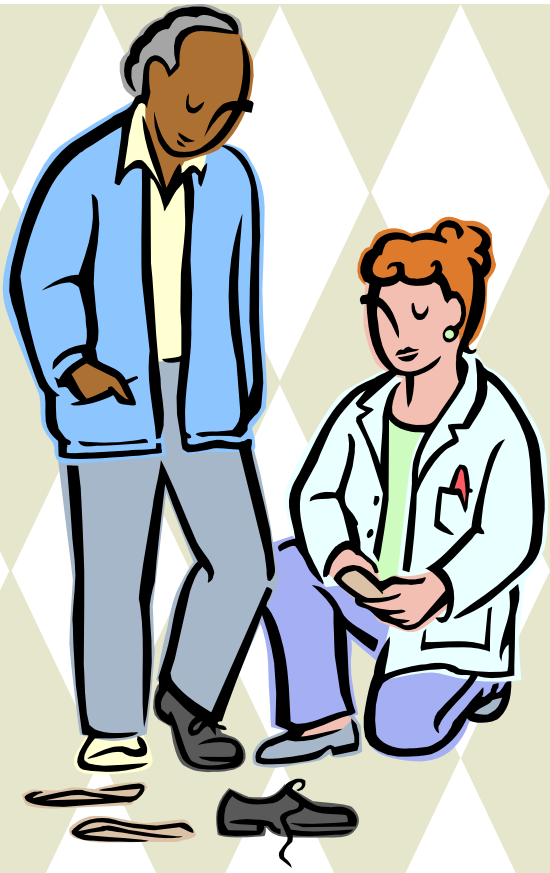
DMEPOS Primer



Published by the
American Podiatric
Medical Association, Inc.

AMERICAN PODIATRIC MEDICAL ASSOCIATION, INC.

October 2005

Dear Colleague:

The American Podiatric Medical Association (APMA) is pleased to present the 2006 Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Primer as a free, online member benefit. The Primer can be downloaded and printed for use in the office. This Primer was written in an effort to assist members in understanding commonly used DMEPOS items.

The DMEPOS Primer addresses definitions of orthotics, equipment, and supplies relevant to the practice of podiatric medicine. It explains coding and modifiers, as well as outlines the necessary documentation requirements for reimbursement. This document is intended to serve as an additional tool to assist podiatric physicians who use DMEPOS items.

Be advised that this Primer is not meant to serve as legal advice nor does it establish a standard of care as individual circumstances vary. Users of this Primer are encouraged to discuss individual coding and billing issues with a competent consultant.

This Primer is copyrighted by APMA and should not be distributed to individuals who are not members of the APMA. To those who are members, enjoy this latest member benefit.

Harold B. Glickman, DPM
President

Ross E. Taubman, DPM
Treasurer
Chair, Health Policy Committee

9312 Old Georgetown Road Bethesda, Maryland 20814-1621
(301) 571-9200 Fax (301) 530-2752 http://www.apma.org

DISCLAIMER

This Primer is designed to set forth general policies and procedures to use as a guideline when dealing with DMEPOS issues in the context of small to medium size podiatry practices. Every effort has been made to ensure the accuracy and thoroughness of the information contained herein. However, this primer does not constitute professional or legal advice. It is strongly recommended that all podiatrists consult with a competent health care advisor or counsel as they seek to finalize and implement the policies and procedures discussed in the Primer. Provisions in this Primer may need to be modified to fit certain practitioners' specific individual circumstances.

APMA would like to acknowledge the following individuals for their hard work and contributions to the 2006 DMEPOS Primer:

DME Subcommittee

Timothy Tillo, DPM – *Chair*
Jeffrey DeSantis, DPM
Paul Kinberg, DPM
Kenneth F. Malkin, DPM

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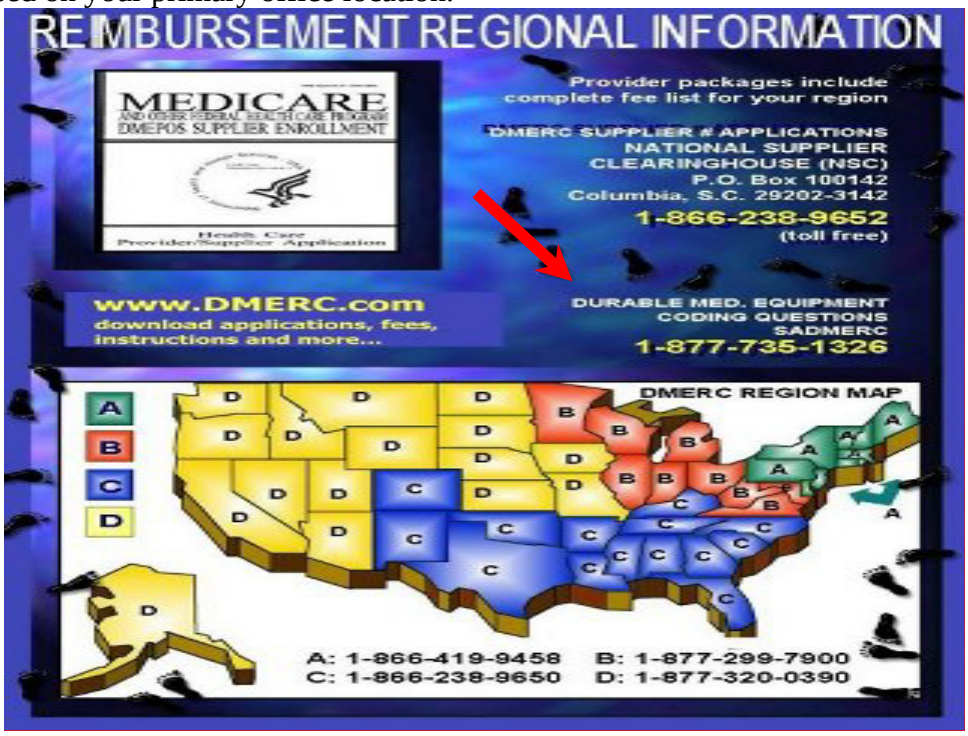
I. **Glossary of Terms**

AFO – Ankle-Foot Orthosis
CMS – Centers for Medicare and Medicaid Services
DME – Durable Medical Equipment
DMEPOS – Durable Medical Equipment, Prosthetics, Orthotics, and Supplies
DMERC – Durable Medical Equipment Regional Carrier
HCPCS – Healthcare Common Procedure Coding System
KAFO – Knee-Ankle-Foot Orthosis
LCD – Local Coverage Determination
LMRP – Local Medical Review Policy
NSC – National Supplier Clearinghouse
SADMERC – Statistical Analysis Durable Medical Equipment Regional Carrier

II. **Getting Started with DMERC**

A. Determine below which of the four regional DMERC carriers you will most often be billing based on your primary office location.



B. Obtain a CMS855S application by calling 1-877-238-9652.

C. **Complete the application in order to obtain a DMEPOS Supplier number. Some DMERC suppliers may offer assistance with this process.**

D. Your participation status with DMERC must mirror you participation with the Part B program. If you participate in Part B, you must participate in the DMERC.

E. National Supplier Clearinghouse (NSC) 21 Supplier Standards Document

1. To qualify for a supplier number and be able to dispense DME products, certain standards must be met. Click below for the 21 Supplier Standards: http://www.pgba.com/palmetto/Other.nsf/f45451e08e6ffeda852569ee00005c6d/85256d430058d01d85256b830076c61d?OpenDocument
2. A copy of these 21 standards must be provided each time a beneficiary receives a DMERC covered item.
3. Compliance with these standards is often confirmed through an on-site inspection by an agent from the DMERC.

F. For a copy of the on-site evaluation form used by the inspectors which pertain to the 21 Supplier Standards, go to the APMA web site to the members only area. Click on Insurance Issues and go to DME/DMERC. Click on "CMS DMEPOS Supplier Standards." http://www.apma.org/s_apma/secmember.asp?CID=446&DID=17255

G. Dispensing requirements for suppliers

1. Proof of delivery/acknowledgment of receipt: the beneficiary must sign and date a form that acknowledges their receipt of the DME. A copy of this receipt should be available upon request by the DMERC.
2. The medical record should reflect that the device was fitted to the patient (if applicable) and instructions were given to the patient for proper use.
3. The medical record should reflect the patient was provided with a copy of the 21 standards
4. If applicable, the medical record should show the patient was given a Copy of Warranty.

III. **Ankle-Foot Orthoses (AFOs)**

A. At this time, the LCD/LMRP for AFOs is the same for each of the four regional DMERCs.

B. Each carrier has posted the same information on its website. For example, the policy for Region C DMERC (Palmetto GBA) may be found at: http://www.cms.hhs.gov/mcd/viewlcd.asp?lcd_id=11517&lcd_version=20&show=all

C. To obtain your regional DMERC's policy from the web, go to the carrier's home page, click on Providers, click on DMERC, go to Medical Policy and click on Ankle/Foot/Knee Orthosis.

D. NOTE: These medical policies are subject to revision on a periodic basis. As such, the information contained herein may not represent the most recent policy. To ensure compliance with current medical policy, readers are advised to review the DMERC website on a frequent basis.

IV. **Prefabricated Ambulatory Ankle-Foot Orthoses**

A. Drop Foot Brace

B. L1930 is defined by HCPCS as "AFO, plastic or other material, prefabricated, includes fitting and adjustment."

NOTE: **Information in *italics* is a direct quote from the DMERC policy.**

C. *For an item to be considered for coverage under the Brace benefit category, it must be a rigid or semi-rigid device which is used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body. It must provide support and counterforce (i.e., a force in a defined direction of a magnitude at least as great as a rigid or semi-rigid support) on the limb or body part that it is being used to brace. Items that do not meet the definition of a brace are non-covered. . .Medicare does not reimburse for a foot drop splint/recumbent positioning device (L4398) or replacement interface (L4394). A foot drop splint/recumbent positioning device and replacement interface is noncovered when it is used solely for the prevention or treatment of a pressure ulcer because for these indications it is not used to support a weak or deformed body member or to restrict or eliminate motion in a diseased or injured part of the body (i.e., it does not meet the definition of a brace). . .The purpose of a brace is to support a weak or deformed body member or to restrict or eliminate motion in a diseased or injured part of the body. When an AFO or KAFO for an ambulatory patient and any related addition is used solely for the treatment of edema and/or for the prevention or treatment of a pressure ulcer, it will be denied as non-covered. For example, codes L4360 and L4386 are ankle-foot orthoses that are referred to as walking boots. Walking boots used to provide immobilization as treatment for an orthopedic condition or after orthopedic surgery are eligible for coverage under the Brace benefit. When walking boots are used primarily to relieve pressure, especially on the sole of the foot, or are used for patients with foot ulcers, they are non-covered – no Medicare benefit. Medicare covers therapeutic shoes, as described in the Therapeutic Shoes for Diabetics LMRP, for the prevention and treatment of diabetic foot ulcers.*

