Autologous Platelet-Rich Plasma (PRP) - GPS

[For the list of services and procedures that need preauthorization, please refer to www.mcs.pr Go to “Comunicados a Proveedores”, and click “Cartas Circulares”.]

Medical Policy: MP-SU-02-11
Original Effective Date: June 23, 2011

Reviewed: July 9, 2012
Revised:

This policy applies to products subscribed by the following corporations, MCS Life Insurance Company (Commercial), and MCS Advantage, Inc. (Classicare) and Medical Card System, provider’s contract; unless specific contract limitations, exclusions or exceptions apply. Please refer to the member’s benefit certification language for benefit availability. Managed care guidelines related to referral authorization, and precertification of inpatient hospitalization, home health, home infusion and hospice services apply subject to the aforementioned exceptions.

DESCRIPTION

A variety of growth factors have been found to play a role in wound healing, including platelet derived growth factors, epidermal growth factor, fibroblast growth factors, transforming growth factors, and insulin-like factors. **Autologous platelet** 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. Recombinant PDGF has also been extensive investigated for clinical use in wound healing.

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 the various growth factors and results in the polymerization of fibrin from fibrinogen, creating a platelet gel. The platelet gel can be then the applied to wounds or may be used as an adjunct to surgery to promote hemostasis and accelerate healing. In the operating room setting, platelet-rich plasma has been investigated as an adjunct to a variety of periodontal, reconstructive, and orthopedic procedures.

Alternatively, platelet-rich plasma may be injected directly into the tissue. Platelet-rich plasma has also been proposed as a primary treatment of miscellaneous conditions, such as epicondylitis, plantar fasciitis, and Dupuytren’s contracture. Injection of Platelet-rich plasma for tendon and ligament pain is theoretically related to prolotherapy. However, prolotherapy
involves injection of chemical irritants that are intended to stimulate inflammatory responses and induce release of endogenous growth factors.

In April 2003, the FDA approved the use of the GPS Platelet Separation Kit. The GPS™ separation kit aids separation of the patient’s own blood components by density through the use of the GPS™-Thermo International Equipment Company (IEC) centrifuge. The GPS separation kit permits platelet rich plasma to be rapidly prepared from small volume of the patient’s blood that is drawn at the time of treatment. The GPS Platelet Separation Kit is designed for use in the clinical laboratory or intraoperative at the point of care, for the safe and effective preparation of platelet poor plasma and platelet concentrate from small sample (50-60 ml) of whole blood.

GPS-Models Available from Different Companies:

I. Mini GPS III Disposable Kit:

   Contents:
   - One Disposable Mini Separation Tube, Two 30 ml Syringes, One 18 gauges Needle Set, One Tourniquet, Two Alcohol Prep Pads, One 30 ml Bottle of ACD-A, One 10 ml Syringe, One 18 gauge Sponges, One Roll Adhesive Tape, Four Syringe Caps, Patient Identification Labels.

II. GPS III Disposable Single Kit:

   Contents:
   - One Disposable Separation Tube, One 30 ml Syringe, One 18 Gauge Needle Set, One Tourniquet, Two Alcohol Prep Pads, One 30 ml Bottle of ACD-A, One 60 ml Syringe, One 10 ml Syringe, One 18 Gauge Needle, Two Gauze Sponges, One Roll Adhesive Tape, Four Syringe Caps, Patient Identification Labels.

III. GPS III Disposable Double Kit:

   Contents:
   - Two disposable Separation Tubes, Two 30 ml Syringes, One 18 gauge Needle Set, One Tourniquet, Two Alcohol Prep Pads, One 30 ml Bottle of ACD-A, Two 60 ml Syringes, Two 10 ml Syringes, One 18 Gauge Needle, Two Gauze Sponges, One Roll Adhesive Tape, Seven Syringe Caps, Patient Identification Labels.

Other Systems available in the market are Accelerate Concentrate System and symphony™ Platelet Concentrate System.
COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate member certificate and subscriber agreement contract for applicable diagnostic imaging, DME, laboratory, medical tests, drug formulary, benefits and coverage.

Medical Card System, Inc., (MCS) will NOT consider medically necessary the use of Autologous Platelet Derived Growth Factors.

- There is inadequate evidence to support its use over standard therapy.

Note: There is a consideration for coverage for the routine costs in Federally sponsored or approved clinical trials assessing the efficacy of autologous PRP in treating chronic, non-healing cutaneous wounds for MCS Classicare line of business.

Routine costs of a clinical trial include all items and services that are otherwise generally available to Medicare beneficiaries (i.e., there exists a benefit category, it is not statutorily excluded, and there is not a national non-coverage decision) that are provided in either the experimental or the control arms of a clinical trial except:

- The investigational item or service, itself unless otherwise covered outside of the clinical trial;
- Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient (e.g., monthly CT scans for a condition usually requiring only a single scan); and
- Items and services customarily provided by the research sponsors free of charge for any enrollee in the trial.

Please see CMS - National Coverage Determination (NCD) for Blood-Derived Products for Chronic Non-Healing Wounds (270.3).
CODING INFORMATION (List may not be all inclusive)

CPT® Codes

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<th>CPT® Codes</th>
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<td>0232T</td>
<td>Injection(s), platelet rich plasma, any site, including image guidance, harvesting and preparation when performed <em>(Not Covered)</em></td>
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REFERENCES


POLICY HISTORY

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<tr>
<td>June 23, 2011</td>
<td>Origination of Policy</td>
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| July 9, 2012 | Revised        | References updated. Modified Note: There is a consideration for coverage for the routine costs in Federally sponsored or approved clinical trials assessing the efficacy of autologous PRP in treating chronic, non-healing cutaneous wounds for MCS Classicare line of business. Explanation of Routine Costs of a Clinical Trial was added.