

OSTEOCHONDRAL GRAFTING

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[Instructions for Use](#) ⓘ

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- [Autologous Chondrocyte Transplantation In The Knee](#)

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COVERAGE RATIONALE

Osteochondral autograft transplantation is proven and medically necessary for treating cartilage defects of the knee when ALL of the following criteria are met:

- Adult who has achieved mature skeletal growth with documented closure of growth plates
- Symptomatic focal full-thickness articular cartilage defect
- Considered unsuitable candidate for total knee replacement
- Presence of debilitating symptoms that significantly limit ambulation
- Normal alignment or correctable varus or valgus deformities
- Minimal to absent degenerative changes in surrounding articular cartilage ([Outerbridge Grade II or less](#))
- Failed conventional medical treatment (including physical therapy and/or bracing techniques) and/or prior surgical treatment
- Willingness to comply with of rehabilitation following surgery

Osteochondral allograft transplantation using human cadaver tissue is proven and medically necessary for treating cartilage defects of the knee when ALL of the following criteria are met:

- Adult who has achieved mature skeletal growth with documented closure of growth plates
- Symptomatic focal full-thickness articular cartilage defect
- Considered unsuitable candidate for total knee replacement
- Presence of debilitating symptoms that significantly limit ambulation
- Normal alignment or correctable varus or valgus deformities
- Minimal to absent degenerative changes in surrounding articular cartilage ([Outerbridge Grade II or less](#))
- Failed conventional medical treatment (including physical therapy and/or bracing techniques) and/or prior surgical treatment
- Willingness to comply with rehabilitation following surgery

The following are unproven and not medically necessary due to insufficient evidence of efficacy:

- Osteochondral autograft and allograft transplantation for all other joints, and any indications other than those listed above
- Minced articular cartilage repair (allograft or autograft) for treating osteochondral defects of the knee

APPLICABLE CODES

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Coverage Determination Guidelines may apply.

CPT Code	Description
27415	Osteochondral allograft, knee, open
27416	Osteochondral autograft(s), knee, open (e.g., mosaicplasty) (includes harvesting of autograft[s])
28446	Open osteochondral autograft, talus (includes obtaining graft[s])
29866	Arthroscopy, knee, surgical; osteochondral autograft(s) (e.g., mosaicplasty) (includes harvesting of the autograft[s])
29867	Arthroscopy, knee, surgical; osteochondral allograft (e.g., mosaicplasty)

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DESCRIPTION OF SERVICES

Damage to cartilage may result from either traumatic injury or from degenerative conditions (e.g., osteochondritis dissecans, osteonecrosis or osteoarthritis).

Cartilage healing and repair are affected by factors such as age, the degree and depth of damage, associated joint instability, the underlying cause, previous meniscectomy, misalignment and genetic factors. Only in limited situations can the damaged articular cartilage remodel and rebuild itself. Undisplaced lesions in skeletally immature individuals generally heal with immobilization; however, in skeletally mature individuals, surgery is often indicated as it is widely accepted that a symptomatic cartilage lesion is likely to persist or worsen without treatment.

Chondral defects of the knee due to trauma or other conditions such as osteochondritis dissecans often fail to heal on their own and may be associated with chronic pain and disability. Nonsurgical treatment options for damage to articular cartilage include weight loss, physical therapy, braces, orthotics, and pain management. Total joint replacement is not advised for younger patients because implants might not withstand the higher levels of physical activity for an extended period of time. A number of surgical options short of total joint replacement are available, including: stimulation of bone marrow through subchondral drilling or debridement, abrasion chondroplasty, or microfracture; fixation with pegs, wires, screws, or bioabsorbable implants; grafts of perichondrium or periosteum; autologous chondrocyte transplantation; and osteochondral allografting or autografting.

