

November 12, 2024

VIA REGULATIONS.GOV FILING

Centers for Medicare & Medicaid Service
Department of Health and Human Services
Attention: CMS–10913
Baltimore, MD 21244–1850

RE: *Enforcing Medicare Advantage Plan Compliance with Federal Utilization Management and Prior Authorization Regulations: Medicare Part C; Information Collection: Medicare Part C Utilization Management Annual Data Submission and Audit Protocol Data Request*

The American Association of Hip and Knee Surgeons (AAHKS) appreciates the opportunity to submit comments to the Centers for Medicare & Medicaid Services (CMS) Medicare Parts C and D Oversight and Enforcement Group in response to its Information Collection Request on *Medicare Part C Utilization Management Annual Data Submission and Audit Protocol Data* (the ICR)¹.

AAHKS is the foremost national specialty organization of more than 5,200 physicians with expertise in total joint arthroplasty (TJA) procedures. Many of our members conduct research in this area and are experts on the evidence-based medicine issues associated with the risks and benefits of treatments for patients suffering from lower extremity joint conditions. AAHKS is guided by four principles:

- Payment reform is most effective when physician-led;
- Reductions in physician reimbursement by public and private payers drives provider consolidation;
- The burden of excessive physician reporting on metrics detracts from care; and
- Patient access, especially for high-risk patients, and physician incentives must remain a focus.

AAHKS responds to this ICR in the interest of ensuring effective and robust enforcement of utilization management (UM) regulations applicable to Medicare Advantage (MA) plans. CMS will use data collected from MA plans during the annual data submission to assess the number of items and services that have associated internal coverage criteria, and to develop a landscape

¹ 89 FR 73420 (Sept. 10, 2024) Medicare Part C Utilization Management Annual Data Submission and Audit Protocol Data Request <https://www.federalregister.gov/documents/2024/09/10/2024-20400/agency-information-collection-activities-proposed-collection-comment-request>.

of items and services across the nation to assess trends related to the development and utilization of internal coverage criteria. Additionally, CMS will use the annual submission to select a number of plans to undergo UM audits each year, and to select specific items and services to audit.

The purpose of our comments is to illustrate the importance of collecting plan data that illuminates the extent of MA plan abuses of UM regulations wherein plans impose on beneficiaries and providers, through overly burdensome prior authorization practices, coverage policies and procedures that are more restrictive than those under Original Medicare.

Below we share results of our internal survey on prior authorization abuses, share anecdotes of burdensome barriers imposed by third-party vendors, and review our prior recommendations for enhanced prior authorization recommendations. Collectively, these points demonstrate the need for CMS to collect data from both plans and their third-party vendors performing UM and prior authorization that illustrate whether MA plans, in practice, are basing UM and coverage decisions on any evidence-based research and imposing processes and standards more burdensome than Original Medicare.

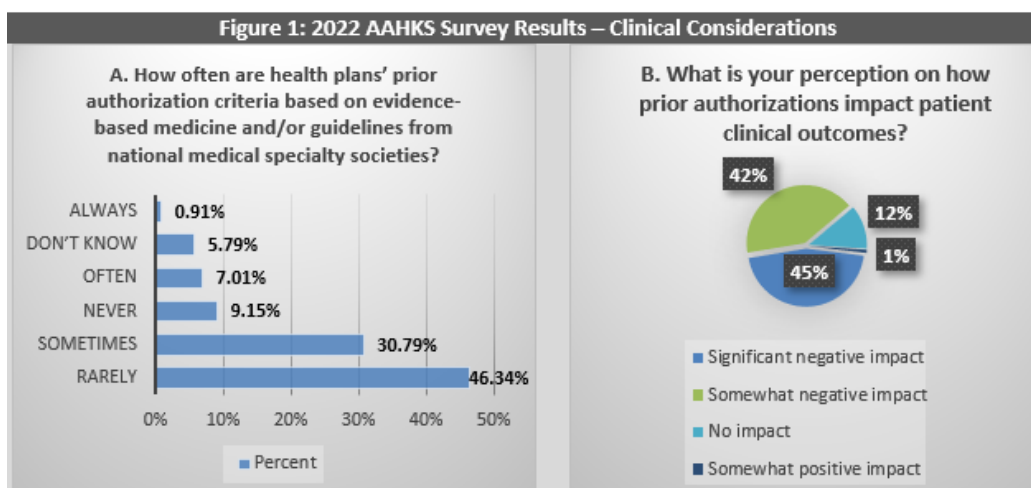
I. AAHKS Member Experience Suggests Plan UM Practices and Policies Not Based on Medical Standards

Inappropriate and overly restrictive UM in MA has been identified by MedPAC as “a major source of administrative burden for many providers and can become a health risk for patients if policies affect the treatments that clinicians offer (e.g., step therapy requirements), inefficiencies in the process cause needed care to be delayed or abandoned, or poor decisions cause necessary care to be denied.”²

AAHKS members report that many MA plans are abusing UM and prior authorization practices in a way that impairs quality care or outcomes. For example, fewer than 1% of respondents to a 2022 AAHKS Survey reported health payors always base prior authorization criteria on evidence-based medicine and/or guidelines from national medical specialty societies. A significant 46% of our respondents reported payors rarely used such data in prior authorization criteria. Approximately 87% of survey respondents perceive prior authorization of having a “significant negative impact” or a “somewhat negative impact” on clinical outcomes. *See Figure 1.*

While these are internal survey results, they demonstrate the overall inconsistency and lack of confidence or transparency around UM and prior authorization standards.

² Medicare Payment Advisory Commission (MedPAC), Report to Congress: Provider Networks and Prior Authorization in Medicare Advantage (June 2024), <https://www.medpac.gov/document/medpac-releases-june-2024-report-to-the-congress-medicare-and-the-health-care-delivery-system/>.



II. AAHKS Study Finds Major Plan Joint Replacement Coverage Policies Unsupported by Their Own Citations

The following is an abstract from a pre-publication draft study (*Low-Level Evidence Used to Substantiate Insurance Coverage Policies for Knee and Hip Arthroplasty*) presented at the AAHKS Annual Meeting on November 10, 2024. The full study is attached at the end of this comment letter.

a. Introduction

In recent years, access to total knee arthroplasty (TKA) or total hip arthroplasty (THA) has become more regulated by commercial healthcare insurance policies that require specific criteria be met prior to authorizing surgery as medically necessary. The purpose of this study was to examine references from coverage policies to assess whether they justify the pre-surgery criteria mandated by insurance providers for approval of total joint arthroplasty (TJA) in patients with symptomatic knee and hip degenerative disease.

b. Methods

The largest private commercial insurance providers in the United States were identified, of which nine had publicly accessible coverage policies for TKA and THA. Coverage criteria for procedural approval and respective references were retrieved. Three coverage criteria were identified: (1) diagnosis of osteoarthritis, 2) nonsurgical treatment (e.g. preoperative physical therapy, nonsteroidal anti-inflammatories, etc.), and 3) exclusion criteria (e.g. BMI thresholds <40). Three reviewers graded references cited in coverage policies by level of evidence (LOE), type of reference, and relationship to the three criteria groupings.

c. Results

In total, out of 824 references, only 450 (54.6%) references were relevant to primary TKA and THA. Of the 824, 259 (31.4%) contained information pertinent to the diagnosis of osteoarthritis, 84 (10.19%) to nonsurgical treatment, and 107 (12.99%) applied to exclusion criteria. Of the 84 references relevant to nonsurgical treatment, only 16 (19.05%) had a LOE I-III. Among all references related to nonsurgical treatment, only four specifically tested the efficacy of nonoperative modalities, representing 0.49% of all references. However, only one had results that were applicable to the clinical management of end-stage osteoarthritic patients.

d. Conclusion

Current criteria found in prior authorization policies for TKA and THA are unsubstantiated. Insurance companies that implement prior authorization criteria should be held to a standard in which recommendations are grounded in evidence-based medicine. This is currently not the case.

III. Real Life Examples from AAHKS Members

a. Opaque Coverage Standards

A female patient with osteoarthritis in the hip failed to see improvement overtime from conservative intervention measures, such as physical therapy (PT). The physician ordered a hip replacement which was denied by the plan's third-party organization reviewing vendor. After much time was lost, the physician secured a peer-to-peer review with a physician at the third-party organization and the denial was overturned. But the reviewer could never explain to the physician what the basis had been for the initial denial: history of smoking; BMI; duration of PT, other? Physicians cannot take a patient's coverage standards into account if those standards are not transparent.

