

Traditional Compliance Packet

This Packet has 10 Pages to insure proper documentation and DME compliance.

Pages:

- 1) Traditional Compliance Packet and Checklist
- 2) Biomechanical Evaluation (page 1)
- 3) Biomechanical Evaluation (page 2)
- 4) Tests and Gait Evaluation
- 5) Document of Medical Necessity Custom Molded Traditional AFO
- 6) Prescription (Rx) Custom Molded Traditional AFO
- 7) Traditional AFO Order Form
- 8) Proof of Delivery
- 9) Medicare DMEPOS Supplier Standards
- 10) Dispensing Documentation Custom Molded Traditional AFO

Below is a check list to ensure all items are completed

To be completed by physician:

Biomechanical Evaluation for Patient Medical Record

Medical necessity documents

Medical Necessity Form

Supports AFO usage qualification
Evaluates necessity for prefabrication device
Demonstrates necessity for custom fitting
Support for selection code(s)

Prescription

Patient name (printed)
Item Description

Diagnosis
Clinician name (printed)
Clinician signature
Date

To be given to patient:

Proof of Delivery (provide copy to patient)

Patient name (printed)
Patient address
Item description
Item code(s):
Patient signature
Delivery date

DMEPOS Supplier Standards

To be completed by supplier/clinician

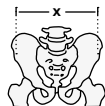
Dispensing Chart Notes

Orthosis type
Demonstrates fitting
Document patient satisfaction

Biomechanical Evaluation (page 1)

Lower Extremity Data

1. ASIS Width (cm)

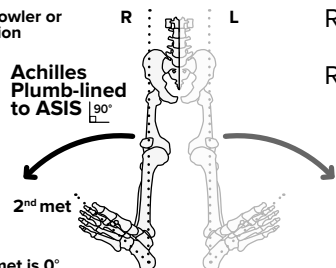


Average male

Average female

2. External Hip Excursion

Perform in Fowler or supine position



R Quality of motion

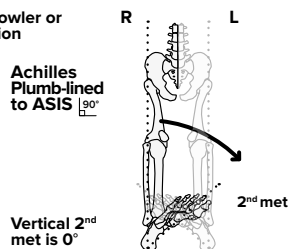
L Quality of motion

R

L

3. Internal Hip Excursion

Perform in Fowler or supine position



R Quality of motion

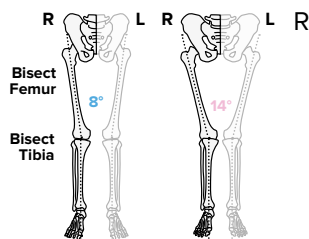
L Quality of motion

R

L

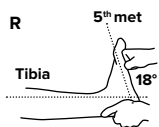
4. Genu Valgum/Varum

Fowlers, supine or standing



L

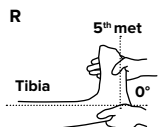
5. Foot Dorsiflexion Excursion



R

Dorsiflexion

L



R

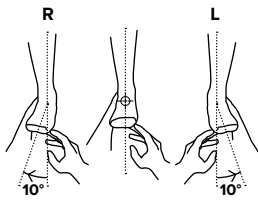
Inverted Dorsiflexion

L

Biomechanical Evaluation (page 2)

6. Subtalar Joint Eversion Excursion

Achilles
plumb-lined
to ASIS \perp 90°



R Quality of motion

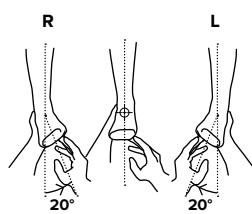
L Quality of motion

R

L

7. Subtalar Joint Inversion Excursion

Achilles
plumb-lined
to ASIS \perp 90°



R Quality of motion

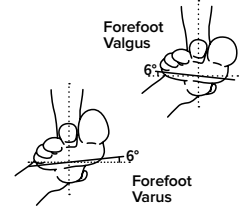
L Quality of motion

R

L

8. Metatarsal Head Mean Alignment

Achilles
plumb-lined
to ASIS \perp 90°



Heel, 5th, 1st are Plantigrade (0°)

Heel, 5th, 1st are Plantigrade (0°)

