Advance Beneficiary Notice (ABN)

Medicare:

For patients with Fee-for-service Medicare coverage, the Centers for Medicare and Medicaid Services (CMS) requires physicians to provide a written notice known as an ABN to a Medicare beneficiary before the procedure is done to advise the patient that the service may not be covered by Medicare. An ABN informs beneficiaries of their financial responsibilities for the anticipated non-covered procedure so they can decide whether or not to receive the service. If a provider does not issue a beneficiary an ABN when one is required and payment for furnished items and/or services is denied by Medicare, the provider cannot bill the beneficiary for the service.

Providers are required to issue an ABN to a beneficiary if they intend to bill the beneficiary for items or services for which it is expected that Medicare may deny payment because, among other reasons, the item or service is not considered reasonable and necessary under Medicare Program standards. However, ABNs may not be used to bill the patient for services that are included in a global or bundled payment. An ABN is not valid unless the beneficiary signs and dates the form, is provided a copy for his or her records, and the original document is retained in the patient's file. An ABN is valid for up to one year. When billing Medicare, modifier GA (waiver of liability on file) must be appended to the claim line.

Instructions on how to complete the ABN, along with a downloadable ABN form (CMS-R-131) can be accessed at:
https://www.cms.gov/Medicare/Medicare-General-Information/BNI/Downloads/ABN-Form-Instructions.pdf

Non-Medicare Payers:

For patients with private insurance, physician practices should consider obtaining a financial waiver from the patient. This waiver informs the patient of his or her responsibility to pay for the costs associated with CMI. All waivers should be kept on file. Non-covered services may not need to be reported to the insurance company, although patients may request that a claim be submitted.

Appealing Denied Claims

- Providers should verify the coverage and reimbursement policies for the CMI on a patient-by-patient and payer-by-payer basis.
- Providers should determine payer specific Prior Authorization requirements and submit the required documentation.
- If a claim is denied, providers should work with the payer to identify the requirements for and procedure to appeal a denied claim.
- A list of published clinical literature relevant to use of CMI may be obtained from the company directly to support the submission of initial claims or appeal of denied claims at 201-831-5000 or by sending the request through the company website at www.stryker.com.

The coding, coverage, and payment information contained herein is gathered from various resources and is subject to change without notice. Stryker cannot guarantee success in obtaining third-party insurance payments. Third-party payment for medical products and services is affected by numerous factors. It is always the provider's responsibility to determine and submit appropriate codes, charges, and modifiers for services that are rendered. Providers should contact their third-party payers for specific information on their coding, coverage, and payment policies.

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Collagen Meniscus Implant (CMI)

Billing Guide

Description

The Collagen Meniscus Implant (CMI) is a biocompatible scaffold that can be used to reinforce and repair a meniscus defect following partial meniscectomy or for irreparable meniscus tears. The implant has the general shape of the human meniscus and is trimmed by the surgeon to match the size of the meniscal defect. The implant is inserted via a minimally invasive procedure and sutured in place to the native meniscus.

To learn more about the CMI and view the FDA approved label, please visit stryker.com or contact us at 201.831.5000

Indications for Use

The CMI implant is intended for use in surgical procedures for the reinforcement and repair of chronic soft tissue injuries of the meniscus. In repairing and reinforcing medial meniscal defects, the patient must have an intact meniscal rim and anterior and posterior horns for attachment of the mesh. In addition, the surgically prepared site for the CMI must extend at least into the red/white zone of the meniscus to provide sufficient vascularization. The CMI reinforces soft tissue and provides a resorbable scaffold that is replaced by the patient's own soft tissue. The CMI is not a prosthetic device and is not intended to replace normal body structure.

Potential CMI Billing Codes

Potential CMI Product Codes

Codes	Descriptors	
A4649	Surgical Supply, Miscellaneous	**Non Medicare Payers** • Providers may report A4649 Surgical Supply, miscellaneous, to describe the CMI. • For non-Medicare payers, providers should check individual payer agreements to verify coverage and reimbursement policies for supplies and implants. **Workers Compensation** • Providers should verify coverage and reimbursement policies for services rendered and products furnished including any prior authorization requirements.
A9270	Non-covered item or service	**Medicare** • Presently, CMS does not consider collagen meniscus implant reasonable and necessary for the treatment of meniscal injury/tear. CMI is not therefore a covered Medicare benefit, as identified in section 150.12 of the National Coverage Determination (NCD) Manual. • CMI is not covered or payable by Medicare in Ambulatory Surgical Centers or Hospital Outpatient Departments.[1] • A Medicare beneficiary's secondary or supplemental insurance may cover and reimburse for the CMI. Providers should verify and submit appropriate codes, charges, and modifiers and documentation for CMI to comply with the coverage and reimbursement policies of any supplemental insurance, if applicable.