Classification of Articular Cartilage Lesions by Severity

Grade	Outerbridge
0	Normal cartilage
I	Softening and swelling
II	Fragmentation and fissures in area less than 0.5 inch in diameter
III	Fragmentation and fissures in area larger than 0.5 inch in diameter
IV	Exposed subchondral bone

Source: Campbell's Operative Orthopaedics, 2007

Allograft

Osteochondral allografting involves transplantation of a piece of articular cartilage and attached subchondral bone from a cadaver donor to a damaged region of the articular surface of a joint. The goal of this procedure is to provide viable chondrocytes and supporting bone that will be sufficient to maintain the cartilage matrix and thereby relieve pain and reduce further damage to the articular surface of the joint. Allografts often are used as a salvage treatment when other cartilage repair procedures have failed. For extensive loss of bone, reconstruction with bulk allograft replacement may be an option. Fresh allografts may be difficult to obtain and creates concerns regarding of a small risk of infectious disease transmission. For these reasons, autologous osteochondral grafts have been investigated.

Autograft

Osteochondral autologous transplant involves the placement of viable hyaline cartilage grafts obtained from the individual into a cartilage defect. The grafts are harvested from a nonweight-bearing region of the joint during an open or arthroscopic procedure and then transplanted into a cartilage defect to restore the articular surface of the bone.

The advantages of using autograft include graft availability, the absence of possible disease transmission risk, and that the procedure is a single-stage procedure. Disadvantages reported include donor site morbidity and limited available graft volume. In addition, tissue may have to be harvested from two different donor sites in order to provide enough material for a large defect without compromising the donor site.

Osteochondral autograft transfer system (OATS) and mosaicplasty are two types of osteochondral autografting.

- **Mosaicplasty:** A technique that consists of removing small osteochondral cylinders from low weight-bearing surfaces of the affected joint or another joint in the same patient and transplanting them in a mosaic-like formation into focal chondral or osteochondral defects in the knee. It is usually utilized to treat larger defects.
- **Osteochondral Autograft Transfer System (OATS) Procedure:** This procedure is similar to mosaicplasty; however, it involves the use of a larger, single plug that usually fills an entire defect (e.g., those associated with anterior cruciate ligament (ACL) tears).

These techniques are limited by the amount of donor tissue available in the joint. Donor site morbidity increases as more tissue is harvested. Treatment of small lesions may be performed arthroscopically, while treatment of larger lesions is typically performed through an open arthrotomy.

Minced cartilage repair is considered a second generation technique that does not require in vitro cell expansion and is described as a single-staged minimally invasive procedure. The procedure uses minced pieces of cartilage seeded over a scaffold which allows for even distribution of the chondrocytes to expand within the defect providing structural and mechanical protection. The first clinical application of the minced cartilage technique was the cartilage autograft implantation system (CAIS) developed by DePuy Mitek. A second technology, DeNOVO NT Graft ("Natural Tissue Graft"; Zimmer Inc, Warsaw, is another application for cartilage regeneration using minced donated juvenile cartilage.

Note: The DeNovo[®] NT Natural Tissue Graft is a tissue based articular cartilage graft that is processed from healthy donors less than 13 years of age and greater than 6 lbs. in weight. Donors are sourced through appropriate Organ and Tissue Procurement Organizations (OTPOs).

CLINICAL EVIDENCE

Osteochondral Autograft Transplantation of the Knee

The medical literature regarding osteochondral autograft transplant (OATS) and mosaicplasty of the knee consists mostly of single-institution case series focusing on chondral lesions of the knee. In addition, there are very few studies currently available comparing the results of osteochondral autografting with other established therapies.

Dozin et al. (2005) reported results from a multicenter randomized clinical trial in which ACI (mean lesion size 1.97 cm²) was compared to osteochondral autografting (mean lesion size 1.88 cm²) in 47 patients. Patients underwent arthroscopic debridement of the lesion at the time of enrollment. They were called for surgery 6 months after the initial debridement. Fourteen patients (31.8%) experienced substantial improvement following the initial debridement and, being clinically cured, received no further treatment. Seven patients (15.9%) were lost to follow-up. Among the 23 patients (52.3%) who could effectively be evaluated, a complete recovery was observed upon clinical examination in 88% of the mosaicplasty-treated patients and in 68% of the ACI-treated ones.

