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Documentation Guidelines for AFOs

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Medical Record

Three purposes:

1. To share important information among clinicians for quality of care

2. To mitigate risk for medical-legal reasons

3. To support coding for payment reasons

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DME Audit Wave

- Audits are being performed nationwide by Noridian, CGS, and Performant, usually in tandem

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DME Audit Wave

- **CERT Audits**
- **Performant:** National RAC audit contractor
- **CGS and Noridian:** The two DME contractors engaged by CMS

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CERT Audits

- “Comprehensive Error Rate Testing”
- Statutory requirement for federal agencies to annually review programs they administer in order to reduce and recover improper payments
- CERT audits look for errors in payments made by carriers
- Approximately 50,000 claims are reviewed annually

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CERT Audits

- After the reviews are completed, the improper payment rate is calculated and reported to HHS
- For year 2020, the Improper Payment Rate for the claim reviews for Podiatry billing of DMEPOS was 46.0%, among the highest of all providers (2/15)
- This has led to the current audits by Noridian, CGS, and Performant

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CERT Audits

- DMEPOS Improper Payment Rates 2024:
  - Lower Limb Orthoses: 35.2%
  - Diabetic Shoes: 47.1%
  - Surgical Dressings: 57.6%

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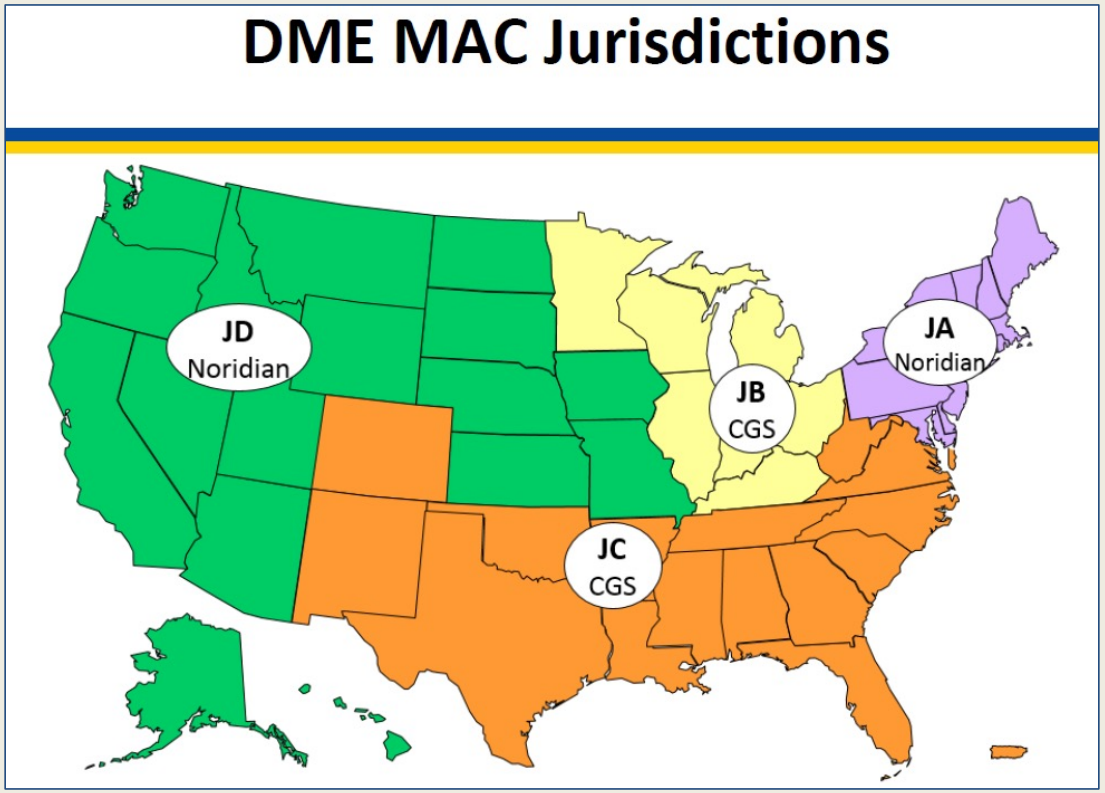
DME Audit Wave



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DME Audit Wave

- Audits initiated by “Additional Documentation Request” (ADR) letters
- Usually only 2-10 patients or services

