| 7.01.144 | Patient-Specific Instrumentation (e.g., Cutting Guides) for Joint Arthroplasty | | |
|---|---|---|---|
| **Original Policy Date:** | November 26, 2014 | **Effective Date:** | June 1, 2022 |
| **Section:** | 7.0 Surgery | **Page:** | Page 1 of 17 |

## 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

## 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. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

## 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 partial or total knee arthroplasty (also called knee replacement). Knee arthroplasty is an established treatment for relief from significant, disabling pain caused by advanced arthritis. This intervention is considered among the most successful medical procedures in the United States regarding the degree of improvement in functional status and quality of life. As a result of the success of knee arthroplasty, the increase in the aging population, and the desire of older adults to remain physically active, the incidence of knee arthroplasty is increasing rapidly. It is projected that by 2030, the demand for knee replacement will approach 3.5 million procedures annually.[1,]

Knee arthroplasty is performed by removing the damaged cartilage surface and a portion of underlying bone using a saw guided by templates and jigs. The cartilage and bone removed from the distal femur and proximal tibia are replaced with implants that recreate the surface of the joint. Patellar resurfacing may also be performed. Three-dimensional implant alignment (coronal, sagittal, axial) is considered to be critical for joint articulation and implant longevity. Less than 3° deviation from the rotational or mechanical axis, as determined by a straight line through the center of the hip, knee, and ankle on the coronal plane, is believed to minimize the risk of implant wear, loosening, instability, and pain.

### *Interventions*

The therapy being considered is patient-specific instrumentation (e.g., cutting guides). The cutting guides are used to aid the surgeon intraoperatively in making the initial distal femoral and the initial proximal tibial bone cuts during knee arthroplasty surgery. The cutting guides also establish the references for component orientations. The placement of conventional cutting guides (templates and jigs) is based on anatomic landmarks or computer navigation (see evidence review 7.01.96). Use of conventional instrumentation has been shown to result in malalignment of approximately one-third of implants in the coronal plane. Computer-assisted navigation can significantly reduce the proportion of malaligned implants compared with conventional instrumentation, but has a number of limitations including a lack of rotational alignment, increased surgical time, and a long learning curve. Also, no studies have demonstrated an improvement in clinical outcomes with computer-assisted navigation.

### *Comparators*

For patients undergoing knee arthroplasty, conventional cutting guides are currently being used for knee arthroplasty (see intervention description).

### *Outcomes*

The general outcomes of interest are symptoms, functional outcomes, and quality of life. Commonly used instruments to measure these outcomes include the Knee Society Score (KSS), Oxford Knee Score, range of movement, Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), and visual analog scales.

The surrogate outcome measure of a reduction in malalignment may be informative to support improvement with the new technology. However, a reduction in the percentage of malaligned implants has not been shown to result in improved clinical outcomes and is, therefore, not sufficient to demonstrate an improvement in clinical outcomes. Also, no long-term studies are currently available that could provide data on revision rates. It should also be noted that the design of these devices is evolving, and results from older studies may be less relevant for contemporary designs.

The proposed benefits of using patient-specific instrumentation during knee arthroplasty include improved alignment, decreased operative time, increased patient throughput, fewer instrument trays, reduced risk of fat embolism and intraoperative bleeding (no intramedullary canal reaming), shorter recovery, reduced postoperative pain, reduced revision rate, and reduced costs. However, the nonsurgical costs of the procedure may be increased due to the requirement for preoperative computed tomography or magnetic resonance imaging, preoperative review of the template, and fabrication of the patient-specific instrumentation. Also, the patient-specific template relies on the same anatomic landmarks as conventional knee arthroplasty and does not take soft tissue balancing into account. Thus, evaluation of this technology should also address the reliability of the cutting guides and the need for intraoperative changes such as conversion to conventional instrumentation.

Component alignment and perioperative outcomes are short-term outcomes. Pain, function, and quality of life should be measured in long-term studies (2 years or longer), in particular because component alignment is hypothesized to correlate to component longevity.

