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Patient-Specific Instrumentation (e.g., Cutting Guides) for Joint Arthroplasty

Table of Contents

Related Policies (if applicable)
None

Disclaimer

Medical policies are a set of written guidelines that support current standards of practice. They are based on current generally accepted standards of and developed by nonprofit professional association(s) for the relevant clinical specialty, third-party entities that develop treatment criteria, or other federal or state governmental agencies. A requested therapy must be proven effective for the relevant diagnosis or procedure. For drug therapy, the proposed dose, frequency and duration of therapy must be consistent with recommendations in at least one authoritative source. This medical policy is supported by FDA-approved labeling and/or nationally recognized authoritative references to major drug compendia, peer reviewed scientific literature and generally accepted standards of medical care. These references include, but are not limited to: MCG care guidelines, DrugDex (IIa level of evidence or higher), NCCN Guidelines (IIb level of evidence or higher), NCCN Compendia (IIb level of evidence or higher), professional society guidelines, and CMS coverage policy.

Carefully check state regulations and/or the member contract.

Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

Use of patient-specific instrumentation (e.g., cutting guides) for joint arthroplasty, including but not limited to use in unicompartmental or total knee arthroplasty, **is considered experimental, investigational and/or unproven.**

Policy Guidelines

None.

Description

Patient-specific instrumentation has been developed as an alternative to conventional cutting guides, with the goal of improving both alignment and surgical efficiency. A number of patient-specific cutting guides are currently being marketed. Patient-specific guides are constructed with the use of preoperative 3-dimensional computed tomography or magnetic resonance imaging scans, which are taken 4 to 6 weeks before the surgery. The images are sent to the planner/manufacturer to create a 3-dimensional model of the knee and proposed implant. After the surgeon reviews the model of the bone, makes adjustments, and approves the surgical plan, the manufacturer fabricates the disposable cutting guides.

Regulatory Status

There are several commercially available patient-specific instrumentation systems for total knee arthroplasty. In 2008, the Smith & Nephew Patient Matched Instrumentation (now called Visionaire™ Patient Matched Instrumentation) was the first patient-specific cutting guide to receive U.S. Food and Drug Administration (FDA) clearance for marketing. Other systems cleared for marketing by the FDA are shown in Table 1 (FDA Product Code OOG).

Table 1. Patient-Specific Cutting Guides for Knee Arthroplasty

Device Name	Manufacturer	510(K) Number	Clearance Date
UNIKO PointCloud Knee Instruments	Unik Orthopedics, Inc	K240327	06/27/2024
X-Psi	Orthosoft	K131409	09/13/2013
iTotal	Conformis	K120068	02/03/2012
Prophecy	Wright Medical Technology	K103598	10/17/2011
Trumatch	Depuy Orthopaedics	K110397	08/16/2011
Shapematch	Stryker	K110533	05/19/2011
Signature	Materialise	K102795	02/02/2011
Zimmer	Materialise	K091263	11/19/2009
Visionaire	Smith & Nephew	K082358	11/25/2008

Source: FDA: U.S. Food and Drug Administration.

Rationale

Medical policies assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life, and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to individuals and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Patient-Specific Cutting Guides

Clinical Context and Therapy Purpose

The purpose of patient-specific cutting guides in individuals undergoing knee arthroplasty is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is individuals undergoing partial or total knee arthroplasty (also called knee replacement). Knee arthroplasty is an established treatment for relief from significant, disabling pain caused by advanced arthritis. This intervention is considered among the most successful medical procedures in the United States regarding the degree of improvement in functional status and quality of life. As a result of the success of knee arthroplasty, the increase in the aging population, and the desire of older adults to remain physically active, the incidence of knee arthroplasty is increasing rapidly. It is projected that by 2030, the demand for knee replacement will approach 3.5 million procedures annually. (1)

Knee arthroplasty is performed by removing the damaged cartilage surface and a portion of underlying bone using a saw guided by templates and jigs. The cartilage and bone removed from the distal femur and proximal tibia are replaced with implants that recreate the surface of the joint. Patellar resurfacing may also be performed. Three-dimensional implant alignment (coronal, sagittal, axial) is considered to be critical for joint articulation and implant longevity. Less than 3° deviation from the rotational or mechanical axis, as determined by a straight line through the center of the hip, knee, and ankle on the coronal plane, is believed to minimize the risk of implant wear, loosening, instability, and pain.

