PREMERA | BLUE CROSS

An Independent Licensee of the Blue Cross Blue Shield Association

MEDICAL POLICY – 7.01.144

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

BCBSA Ref. Policy:	7.01.144	
Effective Date:	Jul. 1, 2025	RELATED MEDICAL POLICIES:
Last Revised:	Jun. 23, 2025	None
Replaces:	N/A	

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | CODING | RELATED INFORMATION
EVIDENCE REVIEW | REFERENCES | HISTORY

Clicking this icon returns you to the hyperlinks menu above.

Introduction

Three-dimensional (3-D) printing technology is being used as part of some joint replacement surgeries. Standard cutting guides — which show where the bone is to be cut — are available and widely used. But 3-D printing allows for custom cutting guides to be created for an individual patient. For a custom cutting guide, an MRI or CT scan is taken before the surgery. The image is then sent out to a company that creates a mold. During surgery, that mold is then fitted over the end of the bone to guide where the bone should be cut. Published studies show that custom cutting guides don't result in better alignment than standard cutting guides. Some studies show the custom materials create worse alignment. More and larger studies are needed to determine how well these custom cutting guides work. For this reason, custom cutting guides are considered investigational (unproven).

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Equipment	Investigational
Patient-specific instrumentation	**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.**

Coding

There are no specific codes for this instrumentation. The joint arthroplasty procedure would be reported using the regular CPT codes for that surgery. You may see any of the following codes billed.

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)
27446	Arthroplasty, knee, condyle and plateau; medial OR lateral compartment
27447	Arthroplasty, knee, condyle and plateau; medial AND lateral compartments with or without patella resurfacing (total knee arthroplasty)

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

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

Evidence Review

Description

Patient-specific instrumentation (PSI) 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 (CT) or magnetic resonance imaging (MRI) scans and proprietary planning software. The goals of PSI are to increase surgical efficiency and to improve implant alignment and clinical outcomes.

Background

PSI 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 four to six 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.

Total Knee Arthroplasty

Total knee arthroplasty (TKA; also called knee replacement) is an established treatment for relief from significant, disabling pain caused by advanced arthritis. TKA 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 TKA, the increase in the aging population, and the desire of older adults to remain physically active, the incidence of TKA is increasing rapidly. It is projected that by 2030, the demand for knee replacement will approach 3.5 million procedures annually.[1]

TKA 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.

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.

Summary of Evidence

For individuals who are undergoing partial or TKA 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 PSI systems. Also, the designs of the devices are evolving, and some of the studies might have assessed now obsolete PSI systems. Available results from RCTs have not shown a benefit of PSI systems in improving clinical outcome measures with follow-up currently extending out to five years. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this policy are listed in **Table 1**.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT06720012	Total Knee Arthroplasty Inserted With Patient Specific or Standard Instruments	70	Dec 2024
NCT06122727	Comparison of Customized and Standard Total Knee Replacements: a Pilot Study	20	March 2025
NCT02177227[a]	Attune With TruMatch TM Personalized Solutions Instruments: A Prospective Randomized Controlled Trial Comparing Clinical and Economic Outcomes in Patients With a BMI Between 30 and 50	194	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.

Practice Guidelines and Position Statements

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

Guidelines or position statements will be considered for inclusion 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).[79,80] The guideline is supported by the American Society of Anesthesiologists and endorsed by several other organizations. The guideline recommends against the use of PSI for TKA, 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.

Medicare National Coverage

There is no national coverage determination.

Regulatory Status

There are eight commercially available PSI 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 US Food and Drug Administration (FDA) clearance for marketing. Other systems cleared for marketing by the FDA are shown in **Table 2**.

FDA product codes: OOG

MyKnee cutting blocks are designed and manufactured from patient imaging data so that the cutting blocks match the individual's anatomy. They are used with the GMK Total Knee System. They are intended for use for a single individual anatomy to assist in the positioning of total knee replacement components intraoperatively and in guiding the marking of bone before cutting.

Product code JWH.

Table 2. Patient-Specific Cutting Guides for Knee Arthroplasty

Device Name	Manufacturer	510(K) Number	Clearance Date
UNIKO PointCloud Knee Instruments	Unik Orthopedics, Inc	K240327	6/27/2024
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: US Food and Drug Administration

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): 780-5. 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): 186-90. 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. 2020; 2020: 2164371. PMID 32258107

5. 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

6. 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

7. 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

8. 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

9. 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

10. 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): 2468-76. PMID 24604110

11. 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): 102-11. PMID 25326759

12. Bali K, Walker P, Bruce W. Custom-fit total knee arthroplasty: our initial experience in 32 knees. J Arthroplasty. Jun 2012; 27(6): 1149-54. PMID 22285230

13. 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): 307-11. PMID 23926734

14. 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): 95-9. PMID 23118393

15. 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): 343-7. PMID 23993343

16. Boonen B, Schotanus MG, Kort NP. Preliminary experience with the patient-specific templating total knee arthroplasty. Acta Orthop. Aug 2012; 83(4): 387-93. PMID 22880715

17. 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): 2206-12. PMID 23928929

18. 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): 939-44. PMID 27365472

19. 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

20. 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): 354-9. PMID 23450020

21. 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): 630-5. PMID 23996069

22. 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): 1724-8. PMID 25937100

23. 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): 185-8. PMID 23999209

24. 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

25. Daniilidis K, Tibesku CO. A comparison of conventional and patient-specific instruments in total knee arthroplasty. Int Orthop. Mar 2014; 38(3): 503-8. PMID 23900384

