Kansas City

An Independent Licensee of the Blue Cross and Blue Shield Association

Patient-Specific Instrumentation (eg, Cutting Guides) for Joint Arthroplasty

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Origination: 11/2014
Last Review: 11/2023
Next Review: 8/2024

This policy is due to be archived 8/1/2024. Please use Turning Point Policy.

Blue KC has developed medical policies that serve as one of the sets of guidelines for coverage decisions. Benefit plans vary in coverage and some plans may not provide coverage for certain services discussed in the medical policies. Coverage decisions are subject to all terms and conditions of the applicable benefit plan, including specific exclusions and limitations, and to applicable state and/or federal law. Medical policy does not constitute plan authorization, nor is it an explanation of benefits.

When reviewing for a Medicare beneficiary, guidance from National Coverage Determinations (NCD) and Local Coverage Determinations (LCD) supersede the Medical Policies of Blue KC. Blue KC Medical Policies are used in the absence of guidance from an NCD or LCD.

NCDs
https://www.cms.gov/medicare-coverage-database/search-results.aspx?keyword=&keywordType=starts&areaId=s29&docType=NCD&contractOption=all

LCDs
https://www.cms.gov/medicare-coverage-database/search-results.aspx?keyword=&keywordType=starts&areaId=s29&docType=F,P&contractOption=all

Policy

Blue Cross and Blue Shield of Kansas City (Blue KC) will not provide coverage for Patient-Specific Instrumentation (eg, Cutting Guides) for Joint Arthroplasty. This is considered investigational.

When Policy Topic is covered

Not Applicable

When Policy Topic is not covered

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

Description of Procedure or Service

Populations	Interventions	Comparators	Outcomes
Individuals: ▪ Who are undergoing partial or total knee arthroplasty	Interventions of interest are: ▪ Patient-specific cutting guides	Comparators of interest are: ▪ Conventional cutting guides	Relevant outcomes include: ▪ Symptoms ▪ Functional outcomes ▪ Quality of life

Summary

Patient-specific instrumentation has been developed as an alternative to conventional cutting guides for joint arthroplasty. Patient-specific cutting guides are constructed with the aid of preoperative 3-dimensional computed tomography or magnetic resonance imaging scans and proprietary planning software. The goals of patient-specific instrumentation are to increase surgical efficiency and to improve implant alignment and clinical outcomes.

For individuals who are undergoing partial or total knee arthroplasty who receive patient-specific cutting guides, the evidence includes 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.

Background

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 8 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
X-Psi	Orthosoft	K131409	9/13/2013
iTotal	Conformis	K120068	2/3/2012
Prophecy	Wright Medical Technology	K103598	10/17/2011
Trumatch	Depuy Orthopaedics	K110397	8/16/2011
Shapematch	Stryker	K110533	5/19/2011
Signature	Materialise	K102795	2/2/2011
Zimmer	Materialise	K091263	11/19/2009
Visionaire	Smith & Nephew	K082358	11/25/2008

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

Rationale

This evidence review was created in September 2014 and has been updated regularly with searches of the PubMed database. The most recent literature update was performed through January 16, 2023.

Evidence reviews 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 patients 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.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

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 question addressed in this evidence review is: Does patient-specific cutting guides improve the net health outcome in patients undergoing knee arthroplasty?

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

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 (see evidence review 7.01.96). 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.

Study Selection Criteria
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.

Review of Evidence

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.[2,3,4,]

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

Study	Lin et al (2020)[4,]	Gong et al (2018)[5,]	Thienpo nt et al (2017)[3,]	Mannan et al (2017)[6,]
Abane et al (2015)[7,]	●	●	●	●
Abane et al(2017) [8,]	●			
Abdel et al (2014)[9,]	●		●	
Anderl et al (2016)[10,]			●	●
Bali et al (2012)[11,]			●	
Barke et al (2013)[12,]			●	
Barrack et al (2012)[13,]			●	
Barrett et al (2014)[14,]			●	
Boonen et al (2012)[15,]			●	

Boonen et al(2013)[16],	●	●	●	
Boonen et al (2016)[17],	●	●		
Chareancholvanich et al (2013)[18],	●	●	●	
Chen et al (2014)[19],			●	
Chen et al (2015)[20],			●	●
Chotanaphuti et al (2014)[21],	●		●	
Cucchi et al (2018)[22],	●			
Daniilidis et al(2014)[23],			●	
De Vloo et al (2017)[24],	●	●		
DeHann et al (2014)[25],			●	
Ferrara et al (2015)[26],			●	
Gan et al (2015)[27],		●		
Hamilton et al(2013)[28],	●	●	●	
Heyse et al (2014)[29],			●	
Huijbregts et al (2016)[30],	●	●		
Kassab et al (2014)[31],			●	
Khuangsirikul et al (2014)[32],		●		
Kosse et al (2018)[33],	●	●		
Kotela et al(2014)[34],	●	●	●	
Kotela et al (2015)[35],	●	●	●	●
MacDessi et al (2014)[36],			●	
Marimuthu et al (2014)[37],			●	
Maus et al	●	●		