**Study Selection Criteria**

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

**Review of Evidence**

**Systematic Reviews**

There are a number of systematic reviews on patient specific instrumentation for total knee arthroplasty. We focus on the most recent, comprehensive, and relevant analyses (Table 2 ). Three of these reported functional outcomes in addition to measures of malalignment outcomes.[2,3,4,]

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

| Study | Lin et al (2020)[4,] | Gong et al (2018)[5,] | Thienpo nt et al (2017)[3,] | Mannan et al (2017)[6,] |
|---|---|---|---|---|
| Abane et al (2015)[7,] | ● | ● | ● | ● |
| Abane et al(2017) [8,] | ● | | | |
| Abdel et al (2014)[9,] | ● | | ● | |
| Anderl et al (2016)[10,] | | | ● | ● |
| Bali et al (2012)[11,] | | | ● | |
| Barke et al (2013)[12,] | | | ● | |
| Barrack et al (2012)[13,] | | | ● | |
| Barrett et al (2014)[14,] | | | ● | |
| Boonen et al (2012)[15,] | | | ● | |
| Boonen et al(2013)[16,] | ● | ● | ● | |
| Boonen et al (2016)[17,] | ● | ● | | |
| Chareancholvanich et al (2013)[18,] | ● | ● | ● | |
| Chen et al (2014)[19,] | | | ● | |
| Chen et al (2015)[20,] | | | ● | ● |

| Study | Lin et al (2020)[4], | Gong et al (2018)[5], | Thienpo nt et al (2017)[3], | Mannan et al (2017)[6], |
|---|---|---|---|---|
| Chotanaphuti et al (2014)[21], | ● | | ● | |
| Cucchi et al (2018)[22], | ● | | | |
| Daniilidis et al(2014)[23], | | | ● | |
| De Vloo et al (2017)[24], | ● | ● | | |
| DeHann et al (2014)[25], | | | ● | |
| Ferrara et al (2015)[26], | | | ● | |
| Gan et al (2015)[27], | | ● | | |
| Hamilton et al(2013)[28], | ● | ● | ● | |
| Heyse et al (2014)[29], | | | ● | |
| Huijbregts et al (2016)[30], | ● | ● | | |
| Kassab et al (2014)[31], | | | ● | |
| Khuangsirikul et al (2014)[32], | | ● | | |
| Kosse et al ( 2018)[33], | ● | ● | | |
| Kotela et al(2014)[34], | ● | ● | ● | |
| Kotela et al (2015)[35], | ● | ● | ● | ● |
| MacDessi et al (2014)[36], | | | ● | |
| Marimuthu et al (2014)[37], | | | ● | |
| Maus et al (2017)[38], | ● | ● | | |
| Molicnik et al (2015)[39], | ● | | ● | |
| Nabav et al (2015)[40], | | | ● | |
| Nam et al (2016)[41], | | | ● | |
| Nankivell et al (2015)[42], | | | ● | |
| Ng et al (2012)[43], | | | ● | |
| Noble et al (2012)[44], | ● | | ● | |
| Nunley et al (2012)[45], | | | ● | |
| Parratte et al (2013)[46], | ● | ● | ● | |
| Pfitzner et al (2014)[47], | ● | | | ● |
| Pietsch et al (2013)[48], | ● | ● | ● | |
| Renson et al (2014)[49], | | | ● | |
| Roh et al (2013)[50], | ● | ● | ● | |
| Schotanus et al (2018) [51], | ● | | | |
| Silva et al (2014)[52], | ● | ● | ● | |
| Stronach et al (2014)[53], | | | ● | |
| Thienpoint et al (2015)[54], | | | ● | |

| Study | Lin et al (2020)[4] | Gong et al (2018)[5] | Thienpo nt et al (2017)[3] | Mannan et al (2017)[6] |
|---|---|---|---|---|
| Van Leeuwen et al (2018)[55] | ● | ● | | |
| Victor et al (2014)[56] | | ● | ● | |
| Vide et al (2017)[57] | ● | ● | ● | |
| Vundelinckx et al (2013)[58] | ● | ● | ● | |
| Woolson et al (2014)[59] | ● | ● | ● | ● |
| Yaffe et al (2014)[60] | | | ● | ● |
| Yan et al (2015)[61] | ● | ● | ● | ● |
| Zhu et al (2015)[62] | | | ● | |

**Table 3. Meta-Analysis Characteristics**

| Study | Dates | Trials | N (Range) | Designs | Outcomes |
|---|---|---|---|---|---|
| Lin et al (2020)[4] | 2012-2018 | 29 | 2487 (24 to 180) | RCTs | Mechanical axis malalignment, functional outcomes |
| Gong et al (2018)[5] | 1966-2018 | 23 | 2058 (40 to 180) | RCTs | Coronal, sagittal, axial malalignment >3° |
| Thienpont et al (2017)[3] | 2011-2015 | 44 | 5822 (29 to 865) | RCTs and cohort | Coronal and sagittal malalignment >3° |
| Mannan et al (2017)[6] | 2000-2015 | 8 | 828 (48 to 232) | RCTs and cohort | Functional outcomes |

RCT: randomized controlled trial.

