



QUALITY FOR LIFE

Overview:

This information is intended to assist practitioners in creating their Letter of Medical Necessity (LMN) and structuring arguments should reimbursement requests be denied for the Sensor Walk KAFO. **This material is not designed to be submitted as the documentation or justification for Sensor Walk reimbursement.** The documentation and justification for reimbursement must be unique to the patient and components being fit, and can only be effectively drafted by the treating Orthotist. Form letters and copied papers of product description are not adequate justification for medical necessity and are commonly rejected by paying sources. Please contact your Sales Representative at 800.328.4058 if you have any questions or concerns.

Sensor Walk Patient Recommendation

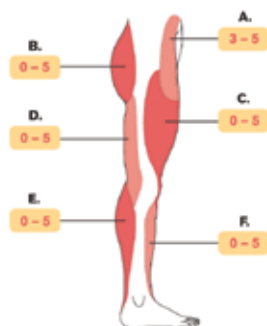
The Sensor Walk was designed for, and is recommended for, patients who have the potential to move about in the community as part of their normal Activities of Daily Living (ADL). The orthosis is intended for patients who exhibit weak or absent quadriceps, or knee instability in the sagittal plane while bearing weight during the stance phase of the gait cycle. Approximately 989,000 people in the United States could benefit from the Sensor Walk. Diagnoses for this population include polio, neurovascular incidents, neurological and developmental defects.

The Sensor Walk accepts patient weight up to 300 lbs and knee flexion contractures of up to 15 degrees. The Sensor Walk is able to lock and unlock under load to allow for a fluid swing phase. The knee joint will also lock at any position within its range to provide stability over a variety of terrains and environmental obstacles.

For successful application, the patient must exhibit hip flexor strength of at least Grade 3 (against gravity) and be able to cognitively understand and carry out Instructions for Use described in the owners' manual. The patient's step length over level ground should exceed the length of the opposing foot. The patient should not exhibit a rigid genu varum or genu valgum deformity above 10 degrees.

Sensor Walk Patient Indications

The Sensor Walk is not recommended for competitive sports, running, jogging or climbing.



Weight Limit	Up to 300 lbs/136 kg	
Hip Abductors	3-5	
Hip ROM	Accommodates full R.O.M.	
Knee ROM	Up to 15° knee flexion contracture	
Ankle ROM	Accommodates full R.O.M. No minimum patient requirements	
Knee Valgum/Varum	Accommodates up to 10° valgum/varum	
Ankle Valgus/Varus	No minimum patient requirement	
A. Hip Flexors	B. Hip Extensors	C. Quadriceps
D. Hamstring	E. Plantarflexors	F. Dorsiflexors

Medical Necessity Checklist

Before you submit a claim for insurance reimbursement, it is important to understand the elements that an insurer requires in order to approve an insurance claim.

Follow these steps to improve the reimbursement process:

- Review the patient's insurance policy. Does your patient's policy include orthotic coverage? If the insurer denies the claim, they must prove that the orthosis is excluded from coverage.
- Review the definition of medical necessity. Different insurance companies use different definitions. Ask the insurer for a copy of their definition of medical necessity. Insurance companies create a Summary Plan Description, which is a document that describes individual insurance plans. If you get a copy, you can review how the plan defines medical necessity.
- Craft your letter of medical necessity specifically for your audience. The letter should give a good description of your patient and specifically state why a Sensor Walk is needed. Remember that the people who review the letter are not experts in orthotics or gait analysis, so use words they will understand.

Elements of an Effective Letter

- Introduce who you are and why you are writing.
- Explain your patient's condition, describe how this impacts their daily activities and indicate how your patient's life will be affected if they do not receive a Sensor Walk.
- Give a clear explanation of the Sensor Walk. Specifically state how the Sensor Walk function is necessary to daily activities. Do not assume that the person reading the letter understands what basic mobility problems are faced by a person with weak or absent quadriceps. Use clear language to explain these challenges.
- Explain why the Sensor Walk will help limit other insurance expenses, such as hospitalizations due to falls.
- Clearly state the insurance company's definition of medical necessity, then provide a simple explanation of how your patient's Sensor Walk meets this criteria.
- When your letter refers to your patient, use his or her name to paint a clearer picture of this person. Include their age, family status and even their job in a short description. The goal is to give the insurance company a picture of who this person is rather than simply thinking of him or her as a policy number.
- Send a copy of the prescription along with the letter of medical necessity. Make sure your letter refers to the prescription so the reader knows what it is.