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DME Audit Wave

- Deficiency issues: AFOs

1. Lack of standard written order
2. Billing on date of order vs. date of dispensing
3. Use of wrong code
4. Off the Shelf vs. Custom Fitted vs. Custom Fabricated
5. Same or similar device

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Coverage Criteria – AFOs

- Local Coverage Determination (L33686) – Ankle-Foot/ Knee-Ankle-Foot Orthosis
- Local Coverage Article (A52457) – Ankle-Foot/Knee-Ankle-Foot Orthoses
- Local Coverage Article (A55426) – Standard Documentation Requirements for All Claims Submitted to DME MACs

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Coverage Criteria – AFOs

- Ambulatory AFOs:

  L1900, L1902, L1904, L1906, L1907, L1910, L1920, L1930, L1932, L1940, L1945, L1950, L1951, L1960, L1970, **L1971**, L1980, L1990, L2106, L2108, L2112, L2114, L2116, L4350, **L4360**, **L4361**, **L4386**, **L4387**, and L4631

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AFO "Categories"

1. L1902 – Ankle orthosis, ankle gauntlet or similar, with or without joints, **prefabricated, off the shelf**
2. L1971 – Ankle-foot orthosis, plastic or other material with ankle joint, **prefabricated, includes fitting and adjustment**
3. L4360 – Walking boot, pneumatic and/or vacuum, with or without joints, with or without interface material, **prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise**
4. L1940 – Ankle-foot orthosis, plastic or other material, **custom fabricated**

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AFO "Categories"

- When providing orthoses, suppliers must:
  - Only bill for the HCPCS code that accurately reflects both the type of orthosis and the appropriate level of fitting
  - Have detailed documentation in the supplier's record that justifies the code selected

AFO "Categories"

1. Prefabricated, off the shelf

- Off-the-shelf (OTS) orthotics are:
  - Items that are prefabricated
  - They may or may not be supplied as a kit that requires some assembly. Assembly of the item and/or installation of add-on components and/or the use of some basic materials in preparation of the item does not change classification from OTS to custom fitted.
  - OTS items require minimal self-adjustment for fitting at the time of delivery for appropriate use and do not require expertise in trimming, bending, and molding, assembling, or customizing to fit an individual.
  - This fitting does not require expertise of a certified orthotist or an individual who has specialized training in the provision of orthoses to fit the item to the individual beneficiary.

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Minimal Self Adjustment

- A52457
  - The term “minimal self-adjustment” is defined at 42 CFR §414.402 as an adjustment the beneficiary, caregiver for the beneficiary, or supplier of the device can perform and that does not require the services of a certified orthotist (that is, an individual who is certified by the American Board for Certification in Orthotics and Prosthetics, Inc., or by the Board for Orthotist/Prosthetist Certification) or an individual who has specialized training.
  - For example, adjustment of straps and closures, bending or trimming for final fit or comfort (not all-inclusive) fall into this category.

AFO "Categories"

2. Prefabricated, includes fitting and adjustment – "Custom Fitted"

- Custom fitted orthotics are:
  - Devices that are prefabricated.
  - They may or may not be supplied as a kit that requires some assembly. Assembly of the item and/or installation of add-on components and/or the use of some basic materials in preparation of the item does not change classification from OTS to custom fitted.
  - Classification as custom fitted requires more than minimal self-adjustment for fitting at the time of delivery in order to provide an individualized fit, i.e., the item must be trimmed, bent, molded (with or without heat), or otherwise modified resulting in alterations beyond minimal self-adjustment.
  - This fitting at delivery does require expertise of a certified orthotist or an individual who has specialized training in the provision of the orthosis to fit the item to the individual beneficiary.

AFO "Categories"

- A52457
  - In contrast to "minimal self-adjustment," "more than minimal self-adjustment" is defined as changes made to achieve an individualized fit during the final fitting at the time of delivery of the item that requires the expertise of a certified orthotist or an individual who has equivalent specialized training in the provision of orthotics in compliance with all applicable Federal and State licensure and regulatory requirements.
  - A certified orthotist is defined as an individual who is certified by the American Board for Certification in Orthotics and Prosthetics, Inc., or by the Board for Orthotist/Prosthetist Certification.
  - Correct coding of prefabricated orthoses is dictated by actions that take place at the time of fitting to the beneficiary, either custom-fitted (requiring expertise) or OTS (requiring minimal self-adjustment).

