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# 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 AFO  
 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 delivery  
 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

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## Biomechanical Evaluation Form

<b>Patient Name:</b>	
<b>Chief Complaint:</b>	
<b>History of problem:</b>	
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°	
	<b>Non-Weight Bearing Evaluation:</b>			
	Limb length:->		Equal	
	Hip sagittal plane-			
	Knee extended		Flexion 120°/extension 20-30°	
	Knee flexed		Flexion 45-60°/extension 20-30°	
	Hip transverse plane-			
	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 <sup>st</sup> ray range of motion		Dorsal & plantar excursion 5mm	
	1 <sup>st</sup> MTPJ range of motion		Dorsal 65° or >unloaded/20-40° loaded	
	Lesser MTPJ's			
	Other comments:			
	<b>Muscle testing (extrinsics):</b>			
	Invertors		5/5: normal strength	
	Evertors		5/5: normal strength	
	Dorsiflexors		5/5: normal strength	
	Plantarflexors		5/5: normal strength	
	<b>Neurological testing:</b>			
	Romberg->		Balance intact	
	Patellar reflex		2+ normal	
	Achilles reflex		2+ normal	
	Babinski		No hallux extension	
	Clonus		Absent	
	Protective sensation		Present	
	<b>Gait Evaluation -</b>			
	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->			
	<b>Biomechanical assessment:</b>			
	<b>Treatment plan:</b>			
	Enter assistant name		Enter date of exam	
	Signature of assistant		Signature of physician	

Save in patient's chart



# Document of Medical Necessity: Prefabricated AFO

Patient Name: \_\_\_\_\_

HICN: \_\_\_\_\_

Prognosis: Good

Duration of usage: 6 Months

I certify that Mr. / Ms. \_\_\_\_\_ qualifies for and will benefit from an ankle foot orthosis used during ambulation based on meeting all of the following criteria. The patient is:

- Ambulatory, and
- Has weakness or deformity of the foot and ankle, and
- Requires stabilization for medical reasons, and
- Has the potential to benefit functionally

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.

**The goal of this therapy: (indicate all that apply)**

- Improve mobility
- Improve lower extremity stability
- Decrease pain
- Facilitate soft tissue healing
- Facilitate immobilization, healing and treatment of an injury

**The patient requires the prescribed ankle foot orthosis because:**

- The patient can be fit with a prefabricated off the shelf 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 has no healing fracture which lacks normal anatomical integrity or anthropometric proportions
- There is a need to limit or restrict range of motion of one or more joints of the lower extremity

A prefabricated AFO is, in my opinion, both reasonable and necessary in reference to accepted standards of medical practice in the treatment of the patient's condition and rehabilitation.

Signature of Prescribing Physician: \_\_\_\_\_

Type I NPI: \_\_\_\_\_

Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

Printed Name of Prescribing Physician \_\_\_\_\_

Phone: \_\_\_\_\_

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# WorryFreeDME

## Rx: Prefabricated AFO

Patient Name: \_\_\_\_\_

Prognosis: Good Duration of usage: 6 Months

Product Brand and Model: \_\_\_\_\_ (Circle base code):

- |  |  |
|--|--|
| R L <b>L1902</b> Ankle Foot Orthotic, Gauntlet Style, Prefabricated            | R L <b>L1971</b> AFO with Ankle Joint, Prefabricated             |
| R L <b>L1906</b> AFO, Multiligamentous Ankle Support, Prefabricated            | R L <b>L4350</b> Ankle Control Orthosis, Stirrup Style, rigid    |
| R L <b>L1930</b> Ankle Foot Orthosis, Plastic or Other Material, Prefabricated | R L <b>L4361</b> Walking boot, pneumatic, off-the-shelf          |
| R L <b>L1932</b> AFO Rigid Anterior Tibial Section                             | R L <b>L4387</b> Walking boot, non-pneumatic, off-the-shelf      |
| R L <b>L1951</b> AFO, Spiral, Plastic or Other Material, Prefabricated         | R L <b>L4397</b> Plantar Fascia Night Splints, off-the-shelf     |
|  | R L <b>L3298</b> Foot Drop Splint, Recumbent, Positioning Device |

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

### Adult Acquired Flatfoot (PTTD)

- Flat foot [pes planus] (acquired)
  - right (M21.41)     left (M21.42)
- Spontaneous rupture of other tendons, ankle and foot
  - right (M66.871)     left (M66.872)
- Disorder of ligament, ankle
  - right (M24.271)     left (M24.272)
- Disorder of ligament, foot
  - right (M24.274)     left (M24.275)
- Other acquired deformities of foot
  - right (M21.6X1)     left (M21.6X2)

