Lower Extremity Amputation (LEA)
Considerations / Issues

Providing Toe Fillers can be an advantageous resource for your patient and business but it also comes with certain considerations. Please review this list below before you begin offering this product / service to your patients:

- **Changes to your Medicare Application**. Some states require you have on staff a state licensed Pedorthist or Orthotic Fitter in order to provide LEA Toe Fillers. Since it is difficult to determine which states have this requirement, we recommend that you first amend your Medicare application. Medicare will then come back with an authorization or ask for additional credentials. This seems to be the only way to find out with certainty the state requirements. Consequently, we recommend that you make the following changes to your Medicare application:
    - Under the Heading – Products and Services to be Furnished by this Supplier – these items should be checked:
        - Diabetic Footwear
        - Orthotics – Custom Fabricated
        - Orthotics – Non-Customized
        - Prosthetics

- **Recommended types of Toe Fillers to provide**. Typically, the type of patient that requires a Toe Filler is very high risk. Since they already have a history of amputations, you must take extreme care in providing and monitoring these devices. It is essential that you check with the patient on a daily basis the condition of their feet – monitoring any rubbing or red marks very closely. Due to the high risk, we recommend that you only provide these devices for the conditions indicated below. If you have a Pedorthist, Orthotic Fitter, or other experienced professional on staff they can use their judgment in providing more complex devices.
        - Missing Big toe
        - Missing Big toe and up to two adjacent toes

  Toe Fillers can be provided for individual toes – however, we do not recommend providing these. Consult the patients' Dr. when these are requested.

  When all of the toes are amputated (trans-metatarsal amputation) – we recommend that the patient is evaluated by a trained professional (Podiatrist, Orthotist, Pedorthist, or other qualified professional). People with this condition typically have other issues that may not be obvious before a Toe Filler is recommended.

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• Lower Extremity Amputation (LEA)

- Diabetic patients with a Lower Extremity Amputation (LEA) of the toe bones (phalanges) are at greater risk for subsequent ulceration and amputations.
- LEA is a costly and disabling procedure that disproportionately affects persons with diabetes.
- The use of therapeutic shoes with custom inserts that have a toe filler is beneficial for both Hallux (big toe) and Tran metatarsal (all toes) LEA patients. The toe filler helps fill the void inside the shoe due to amputation.
- Toe fillers should <u>not</u> be used to correct or realign toes that have migrated due to an amputation.

Toe Fillers for Diabetic LEA Patients

- <u>Hallux</u> Amputation – Removal of the Big Toe
    - Toe filler is beneficial to help minimize drifting of the remaining toes two – five.
    - Hallux toe filler helps normalize the patient's walk or gait.

- Individual 2nd, 3rd, 4th or 5th Toe Amputations
    - Toe filler is <u>not</u> beneficial and can cause additional friction inside the shoe.
    - Remaining toes provide enough support for proper walk or gait.

- <u>Tran metatarsal</u> Amputation - Removal of all five toes at the metatarsal joint
    - This type of amputation is more disabling than simple toe amputations.
    - Toe filler helps prevent creasing of the shoe at the point of the amputation.
    - Toe filler helps prevent the breakdown and eventual collapse of the shoe.
    - Toe filler can also help control the remaining foot inside the shoe, decrease shear, and often eliminate the need for a costly custom-made shoe.

Recommended shoes for LEA patients

- Shoes for LEA patients need to have the ability to rock, replacing the motion lost with the addition of the hard flex/carbon plate.
- The loss of push-off in the ball of the foot is chiefly responsible for impairment of gait.
- The bump style shoes work best for LEA patients with toe fillers.
- <u>The shoe size does not change</u> when the metatarsal heads remain in tact.

Important to protect the remaining portion of the foot

- Since an amputation indicates that a patient has severe foot problems, special care **<u>MUST</u>** be taken to protect the remaining portion of the foot.
- It is very important to pay attention to the presence of skin grafts, scar tissue, or other post surgical complications when fitting for diabetic shoes and custom inserts with toe filler.

