MEDICAL POLICY	Definition: Medical Necessity (All Lines of Business Except Medicare)
Effective Date: 12/1/2022  12/1/2022 Medical Officer Date	Medical Policy Number: 38 Technology Assessment Committee Approved Date: 8/00; 2/00; 11/00; 11/04; 10/05; 5/07; 6/09 Medical Policy Committee Approved Date: 11/01; 12/02; 11/03; 10/10; 6/13; 8/14; 9/15; 12/15; 5/16; 7/17; 3/18; 8/19; 12/19; 5/2020; 11/2020; 12/2020; 10/2021; 11/2022

See Policy CPT/HCPCS CODE section below for any prior authorization requirements

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as "Company" and collectively as "Companies").

APPLIES TO:

All lines of business except Medicare (*unless otherwise directed by a Medicare medical policy. Note that investigational services are considered "**not medically necessary**" for Medicare members.)*

BENEFIT APPLICATION

Medicaid 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.

POLICY CRITERIA

I. Health care services are determined to be **medically necessary** if they are healthcare services or products that a physician, exercising prudent clinical judgement, would provide to a patient for the purpose of evaluating, diagnosing, preventing, or treating illness (including mental illness), injury, disease, or its symptoms, and that are:

   A. In accordance with generally accepted standards of medical practice; **and**
   B. Clinically appropriate, in terms of type, frequency, extent, site, and duration, and considered effective for the patient's medical condition.

Note: Medical necessity determination standards and any other quantitative or non-quantitative treatment limitations applied to Covered Services may be no more restrictive than those applied to Fee-for-Service Covered Services.

II. Health care services that **do not meet the definition of medical necessity** include, but are not limited to:

A. Services primarily for the convenience of the patient, physician, or other health care provider; **or**
B. Services that are more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis, prevention, or treatment of that patient's illness, injury, or disease; **or**
C. Any health care service where evidence demonstrates a lack of clinical utility for the proposed use; **or**
D. Out of network requests for services that are not covered and/or meet above II.A.-C. criteria (e.g., robotic or computer assisted orthopedic procedures – MAKO).

POLICY GUIDELINES

Generally Accepted Standards of Medical Practice

Generally accepted standards of medical practice are standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, physician specialty society recommendations, and the views of physicians practicing in relevant clinical areas and any other relevant factors.

Prudent Clinical Judgement

The "prudent physician" standard of medical necessity ensures that physicians are able to use their expertise and exercise discretion, consistent with good medical care, in determining the medical necessity for care to be provided each individual patient.

Health Care Services

Health care services may include, but are not limited to, medical, behavioral, surgical, diagnostic tests, substance use treatment, other health care technologies, supplies, treatments, procedures, drug therapies or devices.

Out of Network Requests for Non-Covered Services

Requests to go out-of-network for services that do not meet the definition of medical necessity above are not approvable. These service requests are reviewed on a case-by-case basis, and coverage decisions are made on the basis of individualized determinations of medical necessity in the individual case.

REVIEW OF EVIDENCE

In the absence of a specific medical policy, an individualized review of evidence and clinical practice guidelines is conducted for out-of-network requests for medical or behavioral health services to determine if they meet the definition of medical necessity above. Below is a summary of evidence and clinical practice guidelines identified through October of 2022 for out-of-network requests for services that (a) do not meet the definition of medical necessity and (b) are not addressed in a more specific medical policy.

Robotics for Total Joint Arthroplasty

In 2020, Hadley et al. conducted a clinical and radiographic comparison of robotic-assisted versus manually implanted total hip arthroplasty (THA).[5] The primary outcome of the study was comparison of patient outcomes following THA using the Mako Stryker robotic system to outcome sin patients who underwent conventional instrumented THA.

Patients of a single surgeon underwent THA with either robotic assistance or conventional instruments and were followed-up for a minimum of 16 months. The results of the study showed improved patient outcomes compared to conventional; however, there were no significant differences observed in postoperative radiographic outcomes between the two groups. There were also no significant differences between the robotics and conventional groups regarding cup inclination, hip length difference, hip length discrepancy, and global offset differences.

