




enovis™

**OA KNEE BRACING:**

IMPORTANT  
DOCUMENTATION  
INFORMATION



A person is shown from the waist down, running outdoors on a path. They are wearing a dark gray athletic tank top and black shorts. On their right knee, they are wearing a white and black DJO brace. The background consists of green bushes and a clear blue sky with some light clouds.

As a physician or other health care provider (HCP) who prescribes Osteoarthritis (OA) knee braces, DJO® relies on your medical record documentation to determine whether the involved payor's medical necessity coverage criteria are met when DJO submits a claim to the patient's payor. To identify some of the key concepts related to payor requirements for meeting applicable medical necessity rules, we are providing you with this information. We hope this information will assist you in better understanding Medicare and other payor requirements for coverage/payment of OA knee braces.

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We hope this information is useful to you. If you have any questions about the information we've included, please do not hesitate to contact us using the Contact Information provided at the end of this section.





**This is some helpful information for documenting an OA knee brace.**

## MEDICAL NECESSITY DOCUMENTATION

When prescribing an OA knee brace for a patient, detailed medical records are the key to supporting medical necessity and ensuring coverage/payment by the patient's payor. Documentation of an objective assessment related to the condition requiring the knee brace, as well as a treatment plan that explains why the patient needs a specific brace, is required by most payors.

## MEDICARE COVERAGE OF OA KNEE BRACES

For knee braces to be covered for patients who are Medicare beneficiaries, coverage criteria must be met. This is accomplished through the documentation contained in the patient's medical records. For HCPCS codes L1832, L1833, L1843, L1845, L1846, L1850, L1851 and L1852, which are the codes specific to OA knee braces, there are two potential paths to Medicare coverage/ payment of the prescribed brace:

1. **Patient with a Recent Injury or Surgical Procedure:** This approach requires documentation of a recent injury to, or a surgical procedure on, the involved knee, along with an approved ICD-10 code listed in the Knee Orthoses Policy Article (A52465) published by Medicare.
2. **Ambulatory Patient with Knee Instability:** This approach requires documentation indicating the patient is ambulatory and has knee instability. Knee instability may be demonstrated through an objective examination of the affected knee (or knees) with the use of maneuvers (i.e., tests) designed to identify joint laxity, along with an approved ICD-10 code listed in the Knee Orthoses Policy Article (A52465) published by Medicare.

## IMPORTANT POINTS TO CONSIDER

- For patients who have not had a recent injury or surgical procedure involving the knee, payors require evidence (i.e., documentation) of functional testing results demonstrating knee laxity.
- The medical record must clearly indicate that the patient has knee laxity which you, as the treating practitioner, believe has resulted in knee instability.
- Radiologic/imaging tests are not considered to be functional testing. While these tests may provide supporting information, radiologic/imaging results, alone, cannot be used to demonstrate knee laxity or instability.
- Knee deformity does not necessarily equate to knee instability.
- Pain is not a covered diagnosis for OA knee braces.

In addition, patient-reported symptoms of knee laxity or knee instability that you document in your patient's medical record cannot be used as justification for coverage/payment of an OA knee brace by Medicare or other payors.

# FUNCTIONAL KNEE EXAMS

Your documented functional knee exam must demonstrate (+) positive results to support Medicare coverage/payment of an OA knee brace. Documentation must include an objective description of joint laxity determined through your use of various tests (e.g., Anterior/Posterior Drawer, Lachman's, Varus/Valgus Stress, others). (+) Positive test results may be documented on a grade scale or with descriptors.

## Examples of Appropriate Documentation of (+) Positive Functional Test Results:

+, +1, +2, +3	Mild/Moderate/Severe Laxity	(+) Positive
Incompetent	"Corrects to neutral" or "Opening" on exam	
Deficit	Pseudolaxity	

## Examples of Appropriate Documentation of Negative Functional Test Results:

Normal	Within Normal Limits	(-) Negative
Stable	Good or None	Competent
Sufficient		

# SAME AND SIMILAR OA KNEE BRACING PRODUCTS

Coverage/payment of the OA knee brace you've prescribed for your patient may not be available if the patient already has a brace for the same knee. If the patient has an existing brace for the affected knee, your medical record entry/documentation must sufficiently detail why the existing brace is not effective and why there is a need for a new brace. For example, the patient's previous knee brace may have been lost, may no longer be functional, or may no longer perform the functions you believe, in your medical judgement, are necessary to treat the current knee problem. This must be clearly documented in the patient's medical record for a same/similar OA knee brace to be covered/paid.