Recommendation: CMS should collect plan and reviewing vendor data demonstrating whether it is both policy and practice to inform providers of the reason for a denial.

b. Covering Inpatient Surgery as an Exception

A 69-year old male with a need for a hip revision with arteriovenous malformation (AVM) collapsed femoral head, and a history of chronic kidney disease, coronary artery disease, alcohol abuse, Parkinson's, neuropathy, and diabetes, making him a high-risk for surgical complications and unlikely to be safely discharged within 36 hours. Physician booked the patient as an inpatient surgical admit. The plan's third-party organization reviewing vendor stated the procedure would not be covered unless it was booked as an outpatient procedure. Following a peer-to-peer call between the physician and the reviewer, inpatient status was approved.

Recommendation: CMS should collect both plan and vendor data to demonstrate whether plans are trying to cover certain procedures only on an outpatient basis. How do such plan policies account for associated surgical complication risk?

c. Wasted Time Appealing Initial Denials

An obese male with knee osteoarthritis needed a knee replacement. Prior auth request was submitted with clinical history, failed conservative measures (NSAIDs, IA, PT, activity modification, weight loss), physical exam and radiographs all showing matching need for replacement. The plan denied authorization due to imaging not showing "at least moderate joint space narrowing." The denial was overturned after the ordering physician spent time securing a peer-to-peer call and explaining the situation to a reviewing physician.

Recommendation: CMS should collect plan and vendor data to demonstrate the qualifications of those performing UM and prior auth. Our experience is that RNs or other reviewers frequently deny clearly indicated and necessary procedures which are quickly approved when appealed to a physician. However, this process, which can stretch over weeks, wastes significant physician time and delays patient care.

d. Wasted Time Appealing Initial, Confusing Delay

We share this anecdote in its totality:

"10/28 Submitted auth request for 11/12 surgery via portal for payer is subbed out to a 3rd party for revision total knee arthroplasty (Rev TKA). Erythrocyte sedimentation rate (ESR) and C-reactive proteins (CRP) were elevated so within normal limit cell count result was submitted at the same time. After submission it goes to "nurse reviewer" who called on 10/31 about the elevated ESR/CRP and said she could not approve and had to go to one of their MD's for further review. She asked if i would like to set up a per-to-peer (P2P) or submit additional documentation. Asked what type of additional documentation related to this she would like and she offered no suggestion. I asked if the case had been denied and was told no but would be going to an MD for further review. Asked if a P2P could be done if MD reviewer denied and was told yes. Nurse reviewer sent to MD and nothing was done with it for 4 days. 11/4 called reviewer again and was told it was still awaiting MD review and they would resend again to MD and to call back next morning. 11/5 Called back next morning told still at MD review and I could schedule a P2P. Asked why I would do a P2P while awaiting MD review and was told if it didn't get reviewed until the closing date of 11/7 and was then denied there was no opportunity for a P2P to overturn denial and could not resubmit case request for 60 days. All total between hold times and multiple transfers and multiple calls was on the phone for 1 hour and 30 minutes. Ended up having to do a P2P on 11/6 just to avoid a potential denial at the last minute of their defined "case window".

"Most MA's plans have multiple steps required to verify eligibility and then submit request often through another 3rd party vendor. Each site and each 3rd party vendor first must "grant" you access to their portal. No way to tell on the card which 3rd party they partner with so you may

have to submit the same information on the insurance plan’s portal or via phone only to find out you have to do it again on another portal before finding out which portal to use.”

e. UM and Prior Auth Standards With Questionable Basis

The third-party reviewer for one plan asks whether acupuncture has been attempted to treat osteoarthritis before ordering joint replacement.

Recommendation: Collect plan and vendor data to verify the basis for their conservative treatment guidance. We are not aware of reputable peer-reviewed studies or clinical guidelines recommending acupuncture as an effective treatment of osteoarthritis in the knee.

IV. Policy Recommendations to Align Data Collection Efforts with Minimally Burdensome and Clinically Based UM Practices and Policies

With the examples described above in mind, AAHKS appreciates the opportunity to reiterate the following recommendations to ensure utilization management in the MA program continues to center on the provider-patient relationship and are held to the highest objective and transparent standards.

1. *Require MA organizations to report at the plan-level rather than the contract-level.*
 - Plan level data would allow providers to use UM metrics in a more meaningful way to compare across MA plans.
2. *Instruct MA organizations to report more granular item and service-specific data.*
 - More granular data would enable stakeholders to use the UM data to better understand particular UM implications for certain items, services, settings and clinical decision criteria.
 - Further, this granular data could be helpful in identifying where and when policies such as “gold-carding” should be more widely adopted.
3. *Direct MA organizations to report additional data related to MA plans’ UM decision-making processes including “the specific reason for denial” and the degree to which Artificial Intelligence or other algorithmic tools were used in the decision-making process.*
 - A regulatory definition for “the specific reason for denial” and the inclusion of whether AI or other algorithmic tools were used in the decision-making process are key components of understanding any MA denials and how to properly address the denial and figure out an appropriate path forward with the patient.
 - AAHKS agrees with CMS’s statement in the MA Technical Final Rule that “[c]ommunicating all necessary information needed for the enrollee or provider to effectively appeal the decision, including the evidence used to support the internal coverage policy when applicable, is one of the purposes of the denial notice.”

4. *Require MA organizations to report additional data related to the coverage criteria updates imposed by the MA Technical Final Rule.*
 - AAHKS appreciated the updates in the MA Technical Final Rule that provided clarity with regard to the overlap between Traditional Medicare coverage policies and also established more rigorous requirements for MA plans' internal coverage policies. AAHKS believes that in order for CMS and stakeholders to understand the impacts of such changes and to identify potential issues with MA plans' internal coverage criteria, CMS should require that MA organizations to report certain relevant data as part of the PA reporting requirements imposed by the PA Final Rule.
5. *Require MA organizations to report additional data related PA determinations involving site of service changes.*
 - Additional clarity on MA plans' practices of reimbursing a claim on an outpatient basis when a physician has ordered an inpatient procedure is needed to better plan and prepare to address patients' needs.
6. *Require MA organizations to report additional data related to the qualifications of plans' staff that review and make prior authorization determinations and to MA organizations' use of third parties to interpret and make PA determinations.*
 - Additional information regarding the providers or professionals reviewing MA plans' UM requests will better inform future rulemaking as CMS continues to refine the UM clinical criteria requirements.
7. *Standardize reporting across MA organizations through regulations, guidance, and/or implementation guides.*
 - Standardized reporting requirements would ensure patients' and providers' ability to access and use the reported UM aggregated metrics in a meaningful way.
8. *Facilitate use of the reported PA data by posting reports to CMS' website.*
 - Allowing patients and providers the ability to meaningfully access and use aggregated reported data by requiring MA organizations' reports to be posted to CMS' website and to be included in comparative data public reports is crucial for transparency and makes the process less burdensome.
9. *Require MA plans to make prior authorization coverage determination policies publicly available on MA organization websites.*
 - AAHKS specifically urges CMS to require MA plans to make internal coverage criteria publicly available and accessible on their plan website, or—at a minimum—to require MA plans to include a notification on the MA plan website that such coverage determination policies are available upon request.
 - AAHKS believes that without accessibility to MA organizations' internal coverage criteria, providers may still face the same administrative burdens with regard to

MA plans' use of internal coverage criteria that predated the MA Technical Final Rule—particularly if such policies are behind paywalls or not otherwise available on an MA plan's website.

AAHKS appreciates your consideration of our comments. If you have any questions, you can reach Mike Zarski at mzarski@aahks.org or Joshua Kerr at jkerr@aahks.org.

Sincerely,



James I. Huddleston III, MD
President



Michael J. Zarski, JD
Executive Director

cc: Meena Seshamani, MD, PhD, Director, Center for Medicare
Cheri Rice, Deputy Director, Center for Medicare

1 **Low-Level Evidence used to Substantiate Insurance Coverage Policies for Knee and Hip**
2 **Arthroplasty**
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9 **Abstract**

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12 (THA) has become more regulated by commercial healthcare insurance policies that require
13 specific criteria be met prior to authorizing surgery as medically necessary. The purpose of this
14 study was to examine references from coverage policies to assess whether they justify the pre-
15 surgery criteria mandated by insurance providers for approval of total joint arthroplasty (TJA) in
16 patients with symptomatic knee and hip degenerative disease.