Ultimately, the authors concluded that "(f)urther studies, particularly prospective randomized studies, are necessary to investigate the short- and long-term clinical outcomes, possible long-term complications, and cost-effectiveness of robotic-assisted THA in regard to improving outcomes and accuracy."[5]

In 2017, Blyth et al. conducted a secondary exploratory analysis of a randomized controlled trial comparing robotic arm-assisted unicompartmental knee arthroplasty (UKA) with manual UKA using traditional surgical jigs.[6] The primary outcomes evaluated were implant accuracy and gait analysis.

The study recruited 139 patients from a single surgical center and were randomized to receiver either a manual UKA with traditional surgical jigs or a UKA implanted with the aid of a tactile guided robotic arm-assisted system. Early post-operative evaluation favored the robotic arm-assisted group (e.g., median pain scores were 55.4% lower, p=0.040). However, at one year post-operatively, the observed differences were no longer significant. The authors concluded that early results favoring robotic arm-assisted surgery were not observed at one year post-operatively, and the early results did not withstand statistical adjustments for multiple comparisons.

In 2016, Jacofsky and Allen conducted a review of robotics used in arthroplasty.[7] The authors agreed that robotics in the orthopedic operating room may improve precision, lower complication rates, and offer higher patient satisfaction, but robotics in orthopedics will ultimately depend on its cost effectiveness. Another limitation of robotics is the significant amount of education required for both surgeons and staff to optimize the safety and usefulness of robotics. Additionally, there are many surgical techniques that robotic-assisted devices are unable to perform (e.g., soft tissue balancing). The authors concluded that robotics is moving towards becoming a valuable adjunct in optimizing patient-specific arthroplasty; however, "additional research will be required to fully define the costs and benefits of robotics."[7]

Trapeziometacarpal Joint Arthroplasty (e.g., BioPro® Modular Thumb)

A 2017 study by Toffoli et al. evaluated clinical and radiological outcomes of trapeziometacarpal (TMC) joint arthroplasty.[8] The single center retrospective study involved 80 patients who underwent TMC joint replacement and had a minimum of 5 years follow-up.

The mean disabilities score improved, but it was not reported if the improvement was significant or not. The mobility of the thumb was restored to a range of motion comparable with the contralateral thumb. Opposition, pinch, and grip strength also improved (but no significance reported). Among the 96 implants, 4 (4.2%) were surgically revised for trapezium loosening. One dislocation was treated with closed reduction; 3 (3.1%) posttraumatic trapezium fractures were immobilized for 8 weeks. Among the 26 preoperative reducible z-deformities, only 5 (19.2%) were not totally corrected after surgery. The procedure success, by survival analysis over 6 years, was 93% (95% confidence interval, 87-98).

The authors concluded that TMC total joint arthroplasty may be a reliable treatment option for TMC joint osteoarthritis; however, this single study had significant limitations including: 36 patients being lost to follow-up, retrospective single center study with no randomization of participants.

In 2012, Pritchett et al. reviewed trapeziometacarpal (TMC) joint arthroplasty for treatment of TMC osteoarthritis.[9] They specifically evaluated a new implant designed to address subluxation problems seen with previous implants.

A total of 159 basal joint hemiarthroplasties to treat osteoarthritis of the TMC joint were performed. At the last follow-up, pain relief had occurred in 135 thumbs, function had improved in 138 thumbs, 139 thumbs were excellent or good in overall assessment, and 142 thumbs had good or excellent cosmetic appearance. The mean functional outcomes (e.g., tip pinch score) also improved, but no statistical significance was reported.

The authors concluded that their "results are superior to those of other implants and support continued use of this implant." However, "studies with longer follow-up are required to confirm these results."[9]

Cala Trio Nerve Stimulation Device

In 2020, Isaacson and colleagues published the results of, industry funded, prospective, open-label, single-arm study on home-sue of non-invasive neuromodulation therapy for essential tremor using the Cala device.[10] The study included 205 patients who used the therapy twice daily for 3 months. Co-primary endpoints were improvement on the TETRAS scale and patient-related Bain & Findley Activities of Daily Living (BF-ADL) dominant hand scores.

The co-primary endpoints were met ($p \ll 0.0001$), with 62% (TETRAS) and 68% (BF-ADL) of 'severe' or 'moderate' patients improving to 'mild' or 'slight'. Device-related adverse events (e.g., wrist discomfort, skin irritation, pain) occurred in 18% of patients. No device-related serious adverse events were reported. Limitations of the study include observational study design with no comparator group, only 66% of the patients were being treated with standard care at the time of the study, lack of blinding, high risk of bias, there is no consensus on clinically meaningful improvements in TETRAS and BF-ADL, therefore the statistical improvements may not equate to clinical improvements, and among the 58 participants who did not complete the study, 14 withdrew due to lack of device benefit.

