Osteochondral Allografts and Autografts for Cartilaginous Defects

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SCOPE: Providence Health Plan, Providence Health Assurance, and Providence Plan Partners as applicable (referred to individually as “Company” and collectively as “Companies”).

PLAN PRODUCT AND BENEFIT APPLICATION

☒ **Commercial** ☐ **Medicaid/OHP*** ☐ **Medicare****

*Medicaid/OHP Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

Osteochondral Allografts and Autografts: Guideline Note 220

**Medicare Members

This *Company* policy may be applied to Medicare Plan members only when directed by a separate *Medicare* policy. Note that investigational services are considered **"not medically necessary"** for Medicare members.

COVERAGE CRITERIA

Osteochondral Allografting of the Knee

I. Osteochondral allografting of the knee may be considered **medically necessary** for the treatment of symptomatic articular cartilage defects of the knee (medial, lateral or trochlear femoral condyle, or patella) when **ALL** of the following criteria (A. – G.) are met:

   A. Age of <55 years; **and**
   B. Symptoms from acute or chronic trauma interfere with age-appropriate activities of daily living; **and**
   C. Symptoms have failed to improve after 3 months of conservative treatment, including physical therapy, as part of pre-operative planning for surgery; **and**
   D. The following must be confirmed by MRI, CT or arthroscopy:
      1. Defect size of 1cm^2 in total area or greater; **and**
      2. It must be a focal, full thickness defect (grade III or IV on the Outerbridge scale). Please see Policy Guidelines section for scale; **and**
   E. The lesion is surrounded by normal or nearly normal cartilage; **and**
   F. The knee has normal alignment or will be surgically corrected (osteotomy) at the time of the allograft procedure; **and**
   G. No inflammatory arthritis or osteoarthritis is present anywhere in the joint (surrounding the lesion or the opposing surface).

II. Osteochondral allografting of the knee is considered **not medically necessary** when the above criteria (I.A. – I.F.) are not met.

Osteochondral Allografting of the Ankle

III. Osteochondral allografting may be considered **medically necessary** to repair osteochondral lesions of the ankle (talus) when one of the following criteria are met:

A. Large (area greater than 1.5 cm^2 or cystic (volume greater than 3.0 cm^3) osteochondral lesions of the talus when autografting would be inadequate due to lesion size, depth, or location; or
B. Revision surgery after failed prior marrow stimulation for large (area greater than 1.5 cm^2) or cystic (volume greater than 3.0 cm^3) osteochondral lesions of the talus when autografting would be inadequate due to lesion size, depth or location.

IV. Osteochondral allografting is considered **not medically necessary** to repair osteochondral lesions of the ankle (talus) when criterion II is not met.

Osteochondral Autografting of the Knee (Mosaicplasty or Osteochondral Autograft Transplant [OATS])

V. Osteochondral autografting of the knee may be considered **medically necessary** for the treatment of symptomatic articular cartilage defects of the knee (medial, lateral, or trochlear femoral condyle, or patella) when **ALL** of the following criteria (A. – J.) are met:

A. The patient is skeletally mature with documented closure of growth plates (e.g., 15 years or older); **and**
B. The patient is considered too young to be an appropriate candidate for total knee arthroplasty (e.g., patient is under 55 years of age); **and**
C. Body mass index (BMI) of <35; **and**
D. Symptoms from acute or chronic trauma interfere with age-appropriate activities of daily living; **and**
E. Symptoms have failed to improve after 3 months of conservative treatment, including physical therapy, as part of pre-operative planning for surgery; **and**
F. Defect size of 1-3 cm^2 in total area that affects either one of the following (1.-2.):
    1. The patella; **or**
    2. A weight-bearing surface of the femoral condyle or trochlear region; **and**
G. It must be a focal, unipolar, full thickness defect (grade III or IV on the Outerbridge scale). Please see Policy Guidelines section for scale; **and**
H. Stable and aligned knee (or achieved concurrently at time of autograft procedure); **and**
I. Documented minimal to absent degenerative changes in the surrounding articular cartilage (Outerbridge grade II or less); **and**
J. Normal-appearing hyaline cartilage surrounding the border of the defect.

VI. Osteochondral autografting of the knee is considered **not medically necessary** when the above criteria (III.A.) are not met.

Osteochondral Autografting of the Ankle

VII. Osteochondral autografting may be considered **medically necessary** to repair osteochondral lesions of the ankle (talus) when one of the following criteria are met:

A. Large (area greater than 1.5 cm^2 or cystic (volume greater than 3.0 cm^3) osteochondral lesions of the talus; or
B. Revision surgery after failed prior marrow stimulation for large (area greater than 1.5 cm^2) or cystic (volume greater than 3.0 cm^3) osteochondral lesions of the talus.

VIII. Osteochondral allografting is considered **not medically necessary** to repair osteochondral lesions of the ankle (talus) when criterion II is not met.

Non-Covered Procedures and Implants

IX. Treatments for articular cartilage defects of the knee that are considered **not medically necessary**, include, but are not limited to the following:

A. Combination OATS/autologous chondrocyte implantation (ACI) procedures.
B. Minced autograft cartilage, including cartilage processed using systems such as the Cartilage Autograft Implantation System (CAIS) or the Reveille Cartilage Processor.
C. Minced allograft cartilage products (e.g., BioCartilage, DeNovo NT, and DeNovo ET)
D. Decellularized Osteochondral Allograft Plugs (e.g., Chondrofix)
E. Reduced Osteochondral Allograft Discs (e.g., ProChondrix and Cartiform)
F. Procedures using synthetic products, including but not limited to the following (1.-2.):
    1. Granules (e.g., TRUGRAFT)
    2. Plugs (e.g., TruFit® Plugs, POLYGRAFT).

X. Osteochondral allografting (fresh or frozen) to treat defects of the elbow (e.g., osteochondritis dissecans) is considered **not medically necessary**.

