, and to code as skin substitutes would be inappropriate coding. If a specific HCPCS code is assigned to these products and as literature concerning their use sufficiently matures, TrailBlazer will consider requests for LCD reconsideration of this coverage decision per its LCD reconsideration process. Instructions for formal reconsideration requests are provided at http://www.trailblazerhealth.com/Publications/Job%20Aid/LCD%20Reconsideration%20Process.pdf and must be accompanied by

complete copies of relevant peer-reviewed literature that supports the recommendation as well as complete copies of FDA labeling for their uses (providers are reminded that abstracts are not acceptable – by Medicare rule – for this purpose).

- Providers are also reminded that this LCD does not purport to cover use of any skin substitutes or related products in the treatment of burns. This statement is intended to include the list of CPT codes used primarily in burn treatment, which remains outside the purview of this LCD.
- The only reason the burn code treatments and range of burn diagnoses are mentioned in this LCD is due to the HCPCS 2007 J7340 description of direction, “Use this code for Apligraf, Orcel® (sic), TransCyte®.” It appears that currently the only labeled use of the TransCyte® product is in burn wound treatment. Given that, as noted above, the primary thrust of this LCD is toward the use of skin substitute products in ulcers and given that we have not experienced significant misuse of the TransCyte® product or similar burn treatment products, TrailBlazer includes the use of TransCyte® and other similar burn treatments in this LCD only to indicate coverage is available when medically reasonable and necessary in the treatment of burns and when used consistent with FDA labeling. This LCD does not cover any other aspect of these burn treatment products, nor are any other criteria for the burn uses of these products subject to this LCD. Once again, providers are reminded that requirements for use according to FDA labeling and for medical reasonableness and necessity apply. If circumstances in the future warrant LCD consideration of these products and their uses, TrailBlazer will consider establishing an LCD specific to them.
- In most instances, consistent with FDA product labeling, which limits the use of these products to clean wounds, CPT codes 15002 and 15004 are not appropriate (CPT codes 15002–15005 are listed below in the “CPT/HCPCS” section of this LCD, primarily for information only). Minimal wound preparation is considered a part of the procedure. CPT 2007 language in the introductory comments to the “Skin Replacement Surgery and Skin Substitutes” chapter reconfirms this position in stating, “Identify by size and the type of graft or skin substitute; **includes simple debridement of granulation tissue or recent avulsion.”** When more substantial debridement is felt to be warranted, consider use of one of the superficial debridement codes (11040–11042). In either instance, the medical record documentation must clearly support that any amount of debridement was medically reasonable and necessary.

Literature clearly demonstrates that development on as often as a weekly basis of necrosis significant enough to warrant debridement strongly suggests that vascularity is insufficient to allow wound healing, even with the use of skin substitute therapy. Furthermore, TrailBlazer considers the CPT debridement codes to be appropriate for use only by physicians or Non-Physician Practitioners (NPPs) (with the exception of the physical therapy debridement codes). Billing for debridement performed during routine dressing changes in the course of treatments as contemplated in this LCD is **not** appropriate. Debridement carried out by a physical therapist **must** be done within a program of care authorized and closely supervised by the treating physician.

- If at any time procedures are billed and inadvertently paid, providers are reminded that, with special reference to this set of codes, and due especially to the program experience of significant misuse of these products:
  - Compliance with the provisions in this LCD is subject to monitoring by active and ongoing postpayment data analysis and subsequent medical review.
- Providers are reminded that the use of otherwise payable codes must be consistent with state licensure and scope of practice limitations.

J7340 Indications:

For any product used in ulcer treatment and appropriately billed under this code, the FDA labeling instructions –including at least the criteria, frequency and acceptable duration of treatment – must be followed and documentation of same must be included in the medical record.

J7341 (Oasis®) Indications:

FDA labeling removed the phrase “wound dressing” from the product description. Therefore, so long as the product is used according to FDA-labeling instructions and good medical practice, it will be covered. The product has been valued according to a 90-day global period under the Physician Fee Schedule. The application code will be paid no more frequently than at 90-day intervals. It will be incorrect coding and subject to postpay review if multiple claims for this code are billed within a 90-day period with such modifiers as 58, suggesting a staged procedure. However, the product will be reimbursed at a frequency appropriate to the clinical considerations.

Since Oasis® application is considered a physician service, it must be applied by either a physician or an NPP, and **not** by non-advance practice nurses, therapists or medical assistants.

J7342 Indications:

Covered for the treatment of full-thickness diabetic foot ulcers greater than six weeks duration that extend through the dermis, but without tendon, muscle, joint capsule or bone exposure. This product **must** be used in conjunction with standard wound care regimens and in patients who have adequate blood supply to the involved foot.

