Medical Policy

Patient-Specific Cutting Guides and Custom Knee Implants

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Policy Number: 706
BCBSA Reference Number: 7.01.144
NCD/LCD: NA

Related Policies
Computer-Assisted Musculoskeletal Surgical Navigational Orthopedic Procedures, #594

Policy
Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity
Medicare HMO BlueSM and Medicare PPO BlueSM Members

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.

Prior Authorization Information
Pre-service approval is required for all inpatient services for all products.
See below for situations where prior authorization may be required or may not be required for outpatient services.
Yes indicates that prior authorization is required.
No indicates that prior authorization is not required.
N/A indicates that this service is primarily performed in an inpatient setting.

<table>
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<th>Outpatient</th>
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<td>Commercial Managed Care (HMO and POS)</td>
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<td>Commercial PPO and Indemnity</td>
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<td>Medicare HMO BlueSM</td>
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CPT Codes / HCPCS Codes / ICD Codes
Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.
Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

No specific CPT code

Description
Total knee arthroplasty (TKA, also called knee replacement) and unicompartmental knee arthroplasty (UKA) are an established treatment 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 #594). 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.

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 3-dimensional 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.

Summary
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.

A number of small randomized controlled trials (RCTs) have examined whether patient-specific cutting guides improve outcomes for total knee arthroplasty (TKA). Systematic reviews of these trials find no significant improvement in implant alignment, with some studies reporting worse alignment with PSI. In addition, a substantial number of procedures are abandoned intraoperatively. If there is no improvement in alignment, it is unlikely that PSI as a category as a whole will improve clinical outcomes. However, 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. Based on the evidence available at this time, use of custom made implants and patient-specific cutting guides is considered investigational.

**Policy History**

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<tr>
<td>9/2017</td>
<td>New references added from BCBSA National medical policy.</td>
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<tr>
<td>11/2015</td>
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**Information Pertaining to All Blue Cross Blue Shield Medical Policies**

Click on any of the following terms to access the relevant information:

- Medical Policy Terms of Use
- Managed Care Guidelines
- Indemnity/PPO Guidelines
- Clinical Exception Process
- Medical Technology Assessment Guidelines

**References**