In a prospective randomized clinical study Gudas et al. (2006) compared the outcomes of mosaic type autologous osteochondral transplantation (OAT) and microfracture (MF) procedures for the treatment of the articular cartilage defects (mean lesion size 2.8 cm²) of the knee joint in 57 athletes. There were 28 athletes in OAT group and 29 in MF group. According to the modified Hospital for Special Surgery (HSS) and International Cartilage Repair Society (ICRS) scores, functional and objective assessment showed that 96% had excellent or good results after OAT compared with 52% after MF procedure. In 12, 24 and 36 months after the operations, the HSS and ICRS showed statistically significantly better results in the OAT group.

Gudas et al (2009) compared the outcomes of the arthroscopic mosaic-type osteochondral autologous transplantation (OAT) and microfracture (MF) procedures for the treatment of osteochondritis dissecans (OCD) defects of the femoral condyles of the knee joint in 50 children (mean age of 14.3 years) in a prospective randomized clinical trial. Inclusion criteria included the following: 1) grades 3-4 OCD lesion; 2) OCD defects between 2 and 4cm squared in area; and 3) age less than 18 years. Forty-seven patients (94%) were available for follow-up. There were 25 patients in the OAT group and 22 patients in the MF group. The mean follow-up was 4.2 years. After 1 year, both groups had significant clinical improvement and the ICRS functional and objective assessment showed that 92% patients had excellent or good results after OAT compared with 86% after MF, but 83% after OAT and only 63% after MF procedure maintained excellent or good results after 4.2 years. There were 41% failures in the MF group, and none in the OAT group. Magnetic resonance imaging evaluation according to the ICRS evaluation system showed excellent or good repairs in 91% after OAT compared with 56% after MF. According to the investigators, this study showed significant superiority of the mosaic-type OAT over MF for the treatment of osteochondritis dissecans defects in the knee.

Hangody and Fules (2003) described the results after ten years of clinical experience with autologous osteochondral mosaicplasty in 831 patients. According to these investigations, good-to-excellent results were achieved in 92% of the patients treated with femoral condylar implantations, 87% of those treated with tibial resurfacing, 79% of those

treated with patellar and/or trochlear mosaicplasties, and 94% of those treated with talar procedures. The investigators noted slightly diminished result for trochlear and tibial plateau lesions and a 3% overall incidence of donor site morbidity. According to the investigators, autologous osteochondral mosaicplasty appears to be an alternative for the treatment of small and medium-sized focal chondral and osteochondral defects of the weight-bearing surfaces of the knee and other weight-bearing synovial joints.

Hangody et al. (2010) evaluated if mosaicplasty is effective in returning elite athletes to participation in sports. The results of mosaicplasty were prospectively evaluated at 6 weeks, 3 months, 6 months, and yearly in 354 patients. Good to excellent results were found in 91% of femoral mosaicplasties, 86% of tibial, and 74% of patellofemoral; 92% of talar mosaicplasties had similar results. The investigators concluded that despite a higher rate of preoperative osteoarthritic changes in the athletic patients, clinical outcomes of mosaicplasty in this group demonstrated a success rate similar to that of less athletic patients. Higher motivation resulted in better subjective evaluation. Slight deterioration in results occurred during the 9.6-year follow-up. The authors stated that autologous osteochondral mosaicplasty may be a useful alternative for the treatment of 1.0- to 4.0 cm² focal chondral and osteochondral lesions in competitive athletes.

