

<b>Case Number:</b>	CM13-0038382		
<b>Date Assigned:</b>	12/18/2013	<b>Date of Injury:</b>	06/19/2006
<b>Decision Date:</b>	03/12/2014	<b>UR Denial Date:</b>	10/03/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/25/2013

### HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to a physician reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The physician reviewer is Board Certified in General Surgery, and is licensed to practice in Texas. 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 physician 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:

The patient is a 56-year-old male who reported an injury on 06/19/2006. The patient is diagnosed with recurrent DVT, hypercoagulable state, chronic venous insufficiency, hypertension, umbilical hernia, orthopedic condition, and psychiatric condition. The most recent physician progress note was submitted on 11/05/2013 by [REDACTED]. The patient reported an increase in swelling of bilateral legs and ankles. The patient also reported pain in the right lower extremity over the ulcer area. Physical examination revealed increased edema 1+ bilateral and pitting of the lower extremities, as well as a stigmata of chronic venous insufficiency with a well healed venous stasis ulcer. Treatment recommendations included continuation of current medication and a follow-up with wound care specialist.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**request for Apligraf skin substitute for ulcer at right lower leg:** 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 National Center for Biotechnology Information, U.S. National Library of Medicine. Larissa Zaulyanov and Robert S Kirsner. A review of a bi-layered

living cell treatment (Apligraf <sup>Â</sup>®) in the treatment of venous leg ulcers and diabetic foot ulcers.  
Published online

**Decision rationale:** Apligraf is a bi-layered bioengineered skin substitute indicated for a non healing wound that has not adequately responded to conventional, standard therapy within a 3 to 4 week period of time. As per the clinical documentation submitted, the patient has been previously treated by a wound care specialist with topical cream, dressing changes, compression wraps, and oral antibiotics. The patient's ulcer is noted to be 0.8 x 1 x 0.1. It was noted on 11/05/2013, the patient's bandage was removed, and although there appeared to be some erythema and exudation at the sight, the patient's stasis ulcer had a satisfactory healing appearance. Based on the patient's current physical examination and measurement of the patient's wound, Apligraf skin substitute does not appear to be indicated at this time. As the medical necessity has not been established, the current request is non-certified.