17 **Methods:** The largest private commercial insurance providers in the United States were identified,
18 of which nine had publicly accessible coverage policies for TKA and THA. Coverage criteria for
19 procedural approval and respective references were retrieved. Three coverage criteria were
20 identified: (1) diagnosis of osteoarthritis, 2) nonsurgical treatment (e.g. preoperative physical
21 therapy, nonsteroidal anti-inflammatories, etc.), and 3) exclusion criteria (e.g. BMI thresholds
22 <40). Three reviewers graded references cited in coverage policies by level of evidence (LOE),
23 type of reference, and relationship to the three criteria groupings.

24 **Results:** In total, out of 824 references, only 450 (54.6%) references were relevant to primary TKA
25 and THA. Of the 824, 259 (31.4%) contained information pertinent to the diagnosis of
26 osteoarthritis, 84 (10.19%) to nonsurgical treatment, and 107 (12.99%) applied to exclusion
27 criteria. Of the 84 references relevant to nonsurgical treatment, only 16 (19.05%) had a LOE I-III.
28 Among all references related to nonsurgical treatment, only four specifically tested the efficacy of
29 nonoperative modalities, representing 0.49% of all references. However, only one had results that
30 were applicable to the clinical management of end-stage osteoarthritic patients.

31 **Discussion & Conclusion:** Current criteria found in prior authorization policies for TKA and THA
32 are unsubstantiated. Insurance companies that implement prior authorization criteria should be

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77 **Introduction:**

78 With annual total knee arthroplasty (TKA) or total hip arthroplasty (THA) volumes in the
79 United States projected to exceed 600,000 and 1 million by 2030, respectively, these procedures
80 are anticipated to incur significant costs to healthcare payers.[1] Medicare alone is anticipated to
81 spend \$50 billion on TKA and THA in 2030. In spite of the relatively high cost, numerous studies
82 have indicated that the significant improvement in patient function following THA and TKA make
83 these procedures highly cost-effective, with the increased productivity conferred by these
84 procedures more than covering the lifetime costs associated with surgery.[2–7]

85 In spite of the cost effectiveness of arthroplasty, nonoperative management is relatively
86 inexpensive, costing approximately \$764 ± \$764 in the year leading up to THA and \$1,355 ±
87 \$2,087 per year leading up to TKA.[8,9] Given this cost differential, insurers have a clear financial
88 incentive to mandate an extended period of nonoperative treatment before pursuing surgical
89 intervention, despite prevailing clinical evidence suggesting that many nonoperative modalities
90 fail to effectively control symptoms associated with end-stage degenerative joint disease of the hip
91 and knee.[9–12] In a 2023 survey of AAHKS members, Pereira et al. found that 56% of surgeons
92 stated that prior authorization requests rarely or never followed evidence-based guidelines, and
93 87% stated that prior authorization had either a somewhat or significant negative impact on clinical
94 outcomes.[13] Delays to THA and TKA due to prior authorization have been demonstrated to
95 increase postoperative complications, 90-day revision rates, chronic disease and disability, prolong
96 limitations to physical activity in patients with end-stage osteoarthritis (OA), and worsen the
97 quality of life and postoperative outcomes of TJA candidates.[14–20] Furthermore, orthopaedic
98 surgeons cite a high negative burden on themselves from undergoing the prior authorization

99 process and increased administrative burden, requiring more dedicated time and staff to manage
100 prior authorization claims.[13,14]

101 Despite the insistence on nonoperative management as a key criterion for prior
102 authorization requests, previous studies have demonstrated that the references cited in both public
103 and commercial-payer coverage policies for TJA are of low-level evidence.[21,22] The goal of
104 this study is to further assess commercial-payer coverage policies by not only broadening the
105 number of policies evaluated but also determining which references support specific necessity
106 criteria, whether the information found in identified references sufficiently justifies the criteria,
107 and if the criteria align with current best practices set forth by orthopaedic surgeons.

108 **Methods:**

109 In total, fifteen of the largest private healthcare insurance providers in the United States
110 were identified based on the total number of healthcare beneficiaries enrolled.[23] Individual
111 medical coverage policies for the year 2023 from each insurance provider were obtained through
112 publicly available links online or by contacting providers directly through electronic
113 correspondence or telephone to customer service representatives. The coverage policies dictating
114 pre-approval requirements for both knee and hip arthroplasty procedures were examined.
115 Coverage policies were assessed by three authors (S.S.T., A.A., J.B.) through a standardized
116 review process. Reviewers identified the medical necessity criteria used for prior authorization and
117 organized criteria into three overarching groups: diagnosing end-stage OA, non-surgical
118 management, and exclusion factors from being a surgical candidate.

119 References cited in the coverage policies were then classified based on the applicability to
120 primary THA or TKA, type of reference (primary journal article, review, government report,
121 society guideline, or website), level of evidence (LOE)[24], and their relationship to the three

122 criteria grouping. In some instances, references were graded as having a LOE variable with
123 recommendation if a reference had multiple LOE depending on the recommendations. Regarding
124 THA and TKA applicability, references were excluded if the primary topic of study was hip
125 resurfacing or unicompartmental knee arthroplasty as this was beyond the scope of the present
126 investigation. Since insurance companies do not specify which references correspond to which
127 criteria, we were as inclusive as possible in determining a reference's applicability to a criteria
128 group. A reference was deemed applicable to one of the three criteria groups if the manuscript
129 contained any information relevant to said criterion. Of note, a reference could be applicable to
130 more than one criteria group. Furthermore, reviewers stratified applicable references to indicate if
131 a study scientifically tested a medical policy criterion as a primary or secondary study outcome.

132 The grading process was divided amongst three reviewers (S.S.T., A.A., J.B.). To minimize
133 variance in grading, reviewers were first trained using sample references. Upon grading assigned
134 references, the two remaining reviewers evaluated each reviewer's assessments for grading
135 consistency. The senior author (N.H.) settled any discrepancies.

136 **Results:**

137 *Policy Characteristics:*

138 Out of the 15 initially identified private healthcare insurance companies, we attained
139 medical coverage policies from 9 providers (**Table 1a-b**). Health Care Service Corporation in
140 Chicago, IL and Highmark in Pittsburgh, PA jointly utilize a single medical coverage policy for
141 both THA and TKA administered through the medical benefit management company EviCore, a
142 division of Evernorth, headquartered in Bluffton, SC.[25–27] Additionally, it was found that The
143 Cigna Group in Bloomfield, CT utilized the EviCore coverage policies, and were subsequently

144 included in our study as a captured data point.[28] In the case of the private insurance provider
145 Centene Corporation in St. Louis, MO, only the medical policy for TKA could be obtained.

146 Reviewers evaluated a total of 13 medical coverage policies encompassing both THA and
147 TKA. Among these 13 policies, 824 references (THA: 359 (43.58%); TKA 465 (56.43%)) were
148 cited. Of these cited references, 744 (90.29%) references were accessible (THA: 330; TKA 414).
149 The primary reasons for reference inaccessibility included industry references for devices or
150 techniques locked behind paywalls, broken or nonexistent reference links, or references being cited
151 in non-English languages. Of the 744 accessible policies, reviewers determined that only 485
152 (65.19%) contained information deemed applicable to primary THA or TKA procedures, with 241
153 (49.69%) applicable to THA and 244 (50.31%) to TKA. References considered to be not applicable
154 often pertained to studies investigating other surgical techniques including hip resurfacing,
155 unicompartamental or bicompartamental knee arthroplasty. (**Table 1a-b**)

156 *Criteria Characteristics*

157 Within each of the 13 policies assessed, reviewers identified the medical necessity criteria
158 for both THA and TKA and then determined if references contained any information in their
159 respective manuscripts pertaining to the three criteria groups (**Tables 2a-c and 3a-c**). Amongst
160 references for THA policies, all of the 241 references contained information pertaining to the
161 outlined criteria while for TKA policies, 209 of the 244 (85.66%) contained information pertaining
162 to TKA criteria. In total, for THA policies, 112 (53.59%) references were found to contain
163 information applicable to diagnostic criteria, 32 (15.31%) to non-operative management
164 modalities, and 65 (31.10%) to exclusion criteria. For TKA, 147 (70.33%) references were found
165 to contain information applicable to diagnostic criteria, 52 (24.88%) to non-operative management
166 criteria, and 42 (20.10%) to exclusion criteria. The reference types found in each of the criteria

167 groupings are summarized in **Table 4** for THA and **Table 6** for TKA, while the level of evidence
168 (LOE) is summarized in **Table 5** for THA and **Table 7** for TKA.