Link to Evidence Summary

POLICY CROSS REFERENCES

- Autologous Chondrocyte Implantation (ACI) for Cartilaginous Defects of the Knee, MP137
- Meniscal Allograft Transplantation and Other Meniscal Implants, MP150
- Genicular Nerve Blocks and Nerve Ablation for Knee Pain, MP227

The full Company portfolio of current Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

Appropriate Use Criteria for the Management of Osteochondritis Dissecans of the Femoral Condyle

In 2015, the American Academy of Orthopedic Surgeons (AAOS) published appropriate use criteria addressing the management of osteochondritis dissecans of thse femoral condyle.[1] These appropriate use criteria were developed from a list of 288 patient scenarios for which 13 treatments were evaluated for appropriateness, including osteochondral allograft transplantation. Sixty-four clinical scenarios are outlined with treatments presented as "Rarely Appropriate," "May Be Appropriate," and "Appropriate." These scenarios may be accessed at the following link.[1] The 9-point appropriateness scale is defined as follows:

Rating	Explanation
7-9	**Appropriate** Appropriate for the indication provided, meaning treatment is generally acceptable and is a reasonable approach for the indication and is likely to improve the patient's health outcomes or survival.
4-6	**May Be Appropriate**: Uncertain for the indication provided, meaning treatment may be acceptable and may be a reasonable approach for the indication, but with uncertainty implying that more research and/or patient information is needed to further classify the indication.
1-3	**Rarely Appropriate:** Rarely an appropriate option for management of patients in this population due to the lack of a clear benefit/risk advantage; rarely an effective option for individual care plans; exceptions should have documentation of the clinical reasons for proceeding with this care option (i.e. procedure is not generally acceptable and is not generally reasonable for the indication).

Outerbridge Scale Used to Determine Severity of Cartilage Defects of the Knee

This scale was originally created to classify the macroscopic changes of chondromalacia of the patella.[2] Later, the scale was slightly modified to allow for grading of all cartilage lesions.[3]

Grade 1: Softening and swelling of the cartilage.
Grade 2: Fragmentation and fissuring in an area half an inch or less in diameter.
Grade 3: Fragmentation and fissuring in an area more than half an inch in diameter.
Grade 4: Erosion of cartilage down to the bone.

BACKGROUND

Cartilaginous Defects

The articular cartilage that covers the articulating bones in the knee, also called hyaline cartilage, is surrounded by an extracellular matrix that contains collagen and chondrocytes (mature cartilage cells). The knee joint and its articular cartilage may be damaged by a variety of disease processes or from acute traumatic injury. Once injured or lost, articular cartilage is slow to repair itself and regenerate due to its reduced blood supply and hypocellular nature. Loss of articular cartilage does not cause pain but ultimately leads to pain in surrounding tissue, swelling, locking, and/or weakness. Defects in articular cartilage can be classified as chondral (cartilage loss) or osteochondral (cartilage plus bone loss). Defects are categorized further into partial thickness or full thickness, the latter of which extends to the subchondral bone. Although partial-thickness defects do not always produce significant symptoms, over time they can become full-thickness defects and increase the risk of osteoarthritis.[4-6]

Treatments

Currently, there is no standard approach to the treatment of articular cartilage defects in the knee. Conventional noninvasive treatments such as weight reduction, physical therapy, braces and orthotics, and/or nonsteroidal anti-inflammatory drugs may provide effective pain relief for some patients. Conventional invasive treatment options may include arthroscopic lavage and/or debridement of loose tissue and unstable cartilage fragments. If defects progress to severe osteoarthritis, total knee replacement may be required.

There are a number of techniques currently being investigated that are designed to replace or stimulate new articular cartilage, such as bone marrow stem cell infiltration, microfracture, drilling, abrasion arthroplasty, autologous chondrocyte implantation (ACI), osteochondral allografting and osteochondral autograft transfer (OAT). Microfracture involves removing the damaged cartilage and drilling holes into the subchondral bone to stimulate growth of new cartilage by providing a new blood supply. Drilling is similar to microfracture. Holes are drilled through the damaged cartilage to provide a new blood supply and stimulate healing. Abrasion arthroplasty uses a high-speed burr to remove damaged cartilage and reach the subchondral bone. ACI harvests cells from the patient's cartilage, cultures them in the laboratory and implants the cultured chondrocytes into the site of injury.[4-6]

<u>Osteochondral Allografts and Autografts</u>

Allografts are tissue obtained from another individual, typically a cadaver. Autografts are tissue obtained from the patient in whom it will be used. Osteochondral tissue indicates a combination of articulating cartilage and the bone under it.[6]

During osteochondral autografting, autograft cartilage is harvested from a non-weight-bearing area in the form of one or more cylindrical plug(s) that contain healthy cartilage and underlying bone. The plug is matched to the defect and impacted into place in an attempt to provide a smooth cartilage surface. In general, the term OAT (or OATS) refers to the use of one or two larger cylindrical plugs and mosaicplasty is used to describe multiple cylindrical plugs. Autografts are typically only used for small cartilage defects because healthy graft tissue can be taken only from a limited area of the same joint.[6]

Allograft transplants may be considered for larger defects. The tissue is taken from a cadaver donor. A block of cartilage and bone is sterilized and prepared in a lab where it is also tested for infectious disease prior to implantation into the recipient's site of injury.[6]

Other Procedures and Implants

Autologous or allogeneic minced cartilage, decellularized osteochondral allograft plugs, and reduced osteochondral allograft discs are also being evaluated as a treatment of articular cartilage lesions.

Minced Cartilage

Filling defects with minced or particulated articular cartilage (autologous or allogeneic) is another technique being investigated for cartilage repair. It is purported that mincing the tissue helps both with cell migration from the extracellular matrix and with fixation. In the literature, this technique may be referred to as mincing, particulating, morcellating or crushing of the cartilage, or paste grafting.

- Minced Autograft Cartilage:
    - The Cartilage Autograft Implantation System (CAIS) harvests cartilage and disperses chondrocytes on a scaffold in a single-stage treatment.
    - The Reveille Cartilage Processor (Exactech Biologics) has a high-speed blade and sieve to cut autologous cartilage into small particles for implantation.
- Mined Allograft Cartilage:
    - BioCartilage® (Arthrex) consists of a dehydrated, micronized allograft articular cartilage matrix that is intended to provide a scaffold for microfracture. The small particles are mixed with a blood solution to create a paste-like consistency that is applied over a cartilage defect.
    - DeNovo NT (Natural Tissue) Graft is produced by ISTO Technologies and distributed by Zimmer. DeNovo NT consists of manually particulated cartilage obtained from juvenile allograft donor joints. The tissue fragments are mixed intraoperatively with fibrin glue before implantation in the prepared lesion.
    - DeNovo ET (Engineered Tissue) Graft is an in vitro grown, 3-dimensional hyaline-like cartilage tissue created by culturing disaggregated allogeneic chondrocytes derived from juvenile human donors.