26. 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

27. 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): 2065-9. PMID 25065735

28. Ferrara F, Cipriani A, Magarelli N, et al. Implant positioning in TKA: comparison between conventional and patient-specific instrumentation. Orthopedics. Apr 2015; 38(4): e271-80. PMID 25901619

29. 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): 12192-201. PMID 26550129

30. 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

31. Heyse TJ, Tibesku CO. Improved femoral component rotation in TKA using patient-specific instrumentation. Knee. Jan 2014; 21(1): 268-71. PMID 23140905

32. 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): 1043-9. PMID 27482015

33. 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): 140-6. PMID 25153812

34. 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: S47-51. PMID 25518175

35. 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

36. 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): 2099-107. PMID 24968788

37. 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

38. 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): 406-9. PMID 24378337

39. 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): 1138-42. PMID 24524776

40. 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

41. 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): S235-40. PMID 25732915

42. 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): S239-42. PMID 24703790

43. 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;2:5460. **https://savvysciencepublisher.com/jms/index.php/ijor/article/view/722**. Accessed May 15, 2025.

44. 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): 182-4. PMID 26321546

45. 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): 40-6. PMID 25712865

46. 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): 452-5. PMID 25387721

47. 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

48. Noble JW, Moore CA, Liu N. The value of patient-matched instrumentation in total knee arthroplasty. J Arthroplasty. Jan 2012; 27(1): 153-5. PMID 21908169

49. 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): 889-94. PMID 22183476

50. 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): 2213-9. PMID 23942938

51. 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): 2913-22. PMID 25024031

52. 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): 2234-40. PMID 23114870

53. 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): 170-4. PMID 27574257

54. 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

55. 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): 343-50, ix. PMID 26043048

56. 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): 1216-20. PMID 25450010

57. 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): 3988-95. PMID 23907610

58. 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

59. Silva A, Sampaio R, Pinto E. Patient-specific instrumentation improves tibial component rotation in TKA. Knee Surg Sports Traumatol Arthrosc. Mar 2014; 22(3): 636-42. PMID 23989707

60. 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

61. 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): 1705-8. PMID 24890995

62. 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

63. 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

64. 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

65. 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): 2055-60. PMID 24671387

66. 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

67. 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

68. 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): 263-71. PMID 23616267

69. 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

70. 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): 964-70. PMID 23535285

71. 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): 366-72. PMID 24599197

72. 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): 837-44. PMID 24337791

73. 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): 3637-45. PMID 25217311

74. 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

75. 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

76. 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

77. 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

78. 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

79. 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): e87-93. PMID 27355286

80. American Academy of Orthopaedic Surgeons Surgical Management of Osteoarthritis of the Knee Evidence-Based Clinical Practice Guideline. **www.aaos.org/smoak2cpg**. Published December 02, 2022. Accessed May 15, 2025.

History

Date	Comments
01/13/15	New Policy. Add to Surgery section. Policy created with literature review through July 31, 2014. Custom implants or patient-specific instrumentation for knee surgery is considered investigational.

Date	Comments
11/10/15	Annual Review. Policy updated with literature review through July 30, 2015; reference 17 added. Policy statement unchanged.
08/01/16	Annual Review, approved July 12, 2016. No change to policy statements.
10/01/17	Annual Review, approved September 21, 2017. Policy updated with literature review through June 22, 2017; references 3-6 added; some references removed. Policy statement unchanged.
08/01/18	Annual Review, approved July 25, 2018. Policy updated with literature review through February 2018; references 5 and 8-12 added. Custom implants moved to new policy on 3-dimensional printed orthopedic implants. Title changed from "Patient-Specific Cutting Guides and Custom Knee Implants" to "Patient-Specific Cutting Guides for Joint Arthroplasty".
07/01/19	Annual Review, approved June 4, 2019. Policy updated with literature review through February 2019; references added. Policy statement unchanged.
07/01/20	Annual Review, approved June 2, 2020. Policy updated with literature review through February 2020; no references added. Policy statement unchanged.
08/01/20	Coding update. Added CPT codes 27446 and 27447.
07/01/21	Annual Review, approved June 1, 2021. Policy updated with literature review through February 16, 2020; references added. Policy statement unchanged.
12/01/21	Interim Review, approved November 2, 2021. Updated Regulatory Status table to include MyKnee cutting blocks. Added CPT codes 0561T, 0562T. Added HCPCS C1713 and C1776.
07/01/22	Annual Review, approved June 13, 2022. Policy updated with literature review through February 28, 2022; reference added. Policy statement unchanged.
04/01/23	Coding update. Removed HCPCS codes C1776 and C1713. Correction made to the Regulatory Status section as information regarding MyKnee cutting blocks was inadvertently removed at last publication.
07/01/23	Annual Review, approved June 26, 2023. Title changed back to "Patient-Specific Instrumentation (e.g., Cutting Guides) for Joint Arthroplasty" from "Patient-Specific Cutting Guides for Joint Arthroplasty" Policy updated with literature review through January 16, 2023; reference added; Policy statement unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization.
07/01/24	Annual Review, approved June 24, 2024. Policy updated with literature review through February 8, 2024; reference added; Policy statement unchanged.
07/01/25	Annual Review, approved June 23, 2025. Policy updated with literature review through February 25, 2025; no references added; Policy statement unchanged.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2025 Premera All Rights Reserved.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.