



BlueCross BlueShield  
of Alabama

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**Name of Policy:**

**Patient-Specific Instrumentation for Joint Arthroplasty**

Policy #: 716  
Category: Surgical

Latest Review Date: July 2018  
Policy Grade: B

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**Background/Definitions:**

*As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.*

*The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:*

- 1. The technology must have final approval from the appropriate government regulatory bodies;*
- 2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
- 3. The technology must improve the net health outcome;*
- 4. The technology must be as beneficial as any established alternatives;*
- 5. The improvement must be attainable outside the investigational setting.*

*Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:*

- 1. In accordance with generally accepted standards of medical practice; and*
- 2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and*
- 3. Not primarily for the convenience of the patient, physician or other health care provider; and*
- 4. 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 that patient's illness, injury or disease.*

## **Description of Procedure or Service:**

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 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.

### **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.

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 placement of conventional cutting guides (templates and jigs) is based on anatomic landmarks or computer navigation (see medical policy #229- *Computer-Assisted Navigation for Orthopedic Procedures*). Use of conventional instrumentation has been shown to result in malalignment of approximately one-third of implants in the coronal plane.<sup>2</sup> 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 compared with conventional instrumentation.

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 (see the Regulatory Status section). 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.

The proposed benefits of using patient-specific instrumentation during TKA 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 TKA 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.

### Outcome Measures

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 definitively 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.

### **Policy:**

**Use of patient-specific instrumentation (e.g., cutting guides) for joint arthroplasty, including but not limited to use in unicompartmental or total knee arthroplasty does not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered investigational.**

*Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the member's contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.*

### **Key Points:**

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are 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 to 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 the quality and credibility. To be relevant, studies must represent one 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.

## **Patient-Specific Instrumentation**

### Systematic Reviews

There are a number of systematic reviews on patient-specific instrumentation (PSI) for total knee arthroplasty (TKA). We focus on the most comprehensive and relevant analyses.

Thienpont et al (2017) included 20 RCTs and 24 cohort studies (total N=5822 patients) in their systematic review (see Table 1). The PSI systems used in the RCTs were the Signature (Biomet), Zimmer Patient Specific Instruments (Zimmer), TruMatch (DePuy), Visionaire (Smith & Nephew), and MyKnee (Medacta). Meta-analysis of results for PSI vs conventional TKA indicated modest but statistically significant decreases in the likelihood of malalignment in the mechanical axis and femoral/coronal plane, but increases in malalignment of the tibial/sagittal and tibial/coronal planes (see Table 2). There were minor reductions in total operative time (-4.4 minutes, p=0.002) and blood loss (-37.9 mL, p=0.015) that are of uncertain clinical significance. There was some evidence of publication bias for mechanical axis alignment, but the relative risk did not change after adjusting for bias. In the 6 studies (598 knees) that reported clinical outcomes (follow-up, 6-24 months), PSI was associated with a modest improvement in function (4.3 points) assessed on the Knee Society Score.

Rotational alignment was evaluated in a systematic review of 6 RCTs by Mannan and Smith (2016). The most commonly used PSI was TruMatch. Meta-analysis showed a significant decrease in the risk of femoral rotational malalignment (see Table 2). Only 1 study identified evaluated tibial rotational alignment.

Radiologic alignment was evaluated in a systematic review of 12 RCTs by Alcelik et al (2017). Meta-analysis showed no significant benefit from using patient-specific cutting blocks compared with standard instrumentation in TKA to aid in the positioning of the tibial or the femoral components. Furthermore sagittal plane tibial component positioning was worse in the patient-specific group than in the traditional group.

The key question we considered is whether these modest differences in the number of outliers greater than 3° impacted functional outcomes. This question was addressed in a meta-analysis by

Mannan et al (2017), who identified 5 RCTs and 3 prospective comparative studies that assessed functional outcomes. Meta-analysis indicated that functional outcomes did not differ significantly when measured at up to 24 months after surgery (see Table 3).