Decellularized Osteochondral Allograft Plugs

Chondrofix (Zimmer) is a minimally processed osteochondral allograft composed of decellularized hyaline cartilage and cancellous bone. It can be used "off the shelf" with precut cylinders (7-15 mm). Multiple cylinders may be used to fill a larger defect in a manner similar to OAT/mosaicplasty.

Reduced Osteochondral Allograft Discs

ProChondrix (AlloSource) and Cartiform (Arthrex) are wafer-thin allografts where the bony portion of the allograft is reduced. The discs are laser etched or porated and contain hyaline cartilage with

chondrocytes, growth factors, and extracellular matrix proteins. ProChondrix is available in dimensions from 7 - 20 mm and Cartiform is cut to the desired size and shape. The osteochondral discs are typically inserted after microfracture and secured in place with fibrin glue and/or sutures.

Synthetic Products

Synthetic products are being proposed for the repair of osteochondral articular cartilage defects, including in a procedure termed non-autologous mosaicplasty. These implants include polymer scaffolds, granules (e.g., TRUGRAFT™) and plugs (e.g., TruFit® Plugs, POLYGRAFT™) used for grafting. These implants are thought to provide a scaffold for the growth of new bone and are gradually resorbed by the body and replaced with bone.

REGULATORY STATUS

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Approval or clearance by the Food and Drug Administration (FDA) does not in itself establish medical necessity or serve as a basis for coverage. Therefore, this section is provided for informational purposes only.

The FDA regulates human cells and tissues intended for implantation, transplantation, or infusion through the Center for Biologics Evaluation and Research. Tissues such as cartilage and bone, and the tissue products derived from them, are included in these regulations. Under these regulations, these tissues are exempt and therefore, do not follow the traditional FDA regulatory pathway.[7]

CLINICAL EVIDENCE AND LITERATURE REVIEW

EVIDENCE REVIEW

Osteochondral Allografts of the Knee

Due to the large body of evidence on allografting and autografting techniques for cartilage defects of the knee, the evidence review below focused primarily on recent systematic reviews and RCTs.

Systematic Reviews

- In 2011, the Washington State Health Care Authority (WA HCA) published the results of a technology assessment of osteochondral allograft and autograft transplantation, including one technology assessment, two systematic reviews and primary literature.[8] The WA HCA recommended coverage of allograft and autograft transplantation for the following patient population:
    - Age <50, older at the discretion of the agency;

- Excluding malignancy, degenerative and inflammatory arthritis in the joint; and
- Single focal full-thickness articular cartilage defect

Regarding allografts, the WA HCA was unable to define an appropriate patient population to be treated using allografts. However, based on consensus among three nonrandomized studies (2/3 studies), limited patient inclusion criteria were as follows:

- "Mention of symptoms
- Isolated lesions
- Full-thickness lesions
- Excluded participants with ligamentous deficiency, malalignment or knee instability."

A review of comparative studies and case series indicated that most outcomes had significant levels of improvement when allografting was compared to other treatments. Outcomes such as Tegner activity score and SF-12 quality of life scores were among the outcomes reported as significantly favoring allografting over other procedures.

- In 2018, the WA HCA updated their 2011 recommendations based on an updated literature search, including two recent systematic reviews that reported on functional outcomes and safety of allografting.[9,10] Both of these systematic reviews reported that functional outcomes between 5-20 years post-allograft still showed improvement over pre-treatment baseline measures. The new evidence did not change the recommendations from the 2011 report.

- In addition, in 2015 De Caro et al. published the results of a systematic review that included 11 studies (N=374 knees in 358 patients) of patients predominantly treated with fresh osteochondral allografts.[11] The size of the lesions ranged from 1- 27 cm^2 (mean area of 6.4 cm^2). The age of patients ranged from 15 to 68 years. The majority of procedures were performed on femoral condyles, but patellar lesion were treated in one study. Overall results showed improvement in objective and subjective clinical scores and functional scores at long-term follow-up, and graft survival rates of 82% at 10 years and 66% at 20 years. Although cartilage integration was limited, bony integration was usually achieved, demonstrating that allografting is a reasonable cartilage restorative treatment for larger lesions.

Pediatric and Adolescent Populations

- In 2018, Valtanen et al. also published results of a systematic review that evaluated clinical outcomes in patients ranging from 11 to 18 years following various surgical procedures to repair articular cartilage, including osteochondral allografting and autografting.[12] This review only identified and included one small case series on allografting and two studies (one small RCT and one small case series) on autografting. Results were conflicting regarding the benefit of each of these procedures in this population regarding outcomes from various scoring systems used. The authors concluded that outcome data on cartilage repair in pediatric and adolescent populations was limited. Limitations of this review included:

- Limited number of studies, thereby limiting the ability to perform statistical analysis and the ability to draw subjective conclusions regarding the safety and efficacy of OATS and allografting in adolescents.
- Relatively high use of concurrent procedures during allografting in the one included study, making it difficult to draw definitive conclusions about the efficacy of allografting.
- There is a paucity of RCTs published evaluating OATS and allografting in adolescents.
- None if the studies included information on growth plate closure, which is thought to be an important factor in healing and new cartilage formation.

Randomized Controlled Trials (RCTs)

No additional RCTs evaluating osteochondral allografts were identified after the publication of the systematic reviews described above.

Evidence Summary: Osteochondral Allografts

The body of evidence regarding osteochondral allografting of the knee indicates that this procedure has demonstrated acceptable long-term benefit in terms of pain reduction, improved physical function, and sustained osteochondral graft viability. Several long-term studies have demonstrated long-term donor osteochondral grafts viability up to 10 years or longer, with a success rate reported over 60%. Since donor site complications and morbidity are not an issue with allografting, this procedure is consistently reported as being more appropriate than other restorative procedures in patients with larger cartilage lesions of the knee. Lastly, the literature has consistently emphasized the importance adequate joint stability and alignment.

