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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, including care that may be both medically reasonable and necessary.

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 Centers of Medicare and Medicaid Services (CMS) policies and manuals, along with general CMS rules and regulations. 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 a specific CMS coverage determination for a requested service, item or procedure, the health plan may apply CMS regulations, as well as their Medical Policy Manual or other applicable utilization management vendor criteria developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.

Some services or items may appear to be medically indicated for an individual but they may also be a direct exclusion of Medicare or the member's benefit plan. Medicare and member EOCs exclude from coverage, among other things, services or procedures considered to be investigational (experimental) or cosmetic, as well as services or items considered not medically reasonable and necessary under Title XVIII of the Social Security Act, §1862(a)(1)(A). 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. Members, their appointed representative, or a treating provider can request coverage of a service or item by submitting a pre-service organization determination prior to services being rendered.

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 Medicare Coverage Determinations and Articles, see the Medicare Coverage Database

***Blood-Derived Products for Chronic Non-Healing Wounds factors (i.e., Procuren, AutoloGelTM)*- Effective 4/13/2021** - CMS covers PRP for patients who have chronic non-healing diabetic, wounds **for a duration of 20 weeks** when prepared by FDA approved devices. (NCD 270.3)

Services rendered prior to April 13, 2021 required patient enrollment in a clinical research study that is Medicare approved. A list of Medicare approved studies can be found on the Medicare Coverage with Evidence Development (CED) Medicare CED website for PRP

Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCDs) and Articles

For Medicare Coverage Determinations and Articles, see the Medicare Coverage Database

Platelet Rich Plasma Injections for Non-Wound Injections (LCD L39058)

Billing and Coding: Platelet Rich Plasma Injections for Non-Wound Injections (Article A58788)

Links to prior versions can be found at the bottom of the LCD.

Medical Policy Manual

For treatment of chronic non-healing diabetic wounds beyond 20 weeks, or indications not addressed in NCD 270.3 and LCD L39060, the health plan's medical policy is applicable.

Autologous Blood-Derived Growth Factors as a Treatment for Wound Healing and Other Miscellaneous Conditions, Medicine, Policy No. 77 *(see "NOTE" below)*

NOTE: If a procedure or device lacks scientific evidence regarding safety and efficacy because it is investigational or experimental, the service is noncovered as not reasonable and necessary to treat illness or injury. (*Medicare IOM Pub. No. 100-04, Ch. 23, §30 A*). According to Title XVIII of the Social Security Act, §1862(a)(1)(A), only medically reasonable and necessary services are covered by Medicare. In the absence of a NCD, LCD, or other coverage guideline, CMS guidelines allow a Medicare Advantage Organization (MAO) to make coverage determinations, applying an ***objective, evidence-based process, based on authoritative evidence***. (*Medicare IOM Pub. No. 100-16, Ch. 4, §90.5*). The Medicare

Advantage Medical Policy - Medicine Policy No. M-149 - provides further details regarding the plan's evidence-assessment process (see Cross References).

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.
- Documentation detailing the circumstance for which PRP is believed to be indicated for the diagnosis.

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.

Note, the fact a service or procedure has been issued a CPT/HCPCS code or is FDA approved for a specific indication does not, in itself, make the procedure medically reasonable and necessary. Medicare contractors evaluate services, procedures, drugs or technology to determine if they may be considered Medicare covered services.

CROSS REFERENCES

1. Orthopedic Applications of Stem-Cell Therapy, Including Bone Substitutes Used with Autologous Bone Marrow, Medicine, Policy No. M-142
2. Investigational (Experimental) Services, New and Emerging Medical Technologies and Procedures, and Other Non-Covered Services, Medicine, Policy No. M-149
3. Coverage with Evidence Development (CED) Studies and Registries, Medicine, Policy No. M-156

CODING

NOTE: HCPCS code S9055 is a Medicare Status "I" code, and therefore, is not valid for Medicare or Medicare Advantage use. According to Noridian, the local Medicare contractor (MAC):[1]

- HCPCS code P9020 is used for PRP transfused in the treatment of the conditions/coagulopathies for which it is indicated. This code should not be used to describe the injection of PRP into a specific site.
- HCPCS code G0460 should be used for PRP for the treatment of chronic non-healing diabetic, venous/ and or pressure wounds, as described under the CMS NCD 270.3.
- For all other uses of PRP, the CPT code 0232T should be billed, which describes the injection of PRP into a targeted site.

Codes	Number	Description
CPT	0232T	Injection(s) platelet rich plasma, any tissue including image guidance, harvesting and preparation when performed.
	0481T	Injection(s), autologous white blood cell concentrate (autologous protein solution), any site, including image guidance, harvesting and preparation, when performed
	86965	Pooling of platelets or other blood products
HCPCS	G0460	Autologous platelet rich plasma or other blood-derived product for non-diabetic chronic wounds/ulcers, including as applicable phlebotomy, centrifugation or mixing, and all other preparatory procedures, administration and dressings, per treatment
	G0465	Autologous platelet rich plasma (PRP) or other blood-derived product for diabetic chronic wounds/ulcers, using an FDA-cleared device for this indication, (includes as applicable administration, dressings, phlebotomy, centrifugation or mixing, and all other preparatory procedures, per treatment)
	M0076	Prolotherapy

	P9020	Platelet rich plasma, each unit
	S9055	Procuren or other growth factor preparation to promote wound healing *(Not valid for Medicare purposes)*