TrailBlazer will cover a maximum of eight applications of J7342 for the treatment of any given lesion. In addition, the medical record must clearly document that conservative pretreatment wound management has been tried and failed to induce healing. Also, when used for billing of Dermagraft®, the record must document that the **twenty-four (24) steps** involved in the correct use of this product, as described in the clinical trials leading to FDA approval and included in the manufacturer's "Directions for Use," have been followed. The provider must take notice of these specific instructions for use. They will **not** be listed in this LCD.

J7346 Limitations:

This describes injectable dermal tissue, **not** considered under this LCD to be a skin substitute, thus not a part of this LCD. There is not an appropriate CPT code to acknowledge the work involved in injecting this material. J7346 will be considered part of the E/M service.

NOTE: CPT codes 15002, 15003, 15004, 15005, 15170, 15171, 15175, 15176, and HCPCS codes J7343, J7344, J7346, J7347, J7349, in addition to J7350 (noted above), are **not covered** under the terms of this LCD. They are listed below for information only.

Compliance with the provisions in this LCD is subject to monitoring by postpayment data analysis and subsequent medical review.

Product Wastage

Medicare provides payment for the amount of the skin substitute/replacement product that is reasonable and necessary to treat the patient's wound. If the physician has made good faith efforts to minimize the unused portion of the skin substitute/replacement product in how patients are scheduled and how he ordered, accepted,

stored, used the product and made good faith efforts to minimize the unused portion of the product in how it is supplied, then the program will cover the amount of product discarded along with the amount used to treat the wound. Documentation requirements for unused/discarded materials are given below. Discarded materials must be reported separately from the medically necessary material used to treat a wound. Coding and billing instructions for discarded materials are referenced in the attached Article. Coding and billing instructions can be referenced in the attached Article. Reference to national policy: *Medicare Claims Processing Manual* – Pub. 100-04, Chapter 17, Section 40.

Medicare will monitor and evaluate claim data related to discarded materials. Seeking additional payment from Medicare (by reporting on a separate claim materials previously reported as discarded) for wasted/discarded material constitutes a false claim, a felony crime punishable under federal law.

Note: Type of Bill and Revenue Codes DO NOT apply to Part B.

Coverage Topics

Surgical Services

Surgical Dressings

Type of Bill Codes

13X, 18X, 21X, 22X, 83X, 85X

Revenue Codes

Note: TrailBlazer has identified the Type of Bill (TOB) and Revenue Center (RC) codes applicable for use with the CPT/HCPCS codes included in this policy. Providers are reminded that not all the CPT/HCPCS codes listed can be billed with all TOB and/or RC codes listed. CPT/HCPCS codes are required to be billed with specific TOB and RC codes. Providers are encouraged to refer to the CMS *Internet-Only Manual* (IOM) Pub. 100-04 *Claims Processing Manual* for further guidance.

036X, 045X, 049X, 051X, 0636, 076X

CPT / HCPCS Codes

Note: Providers are reminded to refer to the long descriptors of the CPT codes in their CPT book. The American Medical Association (AMA) and the Centers for Medicare & Medicaid Services (CMS) require the use of short CPT descriptors in policies published on the Web.

15002©	Wnd prep, ch/inf, trk/arm/lg
15003©	Wnd prep, ch/inf addl 100 cm
15004©	Wnd prep ch/inf, f/n/hf/g
15005©	Wnd prep, f/n/hf/g, addl cm
15170©	Acell graft trunk/arms/legs
15171©	Acell graft t/arm/leg add-on
15175©	Acellular graft, f/n/hf/g
15176©	Acell graft, f/n/hf/g add-on
15340©	Apply cult skin substitute
15341©	Apply cult skin sub add-on
15360©	Apply cult derm sub, t/a/l
15361©	Aply cult derm sub t/a/l add
15365©	Apply cult derm sub f/n/hf/g
15366©	Apply cult derm f/hf/g add
J7340	Dermal and epidermal (substitute) tissue of human origin, with or without bioengineered or processed elements, with metabolically active elements, per square centimeter
J7341	Dermal (substitute) tissue of non-human origin, with or without bioengineered or processed elements, with metabolically active elements, per square centimeter
J7342	Dermal (substitute) tissue of human origin, with or without bioengineered or processed elements, with metabolically active elements, per square centimeter
J7343	Dermal and epidermal (substitute) tissue of non-human origin, with or without bioengineered or processed elements, without metabolically active elements, per square centimeter
J7344	Dermal (substitute) tissue of human origin, with or without bioengineered or processed elements, without metabolically active elements, per square centimeter
J7347	Dermal (substitute) tissue of non-human origin, with or without other bioengineered or processed elements (Integra Matrix), per square centimeter
J7349	Dermal (substitute) tissue of non-human origin, with or without bioengineered or processed elements, (Primatrix), per square centimeter

ICD-9-CM Codes That Support Medical Necessity

The CPT/HCPCS codes included in this LCD will be subjected to "procedure to diagnosis" editing. The following lists include only those diagnoses for which the identified CPT/HCPCS procedures are covered. If a covered diagnosis is not on the claim, the edit will automatically deny the service as not medically necessary.

