

**MEDICAL POLICY – 7.01.144****Patient-Specific Instrumentation (e.g., Cutting Guides) for Joint Arthroplasty**

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Replaces: N/A

RELATED MEDICAL POLICIES:

None

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## Introduction

Three-dimensional (3-D) printing technology is being used as part of some joint replacement surgeries. Standard cutting guides — which show where the bone is to be cut — are available and widely used. But 3-D printing allows for custom cutting guides to be created for an individual patient. For a custom cutting guide, an MRI or CT scan is taken before the surgery. The image is then sent out to a company that creates a mold. During surgery, that mold is then fitted over the end of the bone to guide where the bone should be cut. Published studies show that custom cutting guides don't result in better alignment than standard cutting guides. Some studies show the custom materials create worse alignment. More and larger studies are needed to determine how well these custom cutting guides work. For this reason, custom cutting guides are considered investigational (unproven).

**Note:** The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

## Policy Coverage Criteria

Equipment	Investigational
<b>Patient-specific instrumentation</b>	<b>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.</b>

## Coding

There are no specific codes for this instrumentation. The joint arthroplasty procedure would be reported using the regular CPT codes for that surgery. You may see any of the following codes billed.

Code	Description
<b>CPT</b>	
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)
27446	Arthroplasty, knee, condyle and plateau; medial OR lateral compartment
27447	Arthroplasty, knee, condyle and plateau; medial AND lateral compartments with or without patella resurfacing (total knee arthroplasty)

**Note:** CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

## Related Information

The preplanning for the surgery may involve magnetic resonance imaging or computed tomography, which may help to identify these procedures.



### Description

Patient-specific instrumentation (PSI) has been developed as an alternative to conventional cutting guides for joint arthroplasty. 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 PSI are to increase surgical efficiency and to improve implant alignment and clinical outcomes.

### Background

PSI 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 four to six 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.<sup>1</sup>

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 cutting guides are used to aid the surgeon intraoperatively in making the initial distal femoral and the initial proximal tibial bone cuts during knee arthroplasty surgery. The cutting guides also establish the references for component orientations. The placement of conventional cutting guides (templates and jigs) is based on anatomic landmarks or computer navigation. 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. Also, no studies have demonstrated an improvement in clinical outcomes with computer-assisted navigation.

## **Summary of Evidence**

For individuals who are undergoing partial or TKA who receive patient-specific cutting guides, the evidence includes randomized controlled trials (RCTs), 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 RCTs have not shown a benefit of PSI 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.



## Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this policy are listed in [Table 1](#).

**Table 1. Summary of Key Trials**

NCT No.	Trial Name	Planned Enrollment	Completion Date
<b>Ongoing</b>			
<a href="#">NCT06122727</a>	Comparison of Customized and Standard Total Knee Replacements: a Pilot Study	20	March 2025
<a href="#">NCT01696552</a>	Patient-specific Positioning Guides (PSPG) Technique Versus Conventional Technique in Total Knee Arthroplasty - a Prospective Randomized Study	109	Jan 2024
<a href="#">NCT02177227<sup>a</sup></a>	Attune With TruMatch™ Personalized Solutions Instruments: A Prospective Randomized Controlled Trial Comparing Clinical and Economic Outcomes in Patients With a BMI Between 30 and 50	194	Aug 2024
<b>Unpublished</b>			
<a href="#">NCT02845206</a>	Randomised Controlled Trial of Patient Specific Instrumentation vs Standard Instrumentation in Total Knee Arthroplasty	172	Feb 2020
<a href="#">NCT03148379<sup>a</sup></a>	A Multi-center, Prospective, Randomized Study Comparing Surgical and Economic Parameters of Total Knee Replacement Performed With Single-use Efficiency Instruments With Patient Specific Technique (MyKnee®) Versus Traditional Metal Instruments With Conventional Surgical Technique	231	Mar 2022
<a href="#">NCT02096393</a>	A Prospective, Randomised Control Trial Assessing Clinical and Radiological Outcomes of Patient Specific Instrumentation in Total Knee Arthroplasty	72	June 2020

NCT: national clinical trial

<sup>a</sup> Denotes industry-sponsored or cosponsored trial.



## Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

## 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).<sup>79,80</sup> The guideline is supported by the American Society of Anesthesiologists and endorsed by several other organizations. The guideline recommends against the use of PSI for TKA, 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.

## Medicare National Coverage

There is no national coverage determination.