Osteochondral Autografts of the Knee

Systematic Reviews

- In 2017 (updated 2020), ECRI published a systematic review evaluating the safety and efficacy of osteochondral autologous and allogeneic grafts for repairing knee cartilage.[6] In total, 2 systematic reviews addressing osteochondral autologous graft transfer (OAT), osteochondral allogeneic graft (OCA) transplantation, microfracture and autologous chondrocyte implantation were included for review. OATS failure rates were not significantly different from microfracture and autologous chondrocyte implantation. Of these studies, 2 were RCTs on OATs and reported 10-year failure rates of 55% and 14%. A meta-analysis of 19 OCA studies reported a 10-year graft survival rate of 78.7% (range 39.0% to 93.0%) and a weighted mean failure rate of 18.2% (range 0% to 31%). OATs patients also experienced a higher return-to-activity rate than microfracture after 10 years. Authors concluded that evidence was insufficient to determine how these procedures compare to autologous chondrocyte implantation or microfracture. Limitations included variation in study designs and conduct, which led to mixed results across studies, making comparisons difficult. Additional RCTs were judged necessary to determine how well OAT and OCA work compared with autologous chondrocyte implantation or microfracture.

- In the 2011 WA HCA technology assessment described above,[8] conducted a systematic review of the literature regarding the efficacy of OATs, including three technology assessments, 12 systematic reviews and five RCTs. Regarding autografts, the assessment indicated that the patient inclusion criteria for autografting were as follows:

    - "Mention of symptoms including pain, locking of the joint, swelling
    - Isolated defects, usually on a weight-bearing surface of the femoral condyle
    - Full thickness cartilage lesions; lesions classified as ICRS 3 or 4 or Outerbridge III or IV lesions
    - Mean lesion sizes ≤ 4 cm^2
    - Less than 45 years old
    - Stability of the knee and/or absence of alignment, ligament or meniscus problems.
    - Excluded individuals with degenerative or rheumatoid joint changes."

Of note, two of the included RCTs reported that functional outcomes were comparable among patients who received OAT regardless of defect size, but among patients who received microfracture, those with defects larger than 2 cm^2 had worse functional outcomes. In addition, based on data from the included RCTs, OAT was consistently associated with statistically better patient-reported and clinician-reported outcomes compared to microfracture, and longevity of treatment (up to 48 months follow-up) for OATS was found to be equal to or better than that of any comparator treatment.

- In 2018, the WA HCA updated their 2011 recommendations based on an updated literature search, including three recent systematic reviews and five RCTs that reported on the efficacy of autografting compared to other treatments.[13-16] Of note, pooled data including new trials suggested no difference between OAT and either microfracture or ACI at ≥5 years for pain/symptom, function, or activity scores. The new evidence did not change the recommendations from the 2011 report.

- Of note, in 2016, Gracitelli et al. published the results of a Cochrane review (also included in the WA HCA updated assessment above) that evaluated the benefits and harms of different surgical interventions for treating cartilage defects of the knee, including three of the four RCTs included in the WA HCA review above, that compared OAT to microfracture.[16] The review included studies with the following inclusion criteria:

    - Adults (typically older than 18 years)
    - Lesions:
        - symptomatic, isolated cartilage lesions on the medial or lateral femoral condyle, trochlea, or patella.
        - Grade 3 or 4 cartilage lesions (International Cartilage Repair Society (ICRS) classification).
    - Defect area ranged from 1.0 cm^2 to 6.0 cm^2; the mean area in all three trials was 2.8 cm^2

Trials focusing primarily on the treatment of people with multiple cartilage lesions, moderate or severe osteoarthritis, rheumatoid diseases, and osteonecrosis were excluded. Pooled results in this review

indicated that patients who underwent OAT had less symptom recurrence at long-term follow-up (mean 6.3 to 10.4 years)(Relative risk [RR] 0.47, 95% CI 0.24 to 0.90) than those underwent microfracture.

Also in 2016, one of the reviews included in the WA HCA review described above, by Pareet et al., compared microfracture (MFX) and OAT with regards to postoperative activity level, subjective patient outcomes, failure rates, and lesion characteristics.[14] The six studies included were all prospective studies and included 249 patients (186 male, 120 female) with an average age of 26.4 years and follow-up of 67.2 months. Tegner activity scores were superior in patients treated with OAT compared with MFX ($p = 0.005$). Failure rates of MFX were higher than OAT (OAT = 11%, MFX = 32%, risk ratio = 2.42, $p < 0.036$). OAT was superior to MFX at three years regarding subjective outcome scores ($p = 0.008$). When assessing OAT lesions larger than 3 cm^2, OAT was superior to MFX with respect to activity level ($p = 0.001$). The reviewers concluded that depending on lesion size, OAT might achieve similar or better activity levels and risk of failure when compared with MFX.

- In 2021 (archived in 2022), Hayes published a review mosaicplasty compared to other treatments, including 17 studies on the knee.[17] Seven studies compared mosaicplasty to microfracture and, overall, suggested that mosaicplasty is somewhat more effective than microfracture, statistically significant increases in mean knee score and greater return to preinjury level of sports 5- to 10-year post mosaicplasty. The significant improvement in outcomes resulting from OATS compared to microfracture was also reported by a 2018 systematic review of six RCTs, conducted by Haien et al., who also reported lower failure rates for OATS.[18] In addition, five RCTs comparing mosaicplasty to autologous chondrocyte implantation (ACI) found similar improvements in outcomes scores between the two treatments. Regarding patient selection criteria for autografting, the review stated:

"Definitive patient selection criteria have not been established for mosaicplasty for articular cartilage injuries of the knee or ankle joint.
In the knee, results may be more favorable for younger patients with sufficient knee stability and when used to treat focal areas of cartilage damage.

In malaligned or unstable joints (varus or valgus, patellar-subluxation), restoration or joint mechanics needs to be addressed separately or at the time of the mosaicplasty procedure. Patellar realignment, anterior cruciate ligament, posterior cruciate ligament, meniscal repair, and osteotomies can be done concurrently.

Contraindications: OC grafting (with the Smith & Nephew Mosaicplasty System) include the following:

- Infectious or tumor defects
- Generalized arthritis, rheumatoid and/or degenerative in type
- Patients younger than 50 years with early unicompartmental arthritis where the donor site cartilage is thin and the cartilage surrounding the defect is of poor quality."

