Medical Policy

Prolotherapy

Policy Number: OCA 3.707
Version Number: 11
Version Effective Date: 10/01/17

Product Applicability

<table>
<thead>
<tr>
<th>Well Sense Health Plan</th>
<th>Boston Medical Center HealthNet Plan</th>
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<tr>
<td>☐ New Hampshire Medicaid</td>
<td>☒ MassHealth</td>
</tr>
<tr>
<td>☐ NH Health Protection Program</td>
<td>☒ Qualified Health Plans/ConnectorCare/Employer Choice Direct</td>
</tr>
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<td>☒ Senior Care Options ◊</td>
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</tbody>
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Notes:
+ Disclaimer and audit information is located at the end of this document.
◊ The guidelines included in this Plan policy are applicable to members enrolled in Senior Care Options only if there are no criteria established for the specified service in a Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) on the date of the prior authorization request. Review the member’s product-specific benefit documents at www.SeniorsGetMore.org to determine coverage guidelines for Senior Care Options.

Policy Summary

The Plan considers prolotherapy to be experimental and investigational when used for the treatment of chronic musculoskeletal pain, temporomandibular joint disorders, and/or for any other condition. It will be determined during the Plan’s standard prior authorization process if the service is considered experimental and investigational for the requested indication. See the Plan’s Experimental and Investigational Treatment medical policy (policy number OCA 3.12) for the product-specific definitions of experimental or investigational treatment.

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The Plan’s medical policies, reimbursement policies, and the member’s applicable benefit documents (including treatment guidelines and age-specific coverage) are available at [www.bmchp.org](http://www.bmchp.org) for BMC HealthNet Plan members (with benefit documents for Senior Care Options members available at [www.SeniorsGetMore.org](http://www.SeniorsGetMore.org)). See the Plan’s Temporomandibular Joint Disorder Treatment medical policy (policy number OCA 3.968) rather than this policy for clinical guidelines related to the treatment of temporomandibular joint disorders.

**Description of Item or Service**

**Prolotherapy:** Also known as joint sclerotherapy, regenerative injection, ligament reconstructive therapy, proliferant therapy, or proliferation therapy, prolotherapy is a procedure that involves a series of injections of sclerosants into the joints or ligaments to stimulate an inflammatory reaction to promote healing. The injection of sclerosants, or prolotherapy, is postulated to cause an influx of fibroblasts to the affected site, thereby causing fibrous new ligament or tendon tissue growth. Advocates of prolotherapy hypothesize that the “hyperproliferation” of tissue will increase joint strength and decrease laxity in cases of low back pain, knee osteoarthritis, and other musculoskeletal disorders. Prior to injection, pain trigger points are identified during the physical exam. In some cases, the patient may be sedated with oral or intravenous medication prior to injections. These solutions may include sclerosing agents such as Sarapin (an herbal extract), phenol, zinc sulfate, glucose, particles of pumice, mixed with glycerin or psyllium seed oil. The sclerosant is injected next to the painful site at the interface between the bone and tendon, ligament, or fascia.

**Medical Policy Statement**

Prolotherapy is considered experimental and investigational when used for the treatment of chronic musculoskeletal pain, temporomandibular joint disorders, and/or for any other condition.

**Limitations**

This service is considered experimental and investigational when used for any indication.

**Definitions**

**Temporomandibular Joint (TMJ):** The area directly in front of the ear on either side of the head where the upper jaw (maxilla) and the lower jaw (mandible) meet. The joints are complex and are composed of muscles, tendons, and bones which are used when chewing, talking, and yawning. See the Plan’s Temporomandibular Joint Disorder Treatment medical policy (policy number OCA 3.968) rather than this policy for clinical guidelines related to the treatment of temporomandibular joint disorders.