R

Valgus

R

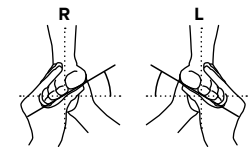
L

Varus

L

9. Midfoot Flexibility Test

Achilles
plumb-lined
to ASIS \perp 90°

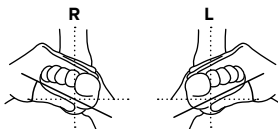


R

L

9. Reverse Midfoot Flexibility Test

Achilles
plumb-lined
to ASIS \perp 90°



R

L

10. Weight-bearing Foot Anatomical Structure



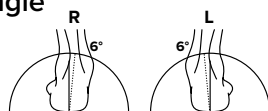
R



L



11. Kevin's Angle






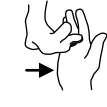




R

L








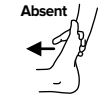





Tests and Gait Evaluation

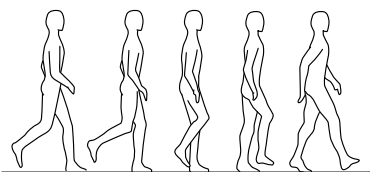
Extrinsic Muscle Testing

R	L			
		R	Invertors	L
		R	Evertors	L
		R	Dorsiflexors	L
		R	Plantar Flexors	L

Neurological Testing

	R	Balance intact Positive Romberg	Romberg	L	Balance intact Positive Romberg
R	L		Patellar Reflex		
		R	Absent despite reinforcement Present only with reinforcement Normal Increased but normal Markedly hyperactive, with clonus	L	Absent despite reinforcement Present only with reinforcement Normal Increased but normal Markedly hyperactive, with clonus
		R	Absent despite reinforcement Present only with reinforcement Normal Increased but normal Markedly hyperactive, with clonus	L	Absent despite reinforcement Present only with reinforcement Normal Increased but normal Markedly hyperactive, with clonus
		R	Absent Positive	L	Absent Positive
		R	Absent Positive (5 beats or more)	L	Absent Positive (5 beats or more)
		R	Absent Present	L	Absent Present

Gait Evaluation



			Gait Pattern		
R	Normal			L	Normal
	Hemiplegic	Parkinsonian			Hemiplegic
	Spastic Diplegic	Choreiform			Parkinsonian
	Neuropathic	Ataxic (cerebellar)			Spastic Diplegic
	Myopathic	Sensory			Choreiform
					Neuropathic
					Ataxic (cerebellar)
					Myopathic
					Sensory

Comment on head, shoulders, spinee, pelvis, sagittal/transverse/frontal posture, etc.

Document of Medical Necessity Custom Molded Traditional AFO

Patient Name:

HICN:

Prognosis: good

Duration of usage: 12 months

I certify that patient..... 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
 - Has weakness or deformity of the foot and ankle
 - Requires stabilization for medical reasons
 - Has the potential to benefit functionally

Sufficient documentation of the medical condition found in the patient's medical record confirms the necessity for the type and quantity of items ordered.

Therapy Goals (mark all that apply):

- To improve mobility
- To improve stability of lower extremity
- Decrease pain
- Aid healing soft tissue
- Promote immobilization, healing and treatment of injury

Necessity of Ankle Foot Orthosis molded to patient model

The following criteria, which are specific to the condition of this patient, has justified the prescription of a custom ankle foot orthosis over prefabricated items. (mark all that apply):

- Patient could not successfully be fitted with a prefabricated AFO
- Condition necessitating the orthosis is expected to be permanent or lasting for a duration of more than 6 months
- Ankle or foot control is required on more than one plane of motion
- Adequate documentation of a neurological, circulatory, or orthopedic condition that requires custom fabrication has been provided by the patient
- Patient has display a lack of normal anatomical integrity or anthropometric proportions regarding a healing fracture

I hereby certify that an ankle foot orthotic described above is a semi-rigid or rigid device whose use is solely intended for the support of a weak or deformed limb or the restriction and/or elimination of motion in an injured and/or diseased part of the body. The AFO is designed to provide the appropriate stabilization, support and counterforces necessary for the limb or other extremity that requires bracing. All of the observations, physical exams, and documentation has provided me with enough sound evidence that it is my opinion that a custom molded ankle foot orthosis is both reasonable and necessary in reference to the accepted guidelines of medical practice in the treatment of the patient condition and rehabilitation.

