



SureFit Therapeutic Footwear Program User's Guide

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Text in this manual placed within a box signifies that the wording was taken verbatim from Medicare guidelines and policies.

IDENTIFYING PATIENTS WHO QUALIFY FOR THERAPEUTIC FOOTWEAR

I. Determine whether patients qualify for shoes and inserts during routine office visits or by a review of their charts.

Type I or Type II diabetic patients qualify. The patient may be diet controlled, on oral hypoglycemics or insulin. The patient requires one or more of the conditions listed below to qualify.

Diabetic shoes, inserts and/ or modifications to the shoes are covered if the following criteria are met:

- 1) The patient has diabetes mellitus (ICD-9 diagnosis codes 250.00-250.91); and*
- 2) The patient has one or more of the following conditions:*
 - a) previous amputation of the other foot, or part of either foot, or*
 - b) history of previous foot ulceration of either foot, or*
 - c) history of pre-ulcerative calluses of either foot, or*
 - d) peripheral neuropathy with evidence of callus formation of either foot, or*
 - e) foot deformity of either foot, or*
 - f) poor circulation in either foot;*

II. If a patient qualifies, find out if they have received shoes in the present year under the Medicare program and/or if they are interested in shoes at this time. Patients may receive one pair of shoes and 3 pair of inserts within one calendar year. If patients have received shoes in the present year they do not qualify for shoes until next year. For example, anyone who has received shoes in 1999 may receive shoes at any time in the year 2000 even if the last time they received shoes was less than one year ago.

For patients meeting the criteria, coverage is limited to one of the following within one calendar year:

- a)** One pair of depth shoes (A5500) and 3 pairs of inserts (A5512 – In-office fabrication) or 3 pairs of inserts (A5513 – Lab fabricated). SureFit Custom Inserts are lab fabricated and qualify for the (A5513) code.
- b)** One pair of custom molded shoes (A5501) (which includes inserts provided with these shoes) and two additional pairs of inserts (A5512 or A5513).



CERTIFYING THE PATIENT FOR SHOES AND INSERTS

The patient needs to be certified for shoes and inserts by their physician in order to be covered by Medicare. A copy of the Statement of Certifying Physician Form that is recommended by the durable medical equipment carrier can be found on page 26 of this manual or in the Business Forms section online at www.surefitlab.com.

I. Identify the patient's certifying physician.

The certifying physician provides the medical care for the beneficiary's diabetic condition. The certifying physician must be an M.D. or D.O., and not a podiatrist.

II. Fill out the Statement of Certifying Physician Form.

The Statement of Certifying Physician Form may be completed by the prescribing physician or supplier but must be reviewed for accuracy of the information and signed by the certifying physician to indicate agreement.

III. (optional) Fill out a cover letter explaining to the physician that you are requesting that he certify the patient for shoes and inserts. A copy of this letter can on page 25 of this manual or in the Business Forms section online at www.surefitlab.com.

Cover letters can be used by a supplier as a method of communication between the supplier and the physician. The cover letter is a form that is not required by HCFA nor regulated by HCFA.

IV. Mail, fax or have the patient take the cover letter and Statement of Certifying Physician Form to their physician. Place a copy of the form in a pending file that you can use to track the status of your pending forms.

V. File the completed and signed Statement of Certifying Physician Form in the patient's chart. **Do not send this form to SureFit.**

A supplier must have a faxed or original signed order and a faxed or original CMN (when applicable) in their records before they can submit a claim to Medicare.

* CMN-certificate of medical necessity.

PRESCRIBING SHOES AND INSERTS

Filling out a prescription and keeping it on file is optional when you are both the prescribing physician and the supplier of the shoes and inserts.

If you choose to write a prescription, it is recommended that you keep it in your patient's file.

The prescribing physician actually writes the order for the therapeutic shoe, modifications and inserts. The prescribing physician may be a podiatrist, M.D. or D.O.

An order for the shoes, inserts or modifications which has been signed and dated by the prescribing physician must be kept on file by the supplier. If the prescribing physician is the supplier, a separate order is not required, but the item provided must be clearly noted in the patient's record.

CHARTING CONDITIONS

Once you have determined that a patient qualifies for shoes and inserts it is recommended that medical necessity be documented in the patient's chart.

The following notes represent charting examples for the prescribing of therapeutic footwear and diabetic inserts under various circumstances, but are not a guarantee of Medicare compliance. Regardless of the source of the information, the final responsibility for correct coding and documentation of medical necessity is the sole responsibility of the provider submitting the claim.

Medical Necessity Documentation for the use of custom inserts and prefabricated inserts

The only published medical policy concerning the criteria for using prefabricated vs. custom molded inserts establishes the need of the device to achieve and maintain total contact with the plantar surface of the foot for the life of the device. However, it is recommended that all other reasons for use of custom inserts be substantiated and documented.

A partial list of conditions that place the patient at increased risk and/or may necessitate the use of custom inserts include, but are not limited to:

- Biomechanical imbalances resulting in overpronation, oversupination, and or plantar shearing.
- Foot deformities such as plantarflexed metatarsals, exostoses, pes cavus, pes planus.
- Presence or history of plantar lesions, pre-ulcerative calluses or ulcers.
- Localized increased plantar pressure as documented on Harris Mat Foot Imprint.
- Weight and activity level of patient

Medical Necessity Requirements for patients receiving custom inserts who were previously fit with prefabricated devices.

Patients who have previously been fit with prefabricated inserts may be fit with custom molded inserts when medically necessary. A partial list of conditions which may necessitate the change to custom molded inserts include, but are not limited to:

- The prefabricated inserts did not maintain total contact with the plantar aspect of the foot for the life of the device.
- The patient has developed a new lesion or a prior lesion did not resolve while using prefabricated devices.
- The patient has developed a focal area of increased pressure on the plantar aspect of the foot as documented by a Harris mat imprint or other pressure mapping device.
- The patient has a foot deformity or shape which can no longer be accommodated by a prefabricated device.
- The presence of a biomechanical imbalance which puts the patient at increased risk and cannot be controlled using a prefabricated device.

Sample Progress note to document eligibility for depth shoes and custom molded inserts

Doe, John 07/24/08.

S: This 78 year old high risk Type II diabetic patient presents today to determine whether the patient is eligible for footwear and or inserts under the Medicare Therapeutic Shoe Bill. The patient has a history of peripheral neuropathy and runs a high risk of developing infections and or ulcerations from improperly fitting shoes.

O: Physical examination revealed that the patient has the qualifying foot conditions checked off below:

- Previous amputation of the other foot, or part of either foot, or
- History of previous foot ulceration of either foot, or
- History of pre-ulcerative calluses of either foot, or
- Peripheral neuropathy with evidence of callus formation of either foot, or
- Poor circulation in either foot;

The patient has peripheral neuropathy with an absence of protective sensation confirmed by an inability to feel the 5.07 monofilament on the plantar aspect of the foot

The patient also has the following conditions which require depth-inlay shoes and custom molded inserts:

Pre-ulcerative calluses/corns in the following locations: an HD on the fifth digit on the left foot and a plantar tyloma beneath the first metatarsal head on the right foot.

There is Increased plantar pressure beneath the first metatarsal head detected by a Harris Mat foot imprint which predisposes the patient to ulceration.

A: Peripheral neuropathy. Pre-ulcerative calluses. Plantarflexed first metatarsal. Diabetes Type II.

P: Depth-inlay therapeutic footwear and custom molded inserts are medically necessary for this patient to achieve and maintain total contact with the plantar aspect of the patient's foot and to prevent infection and ulceration. A negative impression of the patient's foot will be taken using a foam box or plaster cast and the mold will be sent to an outside lab (i.e.: SureFit) for fabrication of custom molded total contact inserts. I am sending a certifying statement to the patient's physician to certify the need for footwear and a copy of these records to verify the presence of the qualifying foot conditions listed on the certifying statement. Shoes and inserts will be dispensed when the certifying letter has been signed and returned by the patient's physician.

<Physician Name>, D.P.M.

Sample Progress note for day of dispensing for custom molded inserts

Doe, John 07/24/08.

