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

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

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. This medical policy focus is on the most recent, comprehensive, and relevant analyses (Table 2). Several of these reported functional outcomes in addition to measures of malalignment outcomes. (2-5)

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

Study	Zhao et al. (2026) (5)	Tibesku et al. (2023) (6)	Lin et al. (2020) (4)	Gong et al. (2018) (7)	Thienpont et al. (2017) (3)	Mannan et al. (2017) (8)
Abane et al. (2015) (9)	●	●	●	●	●	●
Abane et al. (2018) (10)			●			
Abdel et al. (2014) (11)	●		●		●	
Anderl et al. (2016) (12)					●	●
Attard et al. (2019) (13)	●					
Bali et al. (2012) (14)		●			●	
Barke et al. (2013) (15)		●			●	
Barrack et al. (2012) (16)					●	
Barrett et al. (2014) (17)					●	
Boonen et al. (2012) (18)					●	
Boonen et al. (2013) (19)	●		●	●	●	
Boonen et al. (2016) (20)			●	●		
Broberg et al. (2020) (21)		●				

Calliess et al. (2017) (22)	●					
Chareancholvanich et al. (2013) (23)	●		●	●	●	
Chen et al. (2014) (24)					●	
Chen et al. (2015) (25)					●	●
Chotanaphuti et al. (2014) (26)			●		●	
Cucchi et al. (2018) (27)	●		●			
Daniilidis et al. (2014) (28)		●			●	
De Vloo et al. (2017) (29)	●		●	●		
DeHann et al. (2014) (30)		●			●	
Ferrara et al. (2015) (31)	●				●	
Gan et al. (2015) (32)	●			●		
Giannotti et al. (2019) (33)	●					
Hamilton et al. (2013) (34)	●		●	●	●	
Heyse et al. (2014) (35)					●	
Huijbregts et al. (2016) (36)	●	●	●	●		
Kassab et al. (2014) (37)					●	
Khuangsirikul et al. (2014) (38)				●		
Kosse et al. (2018) (39)	●	●	●	●		
Kotela et al. (2014) (40)	●		●	●	●	
Kotela et al. (2015) (41)	●		●	●	●	●
Liao et al. (2024) (42)	●					

Lionberger et al. (2014) (43)	●					
MacDessi et al. (2014) (44)					●	
Marimuthu et al. (2014) (45)		●			●	
Maus et al. (2017) (46)	●		●	●		
Molicnik et al. (2015) (47)	●		●		●	
Moubarak et al. (2014) (48)		●				
Myers et al. (2015) (49)		●				
Nabavi et al. (2015) (50)					●	
Nam et al. (2016) (51)					●	
Nankivell et al. (2015) (52)		●			●	
Ng et al. (2012) (53)					●	
Noble et al. (2012) (54)	●	●	●		●	
Nunley et al. (2012) (55)					●	
Ollivier et al. (2016) (56)	●					
Parratte et al. (2013) (57)	●		●	●	●	
Pfitzner et al. (2014) (58)	●	●	●			●
Pietsch et al. (2013) (59)	●		●	●	●	
Pourgiezis et al. (2016) (60)		●				
Predescu et al. (2017) (61)		●				
Qiu et al. (2017) (62)	●					
Randelli et al. (2019) (63)	●					

Rathod et al. (2015) (64)		●				
Renson et al. (2014) (65)					●	
Roh et al. (2013) (66)	●		●	●	●	
Stimesi et al. (2019) (67)	●					
Schotanus et al. (2018) (68)			●			
Silva et al. (2014) (69)	●		●	●	●	
Stolarczyk et al. (2018) (70)	●	●				
Stronach et al. (2014) (71)					●	
Stone et al. (2018) (72)		●				
Sun et al. (2020) (73)	●					
Tammachote et al. (2018) (74)	●	●				
Teeter et al. (2019) (75)	●	●				
Thienpoint et al. (2015) (76)					●	
Turgeon et al. (2019) (77)	●	●				
Van Leeuwen et al. (2018) (78)	●		●	●		
Victor et al. (2014) (79)	●			●	●	
Vide et al. (2017) (80)	●		●	●	●	
Vundelinskx et al. (2013) (81)	●	●	●	●	●	
Woolson et al. (2014) (82)	●		●	●	●	●
Yaffe et al. (2014) (83)	●				●	●
Yan et al. (2015) (84)			●	●	●	●