**Table 1. Meta-Analytic Characteristics**

Study	Dates	Trials	N (Range) <sup>a</sup>	Designs	Outcomes
Thienpont et al (2017)	2011-2015	44	5822 (29-865)	RCTs and cohort	Coronal and sagittal malalignment >3°
Mannan and Smith (2016)	2000-2014	6	444 (40-128)	RCTs	Femoral rotational malalignment >3°
Alcelik et al (2017)	1966- 2016	12	1087	RCTs	Coronal and sagittal malalignment >3°
Mannan et al (2017)	2000-2015	8	828 (48-232)	RCTs and cohort	Functional outcomes

RCT: randomized controlled trial.

<sup>a</sup>Patients.

**Table 2. Meta-Analytic Results for Malalignment Outcomes**

Study	Trials	N (knees)	Malalignment (>3°)	RR	95% CI	p	I <sup>2</sup> , %
Thienpont et al (2017)	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
Mannan and Smith (2016)	6	444	Femoral rotational alignment	0.40	0.16 to 0.95	0.04	62
Alcelik et al (2017)	12	1087	Mechanical axis	0.96	0.78 to 1.17	0.65	42
			Coronal plane femoral	0.75	0.56 to 1.01	0.06	37
			Coronal plane tibial	1.35	0.94 to 1.95	0.11	43
			Sagittal plane femoral	0.91	0.68 to 1.22	0.04	55
			Sagittal plane tibial	1.41	1.09 to 1.84	0.01	44
Femoral rotation	0.55	0.08 to 1.08	0.08	63			

CI: confidence interval; RR: relative risk.

**Table 3. Meta-Analytic Results for Functional Outcomes**

Study	Trials	N (knees)	Functional Outcome Measures	FU, mo	MD	95% CI	p	I <sup>2</sup> , %
Mannan et al (2017)	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.

### Randomized Controlled Trials

RCTs published between 2016 and 2018 that compared PSI with conventional instrumentation and reported functional outcomes are summarized next.

Boonen et al (2016) reported on a multicenter, double-blind RCT that evaluated clinical outcomes for PSI using Signature instrumentation. With a total of 180 patients, the trial was powered to detect a clinically significant difference on the Knee Society Score at 2 years. At follow-up, there were no statistically or clinically significant differences between groups on any

of the 5 clinical outcome measures (Knee Society Score, Oxford Knee Score, Western Ontario and McMaster Universities Osteoarthritis Index, visual analog scale score for pain, EuroQol-5D-3L index score, EuroQol-5D-3L visual analog scale health). Alvand et al (2017) reported similar component alignment and positioning with no difference in Oxford Knee Score in 43 patients undergoing mobile-bearing medial unicompartmental knee arthroplasty using PSI guides compared with conventional instrumentation. Kosse et al (2017) also reported similar stability and alignment with no difference in multiple functional outcomes at 12 months in 42 patients receiving Genesis II PS prosthesis with PSI guides compared with conventional instrumentation. Additionally, in 4 patients, the PSI did not fit correctly on the tibia and/or femur requiring intraoperative modifications. Maus et al (2017) reported no improvement in reducing outliers in coronal axis alignment, Knee Society Score or Knee Injury and Osteoarthritis Outcome Score in 125 patients randomized to PSI compared with conventional instrumentation. Trialists reported no improvement in reducing outliers in coronal axis alignment, Knee Society Score, or Knee Injury and Osteoarthritis Outcome Score in 125 patients randomized to PSI or conventional instrumentation. Van Leeuwen et al (2018) reported no radiologic or clinical advantages with patient-specific positioning guides for 109 patients undergoing total knee replacement randomized to PSI or to conventional instrumentation. Scores on the Knee injury and Osteoarthritis Outcome Score, the EuroQol-5D-3L descriptive system and visual analog scale, a numeric pain score, and range of motion were recorded preoperatively, and at 3 months, 1 year, and 2 years. The proportions of outliers were similar between groups, as were hip-knee-ankle angle and multiple functional outcomes evaluated. The authors concluded there was no additional benefit with PSI but additional cost. Calliess et al (2017) reported on the results of an RCT in which 200 patients undergoing TKA were randomized to kinematic alignment with custom-made cutting guides or a manual method using mechanical alignment. The Western Ontario and McMaster Universities Osteoarthritis Index scores, combined Knee Society Score, and radiologic alignment scores all showed significant differences in favor of custom-made cutting guides at 1 year. However, more outliers with poor outcomes were also seen in the group using custom cutting guides.

