Patient-Specific Cutting Guides and Custom Knee Implants

Total knee arthroplasty (TKA, also called knee replacement) and unicompartmental knee arthroplasty (UKA) are established treatments for relief of 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.

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 (see policy titled Computer Assisted Surgical Navigational Orthopedic Procedures). 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. 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.
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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

There are a number of patient-specific cutting block systems and custom knee implants that have been cleared for marketing by the United States 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 a 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 FDA 510(k) marketing clearance.

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 that are 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)
- Zimmer® Patient Specific Instruments and Zimmer® Patient Specific Instruments Planner (Materialise N.V. 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)

Related Policy

Computer Assisted Surgical Navigational Orthopedic Procedures

***Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.

Policy

Use of custom implants or patient-specific instrumentation (e.g., cutting guides) for joint arthroplasty is considered investigational for all applications. BCBSNC does not provide coverage for investigational services or procedures.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit
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design; Therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Patient-Specific Cutting Guides and Custom Knee Implants are covered

Not applicable.

When Patient-Specific Cutting Guides and Custom Knee Implants are not covered

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.

Policy Guidelines

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 (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 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.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina website at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

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 (MRI) or CT imaging which may help to identify these procedures.

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

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Specialty Matched Consultant Advisory Panel 6/2017


Policy Implementation/Update Information

11/25/14  New policy developed. Use of custom implants or patient-specific instrumentation (e.g., cutting guides) for joint arthroplasty is considered investigational for all applications. Medical Director review 10/2014. Policy noticed 11/25/14 for effective date 01/27/15.  (sk)


10/30/15  Related policy added. Reference added. (sk)

12/30/15  Code 0396T added to Billing/Coding section. (sk)


Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.