Zahn et al. (2020) (85)	●	●				
Zhu et al. (2015) (86)					●	
Zomar et al. (2021) (87)	●					

Table 3. Meta-Analysis Characteristics

Study	Dates	Trials	N (Range)	Designs	Outcomes
Zhao et al. (2026) (5)	Through January 2025	44	3134	RCTs	Survival of implant, function, alignment, pain
Tibesku et al. (2023) (6)	Through March 2022	25	29 to 356	RCTs	Accuracy; perioperative outcomes
Lin et al. (2020) (4)	2012-2018	29	2487 (24 to 180)	RCTs	Mechanical axis malalignment, functional outcomes
Gong et al. (2018) (7)	1966-2018	23	2058 (40 to 180)	RCTs	Coronal, sagittal, axial malalignment >3°
Thienpont et al. (2017) (3)	2011-2015	44	5822 (29 to 865)	RCTs and cohort	Coronal and sagittal malalignment >3°
Mannan et al. (2017) (8)	2000-2015	8	828 (48 to 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, %
Zhao et al. (2026) (5)	29	2412 patients	Femorotibial coronal alignment	0.86	0.68 to 1.10	0.23	49
Tibesku et al. (2023) (6)	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	0.35	61
	6	1408	Sagittal component alignment	1.35	0.74 to 2.47	0.33	63
	5	677	Femoral component rotation	0.54	0.19 to 1.49	0.23	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) (7)	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). (8) 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. In a 2026 Cochrane review by Zhao et al., neither the KSS nor the Oxford Knee Score was improved with patient-specific cutting guides versus conventional instrumentation in the short term (<2 years follow-up); the Oxford Knee Score was also not significantly improved in the long term (2 to 10 years follow-up). (5)

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, %
Zhao et al. (2026) (5)	12	NR	KSS	Mostly short-term (<2 years)	-1.33	-3.64 to 0.99	NR	NR
	5	NR	Oxford Knee Score	Short term (<2 years)	0.29	-0.92 to 1.49	0.64	NR
	2	NR	Oxford Knee Score	Inter-mediate	0.20	-3.32 to 3.72	NR	NR

				term (2 to 10 years)				
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) (8)	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

Several of the meta-analyses included in this review reported perioperative outcomes (Table 6). (3-7) Total operative time was significantly shorter with patient specific instrumentation in most studies, but the clinical significance of these differences is not clear. There was high heterogeneity among the studies, which limits the applicability to clinical practice. Gong et al. (2018), Lin et al. (2020), Tibesku et al. (2023), and Zhao et al. (2026) reported hospital length of stay. Three 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. Four meta-analyses also showed a significant reduction in blood loss with patient-specific instrumentation; however, there was high heterogeneity among the studies.

Table 6. Meta-Analysis Results for Perioperative Outcomes

Study	Operative Time (Minutes)	Blood Loss (mL)	Hospital LOS
Zhao et al. (2026) (5)			
Total N	2033	1189	1062

MD (94% CI); p-value	-2.79 (-5.66 to 0.08)	-66.47 (-93.30 to -39.64)	-0.23 (-0.46 to 0.00)
I^2	96%	80%	25%
Tibesku et al. (2023) (6)		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) (7)			
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

Some RCTs have yet to be incorporated into available meta-analyses. (88-90) Table 7 highlights some of these RCTs. Additionally, some key RCTs included in available meta-analyses examine functional outcomes that are not evaluated by the meta-analyses. (20, 39) 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 trials 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).

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. In more recent studies, Hermodsson et al. (2025) reported no differences with regard to Oxford Knee score, EuroQoL-5D, and EQ VAS (self-rated overall health on a visual analog scale 0 to 100) at 5-year follow-up. (90) Furthermore, Braun et al. (2026) reported no differences in KSS and WOMAC total scores. (89)

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)
Braun et al. (2026) (89)	Canada	1	2015-2018	158	TRUMATCH Personalized Solutions Resection Guide (DePuy Synthes)
Hermodsson et al. (2025) (90)	Sweden	1	2014-2017	66	NexGen Knee (Zimmer)
Hampton et al. (2022) (91)	UK	2	2013-2015	88	NexGen Knee (Zimmer)
Alvand et al. (2017) (88)	UK	1	2012-2014	46	Signature (Zimmer Biomet)
Kosse et al. (2017) (39)	The Netherlands	1	2012-2013	42	Visionaire (Smith & Nephew)
Boonen et al. (2016) (20)	The Netherlands	2	2010-2013	180	Materialise (Leuven)

