

SENT VIA EMAIL OR FAX ON
Jan/10/2012

Independent Resolutions Inc.

An Independent Review Organization
835 E. Lamar Blvd. #394
Arlington, TX 76011
Phone: (817) 349-6420
Fax: (817) 549-0311
Email: rm@independentresolutions.com

NOTICE OF INDEPENDENT REVIEW DECISION

DATE OF REVIEW:

Jan/09/2012

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

1 Application of Apligraf Skin Substitute between 12/1/2011 and 1/30/2012

DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION:

Board Certified General Surgery
Fellowship: Orthopedic Hand and Upper

REVIEW OUTCOME:

Upon independent review, the reviewer finds that the previous adverse determination/adverse determinations should be:

Upheld (Agree)

Overturned (Disagree)

Partially Overturned (Agree in part/Disagree in part)

INFORMATION PROVIDED TO THE IRO FOR REVIEW

OD Guidelines

Utilization review determination dated 12/02/11

Utilization review determination dated 11/22/11

Request for IRO dated 12/21/11

Clinical records Dr. dated 11/01/11, 11/15/11, 11/29/11, 12/06/11, and 12/20/11

Letter of appeal dated 11/29/11

Lab studies dated 12/05/11

PATIENT CLINICAL HISTORY SUMMARY

The claimant is a male who is a diabetic and receives Metformin 1000 mg bid. He is noted to be on diabetic diet prior to foot injury and hospitalization. His hemoglobin A1c was maintained at 6.5 to 6.8%. Hemoglobin A1c on 11/22/11 was 7.5%. Wound cultures showed he was free of infection. He was recommended to receive Apligraf. Dr. notes Apligraf is

indicated for use of standard therapeutic compression for treatment of non-infected partial and full thickness skin ulcers due to venous insufficiency greater than 1 month duration which has not adequately responded to conventional therapy. He notes that Apligraf is also indicated for the use of standard diabetic foot ulcer care or the treatment of full thickness neuropathic diabetic foot ulcers of greater than three weeks duration that have not responded to conventional ulcer therapy. He notes that the application is directly to the wound and not applied over any meshed autograft.

The initial request was reviewed by Dr. who non-certified the request noting that the claimant stepped on a nail sustaining an infected wound he underwent amputation of the fifth metatarsal. On examination he had a full thickness surgical wound on the right lateral foot amputation site which measures 4cm in length by 9.2cm in width and 0.5cm in depth. 28.903cm area and 14.451cm volume with a moderate and balanced sanguineous drainage with a mild odor. There is an apparent yellow slough and 76-100% bright red firm granulation within the wound bed. Dr. reports that based upon his review there is no documentation that the wound is not infected anymore. He notes that the patient is a diabetic and there is no documentation in the records that this has been addressed. The subsequent appeal request was reviewed by Dr. subsequently non-certified the request again noting that there is no documentation regarding wound infection.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDING CLINICAL BASIS, FINDINGS AND CONCLUSIONS USED TO SUPPORT THE DECISION

The request for Apligraf skin substitute is opined to be medically necessary and the previous utilization review determinations are overturned. The clinical records clearly indicate that the requested application of Apligraf is consistent with FDA guidelines for the use of this material. Furthermore it is consistent with the standard of care to treat a non-healing wound/ulceration. It is well documented in the clinical record that there is no evidence of ongoing infection and therefore the request is deemed to be medically necessary consistent with the standard of care and therefore the previous determinations are overturned.

A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION

ACOEM-AMERICA COLLEGE OF OCCUPATIONAL & ENVIRONMENTAL MEDICINE UM KNOWLEDGEBASE

AHCPR-AGENCY FOR HEALTHCARE RESEARCH & QUALITY GUIDELINES

DWC-DIVISION OF WORKERS COMPENSATION POLICIES OR GUIDELINES

EUROPEAN GUIDELINES FOR MANAGEMENT OF CHRONIC LOW BACK PAIN

INTERQUAL CRITERIA

MEDICAL JUDGEMENT, CLINICAL EXPERIENCE AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS

MERCY CENTER CONSENSUS CONFERENCE GUIDELINES

MILLIMAN CARE GUIDELINES

ODG-OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES

PRESSLEY REED, THE MEDICAL DISABILITY ADVISOR

TEXAS GUIDELINES FOR CHIROPRACTIC QUALITY ASSURANCE & PRACTICE PARAMETERS

TEXAS TACADA GUIDELINES

TMF SCREENING CRITERIA MANUAL

PEER REVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE (PROVIDE A DESCRIPTION)

OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)