## Regulatory Status

There are eight commercially available PSI 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 US Food and Drug Administration (FDA) clearance for marketing. Other systems cleared for marketing by the FDA are shown in [Table 2](#).

FDA product codes: OOG



MyKnee cutting blocks are designed and manufactured from patient imaging data so that the cutting blocks match the individual's anatomy. They are used with the GMK Total Knee System. They are intended for use for a single individual anatomy to assist in the positioning of total knee replacement components intraoperatively and in guiding the marking of bone before cutting.

Product code JWH.

**Table 2. Patient-Specific Cutting Guides for Knee Arthroplasty**

Device Name	Manufacturer	510(K) Number	Clearance Date
X-Psi	Orthosoft	K131409	9/13/2013
iTotal	Conformis	K120068	2/3/2012
Prophecy	Wright Medical Technology	K103598	10/17/2011
Trumatch	Depuy Orthopaedics	K110397	8/16/2011
Shapematch	Stryker	K110533	5/19/2011
Signature	Materialise	K102795	2/2/2011
MyKnee Cutting Blocks	Medacta International	K093806	4/8/2010
Zimmer	Materialise	K091263	11/19/2009
Visionaire	Smith & Nephew	K082358	11/25/2008

Source: FDA: US Food and Drug Administration

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## History

Date	Comments
01/13/15	New Policy. Add to Surgery section. Policy created with literature review through July 31, 2014. Custom implants or patient-specific instrumentation for knee surgery is considered investigational.
11/10/15	Annual Review. Policy updated with literature review through July 30, 2015; reference 17 added. Policy statement unchanged.
08/01/16	Annual Review, approved July 12, 2016. No change to policy statements.
10/01/17	Annual Review, approved September 21, 2017. Policy updated with literature review through June 22, 2017; references 3-6 added; some references removed. Policy statement unchanged.
08/01/18	Annual Review, approved July 25, 2018. Policy updated with literature review through February 2018; references 5 and 8-12 added. Custom implants moved to new policy on 3-dimensional printed orthopedic implants. Title changed from "Patient-Specific Cutting Guides and Custom Knee Implants" to "Patient-Specific Cutting Guides for Joint Arthroplasty".
07/01/19	Annual Review, approved June 4, 2019. Policy updated with literature review through February 2019; references added. Policy statement unchanged.
07/01/20	Annual Review, approved June 2, 2020. Policy updated with literature review through February 2020; no references added. Policy statement unchanged.
08/01/20	Coding update. Added CPT codes 27446 and 27447.
07/01/21	Annual Review, approved June 1, 2021. Policy updated with literature review through February 16, 2020; references added. Policy statement unchanged.
12/01/21	Interim Review, approved November 2, 2021. Updated Regulatory Status table to include MyKnee cutting blocks. Added CPT codes 0561T, 0562T. Added HCPCS C1713 and C1776.
07/01/22	Annual Review, approved June 13, 2022. Policy updated with literature review through February 28, 2022; reference added. Policy statement unchanged.
04/01/23	Coding update. Removed HCPCS codes C1776 and C1713. Correction made to the Regulatory Status section as information regarding MyKnee cutting blocks was inadvertently removed at last publication.
07/01/23	Annual Review, approved June 26, 2023. Title changed back to "Patient-Specific Instrumentation (e.g., Cutting Guides) for Joint Arthroplasty" from "Patient-Specific



Date	Comments
	Cutting Guides for Joint Arthroplasty” Policy updated with literature review through January 16, 2023; reference added; Policy statement unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization.
07/01/24	Annual Review, approved June 24, 2024. Policy updated with literature review through February 8, 2024; reference added; Policy statement unchanged.

**Disclaimer:** This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2024 Premera All Rights Reserved.

**Scope:** Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.





### Discrimination is Against the Law

LifeWise Health Plan of Washington (LifeWise) complies with applicable Federal and Washington state civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, sex, gender identity, or sexual orientation. LifeWise does not exclude people or treat them differently because of race, color, national origin, age, disability, sex, gender identity, or sexual orientation. LifeWise provides free aids and services to people with disabilities to communicate effectively with us, such as qualified sign language interpreters and written information in other formats (large print, audio, accessible electronic formats, other formats). LifeWise provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, contact the Civil Rights Coordinator. If you believe that LifeWise has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, sex, gender identity, or sexual orientation, you can file a grievance with: Civil Rights Coordinator — Complaints and Appeals, PO Box 91102, Seattle, WA 98111, Toll free: 855-332-6396, Fax: 425-918-5592, TTY: 711, Email [AppealsDepartmentInquiries@LifeWiseHealth.com](mailto:AppealsDepartmentInquiries@LifeWiseHealth.com). You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Ave SW, Room 509F, HHH Building, Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD). Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>. You can also file a civil rights complaint with the Washington State Office of the Insurance Commissioner, electronically through the Office of the Insurance Commissioner Complaint Portal available at <https://www.insurance.wa.gov/file-complaint-or-check-your-complaint-status>, or by phone at 800-562-6900, 360-586-0241 (TDD). Complaint forms are available at <https://fortress.wa.gov/oic/onlineservices/cc/pub/complaintinformation.aspx>.