Dispensed one pair of depth shoes and three pairs of custom-molded total contact multidensity plastazote/EVA inserts that were made from a positive model of the patient's foot. Custom molded inserts were required to achieve and maintain total contact with the plantar aspect of the patient's foot for the life of the device and to prevent tissue damage. Three pairs of inserts are required in this patient due to bottoming out and loss of protection after 4 months of wear. The shoes fit well and the inserts achieve total contact with the plantar surface of the patient's foot. A statement of certifying physician is on file in the patient's chart that documents the medical necessity for footwear and or inserts. The patient was given a copy of the supplier standards, the return policy and new shoe break in instructions. A copy of the patient's office records were reviewed and initialed by the primary care physician prior to the signing of the certifying statement. The patient was advised to wear the shoes at home for only one hour on the first day and to check their feet for any sores or irritations. The patient will be seen for a follow-up and will call if any problems arise.

< Physician's Name >

Sample Progress note to document eligibility for depth shoes and prefabricated inserts

Hancock, John 08/15/2008

S: This 66 year old high risk Type II diabetic patient presents today to determine whether the patient is eligible for footwear and or inserts under the Medicare Therapeutic Shoe Bill. The patient has a history of poor circulation and runs a high risk of developing infections and or ulcerations from improperly fitting shoes.

O: Physical examination revealed that the patient has the qualifying foot conditions checked off below:

- Previous amputation of the other foot, or part of either foot, or
- History of previous foot ulceration of either foot, or
- History of pre-ulcerative calluses of either foot, or
- Peripheral neuropathy with evidence of callus formation of either foot, or
- Poor circulation in either foot;

Further examination revealed the following:

- Non-palpable pedal pulses bilaterally.
- Cyanosis of both feet.
- Delayed capillary return, hallux bilaterally.
- Thin, shiny skin.
- Fat pad atrophy resulting in increased plantar pressure.

A: Peripheral vascular disease. Subcutaneous tissue atrophy. Diabetes Type II.



P: Depth-inlay therapeutic footwear and prefabricated heat molded inserts are required in this patient to achieve and maintain total contact with the plantar aspect of the patient's foot for the life of the device. I am sending a certifying statement to the patient's physician to certify the need for footwear and a copy of these records to verify the presence of the qualifying foot conditions listed on the certifying statement. Shoes and inserts will be dispensed when the certifying letter has been signed and returned by the patient's physician.

<Physician Name>, D.P.M.

Sample Progress note for day of dispensing for shoes and prefabricated inserts

Hancock, John 08/15/2008.

Dispensed one pair of depth shoes and three pairs of prefabricated multidensity plastazote/EVA inserts that were heat molded to the patient's foot using an external heat source to achieve total contact with the plantar aspect of the patient's foot. Three pairs of inserts are required in this patient due to bottoming out and loss of cushioning after 4 months of wear. The shoes and inserts fit well after heat molding. A copy of the patient's office records were reviewed and initialed by the primary care physician prior to the signing of the certifying statement. A statement of certifying physician is on file in the patient's chart that documents the medical necessity for footwear and or inserts. The patient was given a copy of the supplier standards, the return policy and new shoe break in instructions. The patient was advised to wear the shoes at home for only one hour on the first day and to check their feet for any sores or irritations. The patient will be seen for a follow-up and will call if any problems arise.

<Physician Name>, D.P.M.

Sample Progress note to document eligibility for depth shoes and custom molded inserts for patients who received shoes last year

Hancock, John 08/15/2008

S: This 66 year old high risk Type II diabetic patient presents today for re-evaluation for footwear and inserts under the Medicare Therapeutic Shoe Bill. Last year the patient received one pair of off the shelf depth shoes and 3 pairs of custom molded inserts. The patient has a history of peripheral neuropathy and pre-ulcerative lesions and and has been fit with therapeutic footwear and inserts to prevent infection and ulceration.

O: Physical examination revealed that the patient has the qualifying foot conditions checked off below:

- Previous amputation of the other foot, or part of either foot, or
- History of previous foot ulceration of either foot, or
- History of pre-ulcerative calluses of either foot, or
- Peripheral neuropathy with evidence of callus formation of either foot, or
- Poor circulation in either foot;



Peripheral neuropathy with an absence of protective sensation confirmed by an inability to feel the 5.07 monofilament on the plantar aspect of the foot

The patient also has the following conditions which require depth-inlay shoes and custom molded inserts:

- Pre-ulcerative calluses beneath the second metatarsal head on the right foot.
- Increased focal pressure beneath the second met head noted on a Harris Mat foot imprint.
- Shoes are worn and require replacement.
- All 3 pairs of inserts have bottomed out and require replacement.

A: Peripheral neuropathy. Pre-ulcerative callus beneath the second metatarsal head. Diabetes Type II.

P: Depth-inlay therapeutic footwear and prefabricated heat molded inserts are required in this patient to achieve and maintain total contact with the plantar aspect of the patient's foot for the life of the device. A negative impression of the patient's foot will be taken using a foam box or plaster cast and the mold will be sent to an outside lab (i.e.: SureFit) for fabrication of custom molded total contact inserts. I am sending a letter to the patient's physician to certify the need for footwear and inserts and a copy of my office records that verify the presence of the foot conditions listed on the certifying statement. Shoes and inserts will be dispensed when the certifying letter has been signed and returned by the patient's physician.

<Physician Name>, D.P.M.

SUREFIT CUSTOM INSERT ORDERS

Filling out this form, taking the measurements and foam impression can be done by either the practitioner, fitter or medical assistant. All instructions which follow are in reference to the **SureFit Custom Order form**.

- I. **Order Type** - SureFit Custom Inserts may be ordered with or without shoes. When ordering custom inserts without shoes, please indicate the style, length and width of the shoes the inserts will be used in.
- II. **Insert Type** – Select either Diabetic Custom Total Contact Multidensity Inserts or Custom Accommodative Inserts.

For the Medicare Diabetic Footwear Program, select Diabetic Custom Total Multidensity Inserts. These inserts are Medicare Approved for Code A5513 and fabricated using a CAD/CAM manufacturing system. The inserts are composed of a base layer of 40 Shore A EVA and a top cover of medium density plastazote.

Select SureFit Custom Accommodative Inserts with cork shell when ordering Toe Fillers and billing L5000. It can also be used as a non-covered accommodative device.

SureFit Custom Accommodative Inserts are comprised of a firm, longer lasting cork shell, a middle layer of PPT and your choice of a washable EVA, plastazote or leather top cover. This insert can be ordered full length, to the sulcus or met heads. The insert can also be used for patients with heel pain, metatarsalgia, tendonitis, arthritis, posterior tibial dysfunction and many other common pedal complaints. The insert is very well tolerated and can be ordered with any of the accommodations on our order form. The insert can be ordered by itself or with any shoe in our catalog.

A foam or plaster cast is required with the custom order form for all of our custom inserts. More information is provided on TAKING THE FOAM IMPRESSION section.

- III. **Insert Quantity** – Inserts may be ordered in *pairs* or *singularly* for the right or left foot. Please check the quantity desired for a pair OR quantity of *LEFT ONLY* or *RIGHT ONLY* inserts. Medicare will not reimburse for an amputated foot. Diabetic inserts will compress over time and last about four months in active patients. Three inserts per foot are therefore recommended. All three may be delivered to the patient and billed upon patient acceptance.

Custom Accommodative inserts will last 1-3 years depending on activity level. Therefore these are generally ordered one pair at a time.

- IV. **Patient's Current Shoes** - Please annotate the brand, style or model number, length and width of the shoe the patient is currently wearing. Assess the fit of the current shoe and note whether it fits well, is too long, too short, too wide or too narrow.
- V. **Comments** – Please note the type of shoe closure, i.e. a laced, velcro or any distinguishing aspects regarding disproportional wear or noted problem areas.

VI. Foot Measurements - All measurements should be taken with the patient wearing the socks they will wear with their new shoes. **You will take a total of 4 measurements for each foot – 3 using the Brannock Device.** You should have two Brannock devices, a men’s and women’s device. The men’s device is black and the women’s is purple. Examine the device. The heel cups are marked left and right. Locate the Arch Length Pointer on the device (measures heel to ball or arch length). Next locate the Movable Width Bar.