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	EUROQOL-5D	KOOS	WOMAC
Braun et al. (2026) (89)							
N (FU)	158 patients (5 years)	NR	NR	NR	NR	NR	
PSI, mean (SD)	177.3 (24.3)						82.5 (18.7)
Conventional, mean (range)	168.2 (31.2)						83.2 (15.9)

Mean difference (95% CI)	-9.12 (-19.51 to 1.26)						0.63 (-5.25 to 6.51)
Hermodsson et al. (2025) (90)							
N (FU)	70 knees (5 years)	NR	NR			NR	NR
PSI, mean (SD)				40.9 (8.5)	0.90 (0.10)		
Conventional, mean (range)				39.0 (7.5)	0.88 (0.09)		
Mean difference (95% CI)				1.9 (-2.3 to 6.1)	0.02 (-0.03 to 0.07)		
Hampton et al. (2022) (91)		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	0.86			0.24	0.78		
Alvand et al. (2017) (88)	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) (20)							
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
Kosse et al. (2017) (39)				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 to 81)			81 (33 to 100)	
p-value	NS	NS	NS			NS	

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). (92, 93) 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
NCT06122727	Comparison of Customized and Standard Total Knee Replacements: a Pilot Study	20	Apr 2026
NCT02845206	Randomised Controlled Trial of Patient Specific Instrumentation vs Standard Instrumentation in Total Knee Arthroplasty.	172	Feb 2020

NCT: national clinical 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®) ©2025 American Medical Association: Chicago, IL.

References

1. Kurtz S, Ong K, Lau E, et al. Projections of primary and revision hip and knee arthroplasty in the United States from 2005 to 2030. J Bone Joint Surg Am. Apr 2007; 89(4):780-785. PMID 17403800
2. Mannan A, Smith TO. Favourable rotational alignment outcomes in PSI knee arthroplasty: A Level 1 systematic review and meta-analysis. Knee. Mar 2016; 23(2):186-190. PMID 26782300
3. Thienpont E, Schwab PE, Fennema P. Efficacy of patient-specific instruments in total knee arthroplasty: A systematic review and meta-analysis. J Bone Joint Surg Am. Mar 15 2017; 99(6):521-530. PMID 28291186

4. Lin Y, Cai W, Xu B, et al. Patient-specific or conventional instrumentations: A meta-analysis of randomized controlled trials. Biomed Res Int. Mar 2020; 2020:2164371. PMID 32258107
5. Zhao C, Jefferies JG, Marimuthu K, et al. Patient-specific cutting guides for total knee arthroplasty. Cochrane Database Syst Rev. Jan 07 2026; 1(1):CD012589. PMID 41498625
6. Tibesku CO, Haas SB, Saunders C, et al. Comparison of clinical outcomes of VISIONAIRE patient-specific instrumentation with conventional instrumentation in total knee arthroplasty: a systematic literature review and meta-analysis. Arch Orthop Trauma Surg. Jul 2023; 143(7):4379-4393. PMID 36449066
7. Gong S, Xu W, Wang R, et al. Patient-specific instrumentation improved axial alignment of the femoral component, operative time and perioperative blood loss after total knee arthroplasty. Knee Surg Sports Traumatol Arthrosc. Apr 2019; 27(4):1083-1095. PMID 30377714
8. Mannan A, Akinyooye D, Hossain F. A meta-analysis of functional outcomes in patient-specific instrumented knee arthroplasty. J Knee Surg. Sep 2017; 30(7):668-674. PMID 27907935
9. Abane L, Anract P, Boisgard S, et al. A comparison of patient-specific and conventional instrumentation for total knee arthroplasty: a multicentre randomised controlled trial. Bone Joint J. Jan 2015; 97-B(1):56-63. PMID 25568414
10. Abane L, Zaoui A, Anract P, et al. Can a single-use and patient-specific instrumentation be reliably used in primary total knee arthroplasty? A multicenter controlled study. J Arthroplasty. Jul 2018; 33(7):2111-2118. PMID 29576488
11. Abdel MP, Parratte S, Blanc G, et al. No benefit of patient-specific instrumentation in TKA on functional and gait outcomes: A randomized clinical trial. Clin Orthop Relat Res. Aug 2014; 472(8):2468-2476. PMID 24604110
12. Anderl W, Pauzenberger L, Kölblinger R, et al. Patient-specific instrumentation improved mechanical alignment, while early clinical outcome was comparable to conventional instrumentation in TKA. Knee Surg Sports Traumatol Arthrosc. Jan 2016; 24(1):102-111. PMID 25326759
13. Attard A, Tawy GF, Simons M, et al. Health costs and efficiencies of patient-specific and single-use instrumentation in total knee arthroplasty: a randomised controlled trial. BMJ Open Qual. 2019; 8(2):e000493. PMID 31206056
14. Bali K, Walker P, Bruce W. Custom-fit total knee arthroplasty: our initial experience in 32 knees. J Arthroplasty. Jun 2012; 27(6):1149-1154. PMID 22285230
15. Barke S, Musanhu E, Busch C, et al. Patient-matched total knee arthroplasty: does it offer any clinical advantages? Acta Orthop Belg. Jun 2013; 79(3):307-311. PMID 23926734
16. Barrack RL, Ruh EL, Williams BM, et al. Patient specific cutting blocks are currently of no proven value. J Bone Joint Surg Br. Nov 2012; 94(11 Suppl A):95-99. PMID 23118393
17. Barrett W, Hoeffel D, Dalury D, et al. In-vivo alignment comparing patient specific instrumentation with both conventional and computer assisted surgery (CAS) instrumentation in total knee arthroplasty. J Arthroplasty. Feb 2014; 29(2):343-347. PMID 23993343
18. Boonen B, Schotanus MG, Kort NP. Preliminary experience with the patient-specific templating total knee arthroplasty. Acta Orthop. Aug 2012; 83(4):387-393. PMID 22880715

