Recombinant and Autologous Platelet-Derived Growth Factors for Wound Healing and Other Non–Orthopedic Conditions

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Products:	Medicaid
Application:	All participating hospitals and providers
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Disclaimer

Highmark Health Options medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

POLICY STATEMENT

Highmark Health Options may provide coverage under medical surgical benefits of the Company's Medicaid products for medically necessary recombinant and autologous platelet-derived growth factors for wound healing and other nonorthopedic conditions.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

The qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and the Delaware Department of Health and Social Services (DHSS) and all applicable state and federal regulations.

DEFINITIONS

Highmark Health Options (HHO) – Managed care organization serving vulnerable populations that have complex needs and qualify for Medicaid. Highmark Health Options members include individuals and families with low income, expecting mothers, children, and people with disabilities. Members pay nothing to very little for their health coverage. Highmark Health Options currently services Delaware Medicaid: Delaware Healthy Children Program (DHCP) and Diamond State Health Plan Plus members.

PROCEDURES

A variety of growth factors have been found to play a role in wound healing, including platelet-derived growth factors (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. PRP is distinguished from fibrin glues or sealants.

Recombinant platelet-derived growth factor (i.e., becaplermin [Regranex]) may be considered medically necessary when used as an adjunct to standard wound management when EITHER of the following criteria has been met:

- Neuropathic diabetic ulcers extending into the subcutaneous tissue or beyond and have an adequate blood supply; or
- Pressure ulcers extending into the subcutaneous tissue.

Becaplermin gel for treatment of neuropathic ulcers may be considered medically necessary when ALL of the following criteria are met:

- Adequate tissue oxygenation of 30 mm Hg or greater measured by EITHER:
  - A transcutaneous partial pressure on the foot dorsum or at the margin of the ulcer; or
  - Toe photoplethysmography (PPG) with infrared reflectance technique; and
- Full-thickness ulcer (i.e., Stage III or IV), extending through dermis into subcutaneous tissues; and
- Participation in a wound-management program, which includes sharp debridement, pressure relief (i.e., non-weight bearing), and infection control.

Becaplermin gel for the treatment of pressure ulcers may be considered medically necessary when ALL of the following criteria are met:

- Full-thickness ulcer (i.e., Stage III or IV), extending through dermis into subcutaneous tissues; and
- Ulcer in an anatomic location that can be off-loaded for the duration of treatment; and
- Albumin concentration greater than 2.5 dL; and
- Total lymphocyte count greater than 1,000; and
- Normal values of vitamins A and C.

All other applications of recombinant platelet-derived growth factor (i.e., becaplermin [Regranex]) are considered experimental/investigational, and therefore, non-covered including, but not limited to, ischemic ulcers, ulcers related to venous stasis, and ulcers not extending through the dermis into the subcutaneous tissue. The safety and/or effectiveness cannot be established by review of the published peer-reviewed literature.

Use of autologous blood-derived preparations (i.e., injection of PRP) is considered experimental/investigational and therefore non-covered for ALL non-orthopedic conditions because the effectiveness cannot be established by published peer-reviewed literature.

Post-payment Audit Statement

The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Health Options at any time pursuant to the terms of your provider agreement.

Place of Service

Experimental/Investigational (E/I) services are not covered regardless of place of service.

Recombinant and autologous platelet-derived growth factors for wound healing and other nonorthopedic conditions is typically an outpatient procedure which is only eligible for coverage as an inpatient procedure in special circumstances, including, but not limited to, the presence of a comorbid condition that would require monitoring in a more controlled environment such as the inpatient setting.

CODING REQUIREMENTS

CPT codes	Description
86999	Unlisted transfusion medicine procedure.
G0460	Autologous platelet rich plasma for chronic wounds/ulcers, including phlebotomy, centrifugation, and all other preparatory procedures and administration, per treatment .

REIMBURSEMENT

Participating facilities will be reimbursed per their Highmark Health Options contract.

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POLICY UPDATE HISTORY

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