<u>Randomized Controlled Trials (RCTs)</u>

No additional RCTs evaluating autografting, including OATS and mosaicplasty, were identified after the publication of the systematic reviews described above.

Evidence Summary: Osteochondral Autografts

The body of evidence regarding osteochondral autograft transplant (OATS) and mosaicplasty of the knee consists mostly of single-institution case series that include heterogeneous populations of individuals, some of whom are undergoing concurrent treatment for additional abnormalities such as ligament or meniscal repair. There are very few studies currently available comparing the results of autografting with other established therapies. However, there is a large collection of small studies demonstrating that autografting procedures confer significant benefit in terms of both functional improvement and pain relief. Several long-term studies report finding stable hyaline cartilage at the operative site at >3 years post-autograft. In the majority of studies, individuals with misalignment, arthritis, unstable knees, and missing or compromised meniscus, were excluded from the studies due to concerns regarding suitability for the procedures. Lastly, there is little agreement on any limitations regarding the size of chondral defects that are appropriate for these procedures. While the literature suggests that mosaicplasty might be appropriate for lesions ranging as large as 16 cm^2, most recent evidence supports the position that the larger the chondral defect, the higher the rates of complications and donor site morbidity. Therefore, at this time it may be appropriate to limit these procedures to small- to moderate-sized lesions (1.0 - 2.5 cm^2), until further evidence is available to clarify this issue.

Hybrid Autologous Chondrocyte Implantation (ACI) and OATS

- In 2019, ECRI conducted a systematic review evaluating the safety and efficacy of combined autologous chondrocyte implantation and osteochondral autograft for repairing osteochondral knee defects.[19] In total, 2 case series and 3 case reports were included for review. The combined sample size was 33 patients. One case series (n = 17) reported 3 treatment failures after 5 years. Lysholm Knee Scoring Scale (a 100-point self-report functional assessment scale) significantly improved from 45 to 77 at 1 year and was 70 at 5 years. One case series (n = 13) reported Knee Society Scores significantly improved from 63.6 to 84.6 at 6 months, 90.2 at 1 year, and 90.6 at 2 years. Three case reports reported patient symptom improvement and implant integration into the defect site. Limitations include the extremely small sample sizes of studies available for review, and lack of control groups, randomization and blinding.

- In 2005, Sharpe et al. published the results of a small case series that evaluated the treatment of large osteochondral lesions (lateral femoral condyle, medial femoral condyle and patella) using a combination of ACI and OAT in 13 patients.[20] The mean age of the patients was 42 years (range: 24 to 48 years). The mean size of the lesions was 4.84 ± 3.45 cm^2 (range: 2.2 to 15.3 cm^2). After one year, the patients reported significant improvement in symptoms and after three years, this level of improvement was maintained in ten of the 13 patients. Arthroscopic examination revealed that the osteochondral cores became well integrated with the surrounding cartilage. However, the actual contribution of each of the elements used in this procedure is unknown. The authors concluded that the hybrid ACI/OATS technique was a promising surgical approach for the treatment of patients with

large degenerative osteochondral defects, but this combination treatment may not be superior to ACI alone for the treatment of smaller traumatic defects.

Not Medically Necessary Procedures and Implants

Minced Autograft Cartilage

In 2011, Cole et al. reported on a small RCT of patients with focal defects of articular cartilage, randomized in a 1:2 ratio to microfracture (n=9) or application of minced cartilage via the Cartilage Autograft Implantation System (CAIS) (n=20).[21] Patients enrolled were heterogeneous in terms of cause of injury, speed of onset of symptoms, and defect size and severity. In addition, there were differences between treatment groups with respect to these baseline characteristics. At 12- and 24- month follow up, subjective outcomes including stiffness, pain, activities of daily living, sports and recreation, knee-related quality of life, quantified using two different knee-specific assessment tools, were significantly higher in the CAIS group compared with the microfracture group. However, objective qualitative analysis of structural changes using MRI at 3 weeks and 6-, 12-, and 24-month follow-up showed no differences in the fill of the graft bed, tissue integration, or presence of subchondral cysts between treatments.

Juvenile Minced Cartilage

Evidence on the efficacy of DeNovo NT is limited to case reports and small case series. The largest series identified was an industry-sponsored prospective study by Farr et al. in 2014, which included 25 patients with cartilage lesions of the femoral condyle or trochlea.[22] Patients reported significantly improved subjective outcomes at 2-years post-treatment compared to baseline, and MRI results suggested the development of normal cartilage and integration of transplanted tissue. Additional small case series (n=13 -45) have also been published.[23-25]

These case series are limited by one of more of the following:

- small sample size
- lack of a control group
- retrospective study design
- inadequate powered for anything other than an analysis of safety
- relatively short follow-up time
- large proportion (20-30%) of the treated knees had evidence of graft hypertrophy
- use of a single radiologist and a single pathologist prevents intra-rater reliability measurements
- large proportion of patient in each study underwent concomitant procedures, limiting the ability to determine the efficacy of minced juvenile cartilage as a stand-alone treatment for cartilage defects[23,25]

Randomized trials with larger patient populations comparing minced cartilage repair with standard methods of cartilage repair are needed to establish long-term efficacy and safety.

In 2015, Bonasia et al., published the results of a systematic review that evaluated the Cartilage Autograft Implantation System (CAIS) or particulated juvenile allograft cartilage (PJAC) and the use of minced chondral fragments for one-stage cartilage repair.[26] Only one clinical study was included regarding CAIS system (the Cole et al. study described above) and only three case series were included regarding PJAC (all three described above). The review stated that the clinical studies for both treatments were preliminary in nature, and the data was limited. However, further studies are necessary to precisely determine the indications, surgical techniques, and long-term outcomes for PJAC and CAIS.

Decellularized Osteochondral Allograft Plugs

In 2017, Johnson et al., published the results of a case series that evaluated the short-term clinical and radiographic outcomes following the use of decellularized osteochondral (OC) allograft plugs in the treatment of distal femoral OC lesions, including 34 patients.[27] MRIs obtained at 1-year postoperatively demonstrated significantly improved osseous integration ($p = 0.0086$) and opposing cartilage ($p = 0.019$). However, the failure rate was unacceptable high, with ten patients (29%) requiring revision surgery with removal of the implant. Implant survivorship was 61% at 2 years. Even higher failure rates were reported in a 2016 case series by Farr et al., who found a 72% failure rate (32 knees) at a mean follow-up of 1.29 years.[28]

Reduced Osteochondral Allograft Discs

No clinical studies were identified that evaluated Prochondrix, Cartiform, or any other reduced osteochondral allograft discs.

