Medical Coverage Policy | Synthetic Cartilage Implants for Joint Pain

EFFECTIVE DATE: 11|01|2019
POLICY LAST UPDATED: 07|16|2019

OVERVIEW

Articular cartilage damage, either from a focal lesion or diffuse osteoarthritis, can result in disabling pain. Cartilage is a hydrogel, comprised mostly of water with collagen and glycosaminoglycans, that does not typically heal on its own. The purpose of a synthetic cartilage implant in patients who have advanced first metatarsophalangeal (MTP) joint OA to provide a treatment option that is an alternative to or an improvement on existing therapies.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

BlueCHiP for Medicare Products

Synthetic cartilage implants are considered not covered for the treatment of articular cartilage damage as the evidence is insufficient to determine the effects of the technology on health outcomes

Commercial Products

Synthetic cartilage implants are considered not medically necessary for the treatment of articular cartilage damage as the evidence is insufficient to determine the effects of the technology on health outcomes

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable not medically necessary/not covered benefits/coverage.

BACKGROUND

Articular Cartilage Damage

Articular cartilage damage may present as focal lesions or as more diffuse osteoarthritis (OA). Cartilage is a biological hydrogel that is comprised mostly of water with collagen and glycosaminoglycans and does not typically heal on its own. OA or focal articular cartilage lesions can be associated with substantial pain, loss of function, and disability. OA is most frequently observed in the knees, hips, interphalangeal joints, first carpometacarpal joints, first metatarsophalangeal (MTP) joint, and apophyseal (facet) joints of the lower cervical and lower lumbar spine. OA less commonly affects the elbow, wrist, shoulder, and ankle. Knee OA is the most common cause of lower-limb disability in adults over age 50. OA of the MTP joint with loss of motion (hallux rigidus) can also be severely disabling due to pain in the "toe-off" position of gait. An epidemiologic study found that OA of the first MTP joint may be present in as many as 1 in 40 people over the age of 50.[1]

Treatment

Conventional treatment options for painful focal damaged articular cartilage of the knee include débridement, abrasion techniques, osteochondral autografting, and autologous chondrocyte implantation. Débridement involves the removal of the synovial membrane, osteophytes, loose articular debris, and diseased cartilage and is capable of producing symptomatic relief. Subchondral abrasion techniques attempt to restore the articular

surface by inducing the growth of fibrocartilage into the chondral defect. Diffuse OA of the knee, hip, or ankle may be treated with joint replacement.

Early-stage OA of the first MTP is typically treated with conservative management, including pain medication and change in footwear. Failure of conservative management in patients with advanced OA of the MTP joint may be treated surgically. Cheliectomy (removal of bone osteophytes) and interpositional spacers with autograft or allograft have been used as temporary measures to relieve pain.

Although partial or total joint replacement have been explored for MTP OA, complications from bone loss, loosening, wear debris, implant fragmentation, and transfer metatarsalgia are not uncommon. Also, since the conversion of a failed joint replacement to arthrodesis has greater complications and worse functional results than a primary arthrodesis (joint fusion), MTP arthrodesis is considered the most reliable and primary surgical option. Arthrodesis can lead to a pain-free foot, but the loss of mobility in the MTP joint alters gait, may restrict participation in running and other sports, and limits footwear options, leading to patient dissatisfaction. Transfer of stress and arthritis in an adjacent joint may also develop over time.

Because of the limitations of MTP arthrodesis, alternative treatments that preserve joint motion are being explored. Synthetic cartilage implants have been investigated as a means to reduce pain and improve function in patients with hallux rigidus. Some materials such as silastic were found to fragment with use. Other causes of poor performance are the same as those observed with metal and ceramic joint replacement materials and include dislocation, particle wear, osteolysis, and loosening.

Synthetic polyvinyl alcohol (PVA) hydrogels have water content, and biomechanical properties similar to cartilage and they are biocompatible. PVA hydrogels have been used in a variety of medical products including soft contact lens, artificial tears, hydrophilic nerve guides, and tissue adhesion barriers. This material is being evaluated for cartilage replacement due to the rubber elastic properties and, depending on the manufacturing process, high tensile strength and compressibility.[2]

The Cartiva implant is an 8- to 10-mm PVA disc that is implanted with a slight (1- to 1.5-mm) protrusion to act as a spacer for the first MTP joint. It comes with dedicated reusable instrumentation, which includes a drill bit, introducer, and placer. The Cartiva PVA implant was approved by the U.S. Food and Drug Administration (FDA) in 2016 for the treatment of arthritis of the MTP joint. It has been distributed commercially since 2002 with approval in Europe, Canada, and Brazil.

For individuals who have early-stage first MTP osteoarthritis who receive a synthetic cartilage implant, the evidence is lacking. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The pivotal study was performed in patients with Coughlin stage 2, 3, or 4 hallux rigidus. No evidence was identified in patients with stage 0 to early-stage 2 hallux rigidus. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have advanced first MTP osteoarthritis who receive a synthetic cartilage implant, the evidence includes a pivotal randomized controlled trial. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Arthrodesis is the established treatment for advanced arthritis of the great toe, although the lack of mobility can negatively impact sports and choice of footwear and is not a preferred option of patients. Implants have the potential to reduce pain and maintain mobility in the first MTP joint but have in the past been compromised by fragmentation, dislocation, particle wear, osteolysis, and loosening. A polyvinyl alcohol hydrogel implant has shown properties similar to articular cartilage in vitro and was approved by the Food and Drug administration in 2016 for the treatment of painful degenerative or posttraumatic arthritis in the MTP joint. The pivotal trial compared the implant with arthrodesis and showed patient-reported pain scores to be slightly worse than arthrodesis with similar outcomes between the 2 groups on scores for activities of daily living and sports. Five-year follow-up was reported in 2017 for about 20% of the original

cohort, which showed no evidence of implant degradation or reduction in pain and function. Continued Food and Drug Administration approval depends on a 5-year follow-up of the complete cohort and will provide needed information on implant durability. There is a high possibility of bias in favor of the novel device. Corroboration of long-term results in an independent study would provide greater confidence in the findings of the pivotal trial. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have articular cartilage damage in joints other than the great toe who receive a synthetic cartilage implant, the evidence includes observational studies. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. No randomized controlled trials were identified. The evidence is insufficient to determine the effects of the technology on health outcomes

Regulatory Status

In July 2016, Cartiva® Synthetic Cartilage Implant (Cartiva, Alpharetta, GA) was approved by the FDA through the premarket approval process (P150017) for painful degenerative or posttraumatic arthritis in the first MTP joint along with hallux valgus or hallux limitus and hallux rigidus. Lesions greater than 10 mm in size and insufficient quality or quantity of bone are contraindications. Continued approval depends on a study evaluating long-term safety and effectiveness. The post-approval study will follow the subjects treated with Cartiva® Synthetic Cartilage Implant for 5 years. FDA product code: PNW.

CODING

BlueCHiP for Medicare Products and Commercial Products

The following code is not covered for BC for Medicare and not medically necessary for Commercial Products:

This is no specific code to the Cartiva "Hydrogel" Implant; claims for this implant should be filed with the following unlisted code:

L8699 Prosthetic Implant, not otherwise specified

NOTE: The following CPT code is not covered for BC for Medicare and not medically necessary for Commercial Products when filed for implantation of a synthetic cartilage implant:

28291 Hallux rigidus correction with cheilectomy, debridement and capsular release of the first metatarsophalangeal joint; with implant

RELATED POLICIES

None

PUBLISHED

Provider Update, September 2020

Provider Update, September 2019

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