D. **Coding**

1. The HCPCS Level II code for "AFO (plastic or other material, prefabricated, includes fitting and adjustment)" is L1930.
2. *The only eligible ICD-9 diagnoses for coverage are:*
   a. *Drop foot 736.79*
   b. *Ankle instability 718.87*
3. *NOTE: This code (L1930) is inappropriate for (dorsal) night splints or devices worn (non- or limited-weight bearing) for plantar fascitis (heel spur) treatment. Those devices should be coded as L4396 (static ankle-foot orthoses, including soft interface material, adjustable for fit, for positioning, pressure reduction, may be used for minimal ambulation, prefabricated, including fitting and adjustment).*
4. *The right (RT) and left (LT) modifiers must be used with orthosis base codes, additions, and replacement parts. When the same code for bilateral items (left and right) is billed on the same date of service, bill both items on the same claim line using the LTRT modifiers and 2 units of service.*
5. *Evaluation of the patient, measurement and/or casting, and fitting of the orthosis are included in the allowance for the orthosis. There is no separate payment for these services.*

6. *Repairs to a covered orthosis due to wear or to accidental damage are covered when they are necessary to make the orthosis functional. The reason for the repair must be documented in the supplier's record. If the expense for repairs exceeds the estimated expense of providing another entire orthosis, no payment will be made for the amount in excess.*
7. *The allowance for the labor involved in replacing an orthotic component that is coded with a specific L code is included in the allowance for that component. The allowance for the labor involved in replacing an orthotic component that is coded with the miscellaneous code L4210 is separately payable in addition to the allowance for that component.*
8. *When the GY modifier is added to a code there must be a short narrative statement indicating why the GY modifier was used – e.g., "used to prevent pressure ulcer" or "used to treat pressure ulcer" or "used to treat edema." This statement should be entered in the narrative field of an electronic claim or attached to a hard copy claim.*

E. **Products**

1. Some of the products approved by SADMERC can be found at the following website: http://www2.palmettogba.com/classifications/orthotics%20and%20prosthetics.pdf
2. A medical supplier may request that SADMERC review their item or supply and provide them with a specific code. This is not a requirement for coverage, but does alleviate any concerns by a provider that s/he is billing for an item or supply that meets the code billed according to SADMERC.
3. *A prefabricated orthosis is one which is manufactured in quantity without a specific patient in mind. A prefabricated orthosis may be trimmed, bent, molded (with or without heat), or otherwise modified for use by a specific patient (i.e., custom-fitted). An orthosis that is assembled from prefabricated components is considered prefabricated. Any orthosis that does not meet the definition of a custom-fabricated orthosis is considered prefabricated.*
4. *Ankle-foot orthoses extend well above the ankle (usually to near the top of the calf) and are fastened around the lower leg above the ankle.*
5. Below are photographic examples of the AFO from two different manufacturers:
   a. Restorative Care of America (RCAI):

b. Maramed Orthopedic Systems:

F. **Documentation Requirements**

1. *Itemize pertinent clinical data, i.e., conservative treatment, physical exam findings, etc.*
2. *Foot drop is a condition in which there is weakness and/or lack of use of the muscles that dorsiflex the ankle but there is the ability to bring the ankle to 0 degrees by passive range of motion.*
3. *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.*
4. *An order for each new or full replacement item must be signed and dated by the treating 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.*
5. *The order must list the unique features of the base code that is billed plus every addition that will be billed on a separate claim line. The medical record must contain information which supports the medical necessity of the item and all additions that are ordered. An order is not necessary for the repair of an orthosis.*

V. **Walker Boot – Pneumatic**

A. L4360 is defined by HCPCS as "Walking boot, pneumatic, with or without joints, with or without interface material, prefabricated, includes fitting and adjustment."

NOTE: **Information in *italics* is a direct quote from the DMERC policy.**

B. **Definitions**

1. *For an item to be considered for coverage under the Brace benefit category, it must be a rigid or semi-rigid device which is used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body. It must provide support and counterforce (i.e., a force in a defined direction of a magnitude at least as great as a rigid or semi-rigid support) on the limb or body part that it is being used to brace. Items that do not meet the definition of a brace are non-covered.*
2. *The purpose of a brace is to support a weak or deformed body member or to restrict or eliminate motion in a diseased or injured part of the body. When an AFO or KAFO for an ambulatory patient and any related addition is used solely for the treatment of edema and/or for the prevention or treatment of a pressure ulcer, it will be denied as non-covered. For example, codes L4360 and L4386 are ankle-foot orthoses that are referred to as walking boots. Walking boots used to provide immobilization as treatment for an orthopedic condition or after orthopedic surgery are eligible for coverage under the Brace benefit. When walking boots are used primarily to relieve pressure, especially on the sole of the foot, or are used for patients with foot ulcers, they are non-covered – no Medicare benefit. Medicare covers therapeutic shoes, as described in the Therapeutic Shoes for Diabetics LMRP, for the prevention and treatment of diabetic foot ulcers.*
3. ***AFOs used during ambulation:** Ankle-foot orthoses (AFO) described by codes L1900-L1990, L2106-L2116, L4350, L4360, and L4386 are covered for ambulatory patients with weakness or deformity of the foot and ankle, who require stabilization for medical reasons, and have the potential to benefit functionally.*

C. **Coding**

1. The HCPCS Level II code for "walking boot, pneumatic, with or without joints, with or without interface material, prefabricated, includes fitting and adjustment" is **L4360**.
2. *The right (RT) and left (LT) modifiers must be used with orthosis base codes, additions, and replacement parts. When the same code for bilateral items (left and right) is billed on the same date of service, bill both items on the same claim line using the LTRT modifiers and 2 units of service.*
3. *Evaluation of the patient, measurement and/or casting, and fitting of the orthosis are included in the allowance for the orthosis. There is no separate payment for these services.*
4. *Repairs to a covered orthosis due to wear or to accidental damage are covered when they are necessary to make the orthosis functional. The reason for the repair must be documented in the supplier's record. If the expense for repairs exceeds the estimated expense of providing another entire orthosis, no payment will be made for the amount in excess.*
5. *The allowance for the labor involved in replacing an orthotic component that is coded with a specific L code is included in the allowance for that component. The allowance for the labor involved in replacing an orthotic component that is coded with the miscellaneous code L4210 is separately payable in addition to the allowance for that component.*

6. *When the GY modifier is added to a code there must be a short narrative statement indicating why the GY modifier was used – e.g., "used to prevent pressure ulcer" or "used to treat pressure ulcer" or "used to treat edema." This statement should be entered in the narrative field of an electronic claim or attached to a hard copy claim.*

D. **Miscellaneous**

1. *Replacement of a complete orthosis or component of an orthosis due to loss, significant change in the patient's condition, or irreparable accidental damage is covered if the device is still medically necessary. The reason for the replacement must be documented in the supplier's record.*
2. *Quantities of supplies greater than those described in the policy as the usual maximum amounts, in the absence of documentation clearly explaining the medical necessity of the excess quantities, will be denied as not medically necessary.*

E. **Products**

1. Some of the products approved by SADMERC can be found at the following website: http://www2.palmettogba.com/classifications/orthotics%20and%20prosthetics.pdf
2. A medical supplier may request that SADMERC review their item or supply and provide them with a specific code. This is not a requirement for coverage, but does alleviate any concerns by a provider that s/he is billing for an item or supply that meets the code billed according to SADMERC.
3. *A prefabricated orthosis is one which is manufactured in quantity without a specific patient in mind. A prefabricated orthosis may be trimmed, bent, molded (with or without heat), or otherwise modified for use by a specific patient (i.e., custom-fitted). An orthosis that is assembled from prefabricated components is considered prefabricated. Any orthosis that does not meet the definition of a custom-fabricated orthosis is considered prefabricated.*
4. Picture example of L4360:

F. **Documentation Requirements**

1. *As previously stated, L4360 is covered for ambulatory patients with weakness or deformity of the foot and ankle, who require stabilization for medical reasons, and have the ability to benefit functionally. Walking boots such as L4360 are used to provide immobilization as treatment for an orthopedic condition or after orthopedic surgery.*
2. *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.*
3. *An order for each new or full replacement item must be signed and dated by the treating 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.*
4. *The order must list the unique features of the base code that is billed plus every addition that will be billed on a separate claim line. The medical record must contain information which supports the medical necessity of the item and all additions that are ordered. An order is not necessary for the repair of an orthosis*

VI. **Walker Boot – Non-Pneumatic**

A. L4386 is defined by HCPCS as "walking boot, non-pneumatic, with or without joints, with or without interface material, prefabricated, includes fitting and adjustment."

B. **Definitions**

1. *For an item to be considered for coverage under the Brace benefit category, it must be a rigid or semi-rigid device which is used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body. It must provide support and counterforce (i.e., a force in a defined direction of a magnitude at least as great as a rigid or semi-rigid support) on the limb or body part that it is being used to brace. Items that do not meet the definition of a brace are non-covered.*
2. *The purpose of a brace is to support a weak or deformed body member or to restrict or eliminate motion in a diseased or injured part of the body. When an AFO or KAFO for an ambulatory patient and any related addition is used solely for the treatment of edema and/or for the prevention or treatment of a pressure ulcer, it will be denied as non-covered. For example, codes L4360 and L4386 are ankle-foot orthoses that are referred to as walking boots. Walking boots used to provide immobilization as treatment for an orthopedic condition or after orthopedic surgery are eligible for coverage under the Brace benefit. When walking boots are used primarily to relieve pressure, especially on the sole of the foot, or are used for patients with foot ulcers, they are non-covered – no Medicare benefit. Medicare covers therapeutic shoes, as described in the Therapeutic Shoes for Diabetics LMRP, for the prevention and treatment of diabetic foot ulcers.*
3. ***AFOs used during ambulation:** Ankle-foot orthoses (AFO) described by codes L1900-L1990, L2106-L2116, L4350, L4360, and L4386 are covered for ambulatory patients with weakness or deformity of the foot and ankle, who require stabilization for medical reasons, and have the potential to benefit functionally.*

C. **Coding**

1. The HCPCS level II code for the Walking Boot, non-pneumatic, with or without joints, with or without interface material, prefabricated, includes fitting and adjustment is L4386.
2. *The right (RT) and left (LT) modifiers must be used with orthosis base codes, additions, and replacement parts. When the same code for bilateral items (left and right) is billed on the same date of service, bill both items on the same claim line using the LTRT modifiers and 2 units of service.*
3. *Evaluation of the patient, measurement and/or casting, and fitting of the orthosis are included in the allowance for the orthosis. There is no separate payment for these services.*
4. *Repairs to a covered orthosis due to wear or to accidental damage are covered when they are necessary to make the orthosis functional. The reason for the repair must be documented in the supplier's record. If the expense for repairs exceeds the estimated expense of providing another entire orthosis, no payment will be made for the amount in excess.*
5. *The allowance for the labor involved in replacing an orthotic component that is coded with a specific L code is included in the allowance for that component. The allowance for the labor involved in replacing an orthotic component that is coded with the miscellaneous code L4210 is separately payable in addition to the allowance for that component.*

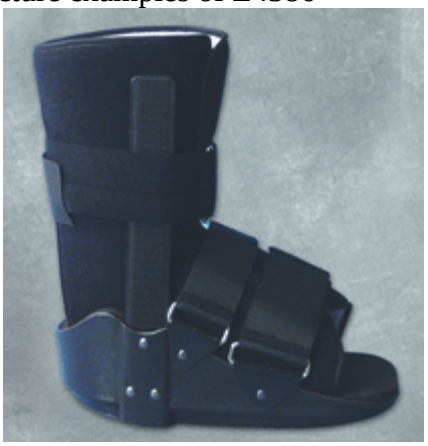
6. *When the GY modifier is added to a code there must be a short narrative statement indicating why the GY modifier was used – e.g., "used to prevent pressure ulcer" or "used to treat pressure ulcer" or "used to treat edema." This statement should be entered in the narrative field of an electronic claim or attached to a hard copy claim.*

