

Surgery of the Hip

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Community Plan Policy

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Application

UnitedHealthcare Commercial

This Medical Policy applies to UnitedHealthcare Commercial benefit plans.

UnitedHealthcare Individual Exchange

This Medical Policy applies to Individual Exchange benefit plans.

Coverage Rationale

Surgery of the hip and surgical treatment for [Femoroacetabular Impingement \(FAI\) Syndrome](#) is proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures:

- Arthroscopy, Diagnostic, +/- Synovial Biopsy, Hip
- Arthroscopy, Surgical, Hip
- Arthroscopy, Surgical, Hip (Pediatric)
- Arthrotomy, Hip
- Hemiarthroplasty, Hip
- Removal and Replacement, Total Joint Replacement (TJR), Hip
- Total Joint Replacement (TJR), Hip

[Click here to view the InterQual® criteria.](#)

Surgical treatment for [Femoroacetabular Impingement \(FAI\) Syndrome](#) is unproven and not medically necessary in the presence of advanced osteoarthritis (i.e., Tönnis Grade 2 or 3) and/or severe cartilage damage (i.e., Outerbridge Grade III or IV).

Medical Records Documentation Used for Reviews

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. Medical records documentation may be required to assess whether the member meets the clinical criteria for coverage but does not guarantee coverage of the service requested; refer to the protocol titled [Medical Records Documentation Used for Reviews](#).

Definitions

Disabling Pain: Western Ontario and McMaster Universities Arthritis Index (WOMAC) pain domain > 40 (Quintana, 2009).

Femoroacetabular Impingement (FAI) Syndrome: FAI occurs because of either 1) hip formation at birth or 2) bone overgrowth (bone spurs) around the femoral head and/or along the acetabulum causing abnormal contact between the hip bones preventing them from moving smoothly during activity. Over time, this may result in tears in the labrum and the breakdown of articular cartilage (osteoarthritis) causing pain and stiffness, limited internal hip rotation, limping, and joint damage (Witstein et al., 2024; Agricola et al., 2024). There are three types of FAI:

- **Pincer:** This type of impingement occurs when extra bone extends out over the normal rim of the acetabulum. The labrum can be crushed under the prominent rim of the acetabulum (i.e., radiographic evidence of FAI by imaging includes: over coverage of the femoral head by the acetabulum with resultant pistol-grip deformity or the lateral center edge angle of greater than 40 degrees, or coxa profunda, or acetabular retroversion) (Witstein et al., 2024; Pun et al., 2015).
- **Cam:** In Cam-type impingement, the femoral head is not round and cannot rotate smoothly inside the acetabulum. A bone spur forms on the edge of the femoral head that grinds the cartilage inside the acetabulum (i.e., radiographic evidence of FAI by imaging includes: the loss of sphericity of the femoral head with resultant bony prominence or alpha angle greater than 50 degrees) (Witstein et al., 2024; Pun et al., 2015).
- **Combined (Mixed):** Combined impingement means that both the Pincer and Cam types are present (Witstein et al., 2024).

Functional Disability: Western Ontario and McMaster Universities Arthritis Index (WOMAC) functional limitation domain > 40 (Quintana, 2009).

Hip Dysfunction and Osteoarthritis Outcome Score (HOOS): The Hip Dysfunction and Osteoarthritis Outcome Score (HOOS) is a self-administered hip-specific questionnaire intended to evaluate symptoms and functional limitations, and it is commonly used to evaluate interventions in individuals with hip dysfunction or hip osteoarthritis. The HOOS consists of 43 questions in five subscales: pain, symptoms, function in daily living, function in sport and recreation and hip-related quality of life (Nielsdotter, 2011).

