

<b>CMS Manual System</b>	Department of Health & Human Services (DHHS)
<b>Pub 100-03 Medicare National Coverage Determinations</b>	Centers for Medicare & Medicaid Services (CMS)
Transmittal 121	Date: May 28, 2010
	Change Request 6903

**SUBJECT: Collagen Meniscus Implant**

**I. SUMMARY OF CHANGES:** Upon completion of a national coverage analysis for the collagen meniscus implant, the decision was made that the collagen meniscus implant is non-covered for Medicare beneficiaries.

National coverage determination (NCD) are binding on all carriers, fiscal intermediaries, quality improvement organizations, qualified independent contractors, the Medicare Appeals Council, and administrative law judges (ALJs) (see 42 CFR section 405.1060(a)(4) (2005)). An NCD that expands coverage is also binding on a Medicare advantage organization. In addition, an ALJ may not review an NCD. (See section 1869(f)(1)(A)(i) of the Social Security Act.)

**EFFECTIVE DATE: MAY 25, 2010**

**IMPLEMENTATION DATE: JULY 6, 2010**

*Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revise information only, and not the entire table of contents.*

**II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)**

**R=REVISED, N=NEW, D=DELETED**

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	1/Table of Contents
N	1/150.12/Collagen Meniscus Implant (Effective May 25, 2010)

**III. FUNDING:**

**For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs) and/or Carriers:**

No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

**For Medicare Administrative Contractors (MACs):**

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the contracting officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the contracting officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

#### **IV. ATTACHMENTS:**

**Business Requirements  
Manual Instruction**

*\*Unless otherwise specified, the effective date is the date of service.*

# Attachment - Business Requirements

<b>Pub. 100-03</b>	<b>Transmittal: 121</b>	<b>Date: May 28, 2010</b>	<b>Change Request: 6903</b>
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**SUBJECT: Collagen Meniscus Implant**

**EFFECTIVE DATE: MAY 25, 2010**

**IMPLEMENTATION DATE: JULY 6, 2010**

## I. GENERAL INFORMATION

**A. Background:** This is a new national coverage determination (NCD). There is no existing NCD on collagen meniscus implants.

On August 27, 2009, the Centers for Medicare and Medicaid Services (CMS) initiated a national coverage analysis on the collagen meniscus implant. The collagen meniscus implant is manufactured from bovine collagen and is used to fill a meniscal defect that results from a partial meniscectomy. This change request (CR) communicates the findings of that analysis.

**B. Policy:** Effective for services performed on or after May 25, 2010, CMS has concluded that the evidence demonstrates that the collagen meniscus implant does not improve health outcomes. Thus, CMS has determined that the collagen meniscus implant is not reasonable and necessary and is non-covered as identified in Pub. 100-03, NCD Manual, section 150.12.

**NOTE:** Effective with the July updates of the Medicare Physician Fee Schedule Database and the Integrated Outpatient Code Editor, a new HCPCS code G0428 will be available for use in non-covering collagen meniscus implant claims with dates of service on and after May 25, 2010.

## II. BUSINESS REQUIREMENTS TABLE

*Use "Shall" to denote a mandatory requirement*

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A D B M A C	D M M A C	F I I E R	C A R I E R	R H H I	Shared-System Maintainers				OTH ER
						F I S S	M C S	V M S	C W F		
6903.1	Effective for claims with dates of service on and after May 25, 2010, contractors shall deny claims submitted for a collagen meniscus implant. See Pub. 100-20, of the same subject for detailed business requirements.	X		X	X						

### III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B  M A C	D M E  M A C	F I	C A R R I E R	R H I	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F	
6903.2	<p>A provider education article related to this instruction will be available at <a href="http://www.cms.hhs.gov/MLNMattersArticles/">http://www.cms.hhs.gov/MLNMattersArticles/</a> shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv.</p> <p>Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.</p>	X		X	X						

### IV. SUPPORTING INFORMATION

**Section A: For any recommendations and supporting information associated with listed requirements, use the box below: N/A**

*Use "Should" to denote a recommendation.*

X-Ref Requirement Number	Recommendations or other supporting information:

**Section B: For all other recommendations and supporting information, use this space: N/A**

### V. CONTACTS

**Pre-Implementation Contact(s):** Deirdre O'Connor, (410) 786-3263, [deirdre.oconnor@cms.hhs.gov](mailto:deirdre.oconnor@cms.hhs.gov), (coverage); Patricia Brocato-Simons, (410) 786-0261, [patricia.brocato-simons@cms.hhs.gov](mailto:patricia.brocato-simons@cms.hhs.gov), (coverage); Michelle Atkinson, (410) 786-2881, [michelle.atkinson@cms.hhs.gov](mailto:michelle.atkinson@cms.hhs.gov), (coverage); Cynthia Glover, (410) 786-2589, [Cynthia.Glover@cms.hhs.gov](mailto:Cynthia.Glover@cms.hhs.gov), carrier claims; Elizabeth Carmody, institutional claims, 410-786-7533, [elizabeth.carmody@cms.hhs.gov](mailto:elizabeth.carmody@cms.hhs.gov).

**Post-Implementation Contact(s):** Appropriate regional office or MAC project officer.

## **VI. FUNDING**

### **Section A: For *Fiscal Intermediaries (FIs)*, *Regional Home Health Intermediaries (RHHIs)*, and/or *Carriers*:**

No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

### **Section B: For *Medicare Administrative Contractors (MACs)*, include the following statement:**

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the contracting officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the contracting officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

# Medicare National Coverage Determinations Manual

## Chapter 1, Part 2 (Sections 90 – 160.25)

### Coverage Determinations

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*(Rev.121, 05-28-10)*

*150.12 – Collagen Meniscus Implant (Effective May 25, 2010)*

**150.12 – Collagen Meniscus Implant (Effective May 25, 2010)**  
**(Rev.121, Issued: 05-28-10, Effective: 05-25-10, Implementation: 07-06-10)**

**A. General**

*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 Menaflex<sup>TM</sup> 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 as 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.*

**B. Nationally Covered Indications**

N/A

**C. Nationally Non-Covered Indications**

*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.*

**D. Other**

N/A

**(This NCD last reviewed May 2010.)**