D. **Miscellaneous**

1. *Replacement of a complete orthosis or component of an orthosis due to loss, significant change in the patient's condition, or irreparable accidental damage is covered if the device is still medically necessary. The reason for the replacement must be documented in the supplier's record.*
2. *Quantities of supplies greater than those described in the policy as the usual maximum amounts, in the absence of documentation clearly explaining the medical necessity of the excess quantities, will be denied as not medically necessary.*

E. **Products**

1. Some of the products approved by SADMERC can be found at the following website: http://www2.palmettogba.com/classifications/orthotics%20and%20prosthetics.pdf
2. A medical supplier may request that SADMERC review their item or supply and provide them with a specific code. This is not a requirement for coverage, but does alleviate any concerns by a provider that s/he is billing for an item or supply that meets the code billed according to SADMERC.
3. *A prefabricated orthosis is one which is manufactured in quantity without a specific patient in mind. A prefabricated orthosis may be trimmed, bent, molded (with or without heat), or otherwise modified for use by a specific patient (i.e., custom-fitted). An orthosis that is assembled from prefabricated components is considered prefabricated. Any orthosis that does not meet the definition of a custom-fabricated orthosis is considered prefabricated.*
4. Picture examples of L4386



F. **Documentation Requirements**

1. *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.*

2. *As previously stated, L4386 is covered for ambulatory patients with weakness or deformity of the foot and ankle, who require stabilization for medical reasons, and have the ability to benefit functionally. Walking boots such as L4386 are used to provide immobilization as treatment for an orthopedic condition or after orthopedic surgery.*
3. *An order for each new or full replacement item must be signed and dated by the treating 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.*
4. *The order must list the unique features of the base code that is billed plus every addition that will be billed on a separate claim line. The medical record must contain information which supports the medical necessity of the item and all additions that are ordered. An order is not necessary for the repair of an orthosis.*

VII. **Prefabricated Ankle Braces**

A. **Multiligamentous Ankle Brace:** L1906 is defined by HCPCS as "AFO, multiligamentous ankle support, prefabricated, includes fitting and adjustment."

1. **Definitions**

a. *For an item to be considered for coverage under the Brace benefit category, it must be a rigid or semi-rigid device which is used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body. It must provide support and counterforce (i.e., a force in a defined direction of a magnitude at least as great as a rigid or semi-rigid support) on the limb or body part that it is being used to brace. Items that do not meet the definition of a brace are non-covered.*

b. *The purpose of a brace is to support a weak or deformed body member or to restrict or eliminate motion in a diseased or injured part of the body. When an AFO or KAFO for an ambulatory patient and any related addition is used solely for the treatment of edema and/or for the prevention or treatment of a pressure ulcer, it will be denied as non-covered. For example, codes L4360 and L4386 are ankle-foot orthoses that are referred to as walking boots. Walking boots used to provide immobilization as treatment for an orthopedic condition or after orthopedic surgery are eligible for coverage under the Brace benefit. When walking boots are used primarily to relieve pressure, especially on the sole of the foot, or are used for patients with foot ulcers, they are non-covered – no Medicare benefit. Medicare covers therapeutic shoes, as described in the Therapeutic Shoes for Diabetics LMRP, for the prevention and treatment of diabetic foot ulcers.*

c. ***AFOs used during ambulation:*** *Ankle-foot orthoses (AFO) described by codes L1900-L1990, L2106-L2116, L4350, L4360, and L4386 are covered for ambulatory patients with weakness or deformity of the foot and ankle, who require stabilization for medical reasons, and have the potential to benefit functionally.*

2. **Coding**

a. The HCPCS Level II code for "AFO, multiligamentous ankle support, prefabricated, includes fitting and adjustment" is L1906.

b. *The right (RT) and left (LT) modifiers must be used with orthosis base codes, additions, and replacement parts. When the same code for bilateral items (left and right) is billed on the same date of service, bill both items on the same claim line using the LTRT modifiers and 2 units of service.*

c. *Evaluation of the patient, measurement and/or casting, and fitting of the orthosis are included in the allowance for the orthosis. There is no separate payment for these services.*

d. *Repairs to a covered orthosis due to wear or to accidental damage are covered when they are necessary to make the orthosis functional. The reason for the repair must be documented in the supplier's record. If the expense for repairs exceeds the estimated expense of providing another entire orthosis, no payment will be made for the amount in excess.*

e. *The allowance for the labor involved in replacing an orthotic component that is coded with a specific L code is included in the allowance for that component. The allowance for the labor involved in replacing an orthotic component that is coded with the miscellaneous code L4210 is separately payable in addition to the allowance for that component.*

f. *When the GY modifier is added to a code there must be a short narrative statement indicating why the GY modifier was used – e.g., "used to prevent pressure ulcer" or "used to treat pressure ulcer" or "used to treat edema." This statement should be entered in the narrative field of an electronic claim or attached to a hard copy claim.*

3. **Miscellaneous**
   a. *Replacement of a complete orthosis or component of an orthosis due to loss, significant change in the patient's condition, or irreparable accidental damage is covered if the device is still medically necessary. The reason for the replacement must be documented in the supplier's record.*
   b. *Quantities of supplies greater than those described in the policy as the usual maximum amounts, in the absence of documentation clearly explaining the medical necessity of the excess quantities, will be denied as not medically necessary.*
4. **Products**
   a. Some of the products approved by SADMERC can be found at the following website: http://www2.palmettogba.com/classifications/orthotics%20and%20prosthetics.pdf
   b. A medical supplier may request that SADMERC review their item or supply and provide them with a specific code. This is not a requirement for coverage, but does alleviate any concerns by a provider that s/he is billing for an item or supply that meets the code billed according to SADMERC
   c. *A prefabricated orthosis is one which is manufactured in quantity without a specific patient in mind. A prefabricated orthosis may be trimmed, bent, molded (with or without heat), or otherwise modified for use by a specific patient (i.e., custom-fitted). An orthosis that is assembled from prefabricated components is considered prefabricated. Any orthosis that does not meet the definition of a custom-fabricated orthosis is considered prefabricated.*
   d. Picture examples of L1906:

4. **Documentation Requirements**
   a. *Itemize pertinent clinical data, i.e., conservative treatment, physical exam findings, etc.*
   b. *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.*

c. *An order for each new or full replacement item must be signed and dated by the treating 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.*

d. *The order must list the unique features of the base code that is billed plus every addition that will be billed on a separate claim line. The medical record must contain information which supports the medical necessity of the item and all additions that are ordered. An order is not necessary for the repair of an orthosis.*

B. **Ankle Gauntlet:** L1902 is defined by HCPCS as "AFO, ankle gauntlet, prefabricated, includes fitting and adjustment."

1. **Definitions**

a. *For an item to be considered for coverage under the Brace benefit category, it must be a rigid or semi-rigid device which is used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body. It must provide support and counterforce (i.e., a force in a defined direction of a magnitude at least as great as a rigid or semi-rigid support) on the limb or body part that it is being used to brace. Items that do not meet the definition of a brace are non-covered.*

b. *The purpose of a brace is to support a weak or deformed body member or to restrict or eliminate motion in a diseased or injured part of the body. When an AFO or KAFO for an ambulatory patient and any related addition is used solely for the treatment of edema and/or for the prevention or treatment of a pressure ulcer, it will be denied as non-covered. For example, codes L4360 and L4386 are ankle-foot orthoses that are referred to as walking boots. Walking boots used to provide immobilization as treatment for an orthopedic condition or after orthopedic surgery are eligible for coverage under the Brace benefit. When walking boots are used primarily to relieve pressure, especially on the sole of the foot, or are used for patients with foot ulcers, they are non-covered – no Medicare benefit. Medicare covers therapeutic shoes, as described in the Therapeutic Shoes for Diabetics LMRP, for the prevention and treatment of diabetic foot ulcers.*

c. ***AFOs used during ambulation:*** *Ankle-foot orthoses (AFO) described by codes L1900-L1990, L2106-L2116, L4350, L4360, and L4386 are covered for ambulatory patients with weakness or deformity of the foot and ankle, who require stabilization for medical reasons, and have the potential to benefit functionally.*

2. **Coding**

a. The HCPCS Level II code for "AFO, ankle gauntlet, prefabricated, includes fitting and adjustment" is L1902.

b. *The right (RT) and left (LT) modifiers must be used with orthosis base codes, additions, and replacement parts. When the same code for bilateral items (left and right) is billed on the same date of service, bill both items on the same claim line using the LTRT modifiers and 2 units of service.*

c. *Evaluation of the patient, measurement and/or casting, and fitting of the orthosis are included in the allowance for the orthosis. There is no separate payment for these services.*

d. *Repairs to a covered orthosis due to wear or to accidental damage are covered when they are necessary to make the orthosis functional. The reason for the repair must be documented in the supplier's record. If the expense for repairs exceeds the estimated expense of providing another entire orthosis, no payment will be made for the amount in excess.*

e. *The allowance for the labor involved in replacing an orthotic component that is coded with a specific L code is included in the allowance for that component. The allowance for the labor involved in replacing an orthotic component that is coded with the miscellaneous code L4210 is separately payable in addition to the allowance for that component.*
f. *When the GY modifier is added to a code there must be a short narrative statement indicating why the GY modifier was used – e.g., "used to prevent pressure ulcer" or "used to treat pressure ulcer" or "used to treat edema." This statement should be entered in the narrative field of an electronic claim or attached to a hard copy claim.*

3. **Miscellaneous**
   a. *Replacement of a complete orthosis or component of an orthosis due to loss, significant change in the patient's condition, or irreparable accidental damage is covered if the device is still medically necessary. The reason for the replacement must be documented in the supplier's record.*
   b. *Quantities of supplies greater than those described in the policy as the usual maximum amounts, in the absence of documentation clearly explaining the medical necessity of the excess quantities, will be denied as not medically necessary.*
4. **Products**
   a. Some of the products approved by SADMERC can be found at the following website: http://www2.palmettogba.com/classifications/orthotics%20and%20prosthetics.pdf
   b. A medical supplier may request that SADMERC review their item or supply and provide them with a specific code. This is not a requirement for coverage, but does alleviate any concerns by a provider that s/he is billing for an item or supply that meets the code billed according to SADMERC.
   c. *A prefabricated orthosis is one which is manufactured in quantity without a specific patient in mind. A prefabricated orthosis may be trimmed, bent, molded (with or without heat), or otherwise modified for use by a specific patient (i.e., custom-fitted). An orthosis that is assembled from prefabricated components is considered prefabricated. Any orthosis that does not meet the definition of a custom-fabricated orthosis is considered prefabricated.*
   d. Picture example of L1902:

5. **Documentation Requirements**
    a. *Itemize pertinent clinical data, i.e., conservative treatment, physical exam findings, etc.*
    b. *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.*
    c. *An order for each new or full replacement item must be signed and dated by the treating 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.*
    d. *The order must list the unique features of the base code that is billed plus every addition that will be billed on a separate claim line. The medical record must contain information which supports the medical necessity of the item and all additions that are ordered. An order is not necessary for the repair of an orthosis.*

C. **Ankle Stirrup Brace:** L4350 is defined by HCPCS as "AFO, stirrup style, rigid, includes any type interface (e.g., pneumatic, gel), prefabricated, includes fitting and adjustment."

1. **Definitions**
    a. *For an item to be considered for coverage under the Brace benefit category, it must be a rigid or semi-rigid device which is used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body. It must provide support and counterforce (i.e., a force in a defined direction of a magnitude at least as great as a rigid or semi-rigid support) on the limb or body part that it is being used to brace. Items that do not meet the definition of a brace are non-covered.*
    b. *The purpose of a brace is to support a weak or deformed body member or to restrict or eliminate motion in a diseased or injured part of the body. When an AFO or KAFO for an ambulatory patient and any related addition is used solely for the treatment of edema and/or for the prevention or treatment of a pressure ulcer, it will be denied as non-covered. For example, codes L4360 and L4386 are ankle-foot orthoses that are referred to as walking boots. Walking boots used to provide immobilization as treatment for an orthopedic condition or after orthopedic surgery are eligible for coverage under the Brace benefit. When walking boots are used primarily to relieve pressure, especially on the sole of the foot, or are used for patients with foot ulcers, they are non-covered – no Medicare benefit. Medicare covers therapeutic shoes, as described in the Therapeutic Shoes for Diabetics LMRP, for the prevention and treatment of diabetic foot ulcers.*
    c. ***AFOs used during ambulation:*** *Ankle-foot orthoses (AFO) described by codes L1900-L1990, L2106-L2116, L4350, L4360, and L4386 are covered for ambulatory patients with weakness or deformity of the foot and ankle, who require stabilization for medical reasons, and have the potential to benefit functionally.*

2. **Coding**
    a. The HCPCS Level II code for "Ankle control orthosis, stirrup style, rigid, includes any type interface (e.g., pneumatic, gel), prefabricated, includes fitting and adjustment" is L4350.
    b. *The right (RT) and left (LT) modifiers must be used with orthosis base codes, additions, and replacement parts. When the same code for bilateral items (left and right) is billed on the same date of service, bill both items on the same claim line using the LTRT modifiers and 2 units of service.*
    c. *Evaluation of the patient, measurement and/or casting, and fitting of the orthosis are included in the allowance for the orthosis. There is no separate payment for these services.*
    d. *Repairs to a covered orthosis due to wear or to accidental damage are covered when they are necessary to make the orthosis functional. The reason for the repair must be documented in the supplier's record. If the expense for repairs exceeds the estimated expense of providing another entire orthosis, no payment will be made for the amount in excess.*
    e. *The allowance for the labor involved in replacing an orthotic component that is coded with a specific L code is included in the allowance for that component. The allowance for the labor involved in replacing an orthotic component that is coded with the miscellaneous code L4210 is separately payable in addition to the allowance for that component.*
    f. *When the GY modifier is added to a code there must be a short narrative statement indicating why the GY modifier was used – e.g., "used to prevent pressure ulcer" or "used to treat pressure ulcer" or "used to treat edema." This statement should be entered in the narrative field of an electronic claim or attached to a hard copy claim.*
3. **Miscellaneous**
    a. *Replacement of a complete orthosis or component of an orthosis due to loss, significant change in the patient's condition, or irreparable accidental damage is covered if the device is still medically necessary. The reason for the replacement must be documented in the supplier's record.*
    b. *Quantities of supplies greater than those described in the policy as the usual maximum amounts, in the absence of documentation clearly explaining the medical necessity of the excess quantities, will be denied as not medically necessary.*
4. **Products**
    a. Some of the products approved by SADMERC can be found at the following website: http://www2.palmettogba.com/classifications/orthotics%20and%20prosthetics.pdf
    b. A medical supplier may request that SADMERC review their item or supply and provide them with a specific code. This is not a requirement for coverage, but does alleviate any concerns by a provider that s/he is billing for an item or supply that meets the code billed according to SADMERC
    c. *A prefabricated orthosis is one which is manufactured in quantity without a specific patient in mind. A prefabricated orthosis may be trimmed, bent, molded (with or without heat), or otherwise modified for use by a specific patient (i.e., custom-fitted). An orthosis that is assembled from prefabricated components is considered prefabricated. Any orthosis that does not meet the definition of a custom-fabricated orthosis is considered prefabricated.*

d. Picture example of L4350:

5. **Documentation Requirements**
   a. *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.*
   b. *Itemize pertinent clinical data, i.e., conservative treatment, physical exam findings, etc.*
   c. *An order for each new or full replacement item must be signed and dated by the treating 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*
   d. *The order must list the unique features of the base code that is billed plus every addition that will be billed on a separate claim line. The medical record must also contain information which supports medical necessity of the item and all additions that are ordered. An order is not necessary for the repair of an orthosis.*

VIII. **Tibial Fracture Orthoses**

A. **Semi-Rigid Tibial Fracture Orthosis:** L2114 is defined by HCPCS as "AFO, fracture orthosis, tibial fracture orthosis, semi rigid, prefabricated, includes fitting and adjustment."

B. **Definitions**

1. *For an item to be considered for coverage under the Brace benefit category, it must be a rigid or semi-rigid device which is used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body. It must provide support and counterforce (i.e., a force in a defined direction of a magnitude at least as great as a rigid or semi-rigid support) on the limb or body part that it is being used to brace. Items that do not meet the definition of a brace are non-covered.*
2. *The purpose of a brace is to support a weak or deformed body member or to restrict or eliminate motion in a diseased or injured part of the body. When an AFO or KAFO for an ambulatory patient and any related addition is used solely for the treatment of edema and/or for the prevention or treatment of a pressure ulcer, it will be denied as non-covered. For example, codes L4360 and L4386 are ankle-foot orthoses that are referred to as walking boots. Walking boots used to provide immobilization as treatment for an orthopedic condition or after orthopedic surgery are eligible for coverage under the Brace benefit. When walking boots are used primarily to relieve pressure, especially on the sole of the foot, or are used for patients with foot ulcers, they are non-covered – no Medicare benefit. Medicare covers therapeutic shoes, as described in the Therapeutic Shoes for Diabetics LMRP, for the prevention and treatment of diabetic foot ulcers.*
3. ***AFOs used during ambulation:** Ankle-foot orthoses (AFO) described by codes L1900-L1990, L2106-L2116, L4350, L4360, and L4386 are covered for ambulatory patients with weakness or deformity of the foot and ankle, who require stabilization for medical reasons, and have the potential to benefit functionally.*

C. **Coding**

1. The HCPCS Level II code for "AFO, fracture orthosis, tibial fracture orthosis, semi-rigid, prefabricated, includes fitting and adjustment" is L2114.
2. *The right (RT) and left (LT) modifiers must be used with orthosis base codes, additions, and replacement parts. When the same code for bilateral items (left and right) is billed on the same date of service, bill both items on the same claim line using the LTRT modifiers and 2 units of service.*
3. *Evaluation of the patient, measurement and/or casting, and fitting of the orthosis are included in the allowance for the orthosis. There is no separate payment for these services.*
4. *Repairs to a covered orthosis due to wear or to accidental damage are covered when they are necessary to make the orthosis functional. The reason for the repair must be documented in the supplier's record. If the expense for repairs exceeds the estimated expense of providing another entire orthosis, no payment will be made for the amount in excess.*
5. *The allowance for the labor involved in replacing an orthotic component that is coded with a specific L code is included in the allowance for that component. The allowance for the labor involved in replacing an orthotic component that is coded with the miscellaneous code L4210 is separately payable in addition to the allowance for that component.*
6. *When the GY modifier is added to a code there must be a short narrative statement indicating why the GY modifier was used – e.g., "used to prevent pressure ulcer" or "used to treat pressure ulcer" or "used to treat edema." This statement should be entered in the narrative field of an electronic claim or attached to a hard copy claim.*

D. **Products**

1. Some of the products approved by SADMERC can be found at the following website: http://www2.palmettogba.com/classifications/orthotics%20and%20prosthetics.pdf
2. A medical supplier may request that SADMERC review their item or supply and provide them with a specific code. This is not a requirement for coverage, but does alleviate any concerns by a provider that s/he is billing for an item or supply that meets the code billed according to SADMERC.
3. *A prefabricated orthosis is one which is manufactured in quantity without a specific patient in mind. A prefabricated orthosis may be trimmed, bent, molded (with or without heat), or otherwise modified for use by a specific patient (i.e., custom-fitted). An orthosis that is assembled from prefabricated components is considered prefabricated. Any orthosis that does not meet the definition of a custom-fabricated orthosis is considered prefabricated.*
4. *Ankle-foot orthoses extend well above the ankle (usually to near the top of the calf) and are fastened around the lower leg above the ankle.*
5. Picture example of L2114:

E. **Documentation Requirements**

1. *Itemize pertinent clinical data, i.e., conservative treatment, physical exam findings, etc.*
2. *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.*
3. *An order for each new or full replacement item must be signed and dated by the treating 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.*
4. *The order must list the unique features of the base code that is billed plus every addition that will be billed on a separate claim line. The medical record must contain information which supports the medical necessity of the item and all additions that are ordered. An order is not necessary for the repair of an orthosis.*

IX. **Rigid Tibial Fracture Orthoses**

A. L2116 is defined by HCPCS as "AFO, fracture orthosis, tibial fracture orthosis, rigid, prefabricated, includes fitting and adjustment"

B. **Definitions**

1. *For an item to be considered for coverage under the Brace benefit category, it must be a rigid or semi-rigid device which is used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body. It must provide support and counterforce (i.e., a force in a defined direction of a magnitude at least as great as a rigid or semi-rigid support) on the limb or body part that it is being used to brace. Items that do not meet the definition of a brace are non-covered.*
2. *The purpose of a brace is to support a weak or deformed body member or to restrict or eliminate motion in a diseased or injured part of the body. When an AFO or KAFO for an ambulatory patient and any related addition is used solely for the treatment of edema and/or for the prevention or treatment of a pressure ulcer, it will be denied as non-covered. For example, codes L4360 and L4386 are ankle-foot orthoses that are referred to as walking boots. Walking boots used to provide immobilization as treatment for an orthopedic condition or after orthopedic surgery are eligible for coverage under the Brace benefit. When walking boots are used primarily to relieve pressure, especially on the sole of the foot, or are used for patients with foot ulcers, they are non-covered – no Medicare benefit. Medicare covers therapeutic shoes, as described in the Therapeutic Shoes for Diabetics LMRP, for the prevention and treatment of diabetic foot ulcers.*
3. ***AFOs used during ambulation:** Ankle-foot orthoses (AFO) described by codes L1900-L1990, L2106-L2116, L4350, L4360, and L4386 are covered for ambulatory patients with weakness or deformity of the foot and ankle, who require stabilization for medical reasons, and have the potential to benefit functionally.*

C. **Coding**

1. The HCPCS Level II code for "AFO, fracture orthosis, tibial fracture orthosis, rigid, prefabricated, includes fitting and adjustment" is L2116.
2. *The right (RT) and left (LT) modifiers must be used with orthosis base codes, additions, and replacement parts. When the same code for bilateral items (left and right) is billed on the same date of service, bill both items on the same claim line using the LTRT modifiers and 2 units of service.*
3. *Evaluation of the patient, measurement and/or casting, and fitting of the orthosis are included in the allowance for the orthosis. There is no separate payment for these services.*
4. *Repairs to a covered orthosis due to wear or to accidental damage are covered when they are necessary to make the orthosis functional. The reason for the repair must be documented in the supplier's record. If the expense for repairs exceeds the estimated expense of providing another entire orthosis, no payment will be made for the amount in excess.*
5. *The allowance for the labor involved in replacing an orthotic component that is coded with a specific L code is included in the allowance for that component. The allowance for the labor involved in replacing an orthotic component that is coded with the miscellaneous code L4210 is separately payable in addition to the allowance for that component.*
6. *When the GY modifier is added to a code there must be a short narrative statement indicating why the GY modifier was used – e.g., "used to prevent pressure ulcer" or "used to treat pressure ulcer" or "used to treat edema." This statement should be entered in the narrative field of an electronic claim or attached to a hard copy claim.*

D. **Products**

1. Some of the products approved by SADMERC can be found at the following website: http://www2.palmettogba.com/classifications/orthotics%20and%20prosthetics.pdf
2. A medical supplier may request that SADMERC review their item or supply and provide them with a specific code. This is not a requirement for coverage, but does alleviate any concerns by a provider that s/he is billing for an item or supply that meets the code billed according to SADMERC.
3. *A prefabricated orthosis is one which is manufactured in quantity without a specific patient in mind. A prefabricated orthosis may be trimmed, bent, molded (with or without heat), or otherwise modified for use by a specific patient (i.e., custom-fitted). An orthosis that is assembled from prefabricated components is considered prefabricated. Any orthosis that does not meet the definition of a custom-fabricated orthosis is considered prefabricated.*
4. *Ankle-foot orthoses extend well above the ankle (usually to near the top of the calf) and are fastened around the lower leg above the ankle.*
5. Picture examples of L2116 are not currently available on the SADMERC website.