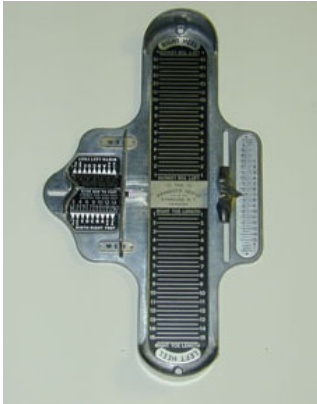


Fig. 1 Men's Brannock Device



Fig. 2 - Movable Arch Length Pointer

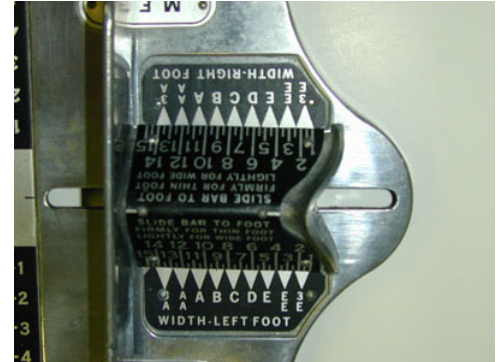


Fig. 3 - Moveable Width Bar

You will take three different measurements using the Brannock device:

- a) *Heel to toe Length*
- b) *Heel to ball Length (or arch length)*
- c) *Width*

Refer to the instructions below for accurate interpretation and recording of measurements using the Brannock Device.

Taking Measurements with the Brannock Device

Remove the patient’s footwear and pull their socks up so they are snug against the toes (without drawing the toes back). Using the counter or a chair for support, ask the patient to stand with both feet together, positioning the right foot closest to the counter. Place the Brannock device on the lateral side of the patient’s left foot. Request the patient lift his/her left foot and place their heel into the heel cup. Weight should be evenly distributed on both feet, hip width apart, with the heel of the foot as far back in the device as possible.

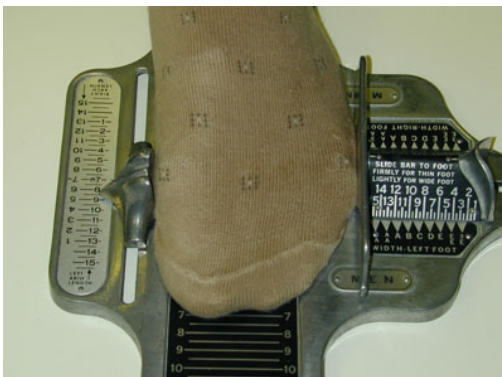


Fig. 4 – Anterior view of proper foot placement in the Brannock Device



Fig. 5 – Lateral view of proper foot placement in the Brannock Device

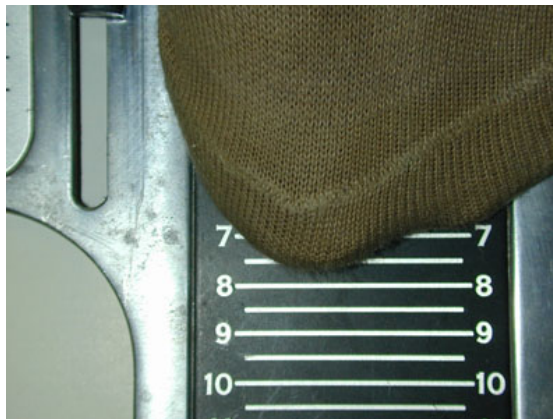
a.) **Heel to Toe Length** -While positioned in front of the patient, press the toes flat against the base of the device. Looking straight down over the foot, obtain the heel to toe length for the longest toe. Viewing at an angle could cause an inaccurate reading.

Fig. 6 – Look directly over the patient for proper viewing of the markings on the Brannock device.



The longest toe is usually the first or second toe, but on a rare occasion the third toe may be the longest. Read the measurement based upon the half and whole scale divisions marked on the device. Use a plus sign (+) to note when the longest toe extends in between a half and whole division. If the patient is wearing an AFO, take the heel to toe measurement with the device on. Only the heel to toe measurement will be needed in this case.

Fig. 7 - The heel to toe length measurement for the foot in this photo is between a 7½ and an 8. Record this heel to toe length as a 7½ +.



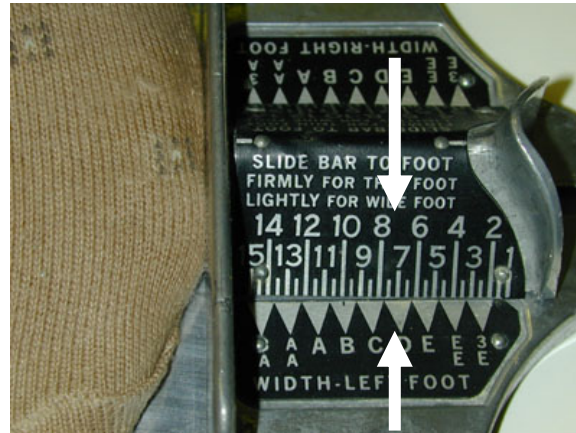
b.) **Heel To Ball Length** –Slide the Arch Length Pointer forward or aft so it is next to the widest part of the foot at the ball (i.e. the pointer is concave and will encircle the medial aspect of the first met head). Record this number on the form in the space provided.

Fig. 8 - In the photo (right), the heel to ball measurement should be recorded as an 8½ +.



c.) **Width Measurement** – Slide the Width Bar firmly against the outside (lateral aspect) of the foot. Do not squeeze the foot with the bar; just move it towards the foot until it meets resistance. Locate the patient’s heel to toe size on the top of the Width Bar. View the width immediately below. If the heel to toe size falls between widths, record the range as in “C-D”. See illustration below.

Fig. 9 – In this photo, the patient’s heel to toe length was 7½ +. The corresponding width is between a C and a D. In this case the width was recorded as C-D.



Turn the patient around and position the brannock device so it is to the right side of the patient’s right foot. Have the patient pick up his/her right foot and guide his right heel into the heel cup. Repeat all three measurements for the right foot and record on the order form.

Semi-Circumference Measurement - Remove the foot from the Brannock device. With the patient weight bearing, socks on, measure the semi-circumference of the widest part of the foot, at the ball, using a tape measure. Measure from the floor on the medial side of the first met head over the top of the foot and down to the floor on the lateral side of the fifth met head. Make sure the tape measure is not pulled too tightly against the foot. Record this measurement in inches rounding up to the nearest ¼ inch, i.e. 5¼ inches, 6½ inches. Most feet will be between 5 - 6½ inches in semi-circumference. Repeat this measurement for the other foot.

Fig. 10 – Measurement taken with tape placed against the floor from edge to edge of foot - not under the foot.



Patient Wearing AFO – If the patient will be wearing an AFO in the shoe being ordered, please check the side (left or right) to assure the shoe will accommodate.

VII. Foot Evaluation: If the patient has any of the conditions and/or deformities listed, please place a check in the appropriate mild, moderate or severe columns for both the left and right foot.

VII. Insert Accommodations - A wide range of accommodations are available and can be ordered with any of our custom inserts. Please indicate on the order form the type and location of the accommodation you are ordering. When ordering reliefs check the appropriate box on the order form and circle the area(s) on the patient's ink imprint. It is not necessary to mark the foam box or cast when ordering reliefs unless no ink imprint was obtained. The following is a list of accommodations and their indications. There is a nominal charge for accommodations (see our price list for details). Toe fillers are the only accommodations that are reimbursable. Please refer to our billing section or call Customer Service at (800) 298-6050 for more information on billing for toe fillers.

Dancer's Pad: A dancer's pad is placed on the bottom of an insert to relieve pressure beneath the first and fifth metatarsal heads, usually when a cavus foot type is present.

Heel Lift: A heel raise made of a non-compressible cork material up to $\frac{3}{8}$ inch in thickness may be ordered to place inside a shoe or on the bottom of an insert. When a patient requires a lift greater than $\frac{3}{8}$ inch to accommodate a limb length discrepancy, it must be placed on the sole of the shoe.

Metatarsal Bar: An oval shaped pad that extends across all of the metatarsal heads. Aimed at relieving pressure beneath any or all of the metatarsal heads this accommodation is used commonly in patients with lesions beneath the first or fifth and/or one or more central metatarsals.

Full Polyurethane Layer: Polyurethane foam material that is used in an insert for additional cushioning. Useful when several adjacent plantar lesions and or fat pad atrophy is present.

Relief: A cut out in an insert to relieve pressure on a particular area of the foot. The relief (pocket) can be placed beneath a metatarsal, a digit or any plantar prominence. The pocket is partially filled with polyurethane to provide additional cushioning. A small dispersion pad is normally placed around the lesion to provide additional off loading. A relief is used to provide additional pressure relief for pre-ulcerative or severe plantar lesions. When ordering please circle the area of increased pressure on the foot imprint. Do not order reliefs for multiple adjacent metatarsal or digital lesions. If multiple adjacent digits or metatarsals require additional off loading, a layer of PPT should be ordered.

Saddle Pad: A "U" shaped pad that is placed on an insert as an accommodation to relieve pressure in the area inside the "U". Saddle pad is used to offload pressure beneath one of the central three metatarsals or other plantar bony prominence. It can be ordered in combination with a relief when necessary for the treatment of intractable plantar lesions or the prevention of recurrent ulcerations.

Toe Filler: Extra material is added to the top of an insert to fill the void that is present in a shoe due to the amputation of one or more toes. The toe filler prevents the shoe upper from collapsing in the area of the amputated digits. Toe fillers should not be ordered to realign digits that have migrated following an

amputation. Fillers may be ordered for hallux, transmetatarsal amputations or ray resections. They are not indicated for amputations of individual lesser digits. Toe fillers are reimbursable under code L5000. Please refer to the billing section for details on billing for toe fillers.

Lateral Wedge:

A lateral wedge can be placed on the bottom of each individual insert or inside the shoe. The wedge will extend from the heel to just proximal to the metatarsal heads, unless other specifications are requested. Can be ordered with a relief in patients who oversupinate and have lesions located under the fourth and or fifth metatarsal heads.

Medial Wedge:

A medial wedge can be placed on the bottom of each individual insert or inside the shoe. The wedge will extend from the heel to just proximal to the metatarsal heads, unless other specifications are requested. A wedge can be ordered with a relief for patients who overpronate and have lesions beneath the medial metatarsals (first and or second) or hallux.

To complete an order of custom inserts, you will need to take a foot imprint and impression using a foam or plaster cast. Please refer to "[IMPRINTING THE FOOT](#)" and "[TAKING THE FOAM IMPRESSION](#)" respectively for more information.

When ordering shoes WITH custom inserts, please select the shoe style, color and closure style of shoe desired per the procedures below.

- I. **Selecting the Shoe** – Use the SureFit Style Section Chart to narrow the selection you will offer the patient. For optimum results, offer the styles that are appropriate for their condition. Choose the condition based upon the most severe deformity present on either foot.

Patients presenting with mild or no deformities may select any style desired.

- II. **Shoe Presentation** – Show the patient the shoe(s) in the catalog or from the SureFit Display Stand that are appropriate for their condition. Explain to the patient that the shoes presented are best suited for their particular circumstances to fit correctly.
- III. **Shoe Size:** Please indicate the desired length and width of the shoe being ordered. All shoes in the SureFit catalog may be ordered using either the Origins or Legacy fitting system.

The Origins System utilizes the two removable insoles in all Adventure Series shoes to achieve the best fit for each patient. Your patients try on a shoe from the New Fitting Display to determine length, you add or subtract insoles as needed to determine width and order the shoe they prefer from the catalog in the required size.

The Legacy System is based upon the original SureFit Fitting System and utilizes Brannock device measurements to determine the proper size of the shoe. SureFit's Shoe Size Calculator provides a cross-reference from the measurements to the actual shoe size to be ordered based on the individual last for each shoe.

- IV. **Shoe Order** – Record the style and color choice on the SureFit Order form.

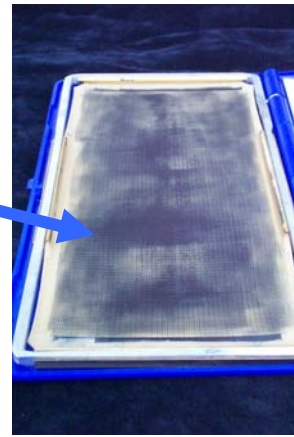
IMPRINTING THE FOOT (FOR CUSTOM INSERT ORDERS)

The Harris Mat (Foot Imprinter) is used to obtain a tracing of the foot and to identify any pressure points on the bottom of the foot. A Foot Imprinter Set (including Harris Mat, Ink Imprinter, Roller and Ink Part No.- Impkt) is available from SureFit.

The following instructions are based on an order for a pair of inserts. Adjust as needed if a single left or right insert is being ordered.

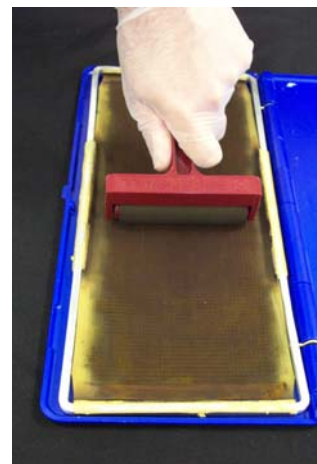
- I. PREPARATION:** Put on rubber gloves to avoid getting any ink on your hands.
- II. EXAMINATION:** Open up the foot imprinter. Inside the foot imprinter is a rubber mat that has a smooth side and a rough side with a grid or crosshatch pattern on it.
- III. INK MAT:** For the **FIRST USE** apply twelve drops of ink to the **rough crosshatched side** of the rubber mat only. The patient will not get any ink on his/her feet because he will be stepping on the smooth side of the mat only. **Do not apply ink to the smooth side of the mat or patient will get ink on his/her feet.**

Fig. 1 – Apply ink onto the ROUGH cross-hatched side of the rubber mat only.



Spread the ink out with the roller as evenly as possible, pressing firmly back and forth with the roller until the ink has been spread over the entire rubber mat. Rinse the roller off with water to remove excess ink and return to the box. **Reapply 3 drops of ink every 2-3 patients as needed when the foot imprints become too light.** It is not necessary to re-ink the imprinter for each patient.

Fig. 2 – Spread ink as evenly as possible over the entire Bladder using the roller.



IV. INSERT PAPER: Change your gloves if you have any ink on them. Insert a legal size sheet of paper on the blue cover opposite the inked rubber mat. Flip the rubber mat over such that the crosshatched ink side is face down on the paper. The smooth side of the rubber mat should be facing up.

Fig. 3 – Insert paper onto the blue cover opposite the inked rubber mat and flip over so the crosshatched side is face down on the paper.



When the patient stands on the imprinter the ink will show up on the paper that is now beneath the rubber mat.

V. STANDING AT THE MAT: Request patient stand next to a counter or chair with both feet together with the right foot closest to the counter. Place the mat on the floor next to the patient's left foot as shown in the photo below.

Fig. 3 – Utilize counter for support as needed during imprinting of the foot.



VI. TAKING THE IMPRINT: Lift patient's left foot and place in the center of the rubber mat while keeping the right foot stationary.

Fig. 4 – Foot should be placed in the center of the rubber mat, with even distribution of weight between feet for best results.



VII TRACE OUTLINE: Using a stylus pen or retractable ballpoint pen with the ballpoint retracted (so ink from the pen does not get on the rubber mat), press down and trace the outline of the entire foot. Excessive pressure is not necessary to obtain a tracing. Do not go in at the arch area or between the toes.

Fig. 5 – Pen should be held vertically, 90° from the mat.



VIII WALK OFF MAT: If possible, request patient take a step forward with their stationary foot. As weight shifts to stationary foot, the patient will lift his/her heel off the mat as they continue to walk off the mat.



Fig. 6, 7, 8 – Stepping forward with stationary foot first to walk off the mat, allows patient to roll through their normal gait sequence insuring a good impression of all pressure points is secured.

IX CHECK IMPRINT and CIRCLE PRESSURE POINTS: Remove the paper from the imprinter. Write the patient's name, practitioner's name and Account number on the imprint paper. If ordering reliefs (pockets), circle the pressure point(s) to indicate the desired position. If you want a lesion accommodated, circle the pressure area on the ink print. If the pressure area does not show up as a darker area on the ink print, place an aperture pad around the lesion and take another imprint so the area is well defined on the print.

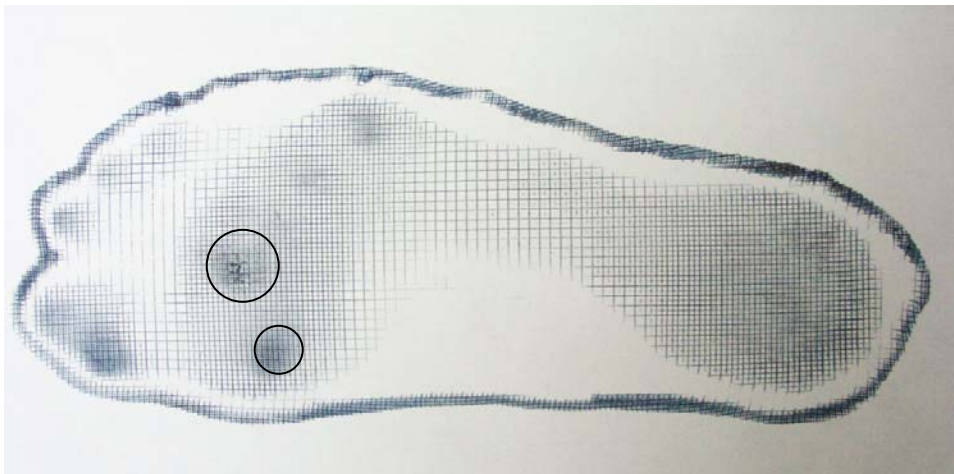


Fig. 9 – Circle pressure points on the imprint to indicate location for reliefs

X. IMPRINT OF RIGHT FOOT: If ordering a pair of inserts, place second blank piece of legal size paper in the imprinter. Flip the rubber mat to cover the new piece of paper. Turn the patient in the opposite direction and repeat steps V through IX for the right foot.

XI FOOT IMPRESSION: Take foot impression to send with paper imprints according to instructions in "TAKING THE FOAM IMPRESSION" section.

TAKING THE FOAM IMPRESSION

SureFit requires a foam impression of the patient's foot to fabricate custom inserts. Please use 14" foam boxes only.

The following instructions are based upon an order for a pair of inserts. Adjust as needed if a single left or right insert is being ordered.

I. POSITIONING THE FOOT: Request patient stand next to a counter for support with both feet together, right foot closest to the counter. A seated impression may be more practical for some patients.

Place the foam box next to the patient's left foot. With patient's weight shifted to the right side, position the patient's left foot so that the foot is *centered in the foam block and the heel is positioned about 1" from the back edge of the box.*



Fig. 2 – Person taking the foot impression should be located in front of the patient to assist throughout the procedure.



Fig. 3 – Before requesting patient place weight on the foot, check that their foot is in the center of the foam block and heel is ½" from the edge.

III. TAKING THE IMPRESSION: With the patient either standing or seated, hold the foot in neutral position by grasping just below the anklebone with your thumb and index finger with one hand. At the same time, with your other hand continuously apply pressure with two or three fingers to the first metatarsal. While continuing to hold the foot in this position, request the patient apply downward pressure on the foam material until they meet resistance.



Fig. 4 – Hold the ankle and first metatarsal firmly as the impression is being made to keep the foot from tilting.



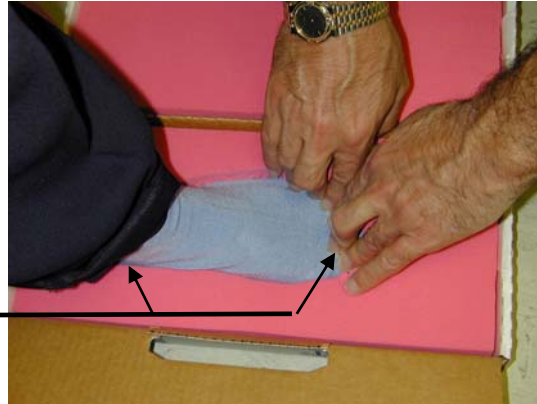
Fig. 5 – Sufficient pressure must be applied to compress the foam by at least 1½" to assure a good impression.

If the impression is taken seated, push down on the patient's knee until some resistance is met.

Whether the impression is taken semi or full weight bearing make sure the patient's heel and forefoot penetrates the foam at least 1 ½" into the foam.

IV PUSH TOES: Firmly push down on the ends of the toes so they are not elevated (dorsiflexed); Toes should be level with the rear of the foot.

Fig. 6 – Press down on toes and request patient press down on their heel until resistance is met for best results.



V FOOT REMOVAL: Assist patient to slowly lift the foot from the foam to avoid cracking the foam. If the patient is standing, request the patient turn in the opposite direction and position the foam box next to the right foot to take an impression of the right foot. If you notice any cracking of the foam, please redo the impression.

VI SHIP ORDER: Mark the impression box with the patient's name, practitioner's name and account number on the inside of the box. Refer to [SHIPPING INSTRUCTIONS FOR CUSTOM ORDERS](#) for additional info.



SHIPPING INSTRUCTIONS FOR CUSTOM ORDERS

Place the following items flat inside the foam box:

- 1) *Custom Insert Order Form*
- 2) *Foot Imprints*

Tape the sides of the box to prevent the forms from slipping out during shipping. The foam box serves as the shipping container. To ship multiple orders together, you may tape the orders securely together and use one shipping label for the package, or you may put the orders in another carton and use one postage paid shipping label.

Please mark the foam box(es) "**FRAGILE**" in large red print.

Follow these easy steps to ship your order:

U.S. POSTAL SERVICE

Affix the pre-printed U.S. Postal mailing label to the box. Give the box to your mail carrier.

UNITED PARCEL SERVICE

(Note: Only use UPS Shipping Labels if you have regular pick-ups or deliveries from UPS)

- a. Affix the pre-printed UPS mailing label to the box. The reference number(s) on this copy will enable you to track any particular patient order or return.
- b. Give the shipment to your UPS driver the next time they are at your office.
- c. The prepaid level of service does not include pick-up service. Do NOT call for pick-up.

Please call SureFit Customer Service at 800.298.6050 when you are running low on the prepaid mailing labels and we will send you more.



SHOES, PREFABRICATED INSERTS OR DME ORDERS

All instructions which follow are in reference to the SureFit Shoe/Prefab/DME Order form. SureFit Customers may call Customer Service at 800.298.6050 to place your order or fax a completed order form to 888.801.3450.

Please complete all information fully to assure your order is received on a timely basis.

- 1. Shoe Order** - For optimum results, offer the styles that are appropriate for the patient's condition from the SureFit Style Section Chart. Choose the condition based upon the most severe deformity present on either foot.

Example: If the patient has mild bunions on his/her left foot and moderate on the right, choose moderate as the condition in the order forms and select a shoe which can accommodate a moderate bunion deformity.

Indicate the part number (example *S646-1*) or model name (example *Florence*) for the style selected. All Part numbers are listed in the photo caption for each shoe in the 2010 Therapeutic Footwear Catalog. Please indicate the desired length and width of the shoe. All shoes in the SureFit catalog may be ordered using either the Origins or Legacy fitting system.

The Origins System utilizes the two removable insoles in all Adventure Series shoes to achieve the best fit for each patient. Your patients try on a shoe from the New Fitting Display to determine length, you add or subtract insoles as needed to determine width and order the shoe they prefer from the catalog in the required size.

The Legacy System is based upon the original SureFit Fitting System and utilizes Brannock device measurements to determine the proper size of the shoe. SureFit's Shoe Size Calculator provides a cross-reference from the measurements to the actual shoe size to be ordered based on the individual last for each shoe.

- 2. PREFABRICATED INSERT Order** - This section is to be used for ordering SureFit Moldable inserts as shown on page 102 of the SureFit Catalog ONLY. All other prefabricated inserts shown in the SureFit Product catalog may be ordered using the DME section immediately below.

- 3. DME ORDER:** - Please use this section to order all items other than shoes or prefabricated moldable inserts.

HEAT MOLDING TECHNIQUE FOR PREFABRICATED INSERTS

The patient may be seated or standing during the direct molding process.

I. Preheating the Insert: Heat the insert using *either* of the following methods:

- a. **Using a heat gun set** at a minimum of 230°F, heat the prefabricated inlay on the top and bottom of the device until it is soft and malleable (approximately 2 minutes).
- b. **Using an oven** set at 250 °F, place the entire device in the oven with the pink side up. Heat inserts for approximately 1-2 minutes until they are soft and malleable.



Caution: Do not heat the inserts to a point where they are too hot to handle with bare hands to avoid burning the patient's skin.

II. Positioning the Foot: Cover the patient's foot with a sock or other protective material. Place the heated device on a foam block. Position the patient's foot on top of the heated device and hold the foot in neutral position.

III. Molding the Prefabricated Insert: Mold the insert up to the patient's arch while the device is warm. Remove the patient's foot from the insert after the device has cooled (approximately two minutes).



