Geisinger Health Plan

POLICIES AND PROCEDURE MANUAL

Policy: MP229

Section: Medical Benefit Policy

Subject: Prolozone® Therapy

I. Policy: Prolozone® Therapy

II. Purpose/Objective:

To provide a policy of coverage regarding Prolozone® Therapy

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

Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

(i) The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
(ii) The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.
(iii) The service or benefit 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: Prolozone® Therapy is a homeopathic injection technique proposed to treat all forms of musculo-skeletal and joint pain including chronic neck and back pain, rotator cuff injuries, degenerative and arthritic hips and knees, degenerated discs, and shoulder and elbow pain. The injected ozone is thought to increase the blood supply and flow of healing nutrients. Furthermore, it is thought to stimulate the deposition and activity of fibroblasts to repair damaged ligaments. A mixture of oxygen and ozone, this form of therapy has been proposed to both heal and detoxify; limiting pain and reducing inflammation through ozone oxidation.

EXCLUSIONS:
The Plan does **NOT** provide coverage for Prolozone® Therapy as a treatment for any indication because it is considered **experimental, investigational or unproven.** There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this treatment when compared to established 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.

For information regarding Prolotherapy, please see **MP 127 - Prolotherapy**

Other Associated Key Words: Ozone Therapy,

CODING ASSOCIATED WITH: Prolozone® Therapy
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.***

M0076 Prolotherapy

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.

REFERENCES:
ECRI Institute (online) Epidural Injection Therapy for Chronic Back Pain [Hotline]. Current as of 03/28/08.

Zambello, A, Fara, B, Tabaracci, G, and Bianchi, M. Epidural steroid injection vs paravertebral O2O3 infiltration for symptomatic herniated disc refractory to conventional treatment: A prospective randomized study. *Rivista Italiana.di Ossigeno.Ozonoterapia.* 2006;5(2):123-127. Cochrane Library CN-00613384

Staal JB, de Bie R, de Vet HC, Hildebrandt J, Nelemans P. Injection therapy for subacute and chronic low-back pain. Cochrane Database Syst Rev. 2008 Jul 16;(3):CD001824.

Muto M, Ambrosanio G, Guarnieri G, Capobianco E, Piccolo G, Annunziata G, Rotondo A. Low back pain and sciatica: treatment with intradiscal-intraforaminal O(2)-O (3) injection. Our experience. Radiol Med. 2008 Aug;113(5):695-706. Epub 2008 Jul 1.

Vanden Bossche L, Vanderstraeten G. A multi-center, double-blind, randomized, placebo-controlled trial protocol to assess Traumeel injection vs dexamethasone injection in rotator cuff syndrome: The TRAumeel in ROtator cuff syndrome (TRARO) study protocol. BMC Musculoskelet Disord. 2015;16:8.

Sanderson LM, Bryant A. Effectiveness and safety of prolotherapy injections for management of lower limb tendinopathy and fasciopathy: A systematic review. J Foot Ankle Res. 2015;8:57.

Lee DH, Kwack KS, Rah UW, Yoon SH. Prolotherapy for refractory rotator cuff disease: Retrospective case-control study of 1-year follow-up. Arch Phys Med Rehabil. 2015;96(11):2027-2032.

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

Devised: 04/20/09

Revised:

Reviewed: 5/10; 5/11, 5/12, 5/13, 5/14, 5/15, 5/16, 4/17, 4/18, 4/19, 4/20