

SENT VIA EMAIL OR FAX ON  
Jun/12/2012

## 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:**

Jun/11/2012

**IRO CASE #:**

**DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:**

Right Posterior Ankle Apligraf Dermal Substitute Times 5 Applications

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

Family Practice

**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)

1 application is overturned

4 applications are upheld

**INFORMATION PROVIDED TO THE IRO FOR REVIEW**

OD Guidelines

Request for IRO dated 05/22/12

Utilization review determination dated 03/30/12

Utilization review determination dated 05/21/12

Letter RN dated 03/27/12

Letter Dr., undated

**PATIENT CLINICAL HISTORY SUMMARY**

The claimant is a male who has history of diabetes. No clinical records were submitted for review. Per undated letter from Dr., the claimant has complicated open wound of right posterior ankle with history of diabetes. He is noted to have had this particular wound since

10/11. He has remote history of wound to this area after being run over by an 18-wheeler. This closed after Apligraf and skin graft application in 2008. He reopened the area next to the posterior ankle in 09/10 after tripping over sprinkler head. This wound healed recently; however, he is reported to have developed wound at right posterior ankle thought to be result of trauma from removing tape from dressing of heel wound. It is reported that this posterior heel wound worsened and involved the tendon. This required wound vac placement which has improved greatly with granulation of Achilles tendon. He still has open wound with measurements of 2.2 cm in length, 1.5 cm in width, and 0.1 cm in depth. These measurements have improved from 4.4 cm x 2.2 x 0.1 in 11/11. He has been treated with antibiotics, weekly debridement, and Santyl ointment. His wound bed is now reported to be clean of infection and well granulated. He is now ready for application of Apligraf to obtain complete closure and healing.

The initial review was performed on 03/30/12 by Dr. Dr. non-certified the request noting FDA has approved use of Apligraf for venous leg ulcers and neuropathic diabetic foot ulcers. According to letter submitted for review, the claimant has complicated open wound to right posterior ankle with history of diabetes. She noted Dr. reported successful wound closure was obtained with Apligraf and skin graft in 2008. Dr. indicates the request appears to be appropriate; however, the request for 5 applications is not established. She notes given subsequent grafts are dependent upon coverage obtained, it would be necessary to evaluate initial Apligraf application prior to any additional.

The appeal request was reviewed by Dr. on 05/21/12. Dr. non-certified the appeal request noting Official Disability Guidelines recommendation of Apligraf when excessive skin loss requires alternatives to skin grafting or when healing is significantly delayed with standard treatment alone. She notes the clinical documentation submitted for review indicates the patient has open wound 2.2 cm in length, 1.5 cm in width, and 0.1 cm in depth. She notes wound vac has been utilized and resulted in granulation of Achilles tendon. She finds initial request for 5 applications would be dependent upon coverage obtained, and subsequently upheld original decision.

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

The request for right posterior ankle Apligraf dermal substitute x 5 applications is partially overturned. The submitted clinical records indicate the claimant has evidence of large non-healing wound and comorbid diabetes. Per the letter submitted the claimant has had prior success with the use of Apligraf and the closure of non healing wounds the request as submitted for five applications is not supported as medically necessary as the use of additional Apligraf would be predicated upon the claimant's response to the initial and subsequent applications of Apligraf. As such it is recommended that the request be approved for Apligraf dermal substitute times one application with a recommendation that specific data be provided to the subsequent reviewers which establishes the response to the prior graft and clearly supports medical necessity for the subsequent treatments.

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

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

**ODG-OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES**