These documents have been provided by

WorryFreeDME

Compliance Documentation Pack

Prefabricated AFOs

To be completed by physician:

Biomechanical Evaluation Form (Medical Record Information)

Documents medical necessity

Document of Medical Necessity

- □ Justifies qualification for use of AF0
- Details reason for prefabricated versus custom device
- □ Justifies level of fitting (off-the-shelf versus custom-fitted)
- □ Justifies code(s) selected

Prescription

- Description of the items
- Patient Name
- □ Physician's printed name
- Diagnosis
- □ Physician's signature (no stamps allowed)
- □ Date (no stamps allowed)
- □ Indication if right and / or left limb affected

To be given to Patient:

Proof of Delivery

- Patient Printed Name
- □ Date of deliverv
- □ Item Description
- □ Item Code(s)
- Patient Signature
- Patient Address

DMEPOS Supplier Standards

To be completed by Supplier / Physician:

Dispensing Chart Notes

- Type of orthosis
- Describes method of fitting
- Documents patient satisfaction
- * Confirms delivery of Supplier Standards

The OHI Family of Brands











Biomechanical Evaluation Form



Created by:

The American College of FOOT & ANKLE ORTHOPEDICS

| Patient Name: | |
|--|--|
| Chief Complaint: | |
| History of problem: | |
| Nature of discomfort/pain | |
| Location (anatomic) | |
| Duration | |
| Onset | |
| Course | |
| Aggravating and/or alleviating factors | |

| Left | Stance Evaluation: | Right | Normative values: | Treatments and response | | | | |
|------------------------------------|---|-------|--|-------------------------|--|--|--|--|
| | Angle of gait:→ | | | | | | | |
| | Base of gait:→ | | | | | | | |
| | Foot appearance | | | | | | | |
| | Tibial influence | | 0°-2° varus or valgus | | | | | |
| | Relaxed calcaneal stance position (RCSP) | | 0° | | | | | |
| | Neutral calcaneal stance position (NCSP) | | 0° | | | | | |
| | Non-Weight Bearing Evaluation: | | 0 | | | | | |
| | Limb length:→ | | Equal | | | | | |
| | Hip sagittal plane- | | Lyuai | | | | | |
| | Knee extended | | Flexion 120°/extension 20-30° | | | | | |
| | | | Flexion 45-60°/extension 20-30° | | | | | |
| | Knee flexed | | Flexion 45-60 /extension 20-30 | | | | | |
| | Hip transverse plane- | | A=0 1 11 11 | | | | | |
| | Knee extended | | 45° each direction | | | | | |
| | Knee flexed | | 45° each direction | | | | | |
| | Hip frontal plane | | 45° each direction | | | | | |
| | Knee sagittal plane | | Flexion 120°/extension 0-10° | | | | | |
| | Knee recurvatum | | Absent | | | | | |
| | Ankle sagittal plane- | | | | | | | |
| | Knee extended | | Dorsiflexion 10°/plantarflexion 40-70° | | | | | |
| | Knee flexed | | Dorsiflexion 10°/plantarflexion 40-70° | | | | | |
| | Subtalar joint- | | | | | | | |
| | Inversion | | 20° | | | | | |
| | Eversion | | 10° | | | | | |
| | Subtalar joint axis location | | | | | | | |
| | Midtarsal joint | | 0° | | | | | |
| | 1 st ray range of motion | | Dorsal & plantar excursion 5mm | | | | | |
| | 1 st MTPJ range of motion | | Dorsal 65° or >unloaded/20-40° loaded | | | | | |
| | Lesser MTPJ's | | | | | | | |
| | Other comments: | | | | | | | |
| | | | | | | | | |
| | Muscle testing (extrinsics): | | | | | | | |
| | Invertors | | 5/5: normal strength | | | | | |
| | Evertors | | 5/5: normal strength | | | | | |
| | Dorsiflexors | | 5/5: normal strength | | | | | |
| | Plantarflexors | | 5/5: normal strength | | | | | |
| | Neurological testing: | | | | | | | |
| | Romberg→ | | Balance intact | | | | | |
| | Patellar reflex | | 2+ normal | | | | | |
| | Achilles reflex | | 2+ normal | | | | | |
| | Babinski | | No hallux extension | | | | | |
| | Clonus | | Absent | | | | | |
| | Protective sensation | | Present | | | | | |
| | Gait Evaluation - | | | | | | | |
| | Gait pattern | | | | | | | |
| | Comment on head/shoulders, spine, pelvis, sagittal/ | | | | | | | |
| | transverse/frontal plane, postural, etc. | | | | | | | |
| | Footgear (size/width, wear pattern(s))→ | | | | | | | |
| | Existing orthoses/type→ | | | | | | | |
| | Weight→ | | | | | | | |
| | Height→ | | | | | | | |
| Biomechanical | l assessment: | | | | | | | |
| Treatment plar | n: | | | | | | | |
| | | | Enter date of exam | | | | | |
| Enter assistant | name | | Enter date of exam | | | | | |
| Enter assistant Signature of as | | | Signature of physician | | | | | |