Initial Submission for Sensor Walk

Reimbursement Guidelines

The documentation required for reimbursement submission must clearly identify the status of the patient and justify the orthotic device being fit. For best reimbursement results the following should be completed and submitted to the payer:

A. Letter of Medical Necessity (LMN)

Medical Necessity is based on the patient's functional abilities. Functional abilities are based on the reasonable expectations of the orthotist and treating physician. This includes but is not limited to:

- Past history of the patient
- Current and/or change of condition of the patient including status of knee and other medical conditions.
- The patient's desire to ambulate. Describe the functional level the patient is expected to reach, and illustrate the patient's desire and what they will do to reach that goal.

A basic model for writing a Letter of Medical Necessity uses the following logic:

- Describe the patient (history, desire to ambulate, physical condition, previous and current conditions)
- Describe the product. Explain the benefits of the Sensor Walk. Include examples of what the Sensor Walk will enable the patient to do that other stance control orthoses will not.

Examples of such benefits could include patient weight and the weight capacity of the product, or the ability of the product to lock at different knee angles – not just during stance phase – in order to accommodate normal stride-to-stride variability in gait, or the patient encounters varied terrain and elevation changes and requires the ability to achieve stance control orthotic capability in these environments. The patient may intermittently not achieve full knee extension prior to Initial Contact which leads to falls in other stance control orthosis, but the Sensor Walk can prevent the types of fall associated with unlocked stance control orthoses at Initial Contact and Loading Response.

- Describe why the patient needs the product. Combine the patient and product description to illustrate how that specific patient will benefit from the use of the Sensor Walk. It is very important to relate the product features to the specific patient and their ADL. Include an explanation of how (if applicable) the Sensor Walk will enable the patient to return to work sooner than if fit with another stance control orthosis.

B. Orthotic Documentation

- Verify the status of the patient's knee. The Sensor Walk Order Form includes a section where the patient's clinical presentation is summarized. This information could be transferred to the documentation section of your reimbursement request.
- Identify rationale to replace existing orthosis.
- Indicate why existing orthosis does not allow the patient to achieve specific ADL.

C. Physical Description

Describe the patient and his/her disability, history and any related physical conditions. Knee alignment (in both sagittal and coronal planes) and weight (or Body Mass Index) could be added to the physical description. Flexion contractures in excess of 10 degrees are contraindicated for other stance control orthoses. Body weights greater than 265 lbs, hip extensors less than Grade 3 (against gravity) and an inability to achieve full knee extension prior to Initial Contact consistently, are also contraindicated for other commercial systems on the market.

D. Functional Description

Describe the patient's activity or functional level and their needs related to ADL.

E. Identify Codes

Clearly indicate all the codes being used and how each one is related specifically to the patient's ADL.

F. Other Key Terms

- 1) Reasonable and necessary.

Medicare defines this as the patient reaching or maintaining a defined functional state within a reasonable period of time and is motivated to ambulate.

- 2) Least costly, most functional.

The least costly alternative compared to another service/product that provides the same benefits. Include what the Sensor Walk can provide that other stance control orthoses cannot. Remember to relate back to your patient's physical condition and the need from a medical necessity perspective.