# PRESCRIPTIONS /ORDERS

An appropriate prescription/order must be provided to DJO® and must contain the following elements before a claim can be submitted to and covered by Medicare or other payors:

- Patient's name or Medicare Beneficiary Identifier (MBI)/Patient Insurance ID Number
- Prescription/order date
- General description of the brace being prescribed. The description can be either a general description (e.g., OA knee brace), a HCPCS code, a HCPCS code narrative, or a brace brand name/model number
- Treating practitioner's name or NPI number
- Treating practitioner's signature

## Please Note:

- A prescription/order is not considered by Medicare to be part of the medical record for billing purposes. While medical information may be included in a prescription/order, that information must be corroborated/supported by information contained in the patient's official medical record.
- A new, signed and dated prescription/order is needed for each patient who will be receiving an OA knee brace.
- For add-on equipment, the prescription/order should include and separately list all concurrently prescribed options, accessories or additional features, in addition to the description of the underlying (i.e., main) brace. Some payors require that the main/primary brace and any options, accessories, or additional features be included on two separate prescriptions/orders.

# CUSTOM FIT OA KNEE BRACES

For prefabricated custom fit OA knee braces you prescribe for your Medicare and other patients (HCPCS codes L1810, L1832, L1843, L1845 and L1847), there are specific documentation requirements for the brace to be considered by Medicare (as well as other payors) to be covered/payable. Medicare requires documentation that describes why the patient requires a custom fit OA knee brace, rather than an off-the-shelf (OTS) knee brace. Your documentation, if you or your staff are doing the custom fitting work, must also clearly indicate that more than minimal self-adjustment to the brace was done to achieve an individualized fit for the involved patient. Those adjustments cannot be of the type that can be done by the patient, a patient's family member, or other untrained individual.

The following conditions or services **DO NOT** support the medical need for or coverage/payment of a custom fit OA knee brace:

- The patient's age
- The amount of time you or the DJO® Field Service Representative spent with the patient
- The need for minimal strap modifications, minimal strap trimming and/or minimal device bending of the brace by you or the DJO Field Service Representative
- The need for the insertion/movement of flexion/extension stops on the brace

If the provider, or the provider's staff, is doing the custom fitting work for which DJO is billing, there must be documentation of that work, along with documentation of the specialized training/expertise the individual doing the fitting work has.

# CUSTOM FABRICATED OA KNEE BRACES

When prescribing custom fabricated OA knee braces (L1846 L1844), you must provide DJO® with a detailed prescription/order for a custom fabricated OA knee brace. In addition, your medical record documentation must clearly support the medical need for a custom fabricated brace, rather than an off-the-shelf OA knee brace.

For example, your patient may have an anatomical abnormality that requires custom fabrication work to be done to the OA knee brace to make it useful/effective for the patient.

Examples of objective documentation that might identify the need for a custom fabricated brace include, but are not limited to:

- Valgus/varus deformity of the knee
- A patient with a disproportionate thigh or calf size
- Minimal muscle mass on which to support the ordered OA knee brace

When prescribing/ordering a custom fabricated OA knee brace for your Medicare or other patient, please be certain to include the applicable HCPCS code for a custom fabricated OA knee brace (or a description that clearly indicates a custom fabricated OA knee brace) on your prescription/order. In addition, please make certain your medical record documentation clearly indicates the reason(s) why the patient needs a custom fabricated OA knee brace, rather than an off-the-shelf OA knee brace.

# LATE MEDICAL RECORD ENTRIES, ADDENDA AND AMENDMENTS

Periodically, late entries, addenda, or amendments to a medical record may be necessary to correct or add to previously documented patient information. These medical record additions/changes are accepted by Medicare and other third-party payors if they are done properly. Any addition/change to a medical record must be initialed and dated or signed and dated by the individual who made the addition/change. Any addition/change also needs to be incorporated into the patient's official medical record, including electronic medical records. The added/changed entry or form, especially one with handwritten changes, must be incorporated into the patient's paper medical record or scanned into the patient's electronic medical record. As always, best practice is to make any necessary additions/changes directly in your electronic medical record (EMR) system, rather than on a printed copy of the patient's record. DJO® cannot accept additions/changes to a patient's medical record that are not also reflected in the patient's "official" medical record.

