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Medical policies in conjunction with other nationally recognized standards of care are used to make medical coverage decisions.

Autologous Platelet-Derived Growth Factors Policy

Indication/Usage:

Autologous platelet-derived growth factors (APDGF) are also referred to as platelet-rich plasma (PRP), platelet gel, autologous platelet gel, platelet rich concentrate, or platelet releasate and have been proposed to treat a variety of conditions including wound care and orthopedic conditions. Platelet-rich plasma is prepared from whole blood collected from the patient using a standard peripheral vein puncture, centrifuge techniques remove most of the larger cells (white and red blood cells), the majority of the fluid, and concentrate the platelets in a small volume of plasma. The concentrate of platelets, and thereby growth factors, can be 5-10 times greater or richer than normal. There are many different ways to prepare PRP. It is proposed that the growth factors and cytokines released by platelets as the clot forms assist in repairing damage and the fibrin formed during the clotting process acts as a scaffold for wound healing.

Degenerative connective tissue conditions are the results of failed or inadequate healing responses to subacute injuries. Connective tissues often have limited blood circulation, and therefore a limited ability to repair the damages of daily wear and tear. It is thought that since the tissue does not suffer an acute injury, the acute healing pathways are not activated. Although it is not exactly clear how PRP works, it is speculated that PRP can activate the acute healing pathway in chronic, painful degenerative connective tissue conditions such as tendinopathies and osteoarthritis.

Medical Indications for Authorization Commercial Members

SummaCare considers autologous PRP medically necessary ONLY for

- Blood is donated by the patient and centrifuged to produce an autologous gel for treatment of chronic, non-healing cutaneous wounds that persist for 30 days or longer and fail to properly complete the healing process. Per CMS Chronic non-healing diabetic wounds can be treated for a duration of 20 weeks.

- Autologous blood derived products for chronic, non-healing wounds includes both: (1) platelet derived growth factor (PDGF) products, and (2) PRP (such as AutoloGel).

Medicare Members

CMS
NCD ID 270.3 Blood-Derived Products for Chronic Non-Healing Wounds

Item/Service Description

A. General

Wound healing is a dynamic, interactive process that involves multiple cells and proteins. There are three progressive stages of normal wound healing, and the typical wound healing duration is about 4 weeks. While cutaneous wounds are a disruption of the normal, anatomic structure and function of the skin, subcutaneous wounds involve tissue below the skin's surface. Wounds are categorized as either acute, where the normal wound healing stages are not yet completed but it is presumed they will be, resulting in orderly and timely wound repair, or chronic, where a wound has failed to progress through the normal wound healing stages and repair itself within a sufficient time period.

Platelet-rich plasma (PRP) is produced in an autologous or homologous manner. Autologous PRP is comprised of blood from the patient who will ultimately receive the PRP. Alternatively, homologous PRP is derived from blood from multiple donors. Blood is donated by the patient and centrifuged to produce an autologous gel for treatment of chronic, non-healing cutaneous wounds that persist for 30 days or longer and fail to properly complete the healing process. Autologous blood derived products for chronic, non-healing wounds includes both: (1) platelet derived growth factor (PDGF) products, and (2) PRP (such as AutoloGel).

The PRP is different from previous products in that it contains whole cells including white cells, red cells, plasma, platelets, fibrin, stem cells, and fibrocyte precursors.

The PRP is used by physicians in clinical settings in treating chronic, non-healing wounds, open, cutaneous wounds, soft tissue and bone. Alternatively, PDGF does not contain cells and was previously marketed as a product to be used by patients at home.

Indications and Limitations of Coverage

B. Nationally Covered Indications

Effective for services performed on or after April 13, 2021, the Centers for Medicare & Medicaid Services (CMS) will cover autologous PRP for the treatment of chronic non-healing diabetic wounds under section 1862(a) (1)(A) of the Social Security Act (the Act) for a duration of 20 weeks, when prepared by devices whose Food and Drug Administration-cleared indications include the management of exuding cutaneous wounds, such as diabetic ulcers.

C. Nationally Non-Covered Indications

Autologous PDGF for the treatment of chronic, non-healing cutaneous wounds, and,

Becaplermin, a non-autologous growth factor for chronic, non-healing subcutaneous wounds, and,

Autologous PRP for the treatment of acute surgical wounds when the autologous PRP is applied directly to the closed incision, or for dehiscent wounds.

CPT codes

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

HCPCS G0465 Autologous platelet rich plasma (prp) or other blood-derived product for diabetic chronic wounds/ulcers, using an fda-cleared device for this indication

Limitations

SummaCare **does not cover** any other forms of autologous platelet-derived growth factors and considers them **investigational and experimental** for the following, but not necessarily limited to:

- Chronic urticaria
- Alopecia areata (androgenetic alopecia)
- Cervical radiculopathy
- Lateral epicondylitis
- Plantar fasciitis
- Temporomandibular joint (TMJ) dislocation

- Tendinopathies (e.g., elbow, heel, knee, patella, and shoulder)
- Achilles tendon ruptures
- Anterior cruciate ligament surgery
- As adjunctive material to bone graft
- Avascular necrosis of the hip
- Cerebral palsy
- Crohn's disease-related perianal fistula
- Gastrocnemius tear
- Hamstring tear
- Hip fractures
- Lumbar facet joint syndrome
- Osteoarthritis
- Rotator cuff injuries
- Urethral stricture
- Platelet gel application following total knee arthroplasty
- Platelet rich plasma combined with stem cells (Regenexx)
- Bone marrow derived mesenchymal stromal cell administration for Crohn's disease and osteoarthritis
- Adipose-tissue-derived stem cell injection treatment for chondromalacia patellae
- Epithelial defects of the cornea, persistent
- Sinus augmentation procedures
- Dupuytren's contracture
- Tonsillectomy
- Ganglion cyst
- Osteonecrosis of the jaw
- Chronic, non-healing cutaneous wounds
- Becaplermin, a non-autologous growth factor for chronic, non-healing subcutaneous
- Autologous PRP for the treatment of acute surgical wounds when the autologous
- PRP is applied directly to the closed incision or for dehiscent wounds

Contraindications include:

- Platelet Dysfunction Syndrome
- Thrombocytopenia
- Malignancies or tumors located in wound
- Hemodynamic instability
- Hyperfibrinogenemia

Coverage Decisions

Coverage decisions made per CMS Guidelines, Hayes Research and industry standards research

Plans Covered By This Policy

Commercial and Medicare

Self-funded Commercial groups refer to plan document for coverage

Sources Reviewed

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