In 2019, Pahwa and colleagues published the results of an industry sponsored RCT on noninvasive peripheral nerve stimulation for essential tremors.[11] Seventy-seven patients were included in the study, 40 receiving stimulation and 37 receiving sham stimulation. The primary endpoint was spiral drawing in the stimulated hand using the TETRAS Archimedes spiral scores.

No significant difference was found in spiral rating when comparing the treatment group (0.55) to the sham group (0.41). Secondary endpoints of upper limb tremor tasks showed significant improvement in the treatment group compared to sham group, specifically forward postural hold rating ($p= 0.004$) and the dominant combined upper limb tremor task ($p= 0.017$). Limitations of the study include small sample size, follow up only consisted of 40 minutes post treatment, improvement was only found in secondary endpoints.

Ankle Distraction Arthroplasty

The literature evaluating ankle distraction arthroplasty is limited to nonrandomized studies, predominately case series ($N \leq 46$), or reports of single-patient experiences.[12-17]

In the largest participant report, Zhao and colleagues included 46 patients with moderate to severe ankle osteoarthritis who underwent ankle joint distraction arthroplasty, followed for a mean of 42.8 ± 10.2 (range, 24–68) months after the external fixator removal. Range of motion of the ankle joint and the talar tile angle were not different between preoperative and last follow-up outcomes. Ankle Osteoarthritis Scale (AOS) and American Orthopaedic Foot and Ankle Society (AOFAS) ankle-hindfoot score were used for functional outcome evaluation; both were reported to be significantly improved. The failure rate was 21.7%. Patients with large TT (≥5°) angle (RR = 3.81, 95% CI 1.28–11.33, P = 0.02) and obesity (RR = 3.58, 95% CI 1.30–9.89, P = 0.01) were found to have positive correlation with failure. No correlation was found between failure and gender, or overweight, or side, or age, or type and stage of OA, or pin infection.

A retrospective database study was performed by Rivera and Beachler regarding joint-preserving procedures for post-traumatic arthritis (PTA), reported as a systematic review in 2019.[18] Of the studies

that included distraction arthroplasty, 36 out of 181 patients requiring reoperation for complications (19.9%), while other joint-preserving procedures studies had 40 out of 177 patients requiring reoperations for complications (22.6%). Mean follow-up time across studies was similar (2-10 years).

A study of factors associated with ankle distraction failure during 10 years of follow-up was published by Greenfield et al. in 2019.[19] A single-center, multi-surgeon review of 144 cases with median follow-up of 4.57 years found 16.7% of ankles failed (24/144). The 5-year survival was 84% (95% CI: 78-91%); Cox regression identified that female sex (HR = 2.68, p = 0.049) and avascular necrosis (AVN) of the talus (HR = 3.77, p = 0.041) were significantly associated with failure risk.

CLINICAL PRACTICE GUIDELINES

Robotics for Total Joint Arthroplasty

American Academy of Orthopaedic Surgeons (AAOS)

The 2016 AAOS evidence-based clinical practice guidelines on Osteoarthritis of the Knee: Surgical Management[20], stated the following regarding surgical navigation:

"Strong evidence supports not using intraoperative navigation in total knee arthroplasty (TKA) because there is no difference in outcomes or complications." This was rated as a 4 star "strong recommendation" and further endorsed by several other clinical practice societies (e.g., American College of Radiology, The Knee Society, American Association of Hip and Knee Surgeons).

Trapeziometacarpal Joint Arthroplasty (e.g., BioPro® Modular Thumb)

No relevant clinical practice guidelines addressing trapeziometacarpal joint arthroplasty broadly or the BioPro Modular Thumb Implant in particular were identified.

Cala Trio Nerve Stimulation Device

No relevant clinical practice guidelines addressing neuromodulation for essential tremor broadly or the Cala Trio Nerve Stimulation device in particular were identified.

Ankle Distraction Arthroplasty

No relevant clinical practice guidelines addressing ankle distraction arthroplasty were identified.

INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to

determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

REGULATORY STATUS

Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

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