Medical Policy

Prolotherapy

Policy Number: PG0170 Last Reviewed Date: 03/01/2025 Last Revised: 03/01/2025

n PARAMOUNT

HMO AND PPO ELITE (MEDICARE ADVANTAGE) MARKETPLACE

GUIDELINES:

- This policy does not certify benefits or authorization of benefits, which is designated by each individual
 policyholder terms, conditions, exclusions, and limitations contract. It does not constitute a contract or
 guarantee regarding coverage or reimbursement/payment. Self-Insured group specific policy will supersede
 this general policy when group supplementary plan document or individual plan decision directs otherwise.
- Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards.
- This medical policy is solely for guiding medical necessity and explaining correct procedure reporting used to assist in making coverage decisions and administering benefits.

SCOPE:

X Professional X Facility

DESCRIPTION:

Prolotherapy describes a procedure intended for healing and strengthening ligaments and tendons by injecting an agent that induces inflammation and stimulates endogenous repair mechanisms. Prolotherapy may also be referred to as proliferant injection, prolo, joint sclerotherapy, regenerative injection therapy, growth factor stimulation injection, or nonsurgical tendon, ligament, and joint reconstruction.

Prolotherapy is a procedure that consists of injecting sclerosing solutions into the joints, muscles, or ligaments in an attempt to increase joint stability. The proliferation of fibrous tissue caused by the body's natural inflammatory response to the injected drug is believed to increase joint stability. Prolotherapy has been investigated as a treatment for various etiologies of pain including musculoskeletal pain, arthritis, degenerative disc disease, fibromyalgia, tendonitis, plantar fasciitis, and soft tissue injuries. Prolotherapy may involve a single injection or a series of injections, often diluted with a local anesthetic.

Sclerosing agents function as inflammatory agents that cause minor injury to the ligament and initiate the first step in the wound healing process, leading to new collagen formation. Proponents suggest this may lead to increased ligament strength for back support. Examples of injection solutions include, but may not be limited to, sodium morrhuate, dextrose (D50), glycerine, zinc sulfate, fibrin glue or platelet rich plasma (PRP) and often includes an anesthetic agent, such as lidocaine.

POLICY:

Paramount Commercial Insurance Plans and Elite (Medicare Advantage) Plans

• Prolotherapy (M0076) is non-covered for all indications, including but not limited to, musculoskeletal pain

COVERAGE CRITERIA:

Paramount Commercial Insurance Plans and Elite (Medicare Advantage) Plans

Paramount has determined that prolotherapy (M0076) is experimental/investigational and therefore non-covered, for all indications, because effectiveness of this procedure has not been established, including the following (not an all-inclusive list):

• Achilles tendinosis

- Back pain
- Bladder pain syndrome / interstitial cystitis
- Buttock pain
- Chronic ankle instability
- Chronic ankle ligament injury
- Chronic supraspinatus tendinopathy
- Coccynodynia
- Core muscle injuries
- Epicondylitis (lateral epicondylopathy)
- Fasciopathies (including plantar fasciopathy)
- Hand osteoarthritis
- Iliotibial band syndrome
- Ischio-femoral impingement
- Knee ligament instability
- Knee osteoarthritis
- Ligament injuries
- Metatarso-phalangeal joint instability
- Musculoskeletal pain
- Myofascial pain
- Neck pain
- Neuropathic pain
- Osgood-Schlatter disease
- Osteomyelitis pubis
- Plantar fasciitis
- Post-herpetic neuralgia
- Rotator cuff disease (including bursitis, glenohumeral osteoarthritis, and rotator cuff tendinopathy)
- Sacroiliac joint pain / instability
- Shoulder pain
- Temporomandibular joint syndrome / Temporomandibular joint hypermobility / Temporomandibular joint luxation
- Tendinopathies

Prolotherapy is inappropriate to be billed under the trigger point injection code (i.e., 20550, 20551, 20552, 27096, 64490, 64491, 64492, 64493, 64494, 64495)

CODING/BILLING INFORMATION:

The appearance of a code in this section does not necessarily indicate coverage. Codes that are covered may have selection criteria that must be met. Payment for supplies may be included in payment for other services rendered.