IV. Checking for Total Contact after Molding: Remove the insert from the foam block and place on the floor. Position the patient's foot on top of the molded insert. Check to see if the arch on the insert is high enough to achieve total contact with the patient's foot.



V. Modification of the Insert to achieve Total Contact: Add additional material to the arch to achieve total contact when necessary.



FITTING SHOES

Arrival and Delivery of Shoes: Please try the shoes on the patient in your office with the custom inserts and check the fit with the patient standing according to the following criteria.



Fig. 1 – Toe Length: Compress the end of the shoe to feel the edge of the longest toe. A ½" of allowance should exist between the end of the longest toe and the shoe.



Fig. 2 – Toe Alternate: If you can't feel the toe through the shoe, remove the shoe and insert. Request patient stand so their heel is at the back edge of the insert. Verify a ½" space exists between the end of the longest toe and the front edge of the insert.



Fig. 3 – Width Length: Foot should fit snugly at the ball with a pinch of material for allowance.



Fig. 4 – Heel: As patient walks, evaluate if there is any heel slippage present. No gaps should be present.

FIT: If you experience any problems with the fit of the shoes, please refer to the SureFit Fitting Solutions Kit for guidance on problem resolution. If the problem persists, please call Customer Service (800.298.6050) while the patient is in your office, for immediate assistance from one of our fitting staff. In many cases, we can solve the problem during the fitting session. If the problem cannot be solved in your office, we will furnish you with a Return Authorization Number. Complete the Return Form and return to SureFit using the prepaid shipping labels.



FURNISHING CUSTOM INSERTS

- I. Your order will arrive with one pair of custom inserts inside the shoes ready to try on the patient. If you ordered two or three pairs of inserts, the additional pair(s) will be in a plastic bag.

FURNISHING PREFABRICATED INSERTS

- I. ***Arrival and Delivery of Shoes:*** Your order will arrive with one pair of prefabricated inserts inside the shoes ready to try on the patient. If you ordered two or three pairs of inserts, the additional pair(s) will be in a plastic bag. If the fit is satisfactory, heat mold one pair of inserts according to instructions provided in section [HEAT MOLDING TECHNIQUE FOR PREFABRICATED INSERTS](#) and recheck the fit. If the fit continues to be satisfactory heat mold the remaining two pair of inserts.

DOCUMENTATION REQUIRED UPON DELIVERY

- I. Upon confirmation of a proper fit, please provide the patient with a copy of the [Supplier Standards](#) and the [Patient Instructions for Use of Footwear and Inserts](#). To ensure backup and proof of delivery under Medicare rules, please request the patient sign the following forms:
 - a. *Return Policy on Shoes*
 - b. *Authorization of Payment*
- II. Provide your business card to the patient and request they call your office if they experience any problems.
- III. Record in the patient's chart exactly what was delivered to the patient. Refer to [Charting Section](#) for sample notes.
- IV. Place a copy of the SureFit invoice for shoes and inserts in the patient's chart.

Date: _____

Re: _____

Dear Dr. _____:

Physical examination revealed that your patient has the condition(s) listed on the enclosed form, and therefore qualifies for footwear and inserts under the Medicare Therapeutic Shoe Bill. This preventive program was established for at risk patients, with or without a history of foot ulceration. Medicare guidelines require that the physician who is managing the patient's diabetic condition certify the patient for footwear and inserts.

A copy of our office records are attached which verify the presence of the conditions indicated on the certifying physician statement. If you agree that the patient has the conditions indicated on the certifying statement, please sign and date the statement and return it to us by fax or mail. If you have any questions concerning this patient please do not hesitate to call. Thank you for your cooperation in this matter.

Sincerely,

<Physician Name>, D.P.M.

STATEMENT OF CERTIFYING PHYSICIAN FOR THERAPEUTIC SHOES

PATIENT NAME: _____

HIC# _____
(Patient's Medicare Number)

I certify that all of the following statements are true:

- 1) The patient has diabetes mellitus, ICD-9 code: _____
- 2) This patient has one or more of the following conditions:
 - History of partial or complete amputation of the foot
 - Peripheral neuropathy with evidence of callus formation
 - History of previous foot ulceration
 - Foot deformity
 - History of pre-ulcerative callus
 - Poor circulation
- 3) I am treating this patient under a comprehensive plan of care for his/her diabetes.
- 4) This patient needs special shoes and or inserts because of his/her diabetes.

I have documented the presence of the above conditions in the patient's medical record and or have reviewed the Podiatrist's records and agree that the patient has the qualifying foot conditions indicated on this form.

Physician Signature: _____ Date _____
(Must be an M.D. or D.O.)

Physician name (please print): _____

Address: _____

NPI # _____

AUTHORIZATION OF PAYMENT
& PROOF OF DELIVERY

Patient:	Date:
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I have received _____ pair of shoes and _____ pair of inserts. I am satisfied with the fit and authorize Medicare and my supplemental insurance carrier to pay <Physician Name> directly. I understand that Medicare will cover up to one pair of shoes and three pair of inserts per calendar year. I understand that I am responsible for any deductible and the 20% co-insurance if my insurance carrier does not pay. I have not received any inserts or shoes from any other supplier during this calendar year. I have been given a copy of the supplier standards and have read and understand them.

The shoes are warranted to be free from defects in material and workmanship for a period of six months from dispensing. Each pair of inserts are warranted to be free from defects in material and workmanship for a period of four months from the start of use.

Patient Signature

Witness

Warranty/Return Policy on Shoes

Patient Name:	Account #:	Date Furnished:
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Please wear your shoes on a carpeted surface until you are sure of a comfortable fit. Shoes that are dirty or have visible wear or damage cannot be returned or exchanged. Shoes without visible wear can be returned or exchanged because of faulty fit within **30 days** from the date they were received. Shoes must be returned in the original box. The shoes are warranted to be free from defects in material and workmanship for a period of six months from dispensing. Each pair of inserts are warranted to be free from defects in material and workmanship for a period of four months from the start of use.

Signature

Date

Witness

Date



Patient Instructions for Use of Footwear and Inserts

I. New shoe break-in period

- Wear your shoes at home on a carpeted surface for one hour the first day.
- Remove your shoes and check your feet for any sores or irritations. Check all areas of your feet including your toes, the tops bottoms and sides of your feet, the back of your heels, etc. If you notice any red spots or other signs of irritation, or if the shoe does not fit properly, stop wearing your shoes immediately. Call your doctor and make an appointment to have the fit of your shoes checked. You must bring the shoes back in the original box.
- If the shoe fits properly increase your wearing time to two hours the second day and three hours on the third day. After each day check your feet again for sores or irritations.
- If you are satisfied with the fit of the shoes after wearing them for three days you can begin wearing them outside. Remember, the shoes can only be returned if they are still in new condition and in the original box.

Home Inspection and Follow-up Office visits

- After the initial break-in period, patients should continue to inspect their feet daily for any sores or irritations after removing their shoes. Consult your doctor if you detect any irregularities.
- Replace inserts at four month intervals to ensure adequate protection.
- Inspect the shoes and inserts periodically and consult your doctor if they show unusual wear.
- See your doctor for routine footcare and inspection of your feet at periodic intervals.
- Enjoy your new shoes and inserts!

CMS MEDICARE DMEPOS SUPPLIER STANDARDS

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. 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 nonprocurement 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.
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, or cell phone 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. Failure to maintain required insurance at all times will result in revocation of the supplier's billing privileges retroactive to the date the insurance lapsed.
11. A supplier must agree not to initiate telephone contact with beneficiaries, with a few exceptions allowed. This standard prohibits suppliers from calling beneficiaries in order to solicit new business.
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 Supplier 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 of DMEPOS and other items and services 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.

23. All DMEPOS suppliers must notify their accreditation organization when a new DMEPOS location is opened. The accreditation organization may accredit the supplier location for three months after it is operational without requiring a new site visit.

24. All DMEPOS supplier locations, whether owned or subcontracted, must meet the DMEPOS quality standards and be separately accredited in order to bill the Medicare. An accredited supplier may be denied enrollment or their enrollment may be revoked, if CMS determines that they are not in compliance with the DMEPOS quality standards.

25. All DMEPOS suppliers must disclose upon enrollment all products and services, including the addition of new product lines for which they are seeking accreditation. If a new product line is added after enrollment, the DMEPOS supplier will be responsible for notifying the accrediting body of the new product so that the DMEPOS supplier can be re-surveyed and accredited for these new products.