Save in patient's chart

The Medicare Program Integrity Manual, states that "For any DMEPOS item to be covered by Medicare, the patients medical record contains sufficient documentation of the patients medical condition to substantiate the necessity for the type and quantity of the items ordered.

These documents have been provided by WorryFreeDME

Document of Medical Necessity: Prefabricated AFO

| Patient Name: | | HICN: | | |
|---|---|--|-------------------------------------|--|
| Prognosis: Good | Duration of usage: 6 Months | | | |
| I certify that Mr. / M | Ms | qualifies for and w | vill benefit from | |
| an ankle foot ortho | sis used during ambulation based on | meeting all of the following criteria | . The patient is: | |
| Ambulatory, an | d | | | |
| Has weakness | or deformity of the foot and ankle, and | | | |
| Requires stabil | ization for medical reasons, and | | | |
| Has the potenti | al to benefit functionally | | | |
| - | al record contains sufficient docume antity of the items ordered. | ntation of the patients medical cond | ition to substantiate the necessity | |
| The goal of this the | erapy: (indicate all that apply) | | | |
| 🗌 Improve mobi | lity | 🗌 Facilitate soft tissue healing | | |
| 🗌 Improve lower | r extremity stability | 🗌 Facilitate immobilization, heali | ng and treatment of an injury | |
| 🗌 Decrease pair | 1 | | | |
| The patient requires | the prescribed ankle foot orthosis beca | ause: | | |
| The patient ca | an be fit with a prefabricated off the she | If orthosis | | |
| The condition necessitating the orthosis is not expected to be permanent or of longstanding duration (more than 6 months) | | | | |
| There is need to control the ankle or foot in only one plane | | | | |
| The patient has no documented neurological, circulatory, or orthopedic condition that requires custom fabrication over a model to prevent tissue injury | | | | |
| 🗌 The patient ha | as no healing fracture which lacks norm | al anatomical integrity or anthropometi | ric proportions | |
| There is a need | ed to limit or restrict range of motion of o | one or more joints of the lower extremi | ty | |
| A prefabricated AFO is, i of the patient's condition | n my opinion, both reasonable and necessary ir n and rehabilitation. | n reference to accepted standards of medical p | practice in the treatment | |
| Signature of Prescribin | ng Physician: | Type I NPI: | Date: // | |
| Printed Name of Presc | ribing Physician | Phone: | | |
| | | | | |





The OHI Family of Brands







Rx: Prefabricated AFO

Patient Name: ____

Prognosis: Good Duration of usage: 6 Months

| Product Brand and Model: | | | | _ (Circle base code): | | |
|--------------------------|---|--|---|-----------------------|---|--|
| R | L | L1902 Ankle Foot Orthotic, Gauntlet Style, Prefabricated | R | L | L1971 AFO with Ankle Joint, Prefabricated | |
| R | L | L1906 AFO, Multiligamentous Ankle Support, Prefabricated | R | L | L4350 Ankle Control Orthosis, Stirrup Style, rigid | |
| R | L | L L1930 Ankle Foot Orthosis, Plastic or Other Material, | | L | L4361 Walking boot, pneumatic, off-the-shelf | |
| | | Prefabricated | R | L | L4387 Walking boot, non-pneumatic, off-the-shelf | |
| R | L | L1932 AFO Rigid Anterior Tibial Section | R | L | L4397 Plantar Fascia Night Splints, off-the-shelf | |
| R | L | L1951 AFO, Spiral, Plastic or Other Material, Prefabricated | R | L | L3298 Foot Drop Splint, Recumbent, Positioning Device | |

