COLLAGEN MENISCUS IMPLANT (NCD 150.12)

Guideline Number: MPG054.04 Approval Date: January 09, 2019

Table of Contents

Policies and Conditions

Table of Contents

POLICY SUMMARY ......................................................1
APPLICABLE CODES ...................................................1
PURPOSE ..................................................................2
REFERENCES .............................................................2
GUIDELINE HISTORY/REVISION INFORMATION ............2
TERMS AND CONDITIONS ...........................................2

POLICY SUMMARY

Overview
The knee menisci are wedge-shaped, semi-lunar discs of fibrous tissue located in the knee joint between the ends of the femur and the tibia and fibula. There is a lateral and medial meniscus in each knee. It is known now that the menisci provide mechanical support, localized pressure distribution, and lubrication of the knee joint. Initially, meniscal tears were treated with total meniscectomy; however, as knowledge of the function of the menisci and the potential long term effects of total meniscectomy on the knee joint evolved, treatment of symptomatic meniscal tears gravitated to repair of the tear, when possible, or partial meniscectomy.

The collagen meniscus implant (also referred to as collagen scaffold (CS), CMI or MenaflexTM meniscus implant throughout the published literature) is used to fill meniscal defects that result from partial meniscectomy. The collagen meniscus implant is not intended to replace the entire meniscus at it requires a meniscal rim for attachment. The literature describes the placement of the collagen meniscus implant through an arthroscopic procedure with an additional incision for capture of the repair needles and tying of the sutures. After debridement of the damaged meniscus, the implant is trimmed to the size of meniscal defect and sutured into place. The collagen meniscus implant is described as a tissue engineered scaffold to support the generation of new meniscus-like tissue. The collagen meniscus implant is manufactured from bovine collagen and should not be confused with the meniscus transplant which involves the replacement of the meniscus with a transplant meniscus from a cadaver donor. The meniscus transplant is not addressed under this national coverage determination.

Guidelines
Effective for claims with dates of service performed on or after May 25, 2010, the Centers for Medicare & Medicaid Services has determined that the evidence is adequate to conclude that the collagen meniscus implant does not improve health outcomes and, therefore, is not reasonable and necessary for the treatment of meniscal injury/tear under section 1862(a)(1)(A) of the Social Security Act. Thus, the collagen meniscus implant is non-covered by Medicare.

APPLICABLE CODES

The following list(s) of codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

Related Medicare Advantage Policy Guidelines

• Surgical or Other Invasive Procedure Performed on the Wrong Body Part (NCD 140.7)
• Surgical or Other Invasive Procedure Performed on the Wrong Patient (NCD 140.8)
• Wrong Surgical or Other Invasive Procedure Performed on a Patient (NCD 140.6)

Related Medicare Advantage Coverage Summary

• Orthopedic Procedures, Devices and Products
COLLAGEN MENISCUS IMPLANT (NCD 150.12)

Page 2 of 3

UnitedHealthcare Medicare Advantage Policy Guideline

Approved 01/09/2019

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PURPOSE

The Medicare Advantage Policy Guideline documents are generally used to support UnitedHealthcare Medicare Advantage claims processing activities and facilitate providers’ submission of accurate claims for the specified services. The document can be used as a guide to help determine applicable:

• Medicare coding or billing requirements, and/or
• Medical necessity coverage guidelines; including documentation requirements.

UnitedHealthcare follows Medicare guidelines such as LCDs, NCDs, and other Medicare manuals for the purposes of determining coverage. It is expected providers retain or have access to appropriate documentation when requested to support coverage. Please utilize the links in the References section below to view the Medicare source materials used to develop this resource document. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

REFERENCES

CMS National Coverage Determinations (NCDs)
NCD 150.12 Collagen Meniscus Implant

CMS Transmittals
Transmittal 121, Change Request 6903, Dated 05/28/2010 (Collagen Meniscus Implant)
Transmittal 1977, Change Request 6903, Dated 05/28/2010 (Collagen Meniscus Implant)

MLN Matters
Article MM6903, Collagen Meniscus Implant

UnitedHealthcare Commercial Policies
Meniscus Implant and Allograft

Others
Decision Memo for Collagen Meniscus Implant (CAG-00414N), CMS Website

GUIDELINE HISTORY/REVISION INFORMATION

Revisions to this summary document do not in any way modify the requirement that services be provided and documented in accordance with the Medicare guidelines in effect on the date of service in question.

<table>
<thead>
<tr>
<th>Date</th>
<th>Action/Description</th>
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<tbody>
<tr>
<td>04/01/2019</td>
<td>• Reorganized policy template; relocated Terms and Conditions and Purpose section</td>
</tr>
<tr>
<td>01/09/2019</td>
<td>• Annual review</td>
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TERMS AND CONDITIONS

The Medicare Advantage Policy Guidelines are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

These Policy Guidelines are provided for informational purposes, and do not constitute medical advice. Treating physicians and healthcare providers are solely responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

Benefit coverage for health services is determined by the member specific benefit plan document* and applicable laws that may require coverage for a specific service. The member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes the Medicare Advantage Policy Guidelines.

Medicare Advantage Policy Guidelines are developed as needed, are regularly reviewed and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making. UnitedHealthcare may modify these Policy Guidelines at any time by publishing a new version of the policy on this website. Medicare source materials used to develop these guidelines include, but are not limited to, CMS National

<table>
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<tr>
<th>HCPCS Code</th>
<th>Description</th>
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<tr>
<td>G0428</td>
<td>Collagen meniscus implant procedure for filling meniscal defects (e.g., CMI, collagen scaffold, Menaflex)</td>
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Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Medicare Benefit Policy Manual, Medicare Claims Processing Manual, Medicare Program Integrity Manual, Medicare Managed Care Manual, etc. The information presented in the Medicare Advantage Policy Guidelines is believed to be accurate and current as of the date of publication, and is provided on an "AS IS" basis. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

You are responsible for submission of accurate claims. Medicare Advantage Policy Guidelines are intended to ensure that coverage decisions are made accurately based on the code or codes that correctly describe the health care services provided. UnitedHealthcare Medicare Advantage Policy Guidelines use Current Procedural Terminology (CPT®), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT® or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee claims payment.

Medicare Advantage Policy Guidelines are the property of UnitedHealthcare. Unauthorized copying, use and distribution of this information are strictly prohibited.

*For more information on a specific member's benefit coverage, please call the customer service number on the back of the member ID card or refer to the Administrative Guide.