(2017)[38],				
Molicnik et al (2015)[39],	●		●	
Nabav et al (2015)[40],			●	
Nam et al (2016)[41],			●	
Nankivell et al (2015)[42],			●	
Ng et al (2012)[43],			●	
Noble et al (2012)[44],	●		●	
Nunley et al (2012)[45],			●	
Parratte et al (2013)[46],	●	●	●	
Pfitzner et al (2014)[47],	●			●
Pietsch et al (2013)[48],	●	●	●	
Renson et al (2014)[49],			●	
Roh et al (2013)[50],	●	●	●	
Schotanus et al (2018) [51],	●			
Silva et al (2014)[52],	●	●	●	
Stronach et al (2014)[53],			●	
Thienpoint et al (2015)[54],			●	
Van Leeuwen et al (2018)[55],	●	●		
Victor et al (2014)[56],		●	●	
Vide et al (2017)[57],	●	●	●	
Vundelinckx et al (2013)[58],	●	●	●	
Woolson et al (2014)[59],	●	●	●	●
Yaffe et al (2014)[60],			●	●
Yan et al (2015)[61],	●	●	●	●

Zhu et al (2015)[62,]			●	

Table 3. Meta-Analysis Characteristics

Study	Dates	Trials	N (Range)	Designs	Outcomes
Lin et al (2020)[4,]	2012-2018	29	2487 (24 to 180)	RCTs	Mechanical axis malalignment, functional outcomes
Gong et al (2018)[5,]	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)[6,]	2000-2015	8	828 (48 to 232)	RCTs and cohort	Functional outcomes

RCT: randomized controlled trial.

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

Study	Trials	N (knees)	Malalignment (>3°)	RR	95% CI	p	I^2, %
Lin et al (2020)[4,]	17	1577	Hip-knee-ankle angle	0.88	0.74 to 1.04	.13	38
Gong et al (2018)[5,]	14	1273	Hip-knee-ankle angle	0.94	0.72 to 11.24	.68	41
	12	1137	Femoral/coronal plane	0.86	0.57 to 1.30	.47	37
	12	1137	Tibial/coronal plane	1.36	0.75 to 2.49	.31	46
	9	941	Femoral sagittal alignment	1.07	0.84 to 1.35	.59	46
	10	989	Tibial/sagittal plane	1.31	0.92 to 1.86	.13	57
Thienpont et al (2017)[3,]	29	3479	Coronal mechanical axis	0.79	0.65 to 0.95	.013	51
	13	1527	Tibial/sagittal plane	1.32	1.12 to 1.56	.001	0
	15	1943	Femoral/coronal plane	0.74	0.55 to 0.99	.043	32
	17	1983	Tibial/coronal plane	1.30	0.92 to 1.83	.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).[6,] More recent meta-analyses have shown mixed outcomes with regard to benefit. Thienpo nt 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, months	MD	95% CI	p	I^2, %
Lin et al (2020)[4,]	3	337	KSS	3	-0.17	-0.33 to -0.02	.02	0
	5	651	Oxford Knee Score	NR	0.07	-0.09 to 0.22	.4	32
Thienpo nt et al (2017)[3,]	6	300	KSS functional score	16.7	4.3	1.5 to 7.2	.003	NR
	6	300	KSS knee score	16.7	1.5	-0.3 to 3.3	.093	NR
Mannan et al (2017)[6,]	3	195	KSS functional score	24	-0.21	-9.31 to 8.88	.96	82
	3	195	KSS knee score	24	0.90	-6.15 to 7.95	.80	85
	5	244	Range of motion (deg)	3 to 24	3.72	-0.46 to 7.91	.08	70
	3	118	Oxford Knee Score	3 to 12	-0.48	-1.83 to 0.86	.48	0

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

Perioperative Outcomes

Systematic Reviews

Three of the meta-analyses included in this review reported perioperative outcomes (Table 6).[5,3,4,] 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) and Lin et al (2020) reported hospital length of stay and did not find a significant difference between patient specific instrumentation and conventional instrumentation groups. All 3 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
Lin et al (2020)[4,]			
Total N	1404	300	543
MD (95% CI); p-value	-0.36 (-0.67 to -0.04); p=.03	-0.49 (-0.92 to -0.05); p=.03	-0.10 (-0.27 to 0.07); p=.24