E. **Documentation Requirements**

1. *Itemize pertinent clinical data, i.e., conservative treatment, physical exam findings, etc.*
2. *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.*
3. *An order for each new or full replacement item must be signed and dated by the treating 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.*
4. *The order must list the unique features of the base code that is billed plus every addition that will be billed on a separate claim line. The medical record must contain information which supports the medical necessity of the item and all additions that are ordered. An order is not necessary for the repair of an orthosis.*

X. **Soft Tibial Fracture Orthoses**

A. L2112 is defined by HCPCS as "AFO, fracture orthosis, tibial fracture orthosis, soft, prefabricated, includes fitting and adjustment."

B. **Definitions**

1. *For an item to be considered for coverage under the Brace benefit category, it must be a rigid or semi-rigid device which is used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body. It must provide support and counterforce (i.e., a force in a defined direction of a magnitude at least as great as a rigid or semi-rigid support) on the limb or body part that it is being used to brace. Items that do not meet the definition of a brace are non-covered.*
2. *The purpose of a brace is to support a weak or deformed body member or to restrict or eliminate motion in a diseased or injured part of the body. When an AFO or KAFO for an ambulatory patient and any related addition is used solely for the treatment of edema and/or for the prevention or treatment of a pressure ulcer, it will be denied as non-covered. For example, codes L4360 and L4386 are ankle-foot orthoses that are referred to as walking boots. Walking boots used to provide immobilization as treatment for an orthopedic condition or after orthopedic surgery are eligible for coverage under the Brace benefit. When walking boots are used primarily to relieve pressure, especially on the sole of the foot, or are used for patients with foot ulcers, they are non-covered – no Medicare benefit. Medicare covers therapeutic shoes, as described in the Therapeutic Shoes for Diabetics LMRP, for the prevention and treatment of diabetic foot ulcers.*
3. ***AFOs used during ambulation:** Ankle-foot orthoses (AFO) described by codes L1900-L1990, L2106-L2116, L4350, L4360, and L4386 are covered for ambulatory patients with weakness or deformity of the foot and ankle, who require stabilization for medical reasons, and have the potential to benefit functionally.*

C. **Coding**

1. The HCPCS Level II code for "AFO, fracture orthosis, tibial fracture orthosis, soft, prefabricated, includes fitting and adjustment" is L2112.
2. *The right (RT) and left (LT) modifiers must be used with orthosis base codes, additions, and replacement parts. When the same code for bilateral items (left and right) is billed on the same date of service, bill both items on the same claim line using the LTRT modifiers and 2 units of service.*
3. *Evaluation of the patient, measurement and/or casting, and fitting of the orthosis are included in the allowance for the orthosis. There is no separate payment for these services.*
4. *Repairs to a covered orthosis due to wear or to accidental damage are covered when they are necessary to make the orthosis functional. The reason for the repair must be documented in the supplier's record. If the expense for repairs exceeds the estimated expense of providing another entire orthosis, no payment will be made for the amount in excess.*
5. *The allowance for the labor involved in replacing an orthotic component that is coded with a specific L code is included in the allowance for that component. The allowance for the labor involved in replacing an orthotic component that is coded with the miscellaneous code L4210 is separately payable in addition to the allowance for that component.*
6. *When the GY modifier is added to a code there must be a short narrative statement indicating why the GY modifier was used – e.g., "used to prevent pressure ulcer" or "used to treat pressure ulcer" or "used to treat edema." This statement should be entered in the narrative field of an electronic claim or attached to a hard copy claim.*

D. **Products**

1. Some of the products approved by SADMERC can be found at the following website: http://www2.palmettogba.com/classifications/orthotics%20and%20prosthetics.pdf
2. A medical supplier may request that SADMERC review their item or supply and provide them with a specific code. This is not a requirement for coverage, but does alleviate any concerns by a provider that s/he is billing for an item or supply that meets the code billed according to SADMERC
3. *A prefabricated orthosis is one which is manufactured in quantity without a specific patient in mind. A prefabricated orthosis may be trimmed, bent, molded (with or without heat), or otherwise modified for use by a specific patient (i.e., custom-fitted). An orthosis that is assembled from prefabricated components is considered prefabricated. Any orthosis that does not meet the definition of a custom-fabricated orthosis is considered prefabricated.*
4. *Ankle-foot orthoses extend well above the ankle (usually to near the top of the calf) and are fastened around the lower leg above the ankle.*
5. Picture examples of L2112 are not currently available on the SADMERC website.

E. **Documentation Requirements**

1. *Itemize pertinent clinical data, i.e., conservative treatment, physical exam findings, etc.*
2. *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.*
3. *An order for each new or full replacement item must be signed and dated by the treating 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.*
4. *The order must list the unique features of the base code that is billed plus every addition that will be billed on a separate claim line. The medical record must contain information which supports the medical necessity of the item and all additions that are ordered. An order is not necessary for the repair of an orthosis.*

XI. **Prefabricated, Non-Ambulatory Ankle-Foot Orthoses**

A. **Night Splint:** L4396 is defined by HCPCS as "static ankle foot orthosis, including soft interface material, adjustable for fit, for positioning, pressure reduction, may be used for minimal ambulation, prefabricated, includes fitting and adjustment."

B. **Definitions**

1. *For an item to be considered for coverage under the Brace benefit category, it must be a rigid or semi-rigid device which is used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body. It must provide support and counterforce (i.e., a force in a defined direction of a magnitude at least as great as a rigid or semi-rigid support) on the limb or body part that it is being used to brace. Items that do not meet the definition of a brace are non-covered.*
2. *Medicare does not reimburse for a foot drop splint/recumbent positioning device (L4398) or replacement interface (L4394). A foot drop splint/recumbent positioning device and replacement interface is non-covered when it is used solely for the prevention or treatment of a pressure ulcer because for these indications it is not used to support a weak or deformed body member or to restrict or eliminate motion in a diseased or injured part of the body (i.e., it does not meet the definition of a brace).*
3. *The purpose of a brace is to support a weak or deformed body member or to restrict or eliminate motion in a diseased or injured part of the body. When an AFO or KAFO for an ambulatory patient and any related addition is used solely for the treatment of edema and/or for the prevention or treatment of a pressure ulcer, it will be denied as non-covered. For example, codes L4360 and L4386 are ankle-foot orthoses that are referred to as walking boots. Walking boots used to provide immobilization as treatment for an orthopedic condition or after orthopedic surgery are eligible for coverage under the Brace benefit. When walking boots are used primarily to relieve pressure, especially on the sole of the foot, or are used for patients with foot ulcers, they are non-covered – no Medicare benefit. Medicare covers therapeutic shoes, as described in the Therapeutic Shoes for Diabetics LMRP, for the prevention and treatment of diabetic foot ulcers.*

C. **Coding**

1. The HCPCS Level II code for "static ankle foot orthosis, including soft interface material, adjustable for fit, for positioning, pressure reduction, may be used for minimal ambulation, prefabricated, includes fitting and adjustment" is L4396.
2. *A static AFO (L4396) is covered if either all of criteria 1-4 or criterion 5 is met:*
   a. *Plantarflexion contracture of the ankle (ICD-9 diagnosis code 718.47) with dorsiflexion on passive range of motion testing of at least 10 degrees (i.e., a nonfixed contracture); and,*
   b. *Reasonable expectation of the ability to correct the contracture; and,*
   c. *Contracture is interfering or expected to interfere significantly with the patient's functional abilities; and,*
   d. *Used as a component of a therapy program which includes active stretching of the involved muscles and/or tendons.*
   e. *The patient has plantar fasciitis (ICD-9 diagnosis code 728.71)*
3. The ICD-9 diagnoses codes are either 728.71 plantar fasciitis or 718.47 if items 1-4 are met above.
4. *The right (RT) and left (LT) modifiers must be used with orthosis base codes, additions, and replacement parts. When the same code for bilateral items (left and right) is billed on the same date of service, bill both items on the same claim line using the LTRT modifiers and 2 units of service.*

5. *Evaluation of the patient, measurement and/or casting, and fitting of the orthosis are included in the allowance for the orthosis. There is no separate payment for these services.*
6. *Repairs to a covered orthosis due to wear or to accidental damage are covered when they are necessary to make the orthosis functional. The reason for the repair must be documented in the supplier's record. If the expense for repairs exceeds the estimated expense of providing another entire orthosis, no payment will be made for the amount in excess.*
7. *The allowance for the labor involved in replacing an orthotic component that is coded with a specific L code is included in the allowance for that component. The allowance for the labor involved in replacing an orthotic component that is coded with the miscellaneous code L4210 is separately payable in addition to the allowance for that component.*
8. *When the GY modifier is added to a code there must be a short narrative statement indicating why the GY modifier was used – e.g., "used to prevent pressure ulcer" or "used to treat pressure ulcer" or "used to treat edema." This statement should be entered in the narrative field of an electronic claim or attached to a hard copy claim*

D. **Products**

1. Some of the products approved by SADMERC can be found at the following website: http://www2.palmettogba.com/classifications/orthotics%20and%20prosthetics.pdf
2. A medical supplier may request that SADMERC review their item or supply and provide them with a specific code. This is not a requirement for coverage, but does alleviate any concerns by a provider that s/he is billing for an item or supply that meets the code billed according to SADMERC.
3. *A prefabricated orthosis is one which is manufactured in quantity without a specific patient in mind. A prefabricated orthosis may be trimmed, bent, molded (with or without heat), or otherwise modified for use by a specific patient (i.e., custom-fitted). An orthosis that is assembled from prefabricated components is considered prefabricated. Any orthosis that does not meet the definition of a custom-fabricated orthosis is considered prefabricated.*
4. *Ankle-foot orthoses extend well above the ankle (usually to near the top of the calf) and are fastened around the lower leg above the ankle.*
5. Picture example of L4396:

E. **Documentation Requirements**

1. *Itemize pertinent clinical data, i.e., conservative treatment, physical exam findings, etc.*
2. ***AFOs not used during ambulation** – A static AFO (L4396) is covered if either all of criteria 1-4 or criterion 5 is met:*
   a. *Plantarflexion contracture of the ankle (ICD-9 diagnosis code 718.47) with dorsiflexion on passive range of motion testing of at least 10 degrees (i.e., a nonfixed contracture); and,*
   b. *Reasonable expectation of the ability to correct the contracture; and,*
   c. *Contracture is interfering or expected to interfere significantly with the patient's functional abilities; and,*
   d. *Used as a component of a therapy program which includes active stretching of the involved muscles and/or tendons.*
   e. *The patient has plantar fasciitis (ICD-9 diagnosis code 728.71)*
3. *If a static AFO is used for the treatment of a plantarflexion contracture, the pre-treatment passive range of motion must be measured with a goniometer and documented in the medical record. There must be documentation of an appropriate stretching program carried out by professional staff (in a nursing facility) or caregiver (at home).*
4. *A static AFO and replacement interface will be denied as not medically necessary if the contracture is fixed. A static AFO and replacement interface will be denied as not medically necessary for a patient with a foot drop but without an ankle flexion contracture. A component of a static AFO that is used to address positioning of the knee or hip will be denied as not medically necessary because the effectiveness of this type of component is not established.*
5. *If code L4396 is covered, a replacement interface (L4392) is covered as long as the patient continues to meet indications and other coverage rules for the splint. Coverage of a replacement interface is limited to a maximum of one (1) per 6 months. Additional interfaces will be denied as not medically necessary.*
6. *Medicare does not reimburse for a foot drop splint/recumbent positioning device (L4398) or replacement interface (L4394). A foot drop splint/recumbent positioning device and replacement interface will be denied as not medically necessary in a patient with foot drop who is nonambulatory because there are other more appropriate treatment modalities.*
7. *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.*
8. *An order for each new or full replacement item must be signed and dated by the treating 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.*
9. *The order must list the unique features of the base code that is billed plus every addition that will be billed on a separate claim line. The medical record must contain information which supports the medical necessity of the item and all additions that are ordered. An order is not necessary for the repair of an orthosis.*

XII. **Custom-Fabricated Ankle-Foot Orthoses**

A. L1904 is defined by HCPCS as "AFO, molded ankle gauntlet, custom-fabricated."

1. **Definitions**

a. *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.*

b. *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 DMERC. If the supplier bills for an item addressed in this policy without first receiving the completed order, the item will be denied as not medically necessary.*

c. *If the basic coverage criteria for an AFO is not met, the orthosis will be denied as not medically necessary.*

d. *AFOs that are molded-to-patient-model, or custom-fabricated, are covered for ambulatory patients when the basic coverage criteria listed above and one of the following criteria are met:*

i. *The patient could not be fit with a prefabricated AFO, or*

ii. *The condition necessitating the orthosis is expected to be permanent or of long standing duration (more than 6 months), or*

iii. *There is a need to control the knee, ankle or foot in more than one plane, or*

iv. *The patient has a documented neurological, circulatory, or orthopedic status that require custom-fabricating over a model to prevent tissue injury, or*

v. *The patient has a healing fracture which lacks normal anatomical integrity or anthropometric proportions.*

e. *If specific criteria for a molded-to-patient-model or custom-fabricated orthosis are not met, but the criteria for a prefabricated, custom-fitted orthosis are met, payment will be based on the allowance for the least costly medically appropriate alternative.*

f. ***AFOs used during ambulation:*** *Ankle-foot orthoses (AFO) described by codes L1900-L1990, L2106-L2116, L4350, L4360, and L4386 are covered for ambulatory patients with weakness or deformity of the foot and ankle, who require stabilization for medical reasons, and have the potential to benefit functionally*

2. **Coding**

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

b. The HCPCS Level II code for "AFO, molded ankle gauntlet, custom-fabricated" is **L1904**.

c. HCPCS

i. *EY – No physician or other health care provider order for this item or service*

ii. *GY – Item or service statutorily excluded or does not meet the definition of any Medicare benefit*

iii. *LT – Left side*

iv. *RT – Right side*

3. **Products**
    a. Some of the products approved by SADMERC can be found at the following website: http://www2.palmettogba.com/classifications/orthotics%20and%20prosthetics.pdf
    b. A medical supplier may request that SADMERC review their item or supply and provide them with a specific code. This is not a requirement for coverage, but does alleviate any concerns by a provider that s/he is billing for an item or supply that meets the code billed according to SADMERC
    c. *A prefabricated orthosis is one which is manufactured in quantity without a specific patient in mind. A prefabricated orthosis may be trimmed, bent, molded (with or without heat), or otherwise modified for use by a specific patient (i.e., custom-fitted). An orthosis that is assembled from prefabricated components is considered prefabricated. Any orthosis that does not meet the definition of a custom-fabricated orthosis is considered prefabricated.*
    d. *Ankle-foot orthoses extend well above the ankle (usually to near the top of the calf) and are fastened around the lower leg above the ankle.*
    e. Picture examples of L1904 are not currently available on the SADMERC website.
4. **Documentation Requirements**
    a. *Itemize pertinent clinical data, i.e., conservative treatment, physical exam findings, etc.*
    b. *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.*
    c. *An order for each new or full replacement item must be signed and dated by the treating 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.*
    d. *The order must list the unique features of the base code that is billed plus every addition that will be billed on a separate claim line. The medical record must contain information which supports the medical necessity of the item and all additions that are ordered. An order is not necessary for the repair of an orthosis.*

B. L1990 is defined by HCPCS as "AFO, double upright free plantar dorsiflexion, solid stirrup, calf band/cuff (double bar BK orthosis), custom-fabricated."

1. **Definitions**
    a. *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.*
    b. *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 DMERC. If the supplier bills for an item addressed in this policy without first receiving the completed order, the item will be denied as not medically necessary.*

c. *If the basic coverage criteria for an AFO is not met, the orthosis will be denied as not medically necessary.*
d. *AFOs that are molded-to-patient-model, or custom-fabricated, are covered for ambulatory patients when the basic coverage criteria listed above and one of the following criteria are met:*
    i. *The patient could not be fit with a prefabricated AFO, or*
    ii. *The condition necessitating the orthosis is expected to be permanent or of longstanding duration (more than 6 months), or*
    iii. *There is a need to control the knee, ankle or foot in more than one plane, or*
    iv. *The patient has a documented neurological, circulatory, or orthopedic status that require custom-fabricating over a model to prevent tissue injury, or*
    v. *The patient has a healing fracture which lacks normal anatomical integrity or anthropometric proportions.*
e. *If specific criteria for a molded-to-patient-model or custom-fabricated orthosis are not met, but the criteria for a prefabricated, custom-fitted orthosis are met, payment will be based on the allowance for the least costly medically appropriate alternative.*
f. ***AFOs used during ambulation:*** *Ankle-foot orthoses (AFO) described by codes L1900-L1990, L2106-L2116, L4350, L4360, and L4386 are covered for ambulatory patients with weakness or deformity of the foot and ankle, who require stabilization for medical reasons, and have the potential to benefit functionally.*

2. **Coding**
    a. The appearance of a code in this section does not necessarily indicate coverage.
    b. The HCPCS Level II code "AFO, double upright free plantar dorsiflexion, solid stirrup, calf band/cuff (double bar BK orthosis), custom-fabricated is L1990.
    c. HCPCS
        i. *EY – No physician or other health care provider order for this item or service*
        ii. *GY – Item or service statutorily excluded or does not meet the definition of any Medicare benefit*
        iii. *LT – Left side*
        iv. *RT – Right side*
3. **Products**
    a. Some of the products approved by SADMERC can be found at the following website: http://www2.palmettogba.com/classifications/orthotics%20and%20prosthetics.pdf
    b. A medical supplier may request that SADMERC review their item or supply and provide them with a specific code. This is not a requirement for coverage, but does alleviate any concerns by a provider that s/he is billing for an item or supply that meets the code billed according to SADMERC.
    c. *A prefabricated orthosis is one which is manufactured in quantity without a specific patient in mind. A prefabricated orthosis may be trimmed, bent, molded (with or without heat), or otherwise modified for use by a specific patient (i.e., custom-fitted). An orthosis that is assembled from prefabricated components is considered prefabricated. Any orthosis that does not meet the definition of a custom-fabricated orthosis is considered prefabricated.*
    d. *Ankle-foot orthoses extend well above the ankle (usually to near the top of the calf) and are fastened around the lower leg above the ankle.*
    e. Picture examples of L1990 are not currently available on the SADMERC website.

4. **Documentation Requirements**
    a. *Itemize pertinent clinical data, i.e., conservative treatment, physical exam findings, etc.*
    b. *Foot drop is a condition in which there is weakness and/or lack of use of the muscles that dorsiflex the ankle but there is the ability to bring the ankle to 0 degrees by passive range of motion.*
    c. *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.*
    d. *An order for each new or full replacement item must be signed and dated by the treating 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.*
    e. *The order must list the unique features of the base code that is billed plus every addition that will be billed on a separate claim line. The medical record must contain information which supports the medical necessity of the item and all additions that are ordered. An order is not necessary for the repair of an orthosis.*

M. L1980 is defined by HCPCS as "AFO, single upright free plantar dorsiflexion, solid stirrup, calf band/cuff (single bar BK orthosis), custom-fabricated."

1. **Definitions**
    a. *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.*
    b. *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 DMERC. If the supplier bills for an item addressed in this policy without first receiving the completed order, the item will be denied as not medically necessary.*
    c. *If the basic coverage criteria for an AFO is not met, the orthosis will be denied as not medically necessary.*
    d. *AFOs that are molded-to-patient-model, or custom-fabricated, are covered for ambulatory patients when the basic coverage criteria listed above and one of the following criteria are met:*
        i. *The patient could not be fit with a prefabricated AFO, or*
        ii. *The condition necessitating the orthosis is expected to be permanent or of longstanding duration (more than 6 months), or*
        iii. *There is a need to control the knee, ankle or foot in more than one plane, or*
        iv. *The patient has a documented neurological, circulatory, or orthopedic status that require custom-fabricating over a model to prevent tissue injury, or*
        v. *The patient has a healing fracture which lacks normal anatomical integrity or anthropometric proportions.*

e. *If specific criteria for a molded-to-patient-model or custom-fabricated orthosis are not met, but the criteria for a prefabricated, custom-fitted orthosis are met, payment will be based on the allowance for the least costly medically appropriate alternative.*
f. ***AFOs used during ambulation:*** *Ankle-foot orthoses (AFO) described by codes L1900-L1990, L2106-L2116, L4350, L4360, and L4386 are covered for ambulatory patients with weakness or deformity of the foot and ankle, who require stabilization for medical reasons, and have the potential to benefit functionally.*

2. **Coding**
   a. The appearance of a code in this section does not necessarily indicate coverage.
   b. The HCPCS Level II code for "AFO, single upright free plantar dorsiflexion, solid stirrup, calf band/ cuff (single bar BK orthosis), custom-fabricated" is L1980.
   c. HCPCS
      i. *EY – No physician or other health care provider order for this item or service*
      ii. *GY – Item or service statutorily excluded or does not meet the definition of any Medicare benefit*
      iii. *LT – Left side*
      iv. *RT – Right side*

3. **Products**
   a. Some of the products approved by SADMERC can be found at the following website: http://www2.palmettogba.com/classifications/orthotics%20and%20prosthetics.pdf
   b. A medical supplier may request that SADMERC review their item or supply and provide them with a specific code. This is not a requirement for coverage, but does alleviate any concerns by a provider that s/he is billing for an item or supply that meets the code billed according to SADMERC.
   c. *A prefabricated orthosis is one which is manufactured in quantity without a specific patient in mind. A prefabricated orthosis may be trimmed, bent, molded (with or without heat), or otherwise modified for use by a specific patient (i.e., custom-fitted). An orthosis that is assembled from prefabricated components is considered prefabricated. Any orthosis that does not meet the definition of a custom-fabricated orthosis is considered prefabricated.*
   d. *Ankle-foot orthoses extend well above the ankle (usually to near the top of the calf) and are fastened around the lower leg above the ankle.*
   e. Picture examples of L1980 are not currently available on the SADMERC website.