DX: (indicate all that apply) - Corresponds to Biomechanical Examination Form

Adult Acquired Flatfoot (PTTD)

| Adult Acquired Flatfoot (PTTD) | DJD of Ankle and Rearfoot | Lateral Ankle Instability | | |
|--|---|---|--|--|
| Flat foot [pes planus] (acquired) | Primary osteoarthritis, ankle and foot | Other specific joint derangements of ankle, not | | |
| right (M21.41) | right (M19.071) | elsewhere classified | | |
| Spontaneous rupture of other tendons, ankle and foot | Pain in ankle and joints of foot | right (M24.871) | | |
| right (M66.871) | right (M25.571) | Other specific joint derangements of foot, not | | |
| Disorder of ligament, ankle | Pain in lower leg | elsewhere classified | | |
| right (M24.271) | right (M79.661) | right (M24.874) | | |
| Disorder of ligament, foot | Pain in foot | Sprain of ankle calcaneofibular ligament | | |
| right (M24.274) | right (M79.671) | right (\$93.411) | | |
| Other acquired deformities of foot | Other specified congenital deformities of feet (Q66.89) | Tendonitis | | |
| right (M21.6X1) | Foot Drop | Achilles tendinitis | | |
| | Foot Drop, acquired | right (M76.61) | | |
| | right (M21.371) [left (M21.372) | Anterior tibial syndrome | | |
| | Hemiplegia | right (M76.811) [] left (M76.812) | | |
| | affecting right dominant side (l69.951) | Posterior tibial tendinitis | | |
| | affecting left dominant side (169.951) | right (M76.821) left (M76.822) | | |
| | affecting right non-dominant side (169.952) | Other synovitis and tenosynovitis, ankle and foot | | |
| | | right (M65.871) [left (M65.872) | | |
| | affecting left non-dominant side (I69.954) | Plantar fasciitis (M72.2) | | |
| | | Other | | |
| | | □ | | |
| Therapeutic Objective(s): (indicate a | □ Facilitate soft tissue hea | aling n, healing and treatment | | |

| Signature of Prescribing Physician: | Type I NPI: | Order Date: // | / |
|-------------------------------------|----------------------------|----------------------------|---|
| | (Must be current with CMS) | (Must be current with CMS) | |
| Prescribing Physician Printed Name: | | | |

The OHI Family of Brands —





Biomechanics :





Proof of Delivery: Prefabricated AFO

| Sup | Supplier Name: | | HICN: | | | |
|-----|----------------|---|---------|--------|---|--|
| Pro | duc | Brand and Model: | _ (Circ | cle ba | ase code): | |
| R | L | L1902 Ankle Foot Orthotic, Gauntlet Style, Prefabricated | R | L | L4350 Ankle Control Orthosis, Stirrup Style, Rigid | |
| R | L | L1906 AFO, Multiligamentous Ankle Support, Prefabricated | R | L | L4361 Walking boot, Prefabricated, Pneumatic, | |
| R | L | L1930 Ankle Foot Orthosis, Plastic or Other Material, Prefabricated | | | Below Knee, OTS | |
| R | L | L1932 AFO Rigid Anterior Tibial Section | R | L | L4387 Walking boot, Non-Pneumatic Walking Splint, OTS | |
| R | L | L1951 AFO, Spiral, Plastic or Other Material, Prefabricated | R | L | L4397 Plantar Fascia Night Splint, Prefabricated, OTS | |
| | | L1971 AFO with Ankle Joint, Prefabricated | R | L | L3298 Foot Drop Splint, Recumbent, Positioning Device | |
| | | | | | | |

Instructions For Use:

You have been dispensed this AFO to immobilize your foot and ankle. It should not be removed unless specifically instructed. If the brace feels too tight, you may be walking too much. Get off your feet, loosen any straps and elevate your foot until the tightness resolves. If your symptoms do not resolve, please contact our office immediately.