**Temporomandibular Joint (TMJ) Disorder:** Also known as myofascial pain dysfunction and Costen’s syndrome, this is a group of complex disorders of the temporomandibular joint(s) causing pain and dysfunction of the jaw joint and muscles that control jaw movement. See the Plan’s Temporomandibular Joint Disorder Treatment medical policy (policy number OCA 3.968) rather than Prolotherapy.
this policy for clinical guidelines related to the treatment of temporomandibular joint disorders. Treatment of TMJ disorder ranges from conservative to surgical, and the symptoms of TMJ disorder may include ONE (1) or more of the following, as specified below in items 1 through 8:

1. Biting or chewing difficulty or discomfort
2. Clicking sound while chewing or opening the mouth
3. Dull, aching pain in the face
4. Earache
5. Grating sensation while chewing
6. Headache
7. Jaw pain or tenderness of the jaw
8. Reduced ability to open or close the mouth

**Applicable Coding**

The Plan uses and adopts up-to-date Current Procedural Terminology (CPT) codes from the American Medical Association (AMA), International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10) diagnosis codes developed by the World Health Organization and adapted in the United States by the National Center for Health Statistics (NCHS) of the Centers for Disease Control under the U.S. Department of Health and Human Services, and the Health Care Common Procedure Coding System (HCPCS) established and maintained by the Centers for Medicare & Medicaid Services (CMS). Because the AMA, NCHS, and CMS may update codes more frequently or at different intervals than Plan policy updates, the list of applicable codes included in this Plan policy is for informational purposes only, may not be all inclusive, and is subject to change without prior notification. Whether a code is listed in the Applicable Coding section of this Plan policy does not constitute or imply member coverage or provider reimbursement. Providers are responsible for reporting all services using the most up-to-date industry-standard procedure and diagnosis codes as published by the AMA, NCHS, and CMS at the time of the service.

Providers are responsible for obtaining prior authorization for the services specified in the Medical Policy Statement section and Limitation section of this Plan policy, even if an applicable code appropriately describing the service that is the subject of this Plan policy is not included in the Applicable Coding section of this Plan policy. Coverage for services is subject to benefit eligibility under the member’s benefit plan. Please refer to the member’s benefits document in effect at the time of

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the service to determine coverage or non-coverage as it applies to an individual member. See Plan reimbursement policies for Plan billing guidelines.

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<tr>
<th>HCPCS Code</th>
<th>Description: Code Considered Experimental and Investigational</th>
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<tr>
<td>M0076</td>
<td>Prolotherapy</td>
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Plan note: This code is not covered for the Senior Care Options members.

Clinical Background Information

The goal of prolotherapy is to promote joint and ligamentous stability and thereby reduce pain associated with abnormal joint motion. Various agents are injected to cause local irritation and inflammation which are proposed to stimulate tissue growth and repair. The most common conditions treated with prolotherapy involve joint or ligament injuries of the neck, lower back, and knees. Prolotherapy has also been used to treat osteoarthritis and is being promoted for other chronic pain conditions that include migraines, temporomandibular joint disorders (TMJ), carpal tunnel syndrome, and fibromyalgia. Complications associated with prolotherapy may include headaches, pain, swelling, and infection after spinal, intra-articular knee and finger joint injections. Accelerated deterioration of bone and cartilage has been reported when frequent injections are administered over an extended period of time.

At the present time, there is insufficient scientific evidence in the peer-reviewed medical literature to support the efficacy of prolotherapy as a treatment for chronic musculoskeletal pain, TMJ disorders, and/or for any other condition. Additional studies would be needed to determine whether or not the use of prolotherapy provides any clinical benefit on health outcomes.

At the time of the Plan’s most recent policy review, the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) #150.7 for prolotherapy, joint sclerotherapy, and ligamentous injections with sclerosing agents states that the medical effectiveness of these therapies has not be verified by scientifically controlled studies and would not be considered medically necessary. Verify CMS criteria in the applicable NCD or local coverage determination (LCD) in effect for this service on the date of the prior authorization request for a Senior Care Options member.