## IMPORTANT REFERENCES AND LINKS

The Medicare Program Integrity Manual (Internet-only Manual 100-08), Chapter 3, Section 3.3.2.5 - guidance on amendments, corrections and delayed entries:

<https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c03.pdf>

Documentation Guidelines for Amended Medical Records

<https://med.noridianmedicare.com/web/jeb/cert-reviews/mr/documentation-guidelines-for-amended-records>

DME MACs Dear Physician Knee Orthoses Letter

[https://cgsmedicare.com/jc/mr/pdf/dear\\_physician\\_knee\\_orthoses.pdf](https://cgsmedicare.com/jc/mr/pdf/dear_physician_knee_orthoses.pdf)

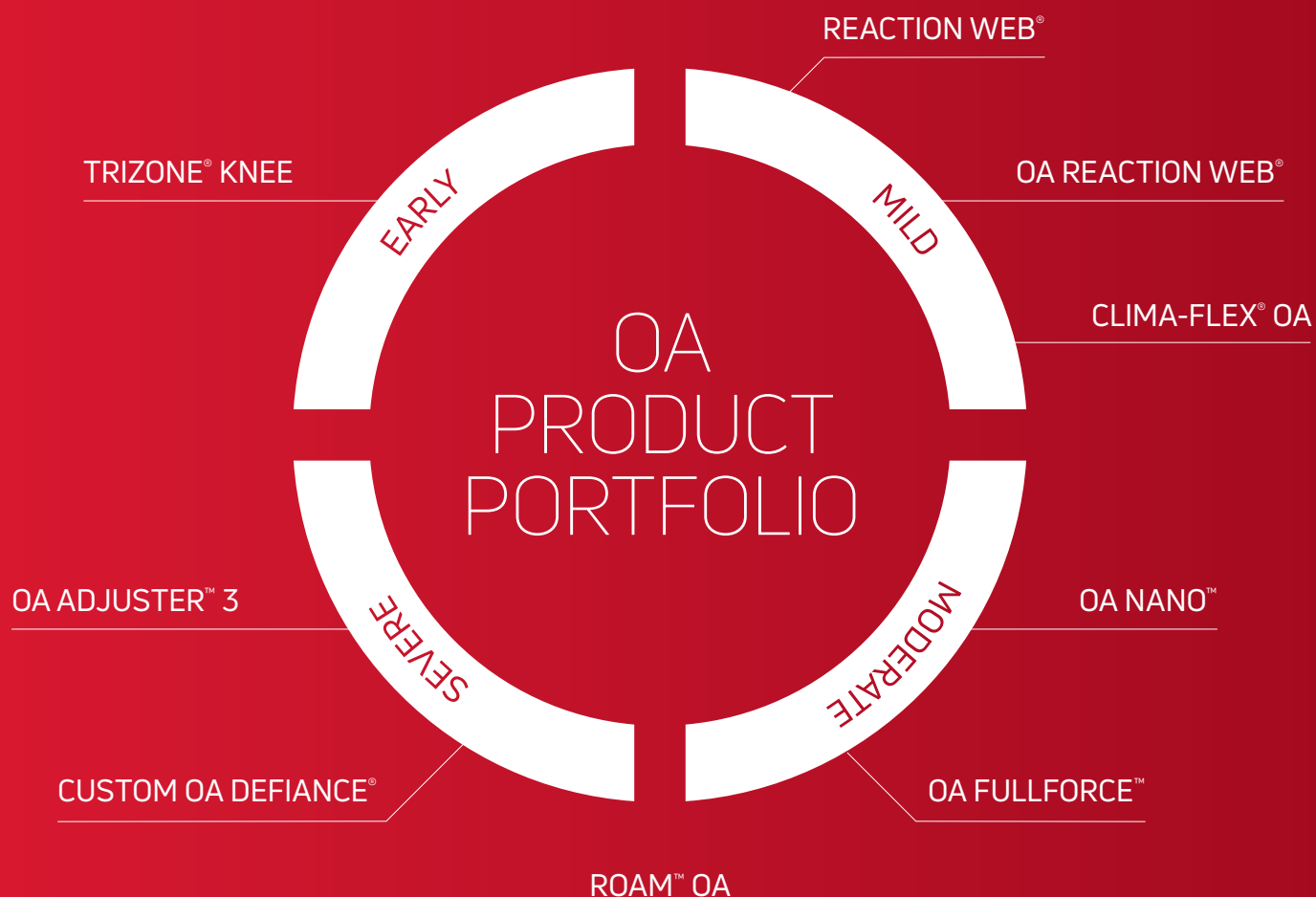
Local Coverage Determination (LCD): Knee Orthoses (L33318)