Material failure warrantee coverage:

- · Hardware, plastic and metal component are covered at no-charge for six months.
- All soft materials: material covers, Velcro straps and limb support pads, are covered at no-charge up to ninety days.

I have read the posted Complaint Resolution Policy and have been provided with a copy of the Medicare Supplier Standards. I certify that I have received the item(s) indicated. The physician has reviewed the instructions for proper use and care and provided me with written instructions. I understand that failure to properly care for these items will result in the warranty being voided. This could result in my responsibility for future repair or replacement costs if my insurance policy will not cover such costs. The physician has instructed me to call the office if I have any difficulties or problems with the device.

Patient Signature

Printed Patient Name

Date Delivered: / /

Patient Address

Original in patient's chart, copy to patient

The codes contained herein are not the official position or endorsement of any organization or company. They are offered as a suggestion based upon input from previous customers. Each prescribing practitioner should contact his or her local carrier or Medicare office to verify billing codes, regulations and guidelines relevant to their geographic location.

The OHI Family of Brands –













These documents have been provided by WorryFreeDME

CMS Medicare DMEPOS Supplier Standards

- 1. A supplier must be in compliance with all applicable Federal and State licensure and regulatory requirements and cannot contract with an individual or entity to provide licensed services.
- 2. A supplier must provide complete and accurate information on the DMEPOS supplier application. Any changes to this information must be reported to the National Supplier Clearinghouse within 30 days.
- 3. An authorized individual (one whose signature is binding) must sign the application for billing privileges.
- 4. A supplier must fill orders from its own inventory, or must contract with other companies for the purchase of items necessary to fill the order. A supplier may not contract with any entity that is currently excluded from the Medicare program, any State health care programs, or from any other Federal procurement or non-procurement programs.
- 5. A supplier must advise beneficiaries that they may rent or purchase inexpensive or routinely purchased durable medical equipment, and of the purchase option for capped rental equipment.
- 6. A supplier must notify beneficiaries of warranty coverage and honor all warranties under applicable State law, and repair or replace free of charge Medicare covered items that are under warranty.
- 7. A supplier must maintain a physical facility on an appropriate site. This standard requires that the location is accessible to the public and staffed during posted hours of business. The location must be at least 200 square feet and contain space for storing records.
- 8. A supplier must permit CMS, or its agents to conduct on-site inspections to ascertain the supplier's compliance with these standards. The supplier location must be accessible to beneficiaries during reasonable business hours, and must maintain a visible sign and posted hours of operation.
- 9. A supplier must maintain a primary business telephone listed under the name of the business in a local directory or a toll free number available through directory assistance. The exclusive use of a beeper, answering machine, answering service or cell phone during posted business hours is prohibited.
- 10. A supplier must have comprehensive liability insurance in the amount of at least \$300,000 that covers both the supplier's place of business and all customers and employees of the supplier. If the supplier manufactures its own items, this insurance must also cover product liability and completed operations.
- 11. A supplier must agree not to initiate telephone contact with beneficiaries, with a few exceptions allowed. This standard prohibits suppliers from contacting a Medicare beneficiary based on a physician's oral order unless an exception applies.
- 12. A supplier is responsible for delivery and must instruct beneficiaries on use of Medicare covered items, and maintain proof of delivery.
- 13. A supplier must answer questions and respond to complaints of beneficiaries, and maintain documentation of such contacts.