169 *Diagnostic Criteria Characteristics*

170 From a total of 824 references within TKA and THA policies, 259 (31.43%) were found to
171 contain information that was applicable to the Diagnostic criteria group. Of these, references were
172 most likely to be primary journal articles (52.12%) or reviews (22.39%). (**Tables 4 and 6**).
173 Additionally, it was found that 10.42% of references were graded at a LOE I, 13.51% at LOE II,
174 22.78% at LOE III, 13.90% at LOE IV, 14.67% at LOE V, and 20.46% at LOE variable with
175 recommendation. (**Tables 5 and 7**) Upon assessment, it was determined that only 2 (0.77%)
176 references of the total 259 directly tested the diagnostic criteria as a primary or secondary outcome
177 of their study. The remaining 257 (99.23%) references did not provide primary evidence in regards
178 to the diagnostic criteria.

179 *Non-operative Management Criteria Characteristics*

180 From a total of 824 references, 84 (10.19%) were identified containing information
181 pertaining to the non-operative management criteria group. References were most likely to be
182 primary journal articles (22.62%), websites (20.24%), or reviews (17.86%). (**Tables 4 and 6**)
183 Furthermore, when graded based on LOE, reviewers identified 8 (9.52%) references graded at
184 LOE I, 2 (2.38%) at LOE II, 6 (7.14%) at LOE III, 6 (7.14%) at LOE IV, 27 (32.14%) at LOE V,
185 20 (35.71%) at LOE that was variable with recommendation, and for 5 (5.95%) references an LOE
186 was not applicable. (**Tables 5 and 7**)

187 Of the 84 references found to have information applicable to non-operative management,
188 51 (60.71%) discussed whether the various non-operative modalities were efficacious in patients

189 with OA. However, only 4 (4.76%) of the 84 references directly tested the efficacy of non-
190 operative management as a primary or secondary outcome of their study.

191 Additionally, 8 of the 13 coverage policies graded acknowledge that there are
192 contraindications to nonoperative therapy. However, 6 of the 8 policies do not outline what the
193 contraindications are, while the remaining 2 policies, Aetna THA and EviCore THA, cite
194 inflammatory arthritis, femoral head collapse and advanced dysplasia as contraindications to non-
195 operative management. The Aetna THA policy also states that “bone on bone arthritis in the
196 weight-bearing portion of the aspect of the hip joint” is a contraindication to conservative
197 management.

198 *Exclusion Criteria*

199 In total, reviewers identified 107 (28.97%) references containing information regarding
200 criteria found in the exclusion group. Reviewers noted that of the 107 references, 73 (68.22%)
201 were primary journal articles. (**Tables 4 and 6**) Furthermore, when graded on LOE, 11 (10.28%)
202 references were graded at LOE I, 13 (12.15%) at LOE II, 50 (46.73%) at LOE III, 21 (19.63%) at
203 LOE IV, 4 (3.74%) at LOE V, 6 (5.61%) at an LOE variable with recommendation, and in 2
204 (1.87%) references an LOE was not applicable. (**Tables 5 and 7**) Out of the 107 references
205 containing information regarding exclusion criteria, 31 (28.97%) references directly tested an
206 exclusion criterion as a primary or secondary outcome of their study.

207 **Discussion:**

208 Across 824 references cited in 13 distinct THA and TKA policies, only 450 (54.61%) were
209 relevant to primary TKA and THA criteria in patients diagnosed with OA. Alarming, most cited
210 literature in the medical coverage policies relied on low-quality evidence. Of the studies with a
211 gradable LOE, 13.41% were level I, 14.58% were level II, 33.53% were level III, 18.37% were

212 level IV and 20.12% were level V. Furthermore, a majority of studies discussing OA diagnosis,
213 nonsurgical treatment, or comorbidity exclusions for surgery failed to provide scientific evidence
214 supporting the insurance companies' claims. Not only were references often low quality, but their
215 information also did not substantiate the coverage criteria for TKA and THA. This comprehensive
216 evaluation underscores the lack of high-quality data directly supporting the coverage criteria for
217 TKA and THA in medical insurance policies.

218 Our study found that references in coverage policies failed to provide scientific evidence
219 distinguishing the severity of OA and the appropriateness of THA or TKA based on severity. Only
220 2 (0.77%) of the 259 references pertaining to diagnostic criteria addressed any of the diagnostic
221 criteria as primary or secondary study outcome. Of the two references directly testing diagnostic
222 criteria, one, within the Aetna THA policy, reviewed the Tönnis classification[29], while the other,
223 within the Guidewell TKA policy, found no clear symptom threshold for surgical indication.[30]
224 The majority of studies that did not directly test the diagnostic criteria for OA simply stated OA
225 as an indication for THA or TKA without providing evidence delineating the appropriateness of
226 TJA based on OA severity. While patients with early or mild OA may benefit from conservative
227 management, those with end-stage symptomatic OA experience severe disability that cannot be
228 alleviated by conservative management.[18] Insurance companies should provide greater
229 evidence-based rationale for diagnostic criteria, as end-stage OA patients are being funneled into
230 generic treatment algorithms, delaying access to THA or TKA.[22]

231 When investigating references pertaining to nonoperative management in our study, we
232 identified a total of 84 (10.19%) references. Of these, 22.62% were journal articles, and 20.24%
233 were websites. Notably, 69.85% were level IV or V. Given that the most common reason cited by
234 orthopaedic surgeons for prior authorization denial for THA and TKA is insufficient or lack of

235 non-operative treatments, it is concerning that these references were primarily low quality and
236 often website based articles.[13]

237 Additionally, while 51 (60.71%) of the 84 citations referenced the use of nonoperative
238 management for hip and knee OA, only four directly tested the efficacy of nonoperative modalities
239 as a primary or secondary outcome of their study, representing just 0.49% of the total 824
240 references. Two of these four references, Gwynes-Jones et al. and Ferrara et al., were found in
241 Cigna’s THA policy.[31,32] In an observational study, Gwynne-Jones et al. found that 44% of
242 patients with hip and knee OA, who were assigned to individualized nonoperative treatments, did
243 not require total joint arthroplasty (TJA) at a 5-7 year follow-up.[31] The individualized program
244 included analgesic optimization, referrals to physical and occupational therapy, dietary counseling,
245 and orthotic management. However, patients with higher Kellgren-Lawrence ratings had up to 5
246 times the odds of requiring surgery. These results indicate that while multimodal nonoperative
247 management can delay surgery, its effectiveness decreases with the severity of OA. Ferrara et al.,
248 in a randomized control trial of 23 patients, found that preoperative physical therapy offered no
249 benefit to postoperative THA outcomes.[32] The other two references, Deyle et al. and Altman et
250 al., were sourced from Cigna’s TKA policy.[33,34] Deyle et al. demonstrated that supervised
251 physical therapy provides greater short term improvements than self-guided home physical therapy
252 in knee OA patients.[33] Altman et al. showed a dose-dependent delay to TKA from initial
253 physician encounter with hyaluronic acid injections for OA patients.[34] None of these four studies
254 found nonoperative treatment to be beneficial for patients with severe OA with respect to
255 modifying the disease process or avoiding surgery. However, prior authorization criteria still
256 mandate non-operative management for patients with severe OA, ignoring the best practice
257 guidelines outlined by the American College of Rheumatology (ACR) and AAHKS, which in a

258 2023 joint report, “conditionally recommended against delaying TJA to pursue additional
259 nonoperative treatment.”[5]

260 Furthermore, when analyzing whether policies delineated contraindications to
261 nonoperative management, only the Aetna THA policy directly states that severe OA of the weight
262 bearing portion of the joint is a contraindication to conservative management. It is alarming that
263 only one policy aligns with the best practices recommended by the ACR and AAHKS; albeit it is
264 unknown how frequently this contraindication is put into practice, particularly when physicians
265 continue to report prior authorization denial in instances where nonoperative management would
266 not be indicated.[13] Our analysis demonstrates that references used to substantiate medical policy
267 criteria on the appropriateness of nonoperative management for severe OA patients are of low-
268 quality, do not directly test the efficacy of nonoperative management in patients with severe OA,
269 and when they do, fail to support claims within the criteria and contradict guidelines put forth by
270 the orthopaedic community.