AFO "Categories"

3. **Prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise**
   - "Custom Fitted"
   - A52457
     - HCPCS codes that describe "PREFABRICATED ITEM THAT HAS BEEN TRIMMED, BENT, MOLDED, ASSEMBLED, OR OTHERWISE CUSTOMIZED TO FIT A SPECIFIC PATIENT BY AN INDIVIDUAL WITH EXPERTISE." These HCPCS codes must be used when more than minimal self-adjustment is necessary and performed at delivery.

AFO "Categories"

- The HCPCS codes located in Column I and Column II within the same row are considered a corresponding HCPCS code set. These codes represent identical products, which are only differentiated by the nature of the final fitting performed at the time of delivery.

Column I	Column II
L4360	L4361
L4386	L4387
L4396	L4397

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AFO "Categories"

4. Custom fabricated

- A custom fabricated item is one that is individually made for a specific patient. No other patient would be able to use this item.

Coverage Criteria – AFOs

- Ankle Foot Orthotics (AFOs) used during ambulation are covered for ambulatory beneficiaries with weakness or deformity of the foot and ankle who:

  1. Require stabilization for medical reasons, and

  2. Have the potential to benefit functionally.

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Coverage Criteria – AFOs

- For all AFOs, documentation should state:

  "The patient is ambulatory and requires stabilization of the foot and ankle due to _____."

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Coverage Criteria – AFOs

- Documentation should state (continued):

  The patient has the potential to benefit functionally from the AFO prescribed by accomplishing the following objectives:
  - Decrease pain
  - Decrease fall risk
  - Improve gait stability
  - Decrease strain on “affected body part”
  - Alternative to surgery

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Coverage Criteria – AFOs

- Custom Fitted AFOs documentation example:

  The beneficiary was custom fitted to achieve an individualized fit. This was accomplished by utilizing handheld trauma shears and removing the hard rubber footplate trimming as necessary to fit the patient's orthopedic shoes. Several trimmings were necessary until the footplate was seated properly, to avoid any potential shifting and rubbing, while avoiding removal of excessive material. A small electronic burr was used to remove rough edges, as necessary. Also, the calf Velcro strap of excessive length was trimmed, as necessary.

- Photos are helpful

Coverage Criteria – AFOs

- Custom fabricated
  - AFOs that are custom-fabricated are covered for ambulatory beneficiaries when the basic coverage criteria listed above and one of the following criteria are met:
    - The beneficiary could not be fit with a prefabricated AFO; or
    - The condition necessitating the orthosis is expected to be permanent or of longstanding duration (more than 6 months); or
    - There is a need to control the knee, ankle or foot in more than one plane; or
    - The beneficiary has a documented neurological, circulatory, or orthopedic status that requires custom fabricating over a model to prevent tissue injury; or
    - The beneficiary has a healing fracture which lacks normal anatomical integrity or anthropometric proportions.

Coverage Criteria – AFOs

- Documentation should state:
  - A custom ankle-foot orthotic is required for this patient because a pre-fabricated AFO is not indicated, due to (hindfoot valgus, forefoot varus, dropfoot, severe collapse of the arch, pes planus, per cavus).
  - This condition is expected to be long standing (more than 6 months). There is a need to control the foot-ankle complex in more than one plane.
  - *Needs to be supported by examination findings*

Documentation Requirements – AFOs

- Local Coverage Article (A55426) – Standard Documentation Requirements for All Claims Submitted to DME MACs
- In addition to your visit note documentation, two pieces of documentation are required:
  1. Standard Written Order
  2. Proof of Delivery

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Documentation Requirements – AFOs

- Standard Written Order – An SWO must contain all of the following elements:
  - Beneficiary's name or Medicare Beneficiary Identifier (MBI)
  - Order date
  - General description of the item
    - The description can be either a general description (e.g., wheelchair or hospital bed), a HCPCS code, a HCPCS code narrative, or a brand name/model number
  - Quantity to be dispensed, if applicable
  - Treating practitioner’s name or NPI
  - Treating practitioner's signature

Documentation Requirements – AFOs

- "In those limited instances in which the treating practitioner is also the supplier and is permitted to furnish specific items of DMEPOS and fulfill the role of the supplier in accordance with any applicable laws and policies, a SWO is not required.

- However, the medical record must still contain all of the required SWO elements."

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Documentation Requirements – AFOs

- If you want to avoid claim denials and the appeals process…

document a separate Standard Written Order

in your medical record

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Documentation Requirements – AFOs

- A55426
  - Records from suppliers or healthcare professionals with a financial interest in the claim outcome are not considered sufficient by themselves for determining that an item is reasonable and necessary. DMEPOS suppliers are reminded that:
    - Supplier prepared statements and physician attestations by themselves do not provide sufficient documentation of medical necessity, even if signed by the ordering physician.