26. Must meet the surety bond requirements specified in paragraph (d) of this section.

Therapeutic Shoes for Persons with Diabetes

MEDICARE DMERC MEDICAL POLICY

Original Policy Effective Date: For services performed on or after 05/01/1993

Revision Effective Date: For services performed on or after 04/01/2004

Benefit Category: Shoes for Patients with Diabetes

Indications and Limitations of Coverage and/or Medical Necessity

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. For the items addressed in this medical policy, the criteria for "reasonable and necessary" are defined by the following indications and limitations of coverage and/or medical necessity.

For an item to be covered by Medicare, a written signed and dated order must be received by the supplier before a claim is submitted to the DMERC. If the supplier bills for an item addressed in this policy without first receiving the completed order, the item will be denied as noncovered.

Therapeutic shoes, inserts and/or modifications to therapeutic shoes are covered if the following criteria are met:

- 1) The patient has diabetes mellitus (ICD-9 diagnosis codes 250.00-250.93); and
- 2) The patient has one or more of the following conditions:
 - a) Previous amputation of the other foot, or part of either foot, or
 - b) History of previous foot ulceration of either foot, or
 - c) History of pre-ulcerative calluses of either foot, or
 - d) Peripheral neuropathy with evidence of callus formation of either foot, or
 - e) Foot deformity of either foot, or
 - f) Poor circulation in either foot; and
- 3) The certifying physician who is managing the patient's systemic diabetes condition has certified that indications (1) and (2) are met and that he/she is treating the patient under a comprehensive plan of care for his/her diabetes and that the patient needs diabetic

shoes.

For patients meeting these criteria, coverage is limited to one of the following within one calendar year (January – December):

1) One pair of custom molded shoes (A5501) (which includes inserts provided with these shoes) and 2 additional pairs of inserts (A5512 or A5513); or

2) One pair of depth shoes (A5500) and 3 pairs of inserts (A5512 or A5513) (not including the non-customized removable inserts provided with such shoes).

Separate inserts may be covered and dispensed independently of diabetic shoes if the supplier of the shoes verifies in writing that the patient has appropriate footwear into which the insert can be placed. This footwear must meet the definitions found in this policy for depth shoes or custom-molded shoes.

Items represented by code A5510 reflect compression molding to the patient's foot over time through the heat and pressure generated by wearing a shoe with the insert present. Since these inserts are not considered total contact at the time of dispensing, they do not meet the requirements of the benefit category and will be denied as noncovered.

Inserts used in noncovered shoes are noncovered.

A custom molded shoe (A5501) is covered when the patient has a foot deformity that cannot be accommodated by a depth shoe. The nature and severity of the deformity must be well documented in the supplier's records and may be requested by the DMERC. If there is insufficient justification for a custom molded shoe but the general coverage criteria are met, payment will be based on the allowance for the least costly medically appropriate alternative, A5500.

A modification of a custom molded or depth shoe will be covered as a substitute for an insert. Although not intended as a comprehensive list, the following are the most common shoe modifications: rigid rocker bottoms (A5503), roller bottoms (A5503), wedges (A5504), metatarsal bars (A5505), or offset heels (A5506). Other modifications to diabetic shoes (A5507) include, but are not limited to flared heels.

Deluxe features of diabetic shoes (A5508) will be denied as noncovered.

Shoes, inserts, and/or modifications that are provided to patients who do not meet the coverage criteria will be denied as noncovered. When codes are billed without a KX modifier (see Documentation section), they will be denied as noncovered.

The particular type of footwear (shoes, inserts, modifications) which is necessary must be prescribed by a podiatrist or other qualified physician, knowledgeable in the fitting of diabetic shoes and inserts. The footwear must be fitted and furnished by a podiatrist, or other qualified individual such as a pedorthist, orthotist or prosthetist.

The certifying physician (i.e., the physician who manages the systemic diabetic condition)

may not furnish the footwear unless he/she practices in a defined rural area or a defined health professional shortage area. The prescribing physician (podiatrist or other qualified physician) can be the supplier (i.e., the one who furnishes the footwear).

There is no separate payment for the fitting of the shoes, inserts or modifications or for the certification of need or prescription of the footwear. Unrelated evaluation and management services provided by the physician are processed by the local carrier.

CPT/HCPCS Codes

The appearance of a code in this section does not necessarily indicate coverage.

- A5500 FOR DIABETICS ONLY, FITTING (INCLUDING FOLLOW-UP), CUSTOM PREPARATION AND SUPPLY OF OFF-THE-SHELF DEPTH-INLAY SHOE MANUFACTURED TO ACCOMMODATE MULTI-DENSITY INSERT(S), PER SHOE.
- A5501 FOR DIABETICS ONLY, FITTING (INCLUDING FOLLOW-UP), CUSTOM PREPARATION AND SUPPLY OF SHOE MOLDED FROM CAST(S) OF PATIENT'S FOOT (CUSTOM MOLDED SHOE), PER SHOE
- A5503 FOR DIABETICS ONLY, MODIFICATION (INCLUDING FITTING) OF OFF-THE-SHELF DEPTH-INLAY SHOE OR CUSTOM-MOLDED SHOE WITH ROLLER OR RIGID ROCKER BOTTOM, PER SHOE
- A5504 FOR DIABETICS ONLY, MODIFICATION (INCLUDING FITTING) OF OFF-THE-SHELF DEPTH-INLAY SHOE OR CUSTOM-MOLDED SHOE WITH WEDGE(S), PER SHOE
- A5505 FOR DIABETICS ONLY, MODIFICATION (INCLUDING FITTING) OF OFF-THE-SHELF DEPTH-INLAY SHOE OR CUSTOM-MOLDED SHOE WITH METATARSAL BAR, PER SHOE
- A5506 FOR DIABETICS ONLY, MODIFICATION (INCLUDING FITTING) OF OFF-THE-SHELF DEPTH-INLAY SHOE OR CUSTOM-MOLDED SHOE WITH OFF-SET HEEL(S), PER SHOE
- A5507 FOR DIABETICS ONLY, NOT OTHERWISE SPECIFIED MODIFICATION (INCLUDING FITTING) OF OFF-THE-SHELF DEPTH-INLAY SHOE OR CUSTOM-MOLDED SHOE, PER SHOE
- A5508 FOR DIABETICS ONLY, DELUXE FEATURE OF OFF-THE-SHELF DEPTH-INLAY SHOE OR CUSTOM-MOLDED SHOE, PER SHOE
- A5510 FOR DIABETICS ONLY, DIRECT FORMED, COMPRESSION MOLDED TO PATIENT'S FOOT WITHOUT EXTERNAL HEAT SOURCE, MULTIPLE-DENSITY INSERT(S) PREFABRICATED, PER SHOE
- A5512 FOR DIABETICS ONLY, MULTIPLE DENSITY INSERT , DIRECT FORMED, MOLDED TO FOOT AFTER EXTERNAL HEAT SOURCE OF 230 DEGREES FAHRENHEIT OR HIGHER, TOTAL CONTACT WITH PATIENT'S FOOT, INCLUDING ARCH, BASE LAYER MINIMUM OF 1/4 INCH MATERIAL OF SHORE A 35 DUROMETER OR 3/16 INCH MATERIAL OF SHORE A 40 (OR HIGHER), PREFABRICATED, EACH
- A5513 FOR DIABETICS ONLY, MULTIPLE DENSITY INSERT, CUSTOM MOLDED FROM MODEL OF PATIENT'S FOOT, TOTAL CONTACT WITH PATIENT'S FOOT, INCLUDING ARCH, BASE LAYER MINIMUM OF 3/16 INCH MATERIAL OF SHORE A 35 DUROMETER OR HIGHER, INCLUDES ARCH FILLER AND OTHER SHAPING MATERIAL, CUSTOM FABRICATED, EACH

HCPCS MODIFIERS:

EY - No physician or other licensed health care provider order for this item or service.

KX - Specific required documentation on file.

LT - Left Side

RT - Right Side

Coding Guidelines

A depth shoe (A5500) is one that 1) has a full length, heel-to-toe filler that when removed provides a minimum of 3/16" of additional depth used to accommodate custom-molded or customized inserts; 2) is made from leather or other suitable material of equal quality; 3) has some form of shoe closure; and 4) is available in full and half sizes with a minimum of three widths so that the sole is graded to the size and width of the upper portions of the shoe according to the American standard last sizing schedule or its equivalent. (The American last sizing schedule is the numerical shoe sizing system used for shoes in the United States.) This includes a shoe with or without an internally seamless toe.