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

| Study | Trials | N (knees) | Malalignment (>3°) | RR | 95% CI | p | $I^2$, % |
|---|---|---|---|---|---|---|---|
| Lin et al (2020)[4] | 17 | 1577 | Hip-knee-ankle angle | 0.88 | 0.74 to 1.04 | .13 | 38 |
| Gong et al (2018)[5] | 14 | 1273 | Hip-knee-ankle angle | 0.94 | 0.72 to 11.24 | .68 | 41 |
| | 12 | 1137 | Femoral/coronal plane | 0.86 | 0.57 to 1.30 | .47 | 37 |
| | 12 | 1137 | Tibial/coronal plane | 1.36 | 0.75 to 2.49 | .31 | 46 |
| | 9 | 941 | Femoral sagittal alignment | 1.07 | 0.84 to 1.35 | .59 | 46 |
| | 10 | 989 | Tibial/sagittal plane | 1.31 | 0.92 to 1.86 | .13 | 57 |
| Thienpont et al (2017)[3] | 29 | 3479 | Coronal mechanical axis | 0.79 | 0.65 to 0.95 | .013 | 51 |
| | 13 | 1527 | Tibial/sagittal plane | 1.32 | 1.12 to 1.56 | .001 | 0 |
| | 15 | 1943 | Femoral/coronal plane | 0.74 | 0.55 to 0.99 | .043 | 32 |
| | 17 | 1983 | Tibial/coronal plane | 1.30 | 0.92 to 1.83 | .13 | 21.5 |

CI: confidence interval; RR: relative risk.

The key question we considered is whether differences in the number of outliers greater than 3° impacted functional outcomes. A meta-analysis by Mannan et al (2017) indicated that functional outcomes did not differ significantly when measured at up to 2 years after surgery (Table 5).[6] More recent meta-analyses have shown mixed outcomes with regard to benefit. Thienpornt et al (2017) showed an improvement in KSS functional score with patient specific instrumentation over conventional instrumentation, but there was no significant improvement in the KSS knee score.[3] In contrast, Lin et al (2020) showed a significant improvement in the overall KSS with patient specific instrumentation but failed to show an improvement in the Oxford Knee Score.[4] The follow-up period for Lin et al was only 3 months and does not provide information on long-term outcomes.

**Table 5. Meta-Analysis Results for Pain and Function Outcomes**

| Study | Trials | N (knees) | Functional Outcome Measures | FU, months | MD | 95% CI | p | $I^2$, % |
|---|---|---|---|---|---|---|---|---|
| Lin et al (2020)[4] | 3 | 337 | KSS | 3 | -0.17 | -0.33 to -0.02 | .02 | 0 |
| | 5 | 651 | Oxford Knee Score | NR | 0.07 | -0.09 to 0.22 | .4 | 32 |

| Study | Trials | N (knees) | Functional Outcome Measures | FU, months | MD | 95% CI | p | $I^2$, % |
|---|---|---|---|---|---|---|---|---|
| **Thienpornt et al (2017)[3,]** | 6 | 300 | KSS functional score | 16.7 | 4.3 | 1.5 to 7.2 | .003 | NR |
| | 6 | 300 | KSS knee score | 16.7 | 1.5 | -0.3 to 3.3 | .093 | NR |
| **Mannan et al (2017)[6,]** | 3 | 195 | KSS functional score | 24 | -0.21 | -9.31 to 8.88 | .96 | 82 |
| | 3 | 195 | KSS knee score | 24 | 0.90 | -6.15 to 7.95 | .80 | 85 |
| | 5 | 244 | Range of motion (deg) | 3 to 24 | 3.72 | -0.46 to 7.91 | .08 | 70 |
| | 3 | 118 | Oxford Knee Score | 3 to 12 | -0.48 | -1.83 to 0.86 | .48 | 0 |

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

## Perioperative Outcomes

### Systematic Reviews

Three of the meta-analyses included in this review reported perioperative outcomes (Table 6).[5,3,4,] Total operative time was significantly shorter with patient specific instrumentation in all studies but the clinical significance of these differences is not clear. There was high heterogeneity among the studies that limits the application to clinical practice. Gong et al (2018) and Lin et al (2020) reported hospital length of stay and did not find a significant difference between patient specific instrumentation and conventional instrumentation groups. All 3 meta-analyses also showed a significant reduction in blood loss with patient specific instrumentation; however, there was high heterogeneity amongst the studies.