Interventions

The therapy being considered is patient-specific instrumentation (e.g., cutting guides). The cutting guides are used to aid the surgeon intraoperatively in making the initial distal femoral and the initial proximal tibial bone cuts during knee arthroplasty surgery. The cutting guides also establish the references for component orientations. The placement of conventional

cutting guides (templates and jigs) is based on anatomic landmarks or computer navigation. Use of conventional instrumentation has been shown to result in malalignment of approximately one-third of implants in the coronal plane. Computer-assisted navigation can significantly reduce the proportion of malaligned implants compared with conventional instrumentation but has a number of limitations including a lack of rotational alignment, increased surgical time, and a long learning curve. Also, no studies have demonstrated an improvement in clinical outcomes with computer-assisted navigation.

Comparators
For individuals undergoing knee arthroplasty, conventional cutting guides are currently being used for knee arthroplasty (see intervention description).

Outcomes
The general outcomes of interest are symptoms, functional outcomes, and quality of life. Commonly used instruments to measure these outcomes include the Knee Society Score (KSS), Oxford Knee Score, range of movement, Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), and visual analog scales.

The surrogate outcome measure of a reduction in malalignment may be informative to support improvement with the new technology. However, a reduction in the percentage of malaligned implants has not been shown to result in improved clinical outcomes and is, therefore, not sufficient to demonstrate an improvement in clinical outcomes. Also, no long-term studies are currently available that could provide data on revision rates. It should also be noted that the design of these devices is evolving, and results from older studies may be less relevant for contemporary designs.

The proposed benefits of using patient-specific instrumentation during knee arthroplasty include improved alignment, decreased operative time, increased patient throughput, fewer instrument trays, reduced risk of fat embolism and intraoperative bleeding (no intramedullary canal reaming), shorter recovery, reduced postoperative pain, reduced revision rate, and reduced costs. However, the nonsurgical costs of the procedure may be increased due to the requirement for preoperative computed tomography or magnetic resonance imaging, preoperative review of the template, and fabrication of the patient-specific instrumentation. Also, the patient-specific template relies on the same anatomic landmarks as conventional knee arthroplasty and does not take soft tissue balancing into account. Thus, evaluation of this technology should also address the reliability of the cutting guides and the need for intraoperative changes such as conversion to conventional instrumentation.

Component alignment and perioperative outcomes are short-term outcomes. Pain, function, and quality of life should be measured in long-term studies (2 years or longer), in particular because component alignment is hypothesized to correlate to component longevity.

<u>Study Selection Criteria</u>
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Systematic Reviews

There are a number of systematic reviews on patient-specific instrumentation for total knee arthroplasty. We focus on the most recent, comprehensive, and relevant analyses (Table 2). Three of these reported functional outcomes in addition to measures of malalignment outcomes. (2-4)

Table 2. Comparison of Trials/Studies Included in Patient-Specific Instrumentation Meta-Analyses

Study	Tibesku et al. (2023) (5)	Lin et al. (2020) (4)	Gong et al. (2018) (6)	Thienpont et al. (2017) (3)	Mannan et al. (2017) (7)
Abane et al. (2015) (8)	●	●	●	●	●
Abane et al. (2018) (9)		●			
Abdel et al. (2014) (10)		●		●	
Anderl et al. (2016) (11)				●	●
Bali et al. (2012) (12)	●			●	
Barke et al. (2013) (13)	●			●	
Barrack et al. (2012) (14)				●	
Barrett et a. (2014) (15)				●	
Boonen et al. (2012) (16)				●	
Boonen et al. (2013) (17)		●	●	●	
Boonen et al. (2016) (18)		●	●		
Broberg et al. (2020) (19)	●				

Chareancholvanich et al. (2013) (20)		●	●	●	
Chen et al. (2014) (21)				●	
Chen et al. (2015) (22)				●	●
Chotanaphuti et al. (2014) (23)		●		●	
Cucchi et al. (2018) (24)		●			
Daniilidis et al. (2014) (25)	●			●	
De Vloo et al. (2017) (26)		●	●		
DeHann et al. (2014) (27)	●			●	
Ferrara et al. (2015) (28)				●	
Gan et al. (2015) (29)			●		
Hamilton et al. (2013) (30)		●	●	●	
Heyse et al. (2014) (31)				●	
Huijbregts et al. (2016) (32)	●	●	●		
Kassab et al. (2014) (33)				●	
Khuangsirikul et al. (2014) (34)			●		
Kosse et al. (2018) (35)	●	●	●		
Kotela et al. (2014) (36)		●	●	●	
Kotela et al. (2015) (37)		●	●	●	●
MacDessi et al. (2014) (38)				●	
Marimuthu et al. (2014) (39)	●			●	
Maus et al. (2017) (40)		●	●		