<https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33318&ContrID=140>

# DONJOY® OFFERS PRODUCTS TO AID IN ALL STAGES OF KNEE OSTEOARTHRITIS: EARLY, MILD, MODERATE AND SEVERE

## MILLIONS OF ADULTS HAVE KNEE OSTEOARTHRITIS¹

In many cases, this chronic condition limits their ability to perform activities of daily living, play sports, and work. DonJoy's multiple knee brace solutions are designed to reduce the load on the impacted compartment, help relieve painful symptoms often associated with this complex disease, and help to improve quality of life.



# MILD OA

## REACTION WEB®

Uses an innovative web approach for absorbing shock to help relieve knee pain caused by Chondromalacia, Patellar Tendonitis/Tendinosis, and general Patellofemoral tracking issues.

- Shock-absorbing web that shifts peak loads away from the painful area of the knee and stabilizes the patella on all sides to help ensure proper tracking position
- Flexible dual-axis hinges that work in conjunction with the elastomeric web for fit and support
- Breathable comfort from an open framework and mesh backing
- Available in sizes XS-XXL, and in a variety of colors: grey, pink-09000, red-01000, and blue-02000

PART NUMBERS	DESCRIPTION
11-0215-2-XXXXX	XS/S 13" - 18.5" (33 - 47 CM)
11-0215-3-XXXXX	M/L 18.5" - 23.5" (47 - 60 CM)
11-0215-4-XXXXX	XL/XXL 23.5" - 29.5" (60 - 75 CM)
11-0215-5-XXXXX	XXXL 29.5" - 31" (75 - 79 CM)

L1810/L1812 (OTS)

Fitting Guide



# MODERATE TO SEVERE OA

## OA REACTION WEB®

A discreet aid for osteoarthritis knee pain. The OA Reaction Web® brace is a way to help treat osteoarthritis knee pain utilizing patented silicone web technology. By combining the web technology with a rigid off-loading bar, OA Reaction helps address both patella OA as well as either medial or lateral joint pain. The easy-to-wear open framework is designed for a comfortable, non-slip fit.

- Lightweight, low-profile pain relief
- Silicone web technology
- Four-way, adjustable wraparound design
- Patented, integrated silicone
- Easy to wear

PART NUMBERS	DESCRIPTION
11-7426-X	RIGHT MED/LEFT LAT
11-7427-X	LEFT MED/RIGHT LAT

L1810/1812 (OTS)

Fitting Guide





# MILD TO MODERATE OA

## CLIMA-FLEX® OA

Clima-Flex® OA helps offer a comfortable, cooling relief through compression and off-loading for patients with mild to moderate OA. Clima-Flex® OA is sleek and ideal for light activities such as walking, golf, or hiking.

- C-6 technology™ advanced cooling material
- Keyless, dual dial off-loading
- Easy wraparound application
- Snug fit & control

PART NUMBERS	DESCRIPTION
11-8810-X	CLIMA-FLEX® OA, RIGHT MED/LEFT LAT
11-8811-X	CLIMA-FLEX® OA, LEFT MED/RIGHT LAT

L1851

Fitting Guide



# MODERATE OA

## OA NANO™

Mighty. Light. Powered by nanoMAG™ and DonJoy's Adjuster™ technology, DonJoy® OA Nano arthritis knee brace. Even with this light weight, OA Nano helps provide powerful off-load through a wider range of motion by using the unique adjuster mechanism—so your patients can keep moving forward.

- Light as air (only 14.2oz)
- Stays in place
- Dependable off-loading
- 4-Points-of-Leverage™ System

PART NUMBERS	DESCRIPTION
11-1214-X	OA NANO, MEDIAL RT
11-1215-X	OA NANO, MEDIAL LT
11-1216-X	OA NANO, LATERAL RT
11-1217-X	OA NANO, LATERAL LT

L1852 (OTS), L1845

\*\* Weight based on L1845 PDAC coded, double-upright rigid knee brace for mild to moderate OA (brace size-medium)

Fitting Guide



# MODERATE OA

## OA FULLFORCE™

DonJoy's lightweight OA knee brace helps off-load the affected compartment of the knee while aiding in the reduction of ligament strain, allowing active patients to go more miles with less pain. The pain of early OA can get in the way of a healthy lifestyle. Keep your patients moving and strong and help prolong the degenerative process of OA.