Prescribing Clinician (printed name):

Signature of Prescribing Clinician:

Phone: Type I NPI:

Date:/...../.....
MM DD YYYY

Tests and Gait Evaluation

Basic Information

Clinician Name: Patient Name:
 Prognosis:
 Duration of usage: Product Brand & Model:

Product Information (Mark all necessary codes and additions that apply)

Traditional AFO Collection

T100 - Leaf Spring AFO

L1960 Ankle foot orthosis, posterior solid ankle, plastic, custom fabricated
 L2275 Addition to lower extremity, varus/valgus correction, plastic modification, padded/lined

T150 - Solid Ankle AFO

L1960 Ankle foot orthosis, posterior solid ankle, plastic, custom fabricated
 L2275 Addition to lower extremity, varus/valgus correction, plastic modification, padded/lined

T200 - Tamarack Free Motion AFO

L1960 Ankle foot orthosis, posterior solid ankle, plastic, custom fabricated
 L2275 Addition to lower extremity, varus/valgus correction, plastic modification, padded/lined

T300 - Tamarack Dorsi-Assist AFO

L1960 Ankle foot orthosis, posterior solid ankle, plastic, custom fabricated
 L2275 Addition to lower extremity, varus/valgus correction, plastic modification, padded/lined
 L2210 Addition to lower extremity, dorsiflexion assist (plantar flexion resist), each joint
 L2210 Addition to lower extremity, dorsiflexion assist (plantar flexion resist), each joint

DX (Mark all that apply) Corresponds to Biomechanical Examination Form

Adult Acquired Flatfoot (PTTD)	Flat foot [pes planus] (acquired)	M21.41	M21.42
	Spontaneous rupture of other tendons, ankle and foot	M66.871	M66.872
	Disorder of ligament, ankle	M24.271	M24.272
	Disorder of ligament, foot	M24.274	M24.275
	Other acquired deformities of foot	M21.6X1	M21.6X2
Lateral Ankle Instability	Other specific joint derangements of ankle, not elsewhere classified	M24.871	M24.872
Amputation	Acquired absence of great toe	Z89.411	Z89.412
	Acquired absence of other toe(s)	Z89.421	Z89.422
	Acquired absence of foot	Z89.431	Z89.432
Foot Drop	Foot Drop, acquired	M21.371	M21.372
	Hemiplegia - affecting [right/left] dominant side	I69.951	I69.952
	Hemiplegia - affecting [right/left] non-dominant side	I69.953	I69.954
DJD of Ankle and Rearfoot	Primary osteoarthritis, ankle and foot	M19.071	M19.072
	Pain in ankle and joints of foot	M25.571	M25.572
	Pain in lower leg	M79.661	M79.662
	Pain in foot	M79.671	M79.672
	Other specified congenital deformities of feet	Q66.89	
	Other		

Therapy Goal(s): (mark all that apply)

To improve mobility To improve stability of lower extremity
 Promote healing soft tissue Treatment of injury
 Decrease pain

Clinician Information

Prescribing Clinician (printed name):
 Signature of Prescribing Clinician:
 Type I NPI: Order Date: MM / DD / YYYY

www.kevinrootmedical.com
hello@kevinrootmedical.com
Tel: 1 800 496 0987
Fax: 1 866 919 9268

Date MM...../DD...../YYYY.....

Clinician

Account Name/Number

Location

PO Number

Clinician

Contact me before processing

Side

Use separate Rx for each side
*G800 exempt BIL standard



Patient

First Name

Last Name

Gender: M F DOB MM...../DD...../YYYY

Height Weight Shoe size

Dx

Ship to Patient

Street Address

City

State Zip

Impression

- Plaster
- STS Casting Socks
- 3D Foot Scanner
- Fiberglass Casting Tape

Fitting

- Fit AFO to submitted:
 - Tracing
 - Shoes

AFO

T100 Leaf Spring



- 4mm Polypropylene frame
- Rearfoot intrinsic post
- No joints
- No top cover
- Tibial strap & pad
- Fibula height
- Reduced posterior trimlines
- Device to mets

L Codes: L1960, L2275

T200 Tamarack Free Motion



- Plantar stop
- Free motion tamarack joints
- 4mm Polypropylene frame
- Rearfoot intrinsic post
- No top cover
- Tibial strap & pad
- Fibula height
- Device to mets
- Low, medial and lateral flanges

L Codes: L1970, L2275

T150 Solid Ankle



Valgus T-Strap (reduces varus rearfoot)
Varus T-Strap (reduces valgus rearfoot)
Additional L Code: L2270

- Extended anterior trimlines
- 4mm Polypropylene frame
- Rearfoot intrinsic post
- No joints
- No top cover
- Tibial strap & pad
- Fibula height
- Device to mets