International Hip Outcome Tool (iHOT-33): A reference instrument among the Patient-Reported Outcome Measures (PROMs) to assess people with hip disorders, including Femoroacetabular Impingement (FAI) Syndrome. The iHOT-33 consists of four subscales: 1) symptoms and functional limitations (iHOT-Symptoms; 16 items), 2) sports and recreational physical activity (iHOT-Sport; 6 items), 3) job-related concerns (iHOT-Job; 4 items), and 4) social, emotional, and lifestyle concerns (iHOT-Social; 7 items). Each item can be answered from 0 to 100 points and the final score is the sum of points divided by 33 (Bissani Gasparin, et al., 2022).

Outerbridge Grades:

- Grade 0: Normal
- Grade I: Cartilage with softening and swelling
- Grade II: Partial-thickness defect with fissures on the surface that do not reach subchondral bone or exceed 1.5 cm in diameter
- Grade III: Fissuring to the level of subchondral bone in an area with a diameter more than 1.5 cm
- Grade IV: Exposed subchondral bone head (Slattery, 2018)

Significant Radiographic Findings: Kellgren-Lawrence classification of osteoarthritis grade 3 or 4 – with 3 defined as: definite narrowing of joint space, moderate osteophyte formation, some sclerosis, and possible deformity of bony ends; or 4, defined as: large osteophytes, marked joint space narrowing, severe sclerosis, definite bone ends deformity (Kohn et al., 2016; Keurentjes et al., 2013; Tilbury et al., 2016).

Tönnis Classification of Osteoarthritis by Radiographic Changes:

- Grade 0: No signs of osteoarthritis (OA)
- Grade 1: Increased sclerosis of femoral head or acetabulum, slight joint space narrowing or slight slipping of joint margin, no or slight loss of head sphericity
- Grade 2: Small cysts in femoral head or acetabulum, moderate joint space narrowing, moderate loss of head sphericity

- Grade 3: Large cysts, severe joint space narrowing or obliteration of joint space, severe deformity of the head, avascular necrosis (Kovalenko, 2018)

Western Ontario and McMaster Universities Arthritis Index (WOMAC): The WOMAC is a disease-specific, self-administered questionnaire developed to evaluate patients with hip or knee osteoarthritis. It uses a multi-dimensional scale composed of 24 items grouped into three dimensions: pain, stiffness, and physical function (Quintana, 2009).

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 Guidelines may apply.

CPT Code	Description
Arthroscopy, Diagnostic, +/- Synovial Biopsy, Hip	
29860	Arthroscopy, hip, diagnostic with or without synovial biopsy (separate procedure)
Arthroscopy, Surgical, Hip	
29861	Arthroscopy, hip, surgical; with removal of loose body or foreign body
29862	Arthroscopy, hip, surgical; with debridement/shaving of articular cartilage (chondroplasty), abrasion arthroplasty, and/or resection of labrum
29863	Arthroscopy, hip, surgical; with synovectomy
Arthrotomy, Hip	
27120	Acetabuloplasty; (e.g., Whitman, Colonna, Haygroves, or cup type)
Hemiarthroplasty, Hip	
27125	Hemiarthroplasty, hip, partial (e.g., femoral stem prosthesis, bipolar arthroplasty)
Removal and Replacement, Total Joint Replacement (TJR), Hip	
27130	Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft
27132	Conversion of previous hip surgery to total hip arthroplasty, with or without autograft or allograft
27134	Revision of total hip arthroplasty; both components, with or without autograft or allograft
27137	Revision of total hip arthroplasty; acetabular component only, with or without autograft or allograft
27138	Revision of total hip arthroplasty; femoral component only, with or without allograft
Femoroacetabular Impingement (FAI) Syndrome	
27299	Unlisted procedure, pelvis or hip joint
29914	Arthroscopy, hip, surgical; with femoroplasty (i.e., treatment of cam lesion)
29915	Arthroscopy, hip, surgical; with acetabuloplasty (i.e., treatment of pincer lesion)
29916	Arthroscopy, hip, surgical; with labral repair
29999	Unlisted procedure, arthroscopy

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HCPCS Code	Description
S2118	Metal-on-metal total hip resurfacing, including acetabular and femoral components

Clinical Evidence

Clinical studies have shown that certain factors are associated with a subjectively defined fair or poor functional score and/or surgical failure. These poor prognostic factors, although variably reported, include more advanced preoperative osteoarthritis, advanced articular cartilage disease, older age, and more severe preoperative pain. These observations highlight the negative impact of secondary osteoarthritis on the long-term results of surgical intervention.

