Code Compendium (Musculoskeletal and Neurologic)



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Policy Number: WI.PA-1048-000 **Line of Business:** Medicare

Medical Coverage Policy

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Disclaimer

Change Summary

The Coverage Summaries are reviewed by the iCare Medicare Utilization Management Committee. Policies in this document may be modified by a member's coverage document. Clinical policy is not intended to preempt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test, or procedure over another. Clinical technology is constantly evolving, and we reserve the right to review and update this policy periodically. References to CPT® codes or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee of claims payment. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any shape or form or by any means, electronic, mechanical, photocopying or otherwise, without permission from iCare.

Related Documents

Please refer to CMS website for the most current applicable National Coverage Determination (NCD)/Local Coverage Determination (LCD)/Local Coverage Article (LCA)/CMS Online Manual System/Transmittals.

Туре	Title	ID Number	Jurisdiction Medicare Administrative Contractors (MACs)	Applicable States/Territories
NCD	Prolotherapy	<u>150.7</u>	N/A	N/A

Description

<u>Autologous Cellular Implant Derived from Adipose Tissue</u>

Autologous cellular implant derived from adipose tissue, also referred to as autologous adipose-derived regenerative cell therapy, autologous microfragmented adipose injection or Lipogems, is in the treatment of musculoskeletal conditions such as degenerative joint disease, osteoarthritis or rotator cuff tears. The procedure involves injecting mesenchymal stem cells (MSCs) into an impacted joint (eg, knee, shoulder) purportedly to aid tissue healing and regeneration. Adipose tissue is a desirable source of MSCs due to large quantities of MSCs found in the tissue, the abundance of adipose tissue and ease of collection. An example of a US Food & Drug Administration (FDA) approved device for processing lipoaspirated adipose tissue is the **Lipogems** system. Following microfragmentation, MSCs are injected intraarticularly into the donor under local anesthetic. Ultrasound guidance may be used in conjunction with the procedure when performed alone or the procedure may be an adjuvant to arthroscopy. The **Transpose Ultra** system is currently under investigation for the use to treat rotator cuff tendinopathy.

Hydrodissection

Hydrodissection is the injection of fluids, usually normal saline, through a peripheral nerve block needle to help release entrapped nerves by moving but not completely releasing the fascia, ligaments or tendons surrounding a nerve to treat neurologic and musculoskeletal conditions. Purportedly, the movement may disrupt adhesions and alleviate inflammation.

Prolotherapy

Prolotherapy is a pain management treatment that involves injecting a sclerosant (irritant) solution into the region of joints, muscles or ligaments that are thought to cause chronic low back or joint pain (as is commonly seen in arthritis). Prolotherapy, also known as reconstructive ligament therapy or joint sclerotherapy, may be used in an attempt to invoke the body's natural inflammatory response purportedly promoting new collagen growth to increase/improve joint stability or muscle regeneration/strengthening. 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.

Coverage Determination

iCare follows the CMS requirements that only allows coverage and payment for services that are reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member except as specifically allowed by Medicare.

In interpreting or supplementing the criteria above and in order to determine medical necessity consistently, iCare may consider the following criteria:

The use of the criteria in this Medicare Advantage Medical Coverage Policy provides clinical benefits highly likely to outweigh any clinical harms. Services that do not meet the criteria above are not medically necessary and thus do not provide a clinical benefit. Medically unnecessary services carry risks of adverse outcomes and may interfere with the pursuit of other treatments which have demonstrated efficacy.

Coverage Limitations

<u>US Government Publishing Office. Electronic code of federal regulations: part 411 – 42 CFR § 411.15 - Particular services excluded from coverage</u>

The following services will not be considered medically reasonable and necessary:

- Autologous cellular implant derived from adipose tissue, autologous adipose derived regenerative cell therapy, autologous microfragmented adipose injection or Lipogems for any musculoskeletal indication.
- Hydrodissection for any musculoskeletal or neurologic indication.
- Prolotherapy- See NCD <u>150.7</u>

A review of the current medical literature shows that the evidence is insufficient to determine that this service is standard medical treatment. There remains an absence of randomized, blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of this service in clinical management.

Summary of Evidence

Autologous cellular implant derived from adipose tissue

Available evidence from several systematic reviews (SRs) with meta-analyses suggests that intra-articular autologous MSC injections may reduce chronic pain in knee OA, but substantial heterogeneity across studies limits the reliability of SR results and the ability to make conclusions about how it compares with other noninvasive treatments for OA knee or ankle joint pain. The strength of evidence on ankle OA was too low to permit conclusions.³

Large multicenter randomized controlled trials (RCTs) that use standardized methods of MSC preparation, dose, and administration are needed to determine how best to use MSC to treat joint OA.³

US Food & Drug Administration (FDA) issued a consumer alert for the use of products derived from adipose tissue stating these substances have not been approved for the treatment of any orthopedic condition, such as osteoarthritis, tendonitis, disc disease, tennis elbow, back pain, hip pain, knee pain, neck pain, or shoulder pain.¹⁵

Hydrodissection

Neurological

An overall low-quality body of evidence from 9 studies suggests that hydrodissection for carpal tunnel syndrome is safe and may be effective over the short term, but hydrodissection may not confer any benefits beyond those resulting from perineural injection alone. The improvement in carpal tunnel syndrome pain intensity, symptom severity, and function was clinically meaningful from before treatment to follow-up periods of 3 to 6 months but may be related to a placebo effect, as shown by a single shamcontrolled trial. There is substantial uncertainty regarding the optimal treatment parameters for HD (e.g.,

injectate used, volume of injectate), long-term effectiveness of hydrodissection and the comparative effectiveness of hydrodissection versus other standard therapies.

Additional studies are needed to address the remaining questions regarding the optimal treatment parameters for hydrodissection (e.g., injectate used, volume of injectate), long-term effectiveness of hydrodissection, and the comparative effectiveness of hydrodissection versus other standard therapies.⁹

Musculoskeletal

A review of peer reviewed medical literature identified no clinical studies that provide suitable evidence to assess hydrodissection's safety and effectiveness for treating musculoskeletal conditions. Case reports of 6 patients in 2 publications reported successful treatment of muscle and tendon adhesions with hydrodissection, but these findings should be viewed as anecdotal until confirmed by prospective controlled clinical studies that compare this approach with other minimally invasive and conservative approaches to lysis of adhesions.⁵

Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

CPT [®] Code(s)	Description	Comments
27599	Unlisted procedure, femur or knee	
64999	Unlisted procedure, nervous system	
CPT® Category III Code(s)	Description	Comments
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	
HCPCS Code(s)	Description	Comments
M0076	Prolotherapy	Not Covered

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