



## CAROLINA PODIATRIC MEDICAL ASSOCIATES, P.A.

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May 26, 2003

Lori Paserchia, M.D.  
Lead Medical Officer  
National Coverage Analysis

Dear Doctor Paserchia,

It is indeed my pleasure to write to you today in support of allowing coverage for the utilization of blood-derived products in the treatment of chronic non-healing wounds (#CAG-00190N). Over the past two years, I, or should I say my patients, have experienced the benefits of this technology and the attendant procedures in the closing of long standing chronic wounds that had failed to respond to usual wound care as well as more extensive and expensive wound care treatments.

While it may be anecdotal, my experience with autologous platelet grafting has essentially a 96% cure rate, as I have treated over 30 patients involving over 50 individual wounds with only two wounds failing to close with use of this treatment modality. Additionally, the integrity of the skin of the wound after healing is also greatly improved versus traditional treatment as is demonstrated by the less than 6% recurrence rate after initial closure. Average number of treatments is 2.6 per wound.

In my practice, any patient that presents a wound undergoes the usual complete evaluation of the wound and its etiology and status. Only if the wound fails to improve or worsens after 4 to 6 weeks of usual therapy is autologous platelet grafting considered. If the patient is a medically suitable candidate, we proceed with debridement and application of the platelet graft. Of course, thorough documentation of the wound along with digital photography for ongoing evaluation of response to therapy/treatment is maintained. Since the number of treatments is greatly reduced, morbidity is greatly reduced and the patients ability to ambulate and be more active without a chronic wound, thus clearly extrapolates to decreased mortality as well. The other psycho-social benefits to the patient who no longer suffers from a chronic wound is well documented in medical literature. The typical wound is present on a neuropathic foot that may have concomitant diabetes or underlying vascular disease as well. I have also utilized APG in severely dehiscing surgical wounds or surgical wound complications. The ability of APG to enhance healing of a surgical wound is well documented in the plastic surgery literature.

I should also make an added comment. I have treated patients who have had Procuren

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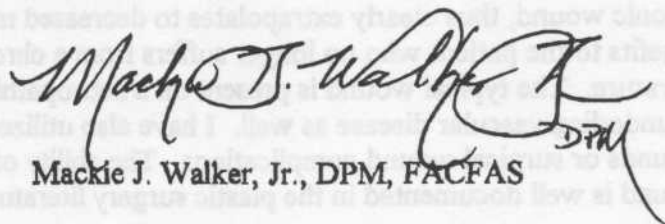
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treatment with and without success. Based upon my understanding, it is clear to me as to why autologous platelet grafting (APG) is effective when Procuren is not. APG and Procuren are two very different products. APG contains platelets, white blood cells, fibrinogen, other proteins along with the chemo-mechanical release of growth factors, some identified, and I believe some we have yet to discover are present in the APG formulation. Procuren does not contain these necessary components that I feel are an integral part of the success of APG.

Presently, I am utilizing Harvest Technology Smart Prep system for my APG procedures. Over the past two years, I have invested over \$40,000.00 in the technology and supplies to provide this treatment modality to my patients, as I had used a Cell Saver 5 machine to obtain platelets for grafting prior to beginning use of the Smart Prep 2. The Smart prep system is much more user friendly, less time consuming and provides a much better platelet yield and requiring less blood volume for processing. It is the state of the art technology today. In comparison of the Harvest Technology to the Cell-Saver, the success rate has increased with the Smart Prep, requiring less treatments per wound thus decreased cost and disability.

I cannot emphasize strongly enough my support for the allowance and appropriate reimbursement for the procedures involved in the delivery of Autologous Platelet Grafting. I know it to be a very medically effective and cost effective modality in the treatment of chronic non healing wounds. Should you require any further information or comment from me, please do not hesitate to contact me.

Sincerely,



Mackie J. Walker, Jr., DPM, FACFAS