4. **Documentation Requirements**
   a. *Itemize pertinent clinical data, i.e., conservative treatment, physical exam findings, etc.*
   b. *Foot drop is a condition in which there is weakness and/or lack of use of the muscles that dorsiflex the ankle but there is the ability to bring the ankle to 0 degrees by passive range of motion.*
   c. *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.*

d. *An order for each new or full replacement item must be signed and dated by the treating 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.*

e. *The order must list the unique features of the base code that is billed plus every addition that will be billed on a separate claim line. The medical record must contain information which supports the medical necessity of the item and all additions that are ordered. An order is not necessary for the repair of an orthosis.*

D. L1970 is defined by HCPCS as "AFO, plastic with ankle joint, custom-fabricated."

1. **Definitions**

a. *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.*

b. *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 DMERC. If the supplier bills for an item addressed in this policy without first receiving the completed order, the item will be denied as not medically necessary.*

c. *If the basic coverage criteria for an AFO is not met, the orthosis will be denied as not medically necessary.*

d. *AFOs that are molded-to-patient-model, or custom-fabricated, are covered for ambulatory patients when the basic coverage criteria listed above and one of the following criteria are met:*

i. *The patient could not be fit with a prefabricated AFO, or*

ii. *The condition necessitating the orthosis is expected to be permanent or of longstanding duration (more than 6 months), or*

iii. *There is a need to control the knee, ankle or foot in more than one plane, or*

iv. *The patient has a documented neurological, circulatory, or orthopedic status that require custom-fabricating over a model to prevent tissue injury, or*

v. *The patient has a healing fracture which lacks normal anatomical integrity or anthropometric proportions.*

e. *If specific criteria for a molded-to-patient-model or custom-fabricated orthosis are not met, but the criteria for a prefabricated, custom-fitted orthosis are met, payment will be based on the allowance for the least costly medically appropriate alternative.*

f. ***AFOs used during ambulation:*** *Ankle-foot orthoses (AFO) described by codes L1900-L1990, L2106-L2116, L4350, L4360, and L4386 are covered for ambulatory patients with weakness or deformity of the foot and ankle, who require stabilization for medical reasons, and have the potential to benefit functionally*

2. **Coding**

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

b. The HCPCS Level II code for "AFO, plastic with ankle joint, custom-fabricated" is L1970.

c. HCPCS
   i. *EY – No physician or other health care provider order for this item or service*
   ii. *GY – No or service statutorily excluded or does not meet the definition of any Medicare benefit*
   iii. *LT – Left side*
   iv. *RT – Right side*

d. *Some examples of possible ICD-9 diagnosis coding are:*
   i. *Drop foot* *736.79*
   ii. *Ankle instability* *718.87*

3. **Products**
   a. Some of the products approved by SADMERC can be found at the following website: http://www2.palmettogba.com/classifications/orthotics%20and%20prosthetics.pdf
   b. A medical supplier may request that SADMERC review their item or supply and provide them with a specific code. This is not a requirement for coverage, but does alleviate any concerns by a provider that s/he is billing for an item or supply that meets the code billed according to SADMERC.
   c. *A prefabricated orthosis is one which is manufactured in quantity without a specific patient in mind. A prefabricated orthosis may be trimmed, bent, molded (with or without heat), or otherwise modified for use by a specific patient (i.e., custom-fitted). An orthosis that is assembled from prefabricated components is considered prefabricated. Any orthosis that does not meet the definition of a custom-fabricated orthosis is considered prefabricated.*
   d. *Ankle-foot orthoses extend well above the ankle (usually to near the top of the calf) and are fastened around the lower leg above the ankle.*
   e. Picture examples of L1970

4. **Documentation Requirements**
   a. *Itemize pertinent clinical data, i.e., conservative treatment, physical exam findings, etc.*
   b. *Foot drop is a condition in which there is weakness and/or lack of use of the muscles that dorsiflex the ankle but there is the ability to bring the ankle to 0 degrees by passive range of motion.*
   c. *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.*

d. *An order for each new or full replacement item must be signed and dated by the treating 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.*

e. *The order must list the unique features of the base code that is billed plus every addition that will be billed on a separate claim line. The medical record must contain information which supports the medical necessity of the item and all additions that are ordered. An order is not necessary for the repair of an orthosis.*

E. L1960 is defined by HCPCS as "AFO, posterior solid ankle, plastic custom-fabricated."

1. **Definitions**

a. *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.*

b. *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 DMERC. If the supplier bills for an item addressed in this policy without first receiving the completed order, the item will be denied as not medically necessary.*

c. *If the basic coverage criteria for an AFO is not met, the orthosis will be denied as not medically necessary.*

d. *AFOs that are molded-to-patient-model, or custom-fabricated, are covered for ambulatory patients when the basic coverage criteria listed above and one of the following criteria are met:*

i. *The patient could not be fit with a prefabricated AFO, or*

ii. *The condition necessitating the orthosis is expected to be permanent or of longstanding duration (more than 6 months), or*

iii. *There is a need to control the knee, ankle or foot in more than one plane, or*

iv. *The patient has a documented neurological, circulatory, or orthopedic status that require custom-fabricating over a model to prevent tissue injury, or*

v. *The patient has a healing fracture which lacks normal anatomical integrity or anthropometric proportions.*

e. *If specific criteria for a molded-to-patient-model or custom-fabricated orthosis are not met, but the criteria for a prefabricated, custom-fitted orthosis are met, payment will be based on the allowance for the least costly medically appropriate alternative.*

f. ***AFOs used during ambulation:*** *Ankle-foot orthoses (AFO) described by codes L1900-L1990, L2106-L2116, L4350, L4360, and L4386 are covered for ambulatory patients with weakness or deformity of the foot and ankle, who require stabilization for medical reasons, and have the potential to benefit functionally.*

2. **Coding**
   a. The appearance of a code in this section does not necessarily indicate coverage.
   b. The HCPCS Level II code for "AFO, posterior solid ankle, plastic, custom-fabricated" is L1960.
   c. HCPCS
      i. *EY – No physician or other health care provider order for this item or service*
      ii. *GY – Item or service statutorily excluded or does not meet the definition of any Medicare benefit*
      iii. *LT – Left side*
      iv. *RT – Right side*
3. **Products**
   a. Some of the products approved by SADMERC can be found at the following website: http://www2.palmettogba.com/classifications/orthotics%20and%20prosthetics.pdf
   b. A medical supplier may request that SADMERC review their item or supply and provide them with a specific code. This is not a requirement for coverage, but does alleviate any concerns by a provider that s/he is billing for an item or supply that meets the code billed according to SADMERC.
   c. *A prefabricated orthosis is one which is manufactured in quantity without a specific patient in mind. A prefabricated orthosis may be trimmed, bent, molded (with or without heat), or otherwise modified for use by a specific patient (i.e., custom-fitted). An orthosis that is assembled from prefabricated components is considered prefabricated. Any orthosis that does not meet the definition of a custom-fabricated orthosis is considered prefabricated.*
   d. *Ankle-foot orthoses extend well above the ankle (usually to near the top of the calf) and are fastened around the lower leg above the ankle.*
   e. Picture examples of L1960 are not currently available on the SADMERC website.
4. **Documentation Requirements**
   a. *Itemize pertinent clinical data, i.e., conservative treatment, physical exam findings, etc.*
   b. *Foot drop is a condition in which there is weakness and/or lack of use of the muscles that dorsiflex the ankle but there is the ability to bring the ankle to 0 degrees by passive range of motion.*
   c. *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.*
   d. *An order for each new or full replacement item must be signed and dated by the treating 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.*
   e. *The order must list the unique features of the base code that is billed plus every addition that will be billed on a separate claim line. The medical record must contain information which supports the medical necessity of the item and all additions that are ordered. An order is not necessary for the repair of an orthosis.*

F. L1940 is defined by HCPCS as "AFO, plastic or other material, custom-fabricated."

1. **Definitions**
   a. *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.*
   b. *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 DMERC. If the supplier bills for an item addressed in this policy without first receiving the completed order, the item will be denied as not medically necessary.*
   c. *If the basic coverage criteria for an AFO is not met, the orthosis will be denied as not medically necessary.*
   d. *AFOs that are molded-to-patient-model, or custom-fabricated, are covered for ambulatory patients when the basic coverage criteria listed above and one of the following criteria are met:*
      i. *The patient could not be fit with a prefabricated AFO, or*
      ii. *The condition necessitating the orthosis is expected to be permanent or of longstanding duration (more than 6 months), or*
      iii. *There is a need to control the knee, ankle or foot in more than one plane, or*
      iv. *The patient has a documented neurological, circulatory, or orthopedic status that require custom-fabricating over a model to prevent tissue injury, or*
      v. *The patient has a healing fracture which lacks normal anatomical integrity or anthropometric proportions.*
   e. *If specific criteria for a molded-to-patient-model or custom-fabricated orthosis are not met, but the criteria for a prefabricated, custom-fitted orthosis are met, payment will be based on the allowance for the least costly medically appropriate alternative.*
   f. ***AFOs used during ambulation:*** *Ankle-foot orthoses (AFO) described by codes L1900-L1990, L2106-L2116, L4350, L4360, and L4386 are covered for ambulatory patients with weakness or deformity of the foot and ankle, who require stabilization for medical reasons, and have the potential to benefit functionally.*
2. **Coding**
   a. The appearance of a code in this section does not necessarily indicate coverage.
   b. The HCPCS Level II code for "AFO, plastic or other material, custom-molded" is L1940.
   c. HCPCS
      i. *EY – No physician or other health care provider order for this item or service*
      ii. *GY – Item or service statutorily excluded or does not meet the definition of any Medicare benefit*
      iii. *LT – Left side*
      iv. *RT – Right side*
3. **Products**
   a. Some of the products approved by SADMERC can be found at the following website: http://www2.palmettogba.com/classifications/orthotics%20and%20prosthetics.pdf
   b. A medical supplier may request that SADMERC review their item or supply and provide them with a specific code. This is not a requirement for coverage, but does alleviate any concerns by a provider that s/he is billing for an item or supply that meets the code billed according to SADMERC.

c. *A prefabricated orthosis is one which is manufactured in quantity without a specific patient in mind. A prefabricated orthosis may be trimmed, bent, molded (with or without heat), or otherwise modified for use by a specific patient (i.e., custom-fitted). An orthosis that is assembled from prefabricated components is considered prefabricated. Any orthosis that does not meet the definition of a custom-fabricated orthosis is considered prefabricated.*

d. *Ankle-foot orthoses extend well above the ankle (usually to near the top of the calf) and are fastened around the lower leg above the ankle.*

e. Picture examples of L1940 are not currently available on the SADMERC website.