### Language Assistance

**ATENCIÓN:** si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 800-817-3056 (TTY: 711).

**注意:** 如果您使用繁體中文，您可以免費獲得語言援助服務。請致電 800-817-3056 (TTY: 711)。

**CHÚ Ý:** Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 800-817-3056 (TTY: 711).

**주의:** 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 800-817-3056 (TTY: 711) 번으로 전화해 주십시오.

**ВНИМАНИЕ:** Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 800-817-3056 (телетайп: 711).

**PAUNAWA:** Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nang walang bayad. Tumawag sa 800-817-3056 (TTY: 711).

**УВАГА!** Якщо ви розмовляєте українською мовою, ви можете звернутися до безкоштовної служби мовної підтримки.

Телефонуйте за номером 800-817-3056 (телетайп: 711).

**ប្រយ័ត្ន:** បើសិនជាអ្នកនិយាយ ភាសាខ្មែរ, សេវាជំនួយផ្នែកភាសា ដោយមិនគិតលុយ គឺអាចមានសំរាប់អ្នក។ ចូរ ទូរស័ព្ទ 800-817-3056 (TTY: 711)។

**注意事項:** 日本語を話される場合、無料の言語支援をご利用いただけます。800-817-3056 (TTY:711) まで、お電話にてご連絡ください。

**ማስታወሻ:** የሚናገሩት ቋንቋ አማርኛ ከሆነ የትርጉም እርዳታ ድርጅቶች፣ በነጻ ሊያገለግሉት ተዘጋጅተዋል። ወደ ሚከተለው ቁጥር ይደውሉ 800-817-3056 (መስማት ለተሳናቸው: 711)።

**XIYYEEFFANNAA:** Afaan dubbattu Oroomiffa, tajaajila gargaarsa afaanii, kanfaltiidhaan ala, ni argama. Bilbilaa 800-817-3056 (TTY: 711).

**ملحوظة:** إذا كنت تتحدث اذكر اللغة، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان. اتصل برقم 800-817-3056 (رقم هاتف الصم والبكم: 711).

**ਧਿਆਨ ਦਿਓ:** ਜੇ ਤੁਸੀਂ ਪੰਜਾਬੀ ਬੋਲਦੇ ਹੋ, ਤਾਂ ਭਾਸ਼ਾ ਵਿੱਚ ਸਹਾਇਤਾ ਸੇਵਾ ਤੁਹਾਡੇ ਲਈ ਮੁਫਤ ਉਪਲਬਧ ਹੈ। 800-817-3056 (TTY: 711) 'ਤੇ ਕਾਲ ਕਰੋ।

**ACHTUNG:** Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 800-817-3056 (TTY: 711).

**ໂປດອຸບ:** ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ, ໂດຍບໍ່ຄ່າສ່ຽງຄ່າ, ຄວນມີພ້ອມໃຫ້ທ່ານ. ໂທ 800-817-3056 (TTY: 711).

**ATANSYON:** Si w pale Kreyòl Ayisyen, gen sévis èd pou lang ki disponib gratis pou ou. Rele 800-817-3056 (TTY: 711).

**ATTENTION:** Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 800-817-3056 (ATS : 711).

**UWAGA:** Jezeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer 800-817-3056 (TTY: 711).

**ATENÇÃO:** Se fala português, encontram-se disponíveis serviços linguísticos, grátis. Ligue para 800-817-3056 (TTY: 711).

**ATTENZIONE:** In caso la lingua parlata sia l'italiano, sono disponibili servizi di assistenza linguistica gratuiti. Chiamare il numero 800-817-3056 (TTY: 711).

**توجہ:** اگر بہ زبان فارسی گفتگو می کنید، تسهیلات زبانی بصورت رایگان برای شما فراهم می باشد. با 800-817-3056 (TTY: 711) تماس بگیرید.