These documents have been provided by

WorryFreeDME

Thermoplastic AFOs Compliance Documentation Packet

WorryFree DME Compliance Documentation Packet

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

These documents have been provided by

WorryFreeDME

Created by:

The American College of Foot & Ankle Orthopedics & Medicine

Biomechanical Evaluation Form

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:			
	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˚	
	1st ray range of motion		Dorsal & plantar excursion 5mm	
	1st 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 assessment:				
Treatment plan:				

Enter assistant name	Enter date of exam
Signature of assistant	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.

Document of Medical Necessity: Thermoplastic AFO

Patient Name: _____ HICN: _____

Prognosis: Good **Duration of usage:** 12 Months **Quantity:** ☐ Bilateral ☐ Unilateral

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 patient's 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

Necessity of Ankle Foot Orthotic molded to patient model:

A custom (vs. prefabricated) ankle foot orthosis has been prescribed based on the following criteria which are specific to the condition of this patient. (indicate all that apply)

- ☐ The patient could not be fit with a prefabricated AFO
- ☐ The condition necessitating the orthosis is expected to be permanent or of longstanding duration (more than 6 months)
- ☐ There is need to control the ankle or foot in more than one plane
- ☐ The patient has a documented neurological, circulatory, or orthopedic condition that requires custom fabrication over a model to prevent tissue injury
- ☐ The patient has a healing fracture that lacks normal anatomical integrity or anthropometric proportions

I hereby certify that the ankle foot orthotic described above is a rigid or semi-rigid device which is used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body. It is designed to provide support and counterforce on the limb or body part that is being braced. In my opinion, the custom molded thermoplastic AFO is both reasonable and necessary according 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: _____

Rx: Thermoplastic AFO

Doctor Name: _____ PatientName:_____

Prognosis: Good **Duration of usage:** 12 Months

Product Information *(Check brand and model, circle base code and addition(s))*:

☐ **Arizona Optima Brace, Standard, Restricted**
- R L **L1970** An articulated molded plastic orthosis with ankle joints that allow for free motion of the ankle, (dorsi-plantar flexion), custom molded from a model of the patient, custom fabricated, includes casting and cast preparation.
- R L **L2820** Addition to lower extremity orthosis, soft interface for molded plastic below knee section.

☐ **Arizona Thermoplastic AFO - Articulated, Dorsi-Assist**
- R L **L1970** Articulated molded plastic orthosis with ankle joints, custom molded from a model of the patient, includes casting and cast preparation.
- R L **L2210** Addition to lower extremity, dorsi-flexion assist (plantarflexion resist), each joint.

☐ **Arizona Thermoplastic AFO - Articulated**
- R L **L1970** An articulated molded plastic orthosis with ankle joints that allow for free motion of the ankle, (dorsi-plantar flexion), custom molded from a model of the patient, custom fabricated, includes casting and cast preparation.

☐ **Arizona Thermoplastic AFO**
- R L **L1960** A molded plastic ankle foot orthosis, posterior solid ankle trim lines, custom molded from a model of the patient, custom fabricated, includes casting and cast preparation

☐ **AZ CROW Walker™**
- R L **L4631** A bivalved custom molded plastic orthosis, with a removable custom arch support, soft interface, and a rocker bottom walking sole. For patients with Charcot.

☐ **Split Upright AFO**
- R L **L1970** An articulated molded plastic orthosis with ankle joints that allow for free motion of the ankle, (dorsi-plantar flexion), custom molded from a model of the patient, custom fabricated, includes casting and cast preparation.
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- R L **L2210** Addition to lower extremity, dorsi-flexion assist (plantarflexion resist), each joint.
- R L **L2820** Addition to lower extremity orthosis, soft interface for molded plastic below knee section

☐ **Supramallleolar Orthosis**
- R L **L1907** Ankle orthosis, supramalleolar, with straps, with or without pads, custom fabricated

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

Adult Acquired Flat Foot (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 (M24.275c
Other acquired deformities of foot
☐ right (M21.6X1) ☐ left (M21.6X2)

DJD of ankle and rearfoot
Primary osteoarthritis, ankle and foot
☐ right (M19.071) c left (M19.072)
Pain in ankle and joints of foot
☐ right (M25.571 c 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)

Tendinitis
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)

Amputation
Acquired absence of great toe
☐ right (Z89.411) ☐ left (Z89.412)
Acquired absence of other toe(s)
☐ right (Z89.421) ☐ left (Z89.422)
Acquired absence of foot
☐ right (Z89.431) ☐ left (Z89.432)
☐ Other

Charcot
☐ Right ankle and foot (M14.671)
☐ Left ankle and foot (M14.672)

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Rx: Thermoplastic AFO (continued)

THERAPEUTIC OBJECTIVE(S): (indicate all that apply)

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

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

Prescribing Physician Printed Name: _____

AZafo ARIZONA™
An OHI Company

Arizona AFO (877) 780-8382
SafeStep (866) 712-7837

Ship to address:
4825 East Ingram St.
Mesa, AZ 85205
Fax: 480.222.1599

Dispense Date: _____

Work Order #:

Thermoplastic AFO Collection

☐ **Thermoplastic AFO**

Color: ☐ Black ☐ White

Trim Line: ☐ **PLS** ☐ **Semi-Solid** ☐ **Solid**

Plastic Type: ☐ Polypropylene 1/8 3/16 1/4
☐ Co-Polymer 1/8 3/16 1/4

☐ **Thermoplastic AFO** - Articulated

Color: ☐ Black ☐ White

Hinge: ☐ Tamarack ☐ Oklahoma ☐ Camber Axis

Tamarack Dorsi - Assist: Durometer - ☐ 75 ☐ 85

Plantar Stops: ☐ 90° stop, plastic buttress
☐ Adjustable Stop
☐ Posterior Spring Assist

