Geisinger Health Plan Policies and Procedure Manual

Policy: MP233

Section: Medical Benefit Policy

Subject: Autologous Injectable Platelet and Blood Products

Applicable Lines of Business

Commercial	**X**	**CHIP**	**X**
Medicare	**X**	**ACA**	**X**
Medicaid	**X**		

I. Policy: Autologous Injectable Platelet and Blood Products

II. Purpose/Objective:

To provide a policy of coverage regarding Autologous Injectable Platelet and Blood Products

III. Responsibility:

A. Medical Directors
B. Medical Management

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards of good medical treatment practiced by the general medical community.
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment

Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.

- Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age

DESCRIPTION:
Autologous platelet-derived growth factors (APDGF), also referred to as platelet gel or platelet-rich plasma, have been proposed for use in the treatment of surgical and chronic wounds (e.g., lower extremity wounds), tendonitis, joint capsular injuries, soft tissue trauma (e.g., tendon and ligament ruptures), and muscle injuries and disorders. Bone marrow-derived mesenchymal stem cells have been proposed as a regenerative treatment for injuries to cartilage and bones.

FOR MEDICARE and MEDICAID BUSINESS SEGMENT:

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 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.

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

EXCLUSIONS: Unless otherwise noted:
The Plan does **NOT** provide coverage for Autologous Platelet-Derived Growth Factor for any indication including but not limited to surgical wounds, chronic non-healing wounds, Epicondylitis, Plantar Fasciitis, Dupuytren's Contracture, bone healing and fusion, tendinopathy and sinus surgery because it is considered **unproven** and therefore not medically necessary**.** The Geisinger Technology Assessment Committee evaluated this technology and concluded that there is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this technology on health outcomes when compared to established other tests or technologies.

The Plan does **NOT** provide coverage for bone marrow plasma or bone marrow-derived mesenchymal stem cell injection for any orthopedic condition because it is considered unproven and therefore not medically necessary. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this technology on health outcomes when compared to established other tests or technologies.

The Plan does **NOT** provide coverage for autologous platelet gel following total knee arthroplasty or for treatment of diabetic foot ulcer because it is considered unproven and therefore not medically necessary. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this technology on health outcomes when compared to established other tests or technologies.

The Plan does **NOT** provide coverage for platelet-rich fibrin for intra-bony defects in chronic periodontitis and rotator cuff tears because it is considered unproven and therefore not medically necessary. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this technology on health outcomes when compared to established other tests or technologies.

The Plan does **NOT** provide coverage for adipose-tissue-derived stem cells injection (Habeo cell therapy) for the treatment of scleroderma (systemic sclerosis) or any other indications because it is considered unproven and therefore not medically necessary. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this technology on health outcomes when compared to established other tests or technologies.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

Medicaid Business Segment:
Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis.

CODING ASSOCIATED WITH: Autologous Platelet-Derived Growth Factor
The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS

Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov ***or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.***

P9020 Platelet rich plasma, each unit
S9055 Procuren or other growth factor preparation to promote wound healing
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)
0489T Autologous adipose-derived regenerative cell therapy for scleroderma in the hands; adipose tissue harvesting, isolation and preparation of harvested cells including incubation with cell dissociation enzymes, removal of non-viable cells and debris, determination of concentration and dilution of regenerative cells
0490T multiple injections in one or both hands
G0460 Autologous platelet rich plasma for non-diabetic chronic wounds/ulcers, including phlebotomy, centrifugation, and all other preparatory procedures, administration and dressings, per treatment
0565T Autologous cellular implant derived from adipose tissue for the treatment of osteoarthritis of the knees; tissue harvesting and cellular implant creation
0566T Autologous cellular implant derived from adipose tissue for the treatment of osteoarthritis of the knees; injection of cellular implant into knee joint including ultrasound guidance, unilateral
0717T Autologous adipose-derived regenerative cell (ADRC) therapy for partial thickness rotator cuff tear; adipose tissue harvesting, isolation and preparation of harvested cells, including incubation with cell dissociation enzymes, filtration, washing and concentration of ADRCs
0718T Autologous adipose-derived regenerative cell (ADRC) therapy for partial thickness rotator cuff tear; adipose tissue harvesting, isolation and preparation of harvested cells, including incubation with cell dissociation enzymes, filtration, washing and concentration of ADRCs; injection into supraspinatus tendon including ultrasound guidance, unilateral
P9099 Blood component or product not otherwise classified

LINE OF BUSINESS:
Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

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This policy will be revised as necessary and reviewed no less than annually.

Devised: 06/2009

Revised: 6/10 (exclusion lang/refs), 9/16 (Title, Description, Exclusion); 11/16 (Add CMS CED provision); 3/18 (title change, add exclusion), 3/19 (add exclusion); 3/21 (add exclusions), 3/22 (revise CMS coverage position); 3/24 (revise exclusion language)

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