L Codes: LL1960, L2275

T300 Tamarack Dorsi-Assist



- Plantar stop
- Foot Frame to mets standard**
- Foot Frame to sulcus
- Foot frame to toes
- Tamarack dorsi-assist joints
- 4mm Polypropylene frame
- Rearfoot intrinsic post
- No top cover
- Tibial strap & pad
- Fibula height

L Codes: L1970, L2275, L2210, L2210

Impression preparation

Ankle As is Correct to 90°

Rearfoot As is Correct to 90°

Forefoot As is Balance FF to RF

Measurements (optional)

Height:

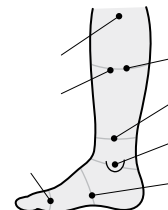
- Fibula Head
- Proximal Trim

Circumference:

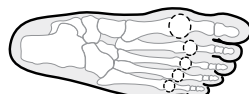
- Forefoot

Circumference:

- Proximal Trim
- Above Ankle
- Ankle
- Mid-Foot



*for more options use device specific Rx available to download at www.kevinrootmedical.com



Special Instructions:

Proof of Delivery - original in patient's chart, copy given to patient

Supplier Information

Supplier Name:
HICN:.....

Product Information (Mark all necessary codes and additions that apply)

Traditional AFO Collection

T100 - Leaf Spring AFO

- L1960 Ankle foot orthosis, posterior solid ankle, plastic, custom fabricated
- L2275 Addition to lower extremity, varus/valgus correction, plastic modification, padded/lined

T150 - Solid Ankle AFO

- L1960 Ankle foot orthosis, posterior solid ankle, plastic, custom fabricated
- L2275 Addition to lower extremity, varus/valgus correction, plastic modification, padded/lined

T200 - Tamarack Free Motion AFO

- L1960 Ankle foot orthosis, posterior solid ankle, plastic, custom fabricated
- L2275 Addition to lower extremity, varus/valgus correction, plastic modification, padded/lined

T300 - Tamarack Dorsi-Assist AFO

- L1960 Ankle foot orthosis, posterior solid ankle, plastic, custom fabricated
- L2275 Addition to lower extremity, varus/valgus correction, plastic modification, padded/lined
- L2210 Addition to lower extremity, dorsiflexion assist (plantar flexion resist), each joint
- L2210 Addition to lower extremity, dorsiflexion assist (plantar flexion resist), each joint

Usage Instructions:

This ankle foot orthosis has been dispensed to you to assist in immobilizing your foot and ankle. Any AFO requires a period of adjustment (usually two weeks) and it is best worn for one hour on the first day, with one additional hour added from the previous day. Please continue this process for two weeks. The device should only be removed as intended and instructed by your physician. If tightening of the brace should occur, you may be walking too frequently. It is recommended to get off your feet and elevate your foot until the tightness resolves. If tightness or uncomfotability continues, please contact the Kevin Orthopedic office immediately. If the device cracks or breaks, remove it promptly and do not wear again until you contacted our office immediately. Do not use a cracked or broken brace. The closures of the brace should be kept clean to ensure the device can be properly secured. Skin moisturizes and knee high socks can be used to prevent skin irritation.

Material failure warranty coverage:

Any hardware, plastic or metal components are covered at no-charge for up to 2 years. All soft materials are covered at no-charge for up to ninety days, including: material covers, Velcro straps, laces, and limb support pads.

I have read the posted Complaint Resolution Policy and have been provided a copy of the Medicare Supplier Standards. I certify that I have received the item(s) that have been indicated. The supplier has reviewed and provided me with written instructions of proper usage and care. I understand that improper care for this item(s) will result in a voided warranty. A voided warranty as a result of improper care could result in my responsibility for future repairs or replacements costs if my insurance policy will not cover those costs. The supplier has instructed me to call the office if any difficulties or problems with the device arise.

Patient Name (printed) Patient Signature:
Patient Address: Delivery Date: MM / DD / YYYY

Provide a copy to patient

Disclaimer: The codes within these pages are the offered suggestion based upon the HCPCS and ICD-10 codes provided by hcpcs.org and icdlist.com. Each prescribing practitioner should contact their local consultant or Medicare office to verify all billing codes, regulations and guidelines according to their geographic region.

MEDICARE DMEPOS SUPPLIER STANDARDS

Note: This is an abbreviated version of the supplier standards every Medicare DMEPOS supplier must meet in order to obtain and retain their billing privileges. These standards, in their entirety, are listed in 42 C.F.R. 424.57(c).