Molicnik et al. (2015) (41)		●		●	
Moubarak et al. (2014) (42)	●				
Myers et al. (2015) (43)	●				
Nabavi et al. (2015) (44)				●	
Nam et al. (2016) (45)				●	
Nankivell et al. (2015) (46)	●			●	
Ng et al. (2012) (47)				●	
Noble et al. (2012) (48)	●	●		●	
Nunley et al. (2012) (49)				●	
Parratte et al. (2013) (50)		●	●	●	
Pfitzner et al. (2014) (51)	●	●			●
Pietsch et al. (2013) (52)		●	●	●	
Pourgiezis et al. (2016) (53)	●				
Predescu et al. (2017) (54)	●				
Rathod et al. (2015) (55)	●				
Renson et al. (2014) (56)				●	
Roh et al. (2013) (57)		●	●	●	
Schotanus et al. (2018) (58)		●			
Silva et al. (2014) (59)		●	●	●	
Stolarczyk et al. (2018) (60)	●				
Stronach et al. (2014) (61)				●	

Stone et al. (2018) (62)	●				
Tammachote et al. (2018) (63)	●				
Teeter et al. (2019) (64)	●				
Thienpoint et al. (2015) (65)				●	
Turgeon et al. (2019) (66)	●				
Van Leeuwen et al. (2018) (67)		●	●		
Victor et al. (2014) (68)			●	●	
Vide et al. (2017) (69)		●	●	●	
Vundelinskx et al. (2013) (70)	●	●	●	●	
Woolson et al. (2014) (71)		●	●	●	●
Yaffe et al. (2014) (72)				●	●
Yan et al. (2015) (73)		●	●	●	●
Zahn et al. (2020) (74)	●				
Zhu et al. (2015) (75)				●	

Systematic review/meta-analyses across the columns. Primary studies across the rows.

Table 3. Meta-Analysis Characteristics

Study	Dates	Trials	N (Range)	Designs	Outcomes
Tibesku et al. (2023) (5)	Through March 2022	25	29 to 356	RCTs	Accuracy; perioperative outcomes
Lin et al. (2020) (4)	2012-2018	29	2487 (24-180)	RCTs	Mechanical axis malalignment, functional outcomes
Gong et al. (2018) (6)	1966-2018	23	2058 (40-180)	RCTs	Coronal, sagittal, axial malalignment >3°
Thienpont et al. (2017) (3)	2011-2015	44	5822 (29-865)	RCTs and cohort	Coronal and sagittal malalignment >3°

Mannan et al. (2017) (7)	2000-2015	8	828 (48-232)	RCTs and cohort	Functional outcomes

RCT: randomized controlled trial.

Table 4. Meta-Analytic Results for Malalignment Outcomes (>3° from Target)

Study	Trials	N (knees)	Malalignment (>3°)	RR	95% CI	P	I^2, %
Tibesku et al. (2023) (5)	15	1895	Mechanical axis outliers	0.60	0.47 to 0.77	<.0001	48
	6	1622	Coronal component alignment	0.72	0.36 to 1.44	.35	61
	6	1408	Sagittal component alignment	1.35	0.74 to 2.47	.33	63
	5	677	Femoral component rotation	0.54	0.19 to 1.49	.23	74
Lin et al. (2020) (4)	17	1577	Hip-knee-ankle angle	0.88	0.74 to 1.04	0.13	38
Gong et al. (2018) (6)	14	1273	Hip-knee-ankle angle	0.94	0.72 to 11.24	0.68	41
	12	1137	Femoral/coronal plane	0.86	0.57 to 1.30	0.47	37
	12	1137	Tibial/coronal plane	1.36	0.75 to 2.49	0.31	46
	9	941	Femoral sagittal alignment	1.07	0.84 to 1.35	0.59	46
	10	989	Tibial/sagittal plane	1.31	0.92 to 1.86	0.13	57
Thienpont et al. (2017) (3)	29	3479	Coronal mechanical axis	0.79	0.65 to 0.95	0.013	51.0
	13	1527	Tibial/sagittal plane	1.32	1.12 to 1.56	0.001	0
	15	1943	Femoral/coronal plane	0.74	0.55 to 0.99	0.043	32
	17	1983	Tibial/coronal plane	1.30	0.92 to 1.83	0.13	21.5

CI: confidence interval; RR: relative risk.