HCPCS CODE	
M0076	Prolotherapy
20999	Unlisted procedure, musculoskeletal system, general [not covered when utilized for prolotherapy]

REVISION HISTORY EXPLANATION: ORIGINAL EFFECTIVE DATE: 06/30/2008

Date	Explanation & Changes
06/15/2009	Updated references
10/09/2018	 Prolotherapy (M0076) continues to be non-covered by all product lines Policy reviewed and updated to reflect most current clinical evidence per Medical Policy Steering Committee
12/15/2020	Medical policy placed on the new Paramount Medical Policy Format
02/09/2023	 Medical Policy updated to reflect Medicaid coverage to Anthem as of 02/01/2023
03/01/2024	 Medical Policy reviewed and updated to reflect the most current clinical evidence

• Medical Policy reviewed and updated to reflect the most current clinical evidence

Paramount reserves the right to review and revise our policies periodically when necessary. When there is an update, we will publish the most current policy to https://www.paramounthealthcare.com/providers/medical-policies/policy-library

REFERENCES/RESOURCES

Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services <u>https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals</u> <u>https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs</u>

CMS IOM Publication 100-03, *Medicare National Coverage Determinations (NCD) Manual*, Chapter 1, Part 2, Section 150.7 for Prolotherapy, Joint Sclerotherapy, and Ligamentous Injections with Sclerosing Agents

Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services <u>https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals</u> <u>https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals</u> <u>https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals</u> <u>https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals</u> <u>https://www.cms.gov/Regulations-and-Guidance/Manuals</u> <u>https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals</u> <u>https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals</u> <u>https://www.cms.gov/Regulations-and-Guidance/Manuals</u> <u>https://www.cms.gov</u>

National Physician Fee Schedule Relative Value File Calendar Year XXXX, Centers for Medicare & Medicaid Services (CMS) <u>https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Relative-Value-Files</u>

NCCI Policy Manual for Medicare Services, current version, Chapter 1, General Correct Coding Policies <u>https://www.cms.gov/files/document/medicare-ncci-policy-manual-2023-chapter-1.pdf</u>

American Medical Association, *Current Procedural Terminology (CPT®)* and associated publications and services <u>https://www.ama-assn.org/amaone/cpt-current-procedural-terminology</u>

Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets <u>https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update</u>

Centers for Medicare & Medicaid Services (CMS), ICD-10-CM Official Guidelines for Coding and Reporting https://www.cms.gov/medicare/coding/icd10

Centers of Medicare & Medicaid Services (CMS), Medicare Claims Processing Manual, Chapter 23-Fee Schedule administration and coding Requirements <u>https://www.cms.gov/Regulations-and-Guidance/Manuals/downloads/clm104c23.pdf</u>

Centers for Medicare & Medicaid Services (CMS), National Correct Coding Initiative (NCCI) Policy Manual for Medicare Services <u>https://www.cms.gov/medicare-medicaid-coordination/national-correct-coding-initiative-ncci/ncci-medicare</u>

Center for Medicare and Medicaid Services, Medicare NCCI Medically Unlikely Edits (MUEs) <u>https://www.cms.gov/medicare/coding-billing/national-correct-coding-initiative-ncci-edits/medically-unlikely-edits</u> U.S. Preventive Services Task Force, <u>https://www.uspreventiveservicestaskforce.org/uspstf/</u>

Hayes, Inc., https://www.hayesinc.com/

Industry Standard Review

Prior to 03/01/2024: DESCRIPTION

Prolotherapy is a procedure that consists of injecting sclerosing solutions into the joints, muscles, or ligaments in an attempt to increase joint stability. The proliferation of fibrous tissue caused by the body's natural inflammatory response to the injected drug is believed to increase joint stability. Prolotherapy has been investigated as a treatment for various etiologies of pain including arthritis, degenerative disc disease, fibromyalgia, tendonitis, plantar fasciitis, and soft tissue injuries. Prolotherapy may involve a single injection or a series of injections, often diluted with a local anesthetic.

Sclerosing agents act as inflammatory agents that cause minor injury to the ligament and initiate the first step in the wound healing process, leading to new collagen formation. Proponents suggest this may lead to increased ligament strength for back support. Examples of injection solutions include, but may not be limited to, sodium morrhuate, dextrose (D50), glycerine, zinc sulfate, fibrin glue or platelet rich plasma (PRP) and often includes an anesthetic agent, such as lidocaine.

There is sufficient published evidence to evaluate prolotherapy for the treatment of osteoarthritis of the knee. However, the study abstracts present conflicting findings regarding this technology. Full-text review is required to confirm abstract content and, therefore, conclusions about the safety and effectiveness of this technology cannot be made until a full assessment has been completed.

POLICY

Paramount Commercial Plans, Medicare Advantage Plans, and Paramount Medicaid Advantage

Prolotherapy (M0076) is non-covered by all product lines.

COVERAGE CRITERIA

Paramount Commercial Plans, Medicare Advantage Plans, and Paramount Medicaid Advantage

Paramount has determined that prolotherapy (M0076) is experimental and investigational and therefore noncovered because there is conflicting findings in the peer-reviewed medical literature of the effectiveness of this procedure.