### DJD of Ankle and Rearfoot

- Primary osteoarthritis, ankle and foot
  - right (M19.071)     left (M19.072)
- Pain in ankle and joints of foot
  - right (M25.571)     left (M25.572)
- Pain in lower leg
  - right (M79.661)     left (M79.662)
- Pain in foot
  - right (M79.671)     left (M79.672)
- Other specified congenital deformities of feet (Q66.89)

### Foot Drop

- Foot Drop, acquired
  - right (M21.371)     left (M21.372)
- Hemiplegia
  - affecting right dominant side (I69.951)
  - affecting left dominant side (I69.952)
  - affecting right non-dominant side (I69.953)
  - affecting left non-dominant side (I69.954)

### Lateral Ankle Instability

- Other specific joint derangements of ankle, not elsewhere classified
  - right (M24.871)     left (M24.872)
- Other specific joint derangements of foot, not elsewhere classified
  - right (M24.874)     left (M24.875)
- Sprain of ankle calcaneofibular ligament
  - right (S93.411)     left (S93.412)

### Tendonitis

- Achilles tendinitis
  - right (M76.61)     left (M76.62)
- Anterior tibial syndrome
  - right (M76.811)     left (M76.812)
- Posterior tibial tendinitis
  - right (M76.821)     left (M76.822)
- Other synovitis and tenosynovitis, ankle and foot
  - right (M65.871)     left (M65.872)
  - Plantar fasciitis (M72.2)

### Other

\_\_\_\_\_

### Therapeutic Objective(s): (indicate all that apply)

- |  |  |
|--|--|
| <input type="checkbox"/> Improve mobility                  | <input type="checkbox"/> Facilitate soft tissue healing                                |
| <input type="checkbox"/> Improve lower extremity stability | <input type="checkbox"/> Facilitate immobilization, healing and treatment of an injury |
| <input type="checkbox"/> Decrease pain                     |  |

Signature of Prescribing Physician: \_\_\_\_\_ Type I NPI: \_\_\_\_\_ Order Date: \_\_\_\_/\_\_\_\_/\_\_\_\_  
(Must be current with CMS) (Must be current with CMS)

Prescribing Physician Printed Name: \_\_\_\_\_

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# Proof of Delivery: Prefabricated AFO

Supplier Name: \_\_\_\_\_

HICN: \_\_\_\_\_

Product Brand and Model: \_\_\_\_\_ (Circle base code):

- |   |   |  |   |   |  |
|---|---|--|---|---|--|
| R | L | <b>L1902</b> Ankle Foot Orthotic, Gauntlet Style, Prefabricated            | R | L | <b>L4350</b> Ankle Control Orthosis, Stirrup Style, Rigid            |
| R | L | <b>L1906</b> AFO, Multiligamentous Ankle Support, Prefabricated            | R | L | <b>L4361</b> Walking boot, Prefabricated, Pneumatic, Below Knee, OTS |
| R | L | <b>L1930</b> Ankle Foot Orthosis, Plastic or Other Material, Prefabricated | R | L | <b>L4387</b> Walking boot, Non-Pneumatic Walking Splint, OTS         |
| R | L | <b>L1932</b> AFO Rigid Anterior Tibial Section                             | R | L | <b>L4397</b> Plantar Fascia Night Splint, Prefabricated, OTS         |
| R | L | <b>L1951</b> AFO, Spiral, Plastic or Other Material, Prefabricated         | R | L | <b>L3298</b> Foot Drop Splint, Recumbent, Positioning Device         |
| R | L | <b>L1971</b> AFO with Ankle Joint, Prefabricated                           |   |   |  |

### 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 \_\_\_\_\_

Date Delivered: \_\_\_\_ / \_\_\_\_ / \_\_\_\_

Printed Patient Name \_\_\_\_\_

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.

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# 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.

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# Dispensing Chart Notes: Prefabricated AFO

Patient Name: \_\_\_\_\_

HICN: \_\_\_\_\_

Product Brand and Model: \_\_\_\_\_ (Circle base code):

- |   |   |  |   |   |  |
|---|---|--|---|---|--|
| R | L | <b>L1902</b> Ankle Foot Orthotic, Gauntlet Style, Prefabricated            | R | L | <b>L4350</b> Ankle Control Orthosis, Stirrup Style, Rigid            |
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| R | L | <b>L1971</b> AFO with Ankle Joint, Prefabricated                           |   |   |  |

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.

O) 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: \_\_\_\_\_

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