A custom-molded shoe (A5501) is one that 1) is constructed over a positive model of the patient's foot; 2) is made from leather or other suitable material of equal quality; 3) has removable inserts that can be altered or replaced as the patient's condition warrants; and 4) has some form of shoe closure. This includes a shoe with or without an internally seamless toe.

An insert described by code A5512 is a total contact, multiple density, prefabricated removable inlay that is directly molded to the patient's foot so that it conforms to the plantar surface and makes total contact with the foot, including the arch. The insert must retain its shape during use for the life of the insert. The material responsible for maintaining the shape of the device is called the base layer and must be heat moldable. This material usually constitutes the bottom layer of the device and must be of a sufficient thickness and durometer to maintain its shape during use (e.g., at least 1/4 inch of Shore A 35 or higher or 3/16 inch of Shore A 40 or higher). Modifications such as additional arch fill may be necessary to achieve and maintain total contact. The materials used should be suitable with regards to the patient's condition.

An insert described by code A5513 is a total contact, custom fabricated, multiple density, removable inlay that is molded to a model of the patient's foot so that it conforms to the plantar surface and makes total contact with the foot, including the arch. The insert must retain its shape during use for the life of the insert. A custom fabricated device is made from materials that do not have predefined trim lines for heel cup height, arch height and length, or toe shape. The bottom layer of the device must be of a sufficient thickness and durometer to maintain its shape during use (e.g., at least 3/16 inch of Shore A 35 material or higher). The bottom layer of the device should have adequate arch fill to maintain shape and achieve total contact. The materials used should be suitable with regards to the patient's condition.

Rigid rocker bottoms (A5503) are exterior elevations with apex position for 51 percent to 75 percent distance measured from the back end of the heel. The apex is a narrowed or

pointed end of an anatomical structure. The apex must be positioned behind the metatarsal heads and tapering off sharply to the front tip of the sole. Apex height helps to eliminate pressure at the metatarsal heads. Rigidity is ensured by the steel in the shoe. The heel of the shoe tapers off in the back in order to cause the heel to strike in the middle of the heel.

Roller bottoms (sole or bar) (A5503) are the same as rocker bottoms, but the heel is tapered from the apex to the front tip of the sole.

Wedges (posting) (A5504) are either of hind foot, fore foot, or both and may be in the middle or to the side. The function is to shift or transfer weight bearing upon standing or during ambulation to the opposite side for added support, stabilization, equalized weight distribution, or balance.

Metatarsal bars (A5505) are exterior bars which are placed behind the metatarsal heads in order to remove pressure from the metatarsal heads. The bars are of various shapes, heights, and construction depending on the exact purpose.

Offset heel (A5506) is a heel flanged at its base either in the middle, to the side, or a combination, that is then extended upward to the shoe in order to stabilize extreme positions of the hind foot.

A deluxe feature (A5508) does not contribute to the therapeutic function of the shoe. It may include, but is not limited to style, color, or type of leather.

Code A5507 is only to be used for not otherwise specified therapeutic modifications to the shoe or for repairs to a diabetic shoe(s).

Deluxe features must be coded using code A5508.

Codes for inserts or modifications (A5503 - A5508, A5510, A5512, A5513) may only be used for items related to diabetic shoes (A5500, A5501). They must not be used for items related to footwear coded with codes L3215 - L3253. Inserts and modifications used with L coded footwear must be coded using L codes (L3000 - L3649).

When a single shoe, insert or modification is provided, the appropriate modifier, right (RT) or left (LT), must be used. If a pair is provided, report as two (2) units of service on the claim – the RT or LT modifiers should not be used.

Inserts for missing toes or partial foot amputation should be coded L5000 or L5999, whichever is applicable.

Suppliers should contact the Statistical Analysis Durable Medical Equipment Regional Carrier (SADMERC) for guidance on the correct coding of these items.

Documentation Requirements

Section 1833(e) of the Social Security Act precludes payment to any provider of services unless "there has been furnished such information as may be necessary in order to determine the amounts due such provider" (42 U.S.C. section 13951(e)). It is expected that the patient's medical records will reflect the need for the care provided. The patient's medical records include the physician's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports. This documentation must be available to the DMERC upon request.

An order for each item billed must be signed and dated by the prescribing physician, kept on file by the supplier, and made available to the DMERC upon request. Items billed to the DMERC before a signed and dated order has been received by the supplier must be submitted with an EY modifier added to each affected HCPCS code. If the prescribing physician is the supplier, a separate order is not required, but the item provided must be clearly noted in the patient's record. A new order is not required for the replacement of an insert or modification within one year of the order on file. However, the supplier's records should document the reason for the replacement. A new order is required for the replacement of any shoe. A new order is also required for the replacement of an insert or modification more than one year from the most recent order on file.

The supplier must obtain a signed statement from the certifying physician specifying that the patient has diabetes mellitus, has one of conditions 2a-2f listed in the policy, is being treated under a comprehensive plan of care for his/her diabetes, and needs diabetic shoes. The certifying physician must be either a M.D. or D.O. and may not be a podiatrist. The Statement of Certifying Physician for Therapeutic Shoes developed by the DMERC is recommended (whatever form is used must contain all of the elements contained on the attached recommended form). This statement may be completed by the prescribing physician or supplier but must be reviewed for accuracy of the information and signed by the certifying physician to indicate agreement. A new Certification Statement is required for a shoe, insert or modification provided more than one year from the most recent Certification Statement on file.

Suppliers must add a KX modifier to codes only if all of the criteria in the "Indications and Limitations of Coverage and/or Medical Necessity" section of this policy have been met. If the requirements for the KX modifier are not met, the supplier may submit additional documentation with the claim to justify coverage, but the KX modifier must not be used.

The ICD-9 code that justifies the need for these items must be included on the claim.

If code A5507 is submitted, the claim must contain a narrative description of the modification or feature provided.

The prescribing physician's name and UPIN number must be listed in Blocks 17 and 17a of the HCFA-1500 form or the electronic equivalent.

Refer to the Supplier Manual for more information on documentation requirements.

Other Comments

The Certifying Physician provides the medical care for the beneficiary's diabetic condition. The certifying physician must be an M.D. or D.O., and may not be a podiatrist.

The Prescribing Physician actually writes the order for the therapeutic shoe, modifications and inserts. The prescribing physician may be a podiatrist, M.D., or D.O.

The Supplier is the person or entity that actually furnishes the shoe, modification, and/or insert to the beneficiary and that bills Medicare. The supplier may be a podiatrist, pedorthist, orthotist, prosthetist or other qualified individual. The Prescribing Physician may be the supplier. The Certifying Physician may only be the supplier if the certifying physician is practicing in a defined rural area or a defined health professional shortage area.

Revision History Explanation

Revision Effective Date: 04/01/2004

HCPCS CODES AND MODIFIERS:

Added: A5512 and A5513

Deleted: A5509 and A5511

CODING GUIDELINES: Added definitions for codes A5512 and A5513

Revision Effective Date: 04/01/2003

POLICY TITLE:

Retitled policy to reflect current American Diabetes Association nomenclature.

HCPCS CODES AND MODIFIERS:

Added: EY

INDICATIONS AND LIMITATIONS OF COVERAGE:

Added standard language concerning coverage of items without an order.

Clarified the term "calendar year" to mean the period from January through December.

DOCUMENTATION REQUIREMENTS:

Added standard language concerning use of the EY modifier for items without an order.

The revision dates listed below are the dates the revisions were published and not necessarily the effective dates for the revisions.

04/01/2002 – Crosswalked HCPCS code A5502 to A5509, A5510 and A5511. Added non-coverage statement for A5510. Updated ICD-9 code range for diabetes mellitus in Coverage and Payment Rules section. Added RT and LT modifiers. Replaced ZX with KX modifier. Clarified that code A5507 can be used for repairs to diabetic shoes. Clarified that the certifying physician may not be a podiatrist.

12/01/2000 – Revised Statement of Certifying Physician for Therapeutic Shoes form adding

"Circle all that apply" for all questions and statement that person signing the form must be an M.D. or D.O.

03/01/1998 – Removed HCPCS L3649, added HCPCS K0401. Added definitions for certifying physician, prescribing physician, and supplier in the Definitions section.

04/01/1995 – Revised definition of ZX modifier in Documentation section.