19. Boonen B, Schotanus MG, Kerens B, et al. Intra-operative results and radiological outcome of conventional and patient-specific surgery in total knee arthroplasty: a multicentre, randomised controlled trial. Knee Surg Sports Traumatol Arthrosc. Oct 2013; 21(10):2206-2212. PMID 23928929
20. Boonen B, Schotanus MG, Kerens B, et al. No difference in clinical outcome between patient-matched positioning guides and conventional instrumented total knee arthroplasty two years post-operatively: a multicentre, double-blind, randomised controlled trial. Bone Joint J. Jul 2016; 98-B(7):939-944. PMID 27365472
21. Broberg JS, Naudie DDR, Howard JL, et al. Contact kinematics of patient-specific instrumentation versus conventional instrumentation for total knee arthroplasty. Knee. Oct 2020; 27(5):1501-1509. PMID 33010767
22. Calliess T, Bauer K, Stukenborg-Colsman C, et al. PSI kinematic versus non-PSI mechanical alignment in total knee arthroplasty: a prospective, randomized study. Knee Surg Sports Traumatol Arthrosc. Jun 2017; 25(6):1743-1748. PMID 27120192
23. Chareancholvanich K, Narkbunnam R, Pornrattanamaneewong C. A prospective randomised controlled study of patient-specific cutting guides compared with conventional instrumentation in total knee replacement. Bone Joint J. Mar 2013; 95-B(3):354-359. PMID 23450020
24. Chen JY, Yeo SJ, Yew AK, et al. The radiological outcomes of patient-specific instrumentation versus conventional total knee arthroplasty. Knee Surg Sports Traumatol Arthrosc. Mar 2014; 22(3):630-635. PMID 23996069
25. Chen JY, Chin PL, Tay DK, et al. Functional outcome and quality of life after patient-specific instrumentation in total knee arthroplasty. J Arthroplasty. Oct 2015; 30(10):1724-1728. PMID 25937100
26. Chotanaphuti T, Wangwittayakul V, Khuangsirikul S, et al. The accuracy of component alignment in custom cutting blocks compared with conventional total knee arthroplasty instrumentation: prospective control trial. Knee. Jan 2014; 21(1):185-188. PMID 23999209
27. Cucchi D, Menon A, Zanini B, et al. Patient-specific instrumentation affects perioperative blood loss in total knee arthroplasty. J Knee Surg. Jun 2019; 32(6):483-489. PMID 29791925
28. Daniilidis K, Tibesku CO. A comparison of conventional and patient-specific instruments in total knee arthroplasty. Int Orthop. Mar 2014; 38(3):503-508. PMID 23900384
29. De Vloo R, Pellikaan P, Dhollander A, et al. Three-dimensional analysis of accuracy of component positioning in total knee arthroplasty with patient specific and conventional instruments: A randomized controlled trial. Knee. Dec 2017; 24(6):1469-1477. PMID 28943039
30. DeHaan AM, Adams JR, DeHart ML, et al. Patient-specific versus conventional instrumentation for total knee arthroplasty: peri-operative and cost differences. J Arthroplasty. Nov 2014; 29(11):2065-2069. PMID 25065735
31. Ferrara F, Cipriani A, Magarelli N, et al. Implant positioning in TKA: Comparison between conventional and patient-specific instrumentation. Orthopedics. Apr 2015; 38(4):e271-e280. PMID 25901619
32. Gan Y, Ding J, Xu Y, et al. Accuracy and efficacy of osteotomy in total knee arthroplasty with patient-specific navigational template. Int J Clin Exp Med. 2015; 8(8):12192-121201. PMID 26550129