Lower Extremity Amputation (LEA)

Fitting a Diabetic Patient with a Lower Extremity Amputation (LEA), usually consist of providing a toe filler, equalizing the patient's weight bearing with custom inserts, and protecting the remaining portion of the foot with Therapeutic shoes.

Hallux Amputation - Big toe Toe filler is beneficial to help minimize drifting of the remaining toes two – five and help normalize the patient's walk or gait.

Right foot
Hallux amputation

Left foot
Hallux Toe Filler

Flex Plate
Placed under insert

A **Tran metatarsal Amputation - All Toes** This toe filler helps prevent creasing of the shoe at the toes and helps prevent the breakdown and eventual collapse of the shoe.

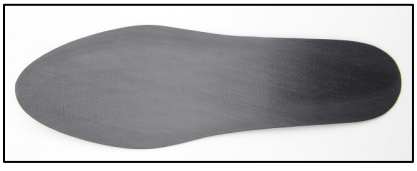
Right foot
Tran metatarsal amputation

Right foot
Tran metatarsal
Toe filler

Flex Plate
Placed under insert

A **Flex Plate**

- A thin hard insert
- Used with a toe filler insert
- Placed <u>under</u> the custom insert
- Holds the custom insert in place
- Provides motion gait push-off



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Prescription & Letter of Medical Necessity
For Therapeutic Shoes & Custom Inserts with Toe Filler for LEA

Patient Name_____
Last First Middle

Address City State Zip Code

Date of Birth _____ Gender: Male ☐ Female ☐
(MM / DD / YYYY)

℞

Physician's Rx

I certify that the following statement is true:

☑ The Patient listed above has Diabetes Mellitus: Yes ☐ No ☐

☑ ICD-9 Diagnosis Code:
(check Dx that applies) 250.00 ☐ 250.01 ☐ 250.02 ☐ 250.03 ☐ Other _____

☑ Partial or complete amputation of the foot: Left ☐ Right ☐

✍ Area of Amputation (LEA) _____

✍ Date of Lower Extremity Amputation (LEA) _____
(mm/dd/yy)

☑ I am treating this patient under a comprehensive plan of care for diabetes mellitus. Yes ☐ No ☐

☑ This patient needs extra depth shoes with a toe filler intergrated in the multiple density inserts because of his/hers diabetes and LEA. Yes ☐ No ☐

☑ I certify that all of the conditions checked above are in my doctor's notes. Yes ☐ No ☐

✍* _____
(Physician Signature M.D. or D.O.) Date

** If a CRNP or PA signs Rx, to meet Insurance Guidelines an M.D. or D.O. wet ink or stamped Signature must accompany signature.**

Physician Information:

Dr. Name UPIN #

Address City State Zip Code

Office Phone Office Fax

Rights Responsibilities and Sales Agreement

Therapeutic Shoes & Custom Inserts with Toe Filler

Shoe Certification

I understand that Medicare will only cover one pair of diabetic shoes each calendar year.

- I have not received diabetic shoes from any other Medicare or insurance supplier this year, nor will I accept them from any other company at another time this year.
- I also understand that if I request, or accept more than one pair in a calendar year, I will be held liable for the full cost of the second order, including the inserts.

Toe Filler & Shoe/Insert Break-in Schedule

Diabetic patients with a Lower Extremity Amputation (LEA) of the phalanges or toe bones are at greater risk for subsequent ulceration and amputations.

It is imperative that the patient follow shoe break-in schedule.

- I acknowledge receiving instructions and agree to follow the Shoe Break-in schedule listed below.
- I understand that it is recommended that I check my feet **every hour** for the first week of the break-in.
- If I see anything that looks different than normal or out of the ordinary that may result in scratches, blisters, cuts, etc. I will stop wearing the shoes and inserts and discontinue use immediately.
- I will not hold the diabetic shoe supplier, company, or fitter liable in anyway whatsoever for any personal injury or property damage that the shoes or inserts may cause.

