Harmony Behavioral Health, Inc.

Harmony Behavioral Health of Florida, Inc.

Harmony Health Plan of Illinois, Inc.

HealthEase of Florida, Inc.

'Ohana Health Plan, a plan offered by
WellCare Health Insurance of Arizona, Inc.

WellCare Health Insurance of Illinois, Inc.

WellCare Health Insurance of New York, Inc.

WellCare Health Plans of New Jersey, Inc.

WellCare of Florida, Inc.

WellCare of Connecticut, Inc.

WellCare of Georgia, Inc.

WellCare of Kentucky, Inc.

WellCare of Louisiana, Inc.

WellCare of New York, Inc.

WellCare of Ohio, Inc.

WellCare of Texas, Inc.

WellCare Prescription Insurance, Inc.

Collagen Meniscus Implant (Medicare)

Policy Number: HS-172

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DISCLAIMER

The Clinical Coverage Guideline is intended to supplement certain standard WellCare benefit plans. The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this Clinical Coverage Guideline. When a conflict exists between the two documents, the Member's Benefit Plan always supersedes the information contained in the Clinical Coverage Guideline. Additionally, Clinical Coverage Guidelines relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

BACKGROUND

Centers for Medicare and Medicaid Services Decision Memo

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. "Meniscal tears are common orthopaedic injuries, affecting patients of various ages and activity levels" (Fabricant and Jokl 2007). The incidence of meniscus injuries has been reported at 61 per 100,000 (Rimington et al. 2009). Medicare Part B claims data for 2007 identified over 125,000 meniscectomies performed on Medicare beneficiaries.

"Meniscus injuries can be divided into 2 groups: traumatic tears and degenerative tears. Traumatic tears occur in a younger population and are usually the result of a discrete traumatic episode. Degenerative tears are thought to progress from intrasubstance degeneration within the menisci" (Rimington et al. 2009). Degenerative tears of the menisci are thought to be part of the normal aging process (Bonamo et al. 1992). "Injuries to a healthy meniscus are induced by compressive force in combination with tibiofemoral rotation in the transverse plane during a movement from flexion to extension or during rapid cutting or pivoting" (Buma et al. 2007). "The pathomechanics of the more complex degenerative tears is still unknown" (Buma et al. 2007).

"Historically, the meniscus was thought to be vestigial tissue; now it is known that the menisci provide mechanical support, localized pressure distribution, and lubrication of the knee joint" (Fabricant and Jokl 2007). Initially, treatment for meniscal tears was total meniscectomy. In 1948, Fairbank concluded, "meniscectomy is not wholly innocuous; it interferes, at least temporarily, with the mechanics of the joint" (Fairbank 1948). In 1968, Jackson summarized that a high proportion of knees after meniscectomy showed degenerative changes. Jackson felt these changes were more frequent than could be accounted for by the normal aging process (Jackson 1968). In 1998, Messner related the substantial change in the therapeutic approach to this common work or sports injury to Fairbank's discovery of the development of cartilage degeneration and bone remodeling after meniscectomy (Messner and Gao 1998).

"As the biomechanical importance of the meniscus has been revealed, it has become clear that procedures that preserve the meniscus have significant long-term advantages for the patient" (Belzer and Cannon 1993). In 1983, Hamberg noted that the complications from complete meniscectomy led some surgeons to adopt a more conservative approach to treatment of meniscal tears, making partial meniscectomy the preferred technique (Hamberg et al. 1983). Fabricant and Jolk stated, "The definitive treatment of meniscal tear is repair or excision of the pathologic tissue; however, not all patients with meniscal tears require surgical intervention. Asymptomatic meniscal tears are relatively common findings on magnetic resonance imaging (MRI)" (Fabricant and Jokl 2007). Belzer noted that if a meniscus tear could not be repaired, a conservative partial meniscectomy should be undertaken to preserve as much meniscal tissue as possible to decrease the risk of late degenerative changes (Belzer and Cannon 1993).

When meniscal tears are symptomatic, patients usually complain of clicking and pain with activity. At times a tear can displace and cause locking of the knee joint.

Sohn and Moorman describe tear types as usually being classified by the pattern of the tear. They provided a further description of tear types as: Acute tear patterns, such as vertical, bucket-handle, and radial tears are seen most often in younger patients. Older patients tend to develop degenerative tear patterns, such as horizontal cleavage tears, oblique tears, and complex combinations of patterns. Tears have also been classified as stable or unstable. All partial thickness tears are stable. Full thickness tears differ based on whether the tear is vertical and longitudinal, or radial. Tear types are also commonly classified by their location relative to the peripheral blood supply with labels of red-red, white-white, and red-white. Red-red tears are peripheral and have blood supply to both sides of the tear and thus have the highest chance of healing. White-white tears are central and avascular and thus have the least chance of healing. Red-white tears have vascularity at the peripheral side of the tear and

no vascularity on the central side of the tear. These have a mixed ability to heal (Sohn and Moorman 2008).