33. Giannotti S, Sacchetti F, Citarelli C, et al. Single-use, patient-specific instrumentation technology in knee arthroplasty: a comparative study between standard instrumentation and PSI efficiency system. Musculoskelet Surg. Aug 2020; 104(2):195-200. PMID 31147964
34. Hamilton WG, Parks NL, Saxena A. Patient-specific instrumentation does not shorten surgical time: a prospective, randomized trial. J Arthroplasty. Sep 2013; 28(8 Suppl):96-100. PMID 23910821
35. Heyse TJ, Tibesku CO. Improved femoral component rotation in TKA using patient-specific instrumentation. Knee. Jan 2014; 21(1):268-271. PMID 23140905
36. Huijbregts HJ, Khan RJ, Fick DP, et al. Component alignment and clinical outcome following total knee arthroplasty: a randomised controlled trial comparing an intramedullary alignment system with patient-specific instrumentation. Bone Joint J. Aug 2016; 98-B(8):1043-1049. PMID 27482015
37. Kassab S, Pietrzak WS. Patient-specific positioning guides versus manual instrumentation for total knee arthroplasty: an intraoperative comparison. J Surg Orthop Adv. 2014; 23(3):140-146. PMID 25153812
38. Khuangsirikul S, Lertcharoenchoke T, Chotanaphuti T. Rotational alignment of femoral component between custom cutting block and conventional technique in total knee arthroplasty. J Med Assoc Thai. Feb 2014; 97 Suppl 2:S47-S51. PMID 25518175
39. Kosse NM, Heesterbeek PJC, Schimmel JJP, et al. Stability and alignment do not improve by using patient- specific instrumentation in total knee arthroplasty: A randomized controlled trial. Knee Surg Sports Traumatol Arthrosc. Jun 2018; 26(6):1792-1799. PMID 29181560
40. Kotela A, Kotela I. Patient-specific computed tomography based instrumentation in total knee arthroplasty: a prospective randomized controlled study. Int Orthop. Oct 2014; 38(10):2099-2107. PMID 24968788
41. Kotela A, Lorkowski J, Kucharzewski M, et al. Patient-specific CT-based instrumentation versus conventional instrumentation in total knee arthroplasty: A prospective randomized controlled study on clinical outcomes and in-hospital data. Biomed Res Int. 2015; 2015:165908. PMID 26301241
42. Liao G, Duoji J, Mu L, et al. Efficiency assessment of intelligent patient-specific instrumentation in total knee arthroplasty: a prospective randomized controlled trial. J Orthop Surg Res. Sep 28 2024; 19(1):593. PMID 39342311
43. Lionberger DR, Crocker CL, Chen V. Patient specific instrumentation. J Arthroplasty. Sep 2014; 29(9):1699-1704. PMID 24810539
44. MacDessi SJ, Jang B, Harris IA, et al. A comparison of alignment using patient specific guides, computer navigation and conventional instrumentation in total knee arthroplasty. Knee. Mar 2014; 21(2):406-409. PMID 24378337
45. Marimuthu K, Chen DB, Harris IA, et al. A multi-planar CT-based comparative analysis of patient-specific cutting guides with conventional instrumentation in total knee arthroplasty. J Arthroplasty. Jun 2014; 29(6):1138-1142. PMID 24524776
46. Maus U, Marques CJ, Scheunemann D, et al. No improvement in reducing outliers in coronal axis alignment with patient-specific instrumentation. Knee Surg Sports Traumatol Arthrosc. Sep 2018; 26(9):2788-2796. PMID 29071356

