Medical Coverage Policy | Recombinant and Autologous Platelet-Derived Growth Factors for Wound Healing and Other Non-Orthopedic Conditions

EFFECTIVE DATE: 02/01/2023
POLICY LAST UPDATED: 10/05/2022

OVERVIEW

The use of blood-derived growth factors, including recombinant platelet-derived growth factors (PDGFs) and platelet-rich plasma (PRP), has been suggested as a treatment for wounds or other miscellaneous non-orthopedic conditions, including but not limited to, diabetic ulcers, pressure ulcers, venous stasis ulcers, and surgical and traumatic wounds

This policy is only applicable to autologous platelet-rich plasma (PRP)

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

Medicare Advantage Plans

Autologous platelet-rich plasma (PRP) for the treatment of chronic non-healing diabetic wounds is covered when filed with a covered diagnosis (See coding section). All other indications are not covered as the evidence is insufficient to determine the effects of the technology on health outcomes.

Commercial Products

Use of platelet-rich plasma (ie, autologous blood-derived preparations) is considered not medically necessary for the treatment of acute or chronic wounds, including surgical wounds and nonhealing ulcers as the evidence is insufficient to determine the effects of the technology on health outcomes.

COVERAGE

Benefits may vary among groups. Please refer to the appropriate section of the Benefit Booklet, Evidence of Coverage or Subscriber Agreement for services not medically necessary.

BACKGROUND

A variety of growth factors have been found to play a role in wound healing, including platelet-derived growth factor (PDGF), epidermal growth factor, fibroblast growth factors, transforming growth factors, and insulin-like growth factors. Autologous platelets are a rich source of PDGF, transforming growth factors (that function as a mitogen for fibroblasts, smooth muscle cells, and osteoblasts), 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. Exposure to a solution of thrombin and calcium chloride degranulates platelets, releasing various growth factors, and results in the polymerization of fibrin from fibrinogen, creating a platelet gel. The platelet gel can then be applied to wounds or may be used as an adjunct to surgery to promote hemostasis and accelerate healing. In the operating room setting, PRP has been investigated as an adjunct to a variety of periodontal, reconstructive, and orthopedic procedures. For example, bone morphogenetic proteins are a type of transforming growth factor, and thus PRP has been used

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in conjunction with bone-replacement grafting (using either autologous grafts or bovine-derived xenograft) in periodontal and maxillofacial surgeries.

PRP is distinguished from fibrin glues or sealants, which have been used for many years as a surgical adjunct to promote local hemostasis at incision sites. Fibrin glue is created from platelet-poor plasma and consists primarily of fibrinogen. Commercial fibrin glues are created from pooled homologous human donors; Tisseel® (Baxter International) and Hemaseel® (Haemacure Corp.) are examples of commercially available fibrin sealants. Autologous fibrin sealants can also be created from platelet-poor plasma.

For individuals who have chronic wounds or acute surgical or traumatic wounds who receive PRP, the evidence includes meta-analyses of a number of small controlled trials. Relevant outcomes are symptoms, change in disease status, morbid events, quality of life (QOL), and treatment-related morbidity. In individuals with lower extremity diabetic ulcers, PRP demonstrated an improvement over the control groups in complete wound closure and healing time, but moderate to high risk of bias and imprecision preclude drawing conclusions on other important outcomes such as recurrence, infection, amputation, and QOL. In individuals with venous ulcers, PRP did not demonstrate an improvement over the control groups in complete wound closure, recurrence, wound infection or QOL, although imprecision likely precluded identifying differences on these outcomes. In individuals with pressure ulcers, although PRP reduced wound size, other important outcomes such as complete wound closure were not measured. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Medicare Advantage Plans
In April 2021, CMS published an updated decision memo following the fourth reconsideration of the national coverage analysis stating that CMS will "cover autologous platelet-rich plasma (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 FDA cleared indications include the management of exuding cutaneous wounds, such as diabetic ulcers. Coverage of autologous PRP for the treatment of chronic non-healing diabetic wounds beyond 20 weeks will be determined by local Medicare Administrative Contractors (MACs).

Coverage of autologous PRP for the treatment of all other chronic non-healing wounds will be determined by local Medicare Administrative Contractors (MACs) under section 1862(a)(1)(A) of the Act

CODING

Medicare Advantage Plans and Commercial Products
The following code is covered when filed with a covered diagnosis for Medicare Advantage Plans and not medically necessary for Commercial Products.
G0465 Autologous platelet rich plasma (PRP) for diabetic chronic wounds/ulcers, using an FDA-cleared device (includes administration, dressings, phlebotomy, centrifugation, and all other preparatory procedures, per treatment)

ICD-10-CM Diagnosis List

The following code is not covered for Medicare Advantage Plans and not medically necessary for Commercial Products as it is used for non-diabetic chronic wounds/ulcers
G0460 Autologous platelet rich plasma for non-diabetic chronic wounds/ulcers, including phlebotomy, centrifugation, and all other preparatory procedures, administration and dressings, per treatment

RELATED POLICIES

No applicable

PUBLISHED

Provider Update, December 2022

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Provider Update, April 2021
Provider Update, May 2020
Provider Update, May 2019
Provider Update, January 2019

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