271 In addition to nonoperative management criteria, our study found that the exclusion criteria
272 set forth by medical coverage policies were often unsubstantiated. Of the 107 references containing
273 information on exclusion criteria, 31 (28.97%) directly assessed these criteria as a primary or
274 secondary study outcome, with the majority of references found in EviCore’s THA or TKA
275 medical policies. Notably, the absolute exclusion criteria for body mass index (BMI) >40 kg/m²,
276 and age <50 years were poorly supported by cited references and contradicted current best
277 practices. Despite BMI exclusion criteria being found in 10 of the 13 medical policies, only two,
278 EviCore THA and TKA, contained scientific articles that directly assessed the effects of BMI on
279 THA and TKA outcomes. The use of absolute BMI thresholds contradict current guidelines put
280 forth by the American College of Rheumatology and AAHKS, which state that the evidence for

281 absolute BMI thresholds is indirect and of very low quality, and that patients with higher BMIs
282 should be able to access TJA with appropriate risk stratification.[5,35–37] Similarly, the use of an
283 absolute age threshold by Aetna for TKA lacks support from the cited reference. Garcia-Rey et al.,
284 the only reference directly testing differences in THA outcomes stratified by age, found no
285 differences in clinical outcomes irrespective of patient age.[38] This study, endorsed by Aetna
286 themselves, along with other published studies highlight the lack of evidence supporting age
287 thresholds in medical coverage policies.[39] Overall, current THA and TKA medical policies
288 continue to utilize absolute exclusion criteria that largely contradict best practices set forth by the
289 American College of Rheumatology and AAHKS.[5]

290 Our study is not without limitations. An inherent limitation of our study is that insurance
291 providers update their medical coverage policies annually, and their criteria and references can
292 change. Thus, our study offers a snapshot of the current criteria and references being used in these
293 policies. Another limitation is that insurance providers do not indicate which criteria each
294 reference supports. To address this, we aimed to be as inclusive as possible when determining a
295 reference’s applicability to a given criterion. Additionally, insurance providers do not publicly
296 disclose their decision-making processes or algorithms for determining a patient's surgical
297 candidacy, which could provide more context to our results. Despite these limitations, our study
298 comprehensively assessed the quality and content of references provided by insurers. While
299 previous literature has highlighted the overall low-quality of evidence in medical coverage
300 policies, our study demonstrated that private healthcare insurance providers failed to substantiate
301 the prior authorization criteria by individually reviewing the cited references within the policies.
302 Further systematic analysis of individual recommendations found in the cited references is
303 currently the subject of investigation within our group.

304 *Conclusion*

305 References used by healthcare insurance providers to support their prior authorization
306 criteria are of low level of evidence and contain information that either does not support the criteria
307 or contradicts current practice guidelines put forth by the arthroplasty community. Given the
308 delays in patient care that prior authorization can cause, insurance companies should implement
309 recommendations that are rooted in evidence-based medicine that are in accordance with the best
310 standard practices. This is currently not the case.

311 **Tables:**

Table 1a: Total Hip Arthroplasty (THA) Reference Count

Insurance Payer	Reference No.	% of Total	No. Accessible	% Accessible	No. Applicable to THA	% Applicable to THA of Accessible References
Aetna	127	35.38%	116	91.34%	92	79.31%
BlueShield	71	19.78%	68	95.77%	57	83.82%
Evicore*	81	22.56%	81	100.00%	41	50.62%
Humana	19	5.29%	11	57.89%	6	54.55%
UPMC	38	10.58%	33	86.84%	27	81.82%
Guidewell	23	6.41%	21	91.30%	18	85.71%
Total:	359	100.00%	330	91.92%	241	73.03%

*Evicore guideline is used by Cigna, Healthcare Service Corp, and Highmark.

Table 1b: Total Knee Arthroplasty (TKA) Reference Count

Insurance Payer	Reference No.	% of Total	No. Accessible	% Accessible	No. Applicable to TKA	% Applicable to TKA of Accessible References
Aetna	165	35.48%	148	89.70%	81	54.73%
BlueShield	50	10.75%	45	90.00%	45	90.00%
Evicore*	124	26.67%	124	100.00%	52	41.94%
Humana	19	4.09%	7	36.84%	6	85.71%
UPMC	50	10.75%	37	74.00%	25	67.67%
Guidewell	18	3.87%	16	88.89%	13	81.25%
Centene	39	8.39%	37	94.87%	22	59.46%
Total:	465	100.00%	414	89.03%	244	58.94%

*Evicore guideline is used by Cigna, Healthcare Service Corp, and Highmark.

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Table 2a. Total Hip Arthroplasty Insurance Payer Diagnostic Criteria

Insurance Payer	Pain / ADL* / Disability	Radiological Grading	Physical Exam Findings	Diagnosis
Aetna	Pain and functional disability	Radiographic evidence of osteoarthritis (Tonnis grade 2 or 3)	Limited ROM**, swelling/effusion of joint	Not found on policy
BlueShield	Not found on policy	Severe osteoarthritis of hip joint as evidenced by two or more of the following: <ul style="list-style-type: none"> • Subchondral cysts • Subchondral sclerosis • Periarticular osteophytes • Joint subluxation • Bone on bone articulation • Joint space narrowing 	History of limited ROM, antalgic gait, pain in hip joint with passive range of motion on physical examination	Not found on policy
Evicore	Function-limiting pain at short distances for at least three (3) months duration	Tönnis Grade 3 osteoarthritis	Not found on policy	Not found on policy
Humana	Documentation of painful, disabling joint disease of the hip that interferes with ADLs	Not found on policy	Not found on policy	Not found on policy
UPMC	Hip pain persists and occurs with all of the following: <ol style="list-style-type: none"> a. Pain with standing and/or walking; and b. Pain at rest or at night; and c. Pain interfering with one or more ADLs. 	Radiographic evidence confirms near end-stage or end-stage joint disease, consisting of one of the following: <ul style="list-style-type: none"> • Bone-on-bone articulation; or • Acetabular protrusion, medial or superior (arthrokatadysis); or • Joint space narrowing with at least two of the following: <ol style="list-style-type: none"> a) Subchondral cysts, b) Subchondral sclerosis, c) Periarticular osteophytes d) Joint subluxation. 	Not found on policy	Diagnosis of osteoarthritis
Guidewell	Not found on policy	Advanced joint disease demonstrated by radiographic or magnetic resonance imaging (MRI) evidence of subchondral cysts, subchondral sclerosis, periarticular osteophytes, joint subluxation, joint space narrowing, avascular necrosis),	Not found on policy	Not found on policy

*Affecting Activities of Daily Living

**Range of Motion

Table 2b. Total Hip Arthroplasty Insurance Payer Non-Operative Management Criteria

Insurance Payer	Duration	Medication	Physical Therapy / Exercise	Activity Modification	Therapeutic injections	Contraindicated
Aetna	At least 12 or 24 weeks depending on age/BMI	Anti-inflammatory medications or analgesics	Flexibility and muscle strengthening exercises. Supervised physical therapy (in-person as opposed to home or virtual physical therapy; ADLs diminished despite completing a plan of care).	Activity modification	Therapeutic injections into the hip (for people with contraindications)	If conservative therapy is not appropriate, the medical record must clearly document why
BlueShield	At least 3 months	Not found on policy	Not found on policy	Not found on policy	Not found on policy	Documentation of rationale if conservative therapy is considered inappropriate
Evicore	At least 3 months; 6 months for those with BMI's > 40	Not found on policy	Not found on policy	Not found on policy	Not found on policy	The medical record must clearly document why provider-directed non-surgical management is not appropriate.
Humana	At least 3 months	Nonsteroidal anti-inflammatory drugs (NSAIDs)	Physical therapy with home exercise program (HEP) (for information regarding coverage determination/ limitations)	Activity/lifestyle modifications	Intra-articular steroid injection if medically appropriate and not contraindicated	Not found on policy
UPMC	At least 6 weeks	Non-opioid oral analgesics and/or anti-inflammatory medications taken for at least 6 weeks,	Home-directed exercise program or physical therapy.	Not found on policy	Not found on policy	If the patient is unable to participate in either program, documentation must be provided in the medical record detailing the reason the patient is unable to tolerate such a regimen.
Guidewell	At least 3 months	Anti-inflammatory medications and/or Analgesics	Flexibility and muscle strengthening exercises and/or Supervised physical therapy	Activity restrictions as is reasonable	Not found on policy	Not found on policy