I^2	88%	71%	33%
Gong et al (2018)[5,]			
Total N	871	450	685
MD (95% CI); p-value	-7.35 (-10.95 to -3.75); p<.0001	-83.42 (-146.65 to -20.18); p=.010	-0.16 (-0.40 to 0.07); p=.17
I^2	78%	74%	19%
Thienpo nt et al (2017)[3,]			NR
Total N	3480	1251	
MD (95% CI); p-value	-4.4 (-7.2 to -1.7); p=.002	-37.9 (-68.4 to -7.4); p=.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.[63,64,65,66,]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.[17,33,] 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.[64,]

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)[66,]	United Kingdom	2	2013-2015	88	NexGen Knee (Zimmer)
Alvand et al (2017)[63,]	United Kingdom	1	2012-2014	46	Signature (Zimmer Biomet)
Kosse et al (2017)[33,]	The Netherlands	1	2012-2013	42	Visionaire (Smith & Nephew)

Calliess et al (2017)[64,]	Germany	2	2012-2013	200	Triathlon System (Stryker)
Boonen et al (2016)[17,]	The Netherlands	2	2010-2013	180	Materialise (Leuven)
Tammachote et al (2017)[65,]	Thailand	1	2012-2014	108	Visionaire (Smith & Nephew)

RCT: randomized controlled trial.

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

Study	KSS	Kujala	VAS Pain	OKS	EuroQoL-5D	KOOS	WOMAC
Hampton et al (2022)[66,]		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)[63,]	NR	NR	NR		NR	NR	NR
N (FU)				45 (1 year)			
PSI, mean (range)				18.3 (4 to 31)			
Conventional, mean (range)				18.2 (5 to 31)			
p-value				NS			
Boonen et al (2016)[17,]							
N (FU)	163 (2 years)		163 (2 years)	163 (2 years)	163 (2 years)		163 (2 years)
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	.807		.227	.304	.968		.753

Calliess et al (2017)[64,]		NR	NR	NR	NR	NR	
N (FU)	200 (1 year)						200 (1 year)
PSI, mean (SD)	190 (18)						13 (16)
Conventional, mean (SD)	178 (17)						26 (11)
p-Value	.02						.001
Kosse et al (2017)[33,]				NR	NR		NR
N (FU)	42 (1 year)	42 (1 year)	42 (1 year)			42 (1 year)	
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	
Tammachote (2017)[65,]							
N (FU)							102 (2 years)
PSI, mean (SD)							5 (6)
Conventional, mean (SD)							4 (6)
MD (CI); p-value							1 (-1.8 to 3), p=.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; RCT: randomized controlled trial; SD: standard deviation; PSI: patient-specific instrumentation; VAS: Visual Analog Scale; WOMAC: Western Ontario and McMaster Universities Osteoarthritis Index.

SUPPLEMENTAL INFORMATION

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

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).[67,68,] 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.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 9.

Table 9. Summary of Key Ongoing Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT01696552	Patient-specific Positioning Guides (PSPG) Technique Versus Conventional Technique in Total Knee Arthroplasty - a Prospective Randomized Study	109	Jan 2024
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	Aug 2024
Unpublished			
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	June 2020

NCT: national clinical trial.
[a] Denotes industry-sponsored or cosponsored trial.

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Billing Coding/Physician Documentation Information

27440 Arthroplasty, knee, tibial plateau;
27445 Arthroplasty, knee, hinge prosthesis (eg, Walldius type)
27447 Arthroplasty, knee, condyle and plateau; medial AND lateral compartments with or without patella resurfacing (total knee arthroplasty)

ICD-10 Codes

M17.0-M17.9 Osteoarthritis of the knee code range

There are no specific codes for these implants or instrumentation. The joint arthroplasty procedure would be reported using the regular CPT codes for that surgery.

The preplanning for the surgery may involve magnetic resonance or computed tomography imaging which may help to identify these procedures.

Additional Policy Key Words

N/A

Policy Implementation/Update Information

11/1/14 New policy; considered investigational.
11/1/15 No policy statement changes.
11/1/16 No policy statement changes.
11/1/17 No policy statement changes.
8/1/18 Custom implants moved to new policy on 3-dimensional printed orthopedic implants. Title and policy statement changed to "Patient-Specific Instrumentation (eg, Cutting Guides) for Joint Arthroplasty."
11/1/18 No policy statement changes.
11/1/19 No policy statement changes.
11/1/20 No policy statement changes.
11/1/21 No policy statement changes.
11/1/22 No policy statement changes.
11/1/23 No policy statement changes.
8/1/24 Archiving Policy. Using Turning Point Policy