Synthetic Products

- In 2014, Hindle et al. published the results of a nonrandomized comparative cohort study that evaluated mosaicplasty versus TruFit synthetic grafts for knee repair in 66 patients.[29] The authors found that mosaicplasty provided a statistically significantly increase in return to sports (69% versus 29% of patients) and decrease in mean pain score (23 versus 34). There were no significant differences in revision rates or overall quality of life between the two treatments.

- In 2015, Verhaegen et al. published the results of a systematic review that examined clinical, radiological, and histological effectiveness of the TruFit plug in restoring osteochondral defects primarily in the kneejoint.[30] The review included four small case series and one comparative study (Hindle et al.[29], described above). Although all five studies reported improvement at 12-month follow-up compared to baseline, two studies reporting longer follow-up showed deterioration of early improvement. MRI findings regarding defect filling and incorporation with adjacent cartilage indicated improvement at 24 months follow-up, but conflicting evidence existed on the properties of the newly formed overlying cartilage surface. None of the included studies showed evidence for bone ingrowth. The authors concluded that “there are no data available that support superiority or equality of TruFit compared to conservative treatment or mosaicplasty/microfracture. Further investigation is needed to improve synthetic biphasic

implants as therapy for osteochondral lesions. RCTs comparing TruFit plugs with an established treatment method are needed before further clinical use can be supported."

Evidence Summary: Not Medically Necessary Procedures and Implants

There is insufficient clinical evidence that the following treatments confer long-term benefits to patients suffering from cartilage defects of the knee. For all of the indications below there is a paucity of comparative studies, including RCTs, as well as studies of large enough sample size to be appropriately powered to detect significant treatment-specific effects:

- *Hybrid ACI/OATS procedure*: only one small case series was identified.
- *Minced cartilage (including autograft, allograft and juvenile)*: The majority of studies identified were case series. All studies suffered from small sample size, lack of sufficient power, short-term follow-up, and large proportions of patients undergoing a variety of concomitant procedures.
- *Decellularized Osteochondral Allograft Plugs*: Two small case series identified, both of which reported high failure rates (29-72%) at approximately one-year follow-up.
- *Reduced Osteochondral Allograft Discs*: no clinical studies were identified that evaluated Prochondrix, Cartiform, or any other reduced osteochondral allograft discs.
- *Synthetic Products*: Clinical evidence was only identified for TruFit plugs. No RCTS were identified and all studies suffered from small sample size, short-term follow-up and inconsistencies regarding improvement of outcomes post-treatment.

Osteochondral Autografts of the Ankle

- In 2022, Feeney and colleagues published a systematic review and meta-analysis that evaluated autologous osteochondral transplantation in the management of osteochondral lesions of the talus.[31] A total of 23 studies were included (Table 1), which were assessed to be of poor to average methodological quality using the modified Coleman Methodology Score. The characteristics of the systematic review are summarized in Table 2. The mean area of the lesion, as reported in 13 studies, was 135.5±45.85 mm2 (range, 85-249). Across 13 studies, 51% of patients had undergone ankle surgery prior to autologous osteochondral transplantation. More than half of the studies reported preoperative and postoperative VAS scores and American Orthopaedic Foot and Ankle Society (AOFAS) scores. Study results are summarized in Table 3. Donor site pain occurred in 9% of cases. Notably, the systematic review did not limit inclusion of studies based on lesion size (i.e., lesions >1.5 cm2 were also included) or whether autologous osteochondral transplantation was used as a primary or secondary procedure.

- In September 2020, ECRI systematically searched the literature for studies addressing the efficacy of BioCartilage Extracellular Matrix for repairing cartilage defects in the foot and ankle.[32] No published studies compared BioCartilage with other available treatments for repairing cartilage defects in the foot and ankle. One small before-and-after treatment study (case series) suggests that BioCartilage reduces pain and improves patient functional status compared with baseline in patients with primary osteochondral lesions of the talus, but the study assessed too few patients and was at too high a risk of bias to be conclusive about how well BioCartilage

works for treating foot and ankle cartilage defects. Large randomized controlled trials (RCTs) that compare microfracture procedures with and without BioCartilage and report on patient-oriented outcomes are needed to address evidence gaps, as are studies that compare BioCartilage with other cartilage grafts. Evidence limitations: Findings of a single case series need independent validation. The study is at high risk of bias due to small study size, single-center focus, and lack of blinding, randomization, and an independent control group. Additionally, the study did not use a validated instrument to measure patient satisfaction. Investigators concluded that evidence was inconclusive and that too few data on clinical outcomes of interest exist.

- In 2018, The Washington State Health Care Authority technology assessment program published a technology assessment evaluating Osteochondral Allograft/Autograft Transplantation (published: 2011, reaffirmed: 2018).[13] The review determined that there was insufficient evidence to support osteochondral allograft for joints other than the knee.

- In 2018, Shimozono and colleagues published a systematic review evaluating functional outcomes at mid-term following autologous osteochondral transplantation for osteochondral lesions of the talus (OLT).[33] In total, 11 studies, with 500 ankles were included at a mean 62.8 months follow-up. The quality of evidence of the included studies was poor, and the LOE was also low with no Level I or II study. Seven studies used the American Orthopaedic Foot and Ankle Society (AOFAS) score. The weighted mean preoperative AOFAS score was 55.1±6.1, and the postoperative score was 86.2±4.5, with 87.4% of patients (132 of 151) being reported as excellent or good results. Authors concluded that patients can be reasonably counselled to expect good clinical outcomes in the mid-term, but that the low level quality of evidence included for review made further well-designed studies are necessary to determine the effectiveness of autologous osteochondral transplantation in the treatment for OLT.

