

Positive Data Released on AutoloGel™ System to Treat Complex Chronic Wounds

A new study in the June 2010 issue of *Ostomy Wound Management* found that the Cytomedix AutoloGel™ System provided a rapid reduction in wound size for nearly all observed chronic wounds, offering a safe, effective treatment for long-term, non-healing wounds. The study ascertained “these results have important clinical implications and suggest this treatment can reverse the non-healing trend in chronic wounds.” The study’s lead author is Robert G. Frykberg, DPM, MPH, Chief, Podiatry and Residency Director, Phoenix VA Healthcare System in Phoenix, Arizona. **These positive findings suggest the Centers for Medicare and Medicaid Services should reconsider its non-coverage determination for chronic, non-healing cutaneous wounds.**

Background: The AutoloGel™ System utilizes a unique technology that enables rapid isolation and activation of platelet rich plasma (PRP) from a patient’s own blood.

- The PRP is subsequently processed to produce a gel for application to the wound bed, re-establishing a balance needed for natural healing to occur.
- AutoloGel™ contains growth factors, cytokines and chemokines that are essential for normal wound healing.
- The AutoloGel™ System is used at the point-of care and is the only PRP system indicated for use in exuding wounds such as leg ulcers, pressure ulcers, diabetic ulcers, and for the management of mechanically or surgically-debrided wounds.

Study Results: The study concluded that treatment with physiologically relevant concentrations of PRP derived from the AutoloGel™ System “showed the product can be utilized by healthcare providers in various healthcare settings to restart the healing process in complex chronic wounds, even wounds recalcitrant to other treatments, and in patients with advanced age, compromised lab values, and co-morbidities.”

- Sixty-three of sixty-five (97%) wounds responded with reductions in area, volume, undermining, and/or sinus tracts/tunneling in a mean of 2.8 weeks with an average of 3.2 treatments. This compares to an average wound duration of 47.8 weeks without healing.

Potential Cost Savings:

- Average weekly cost of Medicare-covered Negative Pressure Wound therapy -- \$455-\$955 per week for an average of 13.7 weeks = \$6240-\$8160 for full treatment.
- Average cost of AutoloGel™ therapy -- \$350 per week for the study average of 2.8 weeks = \$980 and for an average of 6 weeks to complete healing = \$2,100.
- Potential cost savings: \$4,140-\$7,180 per patient

Current Government Approval:

- Denied Coverage by CMS in 2008. CMS stated “data was suggestive” and requested additional data on AutoloGel’s efficacy --this study provides additional evidence.
- Reimbursed by two State Medicaid Programs
- Used in two Veterans Affairs Hospitals
- Accessible on Federal Supply Schedule

Recommendation: Given the newly released study confirming rapid improvement in wounds in a variety of care settings, CMS should reconsider and approve coverage of the AutoloGel™ System for treatment of long-term, non-healing wounds.