

Corporate Medical Policy

Patient-Specific Instrumentation (e.g., Cutting Guides) for Joint Arthroplasty

File Name: patient_specific_instrumentation_eg_cutting_guides_for_joint_arthroplasty
Origination: 11/2014
Last Review: 6/2023

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 (see 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 about four to six weeks before the surgery. The images are sent to the planner/manufacture 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 total knee arthroplasty 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. In addition, the patient-specific template relies on the same anatomic landmarks as conventional total knee arthroplasty 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 eight 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.

- Signature™ Planner/Signature Guides (Materialise N.V. and Biomet)
- Visionaire Patient Matched Cutting Blocks (Smith & Nephew)
- TruMatch® Personalized Solutions (Depuy Orthopaedics)
- X-PSI Knee System (ORTHOsoft)
- iTTotal (Conformis)
- Shapematch (Stryker)
- Prophecy™ Pre-operative Navigation Alignment Guides (Wright Medical Technology)
- Zimmer® Patient Specific Instruments and Zimmer® Patient Specific Instruments Planner (Materialise N.V. and Zimmer)

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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 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 design; Therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Patient-Specific Instrumentation (e.g., Cutting Guides) for Joint Arthroplasty are covered

Not applicable.

When Patient-Specific Instrumentation (e.g., Cutting Guides) for Joint Arthroplasty are not covered

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.

Policy Guidelines

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 (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 patient specific instrumentation systems. Also, the designs of the devices are evolving, and some of the studies may have assessed now obsolete patient specific instrumentation systems. Available results from RCTs have not shown a benefit of patient specific instrumentation systems in improving clinical outcome measures with follow-up currently extending out to five years. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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 web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

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Applicable codes: 0561T, 0562T

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

BCBSA Medical Policy Reference Manual, [Electronic Version]. 7.01.144, 9/11/14

Specialty Matched Consultant Advisory Panel 6/2015

BCBSA Medical Policy Reference Manual, [Electronic Version]. 7.01.144, 9/10/15

Specialty Matched Consultant Advisory Panel 6/2016

Specialty Matched Consultant Advisory Panel 6/2017

BCBSA Medical Policy Reference Manual, [Electronic Version]. 7.01.144, 8/10/2017

BCBSA Medical Policy Reference Manual, [Electronic Version]. 7.01.144, 5/4/2018

BCBSA Medical Policy Reference Manual, [Electronic Version]. 7.01.144, 4/8/2019

Specialty Matched Consultant Advisory Panel 7/2019

BCBSA Medical Policy Reference Manual, [Electronic Version]. 7.01.144, 4/16/2020

Specialty Matched Consultant Advisory Panel 6/2020

BCBSA Medical Policy Reference Manual, [Electronic Version]. 7.01.144, 4/8/2021

Specialty Matched Consultant Advisory Panel 6/2021

Lin Y, Cai W, Xu B, et al. Patient-Specific or Conventional Instrumentations: A Meta-analysis of Randomized Controlled Trials. *Biomed Res Int.* 2020; 2020: 2164371.

Hampton MJ, Blakey CM, Anderson AA, et al. Minimum 5-Year Outcomes of a Multicenter, Prospective, Randomized Control Trial Assessing Clinical and Radiological Outcomes of Patient-Specific Instrumentation in Total Knee Arthroplasty. *J Arthroplasty.* Jan 22 2022.

Specialty Matched Consultant Advisory Panel 6/2022

Specialty Matched Consultant Advisory Panel 6/2023

Medical Director Review 6/2023

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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)
- 7/28/15 Specialty Matched Consultant Advisory Panel review 6/24/2015. (sk)
- 10/30/15 Related policy added. Reference added. (sk)
- 12/30/15 Code 0396T added to Billing/Coding section. (sk)
- 7/26/16 Policy Guidelines updated. Specialty Matched Consultant Advisory Panel review 6/29/2016. (sk)
- 7/28/17 Specialty Matched Consultant Advisory Panel review 6/28/2017. Code 0396T removed from policy. (sk)
- 9/29/17 Reference added. Policy Guidelines updated. (sk)
- 6/29/18 Reference added. Custom implants moved to new policy on 3-dimensional printed orthopedic implants. Title and policy statement changed to “Patient-Specific Instrumentation (e.g., Cutting Guides) for Joint Arthroplasty.” (sk)
- 7/1/19 Reference added. Background section updated. Regulatory Status updated. New codes 0561T and 0562T added to Billing/Coding section. (sk)
- 6/30/20 Reference added. Specialty Matched Consultant Advisory Panel review 6/17/2020. (sk)
- 3/8/22 Reference added. Related policy removed. Specialty Matched Consultant Advisory Panel review 6/16/2021. (sk)
- 7/26/22 References added. Specialty Matched Consultant Advisory Panel review 6/29/2022. (sk)
- 6/30/23 Reference added. Specialty Matched Consultant Advisory Panel review 6/2023. Medical Director review 6/2023. (rp)

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.