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 — are available and widely used. But 3-D printing allows for custom cutting guides 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 then fitted over the end of the bone to guide where the bone should be cut. Published studies show that custom cutting guides don’t result in better alignment than standard cutting guides. Some studies show the custom materials create worse alignment. More and larger studies are needed to determine how well these custom cutting guides work. For this reason, custom cutting guides 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.
<table>
<thead>
<tr>
<th>Equipment</th>
<th>Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient-specific instrumentation</strong></td>
<td>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.</td>
</tr>
</tbody>
</table>

**Coding**

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

**Related Information**

N/A

**Evidence Review**

**Description**

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 (CT) or magnetic resonance imaging (MRI) scans and proprietary planning software. The goals of PSI are to increase surgical efficiency and to improve implant alignment and clinical outcomes.
Background

**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.¹

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. 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. 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 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.

**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.

**Summary of Evidence**

For individuals who are undergoing partial or total knee arthroplasty (TKA) who receive patient-specific cutting guides, the evidence includes a number of randomized controlled trials (RCTs), 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 two years. 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>
</tr>
</thead>
<tbody>
<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>
</tr>
<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>
</tbody>
</table>

NCT: national clinical trial

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

No guidelines or position statements were identified.

Medicare National Coverage

There is no national coverage determination.

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 Food and Drug Administration (FDA) clearance for marketing. Other systems cleared for marketing by the FDA are shown in Table 2.

FDA product codes: OOG

Table 2. Patient-Specific Cutting Guides for Knee Arthroplasty

<table>
<thead>
<tr>
<th>Device Name</th>
<th>Manufacturer</th>
<th>510(K) Number</th>
<th>Clearance Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>X-Psi</td>
<td>Orthosoft</td>
<td>K131409</td>
<td>9/13/2013</td>
</tr>
<tr>
<td>iTotal</td>
<td>Conformis</td>
<td>K120068</td>
<td>2/3/2012</td>
</tr>
<tr>
<td>Prophecy</td>
<td>Wright Medical Technology</td>
<td>K103598</td>
<td>10/17/2011</td>
</tr>
<tr>
<td>Trumatch</td>
<td>Depuy Orthopaedics</td>
<td>K110397</td>
<td>8/16/2011</td>
</tr>
<tr>
<td>Shapematch</td>
<td>Stryker</td>
<td>K110533</td>
<td>5/19/2011</td>
</tr>
<tr>
<td>Signature</td>
<td>Materialise</td>
<td>K102795</td>
<td>2/2/2011</td>
</tr>
<tr>
<td>Zimmer</td>
<td>Materialise</td>
<td>K091263</td>
<td>11/19/2009</td>
</tr>
<tr>
<td>Visionaire</td>
<td>Smith &amp; Nephew</td>
<td>K082358</td>
<td>11/25/2008</td>
</tr>
</tbody>
</table>

Source: FDA


<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>
<tr>
<td>08/01/18</td>
<td>Annual Review, approved July 25, 2018. Policy updated with literature review through February 2018; references 5 and 8-12 added. Custom implants moved to new policy on 3-dimensional printed orthopedic implants. Title changed from “Patient-Specific Cutting Guides and Custom Knee Implants” to “Patient-Specific Cutting Guides for Joint Arthroplasty”.</td>
</tr>
</tbody>
</table>

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  • Written information in other formats (large print, audio, accessible electronic formats, other formats)
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  • Qualified interpreters
  • Information written in other languages

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Toll free 855-332-6396, Fax 425-918-5592. TTY 800-842-5357
Email AppealsDepartmentInquiries@LifeWiseHealth.com

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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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Français (French):

Deutsche (German):

Italiano (Italian):