### **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 randomized controlled trials, comparative cohort studies, and systematic reviews of these studies. Relevant outcomes 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 randomized controlled trials have not shown a benefit of PSI systems in improving clinical outcome measures with follow-up currently extending out to 2 years. The evidence is insufficient to determine the effects of the technology on health outcomes.

### **Key Words:**

Patient-specific instrumentation, cutting guides, total knee arthroplasty, TKA, PSI systems, MyKnee, TruMatch, Prophecy, Visionaire, Signature Planner, X-PSI Knee System, Zimmer Patient-specific instruments

### **Approved by Governing Bodies:**

A number of patient-specific cutting block systems have been cleared for marketing by the U.S. Food and Drug Administration (FDA). An example is the single-use, disposable cutting guides designed and manufactured from patient imaging data (magnetic resonance imaging, computed tomography). The cutting guides are used to aid the surgeon intraoperatively in making the initial distal femoral and the initial proximal tibial bone cuts during TKA surgery. The cutting guides also establish the references for component orientations. Planning systems (e.g., from Materialise NV) for the personalized instruments have also cleared for marketing by FDA through the 510(k) process.

In 2008, the Smith & Nephew Patient Matched Instrumentation (now called Visionaire™ Patient Matched Instrumentation) was the first patient-specific cutting guide to receive FDA clearance for marketing. Other patient-specific cutting guide systems cleared for marketing include:

- MyKnee® Patient Matched Cutting Blocks (Medacta)
- Prophecy™ Pre-operative Navigation Alignment Guides (Wright Medical Technology)
- Signature™ Planner/Signature Guides (Materialise NV and Biomet)
- Visionaire Patient Matched Cutting Blocks (Smith & Nephew)
- TruMatch® Personalized Solutions (DePuy Orthopaedics)
- X-PSI Knee System (ORTHOsoft)
- Zimmer® Patient Specific Instruments and Zimmer® Patient Specific Instruments Planner (Materialise NV and Zimmer).

### **Benefit Application:**

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

ITS: Home Policy provisions apply.

FEP: Special benefit consideration may apply. Refer to member's benefit plan. FEP does not consider investigational if FDA approved and will be reviewed for medical necessity.

### **Current Coding:**

CPT Codes:

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

## **References:**

1. Alcelik I, Blomfield M, Ozturk C, et al. A comparison of short term radiological alignment outcomes of the patient specific and standard instrumentation for primary total knee arthroplasty: A systematic review and meta-analysis. *Acta Orthop Traumatol Turc.* May 2017; 51(3):215-222.
2. 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.* Aug 22 2017.
3. Blue Cross and Blue Shield Association Technology Evaluation Center. Computer-assisted navigation for total knee arthroplasty. *Technology Assessment* Feb 2007; Volume 22:Tab 10.
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6. 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.* Nov 28 2017.
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8. 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.* Oct 25 2017.
9. 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.
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11. 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.
12. Van Leeuwen J, 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.

## **Policy History:**

Medical Policy Panel, May 2018

Medical Policy Group, July 2018 (7): New Policy.

Medical Policy Administration Committee, July 2018

Available for comment July 5 through August 18, 2018

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*This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date*



*hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.*

*This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.*