A Hayes Medical Technology Directory report on the comparative effectiveness of mosaicplasty for the treatment of articular cartilage injuries does not recommend this procedure for children due to insufficient clinical evidence of safety and efficacy for this patient population. (Hayes, 2017)

According to the National Institute for Health and Care Excellence (NICE) guidance document on mosaicplasty for symptomatic articular cartilage defects of the knee, current evidence on the safety and efficacy of mosaicplasty for knee cartilage defects is adequate to support the use of this procedure, providing the procedure is done by surgeons experienced in cartilage surgery and with specific training in mosaicplasty for knee cartilage defects. Additionally, standard arrangements should be in place for clinical governance, consent and audit. However, their Interventional Procedures Advisory Committee (IPAC) concedes that "the terms mosaicplasty and osteochondral autograft transfer refer to slight variations of the same procedure and may have been used interchangeably in the literature" that was reviewed to reach their conclusion. (NICE 2018)

Evidence from the peer-reviewed published scientific literature, textbook and some professional societies support short to intermediate-term efficacy of osteochondral autograft transplant of the knee in specific patient subgroups.

Osteochondral Allograft Transplantation of the Knee

The current medical literature regarding osteochondral allografting of the knee shows that this procedure has demonstrated acceptable long-term results measured by reduction in pain, improved physical function, and sustained osteochondral graft viability.

Gross et al. (2008) examined histologic features of 35 fresh osteochondral allograft specimens retrieved at the time of subsequent graft revision, osteotomy, or total knee arthroplasty (TKA). Histologic features of early graft failures were lack of chondrocyte viability and loss of matrix cationic staining. Histologic features of late graft failures were fracture through the graft, active and incomplete remodeling of the graft bone by the host bone, and resorption of the graft tissue by synovial inflammatory activity at graft edges. Histologic features associated with long-term allograft survival included viable chondrocytes, functional preservation of matrix, and complete replacement of the graft bone with the host bone. Given chondrocyte viability, long-term allograft survival depends on graft stability by rigid fixation of host bone to graft bone. According to the investigators, with the stable osseous graft base, the hyaline cartilage portion of the allograft can survive and function for 25 years or more.

Emmerson et al. (2007) evaluated 66 knees in 64 patients who underwent fresh osteochondral allografting for the treatment of osteochondritis dissecans. Mean follow-up was 7.7 years (range, 2-22 years). There were 45 men and 19 women with a mean age of 28.6 years (range, 15-54 years). All patients had undergone previous surgery. Forty-one lesions involved the medial femoral condyle, and 25 involved the lateral femoral condyle. All were osteochondritis dissecans type 3 or 4. The mean allograft size was 7.5 cm². One knee was lost to follow-up. Of the remaining 65 knees, 47 (72%) were rated good/excellent, 7 (11%) were rated fair, and 1 (2%) was rated poor. Ten patients (15%) underwent reoperation. The authors concluded that with greater than 70% good or excellent results, fresh osteochondral allograft transplantation is a successful surgical treatment for osteochondritis dissecans of the femoral condyle.

Gortz et al. (2010) evaluated osteochondral allografts for treatment of steroid-associated osteonecrosis in 22 patients (28 knees). Patient average age was 24.3 years (range, 16-44 years). The mean graft surface area was 10.8 cm². The minimum follow-up was 25 months (mean, 67 months). Five knees failed. The graft survival rate was 89% (25 of 28). According to the authors, osteochondral allografting is a reasonable salvage option for osteonecrosis of the femoral condyles. Total knee arthroplasty (TKA) was avoided in 27 of the 28 of knees at last follow-up.

Several other case series (n= 9 to 25 patients) have demonstrated encouraging early results with osteochondral allograft transplantation of the knee (LaPrade et al. 2009 (n=23); Williams et al. 2007 (n=19); McCulloch et al., 2007 (n=25); Davidson et al., 2007 (n=10); et al. 2003 (n=17)). However, these were small, non-comparative studies.

Patient selection criteria for osteochondral allografting in the knee have not been definitively established. However, the available scientific evidence and medical consensus supports the use of osteochondral allografting in patients who fulfill all of the following criteria (Bugbee and Convery, 1999):

- Have symptomatic and debilitating focal chondral lesions of an articular surface of the knee
- Failed conventional medical and surgical treatments
- Are not considered suitable candidates for total knee replacement
- Are willing to comply with extensive period of non-weight-bearing and rehabilitation following surgery
- Do not have an inflammatory joint disease
- Do not have steroid-induced cartilage or bone disease
- Do not have extensive osteoarthritis
- Do not have uncorrected joint instability or malalignment