Differences between Sensor Walk and other devices include:

- 1) The locking mechanism can release under load. All other options on the market today have a lock mechanism that has to be unloaded in order to disengage. This means that the wearer has to alter their gait pattern to enable the joint to unlock; allowing them to bend their knee to swing their leg through and clear their foot to prevent a trip or stumble. Published research shows that the moment in the gait cycle before the foot comes off the ground for swing the external moment on the knee is predisposing the knee to flex instead of extend. Knee extension is what is needed to make the other SCOs release for swing¹.
- 2) Knee joint stability is not dependent on the foot making contact with the ground. Previous explanation shows microprocessor control anticipating the need for flexion blocking upon weight bearing before the foot contacts the ground. All other SCO options either have to come to full extension to lock or are dependent on contact with the ground to be stable again.
- 3) One of the few devices that a knee flexion contracture of 15 degrees can be accommodated. This is due to the difficulty to disengage the joint because of the knee flexion load that is occurring, in conjunction with the difficulty of generating the needed knee extension moment to get the joint to release. This is a significant difference between the Sensor Walk other SCO technology.
- 4) Microprocessor control ensures the appropriate timing for release of locking mechanism and reengagement of locking mechanism. Unlike mechanical locking, non-microprocessor controlled KAFOs, the Sensor Walk enables precisely timed knee flexion block which can prevent stumbles and falls. This feature is highly important in that the prevalence of falling is significant among these patient populations due to compromise of the sensorimotor system, muscle weakness and reduced postural control or balance².
- 5) The Sensor Walk knee joint accommodates up to 300 lbs.
- 6) Existing non-microprocessor Stance Controlled Knee Orthosis (SCOs) do not contain a mechanism to ensure that knee joint locking and unlocking occurs at the appropriate time in the gait cycle. Non-microprocessor SCOs require the patient to think about each step they are taking in order to allow the knee joint to unlock for swing phase. That means that the patient's cognitive energy is being spent on making this event (unlocking) happen. Thus, the patient is being distracted from their environment and can be more susceptible to mishap^{3,4}. The Sensor Walk, on the other hand, enables the patient to ambulate without the need to concentrate on whether or not the knee joint will lock or unlock during the gait cycle. Therefore, the gait training instruction to the patient is simply to tell them to "walk".

References

1. Irby SE, Kaufman KR, Mathewson JW, Sutherland DH. 1999. Automatic Control Design for a Dynamic Knee-Brace System. *IEEE Transactions on Rehabilitation Engineering*; 7(2): 135-139
2. Lord SR, Allen GM, Williams P, Gandevia SC. Risk of falling: predictors based on reduced strength in persons previously affected by polio. *APMR* 2002;83:757-63.
3. Hafner BJ, Willingham LL, Buell NC, Allyn KJ, Smith DG. Evaluation of Function, Performance, and Preference as Transfemoral Amputees Transition From Mechanical to Microprocessor Control of the Prosthetic Knee. *Arch Phys Med Rehabil* 2007;88:207-17.
4. Seymour R, Engbretson, B, Kott K, Ordway N, Brooks G, Crannell J, Hickernell E, Wheeler K. Comparison between the C-leg microprocessor-controlled prosthetic knee and non-microprocessor control prosthetic knees: A preliminary study of energy expenditure, obstacle course performance, and quality of life survey. *Prosthetics and Orthotics International*. March 2007; 31(1): 51 – 61

Suggested Reimbursement Code List

The responsibility for accurate coding lies with the patient care facility that selects a product and fits the patient. Otto Bock's coding recommendations are based on our best judgment. These recommendations are open to revision based on additional information or changes in the alphanumeric system.

