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Medicare Advantage Policy Manual **Policy ID:** M-MED77

Autologous Blood-Derived Growth Factors as a Treatment for Wound Healing and Other Miscellaneous Conditions

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IMPORTANT REMINDER

The Medicare Advantage Medical Policy manual is not intended to override the member Evidence of Coverage (EOC), which defines the insured's benefits, nor is it intended to dictate how providers are to practice medicine. Physicians and other health care providers are expected to exercise their medical judgment in providing the most appropriate care for the individual member.

The Medicare Advantage Medical Policies are designed to provide guidance regarding the decision-making process for the coverage or non-coverage of services or procedures in accordance with the member EOC and the Centers of Medicare and Medicaid Services (CMS) policies, when available. In the event of a conflict, applicable CMS policy or EOC language will take precedence over the Medicare Advantage Medical Policy. In the absence of CMS guidance for a requested service or procedure, the health plan may apply their Medical Policy Manual or MCG™ criteria, both of which are developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.

Medicare and EOCs exclude from coverage, among other things, services or procedures considered to be investigational, cosmetic, or not medically necessary, and in some cases, providers may bill members for these non-covered services or procedures. Providers are encouraged to inform members in advance when they may be financially responsible for the cost of non-covered or excluded services.

DESCRIPTION

A variety of growth factors have been found to play a role in wound healing, including platelet-derived growth factors (PDGFs), epidermal growth factor, fibroblast growth factors, transforming growth factors, and insulin-like growth factors. Topically applied autologous PDGFs have been extensively investigated for clinical use in wound healing, as platelets are a rich source of PDGFs, transforming growth factors, and vascular endothelial growth factors.

Autologous platelet concentrate suspended in plasma, also known as platelet-rich plasma (PRP), can be prepared from samples of centrifuged autologous blood. The polymerization of fibrin from fibrinogen creates a platelet gel, which can then be used as an adjunct to surgery with the intent of promoting hemostasis and accelerating healing. In the operating room setting, PRP has been investigated as an adjunct to a variety of periodontal, reconstructive, and orthopedic procedures, such as in conjunction with bone-replacement grafting (using either autologous grafts or bovine-derived xenograft) in periodontal and maxillofacial surgeries.

Alternatively, PRP may be injected directly into various tissues, and has been proposed as a primary treatment of miscellaneous conditions such as epicondylitis, plantar fasciitis, and Dupuytren contracture.

MEDICARE ADVANTAGE POLICY CRITERIA

CMS Coverage Manuals*	None
National Coverage Determinations (NCDs)*	For the use of blood-derived growth factors (i.e., Procuren, AutoloGel™, etc.) in the treatment of ***acute surgical and chronic non-healing diabetic, venous and/or pressure wounds:*** ✓ Blood-Derived Products for Chronic Non-Healing Wounds (270.3) Medicare only covers autologous platelet-rich plasma (PRP) for patients who have chronic non-healing diabetic, pressure, and/or venous wounds when the member is enrolled in a clinical research study that has been approved by Medicare, and the clinical study must be approved by August 2, 2014. For a list of Medicare-approved research studies, see the Medicare CED website for PRP.
Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCDs) and Articles (LCAs)*	For ***non-coverage of the following (with or without the use of mesenchymal stem cells [MSCs]):*** ✓ ***gel platelet application,*** ✓ ***platelet rich plasma for osteoarthrosis,*** ✓ ***platelet plasma mixed with laminate, protein bone growth stimulator*** ✓ ***platelet rich plasma injections (Category III code 0232T)***: • Non-Covered Services (L35008) **Scroll to the “Public Version(s)” section at the bottom of the LCD for links to prior versions if necessary.

POLICY GUIDELINES

REQUIRED DOCUMENTATION

The information below **must** be submitted for review to determine whether policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome:

- Description of the wound type (chronic, non-healing diabetic, venous, pressure, chronic, non-healing cutaneous, acute surgical, etc.);
- Description of planned treatment;
- If applicable, documentation of the Medicare-approved clinical trial as required by the Coverage with Evidence Development (CED) criteria found within NCD 270.3.

REGULATORY STATUS

Several commercially available PRP preparation services have been approved by the U.S. Food and Drug Administration (FDA). Examples include, but may not be limited to, the following:

- Aurix™ (Nuo Therapeutics) (previously AutoloGel™, Cytomedix) and SafeBlood® (SafeBlood Technologies) are two related but distinct autologous blood-derived preparations that can be prepared at the bedside for immediate application.
    - Both Aurix™ and SafeBlood® have been specifically marketed for wound healing.
- Other devices may be used in the operating room setting, such as Medtronic Electromedic, Elmd-500 Autotransfusion system, the Plasma Saver device, or the Smart PreP device.
- The Magellan® Autologous Platelet Separator System (Medtronic) includes a disposables kit designed for use with the Magellan Autologous Platelet Separator portable tabletop centrifuge.
- BioMet Biologics received marketing clearance through the FDA's 510(k) process for a gravitational platelet separation system (GPS®II), which uses a disposable separation tube for centrifugation and a dual cannula tip to mix the platelets and thrombin at the surgical site.
- The Jen Device (DSM Biomedical) is a compact centrifugal-based system for rapid preparation of PRP from small samples.
- The Amicus Separator System (Fresenius Kabi USA LLC) is a continuous-flow, centrifugal device that draws whole blood, separates the blood into its components, and collects the component of interest.
- Filtration or plasmapheresis may also be used to produce platelet-rich concentrates.
- The use of different devices and procedures can lead to variable concentrations of active platelets and associated proteins, increasing variability between studies of clinical efficacy.

CROSS REFERENCES

Orthopedic Applications of Stem-Cell Therapy, Including Bone Substitutes Used with Autologous Bone Marrow, Medicine, Policy No. M-142

Coverage with Evidence Development (CED) Studies and Registries, Medicine, Policy No. M-156

REFERENCES

None

CODING

NOTE: HCPCS code S9055 is a Medicare Status "I" code, and therefore, is not valid for Medicare or Medicare Advantage use.

Codes	Number	Description
CPT	0232T	Injection(s) platelet rich plasma, any tissue including image guidance, harvesting and preparation when performed.
HCPCS	G0460	Autologous platelet rich plasma for chronic wounds/ulcers, including phlebotomy, centrifugation, and all other preparatory procedures and administration, per treatment
	P9020	Platelet rich plasma, each unit
	S9055	Procuren or other growth factor preparation to promote wound healing *(Not valid for Medicare purposes)*

***IMPORTANT NOTE:** Medicare Advantage medical policies use the most current Medicare references available at the time the policy was developed. Links to Medicare references will take viewers to external websites outside of the health plan's web control as these sites are not maintained by the health plan.*