Name of Blue Advantage Policy:
Patient-Specific Instrumentation for Joint Arthroplasty

Policy #: 716  Latest Review Date: April 2020
Category: Surgical  Policy Grade: B

BACKGROUND:
Blue Advantage medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:

1. Safe and effective;
2. Not experimental or investigational*;
3. Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:
   • Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient’s condition or to improve the function of a malformed body member;
   • Furnished in a setting appropriate to the patient’s medical needs and condition;
   • Ordered and furnished by qualified personnel;
   • One that meets, but does not exceed, the patient’s medical need; and
   • At least as beneficial as an existing and available medically appropriate alternative.

*Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill Original Medicare for covered services that are related to clinical trials that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).
POLICY:
Blue Advantage will treat the use of patient-specific instrumentation (e.g., cutting guides) for joint arthroplasty, including but not limited to use in unicompartmental or total knee arthroplasty as a noncovered benefit and as investigational.

Blue Advantage 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 Advantage administers benefits based on the members' contract and 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.

DESCRIPTION OF PROCEDURE OR SERVICE:
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.

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.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 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 maligned 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.
KEY POINTS:
The most recent literature update was performed through February 11, 2020.

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 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 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 and systematic reviews 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:

- Prophecy™ Pre-operative Navigation Alignment Guides (Wright Medical Technology)
- Signature™ Planner/Sigature 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)
• iTotal
• Shapematch

**BENEFIT APPLICATION:**
Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.

**CURRENT CODING:**
CPT Codes:
Effective 07/01/19:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>0561T</td>
<td>Anatomic guide 3D-printed and designed from image data set(s); first anatomic guide</td>
</tr>
<tr>
<td>0562T</td>
<td>Anatomic guide 3D-printed and designed from image data set(s); each additional anatomic guide (List separately in addition to code for primary procedure)</td>
</tr>
</tbody>
</table>

**PREVIOUS CODING:**
CPT
Prior to 07/01/19, there were no specific codes for this instrumentation. The joint arthroplasty procedure would be reported using the regular CPT codes for that surgery.

**REFERENCES:**


POLICY HISTORY:
Medical Policy Panel, May 2018
Adopted for Blue Advantage, July 6, 2018
Medical Policy Administration Committee, July 2018
Available for comment July 7 through August 20, 2018
Medical Policy Group, April 2019
Medical Policy Group, July 2019
Medical Policy Group, April 2020

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.