Treatments of meniscal tears are not without controversy. Menetrey stated, "Meniscectomy in the older patient remains a controversial topic. …Arthroscopic medial meniscectomy in older patients provides 90% good results six years after non-degenerative meniscal tear, but only 20% of good results after degenerative meniscal tear. However, based on this study, neither symptoms nor physical examination are able to differentiate between traumatic meniscal tears and degenerative meniscal changes in older patients" (Menetrey et al. 2002). Belzer felt that meniscus repair should be limited to patients under 50 years of age (Belzer and Cannon 1993). Herrlin stated that there was still no consensus about the treatment of choice for degenerative meniscus tears. Herrlin found arthroscopic partial medial meniscectomy followed by supervised exercise was not superior to supervised exercise alone (Herrlin et al. 2007). Studies have shown limited and conflicting data on whether age, gender, and weight are important factors relative to clinical outcomes after arthroscopic meniscal debridement (Sohn and Moorman 2008). Sohn and Mooreman also felt meniscal debridement should be reserved for unstable, symptomatic tears. In 1996, Rockborn and Gillquist stated, "…knowledge as to the physiological characteristics of knee joint menisci has advanced, but these advances have not been reflected in further adjustment of clinical therapy. On the contrary, we still have little evidence that the previous `advances' in therapy are genuinely superior to the earlier methods with complete removal of the meniscus" (Messner and Gao 1998). Messner also felt that there was no evidence that repair of a tear in the avascular region is better than partial meniscectomy (Messner and Gao 1998). Starke stated that the results found in the literature regarding whether meniscal repair resulted in improved outcomes compared with meniscectomy were equivocal (Stark et al. 2009).

Because of the recognized important functions of the intact menisci and the risk for development of osteoarthrosis after meniscal removal, meniscal replacement has been advocated in cases with extensive meniscal damage or after total meniscectomy (Messner and Gao 1998). Steadman stated, "Replacement of the damaged or lost portion of the meniscus cartilage would seem an appropriate approach to prevent or minimize the progressive degenerative joint disease that may develop as a sequel" (Steadman and Rodkey 2006). The collagen meniscus implant can be 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 (Rodkey et al. 2008).

The focus of this national coverage analysis (NCA) is on collagen meniscus implants. The collagen meniscus implant is also identified as collagen scaffold (CS) or CMI throughout the literature, FDA documents, and consequently, this document. 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 the meniscal defect and sutured into place (Rodkey et al. 1999). No mention is made in the literature of placement of the collagen meniscus implant in combination with a knee arthrotomy procedure.

There were six small observational clinical case studies and one randomized controlled trial (RCT) for the collagen meniscus implant identified and reviewed. The RCT was designed to show superiority of the collagen meniscus implant with partial medial meniscectomy compared to partial medial meniscectomy alone. The RCT failed to show superiority on any of the a priori primary endpoints – pain, function, patient satisfaction. Although the Tegner index was reported to show a patient benefit in the treatment group of the chronic arm of the RCT, this was not a pre-specified primary or secondary endpoint for the trial. In fact, the Tegner index was an author-defined measure based on the Tegner activity score and has not been validated as an outcome measure nor has its clinical significance been reported in the literature. The Tegner index fails to meet any evidentiary standard to show a benefit of improved patient outcomes for this device.

The FDA analysis of the adverse events data is concerning and brings into question possible patient harms related to the collagen meniscus implant. In addition, the discrepancy in the adverse events reported in the published article on the RCT and the data provided to the FDA is disconcerting. Discrepancies in reported patient outcomes data also creates concerns about the reliability of study results published in peer reviewed journals and begs the

question of what resources can be relied on with confidence to make evidence based decisions in healthcare. The reported reoperation rate data is potentially biased by the additional procedures performed during the protocol-specified re-look procedures on the treatment group in the trial. The RCT for the collagen meniscus implant failed to meet any of the primary endpoints in the trial.

The CMS has concluded that the collagen meniscus implant does not improve health outcomes in the Medicare population. Therefore, CMS has determined that the collagen meniscus implant is not reasonable and necessary for the treatment of meniscal injury/tear and we are issuing a national non-coverage determination under §1862(a)(1)(A) of the Social Security Act.

POSITION STATEMENT

The collagen meniscus implant does not improve health outcomes in the Medicare population and **is considered NOT medically necessary.**

CODING

Non Covered HCPCS© Level II Code

G0428 Collagen or other tissue engineered meniscus knee implant procedure for filling meniscal defect (e.g., collagen scaffold, Menaflex)

Related CPT© Code

29868 Arthroscopy, knee, surgical; meniscal transplantation (includes arthrotomy for meniscal insertion) medial or lateral.

Related ICD-9-CM Procedure Code

81.47 Other repair of the knee

Related ICD-9-CM Diagnosis Codes

717.0 Old bucket handle tear of medial meniscus
717.1 Derangement of anterior horn of medial meniscus
717.2 Derangement of posterior horn of medial meniscus
717.3 Other and unspecified derangement of medial meniscus
717.40 Derangement of lateral meniscus, unspecified
717.41 Bucket handle tear of lateral meniscus
717.42 Derangement of anterior horn of lateral meniscus
717.43 Derangement of posterior horn of lateral meniscus
717.49 Other derangement of lateral meniscus
717.5 Derangement of meniscus, not elsewhere classified
836.0 Tear of medial cartilage or meniscus of knee, current
836.1 Tear of lateral cartilage or meniscus of knee current
836.2 Other tear of cartilage or meniscus of knee, current

REFERENCES

Peer Reviewed

N/A

Government Agencies, Professional and Medical Organizations

1. Center for Medicare and Medicaid Services (CMS) Decision Memo for Collagen Meniscus Implant (CAG-00414N). May 25, 2010. NOTE: All cited references contained in Decision Memo.

HISTORY AND REVISIONS

Date	Action
12/1/2011	• New template design approved by MPC.
8/2/2011	• Approved by MPC. No changes.