Table 2c. Total Hip Arthroplasty Insurance Payer Contraindication and Exclusion Criteria

Insurance Payer	Weight	Age	Systemic	Smoking/Substance Use	Other
Aetna	Morbid obesity (body mass index (BMI) greater than 40)	age less than 50 years	Not found on policy	Not found on policy	Not found on policy
BlueShield	Not found on policy	Not found on policy	Not found on policy	Not found on policy	Not found on policy
Evicore	For patients with BMI > 40, there must be failure of at least six (6) months of provider-directed non-surgical management	Not found on policy	One or more uncontrolled or unstable medical conditions that would significantly increase the risk of morbidity (e.g., cardiac, pulmonary, liver, genitourinary, or metabolic disease; hypertension; abnormal serum electrolyte levels)	Not found on policy	Patients on dialysis who are on a renal transplant list
Humana	A BMI greater than 40 has documentation of attempted weight loss	Not found on policy	Multiple uncontrolled comorbid medical conditions	Individual who is a smoker or nicotine user is provided assistance in developing a plan for quitting (cessation) that includes pharmacotherapy (eg, bupropion, varenicline) and/or referral to a smoking cessation program prior to the surgical procedure	Not found on policy
UPMC	If the patient's BMI is > 50, weight reduction as appropriate	Not found on policy	<ul style="list-style-type: none"> • Stage IV cancer or active cancer treatment without any one of the following exceptions: <ul style="list-style-type: none"> ▪ Hormonal remission therapy such as Lupron or Tamoxifen; or ▪ Primary tumor involves the hip; or ▪ Remission therapy for leukemia and lymphomas. 	If patient is an active smoker, including recreational marijuana use, e-cigarettes, or vaping of any substance, patient must be counseled and referred to a smoking cessation program. If the patient has a current prescription for opioids, documentation for review must include the rationale as to the reason the patient is using opioids, the patient's usage (dosage/frequency), and a written plan for opioid use reduction.	End-stage renal disease
Guidewell	Not found on policy	Not found on policy	Not found on policy	Not found on policy	Not found on policy

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Table 3a. Total Knee Arthroplasty Insurance Payer Diagnostic Criteria

Insurance Payer	Pain / ADL / Disability	Radiological Grading	Physical Exam Findings	Diagnosis
Aetna	Pain and functional disability	Radiographic evidence of osteoarthritis (Kellgren-Lawrence Grade 3 or 4)	Limited ROM, crepitus, or effusion or swelling of knee joint	Not found on policy
BlueShield	Not found on policy	Radiographic evidence of severe osteoarthritis as evidenced by either of the following: <ul style="list-style-type: none"> • The presence of definite joint space narrowing with sclerosis and possible deformity of bone ends • The presence of large osteophytes, marked narrowing of joint space, severe sclerosis and definite deformity of the proximal tibia or distal femur 	Documentation of limited range of motion, antalgic gait, and pain in knee joint with passive ROM on physical examination	Diagnosis of osteoarthritis
Evicore	Function-limiting pain at short distances for at least three (3) months duration, Loss of knee function which interferes with the ability to carry out age appropriate ADL and/or demands of employment	Radiographic or arthroscopic findings of EITHER of the following: <ul style="list-style-type: none"> • Severe unicompartmental (medial, lateral, or patellofemoral), bicompartamental, or tricompartmental degenerative arthritis evidenced by either of the following: <ol style="list-style-type: none"> a) Large osteophytes, marked narrowing of joint space, severe sclerosis, and definite deformity of bone contour (i.e., Kellgren-Lawrence Grade IV radiographic findings) b) Exposed subchondral bone (i.e., Outerbridge Classification Grade IV arthroscopy findings) 	Not found on policy	Not found on policy
Humana	Documentation of painful, disabling joint disease of the knee that interferes with ADLs resulting from non-inflammatory joint disease	Radiographic confirmation of bone and joint pathology of the knee joint as evidenced either of the following: <ul style="list-style-type: none"> • Exposed subchondral bone (Outerbridge Grade); or • Large osteophytes, marked narrowing of joint space, definite deformity of bone ends, severe sclerosis (Kellgren Lawrence Grade) 	Angular deformity of greater than 20 degrees,	Kellgren Lawrence Grade 4 osteoarthritis with bone-on-bone articulation in the weight-bearing portion of the joint (lateral, medial, patellofemoral)
UPMC	Persistent Knee pain with all of the following: <ul style="list-style-type: none"> • Significant pain that interferes with ADLs; and • Significant pain that increases with weight bearing and/or standing; and • Significant pain with active or passive range of motion 	Radiological evidence of end stage joint disease (bone-on-bone articulation) in one to three compartments, or near-end stage joint disease with joint space narrowing in one to three compartments with at least two of the following: Malalignment, Joint subluxation, Subchondral cyst(s), Subchondral sclerosis, Periarticular osteophyte(s)	Not found on policy	Near end-stage to end-stage osteoarthritis (primary or secondary) (i.e., near or complete loss of joint space, bone-on-bone with or without varus, or valgus malalignment)
Guidewell	Pain or functional disability from injury due to trauma or arthritis of the joint	Advanced joint disease demonstrated by radiographic or magnetic resonance imaging (MRI) evidence of subchondral cysts, subchondral sclerosis, periarticular osteophytes, joint subluxation, joint space narrowing	Not found on policy	Not found on policy

Centene	Presence of significant pain or disability that interferes with ability to perform daily activities	Confirmed by standing x-rays with documentation of all of the following: <ul style="list-style-type: none"> • Significant (at least moderate-to-severe) joint destruction • Descriptive criteria including at least two of the following: Subchondral cysts, Subchondral sclerosis, Joint space narrowing, Joint subluxation, Osteophyte formation 	Symptoms correlate with knee pathology, supported by physical exam findings (e.g. antalgic gait, pain or limitation with range of motion, crepitus, joint effusion, swelling)	Advanced degenerative joint disease as indicated by osteoarthritis
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Table 3b. Total Knee Arthroplasty Insurance Payer Non-Operative Management Criteria

Insurance Payer	Duration	Medication	Physical Therapy / Exercise	Activity Modification	Therapeutic injections	Contraindicated
Aetna	12 or 24 weeks depending on age/BMI	Anti-inflammatory medications or analgesics	Flexibility and muscle strengthening exercises. Supervised physical therapy (in-person as opposed to home or virtual physical therapy; ADLs diminished despite completing a plan of care).	Activity modification	Therapeutic injections into the knee (for people with contraindications)	Conservative therapy may be inappropriate for severe osteoarthritis with bone-on-bone articulation in the weight-bearing portion of the joint (medial and/or lateral but not patello-femoral) or severe angular deformity,
BlueShield	Not found on policy	Not found on policy	Not found on policy	Not found on policy	Not found on policy	documentation of rationale if conservative therapy is considered inappropriate
Evicore	At least 3 months; 6 months for those with BMI's>40	Not found on policy	Not found on policy	Not found on policy	Not found on policy	The medical record must clearly document why provider-directed non-surgical management is not appropriate.
Humana	At least 3 months	Medications (eg, nonsteroidal anti-inflammatory drugs [NSAIDs] or non-narcotic analgesics) when medically appropriate and not contraindicated	Physical therapy including home exercise program (HEP) (for information regarding coverage determination/ limitations	Activity/lifestyle modifications	Intra-articular injections when medically appropriate and not contraindicated	Not found on policy
UPMC	At least 6 weeks	non-opioid oral analgesics and/or anti-inflammatory medications taken for at least 6 weeks, if not contraindicated	At least six weeks of participation in a home-directed exercise program (preferred) or a minimum of six weeks of physical therapy. If the patient is unable to participate in either program, documentation must be provided in the medical record detailing the reason the patient is unable to tolerate such a regimen.	Not found on policy	Not found on policy	Rapid progression of symptoms with severe disability and progressive radiologic deterioration;
Guidewell	At least 3 months	Anti-inflammatory medications and/or Analgesics	Flexibility and muscle strengthening exercises and/or Supervised physical therapy	Activity restrictions as is reasonable	Therapeutic injections into the knee as appropriate	Not found on policy

