Policy

Use of custom implants or 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.

Related Policies

7.01.550 Knee Arthroplasty, Adults

Policy Guidelines

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

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

Description

Custom knee implants and patient-specific instrumentation (PSI) have been developed as alternatives to off-the-shelf implants and conventional cutting guides for joint arthroplasty. Custom implants and 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 custom implants and patient-specific cutting guides are to increase surgical efficiency and to improve implant alignment and clinical outcomes.

Total knee arthroplasty (TKA; also called knee replacement) and unicompartmental knee arthroplasty (UKA) are established treatments for relief from significant, disabling pain caused by advanced arthritis. TKA is considered
among the most successful medical procedures in the United States in terms of 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 and UKA are performed by removing the damaged cartilage surface and a portion of underlying bone using a saw guided by templates and jigs. The removed cartilage and bone 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. Generally, 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.

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. (2) 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. In addition, no studies have demonstrated an improvement in clinical outcomes with computer-assisted navigation compared with conventional instrumentation.

Custom implants and patient-specific instrumentation (PSI) have been developed as alternatives to off-the-shelf implants and conventional cutting guides, with the goal of improving both alignment and surgical efficiency. A number of patient-specific cutting guides and custom implants (with their associated cutting guides) are currently being marketed (see Regulatory Status section). Custom implants and patient-specific guides are constructed with the use of preoperative 3-dimensional CT or MRI scans, which are taken about 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 and implants, makes adjustments, and approves the surgical plan, the manufacturer fabricates the custom knee implants and/or disposable cutting guides.

The proposed benefits of using patient-specific implants and 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 CT or MRI, preoperative review of the template, and fabrication of the PSI. In addition, 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.

Regulatory Status
A number of patient-specific cutting block systems and custom knee implants have been cleared for marketing by the U.S. Food and Drug Administration (FDA). An example of one device description is single-use, disposable cutting guides designed and manufactured from patient imaging data (MRI/CT). The cutting guides are used to aid the surgeon intraapeutically 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 N.V.) for the personalized instruments have also received marketing clearance 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)
  - Signature™ Planner/Signature Guides (Materialise N.V. and Biomet),
  - ShapeMatch® Cutting Guide (Stryker)
  - TruMatch® Personalized Solutions (DePuy Orthopaedics)
  - Prophecy™ Pre-operative Navigation Alignment Guides (Wright Medical Technology)
Custom knee implants with their associated patient-specific cutting guides (iJig® instrumentation, ConforMIS) include:
  - ConforMIS iTotal® Cruciate Retaining Knee Replacement System (ConforMIS)
  - ConforMIS iTotal® Posterior Stabilized Knee Replacement System (ConforMIS)
  - ConforMIS iUni® Unicondylar Knee Replacement System (ConforMIS)

FDA product codes: JWH, MBH, OIY, OOG.

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.

Benefit Application

N/A

Rationale

This evidence review was created September 2014 and updated with a literature search using the MEDLINE database. The most recent literature review was performed through June 20, 2016.

Assessment of efficacy for new technology involves a determination of whether the technology improves health outcomes. The optimal study design for a therapeutic intervention is a randomized controlled trial (RCT) that includes clinically relevant measures of health outcomes. Intermediate outcome measures, also known as surrogate outcome measures, may also be adequate if there is an established link between the intermediate outcome and true health outcomes. Nonrandomized comparative studies and uncontrolled studies can sometimes provide useful information on health outcomes, but are prone to biases such as noncomparability of treatment groups, the placebo effect, and variable natural history of the condition.

A number of RCTs compare patient-specific instrumentation (PSI) versus conventional instrumentation for total knee arthroplasty (TKA). Therefore, this evidence review will focus on systematic reviews and RCTs that address clinical outcomes. 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. In addition, because this is a relatively new technology, no long-term studies are currently available that could provide data on revision rates.

Patient-Specific Instrumentation

Systematic Reviews

Systematic reviews published to date have not found an improvement in accuracy or clinically significant decrease in operative time with PSI.
Thienpont et al. included 8 RCTs and 8 cohort studies (total N=1755 patients) in their 2014 meta-analysis. (3) The PSI systems used in the RCTs were Signature™ (Biomet), 4-7 Zimmer Patient Specific Instruments® (Zimmer), (8,9,7) TruMatch® (DePuy), (10,11,7) and Visionaire (Smith & Nephew). (7) This systematic review found no significant difference in the likelihood of mechanical axis malalignment with PSI versus conventional TKA across all studies, or when divided by RCTs (RR [risk ratio], 1.14, p=0.445) and cohort studies (RR=0.70, p=0.289). Alignment of the tibial component was significantly worse in the coronal and sagittal planes when using PSI. For the femoral component, alignment was significantly better in the coronal plane but not in the sagittal plane with PSI. Axial alignment of the tibial and femoral components did not differ significantly between PSI and conventional instrumentation. Funnel plots showed no strong evidence of publication bias.