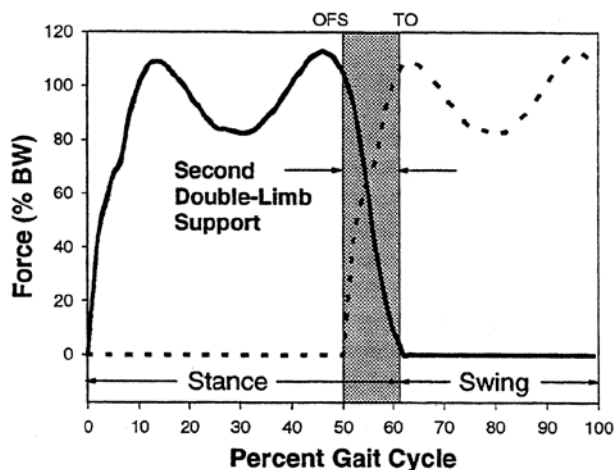
- L2036, KAFO, full plastic, double upright, with or without free motion knee, with or without free motion ankle, custom fabricated
- L2385, Addition to lower extremity, straight knee joint, heavy duty, each joint
- L2220, Addition to lower extremity, dorsiflexion and plantar flexion assist/resist, each joint (x2)
- L2250, Addition to lower extremity, foot plate, molded to patient model, stirrup attachment
- L2425, Addition to knee joint, disc or dial lock for adjustable knee flexion, each joint
- L2780, Addition to lower extremity orthosis, non-corrosive finish, per bar (x4)
- L2820, Addition to lower extremity orthosis, soft interface for molded plastic, below knee section
- L2830, Addition to lower extremity orthosis, soft interface for molded plastic, above knee section
- L7368, Lithium ion battery charger
- L2755, Addition to lower extremity orthosis, high strength, lightweight material, all hybrid lamination/prepreg composite, per segment, for custom fabricated orthosis only (x3)
- L2999, Addition to lower extremity orthosis, microprocessor stance control feature, limitless knee flexion block in stance, includes sensors, any type.

Replacement Only

- L7367, Replacement lithium ion battery

Using the miscellaneous code, you will be required to describe the unique functioning of the Sensor Walk microprocessor. The following points should be made:

- 1) The microprocessor enables the Sensor Walk to be responsive to both the load on the brace and the position of the knee joint. The microprocessor utilizes electronic sensing technology to determine the loading of the braced limb and therewith determine the appropriate instance in time to release the knee joint. This makes the Sensor Walk much more responsive than a stance control orthosis that depends on a mechanical event to lock or unlock. The chart below, from published research, shows the brace supported leg (solid line) and the opposite limb (dashed line). The steep descending solid line in the shaded area shows the rapidly changing foot/floor force during which the stance control brace must release. The electronic control system can precisely trigger knee joint release for optimum performance.



Problems may arise with imprecise control schema that release the knee joint too soon or too late in the gait cycle. Early knee joint release may lead to a patient fall because a significant portion of body weight is still supported by the braced limb. Delayed release will compromise pre-swing knee flexion and hence limb clearance. This will cause the patient to adopt compensations at the hip, such as hip hike or circumduction and/or contralateral vaulting to ensure foot clearance during swing. These compensatory measures do not allow a fluid swing or a natural gait pattern, and will require more energy on the part of the patient.

- 2) Footswitch connectivity to the microprocessor enables the Sensor Walk to not depend on ankle angle/flexion to determine whether to lock or unlock, as is the case with other stance control orthoses. As a result, the Sensor Walk patient can use rigid or articulating ankle joints.

Published Peer Reviewed Clinical Research

Clinical benefit and design of the Sensor Walk has been documented and measured in published research studies:

1. Irby SE, Kaufman KR, Mathewson JW, Sutherland DH. 1999. Automatic Control Design for a Dynamic Knee-Brace System. IEEE Transactions on Rehabilitation Engineering; 7(2): 135-139
2. Irby, SE, Bernhardt, KA and Kaufman, KR. Gait of stance control orthosis user: The Dynamic Knee Brace System. Prosthetics & Orthotics International 2005; 29(3):269-282.

These published studies evaluate gait performance of both novice and experienced Knee-Ankle-Foot Orthosis wearers during the earliest stages of SCO adoption. The research concluded that all users demonstrated increased knee flexion and a reduction in compensatory contralateral vaulting with the use of the SCO.

3. Kaufman KR, Irby SE, Mathewson JW, Wirta RW, Sutherland DH. Energy Efficient Knee Ankle Foot Orthosis. J Prosthetics Orthotics 1996; 8(3):79-85.

This publication proves that less energy is required to walk when using the Sensor Walk as compared to a conventional locked-knee KAFO.