The key question we considered is whether differences in the number of outliers greater than 3° impacted functional outcomes. A meta-analysis by Mannan et al. (2017) indicated that functional outcomes did not differ significantly when measured at up to 2 years after surgery (Table 5). (7) More recent meta-analyses have shown mixed outcomes with regard to benefit. Thienpont et al. (2017) showed an improvement in KSS functional score with patient specific instrumentation over conventional instrumentation, but there was no significant improvement in the KSS knee score. (3) In contrast, Lin et al. (2020) showed a significant improvement in the

overall KSS with patient specific instrumentation but failed to show an improvement in the Oxford Knee Score. (4) The follow-up period for Lin et al. was only 3 months and does not provide information on long-term outcomes.

Table 5. Meta-Analysis Results for Pain and Function Outcomes

Study	Trials	N (knees)	Functional Outcome Measures	FU, mo	MD	95% CI	P	I^2, %
Lin et al. (2020) (4)	3	337	KSS	3	-0.17	-0.00 to -0.02	0.02	0
	5	651	Oxford Knee Score	NR	0.07	-0.09 to 0.22	0.4	32
Thienpont et al. (2017) (3)	6	300	KSS functional score	16.7	4.3	1.5 to 7.2	0.003	NR
	6	300	KSS knee score	16.7	1.5	-0.3 to 3.3	0.093	NR
Mannan et al. (2017) (7)	3	195	KSS functional score	24	-0.21	-9.31 to 8.88	0.96	82
	3	195	KSS knee score	24	0.90	-6.15 to 7.95	0.80	85
	5	244	Range of motion (degrees)	3-24	3.72	-0.46 to 7.91	0.08	70
	3	118	Oxford Knee Score	3-12	-0.48	-1.83 to 0.86	0.48	0

CI: confidence interval; FU: follow-up; KSS: Knee Society Score; MD: mean difference; mo: month(s); NR: not reported.

Perioperative Outcomes

Systematic Reviews

Four of the meta-analyses included in this review reported perioperative outcomes (Table 6). (3-6) Total operative time was significantly shorter with patient specific instrumentation in all studies, but the clinical significance of these differences is not clear. There was high heterogeneity among the studies that limits the application to clinical practice. Gong et al. (2018), Lin et al. (2020), and Tibesku et al. (2023) reported hospital length of stay. Two of these analyses did not find a significant difference between patient specific instrumentation and conventional instrumentation groups, whereas Tibesku et al. (2023) found a statistically significant -0.39-day reduction with patient specific instrumentation. Three meta-analyses also showed a significant reduction in blood loss with patient specific instrumentation; however, there was high heterogeneity amongst the studies.

Table 6. Meta-Analysis Results for Perioperative Outcomes

Study	Operative Time (Minutes)	Blood Loss (mL)	Hospital LOS

Tibesku et al. (2023) (5)		NR	
Total N	1973		589
MD (95% CI); p-value	-6.16 (-11.42 to -0.89)		-0.39 (-0.53 to -0.25)
I^2	30%		45%
Lin et al. (2020) (4)			
Total N	1404	300	543
MD (95% CI); p-value	-0.36 (-0.67 to -0.04); p=0.03	-0.49 (-0.92 to -0.05); p=0.03	-0.10 (-0.27 to 0.07); p=0.24
I^2	88%	71%	33%
Gong et al. (2018) (6)			
Total N	871	450	685
MD (95% CI); p-value	-7.35 (-10.95 to -3.75) p<0.0001	-83.42 (-146.65 to -20.18) p=0.010	-0.16 (-0.40 to 0.07) p=0.17
I^2	78%	74%	19%
Thienpont et al. (2017) (3)			NR
Total N	3480	1251	
MD (95% CI); p-value	-4.4 (-7.2 to -1.7) p=0.002	-37.9 (-68.4 to -7.4) p=0.015	
I^2	94%	91%	

CI: confidence interval; LOS: length of stay; MD: mean difference; NR: not reported.