A 2014 meta-analysis by Fu et al. included 10 RCTs (total N=837 knees) comparing PSI with conventional instrumentation. (12) There were no significant differences between the 2 groups for outliers from a neutral mechanical axis or femoral component placement. Malalignment of the tibial component was higher with PSI in both the coronal plane (RR=2.50, p=0.02) and the sagittal plane (RR=1.47, p=0.02). Surgical time was shorter by a modest 3.54 minutes (weighted mean difference) with PSI. A funnel plot showed minimal evidence of publication bias. The 9 comparative studies (2 RCTs) in a 2014 meta-analysis by Voleti et al. used 4 different PSI systems and included 957 knee arthroplasties. (13) There was no significant difference between the treatment groups in the percentage of outliers greater than 3 degrees from target alignment (p=0.7), while standard instrumentation had greater accuracy in the mechanical axis (p=0.02). Sagittal alignment, operative time, intraoperative blood loss, and cost were similar between groups (p>0.1).

**Randomized Controlled Trials**

Additional RCTs, published after the search dates of the systematic reviews, have compared PSI and conventional instrumentation. One RCT of 112 patients found no significant improvement in alignment with use of the Signature™ Personalized Patient Care System. (14) Another RCT with 50 patients found no significant improvement in Knee Society Scores (KSS) at a minimum 6-month follow-up and an increase in the percentage of outliers with TruMatch® PSI (47% vs 6%, p<0.000). (15) It was also reported that PSI was abandoned during surgery in 7 of 22 knees (31.8%) because of possible malalignment. In 55%, the surgeon adjusted the joint space by increasing the bone (vs 23% of control knees), and a different size of implant than planned was needed in 41% of PSI procedures. A 2014 publication reported clinical outcomes from 40 patients randomized to Zimmer® PSI or conventional instrumentation; alignment data had previously been reported and was included in the systematic reviews. (9,16) Similar scores were obtained for the 2 groups for gait parameters and patient-reported outcomes (KSS, Knee Injury and Osteoarthritis Outcome Score, and 12-Item Short-Form Health Survey) at 3-month follow-up. In 2015, an RCT of 60 patients found no benefit in alignment, gait, function, or quality of life after PSI for unicompartmental knee arthroplasty. (17)

**Ongoing and Unpublished Clinical Trials**

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

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
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<td>NCT02186587</td>
<td>CT-navigated, Patient-specific Custom Total Knee Replacement Versus Standard Total Knee Replacement: Comparison With a Marker-less Gait Analysis System and Validated Outcome Scores</td>
<td>115</td>
<td>Dec 2015</td>
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<td>NCT01696552</td>
<td>Patient-specific Positioning Guides (PSPG) Technique Versus Conventional Technique in Total Knee Arthroplasty - a Prospective Randomized Study</td>
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<td>May 2020</td>
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<td>NCT01117571*</td>
<td>A Prospective, Multi-Center Study to Evaluate the ConforMIS iUni® G2 Unicompartmental Knee Resurfacing Device</td>
<td>120</td>
<td>Dec 2020</td>
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<tr>
<td>NCT02096393</td>
<td>A Prospective, Randomised Control Trial Assessing Clinical and Radiological Outcomes of Patient Specific Instrumentation In Total Knee Arthroplasty</td>
<td>100</td>
<td>Dec 2024</td>
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<tr>
<td>NCT02494544*</td>
<td>A Prospective, Randomized, Multicenter Study to Evaluate the ConforMIS iTotal® (CR) Knee Replacement System Versus Off-the-Shelf Replacement</td>
<td>800</td>
<td>Aug 2025</td>
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**Unpublished**
Summary of Evidence
The evidence on patient-specific cutting guides and custom knee implants in patients undergoing unicompartmental or total knee arthroplasty (TKA) includes a number of small randomized controlled trials (RCTs) and Systematic reviews. Relevant outcomes include symptoms, functional outcomes, quality of life, resource utilization, and treatment-related morbidity. The systematic reviews found no significant improvement in implant alignment, with some studies reporting worse alignment with PSI. To date, no functional benefits have been demonstrated. Larger RCTs examining the various PSI systems are in progress, and these systems differ in both planning and manufacturing; therefore, future assessment of PSI should address the specific system used. The evidence is insufficient to determine the effects of the technology on health outcomes.

Practice Guidelines and Position Statements
No guidelines or position statements that mention custom cutting guides or blocks for TKA were identified.

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

References

2. Blue Cross and Blue Shield Association Technology Evaluation Center. Computer-assisted navigation for total knee arthroplasty. Technology Assessment Feb 2007;Volume 22, Tab 10. PMID 18411501

Appendix

N/A

History

<table>
<thead>
<tr>
<th>Date</th>
<th>Reason</th>
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<tbody>
<tr>
<td>01/13/15</td>
<td>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.</td>
</tr>
<tr>
<td>07/12/16</td>
<td>Annual Review. No change to policy statements.</td>
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U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at
https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

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Hmoob (Hmong):

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