



## MASSACHUSETTS

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### Medical Policy

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

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### Policy Number: 706

BCBSA Reference Number: 7.01.144 (For Plan internal use only)

NCD/LCD: NA

### Related Policies

Computer-Assisted Musculoskeletal Surgical Navigational Orthopedic Procedures, #[594](#)

### Policy

#### Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO Blue<sup>SM</sup> and Medicare PPO Blue<sup>SM</sup> Members

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](#).

### Prior Authorization Information

#### Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

#### Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	This is <b>not</b> a covered service.
Commercial PPO and Indemnity	This is <b>not</b> a covered service.
Medicare HMO Blue <sup>SM</sup>	This is <b>not</b> a covered service.
Medicare PPO Blue <sup>SM</sup>	This is <b>not</b> a covered service.

### CPT Codes / HCPCS Codes / ICD Codes

*Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.*

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

## CPT Codes

There is no specific CPT code for this service.

## Description

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

## 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.

## Policy History

Date	Action
6/2022	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
5/2021	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
6/2020	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
5/2019	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
7/2018	Annual policy review. Title changed to Patient-Specific Instrumentation (eg, Cutting Guides) for Joint Arthroplasty.7/1/2018
5/2018	Prior Authorization Information reformatted.
11/2017	Policy clarified to remove custom knee implants from the policy. 11/14/2017
9/2017	Annual policy review. New references added.
11/2015	Annual policy review. New references added.
2/2015	New medical policy describing investigational indications. Effective 2/1/2015.

## Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

[Medical Policy Terms of Use](#)

[Managed Care Guidelines](#)

[Indemnity/PPO Guidelines](#)

[Clinical Exception Process](#)

[Medical Technology Assessment Guidelines](#)

## 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. 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
6. 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
7. 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
8. 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
9. 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
10. Anderl W, Pauzenberger L, Kolblinger 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
11. 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
12. 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
13. 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
14. 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
15. 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
16. 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
17. 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

18. 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
19. 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
20. 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
21. 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
22. 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
23. 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
24. 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
25. 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
26. 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
27. 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
28. 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
29. Heyse TJ, Tibesku CO. Improved femoral component rotation in TKA using patient-specific instrumentation. *Knee.* Jan 2014; 21(1): 268-71. PMID 23140905
30. Huijbrechts 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
31. 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
32. 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
33. 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
34. 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
35. 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
36. 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
37. 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

38. 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
39. 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: S235-40. PMID 25732915
40. 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
41. 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
42. 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
43. 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
44. 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
45. 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
46. 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
47. 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
48. 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
49. 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
50. 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
51. 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
52. 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
53. 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
54. 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
55. Van Leeuwen JAMJ, Snorrason F, Rohrl 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
56. 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
57. 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

58. 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
59. 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
60. 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
61. 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
62. 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
63. 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
64. 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
65. 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
66. 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*. Jan 22 2022. PMID 35077818
67. 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