MEDICAL POLICY – 7.01.144

Patient-Specific Cutting Guides and Custom Knee Implants

Effective Date: Oct. 1, 2017
Last Revised: Sept. 21, 2017
Replaces: N/A

RELATED MEDICAL POLICIES:
7.01.550 Knee Arthroplasty in Adults

Select a hyperlink below to be directed to that section.

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

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Introduction

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

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

<table>
<thead>
<tr>
<th>Equipment</th>
<th>Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td>Custom implants or patient-specific instrumentation</td>
<td>Use of custom implants or patient-specific instrumentation (eg, cutting guides) for joint arthroplasty, including but not limited to use in unicompartmental or total knee arthroplasty, is considered investigational.</td>
</tr>
</tbody>
</table>

Coding

There are no specific codes for cutting guides and custom knee implants.

Related Information

N/A

Evidence Review

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.
Background

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 based on the degree of improvement in functional status and quality of life. The incidence of TKA is rapidly increasing due to its rate of success, the increase in the aging population, and the desire of older adults to remain physically active. It is projected that by 2030, the demand for knee replacement will approach 3.5 million procedures annually.\(^1\)

TKA is performed by using a saw guided by templates and jigs to remove the knee’s damaged cartilage surface and a portion of underlying bone. 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.

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 in the coronal plane of approximately one-third of implants.\(^2\) 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. Also, no studies have demonstrated an improvement in clinical outcomes with computer-assisted navigation compared with conventional instrumentation.

Custom implants and patient-specific instrumentation 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 the Regulatory Status section). Custom implants and 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 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 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.

Summary of Evidence

For individuals who are undergoing total knee arthroplasty who receive patient-specific cutting guides and custom knee implants, 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 may have assessed now obsolete PSI systems. Larger randomized controlled trials examining specific PSI systems and patient-specific implants are in progress and should address some of the limitations of the current literature. Most importantly, trials should demonstrate an improvement in clinical outcome measures. With follow-up currently extending out to 2-years, no functional benefits have been demonstrated. The evidence is insufficient to determine the effects of the technology on health outcomes.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this policy are listed in Table 1.
Table 1. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
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<tbody>
<tr>
<td><strong>Ongoing</strong></td>
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<tr>
<td>NCT02845206</td>
<td>Randomised Controlled Trial of Patient Specific Instrumentation vs Standard Instrumentation in Total Knee Arthroplasty</td>
<td>172</td>
<td>Feb 2020</td>
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<tr>
<td>NCT03148379*</td>
<td>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.</td>
<td>300</td>
<td>Apr 2020</td>
</tr>
<tr>
<td>NCT01696552</td>
<td>Patient-specific Positioning Guides (PSPG) Technique Versus Conventional Technique in Total Knee Arthroplasty - a Prospective Randomized Study</td>
<td>109</td>
<td>Jan 2024</td>
</tr>
<tr>
<td>NCT02177227*</td>
<td>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</td>
<td>184</td>
<td>Aug 2024</td>
</tr>
<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>
</tr>
<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>
</tr>
<tr>
<td><strong>Unpublished</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT02128464</td>
<td>Comparison of Customized Cutting Block (Visionaire™) and Conventional Total Knee Arthroplasty: A Prospective Randomized Control Trial</td>
<td>108</td>
<td>May 2014 (completed)</td>
</tr>
<tr>
<td>NCT01483066*</td>
<td>A Prospective, Randomized, Post-market, Multi-center Study and Cost-effectiveness Analysis of ShapeMatch Technology A Prospective, Randomized, Post-market, Multi-center Study and Cost-effectiveness Analysis of ShapeMatch Technology</td>
<td>150</td>
<td>Dec 2018 (suspended)</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.

* Denotes industry-sponsored or cosponsored trial.
**Practice Guidelines and Position Statements**

No guidelines or position statements that mention custom cutting guides or blocks for TKA were identified.

**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.

**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 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 (eg, from Materialise N.V.) for the personalized instruments have also received marketing clearance by the 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 NV and Biomet)
- TruMatch® Personalized Solutions (DePuy Orthopaedics)
- Prophecy™ Pre-operative Navigation Alignment Guides (Wright Medical Technology)
- Zimmer® Patient Specific Instruments and Zimmer® Patient Specific Instruments Planner (Materialise NV and Zimmer).

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

References


History

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<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>08/01/16</td>
<td>Annual Review, approved July 12, 2016. No change to policy statements.</td>
</tr>
</tbody>
</table>
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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)

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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)
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