47. Molicnik A, Naranda J, Dolinar D. Patient-matched instruments versus standard instrumentation in total knee arthroplasty: a prospective randomized study. Wien Klin Wochenschr. Dec 2015; 127 Suppl 5(Suppl 5):S235-S240. PMID 25732915
48. Moubarak H, Brilhault J. Contribution of patient-specific cutting guides to lower limb alignment for total knee arthroplasty. Orthop Traumatol Surg Res. Jun 2014; 100(4 Suppl):S239-S242. PMID 24703790
49. Myers K, Merwin SL, Cabrera B, Lementowski P. An evaluation of the need for blood transfusion when using patient specific instrumentation for total knee arthroplasty. Int J Orthop Rehab. 2014; 1(2):54-60.
50. Nabavi A, Olwill CM. Early outcome after total knee replacement using computed tomography-based patient-specific cutting blocks versus standard instrumentation. J Orthop Surg (Hong Kong). Aug 2015; 23(2):182-184. PMID 26321546
51. Nam D, Park A, Stambough JB, et al. The Mark Coventry award: Custom cutting guides do not improve total knee arthroplasty clinical outcomes at 2 years followup. Clin Orthop Relat Res. Jan 2016; 474(1):40-46. PMID 25712865
52. Nankivell M, West G, Pourgiezis N. Operative efficiency and accuracy of patient-specific cutting guides in total knee replacement. ANZ J Surg. Jun 2015; 85(6):452-455. PMID 25387721
53. Ng VY, DeClaire JH, Berend KR, et al. Improved accuracy of alignment with patient-specific positioning guides compared with manual instrumentation in TKA. Clin Orthop Relat Res. Jan 2012; 470(1):99-107. PMID 21809150
54. Noble JW, Moore CA, Liu N. The value of patient-matched instrumentation in total knee arthroplasty. J Arthroplasty. Jan 2012; 27(1):153-155. PMID 21908169
55. Nunley RM, Ellison BS, Ruh EL, et al. Are patient-specific cutting blocks cost-effective for total knee arthroplasty? Clin Orthop Relat Res. Mar 2012; 470(3):889-894. PMID 22183476
56. Ollivier M, Tribot-Laspiere Q, Amzallag J, et al. Abnormal rate of intraoperative and postoperative implant positioning outliers using "MRI-based patient-specific" compared to "computer assisted" instrumentation in total knee replacement. Knee Surg Sports Traumatol Arthrosc. Nov 2016; 24(11):3441-3447. PMID 25994474
57. Parratte S, Blanc G, Boussemart T, et al. Rotation in total knee arthroplasty: no difference between patient-specific and conventional instrumentation. Knee Surg Sports Traumatol Arthrosc. Oct 2013; 21(10):2213-2219. PMID 23942938
58. Pfitzner T, Abdel MP, von Roth P, et al. Small improvements in mechanical axis alignment achieved with MRI versus CT-based patient-specific instruments in TKA: a randomized clinical trial. Clin Orthop Relat Res. Oct 2014; 472(10):2913-2922. PMID 25024031
59. Pietsch M, Djahani O, Zweiger Ch, et al. Custom-fit minimally invasive total knee arthroplasty: effect on blood loss and early clinical outcomes. Knee Surg Sports Traumatol Arthrosc. Oct 2013; 21(10):2234-2240. PMID 23114870
60. Pourgiezis N, Reddy SP, Nankivell M, et al. Alignment and component position after patient-matched instrumentation versus conventional total knee arthroplasty. J Orthop Surg (Hong Kong). Aug 2016; 24(2):170-174. PMID 27574257
61. Predescu V, Prescura C, Olaru R, et al. Patient specific instrumentation versus conventional knee arthroplasty: comparative study. Int Orthop. Jul 2017; 41(7):1361-1367. PMID 27995304