- 14. A supplier must maintain and replace at no charge or repair directly, or through a service contract with another company, Medicare covered items it has rented to beneficiaries.
- 15. A supplier must accept returns of substandard (less than full quality for the particular item) or unsuitable items (inappropriate for the beneficiary at the time it was fitted and rented or sold) from beneficiaries.
- 16. A supplier must disclose these supplier standards to each beneficiary to whom it supplies a Medicare covered item.
- 17. A supplier must disclose to the government any person having ownership, financial, or control interest in the supplier.
- 18. A supplier must not convey or reassign a supplier number i.e., the supplier may not sell or allow another entity to use its Medicare billing number.
- 19. A supplier must have a complaint resolution protocol established to address beneficiary complaints that relate to these standards. A record of these complaints must be maintained at the physical facility.
- 20. Complaint records must include: the name, address, telephone number and health insurance claim number of the beneficiary, a summary of the complaint, and any actions taken to resolve it.
- 21. A supplier must agree to furnish CMS any information required by the Medicare statute and implementing regulations.
- 22. All suppliers must be accredited by a CMS approved accreditation organization in order to receive and retain a supplier billing number. The accreditation must indicate the specific products and services, for which the supplier is accredited in order for the supplier to receive payment of those specific products and services (except for certain exempt pharmaceuticals). Implementation Date October 1, 2009
- 23. All suppliers must notify their accreditation organization when a new DMEPOS location is opened.
- 24. All supplier locations, whether owned or subcontracted, must meet the DMEPOS quality standards and be separately accredited in order to bill Medicare.
- 25. All suppliers must disclose upon enrollment all products and services, including the addition of new product lines for which they are seeking accreditation.
- 26. Must meet the surety bond requirements specified in 42 C.F.R. 424.57(c). Implementation date May 4, 2009
- 27. A supplier must obtain oxygen from a state-licensed oxygen supplier.
- 28. A supplier must maintain ordering and referring documentation consistent with provisions found in 42 C.F.R. 424.516(f).
- 29. DMEPOS suppliers are prohibited from sharing a practice location with certain other Medicare providers and suppliers.
- 30. DMEPOS suppliers must remain open to the public for a minimum of 30 hours per week with certain exceptions.





The OHI Family of Brands -







Dispensing Chart Notes: Prefabricated AFO

| Patient Name: I | | HICN: | | | |
|-----------------|------|---|---------|-------|---|
| Pro | duct | Brand and Model: | _ (Circ | le ba | ase code): |
| R | L | L1902 Ankle Foot Orthotic, Gauntlet Style, Prefabricated | R | L | L4350 Ankle Control Orthosis, Stirrup Style, Rigid |
| R | L | L1906 AFO, Multiligamentous Ankle Support, Prefabricated | R | L | ·····, ····, |
| R | L | L1930 Ankle Foot Orthosis, Plastic or Other Material, Prefabricated | | | Below Knee, OTS |
| R | L | L1932 AFO Rigid Anterior Tibial Section | R | L | L4387 Walking boot, Non-Pneumatic Walking Splint, OTS |
| R | | L1951 AFO, Spiral, Plastic or Other Material, Prefabricated | R | L | L4397 Plantar Fascia Night Splint, Prefabricated, OTS |
| R | | L1971 AFO with Ankle Joint, Prefabricated | R | L | L3298 Foot Drop Splint, Recumbent, Positioning Device |
| | | | | | |

- S) (Brand and model name) ______ was dispensed and fit at this visit. Patient is ambulatory. There is pain with range of motion that requires stabilization. Due to the indicated diagnosis(s) and related symptoms this device is medically necessary as part of the overall treatment. It is anticipated that the patient will benefit functionally with the use of this device. The custom device is utilized in an attempt to avoid the need for surgery.
- 0) Upon gait analysis, the device appeared to be fitting well and the patient states that the device is comfortable.
- A) Good fit. The patient was able to apply properly and ambulate without distress. The function of this device is to restrict and limit motion and provide stabilization in the ankle joint.
- P) The goals and function of this device were explained in detail to the patient. The patient was shown how to properly apply, wear, and care for the device. It was explained that the device will fit and function best in a lace-up shoe with a stiff heel counter and a wide base of support. When the device was dispensed, it was suitable for the patient's condition and not substandard. No guarantees were given. Precautions were reviewed. Written instructions, warranty information and a copy of DMEPOS Supplier Standards were provided. All questions were answered.

Additional Notes:

Supplier Signature: _____

Dispensing Date: _____

Print Supplier Name: _____