Lamo-Espinosa et al. (2023) performed a systematic review and meta-analysis aimed to compare the efficacy and safety of arthroscopy with physiotherapy or joint lavage in patients with femoro-acetabular impingement (FAI). A meta-analysis using PubMed, Embase, Scopus, and the Cochrane Collaboration Library databases was performed. The authors included studies focusing on patients with FAI who underwent arthroscopic surgery versus those who underwent physiotherapy or arthroscopic lavage. The outcomes were functional scores (iHOT-33 and HOOS ADL) and adverse events. Randomized clinical trials (RCTs) were included in the study. The risk of bias in each study was assessed according to Cochrane guidelines for clinical trials. Six RCTs were included, from a pool of 839 patients (407 females). The iHOT-33 and HOOS ADL scales showed differences at 12 months in favor of the arthroscopy group (MD, 10.65; 95% CI 6.54-4.76) and (MD, 8.09; 95% CI 3.11-13.07). Minimal clinically important difference (MCID) was not achieved through arthroscopy in functional variables. The rates of osteoarthritis (OR, 6.18; 95% CI 1.06-36.00) and numbness (OR, 73.73; 95% CI 10.00-43.92) were higher in the arthroscopy group. The authors concluded that arthroscopic surgery showed statistical superiority over the control group without exceeding the MCID in most studies; however, the results might have been influenced by secondary variables. Finally, arthroscopic surgery results in a high rate of conversion to osteoarthritis. There are limitations to this systematic review and meta-analysis. Almost all the studies were of low or critically low quality. The authors noted that this meta-analysis included a small number of articles, and the sensitivity analysis was affected by the study with the highest weight in the case of HOOS ADL at 6 months. In addition, regression analysis was performed. Although Cochrane recommends including at least ten studies to perform this type of analysis, caution should be exercised when interpreting these results. In addition, because of the limited number of articles, the statistical program was unable to assess the subgroup analyses of these variables in many cases. Further research with randomized controlled trials is needed to validate these findings.

Zhu et al. (2022) performed a systematic review and meta-analysis to compare the efficacy and outcomes of patients with femoro-acetabular impingement (FAI) syndrome treated with hip arthroscopy versus those treated with conservative care alone. Identified randomized trials were assessed for inclusion by two reviewers. Any disagreement between them on the eligibility of certain studies was resolved through discussion with a third reviewer. The titles of journals and names of authors were not masked during the study selection process. Six observational studies were assessed. The data were extracted and analyzed by RevMan5.3. Mean differences and 95% confidence intervals were calculated. The methodological quality of the trials indicated five of six studies had a low risk of bias and one article had a high risk of bias. The authors stated that differences were statistically significant between arthroscopy and conservative treatment for Hip Outcome Score (HOOS) (follow-up for 6 months), iHOT-33 (follow-up for 6 months) improvement, iHOT-33 (follow-up for 12 months) improvement, iHOT-33 (follow-up for 12 months), EQ-5D-5L index score (follow-up for 12 months) and arthroscopic surgery showed higher benefits than conservative therapy. No statistically significant differences were found in iHOT-33 (follow-up for 6 months), EQ-5D-5L index score (follow-up for 6 months), EQ5D-VAS (follow-up for 6 months) and EQ5D-VAS (follow-up for 12 months). The authors concluded that arthroscopy and conservative therapy both can have clinical effects when facing FAI, and that in this meta-analysis, hip arthroscopy is statistically superior to conservative treatment in both long-term and short-term effects. Further research is needed to determine the clinical relevance of these findings.