**Table 6. Meta-Analysis Results for Perioperative Outcomes**

| Study | Operative Time (Minutes) | Blood Loss (mL) | Hospital LOS |
|---|---|---|---|
| **Lin et al (2020)[4,]** | | | |
| **Total N** | 1404 | 300 | 543 |
| **MD (95% CI); p-value** | -0.36 (-0.67 to -0.04); p=.03 | -0.49 (-0.92 to -0.05); p=.03 | -0.10 (-0.27 to 0.07); p=.24 |
| **$I^2$** | 88% | 71% | 33% |
| **Gong et al (2018)[5,]** | | | |
| **Total N** | 871 | 450 | 685 |
| **MD (95% CI); p-value** | -7.35 (-10.95 to -3.75); p<.0001 | -83.42 (-146.65 to -20.18); p=.010 | -0.16 (-0.40 to 0.07); p=.17 |
| **$I^2$** | 78% | 74% | 19% |
| **Thienpo nt et al (2017)[3,]** | | | NR |
| **Total N** | 3480 | 1251 | |
| **MD (95% CI); p-value** | -4.4 (-7.2 to -1.7); p=.002 | -37.9 (-68.4 to -7.4); p=.015 | |
| **$I^2$** | 94% | 91% | |

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

### Randomized Controlled Trials

Several RCTs have yet to be incorporated into available meta-analyses.[63,64,65,66,]Table 7 highlights some of these RCTs. Additionally, several key RCTs included in available meta-analyses examine functional outcomes that are not evaluated by the meta-analyses.[17,33,] These key trials include Boonen et al (2016) and Kosse et al (2017) and are also included in Table 7. Results for the trials included in Table 7 were consistent with previous studies as summarized in Table 6. All but 1 trial reported no significant differences between patient specific instrumentation and conventional intervention on measures of pain, function, and quality of life for up to 5 years (Table 8). Calliess et al (2017) reported significant outcomes with regard to KSS and WOMAC; however, follow-up did not extend beyond 1 year.[64,]

Both Boonen et al (2016) and Kosse et al (2017) also reported on the outcome of pain measured by the visual analog score. Neither study reported a difference in pain improvement between groups. Boonen et al (2016) also reported no differences with regard to WOMAC index and EuroQoL-5D quality of life index. Kosse et al (2017) did not report any significant differences between groups for various outcomes, including the Kujala score (also referred to as the Patella score) and the Knee Injury and Osteoarthritis Outcome Score. The RCTs used a variety of patient specific instrumentation systems.

**Table 7. Characteristics of Key RCTs of Patient Specific Instrumentation for Total Knee Arthroplasty**

| Study; Trial | Countries | Sites | Dates | Participants | System (Manufacturer) |
|---|---|---|---|---|---|
| **Hampton et al (2022)[66],** | United Kingdom | 2 | 2013-2015 | 88 | NexGen Knee (Zimmer) |
| **Alvand et al (2017)[63],** | United Kingdom | 1 | 2012-2014 | 46 | Signature (Zimmer Biomet) |
| **Kosse et al (2017)[33],** | The Netherlands | 1 | 2012-2013 | 42 | Visionaire (Smith & Nephew) |
| **Calliess et al (2017)[64],** | Germany | 2 | 2012-2013 | 200 | Triathlon System (Stryker) |
| **Boonen et al (2016)[17],** | The Netherlands | 2 | 2010-2013 | 180 | Materialise (Leuven) |
| **Tammachote et al (2017)[65],** | Thailand | 1 | 2012-2014 | 108 | Visionaire (Smith & Nephew) |

RCT: randomized controlled trial.