Proof of Delivery – AFOs

- Proof of Delivery elements:
  - Beneficiary's name
  - Delivery address
  - Quantity delivered
  - Description of the item(s) being delivered – the description can be either a narrative description, a HCPCS code, the long description of a HCPCS code, or a brand name/model number
  - Signature of the person accepting delivery (if the signature is illegible, print the name underneath)
  - Relationship to the beneficiary
  - Delivery date

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“Same or Similar” – AFOs

Defined as:

- Dispensing multiple Ankle-Foot Orthoses (AFOs) within the Reasonable Useful Lifetime
- Claims paid with dates of service within 1,825 days (5 years) of the date of service of a previously paid AFO for the same anatomical site

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"Same or Similar" – AFOs

- **Reasonable Useful Lifetime**, for the DME prescribed by podiatrists, is not less than 5 years. This is defined in the Medicare Benefit Policy Manual.
- Replacement during the first five years of use, during the "reasonable useful lifetime," is covered if the item is lost, irreparably damaged, or the patient's medical condition changes such that the current equipment no longer meets the patient's needs.

"Same or Similar" – AFOs

- Same extremity within 5 years – RT, LT – does not affect contralateral devices
- Medicare considers all DME that can be dispensed by a podiatrist same or similar

Example: A walking boot that was dispensed 4 years ago post surgically is deemed to be same or similar as a brace dispensed today for PTTD

- Automated Review

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"Same or Similar" – AFOs

- Common scenarios:
  - OTS transition to custom fabricated
  - Change in patient's condition – document objective examination findings

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"Same or Similar" – AFOs

- Use the Medicare DME Portal to check for prior prescribed devices:
  - CGS Jurisdictions – JB, JC (North Carolina)
  - Noridian Jurisdictions – JA, JD

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"Use of ABNs" – AFOs

- Advanced Beneficiary Notice (ABN)
  - Use if and when you have determined patient has been prescribed an AFO previously in the last 5 years for the same extremity
  - Reason Medicare may not pay must be specific to this date of service

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"Use of ABNs" – AFOs

A. Notifier:
B. Patient Name: C. Identification Number:

Advance Beneficiary Notice of Non-coverage (ABN)

NOTE: If Medicare doesn't pay for D. L4361 below, you may have to pay.
Medicare does not pay for everything, even some care that you or your health care provider have good reason to think you need. We expect Medicare may not pay for the **D.** L4361 below.

D.	E. Reason Medicare May Not Pay:	F. Estimated Cost
	Any reason they give	$610.00

WHAT YOU NEED TO DO NOW:
- Read this notice, so you can make an informed decision about your care.
- Ask us any questions that you may have after you finish reading.
- Choose an option below about whether to receive the **D.** L4361 listed above.

Note: If you choose Option 1 or 2, we may help you to use any other insurance that you might have, but Medicare cannot require us to do this.

G. OPTIONS: Check only one box. We cannot choose a box for you.

☐ **OPTION 1.** I want the **D.** L4361 listed above. You may ask to be paid now, but I also want Medicare billed for an official decision on payment, which is sent to me on a Medicare Summary Notice (MSN). I understand that if Medicare doesn't pay, I am responsible for payment, but I can appeal to Medicare by following the directions on the MSN. If Medicare does pay, you will refund any payments I made to you, less co-pays or deductibles.

☐ **OPTION 2.** I want the **D.** L4361 listed above, but do not bill Medicare. You may ask to be paid now as I am responsible for payment. I cannot appeal if Medicare is not billed.

☐ **OPTION 3.** I don't want the **D.** L4361 listed above. I understand with this choice I am **not** responsible for payment, and I cannot appeal to see if Medicare would pay.

H. Additional Information:

This notice gives our opinion, not an official Medicare decision. If you have other questions on this notice or Medicare billing, call **1-800-MEDICARE** (1-800-633-4227/**TTY:** 1-877-486-2048).
Signing below means that you have received and understand this notice. You may ask to receive a copy.

I. Signature:	J. Date: 2/19/24

You have the right to get Medicare information in an accessible format, like large print, Braille, or audio. You also have the right to file a complaint if you feel you've been discriminated against. Visit Medicare.gov/about-us/accessibility-nondiscrimination-notice.

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Questions?

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