

7.01.144 Patient-Specific Instrumentation (e.g., Cutting Guides) for Joint Arthroplasty	
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Section: 7.0 Surgery	Page: Page 1 of 16

Policy Statement

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 **investigational**.

NOTE: Refer to [Appendix A](#) to see the policy statement changes (if any) from the previous version.

Policy Guidelines

The following category III CPT codes are specific to cutting guides:

- **0561T:** Anatomic guide 3D-printed and designed from image data set(s); first anatomic guide
- **0562T:** Anatomic guide 3D-printed and designed from image data set(s); each additional anatomic guide (List separately in addition to code for primary procedure)

The joint arthroplasty procedure would be reported using the regular CPT codes for that surgery.

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

Description

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.

Related Policies

- Computer-Assisted Navigation for Orthopedic Procedure
- Three-Dimensional Printed Orthopedic Implants

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

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 the 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

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.

Literature review

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. RCTs 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.

Clinical Context and Therapy Purpose

The purpose of patient-specific cutting guides in patients 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 patients undergoing total knee arthroplasty (also called knee replacement). Total knee arthroplasty is an established treatment for relief from significant, disabling pain caused by advanced arthritis. Total knee arthroplasty 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 total knee arthroplasty, the increase in the aging population, and the desire of older adults to remain physically active, the incidence of total knee arthroplasty is increasing rapidly. It is projected that by 2030, the demand for knee replacement will approach 3.5 million procedures annually.¹

Total 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 total 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 comp. Total knee arthroplasty is a surgical technique requiring inpatient hospitalization. Results of studies conducted outside of the United States and in the context of clinical trials may not be applicable to the general United States population.

Comparators

For patients undergoing knee arthroplasty, conventional cutting guides are currently being used for total knee arthroplasty (see intervention description). Thus, the primary comparator of interest is conventional cutting guides.

Outcomes

The general outcomes of interest are symptoms, function, 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, because this is a relatively new technology, 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 total 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 total 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 (see Tables 1, 2, and 3). Three of these reported functional outcomes in addition to measures of malalignment.^{2,3,4}

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

Study ²	Lin, et al. (2020) ¹⁴	Gong, et al. (2018) ⁵	Thienpoint, et al. (2017) ³	Mannan, et al. (2017) ⁶
Abane, et al. (2015) ²	●	●	●	●
Abane, et al. (2017) ⁸	●			
Abdel, et al. (2014) ²	●		●	
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	●		●	
Nabavi, 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	●	●	●	
Pfizner, 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			●	

¹Systematic review/meta-analyses across the columns.

²Primary studies across the rows.

Table 3. Meta- Analysis Characteristics

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

RCT: randomized controlled trial.

^a Patients.

Table 4. Meta- Analysis Results for Malalignment Outcomes (>3 Degrees 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	0.13	38
Gong et al (2018) ⁵	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
	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 (see Table 5).⁶ 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 score 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	0.02	0
	5	651	Oxford Knee Score	NR	0.07	-0.09 to 0.22	0.4	32
Thienport 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) ⁶	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 (deg)	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.

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 statistically 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	543
	Mean difference (95% CI); p-value	-0.36 (-0.67 to -0.04); p=0.03	-0.49 (-0.92 to -0.05); p=0.03
	I ²	88%	71%
			33
Gong et al (2018) ⁵	Total N	871	450
	Mean difference (95% CI); p-value	-7.35 (-10.95 to -3.75); p<0.0001	-83.42 (-146.65 to -20.18); p=0.010
	I ²	78%	74%
			19%
Thienpoint et al (2017) ³	Total N	3480	1251
	Mean difference (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%
			NR

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

Randomized Controlled Trials

Several RCTs have yet to be incorporated into available meta-analyses.^{63,64,65} 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 2 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)
Alvand et al (2017) ⁶³ .	United Kingdom	1	2012-2014	N=46	Signature (Zimmer Biomet)
Kosse et al (2017) ³³ .	The Netherlands	1	2012-2013	N=42	Visionaire (Smith & Nephew)
Calliess et al (2017) ⁶⁴ .	Germany	2	2012-2013	N=200	Triathlon System (Stryker)
Boonen et al (2016) ¹⁷ .	The Netherlands	2	2010-2013	N=180	Materialise (Leuven)
Tammachote et al (2017) ⁶⁵ .	Thailand	1	2012-2014	N=108	Visionaire (Smith & Nephew)

RCT: randomized controlled trial; TKA: total knee arthroplasty.

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

Study	KSS	Kujala	VAS Pain	OKS	EuroQoL-5D	KOOS	WOMAC
Alvand (2017) ⁶³ .	NR	NR	NR		NR	NR	NR
N (FU)				45 (1 year)			
PSI, mean (range)				18.3 (4-31)			
Conventional, mean (range)				18.2 (5-31)			
P-value				NS			
Boonen (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	0.807		0.227	0.304	0.968		0.753
Calliess (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	0.02						0.001
Kosse (2017) ³³ .				NR	NR		NR
N (FU)	42 (1 year)	42 (1 year)	42 (1 year)			42 (1 year)	

PSI, median (range)	180 (135- 200)	70 (44- 100)	5 (0- 40)	94 (50- 100)
Conventional, median (range)	175 (115- 200)	62 (33- 95)	11 (0- 81)	81 (33- 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)
Mean difference (CI); p-value				1 (-1.8 to 3), p =0.62

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

Summary of Evidence

For individuals who are undergoing partial or total knee arthroplasty who receive patient-specific cutting guides, the evidence includes a number of 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 2 years. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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.⁶⁶ 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
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	300	Apr 2021
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™ Personalized Solutions Instruments: A Prospective Randomized Controlled Trial Comparing Clinical and Economic Outcomes in Patients With a BMI Between 30 and 50	184	Aug 2024
NCT02096393	A Prospective, Randomised Control Trial Assessing Clinical and Radiological Outcomes of Patient Specific Instrumentation in Total Knee Arthroplasty	100	Dec 2024
Unpublished			
NCT02845206	Randomised Controlled Trial of Patient Specific Instrumentation vs Standard Instrumentation in Total Knee Arthroplasty	172	Feb 2020

NCT: national clinical trial.

^a Denotes industry-sponsored or cosponsored trial.

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Documentation for Clinical Review

- No records required

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

Type	Code	Description
CPT®	0561T	Anatomic guide 3D-printed and designed from image data set(s); first anatomic guide
	0562T	Anatomic guide 3D-printed and designed from image data set(s); each additional anatomic guide (List separately in addition to code for primary procedure)
HCPCS	None	

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
11/26/2014	BCBSA Medical Policy adoption
01/01/2017	Policy revision without position change
10/01/2017	Policy revision without position change
07/01/2018	Policy title change from Patient-Specific Cutting Guides and Custom Knee Implants Policy revision without position change
06/01/2019	Policy revision without position change Coding update
06/01/2020	Annual review. No change to policy statement. Literature review updated.
06/01/2021	Annual review. No change to policy statement. Literature review updated.

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT (No changes)	
BEFORE	AFTER
<p>Patient-Specific Instrumentation (e.g., Cutting Guides) for Joint Arthroplasty 7.01.144</p> <p>Policy Statement: 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 investigational.</p>	<p>Patient-Specific Instrumentation (e.g., Cutting Guides) for Joint Arthroplasty 7.01.144</p> <p>Policy Statement: 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 investigational.</p>