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

| Study | KSS | Kujala | VAS Pain | OKS | EuroQoL-5D | KOOS | WOMAC |
|---|---|---|---|---|---|---|---|
| **Hampton et al (2022)[66],** | | NR | NR | | | NR | NR |
| **N (FU)** | 77 knees (5 years) | | | 77 knees (5 years) | 77 knees (5 years) | | |
| **PSI increase from baseline, mean (SD)** | 92.5 (6.8) | | | 40.8 (6.9) | | | |
| **Conventional increase from baseline, mean (SD)** | 92.4 (7.1) | | | 42.5 (7.4) | | | |
| **p-value** | .86 | | | .24 | .78 | | |
| **Alvand et al (2017)[63],** | NR | NR | NR | | NR | NR | NR |
| **N (FU)** | | | | 45 (1 year) | | | |
| **PSI, mean (range)** | | | | 18.3 (4 to 31) | | | |
| **Conventional, mean (range)** | | | | 18.2 (5 to 31) | | | |
| **p-value** | | | | NS | | | |
| **Boonen et al (2016)[17],** | | | | | | | |
| **N (FU)** | 163 (2 years) | | 163 (2 years) | 163 (2 years) | 163 (2 years) | | 163 (2 years) |
| **PSI, mean (95% CI)** | 81.9 (78.1 to 85.8) | | 20.4 (14.4 to 26.5) | 15.2 (13.1 to 17.2) | 72.5 (68.2 to 76.7) | | 80.7 (76.3 to 85.0) |
| **Conventional, mean (95% CI)** | 82.2 (78.6 to 85.8) | | 17.4 (12.2 to 22.6) | 15.1 (13.1 to 17.1) | 76.2 (71.9 to 80.5) | | 86.6 (83.4 to 89.8) |
| **p-value** | .807 | | .227 | .304 | .968 | | .753 |
| **Calliess et al (2017)[64],** | | NR | NR | NR | NR | NR | |

| Study | KSS | Kujala | VAS Pain | OKS | EuroQoL-5D | KOOS | WOMAC |
|---|---|---|---|---|---|---|---|
| **N (FU)** | 200 (1 year) | | | | | | 200 (1 year) |
| **PSI, mean (SD)** | 190 ( 18) | | | | | | 13 ( 16) |
| **Conventional, mean (SD)** | 178 ( 17) | | | | | | 26 ( 11) |
| **p-Value** | .02 | | | | | | .001 |
| **Kosse et al (2017)[33],** | | | | NR | NR | | NR |
| **N (FU)** | 42 (1 year) | 42 (1 year) | 42 (1 year) | | | 42 (1 year) | |
| **PSI, median (range)** | 180 (135 to 200) | 70 (44 to 100) | 5 (0 to 40) | | | 94 (50 to 100) | |
| **Conventional, median (range)** | 175 (115 to 200) | 62 (33 to 95) | 11 (0 to 81) | | | 81 (33 to 100) | |
| **p-value** | NS | NS | NS | | | NS | |
| **Tammachote (2017)[65],** | | | | | | | |
| **N (FU)** | | | | | | | 102 (2 years) |
| **PSI, mean (SD)** | | | | | | | 5 ( 6) |
| **Conventional, mean (SD)** | | | | | | | 4 ( 6) |
| **MD (CI); p-value** | | | | | | | 1 (-1.8 to 3), p=.62 |

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

### Summary of Evidence

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.

### 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.[67] 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 2023 |
| **NCT01696552** | Patient-specific Positioning Guides (PSPG) Technique Versus Conventional Technique in Total Knee Arthroplasty - a Prospective Randomized Study | 109 | Jan 2024 |
| **NCT02177227**[a] | Attune With TruMatch TM Personalized Solutions Instruments: A Prospective Randomized Controlled Trial Comparing Clinical and Economic Outcomes in Patients With a BMI Between 30 and 50 | 194 | Aug 2024 |
| **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<br>Policy revision without position change |
| 06/01/2019 | Policy revision without position change<br>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. |
| 06/01/2022 | 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** |
| **Patient-Specific Instrumentation (e.g., Cutting Guides) for Joint Arthroplasty 7.01.144**<br><br>**Policy Statement:**<br>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**. | **Patient-Specific Instrumentation (e.g., Cutting Guides) for Joint Arthroplasty 7.01.144**<br><br>**Policy Statement:**<br>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**. |