Randomized Controlled Trials

Several RCTs have yet to be incorporated into available meta-analyses. (63, 76-78) Table 7 highlights some of these RCTs. Additionally, several key RCTs included in available meta-analyses examine functional outcomes that are not evaluated by the meta-analyses. (18, 35) These key trials include Boonen et al. (2016) and Kosse et al. (2017) and are also included in Table 7. Results for the trials included in Table 7 were consistent with previous studies as summarized in Table 6. All but 1 trial reported no significant differences between patient specific instrumentation and conventional intervention on measures of pain, function, and quality of life for up to 5 years (Table 8). Calliess et al. (2017) reported significant outcomes with regard to KSS and WOMAC; however, follow-up did not extend beyond 1 year. (77)

Both Boonen et al. (2016) and Kosse et al. (2017) also reported on the outcome of pain measured by the visual analog score. Neither study reported a difference in pain improvement between groups. Boonen et al. (2016) also reported no differences with regard to WOMAC index and EuroQoL-5D quality of life index. Kosse et al. (2017) did not report any significant differences between groups for various outcomes, including the Kujala score (also referred to

as the Patella score) and the Knee Injury and Osteoarthritis Outcome Score. The RCTs used a variety of patient specific instrumentation systems.

Table 7. Characteristics of Key RCTs of Patient Specific Instrumentation for Total Knee Arthroplasty

Study; Trial	Countries	Sites	Dates	Participants	System (Manufacturer)
Hampton et al. (2022) (78)	UK	2	2013-2015	N=88	NexGen Knee (Zimmer)
Alvand et al. (2017) (76)	UK	1	2012-2014	N=46	Signature (Zimmer Biomet)
Kosse et al. (2017) (35)	The Netherlands	1	2012-2013	N=42	Visionaire (Smith & Nephew)
Calliess et al. (2017) (77)	Germany	2	2012-2013	N=200	Triathlon System (Stryker)
Boonen et al. (2016) (18)	The Netherlands	2	2010-2013	N=180	Materialise (Leuven)
Tammachote et al. (2017) (63)	Thailand	1	2012-2014	N=108	Visionaire (Smith & Nephew)

N: number; RCT: randomized controlled trial; UK: United Kingdom.

Table 8. Summary of Pain, Function, and Quality of Life Outcomes from Key RCTs

Study	KSS	Kujala	VAS Pain	OKS	EURO QOL-5D	KOOS	WOMAC
Hampton et al. (2022) (78)		NR	NR			NR	NR
N (FU)	77 knees (5 years)			77 knees (5 years)	77 knees (5 years)		
PSI increase from baseline, mean (SD)	92.5 (6.8)			40.8 (6.9)			
Conventional increase from baseline, mean (SD)	92.4 (7.1)			42.5 (7.4)			
p-value	.86			.24	.78		
Alvand et al. (2017) (76)	NR	NR	NR		NR	NR	NR
N (FU)				45 (1 yr)			
PSI, mean (range)				18.3 (4 to 31)			

Conventional, mean (range)				18.2 (5 to 31)			
p-value				NS			
Boonen et al. (2016) (18)							
N (FU)	163 (2 yr)		163 (2 yr)	163 (2 yr)	163 (2 yr)		163 (2 yr)
PSI, mean (95% CI)	81.9 (78.1 to 85.8)		20.4 (14.4 to 26.5)	15.2 (13.1 to 17.2)	72.5 (68.2 to 76.7)		80.7 (76.3 to 85.0)
Conventional, mean (95% CI)	82.2 78.6 to 85.8)		17.4 (12.2 to 22.6)	15.1 (13.1 to 17.1)	76.2 (71.9 to 80.5)		86.6 (83.4 to 89.8)
p-value	0.807		0.227	0.304	0.968		0.753
Calliess et al. (2017) (77)		NR	NR	NR	NR	NR	
N (FU)	200 (1 yr)						200 (1 yr)
PSI, mean (SD)	190 (18)						13 (16)
Conventional, mean (SD)	178 (17)						26 (11)
p-value	0.02						0.001
Kosse et al. (2017) (35)				NR	NR		NR
N (FU)	42 (1 yr)	42 (1 yr)	42 (1 yr)			42 (1 yr)	
PSI, median (range)	180 (135 to 200)	70 (44 to 100)	5 (0 to 40)			94 (50 to 100)	
Conventional, median (range)	175 (115 to 200)	62 (33 to 95)	11 (0-81)			81 (33 to 100)	
p-value	NS	NS	NS			NS	
Tammachote et al. (2017) (63)							
N (FU)							102 (2 yr)
PSI, mean (SD)							5 (6)
Conventional, mean (SD)							4 (6)
Mean difference (CI); p-value							1 (-1.8 to 3), p=0.62

CI: confidence interval; EuroQol-5D: standardized instrument as a measure of quality of life; FU: follow-up; KOOS: Knee Injury and Osteoarthritis Outcome Score; KSS: Knee Society Score; MD: mean difference; NR: not reported; NS: not significant; OKS: Oxford Knee Score; PSI: patient-specific instrumentation; RCT: randomized controlled trial; SD: standard deviation; VAS: Visual Analog Scale; WOMAC: Western Ontario and McMaster Universities Osteoarthritis Index; yr: year(s).