- 3-Point Off-Loading mechanically helps shift the painful joint loads from the degenerative compartment to the healthy compartment, while the hinge allows the ability to fine-tune the load
- 4-Points-of-Leverage™ is clinically shown to help reduce ACL strain by keeping the knee in a stable position to minimize further cartilage damage
- DonJoy's lightweight OA frame provides a snug comfortable fit, allowing maximum knee function

PART NUMBERS	DESCRIPTION
11-1578-X	MEDIAL RIGHT
11-1579-X	MEDIAL LEFT
11-1580-X	LATERAL RIGHT
11-1581-X	LATERAL LEFT

L1852 (OTS), L1845

Fitting Guide



## ROAM™ OA

The latest innovation in unloader knee braces, the new DonJoy ROAM™ OA brace helps improve mobility and dynamically provides relief by unloading the pressure of unicompartmental osteoarthritis or other knee pain. Comfortable and easy to use with lightweight, low-profile joint unloading and support, ROAM is ideal for conservative care in active patients, in preparation for surgery or for post-operative meniscal tears when indicated.

- Set and Forget Technology encourages compliance by letting patients don and remove the brace without changing their provider's settings
- BOA® Dials allow patients to independently dial up or down tension on the thigh and/or calf to manage level of needed support and pain relief
- Easy Mag-Align magnetic clips help align the strap connections quickly with a single click
- Dynamic strapping, unique condyle harness and anti-migration technology for a secure, comfortable fit

PART NUMBERS	DESCRIPTION
11-1725-1-06000	OTS, LEFT MEDIAL/RIGHT LATERAL
11-1725-3-06000	OTS, LEFT MEDIAL/RIGHT LATERAL
11-1725-5-06000	OTS, LEFT MEDIAL/RIGHT LATERAL
11-1726-1-06000	OTS, RIGHT MEDIAL/LEFT LATERAL
11-1726-3-06000	OTS, RIGHT MEDIAL/LEFT LATERAL
11-1726-5-06000	OTS, RIGHT MEDIAL/LEFT LATERAL

L1851 (OTS), L1843, L1844 (CST)

ROAM requires minimal inventory. Designed to simplify product search and make ordering and support easy with only a handful of SKUs.

Fitting Guide





# SEVERE OA

## OA ADJUSTER™ 3

Mighty. Tough. The improved OA Adjuster™ 3 is powered by nanoMAG™ and reinforced with a tough aluminum frame making it a durable and functional DonJoy® OA knee brace.

- Adjuster technology
- Lightweight and tough
- Functional comfort
- 4-Points-of-Leverage™ System
- Contoured calf cuff
- Anti-migration band & strap pads

PART NUMBERS	DESCRIPTION
11-1590-X	RIGHT MED
11-1591-X	LEFT MED
11-1592-X	RIGHT LAT
11-1593-X	LEFT LAT

L1852 (OTS), L1845

Fitting Guide



## OA DEFIANCE®

DonJoy's premier custom OA product. It is designed for the active OA patient, is extremely lightweight, and provides durable support for moderate to severe levels of osteoarthritis. The bilateral hinge bars offers support for ligament instabilities and work in conjunction with a patented telescoping condyle pad which helps put the load control in the hands of the patient.

- 4-Points-of-Leverage™ System
- 1° to 7° of correction
- Patient controlled Telescoping Condyle Pad can be built into the frame at time of measurement
- 24-hour turnaround time
- Over 30 custom frame colors and graphics
- Swooping thigh cuff
- Swiveling strap tabs
- Reinforced carbon composite frame
- Provides additional force to customize control and pain relief forces
- OA offloading key helps offload an additional 3 degrees at the hinge

L1846

EVERY DONJOY CUSTOM OA KNEE BRACE COMES WITH A 5 YEAR WARRANTY ON THE FRAME AND HINGE(S) AND A 6 MONTH WARRANTY ON SOFT GOOD MATERIALS.

Fitting Guide





T 800.556.5572 F 262.242.9300

DJO, LLC  
5919 Sea Otter Place, Suite 200 | Carlsbad, CA 92010 | U.S.A.  
enovis.com

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REFERENCES:

<sup>1</sup> <https://www.cdc.gov/arthritis/basics/osteoarthritis.htm>