Mok et al. (2021) conducted a meta-analysis to compare the outcome and differences between arthroscopic hip surgery versus conservative therapy in the management of femoro-acetabular impingement (FAI) syndrome. Only randomized controlled trials (RCTs) comparing arthroscopic hip surgery (AHS) and conservative therapy were included in this meta-analysis of FAI syndrome management. Two authors determined eligibility, extracted the needed data, and assessed the risk of bias of eligible studies independently. The authors collected 52 articles in total after removing duplicates and screened by titles and abstracts. A total of three RCTs were included with a total of 650 individuals. Evidence of additional benefit of arthroscopic hip surgery against conservative therapy in the field of improving quality of life (three trials, 575 participants, ES = 2.109, 95% CI: 1.373 to 2.845, $I^2 = 42.8\%$, $p = 0.000$) and activity of daily living (two trials, 262 participants, ES = 9.220, 95% CI: 5.931 to 12.508, $I^2 = 16.5\%$, $p = 0.000$) was noted. However, no significant difference could be seen in sports function improvement (two trials, ES = 7.562, 95% CI: -2.957 to 18.082, $I^2 = 60.1\%$, $p = 0.159$). The authors concluded that this meta-analysis suggests that AHS provided essential benefit compared with conservative therapy in improving activity of daily living and quality of life. In addition, the authors stated this meta-analysis was designed to assess the better choice between AHS and conservative therapy, while several factors, such as complications, BMI, occupation, alcohol abuse, or diabetes mellitus, could lead to a different condition of the hip resulting in different outcomes. The option of treatment strategy could be changed in the above situations. Accordingly, further specific investigations targeting patients with different baseline characteristics and complications are still necessary as well as long-term evaluations of the results and prospective randomized studies.

Kim et al. (2021) performed a systematic review and meta-analysis to compare the clinical outcomes of femoro-acetabular impingement (FAI) patients who underwent hip arthroscopy with those who underwent non-operative treatment. Presently, hip arthroscopy is a widely adopted surgical intervention for the treatment of femoro-acetabular impingement (FAI). However, there is insufficient evidence regarding which between arthroscopy and non-operative treatment is more optimal

for symptomatic FAI. The authors included studies that directly compared surgical and nonsurgical treatment for symptomatic FAI and excluded those that did not use arthroscopic treatment as a surgical technique and studies performed on patients with concomitant diagnoses instead of pure FAI. The authors compared clinical outcome scores at 6 and 12 months of follow-up for iHOT-33, HOOS, EuroQol-visual analog scale (EQ-VAS), modified Harris hip score (mHHS), and nonarthritic hip score (NAHS). Five studies totaling 838 patients were included in the qualitative and quantitative synthesis; 382 patients underwent hip arthroscopy, and 456 patients were treated by nonoperative interventions. At 6 months of follow-up, the authors noted no statistically significant differences in iHOT-33 ratings (mean difference [MD] = 7.92, $p = .15$), HOOS (MD of HOOS-ADL = 5.15, $p = .26$ and MD of HOOS-Sports = 2.65, $p = .79$, respectively), and EQ-VAS (MD = 1.22, $p = .76$) between the two treatment strategies. At 12 months of follow-up, the arthroscopy group had a greater mean improvement in iHOT-33 score than the conservative treatment group (MD = 8.42, $p = .002$), but there was no difference between the groups in terms of mHHS rating (MD = -0.24, $p = .83$) and NAHS (MD = -2.08, $p = .09$). The authors concluded that despite arthroscopy being associated with significantly superior iHOT-33 scores after 12 months of follow-up, they were unable to discern the difference between the treatment strategies using other scoring methods, such as HOOS, EQ-VAS, mHHS, and NAHS. Further studies will be needed to conclusively determine if 1 strategy is superior to the other for treating FAI. This analysis had several limitations. First, the number of included studies was relatively small, and particularly for each sub-outcome of the pooled analysis, only a couple of studies dictated most results. Owing to the characteristics of the study materials, it is difficult to unify the treatment protocols. Most studies adopted different physical therapy protocols, and some studies even combined injection therapy with nonsurgical treatment. The main weakness of this analysis was that the authors could not investigate longer-term outcomes. There were a few studies that evaluated clinical outcomes 2 years after the intervention, but data were insufficient to perform a pooled analysis. Moreover, the authors could not find previous studies that compared the results of surgical and non-surgical FAI treatment over the long term. Further long-term follow-up studies are needed because the rationale supporting surgical FAI correction is not only instant symptom alleviation but also meaningful delayed joint degeneration. Further investigation is needed before clinical usefulness of this procedure is proven.