Potential CMI Procedure Codes

Codes	Descriptors	
G0428	Collagen meniscus implant procedure for filling meniscal defects (e.g., CMI, collagen scaffold, Menaflex)	**Medicare** • HCPCS code G0428 describes the procedure for implanting the CMI • CMS has determined that the CMI is not reasonable and necessary for the treatment of meniscal injury/tear and is not covered by Medicare. • Medicare claims submitted for a collagen meniscus implant procedure described by G0428 will thus be denied. • In denying claims, Medicare will use Claim Adjustment Reason Code 96 (Non-covered charge(s)" and Remittance Advice Remark Code N386 (This decision was based on a National Coverage Determination (NCD).[2] • Payment may be collected from the patient for this surgical service, when the provider obtains an advance beneficiary notice (ABN) form from the patient. • Medicare contractors will use Group Code PR (Patient Responsibility) assigning responsibility to the patient if a valid ABN is on file. Otherwise Group Code CO (Contractual Obligation) will be used assigning financial liability to the provider if no valid ABN is on file.[3] **Non-Medicare Payers:** Coverage and reimbursement for physician services performed in a facility setting for implanting the CMI will likely vary from payer to payer. Coverage and reimbursement policies for any CPT or HCPCS codes reported to describe any such services should be verified with the potential third-party payer. **Workers Compensation** Providers should verify coverage and reimbursement policies for services rendered and products furnished including any prior authorization requirements. Workers Compensation guidelines and requirements followed by the state or insurer will vary. Providers should verify coverage and reimbursement policies, permitted fees, documentation requirements, and other policies applicable to CMI. Some workers' compensation programs refer to the Official Disability Guidelines (ODG) from the Work Loss Data Institute. ODG has a favorable coverage position for the collagen meniscus implant in specific patients that have chronic meniscectomies. For more information about the ODG's guidelines and their coverage position on CMI, please visit http://www.odg-twc.com. To see an overview of the ODG, please click on the below link to attend a free webinar.https://attendee.gotowebinar.com/rt/5512752652931937793.
29999	Unlisted procedure, arthroscopy	**Medicare** Claims submitted for a collagen meniscus implant procedure using CPT code 29999 will be denied since the procedure is a non-covered service under Medicare. **Non-Medicare Payers:** Providers may report CPT code 29999 when G0428 is not recognized by non-Medicare payers. CPT code 29999 is an unlisted procedure code and will not have a predetermined payment rate in any fee schedule. Providers must submit additional documentation, often payer specific, for adjudication of the claim. Providers should determine and report appropriate modifiers with these procedure codes to identify the service setting of care. Coverage and reimbursement policies may vary among settings of care.

Potential Revenue Codes

Codes	Descriptors	
0278	Medical/Surgical Supplies and Devices, Other Implant.	Report the implant under Revenue code 0278 on the UB04 claim form. **Medicare** CMI and related procedures are not separately payable by Medicare. The cost of the implant and disposable supplies are reflected in the APC payment rate for the procedure. **Non-Medicare Payers:** Coverage and reimbursement for supplies and implants used in clinical procedures will likely vary from payer to payer. Providers should check individual payer agreements to verify coverage and reimbursement policies for these items

Potential Revenue Codes

The provider is responsible for selecting the most appropriate ICD-10 diagnosis codes

1 CMS, MLN Matters: Collagen Meniscus Implant, May 28, 2010, available at https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM6903.pdf.

2 CMS, National Coverage Determination (NCD) for Collagen Meniscus Implant (150.12) available at https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=337&ncdver=1&DocID=150.12&SearchType=Advanced&bc=IAAAABAAAAAA&. Last viewed 3/03/2016

3 CMS, MLN Matters: Collagen Meniscus Implant, May 28, 2010, available at https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM6903.pdf.

Stryker provides this reimbursement guide for informational purposes only and is subject to change at any time without notice. This guide is not an affirmative instruction as to which codes and modifiers to use for a particular service, supply, procedure or treatment. Stryker makes no representation or warranty regarding this information or its completeness, accuracy or timeliness. It is the provider's responsibility to determine and submit the appropriate codes and modifiers for any service, supply, procedure or treatment rendered. Actual codes and/or modifiers used are at the sole discretion of the treating physician and/or facility. Contact your local payer for specific coding and coverage guidelines. Stryker cannot guarantee medical benefit coverage or reimbursement with the codes listed in this guide. 1000902212 Rev A

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