Osteochondral Autografts of the Elbow

- A 2020 systematic review by Logli and colleagues investigated osteochondral graft reconstruction options for capitellar osteochondritis dissecans (OCD) lesions of the elbow. Eighteen studies were included on osteochondral autograft transfer (OAT) surgery, and one study on osteochondral allograft transplantation. Of the 18 studies included, all were nonrandomized, with one prospective study and 17 retrospective studies (mainly case series). Sample size ranged from 3- 87 patients. The authors rated 16 of 18 studies as poor quality. Outcome measures across studies were heterogeneously reported. Authors reported "A significant improvement in Timmerman-Andrews scores from preoperatively to postoperatively was reported in 9 of 10 studies. Return-to-play rates to the preinjury level of competitive play ranged from 62% to 100% across 16 studies. Significant improvement in motion, most often extension, was noted in most studies. Reported complication, reoperation, and failure rates ranged from 0% to 11%, 0% to 26%, and 0% to 20%, respectively. When used, knee autografts resulted in low donor-site morbidity (Lysholm scores, 70-100)." The review had a number of limitations, including heterogeneity across studies, small sample sizes, lack of comparator

groups, low quality, non-randomized retrospective study designs, and a high risk of potential bias. No conclusions can be made on the benefit of OATS versus conservative management.

- The Washington State Health Care Authority technology assessment program published a technology assessment evaluating Osteochondral Allograft/Autograft Transplantation (published: 2011, reaffirmed: 2018).[13] The review determined that there was insufficient evidence to support osteochondral allograft for joints other than the knee.

- In 2015, Saltzman and colleagues published the results of a systematic review evaluating clinical or radiographic outcomes of osteochondral allograft transplantation for humeral head defects, including 12 studies (8 case reports and 4 case series, n=35 patients).[34] Complication rates were between 20% and 30%, and the reoperation rate was 26.67%, which is substantial. In addition, there was heterogeneity between studies including:
    - Lesion type: 37 patients had large Hill-Sachs lesions due to instability, 1 had an osteochondritis dissecans lesion, and 1 had an iatrogenic lesion after resection of synovial chondromatosis.
    - Type of allograft: three received a fresh graft, and 32 received frozen grafts.
    - Site of donor graft: 23 femoral heads, 10 humeral heads, and 2 sets of osteochondral plugs

CLINICAL PRACTICE GUIDELINES

National Institute for Health and Care Excellence (NICE)

The 2018 NICE guidance on mosaicplasty as a treatment for symptomatic articular cartilage defects of the knee, stated the following:[35]

- "Current evidence on the safety and efficacy of mosaicplasty for knee cartilage defects is adequate to support the use of this procedure.
- Earlier mobilization may lead to better outcomes.
- Most of the evidence was from patients aged between 16 years and 30 years.
- Outcomes are better and donor-site morbidity is less when the procedure is used to treat smaller defects."

American Academy of Orthopaedic Surgeons (AAOS)

In 2015, the AAOS published appropriate use criteria addressing the management of osteochondritis dissecans of the femoral condyle.[1] These appropriate use criteria were developed from a list of 288 patient scenarios for which 13 treatments were evaluated for appropriateness, including osteochondral allograft transplantation. Sixty-four clinical scenarios are outlined with treatments presented as "Rarely Appropriate," "May Be Appropriate," and "Appropriate." These scenarios may be accessed at the following link. The 9-point appropriateness scale is defined as follows:

Rating	Explanation
7-9	**Appropriate**

	Appropriate for the indication provided, meaning treatment is generally acceptable and is a reasonable approach for the indication and is likely to improve the patient's health outcomes or survival.
4-6	**May Be Appropriate**: Uncertain for the indication provided, meaning treatment may be acceptable and may be a reasonable approach for the indication, but with uncertainty implying that more research and/or patient information is needed to further classify the indication.
1-3	**Rarely Appropriate:** Rarely an appropriate option for management of patients in this population due to the lack of a clear benefit/risk advantage; rarely an effective option for individual care plans; exceptions should have documentation of the clinical reasons for proceeding with this care option (i.e. procedure is not generally acceptable and is not generally reasonable for the indication).

American Orthopaedic Foot and Ankle Society

In 2022, the American Orthopaedic Foot and Ankle Society endorsed osteochondral autograft and allograft transplantation for the treatment of osteochondral lesion of the talus in "especially large diameter lesions, cystic lesions, and those that have failed previous surgical treatment."[36] The evidence cited are mostly retrospective reviews and case series. Authors also endorsed the procedure for patients who had failed conservative treatment but had yet to undergo any surgery.

International Consensus Group on Cartilage Repair of the Ankle

In 2017, the International Consensus Group on Cartilage Repair of the Ankle convened to review the best available evidence and develop consensus statements to guide management of patients needing cartilage repair of the ankle. The Consensus Group, consisting of 75 experts from 25 countries, acknowledged that evidence in the field of cartilage repair of the ankle is both low-quality and at low levels. One topic addressed by the Consensus Group was the use of osteochondral allografts. Through a process based on the Delphi method of achieving consensus, the following recommendations were issued:

- Osteochondral allograft plugs may be preferred over autografts in the following conditions: lesions >1.5 cm; knee osteoarthritis; history of knee infection; patients expressing concern of donor site morbidity of the knee. (grade of evidence: prospective cohort study)
- The source of osteochondral allograft plugs for the ankle should come from the ankle, not the knee. (grade of evidence: basic science)
- There is an absence of clinical evidence and clinical experience for the use of decellularized osteochondral allograft plugs
- The preferred type of allograft for the ankle is fresh, nonfrozen. (grade of evidence: basic science)

EVIDENCE SUMMARY

Osteochondral Allografting

The body of evidence regarding osteochondral allografting of the knee and ankle has limitations. However, overall the evidence indicates that this procedure has demonstrated acceptable long-term benefit in terms of pain reduction, improved physical function, and sustained osteochondral graft viability. Several long-term studies have demonstrated long-term donor osteochondral grafts viability up to 10 years or longer, with a success rate reported over 60%. Since donor site complications and morbidity are not an issue with allografting, this procedure is consistently reported as being more appropriate than other restorative procedures in patients with larger cartilage lesions of the knee or ankle. Lastly, the literature has consistently emphasized the importance adequate joint stability and alignment.