Gatz et al. (2020) conducted a meta-analysis to compare the treatment outcomes of physiotherapy versus arthroscopic treatment for femoro-acetabular impingement (FAI). FAI is thought to play an important role in the development of hip osteoarthritis. However, there is no consensus about the optimal treatment options, since non-operative therapy such as physiotherapy and surgical treatment such as arthroscopic hip surgery can both improve symptoms. The present meta-analysis was carried out according to the PRISMA guidelines. In November 2019, the main online databases were accessed. All randomized clinical trials (RCTs) comparing surgical arthroscopic treatment versus physiotherapy for FAI were considered for inclusion. Data from 644 patients were evaluated with a mean follow-up of 14.67 ± 8.3 months. The unpaired t-test detected an optimal baseline comparability in terms of side, gender, years, duration of symptoms and BMI ($p = 0.08$ – 0.9). The VAS subscale of the score EQ-5D and the mean iHOT33 reported favorable values in the arthroscopic group ($p = 0.03$ and $p < 0.0001$, respectively). Similar findings were evidenced in the iHOT33 subgroup 6-months ($p = 0.70$) and 12-months ($p = 0.0002$). The HOOS score, the ADL ($p < 0.0001$) and the sport ($p = 0.0003$) subscales reported both greater values in the arthroscopic group. No statistical significance was found concerning the risk to incur in further total hip arthroplasty ($p = 0.72$). The authors concluded that based on only three high-quality RCTs, arthroscopic hip surgery is an effective therapeutic treatment for FAI revealing superior results than a non-surgical approach with physiotherapy. The most relevant limitation of the present study is the reduced number of papers eligible for inclusion and overall procedures. Having a small study sample, specific limitations of each single study influence the results of the present meta-analysis. Further relevant limitation of this meta-analysis is the relatively short follow-up period. Only the study by Mansell et al. evaluated the outcome after 24 months, while the FAIT and UK FASHIoN trial had a follow-up of only 8 months and 12 months, respectively. This limits the evaluation of long-term outcome parameters like the prevention of hip arthroplasty. Moreover, no analysis of the various impingement morphologies was possible because CAM Impingement was the predominant type in the analyzed studies with only limited cases of Pincer and mixed FAI. A further considered limitation is the incongruence between clinical score improvement and general subjective changes, reducing the explanatory power of clinical results. Even though the iHOT-33 and HOOS score are validated scores for FAI, the MCID does not seem to directly correlate to the subjective improvement of the patients. Further research is necessary as participation, load, and performance in sports is still remarkably reduced 1 year after arthroscopic surgery. For the future direction in the field of research, studies need to consider the relation between clinical scores and the MCID, patient acceptable symptomatic state (PASS) and the fragility index to find out what really contributes to the clinical changes, besides reporting only significant score differences between study cohorts. Future studies need to reveal the influence of perioperative physiotherapy and the placebo effect of the surgical procedures. There is a need to provide data about the right timing for arthroscopic surgery since physiotherapy might be still considered as a useful first therapeutic module. In this case, long-term studies are of particular interest considering further factors like the specific type of impingement, the exact anatomic pathological and the conducted surgical procedure. Consequently, future studies need to define clear indications for surgical therapy and to provide data for supporting evidence.