Custom Inserts with Toe Filler & Shoe Wearing Time – Check Feet Often

Day 1 - 3	1 hour each AM + PM
Day 4 - 6	2 hours each AM + PM
Day 7 - 9	3 hours each AM + PM
Day 10 - 12	4 hours each AM + PM

Custom Inserts

I acknowledge receiving instructions and agree to follow the scheduled dates listed to change the custom inserts in my Therapeutic Shoes.

Change Inserts (4 months) _____ (mm/dd/yy) Change Inserts (8 months) _____ (mm/dd/yy)

Return Policy & Equipment Warranty

Return sales will be accepted within 14 days from the date merchandise is received and refunds will be issued for such merchandise. Items must be returned in re-salable condition, in the original boxes. Dirty or used-looking items will not be accepted. Returns after 14 days and Custom Order Items are subject to fees. DME will notify all Medicare beneficiaries of the warranty coverage, and we will honor all warranties under applicable law. DME will repair or replace, free of charge, Medicare-covered equipment that is under warranty.

Instruction to Patient-Return/Demonstration Acknowledgement

I acknowledge receiving instructions in the proper use and care of the equipment and/or supplies described.

- I have had my financial responsibilities explained.
- I also acknowledge and agree to this entire agreement.

✍*I,* _____ *have read and acknowledged the above information* **Date:**_____

(PATIENT SIGNATURE)

Lower Extremity Amputation (LEA)

Patient Procedures

- Doctor Rx
    - Include area of amputation
    - Date of amputation
- Foot Evaluation
    - Document the LEA and circle area on the foot diagram.
- Custom Inserts
    - Toe filler is incorporated onto patient's custom inserts.
- Impression Box
    - Take an impression of BOTH feet.
    - Label impression box with:
        - Patient name
        - Toe filler
- Shoe Order Form
    - Type-in Other Information box toe filler information
        - Hallux toe filler order or
        - Tran metatarsal toe filler order
    - Foot diagrams on printed shoe order
        - Circle area of amputation
- Toe Filler Order Expectations
    - Toe fillers take Evolution Labs 2-3 weeks to make.
    - Patient expectations, shoe delivery in 6-8 weeks from impression box shipment.
- Shoe Break-in Period is VERY important for LEA patients.
    - Since an LEA indicates that a patient has had severe foot problems, **special care MUST be taken** to protect the remaining portion of the at-risk foot.
    - Advise LEA Patients to remove their shoes and check their feet **every hour** when wearing the shoes during the first week of the Shoe Break-in schedule.
    - Follow-up calls with handwritten notes documenting patient's status very important.

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Billing Medicare & Supplemental Insurance 2007 fees
Therapeutic Shoes, Custom Inserts with Toe fillers

When to Bill Medicare

- Once the diabetic shoes and inserts have been delivered to the patient.
- The patient is satisfied with the products and signed all necessary papers.

Description	HCPCS	Qty	Amount	
Therapeutic Shoes	A5500	2	$124	
Custom Inserts - One Foot	A5513	3	$113	
Custom Inserts with Hallux (Big Toe) Filler - One foot	L5000	3	$493 *	
Total Billed			$730	
Medicare Reimburse 80%				$584
Average Cost				$280 **
Medicare Margin				$304
Other 20% Margin				$146
Total Potential Margin				$450

Description	HCPCS	Qty	Amount	
Therapeutic Shoes	A5500	2	$ 124	
Custom Inserts – One Foot	A5513	3	$ 113	
Custom Insert with Tran metatarsal (All Toes) Filler - One foot Ability to bill max 3 toes.	L5000	3	$1,479 *	
Total Billed			$1,716	
Medicare Reimburse 80%				$1,372
Average Cost				$ 580
Medicare Margin				$ 792
Other 20% Margin				$ 343
Total Potential Margin				$1,135

* L5000 average reimbursement $493. State reimbursement $422.63 to $563.50 per Toe. See 2007 Medicare fee schedule for specific State reimbursement amount.

** Average Cost includes: $50 per toe filler. 3 toe filler add-on to inserts cost $150. Average cost of shoes and six custom inserts are $130. Total average cost is $280.