MAXIMUS Federal Services

Case Number:	CM13-0071659		
Date Assigned:	01/08/2014	Date of Injury:	02/11/2013
Decision Date:	06/19/2014	UR Denial Date:	12/03/2013
Priority:	Standard	Application Received:	12/30/2013

HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to an expert reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The expert reviewer is Board Certified in Podiatric Surgery and is licensed to practice in New York. He/she has been in active clinical practice for more than five years and is currently working at least 24 hours a week in active practice. The expert reviewer was selected based on his/her clinical experience, education, background, and expertise in the same or similar specialties that evaluate and/or treat the medical condition and disputed items/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

On 2/15/2013 he underwent surgical correction of his right fibular fracture. The patient developed cellulitis and wound dehissence after his surgery and was treated with antibiotics. Pt underwent physical therapy after surgery as well. On 9/17/2013 this patient underwent removal of painful hardware right ankle. A post operative wound was noted, and a wound VAC was recommneded by the surgeon. On 11/14/2013 wound care was initiated at a wound care clinic. Care included debridement of wound with cleansing and dressings. On 11/25/2013 a recommnedation for a wound VAC and Apligraf application to wound was made.

IMR ISSUES, DECISIONS AND RATIONALES

The Final Determination was based on decisions for the disputed items/services set forth below:

APLIGRAF: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: Apligraf manufacturer website, Apligraf fact sheet.

Decision rationale: Apligraf, according to the reviewed information, is a bioengineered bilayer living cell product applied to open wounds. The manufacturer information and FDA approval

advises that this particular wound application is only approved for venous leg ulcers and diabetic foot ulcers. The enclosed progress notes do not advise that this patient is diabetic nor that his wound is a venous leg ulcer or a diabetic wound. In fact it is well-documented that this is a non-healing surgical wound. Because it appears that Apligraf is being recommended for a non-FDA approved application, it cannot be recommended or medically reasonable for this patient.