Professional Societies

American Academy of Orthopaedic Surgeons (AAOS)

In a Clinical Practice Guideline for the diagnosis and treatment of osteochondritis dissecans, the AAOS states that they are unable to recommend for or against a specific cartilage repair technique in symptomatic skeletally immature patients with unsalvageable fragment. (AAOS 2012)

In an updated consensus statement, the AAOS states that skeletally immature patients, who have continued or progressing symptoms and signs of loosening, are unlikely to heal without treatment and may be at higher risk of severe osteoarthritis (osteoarthrosis) at an early age. Therefore, even in the absence of reliable evidence, symptomatic skeletally immature patients with salvageable unstable or displaced OCD lesions should be offered the option of surgery. However, no specific surgical procedures were recommended. (AAOS 2015)

An AAOS information statement for use of musculoskeletal tissue allografts indicates that the AAOS believes that for appropriate patients musculoskeletal allografts represent a therapeutic alternative. These tissues should be acquired from facilities that demonstrate compliance, use well-accepted banking methodology and follow Food and Drug Administration (FDA) Good Tissue Practices. The AAOS urges all tissue banks to follow rigorous national guidelines and standards and recommends the use of tissue from banks that are accredited by the American Association of Tissue Banks. (AAOS 2011)

There is also sufficient evidence to support the use of osteochondral allograft of the knee in patients who are physically active, have failed standard medical and surgical treatments, and are considered too young for total knee arthroplasty.

Osteochondral Autograft Transplantation of the Talus

Evidence evaluating the use of autograft for osteochondral defects of the talus is still elusive. The use of osteochondral autograft in ankles is limited to retrospective and prospective case series and few randomized controlled trials, nonrandomized controlled trials involving small patient populations and published reviews. Controlled trials with longer follow-up are needed to demonstrate that use of osteochondral autografts as a primary treatment results in improved clinical outcomes. The evidence base is not as robust when compared to that evaluating the knee, although reported clinical outcomes extend short-to intermediate-term; on average two to eight years post-operatively. In general, the clinical outcomes have been mixed regarding improvement in postoperative pain and function, with some authors reporting high failure rates and the need for further surgery.

In 2004 Kolker et al. reported their concern as to the overall efficacy of the procedure when used in the treatment of full-thickness, advanced, osteochondral defects of the talar dome. Open bone grafting did not predictably improve symptoms and yielded poor results in the patient population studied. The authors have acknowledged further well-designed studies with larger sample size are needed to assess improved long-term outcomes (Balzer and Arnold, 2005; Scranton, et al., 2006 Imhoff et al., 2011, Liu et al., 2011).

Zengerink M, et al. (2010) – The aim of this study was to summarize all eligible studies to compare the effectiveness of treatment strategies for osteochondral defects (OCD) of the talus. For each treatment strategy, study size weighted success rates were calculated. Fifty-two studies described the results of 65 treatment groups of treatment strategies for OCD of the talus. Nine of the studies were for osteochondral transplantation (OATS). OATS scored success rates of 87%, respectively. However, due to great diversity in the articles and variability in treatment results, no definitive conclusions can be drawn. Further sufficiently powered, randomized clinical trials with uniform methodology and validated outcome measures should be initiated to compare the outcome of surgical strategies for OCD of the talus.

Minced Cartilage Repair

Minced cartilage techniques are either not approved in the United States and/or in the early stages of development and testing (e.g., particulated juvenile articular cartilage). Early results from case series appear to show similar outcomes compared with other treatments for cartilage defects, but these case series do not permit conclusions regarding the effect of this treatment on health outcomes. Further studies with a larger number of patients and longer follow-up are needed, especially randomized controlled trials that directly compare particulated juvenile articular cartilage with other established treatments.