Centene	at least 3 months	Analgesics or anti-inflammatory medications	Muscle strengthening and flexibility exercises, instructed by medical professional, in preparation for post-operative interval and recovery	Activity modification	Therapeutic knee injections (optional)	Not found on policy
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Table 3c. Total Knee Arthroplasty Insurance Payer Contraindication and Exclusion Criteria

Insurance Payer	Weight	Age	Systemic	Smoking/Substance Use	Other
Aetna	Relative contraindications to joint replacement include the following: morbid obesity (body mass index (BMI) greater than 40)	age less than 50 years	Not found on policy	Not found on policy	Not found on policy
BlueShield	Not found on policy	Not found on policy	Not found on policy	Not found on policy	Not found on policy
Evicore	For patients with BMI > 40, there must be failure of at least six (6) months of provider-directed non-surgical management	Not found on policy	Not found on policy	Not found on policy	Patients on dialysis who are on a renal transplant list
Humana	Not found on policy	Not found on policy	Multiple uncontrolled comorbid medical conditions	Individual who is a smoker or nicotine user is provided assistance in developing a plan for quitting (cessation) that includes pharmacotherapy (eg, bupropion, varenicline) and/or referral to a smoking cessation program prior to the surgical procedure	Not found on policy
UPMC	If the patient's BMI is > 50	Not found on policy	<ul style="list-style-type: none"> • Stage IV cancer or active cancer treatment without any one of the following exceptions: <ul style="list-style-type: none"> ▪ Hormonal remission therapy such as Lupron or Tamoxifen; or ▪ Primary tumor involves the hip; or ▪ Remission therapy for leukemia and lymphomas. 	Limitation: If a patient is an active smoker, including recreational marijuana use, e-cigarettes, or vaping of any substance, unless the patient is counseled and referred to a smoking cessation program. / If the patient has a current prescription for opioids, documentation for review must include the rationale as to the reason the patient is using opioids, the patient's usage (dosage/frequency), and a written plan for opioid use reduction.	End-stage renal disease (dialysis)

Guidewell	Not found on policy	Not found on policy	Not found on policy	Not found on policy	Not found on policy
Centene	BMI greater than 40 is a contraindication for total knee replacement, unless significant weight loss is clearly	Not found on policy	Not found on policy	Not found on policy	Not found on policy

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Table 4: Total Hip Arthroplasty (THA) Reference Type

Criteria	Total	Primary Journal Article	Review	Society Guideline	Government Report	Expert Opinion	Website
Diagnostic	112	56	24	7	7	6	12
		50.00%	21.43%	6.25%	6.25%	5.36%	10.71%
Non-Operative	32	6	6	5	5	1	9
		18.75%	18.75%	15.63%	15.63%	3.13%	28.13%
Exclusions	65	35	21	0	4	2	3
		53.85%	32.31%	0.00%	6.15%	3.08%	4.62%

*All values are represented as counts with their corresponding percentage below.

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Table 5: Total Hip Arthroplasty (THA) Reference LOE

Criteria	LOE I	LOE II	LOE III	LOE IV	LOE V	LOE Variable	LOE N/A
Diagnostic	5	19	30	14	19	21	4
	4.46%	16.96%	26.79%	12.50%	16.96%	18.75%	3.57%
Non-Operative	3	1	1	3	13	11	0
	9.38%	3.13%	3.13%	9.38%	40.63%	34.38%	0.00%
Exclusions	3	10	33	9	4	5	1
	4.62%	15.38%	50.77%	13.85%	6.15%	7.69%	1.54%

*All values are represented as counts with their corresponding percentage below.

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Table 6: Total Knee Arthroplasty (TKA) Reference Type

Criteria	Total	Primary Journal Article	Review	Society Guideline	Government Report	Expert Opinion	Website
Diagnostic	147	79	34	13	6	5	10
		53.74%	23.13%	8.84%	4.08%	3.40%	6.80%
Non-Operative	52	13	9	11	8	3	8
		25.00%	17.31%	21.15%	15.38%	5.77%	15.38%
Exclusions	42	38	2	1	1	0	0
		90.48%	4.76%	2.38%	2.38%	0.00%	0.00%

*All values are represented as counts with their corresponding percentage below.

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Table 7: Total Knee Arthroplasty (TKA) Reference LOE

Criteria	LOE I	LOE II	LOE III	LOE IV	LOE V	LOE Variable	LOE N/A
Diagnostic	22	16	29	22	19	32	7
	14.97%	10.88%	19.73%	14.97%	12.93%	21.77%	4.76%
Non-Operative	5	1	5	3	14	19	5
	9.62%	1.92%	9.62%	5.77%	26.92%	36.54%	9.62%
Exclusions	8	3	17	12	0	1	1
	19.05%	7.14%	40.48%	28.57%	0.00%	2.38%	2.38%

*All values are represented as counts with their corresponding percentage below.

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356 **References:**

- 357 [1] Sloan M, Premkumar A, Sheth NP. Projected Volume of Primary Total Joint Arthroplasty
358 in the U.S., 2014 to 2030. *J Bone Joint Surg Am* 2018;100:1455–60.
- 359 [2] Lavernia CJ, Guzman JF, Gachupin-Garcia A. Cost effectiveness and quality of life in knee
360 arthroplasty. *Clin Orthop Relat Res* 1997:134–9.
- 361 [3] Losina E, Walensky RP, Kessler CL, Emrani PS, Reichmann WM, Wright EA, et al. Cost-
362 effectiveness of total knee arthroplasty in the United States: patient risk and hospital
363 volume. *Arch Intern Med* 2009;169:1113–21; discussion 1121–2.
- 364 [4] Koenig L, Zhang Q, Austin MS, Demiralp B, Fehring TK, Feng C, et al. Estimating the
365 Societal Benefits of THA After Accounting for Work Status and Productivity: A Markov
366 Model Approach. *Clin Orthop Relat Res* 2016;474:2645–54.
- 367 [5] Hannon CP, Goodman SM, Austin MS, Yates A Jr, Guyatt G, Aggarwal VK, et al. 2023
368 American College of Rheumatology and American Association of Hip and Knee Surgeons
369 Clinical Practice Guideline for the Optimal Timing of Elective Hip or Knee Arthroplasty for
370 Patients With Symptomatic Moderate-to-Severe Osteoarthritis or Advanced Symptomatic
371 Osteonecrosis With Secondary Arthritis for Whom Nonoperative Therapy Is Ineffective.
372 *Arthritis Rheumatol* 2023;75:1877–88.
- 373 [6] Mancuso CA, Ranawat CS, Esdaile JM, Johanson NA, Charlson ME. Indications for total
374 hip and total knee arthroplasties. Results of orthopaedic surveys. *J Arthroplasty*
375 1996;11:34–46.
- 376 [7] Ethgen O, Bruyère O, Richy F, Dardennes C, Reginster J-Y. Health-related quality of life in
377 total hip and total knee arthroplasty. A qualitative and systematic review of the literature. *J*
378 *Bone Joint Surg Am* 2004;86:963–74.
- 379 [8] Malik AT, Alexander JH, Li DD, Li M, Khan SN, Scharschmidt TJ. What Are the Costs of
380 Hip Osteoarthritis in the Year Prior to a Total Hip Arthroplasty? *J Arthroplasty*
381 2020;35:313–7.e1.
- 382 [9] Nin DZ, Chen Y-W, Talmo CT, Hollenbeck BL, Mattingly DA, Niu R, et al. Costs of
383 Nonoperative Procedures for Knee Osteoarthritis in the Year Prior to Primary Total Knee
384 Arthroplasty. *J Bone Joint Surg Am* 2022;104:1697–702.
- 385 [10] Grace TR, Eralp I, Khan IA, Goh GS, Siqueira MB, Austin MS. Are Patients With End-
386 Stage Arthritis Willing to Delay Arthroplasty for Payer-Mandated Physical Therapy? *J*
387 *Arthroplasty* 2022;37:S27–31.
- 388 [11] Goh S-L, Persson MSM, Stocks J, Hou Y, Lin J, Hall MC, et al. Efficacy and potential
389 determinants of exercise therapy in knee and hip osteoarthritis: A systematic review and
390 meta-analysis. *Ann Phys Rehabil Med* 2019;62:356–65.
- 391 [12] Cohen JR, Bradley AT, Lieberman JR. Preoperative Interventions and Charges Before Total
392 Knee Arthroplasty. *J Arthroplasty* 2016;31:2730–5.e7.
- 393 [13] Pereira DE, Kamara E, Krueger CA, Courtney PM, Austin MS, Rana A, et al. Prior
394 authorization in total joint arthroplasty: A survey of the American Association of Hip and
395 Knee Surgeons membership. *J Arthroplasty* 2023;38:1203–8.e3.
- 396 [14] Lizcano JD, Goh GS, Tarabichi S, Krueger CA, Austin MS, Courtney PM. Prior
397 Authorization Leads to Administrative Burden and Delays in Treatment in Primary Total
398 Joint Arthroplasty Patients. *J Arthroplasty* 2024. <https://doi.org/10.1016/j.arth.2024.03.013>.
- 399 [15] Holzapfel DE, Meyer M, Thieme M, Pagano S, von Kunow F, Weber M. Delay of total
400 joint replacement is associated with a higher 90-day revision rate and increased