References

http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=15&ncdver=1&SearchType=Advanced&CoverageSelection=Both&NCSelection=NC\%7CCAL%7CNCND%7CMEDCAC%7CTA%7CMCD&ArticleType=Ed\%7CKey%7CSAD%7CFAQ&PolicyType=Final&s=---%7C5%7C6%7C66%7C67%7C9%7C38%7C63%7C41%7C65%7C44&KeyWord=Prolotherapy%2C+Joint+Sclerotherapy%2C+and+Ligamentous+Injections+with+Sclerosing+Agents&KeyWordLookUp=Doc&KeyWordSearchType=Exact&kq=true&bc=IAAAABAAAAA&A

Centers for Medicare & Medicaid Services (CMS). Welcome to the Medicare Coverage Database. Accessed at:  


https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4938120/


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<table>
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<tr>
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<td>Internal Approval:</td>
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<td>Technology Assessment Committee (MPCTAC)</td>
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<td>01/27/09: Utilization Management Committee (UMC)</td>
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<td>02/25/09: Quality Improvement Committee (QIC)</td>
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*Effective Date for the BMC HealthNet Plan Commercial Product(s): 01/01/12
*Effective Date for Senior Care Options Product(s): 01/01/16

Note: Policy title was Prolotherapy for the Treatment of Chronic Musculoskeletal Pain until 09/30/17. Policy title changed to Prolotherapy as of 10/01/17.
### Policy Revisions History

<table>
<thead>
<tr>
<th>Review Date</th>
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<th>Revision Effective Date and Version Number</th>
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<td>Version 3</td>
<td>01/19/11: MPCTAC</td>
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<td>02/23/11: QIC</td>
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<td>08/01/12</td>
<td>Review with effective date of 10/01/12. Updated references. Revisions made to the following sections: Summary, Description of Item or Service, Medical Policy Statement, and Applicable Coding. Deleted redundant text in Clinical Background Information section.</td>
<td>10/01/12 Version 4</td>
<td>08/15/12: MPCTAC</td>
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<td>07/01/13</td>
<td>Review for effective date 09/01/13. Reformatted text in Clinical Background Information section. Updated references.</td>
<td>09/01/13 Version 5</td>
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<td>08/15/13: QIC</td>
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<td>03/01/14</td>
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<td>05/01/14 Version 6</td>
<td>03/19/14: MPCTAC</td>
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<td>04/16/14: QIC</td>
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<td>02/01/15</td>
<td>Review for effective date 04/01/15. No changes to the code list or criteria. Removed Commonwealth Care, Commonwealth Choice, and Employer Choice from the list of applicable products because the products are no longer available.</td>
<td>04/01/15 Version 7</td>
<td>02/18/15: MPCTAC</td>
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<td>03/11/15: QIC</td>
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<td>11/25/15</td>
<td>Review for effective date 01/01/16. Updated template with list of applicable products and notes. Revised language in the Applicable Coding section.</td>
<td>01/01/16 Version 8</td>
<td>11/18/15: MPCTAC</td>
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<tr>
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<td>Updated Description of Item or Service and References sections. Plan note added to the Applicable Coding section without revising the code list.</td>
<td>Version 10</td>
<td>02/08/17: QIC</td>
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<td>10/01/17</td>
<td>Review for effective date 10/01/17. Revised policy title. Updated Policy Summary, Description of Item or Service, Definitions, Clinical Background Information, References, and Other Applicable Policies sections. Administrative changes made to the Medical Policy Statement and Limitations sections.</td>
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Last Review Date

09/01/17

Next Review Date

09/01/18

Authorizing Entity

MPCTAC

Other Applicable Policies

Medical Policy – Experimental and Investigational Treatment, policy number OCA 3.12
Medical Policy – Temporomandibular Joint Disorder Treatment, policy number OCA 3.968

Reference to Applicable Laws and Regulations


Disclaimer Information: +

Medical Policies are the Plan’s guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as

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the Member’s benefit document, and when appropriate, coordinates with the Member’s health care Providers to consider the individual Member’s health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan’s service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member’s benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

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