DeNovo NT Graft

Farr et al (2012) noted that the DeNovo Natural Tissue is a novel treatment option for focal articular cartilage defects in the knee. In the laboratory and in animal models, DeNovo NT has demonstrated the ability of the transplanted cartilage cells to "escape" from the extracellular matrix, migrate, multiply, and form a new hyaline-like cartilage tissue matrix that integrates with the surrounding host tissue. In clinical practice, the technique for DeNovo NT is straightforward, requiring only a single surgery to affect cartilage repair. Clinical experience is limited, with short-term studies demonstrating the procedure to be safe, feasible, and effective, with improvements in subjective patient scores, and with magnetic resonance imaging evidence of good defect fill. The authors concluded that while this treatment option appears promising, prospective randomized controlled studies are needed to refine the indications and contraindications for DeNovo NT.

Farr et al. (2014) performed a case study of twenty-five patients that were followed pre- and post-operatively through 2 years. Physical knee examinations, as well as multiple clinical surveys and MRI were performed at baseline and 3, 6, 12 and 24 month intervals. In some cases, patients voluntarily underwent diagnostic arthroscopic surgery with cartilage biopsy at 2 years post-op to assess the histological appearance of the cartilage repair. Clinical outcomes demonstrated statistically significant increases at 2 years compared with baseline, with improvement seen as early as 3 months. MRI results suggested the development of normal cartilage by 2 years. Histologically, biopsied repair tissue was noted to be composed of a mixture of hyaline and fibrocartilage and there appeared to be excellent integration of the transplanted tissue with the surrounding native articular cartilage.

While the studies investigating the use of minced cartilage repair as a treatment of osteochondral defects of the knee appear promising, larger studies are needed to confirm these findings. Randomized trials comparing this technique with standard methods of cartilage repair and long-term studies involving larger populations are needed to establish its safety and a durable outcome benefit.

Clinical Trials

A registered single-group assignment study of DeNovo NT Natural Tissue Graft Stratified Knee Study is ongoing but not currently recruiting participants. The purpose of this study is to determine the long-term pain relief and return to function for patients receiving DeNovo NT Graft for cartilage lesions in the knee. Estimated completion date of December 2021. (#NCT01670617)

An observational cohort study of long-term outcomes of DeNovo NT Graft treatment of the knee is ongoing but not currently recruiting participants. The purpose of this study is to evaluate the long-term outcomes of DeNovo NT, a tissue product used for the repair of cartilage damage in the knee. Estimated date of completion December 2021. (#NCT01329445)

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Transplantation of osteochondral autografts is a surgical procedure and, as such, is not subject to regulation by the FDA. However, the FDA does regulate manufacturing practice requirements applicable to drugs and devices. The FDA does regulate certain aspects of tissue banking, and tissues are subject to FDA requirements for good tissue practices, and infectious disease screening and testing, as well as to the good manufacturing practice requirements applicable to drugs and devices.

Donor tissue products derived from human cartilage, such as the DeNovo NT tissue graft, are regulated under the guidelines for Human Cell, Tissues and Cellular and Tissue-Based Products (HCT/P) issued by the Center for Biologics Evaluation and Research (CBER) of the FDA. The CBER does not regulate the transplantation of these products per se, but it does require tissue establishments to register with the FDA in the Establishment Registration & Device Listing database. As part of the FDA regulations, tissue establishments are required to screen and test donors, to prepare and follow written procedures for the prevention of the spread of communicable disease, and to maintain records.

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Medicare does not have National Coverage Determination (NCD) for osteochondral grafting. Local Coverage Determinations (LCDs) do not exist at this time.

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POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
01/01/2019	<ul style="list-style-type: none"> • Reorganized policy template: <ul style="list-style-type: none"> ○ Simplified and relocated <i>Instructions for Use</i> ○ Removed <i>Benefit Considerations</i> section • Updated and reformatted coverage rationale: <ul style="list-style-type: none"> ○ Simplified content ○ Replaced criterion requiring "willingness to comply with <i>an extensive period of rehabilitation following surgery</i>" with "willingness to comply with <i>rehabilitation following surgery</i>" • Archived previous policy version 2018T0537I

INSTRUCTIONS FOR USE

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. UnitedHealthcare Medical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.