- 401 postoperative complications. *Arch Orthop Trauma Surg* 2023;143:3957–64.
- 402 [16] Ravi B, Croxford R, Austin PC, Lipscombe L, Bierman AS, Harvey PJ, et al. The relation
403 between total joint arthroplasty and risk for serious cardiovascular events in patients with
404 moderate-severe osteoarthritis: propensity score matched landmark analysis. *BMJ*
405 2013;347:f6187.
- 406 [17] Turkiewicz A, Kiadaliri AA, Englund M. Cause-specific mortality in osteoarthritis of
407 peripheral joints. *Osteoarthritis Cartilage* 2019;27:848–54.
- 408 [18] Ghomrawi HMK, Mushlin AI, Kang R, Banerjee S, Singh JA, Sharma L, et al. Examining
409 Timeliness of Total Knee Replacement Among Patients with Knee Osteoarthritis in the
410 U.S.: Results from the OAI and MOST Longitudinal Cohorts. *J Bone Joint Surg Am*
411 2020;102:468–76.
- 412 [19] Ho KW, Pong G, Poon WC, Chung KY, Kwok Y-Y, Chiu KH. Progression of health-
413 related quality of life of patients waiting for total knee arthroplasty. *J Eval Clin Pract*
414 2021;27:69–74.
- 415 [20] Scott CEH, MacDonald DJ, Howie CR. “Worse than death” and waiting for a joint
416 arthroplasty. *Bone Joint J* 2019;101-B:941–50.
- 417 [21] Chen AF, Bloomfield MR, Lichstein PM, Yates AJ Jr, Austin MS. What is the level of
418 evidence substantiating the Medicare local coverage determinations? *J Arthroplasty*
419 2015;30:356–60.
- 420 [22] Austin MS, Ashley BS, Bedard NA, Bezwada HP, Hannon CP, Fillingham YA, et al. What
421 is the Level of Evidence Substantiating Commercial Payers’ Coverage Policies for Total
422 Joint Arthroplasty? *J Arthroplasty* 2021;36:2665–73.e8.
- 423 [23] Kissell C. Largest Health Insurance Companies 2024. *Forbes Magazine* 2024.
- 424 [24] Wright JG, Swiontkowski MF, Heckman JD. Introducing levels of evidence to the journal. *J*
425 *Bone Joint Surg Am* 2003;85:1–3.
- 426 [25] Medical Policies. Health Care Service Corporation n.d.
427 <https://medicalpolicy.hcsc.com/disclaimer?corpEntCd=HCSC> (accessed March 30, 2024).
- 428 [26] Medical Policy: S-261-002. Highmark n.d.
429 [https://securecms.highmark.com/content/medpolicy/en/highmark/pa/commercial/policies/Su](https://securecms.highmark.com/content/medpolicy/en/highmark/pa/commercial/policies/Surgery/S-261/S-261-002.html)
430 [rgery/S-261/S-261-002.html](https://securecms.highmark.com/content/medpolicy/en/highmark/pa/commercial/policies/Surgery/S-261/S-261-002.html) (accessed March 30, 2024).
- 431 [27] Medical Policy: S-247-004. Highmark n.d.
432 [https://securecms.highmark.com/content/medpolicy/en/highmark/pa/commercial/policies/Su](https://securecms.highmark.com/content/medpolicy/en/highmark/pa/commercial/policies/Surgery/S-247/S-247-004.html)
433 [rgery/S-247/S-247-004.html](https://securecms.highmark.com/content/medpolicy/en/highmark/pa/commercial/policies/Surgery/S-247/S-247-004.html) (accessed March 30, 2024).
- 434 [28] CHCP - Resources - Coverage Policies n.d.
435 https://static.cigna.com/assets/chcp/resourceLibrary/coveragePolicies/index.html?_gl=1*7fi
436 [biz*_gcl_au*MTM4NjA3Mjc5NS4xNzExMjQ1MzY0](https://static.cigna.com/assets/chcp/resourceLibrary/coveragePolicies/index.html?_gl=1*7fi) (accessed March 30, 2024).
- 437 [29] Kovalenko B, Bremjit P, Fernando N. Classifications in Brief: Tönnis Classification of Hip
438 Osteoarthritis. *Clin Orthop Relat Res* 2018;476:1680–4.
- 439 [30] Gossec L, Paternotte S, Maillefert JF, Combescure C, Conaghan PG, Davis AM, et al. The
440 role of pain and functional impairment in the decision to recommend total joint replacement
441 in hip and knee osteoarthritis: an international cross-sectional study of 1909 patients. Report
442 of the OARSI-OMERACT Task Force on total joint replacement. *Osteoarthritis Cartilage*
443 2011;19:147–54.
- 444 [31] Gwynne-Jones JH, Wilson RA, Wong JMY, Abbott JH, Gwynne-Jones DP. The Outcomes
445 of Nonoperative Management of Patients With Hip and Knee Osteoarthritis Triaged to a
446 Physiotherapy-Led Clinic at Minimum 5-Year Follow-Up and Factors Associated With

- 447 Progression to Surgery. *J Arthroplasty* 2020;35:1497–503.
- 448 [32] Ferrara PE, Rabini A, Maggi L, Piazzini DB, Logroscino G, Magliocchetti G, et al. Effect
449 of pre-operative physiotherapy in patients with end-stage osteoarthritis undergoing hip
450 arthroplasty. *Clin Rehabil* 2008;22:977–86.
- 451 [33] Deyle GD, Allison SC, Matekel RL, Ryder MG, Stang JM, Gohdes DD, et al. Physical
452 therapy treatment effectiveness for osteoarthritis of the knee: a randomized comparison of
453 supervised clinical exercise and manual therapy procedures versus a home exercise
454 program. *Phys Ther* 2005;85:1301–17.
- 455 [34] Altman R, Lim S, Steen RG, Dasa V. Hyaluronic Acid Injections Are Associated with
456 Delay of Total Knee Replacement Surgery in Patients with Knee Osteoarthritis: Evidence
457 from a Large U.S. Health Claims Database. *PLoS One* 2015;10:e0145776.
- 458 [35] Wagner ER, Kamath AF, Fruth KM, Harmsen WS, Berry DJ. Effect of Body Mass Index on
459 Complications and Reoperations After Total Hip Arthroplasty. *J Bone Joint Surg Am*
460 2016;98:169–79.
- 461 [36] Wagner ER, Kamath AF, Fruth K, Harmsen WS, Berry DJ. Effect of Body Mass Index on
462 Reoperation and Complications After Total Knee Arthroplasty. *J Bone Joint Surg Am*
463 2016;98:2052–60.
- 464 [37] Foreman CW, Callaghan JJ, Brown TS, Elkins JM, Otero JE. Total Joint Arthroplasty in the
465 Morbidly Obese: How Body Mass Index ≥ 40 Influences Patient Retention, Treatment
466 Decisions, and Treatment Outcomes. *J Arthroplasty* 2020;35:39–44.
- 467 [38] Garcia-Rey E, Cruz-Pardos A, Garcia-Cimbrelo E. Alumina-on-alumina total hip
468 arthroplasty in young patients: diagnosis is more important than age. *Clin Orthop Relat Res*
469 2009;467:2281–9.
- 470 [39] Bayliss LE, Culliford D, Monk AP, Glyn-Jones S, Prieto-Alhambra D, Judge A, et al. The
471 effect of patient age at intervention on risk of implant revision after total replacement of the
472 hip or knee: a population-based cohort study. *Lancet* 2017;389:1424–30.

473