Note: Diagnoses criteria **do not apply** to the following CPT/HCPCS codes per this LCD: 15002, 15003, 15004, 15005, 15170, 15171, 15175, 15176, J7343, J7344, J7346, J7347 and J7349.

Coverage is limited to lower limb ulcers caused by varicose veins (single ICD-9-CM requirement) or diabetes (dual diagnosis requirement) consistent with FDA labeling.

Medicare is establishing the following limited coverage **dual diagnosis** requirement for CPT/HCPCS codes **15340, 15341, 15360, 15361, 15365, 15366 J7340, J7341 and J7342:**

Billing for lower limb ulcers caused by diabetes: use the ICD-9-CM code from the ulcer of lower limb range (707.10–707.19) as the primary diagnosis with the secondary code from the diabetes range (250.60–250.83).

Covered for primary ICD-9-CM codes:

707.10* –707.19*	Ulcer of lower limb, except decubitus

Covered for secondary ICD-9 CM codes:

250.60-250.63	Diabetes with neurological manifestations
250.70-250.73	Diabetes with peripheral circulatory manifestations
250.80-250.83	Diabetes with other specified manifestations

Medicare is establishing the following additional limited coverage for CPT/HCPCS codes **15340, 15341, 15360, 15361, 15365 and 15366:**

Covered for:

454.0	Varicose veins of lower extremities with ulcer
454.2	Varicose veins of lower extremities with ulcer and inflammation

Medicare is establishing the following limited coverage for CPT/HCPCS codes **J7340 and J7341:**

Covered for:

454.0	Varicose veins of lower extremities with ulcer
454.2	Varicose veins of lower extremities with ulcer and inflammation
940.0*–940.5*	Burn confined to eye and adnexa
Note:	940.0*–949.5* to be used only for TransCyte™, OrCel™ and other similar products when used in burn treatment when such use is medically reasonable and necessary and consistent with FDA labeling.

Medicare is establishing the following limited coverage for CPT/HCPCS code **J7342:**

Covered for:

757.39*	Other specified anomalies of skin
Note:	757.39* may be used only to indicate epidermolysis bullosa.

Note: Providers should continue to submit ICD-9-CM diagnosis codes without decimals on their claim forms and electronic claims.

Diagnoses That Support Medical Necessity

N/A

ICD-9-CM Codes That DO NOT Support Medical Necessity

N/A

Diagnoses That DO NOT Support Medical Necessity

All diagnoses not listed in the “ICD-9-CM Codes That Support Medical Necessity” section of this LCD, including but not limited to the following:

- Infected ulcer.
- Osteomyelitis.
- Allergy to bovine collagen.

- 757.39 may be used only to indicate epidermolysis bullosaropathic diabetic foot ulcers without pedal pulses.
- Uncontrolled diabetes ("controlled" diabetes for purposes of this LCD would be based on documentation in the medical record).
- Active charcot arthropathy of the ulcer extremity.
- Vasculitis.
- Uncontrolled rheumatoid arthritis and/or rheumatoid ulcers.
- Other uncontrolled collagen vascular disease.
- Patients being treated with high-dose corticosteroids or immunosuppressants (NAS considers the definition of "high dose" to be a medical determination based on medical record documentation and to be outside the purview of this LCD, so we do not set a dose limit.)
- Patients who have undergone radiation and/or chemotherapy within the month immediately preceding proposed skin substitute treatment.

Documentation Requirements

Documentation supporting medical necessity should be legible, maintained in the patient's medical record and made available to Medicare upon request.

The medical record must clearly show that the criteria listed in the "Indications and Limitation of Coverage and/or Medical Necessity" section have been met. The ulcer must be measured at the beginning of conservative treatment, following cessation of conservative treatment and at the beginning of the skin substitute treatment. Clearly, if during treatment the ulcer shows obvious signs of worsening or lack of treatment response, continuing skin substitute treatment would be considered questionable, absent documentation of a reasonable rationale for doing so.

Studies have documented that, for J7342, survival of the dermal substitute decreases significantly when the 24 steps noted in the FDA labeling are not followed. The documentation must show that these 24 steps were followed.