Osteochondral Autografting (Mosaicplasty and OATS)

The body of evidence regarding osteochondral autograft transplant (OATS) and mosaicplasty of the knee and ankle has limitations. The evidence consists mostly of single-institution case series that include heterogeneous populations of individuals, some of whom are undergoing concurrent treatment for additional abnormalities such as ligament or meniscal repair. There are very few studies currently available comparing the results of autografting with other established therapies. However, there is a large collection of small studies demonstrating that autografting procedures confer significant benefit in terms of both functional improvement and pain relief. Several long-term studies report finding stable hyaline cartilage at the operative site at >3 years post-autograft. In the majority of studies, individuals with misalignment, arthritis, unstable knees, and missing or compromised meniscus, were excluded from the studies due to concerns regarding suitability for the procedures. Lastly, there is little agreement on any limitations regarding the size of chondral defects that are appropriate for these procedures. While the literature suggests that mosaicplasty might be appropriate for knee lesions ranging as large as 16 cm^2, most recent evidence supports the position that the larger the chondral defect, the higher the rates of complications and donor site morbidity. Therefore, at this time it may be appropriate to limit procedures of the knee to small- to moderate-sized lesions (1.0 - 2.5 cm^2), until further evidence is available to clarify this issue. Conversely, ankle procedures are more supported by clinical data and evidence for large areas (greater than 1.5 cm^2).

Not Medically Necessary Procedures and Implants

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- *Synthetic Products*: Clinical evidence was only identified for TruFit plugs. No RCTS were identified and all studies suffered from small sample size, short-term follow-up and inconsistencies regarding improvement of outcomes post-treatment.

Other Non-Covered Procedures

Evidence is insufficient to support the use of osteochondral allograft of the elbow. Large, well-designed studies with comparator groups and long-term follow-up are needed to establish treatment safety and efficacy.

HEALTH EQUITY CONSIDERATIONS

The Centers for Disease Control and Prevention (CDC) defines health equity as the state in which everyone has a fair and just opportunity to attain their highest level of health. Achieving health equity requires addressing health disparities and social determinants of health. A health disparity is the occurrence of diseases at greater levels among certain population groups more than among others. Health disparities are linked to social determinants of health which are non-medical factors that influence health outcomes such as the conditions in which people are born, grow, work, live, age, and the wider set of forces and systems shaping the conditions of daily life. Social determinants of health include unequal access to health care, lack of education, poverty, stigma, and racism.

The U.S. Department of Health and Human Services Office of Minority Health calls out unique areas where health disparities are noted based on race and ethnicity. Providence Health Plan (PHP) regularly reviews these areas of opportunity to see if any changes can be made to our medical or pharmacy policies to support our members obtaining their highest level of health. Upon review, PHP creates a Coverage Recommendation (CORE) form detailing which groups are impacted by the disparity, the research surrounding the disparity, and recommendations from professional organizations. PHP Health Equity COREs are updated regularly and can be found online here.

BILLING GUIDELINES AND CODING

Arthroscopy code 29879 is not appropriate for OATS or osteochondral allografting. This should not be billed in conjunction with OATS or osteochondral allografting unless performed in a different compartment of the knee.

General

Many of the codes in this policy are not specific to osteochondral autografting or allografting and may be used for other restorative procedures for the knee, which may be addressed in other medical policies. For example: 27415, 27416, 29866 and/or 29867 may also be requested for autologous chondrocyte implantation (ACI) and CPT code 29892 is also used for other procedures of the ankle. Please see the Medical Policy Cross References section below for applicable medical policies. See Table 1 below for additional information regarding appropriate reporting of OATS procedures.

Table 1. Coding Guidelines for OATS

JOINT	GRAFT TYPE	CPT CODING		NOTES
		OPEN	ARTHROSCOPIC	
Knee	***Autograft***	27416	29866	• CPT instructions state that CPT code 27416 should not be reported with: ○ CPTs 27415, 29870, 29871, 29875, 29884 when performed at the same session and/or ○ CPTs 29874, 29877, 29879, 29885-29887 when performed in the same compartment. • CPT instructions also state codes for obtaining grafts or other tissues through separate incisions can only be reported when obtaining the graft is not already included as part of the basic procedure. CPT codes 27416 and 29866 both include harvesting of the graft. Thus, separate reporting for this would not be appropriate. • Arthroscopy code 29879 *(Arthroscopy, knee, surgical; abrasion arthroplasty (includes chondroplasty where necessary) or multiple drilling or microfracture)* is not appropriate for OATS or osteochondral allografting. • Since specific Category I codes are available for both open and arthroscopic approaches, the use of unlisted code 27599 *(Unlisted procedure, femur or knee)* should not be used for OATS of the knee.
	Allograft	27415	29867	
Ankle	***Autograft***	28446	29892	The use of CPT 29892 for arthroscopic osteochondral talus graft is per CPT instruction and is regardless of whether using an allograft or autograft; however, CPT codes 27899 or 28899 may also be seen.
	Allograft	28899		
Elbow	***Autograft***	24999	29999	For osteochondral graft of the elbow, the same unlisted code may be used regardless of if using an allograft or autograft.
	Allograft			

CODES*		
CPT	27415	Osteochondral allograft, knee, open
	27416	Osteochondral autograft(s), knee, open (eg, mosaicplasty) (includes harvesting of autograft[s])
	29866	Arthroscopy, knee, surgical; osteochondral autograft(s) (eg, mosaicplasty) (includes harvesting of the autograft[s])
	29867	Arthroscopy, knee, surgical; osteochondral allograft (eg, mosaicplasty)
	29892	Arthroscopically aided repair of large osteochondritis dissecans lesion, talar dome fracture, or tibial plafond fracture, with or without internal fixation (includes arthroscopy)
	28446	Open osteochondral autograft, talus (includes obtaining graft[s])
	24999	Unlisted procedure, humerus or elbow
	27599	Unlisted procedure, femur or knee
	27899	Unlisted procedure, leg or ankle
	28899	Unlisted procedure, foot or toes
	29999	Unlisted procedure, arthroscopy

***Coding Notes:**

- The above code list is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit.
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- **See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

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POLICY REVISION HISTORY

DATE	REVISION SUMMARY
2/2023	Converted to new policy template.
1/2024	Annual update. Change denial language from 'investigational' to 'not medically necessary'
2/2024	Interim update. Change size requirements for graft sizes.
1/2025	Annual update. Add criterion addressing osteochondral autograft of the ankle.
11/2025	Annual update. No changes.
4/2026	Interim update. Added medical necessity for ankle defects.
11/2026	Annual update. No changes.