Prolotherapy

Date of Origin: 05/2011  
Last Review Date: 12/06/2017  
Effective Date: 12/06/2017  

Dates Reviewed: 05/2011, 04/2012, 02/2013, 02/2014, 08/2015, 12/2017

Developed By: Medical Necessity Criteria Committee

I. Description
Prolotherapy is a technique utilizing the injection of a sclerosing agent into the joints, muscles, tendons, or ligaments for the purpose of inducing an inflammatory response. Prolotherapy may also be referred to as proliferant injection or proliferation therapy, prolo, joint sclerotherapy, growth factor stimulation injection, non surgical tendon, ligament, and joint reconstruction, intra-articular regenerative injection therapy. Common prolotherapy agents used are zinc sulfate, dextrose, glucose, glycerin, fibrin glue, phenol, sodium morrhuate, or platelet-rich plasma. Typically prolotherapy involves multiple sessions with each session requiring multiple injections.

Extensive prolotherapy literature exists. Evidence in the peer-reviewed literature evaluating prolotherapy consists of case series and systematic reviews with few randomized controlled clinical trials. Peer review literature does not substantiate the value of this therapy. Cochrane review of 2004 concluded that prolotherapy injections have not been proven to be more effective than placebo injections. American College of Occupational and Environmental Medicine guideline of 2007 does not recommend prolotherapy injections for acute, subacute, chronic low back pain or radicular pain syndrome.

II. Criteria: CWQI HCS-0055
A. Prolotherapy is considered investigational and is NOT covered by Moda Health.

III. Information Submitted with the Prior Authorization Request:
1. None. Prolotherapy is considered investigational.

IV. CPT or HCPC codes NOT covered:

<table>
<thead>
<tr>
<th>Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>M0076</td>
<td>Prolotherapy</td>
</tr>
</tbody>
</table>
V. Annual Review History

<table>
<thead>
<tr>
<th>Review Date</th>
<th>Revisions</th>
<th>Effective Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>02/2013</td>
<td>Annual Review: Added table with review date, revisions, and effective date.</td>
<td>03/1/2013</td>
</tr>
<tr>
<td>02/2014</td>
<td>Annual Review: No change</td>
<td>02/25/2014</td>
</tr>
<tr>
<td>08/2015</td>
<td>Annual Review: Added Medicare criteria, ICD-10 codes</td>
<td>08/26/2016</td>
</tr>
<tr>
<td>12/2017</td>
<td>Annual Review: Removed criteria for Platelet Rich Plasma injections and will refer to MCG A-0630</td>
<td>12/06/2017</td>
</tr>
</tbody>
</table>

VI. References

17. Centers for Medicare & Medicaid Services; National Coverage Determination (NCD) for Blood-Derived Products for Chronic Non-Healing Wounds (270.3); Effective 8/2/2012; Implementation date 7/1/2013.
18. Physician advisors.

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

**Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD):**

<table>
<thead>
<tr>
<th>Jurisdiction(s): 5, 8</th>
<th>NCD/LCD Document(s):</th>
</tr>
</thead>
</table>

**NCD/LCD Document(s):**

<table>
<thead>
<tr>
<th>Jurisdiction</th>
<th>Applicable State/US Territory</th>
<th>Contractor</th>
</tr>
</thead>
<tbody>
<tr>
<td>F (2 &amp; 3)</td>
<td>AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ</td>
<td>Noridian Healthcare Solutions, LLC</td>
</tr>
</tbody>
</table>