Medicare will cover a maximum of eight applications of J7342 for the treatment of any given lesion. The medical record must clearly document that conservative pretreatment wound management has been tried and failed to induce healing. When used for billing of Dermagraft®, the record must document that the **twenty-four (24)**

steps involved in the correct use of this product, as described in the clinical trials leading to FDA approval and included in the manufacturer's "Directions for Use" as of the date of development of this LCD, have been followed. The provider must take notice of these specific instructions for use. They will not be listed in this LCD.

The medical record must document that wound treatment by this method is accompanied by appropriate wound dressing during the healing period and by appropriate compressive therapy for foot ulcer(s) and appropriate steps to off-load wound pressure during follow-up. Adequate patient compliance must be clearly ascertained and documented during such treatment.

Since application of Oasis®, Apligraf®, Dermagraft® as well as any subsequently accepted similar product is considered a physician service, it must be applied by either a physician or an NPP, and **not** by non-advance practice nurses, therapists or medical assistants.

In most instances, consistent with FDA product labeling, and current CPT language included in the introductory information on the family of skin substitute codes, which limit the use of these products to clean wounds, CPT codes 15002–15005 are **not** appropriate. Standard, routine minimal wound preparation is considered a part of the procedure. In any instance of utilization of a separate debridement code, there is a high likelihood of contractor record review; therefore, the medical record documentation must clearly support that any amount of separately billed debridement was substantial and was medically reasonable and necessary, both in terms of extent and frequency. Providers are reminded that FDA labeling should be reviewed in order to determine that the skin substitute itself is even indicated in such cases of significant same-day debridement.

The HCPCS/CPT code(s) may be subject to Correct Coding Initiative (CCI) edits. This LCD does not take precedence over CCI edits. Please refer to the CCI for correct coding guidelines and specific applicable code combinations prior to billing Medicare.

When the documentation does not meet the criteria for the service rendered or the documentation does not establish the medical necessity for the services, such services will be denied as not reasonable and necessary under Section 1862(a)(1) of the Social Security Act.

When requesting a written redetermination (formerly appeal), providers must include all relevant documentation with the request.

Product Wastage Documentation Requirements

Any amount of wasted material must be clearly documented in the medical record with the following information:

- Date, time and location of ulcer treated.
- Approximate amount of product unit used.
- Approximate amount of product unit discarded.
- The reason for the wastage.
- Manufacturer's serial/lot/batch or other unit identification number of graft material. When manufacturer does not supply unit identification, record must document such.

Appendices

N/A

Utilization Guidelines

- Treatment of any ulcer will typically last no more than twelve (12) weeks
  - Venous stasis ulcers treatment will normally last approximately twelve (12) weeks. If after 12 weeks of compression treatment and the appropriate number of applications of the skin substitute, consistent with the "Indications and Limitations" above, satisfactory healing progress is not noted, then reapplication of the skin substitute should not be billed and other treatment modalities should be considered.
  - For neuropathic diabetic foot ulcers, treatment will normally last approximately twelve (12) weeks. If after nine (9) weeks of treatment, and three (3) applications of the skin substitute, satisfactory healing progress is not noted, then reapplication of the skin substitute is not recommended and other treatment modalities should be considered.
- No retreatment would be expected within the first year following successful initial treatment.
- Medicare will cover a maximum of eight applications of J7342 for the treatment of any given lesion.

Sources of Information and Basis for Decision

J4 (CO, NM, OK, TX) MAC Integration

TrailBlazer Health Enterprises, LLC adopted the Noridian Administrative Services, LLC LCD, "Application of Bioengineered Skin Substitutes," for the Jurisdiction 4 (J4) MAC transition.

Full disclosure of sources of information is found with original contractor LCDs.

Other Contractor Local Coverage Determinations

"Skin Substitutes/Replacements," TrailBlazer Health Enterprises, LLC LCD, (00400) L23021, (00900) L23037.

"Application of Bioengineered Skin Substitutes: Ulcers (of Lower Extremities)," Noridian Administrative Services, LLC LCD, (CO) L23684.

"Dermal Skin Substitutes," Arkansas, BlueCross BlueShield (Pinnacle) LCD, (Retired – OK, NM) L13422, L13443 and L13456.

"Bilaminate Skin Substitutes", Arkansas, BlueCross BlueShield (Pinnacle) LCD, (Retired – OK, NM) L19318, L19319 and L19320.

Start Date of Notice Period

12/20/2007

Revision History

Number	Date	Explanation
N/A	06/13/2008	LCD effective in TX Part A and Part B and Part A CO and NM 06/13/2008
N/A	03/21/2008	LCD effective in CO Part B 03/21/2008
N/A	03/01/2008	LCD effective in NM Part B and OK Part A and Part B 03/01/2008
	12/20/2007	Consolidated LCD posted for notice effective: 12/20/2007