Plastic Type: ☐ Polypropylene 1/8 3/16 1/4
☐ Co-Polymer 1/8 3/16 1/4

☐ **Arizona Optima Brace**

Color: ☐ Black

Hinge: ☐ Free Motion ☐ Restricted

☐ **Supra Malleolar Orthosis**

Color: ☐ Black ☐ White

☐ **Split Upright**

Color: ☐ Black

Hinge: ☐ Tamarack ☐ Oklahoma ☐ Camber Axis

Tamarack Dorsi - Assist: Durometer - ☐ 75 ☐ 85

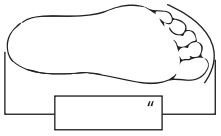
☐ **AZ CROW Walker™**

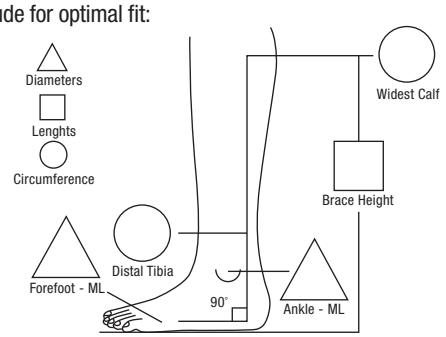
Color: ☐ Black ☐ White

Additions: ☐ Carbon Ankle Inserts ☐ Full Toe Plate
☐ Foam lining: Plastazote 1/8 3/16 ☐ Foam lining: Aliplast 1/8 3/16

Measurements - please include for optimal fit:

Indicate Location for Ulcer Reliefs





Patient Information: ☐ Right Foot ☐ Left Foot ☐ Bilateral

Patient Name: _____

Height: _____ Weight: _____ Shoe Size: _____ Gender: ☐ M ☐ F

Dx: _____ D.O.B: _____

Shipping and Billing Information:

Bill to my account:
☐ Arizona ☐ SafeStep Account # _____

Practitioner: _____

Email: _____

PO#: _____

Facility Name: _____

Phone: _____

Fax: _____

Ship to address: _____

Bill to address: _____

Shipping Options:
☐ Ground ☐ 3 Day Air ☐ 2 Day Air ☐ Overnight

Special Instructions: If you do not want the dorsi-plantar angle of the cast set to our recommendations, please choose:
☐ Leave cast exactly as is ☐ Correct Ankle Varus / Valgus
☐ Correct Forefoot to Neutral ☐ Other _____

Remarks: _____

_____

_____

Proof of Delivery: Thermoplastic AFO

Supplier Name: _____ HICN: _____

Product Information *(Check brand and model, circle base code and addition(s))*:

☐ **Arizona Optima Brace, Standard, Restricted**
- R L **L1970** An articulated molded plastic orthosis with ankle joints that allow for free motion of the ankle, (dorsi-plantar flexion), custom molded from a model of the patient, custom fabricated, includes casting and cast preparation.
- R L **L2820** Addition to lower extremity orthosis, soft interface for molded plastic below knee section.

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- R L **L1970** Articulated molded plastic orthosis with ankle joints, custom molded from a model of the patient, includes casting and cast preparation.
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☐ **Supramallleolar Orthosis**
- R L **L1907** Ankle orthosis, supramalleolar, with straps, with or without pads, custom fabricated

Instructions For Use:

You have been dispensed this custom molded ankle brace to immobilize your foot and ankle. An AFO often requires a period of adjustment. It is best to wear it for one hour more each day and to continue this for two weeks. It should only be removed as 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. Should the device crack or break, remove it and do not use it again until you contact our office. Straps, laces should be kept clean of clothing fabric to insure the device is properly secured to your extremity. Applying a skin moisturizer and wearing knee high socks will prevent your skin from irritation.

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 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 supplier has reviewed the instructions for proper use and care and provided me with written instructions. I understand that failure to properly care for this item(s) 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 supplier 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

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Medicare 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.

Dispensing Chart Notes: Thermoplastic AFO

Patient Name: _____ HICN: _____

Product Information *(Check brand and model, circle base code and addition(s))*:

☐ **Arizona Optima Brace, Standard, Restricted**
- R L **L1970** An articulated molded plastic orthosis with ankle joints that allow for free motion of the ankle, (dorsi-plantar flexion), custom molded from a model of the patient, custom fabricated, includes casting and cast preparation.
- R L **L2820** Addition to lower extremity orthosis, soft interface for molded plastic below knee section.

☐ **Arizona Thermoplastic AFO - Articulated, Dorsi-Assist**
- R L **L1970** Articulated molded plastic orthosis with ankle joints, custom molded from a model of the patient, includes casting and cast preparation.
- R L **L2210** Addition to lower extremity, dorsi-flexion assist (plantarflexion resist), each joint.

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- R L **L4631** A bivalved custom molded plastic orthosis, with a removable custom arch support, soft interface, and a rocker bottom walking sole. For patients with Charcot.

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☐ **Supramallleolar Orthosis**
- R L **L1907** Ankle orthosis, supramalleolar, with straps, with or without pads, custom fabricated

S) A thermoplastic AFO 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 firm 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: _____