1. A supplier must be in compliance with all applicable Federal and State licensure and regulatory requirements.
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. A supplier must have an authorized individual (whose signature is binding) sign the enrollment application for billing privileges.
4. A supplier must fill orders from its own inventory, or contract with other companies for the purchase of items necessary to fill orders.
A supplier may not contract with any entity that is currently excluded from the Medicare program, any State health care programs, or 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 and must maintain a visible sign with posted hours of operation. The location must be 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.
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 is prohibited from direct solicitation to Medicare beneficiaries. For complete details on this prohibition see 42 CFR § 424.57 (c) (11).
12. A supplier is responsible for delivery of and must instruct beneficiaries on the use of Medicare covered items, and maintain proof of delivery and beneficiary instruction.
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 cost either directly, or through a service contract with another company, any 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 standards to each beneficiary it supplies a Medicare-covered item.
17. A supplier must disclose 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 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 for those specific products and services (except for certain exempt pharmaceuticals).
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. A supplier must meet the surety bond requirements specified in 42 CFR § 424.57 (d).
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 CFR § 424.516(f).
29. A supplier is prohibited from sharing a practice location with other Medicare providers and suppliers.
30. A supplier must remain open to the public for a minimum of 30 hours per week except physicians (as defined in section 1848(j) (3) of the Act) or physical and occupational therapists or a DMEPOS supplier working with custom made orthotics and prosthetics. DMEPOS suppliers have the option to disclose the following statement to satisfy the requirement outlined in Supplier Standard 16 in lieu of providing a copy of the standards to the beneficiary. The products and/or services provided to you by (Kevin Orthopedic) are subject to the supplier standards contained in the Federal regulations shown at 42 Code of Federal Regulations Section 424.57(c). These standards concern business professional and operational matters (e.g. honoring warranties and hours of operation). The full text of these standards can be obtained at <http://www.ecfr.gov>. Upon request we will furnish you a written copy of the standards.

Dispensing Documentation Custom Molded Traditional AFO

Patient Information

Patient Name:
HICN:.....

Product Information (Mark all necessary codes and additions that apply)

Traditional AFO Collection

T100 - Leaf Spring AFO

- L1960 Ankle foot orthosis, posterior solid ankle, plastic, custom fabricated
- L2275 Addition to lower extremity, varus/valgus correction, plastic modification, padded/lined

T150 - Solid Ankle AFO

- L1960 Ankle foot orthosis, posterior solid ankle, plastic, custom fabricated
- L2275 Addition to lower extremity, varus/valgus correction, plastic modification, padded/lined

T200 - Tamarack Free Motion AFO

- L1960 Ankle foot orthosis, posterior solid ankle, plastic, custom fabricated
- L2275 Addition to lower extremity, varus/valgus correction, plastic modification, padded/lined

T300 - Tamarack Dorsi-Assist AFO

- L1960 Ankle foot orthosis, posterior solid ankle, plastic, custom fabricated
- L2275 Addition to lower extremity, varus/valgus correction, plastic modification, padded/lined
- L2210 Addition to lower extremity, dorsiflexion assist (plantar flexion resist), each joint
- L2210 Addition to lower extremity, dorsiflexion assist (plantar flexion resist), each joint

Note:

- S)** At the time of the patient's visit, a custom fabricated AFO was dispensed and fitted. Although the patient is ambulatory, their condition and related symptoms deem that this medical device is necessary as part of their treatment. It is anticipated that this device will functionally benefit the patient. This custom device is appropriate and utilized in an attempt to avert surgery and because a prefabricated device is inappropriate for the patient's condition.
- O)** The device appears to fit well and comfortably on the patient during a gait analysis.
- A)** Regarding the good fit, the patient was able to wear properly and ambulate without concern or distress. This device's function is to assist motion and provide ankle joint stabilization.
- P)** The patient had received satisfactory information on the goals and functions of the device. Demonstrations of proper application, wear, and care for the device were shown to the patient. The patient was told that the device will function and can fit best externally on a variety of shoes, including: running shoes, lace and velcro-fastening shoes/boots, walking shoes/boots, safety work boots/shoes, dress shoes and sandals. The device was suitable for the patient's condition and not substandard when dispensed. The patient received no guarantees and reviewed all precautions. Written instructions, warranty information and a copy of DMEPOS Supplier standards were provided to the patient. All and any questions were answered.

Additional Notes:.....
Print Supplier Name:..... Supplier Signature:
Dispensing Date:/...../.....
MM DD YYYY