62. Qiu B, Liu F, Tang B, et al. Clinical Study of 3D Imaging and 3D Printing Technique for Patient-Specific Instrumentation in Total Knee Arthroplasty. J Knee Surg. Oct 2017; 30(8):822-828. PMID 28122388
63. Randelli PS, Menon A, Pasqualotto S, et al. Patient-Specific Instrumentation Does Not Affect Rotational Alignment of the Femoral Component and Perioperative Blood Loss in Total Knee Arthroplasty: A Prospective, Randomized, Controlled Trial. J Arthroplasty. Jul 2019; 34(7):1374-1381.e1. PMID 30979672
64. Rathod PA, Deshmukh AJ, Cushner FD. Reducing blood loss in bilateral total knee arthroplasty with patient-specific instrumentation. Orthop Clin North Am. Jul 2015; 46(3):343-350, ix. PMID 26043048
65. Renson L, Poilvache P, Van den Wyngaert H. Improved alignment and operating room efficiency with patient-specific instrumentation for TKA. Knee. Dec 2014; 21(6):1216-1220. PMID 25450010
66. Roh YW, Kim TW, Lee S, et al. Is TKA using patient-specific instruments comparable to conventional TKA? A randomized controlled study of one system. Clin Orthop Relat Res. Dec 2013; 471(12):3988-3995. PMID 23907610
67. Stimesi E, Kajetanek C, Catonné Y. Comparison of custom cutting guides based on three-dimensional computerized CT-scan planning and a conventional ancillary system based on two-dimensional planning in total knee arthroplasty: a randomized controlled trial. Int Orthop. Nov 2019; 43(11):2529-2538. PMID 31227853
68. Schotanus MGM, Boonen B, van der Weegen W, et al. No difference in mid-term survival and clinical outcome between patient-specific and conventional instrumented total knee arthroplasty: a randomized controlled trial. Knee Surg Sports Traumatol Arthrosc. May 2019; 27(5):1463-1468. PMID 29725747
69. Silva A, Sampaio R, Pinto E. Patient-specific instrumentation improves tibial component rotation in TKA. Knee Surg Sports Traumatol Arthrosc. Mar 2014; 22(3):636-642. PMID 23989707
70. Stolarczyk A, Nagraba L, Mitek T, et al. Does Patient-Specific Instrumentation Improve Femoral and Tibial Component Alignment in Total Knee Arthroplasty? A Prospective Randomized Study. Adv Exp Med Biol. 2018; 1096:11-17. PMID 29623574
71. Stronach BM, Pelt CE, Erickson JA, et al. Patient-specific instrumentation in total knee arthroplasty provides no improvement in component alignment. J Arthroplasty. Sep 2014; 29(9):1705-1708. PMID 24890995
72. Stone AH, Sibia US, MacDonald JH. Functional Outcomes and Accuracy of Patient-Specific Instruments for Total Knee Arthroplasty. Surg Innov. Oct 2018; 25(5):470-475. PMID 30024349
73. Sun ML, Zhang Y, Peng Y, et al. Accuracy of a Novel 3D-Printed Patient-Specific Intramedullary Guide to Control Femoral Component Rotation in Total Knee Arthroplasty. Orthop Surg. Apr 2020; 12(2):429-441. PMID 32087620
74. Tammachote N, Panichkul P, Kanitnate S. Comparison of Customized Cutting Block and Conventional Cutting Instrument in Total Knee Arthroplasty: A Randomized Controlled Trial. J Arthroplasty. Mar 2018; 33(3):746-751.e3. PMID 29108794