A systematic review and meta-analysis were conducted by Gohal et al. (2019) to assess the health-related quality of life (HRQL) outcomes after arthroscopic management of FAI. A total of 29 studies (24 case series, 3 case-control studies, 1 retrospective comparative study, and 1 RCT; some with control groups) were included for assessment. Of the 6476 patients (6959 hips), significant improvements were reported in all studies assessing generic HRQL outcomes, including the 12-Item Short Form Health Survey (range of mean postoperative scores, 82.2-89.8), and EuroQOL-5D scores (range of mean postoperative scores, 0.74-0.87) between 12 and 24 months postoperatively. Significant improvements were similarly identified in the hip-specific HRQL outcomes scores, with the majority of studies also reporting improvement between 12 and 24 months postoperatively. Mean improvement in International Hip Outcome Tool-33 scores from preoperative values to postoperative values ranged from 22.7 to 43.2, for studies with follow-up between 12 and 24 months. The authors concluded that hip arthroscopy can lead to significant improvement in generic and hip-specific HRQL outcomes at 12 to 24 months postoperatively in patients with FAI who do not have advanced hip osteoarthritis.

In a meta-analysis performed by Lei et al. (2019), the prognostic value of osteoarthritis (OA) on the overall failure rate, pain, and function of surgical management of femoroacetabular impingement (FAI) was evaluated. Seven studies were identified with 1,129 total patients, with 819 patients in the FAI group and 310 patients in the FAI with OA group. Pooled analyses showed that the overall failure rate was significantly higher in the FAI-OA group than in the FAI group. In addition, the rate of conversion to total hip arthroplasty was significantly higher in the FAI-OA group (37.3%) than in the FAI group (9.7%). The authors concluded that radiographic OA was correlated with higher failure rates, increased conversion to total hip arthroplasty, and worse outcomes after surgical management of FAI. Sansone et al. (2015) performed a prospective study to evaluate the arthroscopic treatment of FAI in the presence of osteoarthritis (OA) in terms of pain, symptoms, function, physical activity level and quality of life using outcome measures validated for young, active patients with hip symptoms. Seventy-five patients undergoing arthroscopic surgery for FAI, all with preoperative radiological signs of mild to moderate OA (Tonnis grades 1 or 2) were included in this study. All patients completed patient reported outcome measures, including the International Hip Outcome Tool (iHOT), Copenhagen Hip and Groin Outcome (HAGOS), EQ-5D, Hip Sports Activity Scale (HSAS) for physical activity level. A visual analogue scale (VAS) for overall hip function, was performed, with radiographic evaluation. At two-year follow-up, comparison with the preoperative scores revealed improvements for all measured outcomes; the iHOT-12 (42 versus 65), VAS for global hip function (48 versus 68), HSAS (2.5 versus 3), EQ5D index (0.62 versus 0.76), EQ VAS (69 versus 75) and different HAGOS subscales (54 versus 72, 47 versus 67, 56 versus 75, 40 versus 61, 33 versus 56, 31 versus 55). Fifty-six (82%) patients reported that they were satisfied with the outcome of surgery. The authors concluded that arthroscopic treatment for patients with FAI in the presence of mild to moderate OA resulted in statistically significant and clinically relevant improvements in outcome measures related to pain, symptoms, function, physical activity level and quality of life in the majority of patients.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Surgeries of the hip are procedures and, therefore, not regulated by the FDA. However, devices and instruments used during the surgery may require FDA approval. Refer to the following website for additional information:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>. (Accessed August 15, 2024)

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Policy History/Revision Information

Date	Summary of Changes
08/01/2025	<p>Medical Records Documentation Used for Review</p> <ul style="list-style-type: none">Updated list of Medical Records Documentation Used for Reviews; replaced “complete diagnostic imaging report(s) that are separate and distinct from the professional component of an evaluation and management office visit” with “complete diagnostic interpretation of imaging findings including, at a minimum: relevant clinical information, detailed report of imaging findings, impression, and specialty(ies) of the provider(s) who interpreted the images” <p>Supporting Information</p> <ul style="list-style-type: none">Archived previous policy version 2025T0503GG

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.

This Medical Policy may also be applied to Medicare Advantage plans in certain instances. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence ([Medicare IOM Pub. No. 100-16, Ch. 4, §90.5](#)).

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, 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.