Summary of Evidence

For individuals who are undergoing partial or total knee arthroplasty who receive patient-specific cutting guides, the evidence includes randomized controlled trials (RCTs), comparative cohort studies, and systematic reviews of these studies. Relevant outcomes of interest are symptoms, functional outcomes, and quality of life. Results from the systematic reviews are mixed, finding significant improvements in some measures of implant alignment but either no improvement or worse alignment for other measures. The available systematic reviews are limited by the small size of some of the selected studies, publication bias, and differences in both planning and manufacturing of the patient specific instrumentation systems. Also, the designs of the devices are evolving, and some of the studies might have assessed now obsolete patient specific instrumentation systems. Available results from individual RCTs have not shown a benefit of patient-specific instrumentation systems in improving clinical outcome measures with follow-up currently extending out to 5 years. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Practice Guidelines and Position Statements

American Academy of Orthopaedic Surgeons

In 2016, the American Academy of Orthopaedic Surgeons published a guideline on the surgical management of osteoarthritis of the knee (updated December 2, 2022). (79, 80) The guideline is supported by the American Society of Anesthesiologists and endorsed by several other organizations. The guideline recommends against the use of patient specific instrumentation for total knee arthroplasty, since strong evidence has not shown a difference in pain or functional outcomes when compared to conventional instrumentation. Additionally, moderate evidence has not shown a difference between patient specific and conventional instrumentation with regard to transfusions or complications.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and/or unpublished trials that might influence this policy are listed in Table 9.

Table 9. Summary of Key Ongoing Trials

NCT Number	Trial Name	Planned Enrollment	Completion Date
NCT06720012	Total Knee Arthroplasty Inserted With Patient Specific or Standard Instruments	70	Dec 2024
NCT06122727	Comparison of Customized and Standard Total Knee Replacements: a Pilot Study	20	Mar 2025

NCT02177227[a]	Attune With TruMatch TM Personalized Solutions Instruments: A Prospective Randomized Controlled Trial Comparing Clinical and Economic Outcomes in Patients With a BMI Between 30 and 50.	194 (actual)	Aug 2024 (estimated)
NCT02845206	Randomised Controlled Trial of Patient Specific Instrumentation vs Standard Instrumentation in Total Knee Arthroplasty.	172	Feb 2020
NCT03148379[a]	A Multi-center, Prospective, Randomized Study Comparing Surgical and Economic Parameters of Total Knee Replacement Performed With Single-use Efficiency Instruments With Patient Specific Technique (MyKnee®) Versus Traditional Metal Instruments With Conventional Surgical Technique.	231	Mar 2022
NCT02096393	A Prospective, Randomised Control Trial Assessing Clinical and Radiological Outcomes of Patient Specific Instrumentation In Total Knee Arthroplasty.	72	Jun 2020

NCT: national clinical trial.

[a] Denotes industry-sponsored or cosponsored trial.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	0561T, 0562T
HCPCS Codes	None

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
11/15/2025	Document updated. Coverage unchanged. No new references added.
09/15/2024	Document updated with literature review. Coverage unchanged. Added references 5, 19, 42, 43, 53-55, 60, 62, 64, 66, & 74.

01/01/2024	Document updated with literature review. Coverage unchanged. Added references 66 and 68.
07/15/2022	Reviewed. No changes.
11/01/2021	Document updated with literature review. Coverage unchanged. Added the following references: 4, 7-16, 18-32, 34-37, 39-62, and 66.
09/01/2020	Reviewed. No changes.
10/01/2019	Document updated with literature review. The following change was made to Coverage: Content on custom implants removed as it is now addressed on medical policy SUR705.042. Title of policy changed from: Patient-Specific Cutting Guides and Custom Knee Implants. The following references were added: 4, 6, 8-12, and 14.
06/15/2018	Reviewed. No changes.
10/15/2017	Document updated with literature review. Coverage unchanged.
09/01/2016	Reviewed. No changes.
03/15/2016	New medical document. Use of custom implants or patient-specific instrumentation (e.g., cutting guides) for joint arthroplasty, including but not limited to use in unicompartmental or total knee arthroplasty, is considered experimental, investigational and/or unproven.