75. Teeter MG, Marsh JD, Howard JL, et al. A randomized controlled trial investigating the value of patient-specific instrumentation for total knee arthroplasty in the Canadian healthcare system. Bone Joint J. May 2019; 101-B(5):565-572. PMID 31038991
76. Thienpont E, Grosu I, Paternostre F, et al. The use of patient-specific instruments does not reduce blood loss during minimally invasive total knee arthroplasty? Knee Surg Sports Traumatol Arthrosc. Jul 2015; 23(7):2055-2060. PMID 24671387
77. Turgeon TR, Cameron B, Burnell CD, et al. A double-blind randomized controlled trial of total knee replacement using patient-specific cutting block instrumentation versus standard instrumentation. Can J Surg. Dec 01 2019; 62(6):460-467. PMID 31782643
78. Van Leeuwen JAMJ, Snorrason F, Röhrl SM. No radiological and clinical advantages with patient-specific positioning guides in total knee replacement. Acta Orthop. Feb 2018; 89(1):89-94. PMID 29161930
79. Victor J, Dujardin J, Vandenneucker H, et al. Patient-specific guides do not improve accuracy in total knee arthroplasty: a prospective randomized controlled trial. Clin Orthop Relat Res. Jan 2014; 472(1):263-271. PMID 23616267
80. Vide J, Freitas TP, Ramos A, et al. Patient-specific instrumentation in total knee arthroplasty: simpler, faster and more accurate than standard instrumentation-a randomized controlled trial. Knee Surg Sports Traumatol Arthrosc. Aug 2017; 25(8):2616-2621. PMID 26585908
81. Vundelinckx BJ, Bruckers L, De Mulder K, et al. Functional and radiographic short-term outcome evaluation of the Visionaire system, a patient-matched instrumentation system for total knee arthroplasty. J Arthroplasty. Jun 2013; 28(6):964-970. PMID 23535285
82. Woolson ST, Harris AH, Wagner DW, et al. Component alignment during total knee arthroplasty with use of standard or custom instrumentation: a randomized clinical trial using computed tomography for postoperative alignment measurement. J Bone Joint Surg Am. Mar 05 2014; 96(5):366-372. PMID 24599197
83. Yaffe M, Luo M, Goyal N, et al. Clinical, functional, and radiographic outcomes following total knee arthroplasty with patient-specific instrumentation, computer-assisted surgery, and manual instrumentation: a short-term follow-up study. Int J Comput Assist Radiol Surg. Sep 2014; 9(5):837-844. PMID 24337791
84. Yan CH, Chiu KY, Ng FY, et al. Comparison between patient-specific instruments and conventional instruments and computer navigation in total knee arthroplasty: a randomized controlled trial. Knee Surg Sports Traumatol Arthrosc. Dec 2015; 23(12):3637-3645. PMID 25217311
85. Zahn RK, Graef F, Conrad JL, et al. Accuracy of tibial positioning in the frontal plane: a prospective study comparing conventional and innovative techniques in total knee arthroplasty. Arch Orthop Trauma Surg. Jun 2020; 140(6):793-800. PMID 32124032
86. Zhu M, Chen JY, Chong HC, et al. Outcomes following total knee arthroplasty with CT-based patient-specific instrumentation. Knee Surg Sports Traumatol Arthrosc. Aug 2017; 25(8):2567-2572. PMID 26410097
87. Zomar BO, Vasarhelyi EM, Somerville LE, et al. A Randomized Trial Investigating the Cost-Utility of Patient-Specific Instrumentation in Total Knee Arthroplasty in an Obese Population. J Arthroplasty. Sep 2021; 36(9):3078-3088. PMID 34053752

88. Alvand A, Khan T, Jenkins C, et al. The impact of patient-specific instrumentation on unicompartmental knee arthroplasty: a prospective randomised controlled study. Knee Surg Sports Traumatol Arthrosc. Jun 2018; 26(6):1662-1670. PMID 28831554
89. Braun S, Allen J, Somerville L, et al. Patient-Specific Instrumentation Versus Standard of Care in Total Knee Arthroplasty in an Obese Population: Minimum 5-year Follow-Up. J Arthroplasty. Feb 2026; 41(2):458-464. PMID 40562084
90. Hermodsson J, Saari T, Shareghi B, et al. Effect of patient specific instruments compared with conventional instruments in total knee arthroplasty: a randomized controlled trial. Acta Orthop. Dec 02 2025; 96:875-884. PMID 41329855
91. Hampton MJ, Blakey CM, Anderson AA, et al. Minimum 5-Year Outcomes of a Multicenter, Prospective, Randomized Control Trial Assessing Clinical and Radiological Outcomes of Patient-Specific Instrumentation in Total Knee Arthroplasty. J Arthroplasty. Aug 2022; 37(8):1579-1585. PMID 35077818
92. McGrory BJ, Weber KL, Jevsevar DS, et al. Surgical management of osteoarthritis of the knee: Evidence-based guideline. J Am Acad Orthop Surg. Aug 2016; 24(8):e87-e93. PMID 27355286
93. American Academy of Orthopaedic Surgeons Surgical Management of Osteoarthritis of the Knee Evidence-Based Clinical Practice Guideline. Published December 02, 2022. Available at <https://www.aaos.org> (accessed February 19, 2026).

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
09/01/2026	Document updated. Coverage unchanged. Added references 5, 13, 22, 33, 42, 43, 56, 62, 63, 67, 73, 87, 89, and 90; others updated/removed.
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.