

Policy Name:	Autologous Blood-Derived Products for Chronic Non-Healing Wounds
Current Policy Effective Date:	3/1/2007

Product Application

The policy applies to all fully insured Medica Health Plans, Medica Insurance Company, and Medica Health Plans of Wisconsin products, unless a specific limitation or exception exists. For self-insured plans, consult individual plan sponsor benefit documents. If there is a discrepancy between a coverage policy and a self-insured benefit plan, the provisions of the benefit plan will govern. With respect to Medicare and Medicaid members, this policy will apply unless Medicare or Medicaid policies require different coverage.

Important Information - Please Read Before Using This Policy

Medica updates its Coverage Policies regularly, and reserves the right to amend these policies without notice to Medica members. Medica also reserves the right to amend these policies without notice to contracted health care providers unless the amendment materially alters the policy. If the amendment materially alters the policy, Medica will disclose the change to contracted health care providers not less than 45 days prior to implementation of the policy. Medica's Coverage Policies contain general information only and do not guarantee coverage. Receipt of benefits is subject to all terms and conditions of the member's coverage document. Members should consult their Certificates of Coverage or Plan Documents/Summary Plan Descriptions, to review the provisions relating to a specific coverage determination. If there is a conflict between a Coverage Policy and the applicable coverage document, the coverage document will govern. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Coverage Policy may call Medica's Provider Service Center toll free at 1-800-458-5512.

Medica's Coverage Policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.

Coverage Policy

Autologous blood-derived products for chronic non-healing wounds are investigative and therefore NOT COVERED.

Description

Autologous platelet-derived growth factor (PDGF) and autologous platelet rich plasma are topically applied preparations proposed for the treatment of chronic non-healing wounds. Autologous platelet rich plasma products include, but are not limited to, AutoloGel™ (Cytomedix, Inc.) and SafeBlood (SafeBlood Technologies). A related product, Procuren (Curative Technologies, Inc.), is an autologous platelet releasate, a formulation of growth factors derived from the patient's platelets. Procuren is currently only available through outpatient Wound Healing Centers (WHC) associated with Curative Health Services. This and similar products may also be referred to as topical activated platelet solutions and thrombin-induced platelet releasates – homologous.

AutoloGel is prepared by drawing blood from the patient, then separating the platelets from the blood using a portable centrifuge at the point of service or in a laboratory. The platelet rich plasma is mixed with other ingredients to create a gel. A health care provider applies the gel to a debrided wound, which is then covered with a dressing. The treatment is repeated as needed, usually every four to seven days depending on the size of the wound. The dressings are left in place between treatments. It is used in all health care settings: hospital, long-term care, home care, and physician's office.

FDA Approval

The December 15, 2003 Centers for Medicare & Medicaid Services decision memorandum for this technology states, "At present, no blood-derived products are licensed and marketed for use in chronic non-healing wounds. FDA is considering the appropriate approval process for this technology."

The equipment used to produce and apply autologous blood-derived products has been FDA approved for general or diagnostic indications, but not for the specific indication of treatment of a chronic wound. For example, the AutoloGel Process Centrifuge received 510(k) FDA approval in April 2003 with the following intended use: to be used at the patient's point of care for the safe and rapid preparation of platelet-rich plasma (PRP) from a small sample of the patient's blood (up to 60 ml). The FDA also required that the following limitation must appear in the Warnings and Precautions section of the device's labeling: "The safety and effectiveness of this device for in vivo indications for use has not been established."

Prior Authorization

Prior authorization is not applicable.

Coding Considerations

Use the current applicable CPT/HCPCS code(s). To obtain the current code(s), please contact Medica's Coding Department at coding.questions@medica.com or by fax at 952-992-2504.

Decision Date: 11/28/2006

Re-Review Date(s): 11/28/2006

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