Effective November 1, 2023, refer to CMS Manual 100-02, Chapter 16-General Exclusions from Coverage for services included in this policy.

BlueCross BlueShield of Alabama

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

Policy #: 716
Latest Review Date: April 2023
Category: Surgical
ARCHIVED EFFECTIVE 11/1/2023

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 **non-covered 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.

KEY POINTS:

The most recent literature update was performed through January 16, 2023.

Summary of Evidence

For individuals who are undergoing partial or total knee arthroplasty who receive patient-specific cutting guides, the evidence includes 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.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Practice Guidelines and Position Statements
American Academy of Orthopaedic Surgeons
In 2016, the American Academy of Orthopaedic Surgeons published a guideline on the surgical management of osteoarthritis of the knee (updated December 2, 2022). The guideline is supported by the American Society of Anesthesiologists and endorsed by several other organizations. The guideline recommends against the use of patient specific instrumentation for total knee arthroplasty, since strong evidence has not shown a difference in pain or functional outcomes when compared to conventional instrumentation. Additionally, moderate evidence has not shown a difference between patient specific and conventional instrumentation with regard to transfusions or complications.

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:
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 U.S. Food and Drug Administration (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/Signature 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:

0561T	Anatomic guide 3D-printed and designed from image data set(s); first anatomic guide
0562T	Anatomic guide 3D-printed and designed from image data set(s); each additional anatomic guide (List separately in addition to code for primary procedure)

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POLICY HISTORY:

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