4. **Documentation Requirements**

a. *Itemize pertinent clinical data, i.e., conservative treatment, physical exam findings, why a prefabricated device could not be used, etc.*

b. *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.*

c. *An order for each new or full replacement item must be signed and dated by the treating 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.*

d. *The order must list the unique features of the base code that is billed plus every addition that will be billed on a separate claim line. The medical record must contain information which supports the medical necessity of the item and all additions that are ordered. An order is not necessary for the repair of an orthosis.*

XIII. **Therapeutic Innersoles and Shoes for Persons with Diabetes (A5500, A5501, K0628, or K0629)**

A. **LCDs**

1. There are 4 LCDs posted, one for each DMERC carrier. The content is identical.
2. The policy for Region A can be found at http://www.tricenturion.com/content/Doc_View.cfm?type=LCDCurr&File=therapeutic%20shoes%20for%20persons%20with%20diabetes%2Ehtm

B. **Certificate of Medical Necessity (CMN)**

1. Technically, there is no CMN required. However, a specific form has been created by the DMERCs to properly document that a beneficiary qualifies for the therapeutic shoe program for diabetics. The form may be completed by the prescribing podiatrist but must be reviewed and signed by the M.D. or D.O. who is responsible for the overall treatment of the patient's diabetes. The M.D. or D.O. is considered the certifying physician for this program.
2. Download the physician statement here: http://www.adminastar.com/Providers/DMERC/MedicalPolicy/CMNs/StatementOfCertifyingPhysicianForTherapeuticShoes.pdf
3. 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 non-covered.

C. **Basic Eligibility**

1. *Therapeutic shoes, inserts and/or modifications to therapeutic shoes are covered if the following criteria are met:*
   a. *The patient has diabetes mellitus (ICD-9 diagnosis codes 250.00-250.93); and*
   b. *The patient has one or more of the following conditions:*
      i. *Previous amputation of the other foot, or part of either foot, or*
      ii. *History of previous foot ulceration of either foot, or*
      iii. *History of pre-ulcerative calluses of either foot, or*
      iv. *Peripheral neuropathy with evidence of callus formation of either foot, or*
      v. *Foot deformity of either foot, or*
      vi. *Poor circulation in either foot; and*
   c. *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.*

D. **Quantity of Shoe Inserts Per Year**

1. *For patients meeting these criteria, coverage is limited to one of the following within one calendar year (January – December):*
2. *One pair of custom molded shoes (A5501) (which includes inserts provided with these shoes) and 2 additional pairs of inserts (K0628 or K0629); or*
3. *One pair of depth shoes (A5500) and 3 pairs of inserts (K0628 or K0629) (not including the non-customized removable inserts provided with such shoes).*

E. **Inserts May be Payable Without Shoes**

1. *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*

F. **Inserts Created by Pressure Molding Over Time are Non-Covered**
   1. *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.*
   2. *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 non-covered.*

G. **Inserts Used in Non-Covered Shoes are Non-Covered**

H. **When a Custom Shoe Is Allowed Rather Than a Depth Shoe**
   1. *A custom molded shoe (A5501) is covered when the patient has a foot deformity that cannot be accommodated by a depth shoe.*
   2. ***The nature and severity of the deformity must be well-documented in the supplier's records and may be requested by the DMERC**.*
   3. *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.*

I. **Shoe Modifications**
   1. *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.*
   2. ***Deluxe features of diabetic shoes (A5508) will be denied as non-covered.***

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

K. **Mechanics of the Program**
   1. *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.*
   2. *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).*
   3. *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.*

L. **Coding**

The ICD-9 diagnoses coding are:

   a. 250.00 – diabetes mellitus without complication, type II or unspecified type, not stated as uncontrolled
   b. 250.01 – diabetes mellitus without complication, type I, not stated as uncontrolled
   c. 250.02 – diabetes mellitus without complication, type II or unspecified type, uncontrolled
   d. 250.03 – diabetes mellitus without complication, type I, uncontrolled
   e. 250.10 – diabetes with ketoacidosis, type II or unspecified type, not stated as uncontrolled
   f. 250.11 – diabetes with ketoacidosis, type I, not stated as uncontrolled
   g. 250.12 – diabetes with ketoacidosis, type II or unspecified type, uncontrolled
   h. 250.13 – diabetes with ketoacidosis, type I, uncontrolled

i. 250.20 – diabetes with hyperosmolarity, type II or unspecified type, not stated as uncontrolled
j. 250.21 – diabetes with hyperosmolarity, type I, not stated as uncontrolled
k. 250.22 – diabetes with hyperosmolarity, type II or unspecified type, uncontrolled
l. 250.23 – diabetes with hyperosmolarity, type I, uncontrolled
m. 250.30 – diabetes with other coma, type II or unspecified type, not stated as uncontrolled
n. 250.31 – diabetes with other coma, type I, not stated as uncontrolled
o. 250.32 – diabetes with other coma, type II or unspecified type, uncontrolled
p. 250.33 – diabetes with other coma, type I, uncontrolled
q. 250.40 – diabetes with renal manifestations, type II or unspecified type, not stated as uncontrolled
r. 250.41 – diabetes with renal manifestations, type I, not stated as uncontrolled
s. 250.42 – diabetes with renal manifestations, type II or unspecified type, uncontrolled
t. 250.43 – diabetes with renal manifestations, type I, uncontrolled
u. 250.50 – diabetes with ophthalmic manifestations, type II or unspecified type, not stated as uncontrolled
v. 250.51 – diabetes with ophthalmic manifestations, type I, not stated as uncontrolled
w. 250.52 – diabetes with ophthalmic manifestations, type II or unspecified type, uncontrolled
x. 250.53 – diabetes with ophthalmic manifestations, type I, uncontrolled
y. 250.60 – diabetes with neurological manifestations, type II or unspecified type, not stated as uncontrolled
z. 250.61 – diabetes with neurological manifestations, type I, not stated as uncontrolled
aa. 250.62 – diabetes with neurological manifestations, type II or unspecified type, uncontrolled
bb. 250.63 – diabetes with neurological manifestations, type I, uncontrolled
cc. 250.70 – diabetes with peripheral circulatory disorders, type II or unspecified type, not stated as uncontrolled
dd. 250.71 – diabetes with peripheral circulatory disorders, type I, not stated as uncontrolled
ee. 250.72 – diabetes with peripheral circulatory disorders, type II or unspecified type, uncontrolled
ff. 250.73 – diabetes with peripheral circulatory disorders, type I, uncontrolled
gg. 250.80 – diabetes with other specified manifestations, type II or unspecified, type not stated as uncontrolled
hh. 250.81 – diabetes with other specified manifestations, type I, not stated as uncontrolled
ii. 250.82 – diabetes with other specified manifestations, type II or unspecified type, uncontrolled
jj. 250.83 – diabetes with other specified manifestations, type I, uncontrolled
kk. 250.90 – diabetes with unspecified complication, type II or unspecified type, not stated as uncontrolled
ll. 250.91 – diabetes with unspecified complication, type I, not stated as uncontrolled
mm. 250.92 – diabetes with unspecified complication, type II or unspecified type, uncontrolled
nn. 250.93 – diabetes with unspecified complication, type I, uncontrolled

M. **Technical Definitions for Shoes, Innersoles, and Shoe Modifications**

1. *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.*
2. *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.*
3. *An **insert** described by code **K0628** 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.*
4. *An **insert** described by code **K0629** 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.*
5. *Specific shoe modifications are defined in detail in the LCD referenced earlier*
6. *Codes for inserts or modifications (A5503-A5508, A5510, K0628, K0629) 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).*
7. *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.*
8. *Inserts for missing toes or partial foot amputation should be coded L5000 or L5999, whichever is applicable.*
9. *Suppliers should contact the Statistical Analysis Durable Medical Equipment Regional Carrier (SADMERC) for guidance on the correct coding of these items. In addition SADMERC maintains a list of those manufacturers that have submitted their product and obtained approval for their specific shoe or innersole.* See http://www2.palmettogba.com/classifications/diabetic%20inserts.pdf

N. **Documentation Guidelines**

1. *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.*
2. *The supplier must obtain a signed statement from the certifying physician specifying that the patient has diabetes mellitus, has one of conditions a (1) (b) (i-vi) 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.*
3. *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.***
4. *The ICD-9 code that justifies the need for these items must be included on the claim.*
5. *If code A5507 is submitted, the claim must contain a narrative description of the modification or feature provided.*
6. *The prescribing physician's name and UPIN number must be listed in Blocks 17 and 17a of the CMS-1500 form or the electronic equivalent.*
7. *Documentation that the patient received the innersoles and/or shoes must be maintained. Documentation that the patient received a warrantee at the time of dispensing of the shoes must be maintained.*

XIV. **Surgical Dressings**

The LMRPs for the following surgical dressings are identical. There are four posted, one for each DMERC carrier. The content is identical. The Region C policy may be found at: http://www.cms.hhs.gov/mcd/viewlcd.asp?lcd_id=11449&lcd_version=23&basket=lcd%3A11449%3A23%3ASurgical+Dressings%3ADMERC%3APalmetto+GBA+%2800885%29%3Am

A. A6212 is defined by HCPCS as "foam dressing, wound cover, pad size 16 sq. in. or less, with any size adhesive border, each dressing

1. **Definitions**

a. *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.*

b. *If the coverage criteria described below are not met, the claim will be denied as not medically necessary.*

c. *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 without first receiving the completed order, the item will be denied as not medically necessary.*

d. *Surgical dressings are covered for as long as they are medically necessary. Dressings over a percutaneous catheter or tube (e.g., intravascular, epidural, nephrostomy, etc.) are covered as long as the catheter or tube remains in place and after removal until the wound heals.*

e. *Surgical dressings used in conjunction with investigational wound healing therapy (e.g., platelet derived wound healing formula) may be covered if all applicable coverage criteria are met based on the number and type of surgical dressings that are appropriate to treat the wound if the investigational therapy were not being used.*

f. *When a wound cover with an adhesive border is being used, no other dressing is needed on top of it and additional tape is usually not required. Reasons for use of additional tape must be well-documented. An adhesive border is usually more binding than that obtained with separate taping and is therefore indicated for use with wounds requiring less frequent dressing changes.*

g. *Use of more than one type of wound filler or more than one type of wound cover in a single wound is rarely medically necessary and the reasons must be well-documented. An exception is an alginate or other fiber gelling dressing wound cover or a saline, water, or hydrogel impregnated gauze dressing which might need an additional wound cover.*

h. *It may not be appropriate to use some combinations of a hydrating dressing on the same wound at the same time as an absorptive dressing (e.g., hydrogel and alginate).*

i. *Because composite dressings, foam and hydrocolloid wound covers, and transparent film, when used as secondary dressings, are meant to be changed at frequencies less than daily, appropriate clinical judgment should be used to avoid their use with primary dressings which require more frequent dressing changes. When claims are submitted for these dressings for changes greater than once every other day, the quantity in excess of that amount will be denied as not medically necessary. While a highly exudative wound might require such a combination initially, with continued proper management the wound usually progresses to a point where the appropriate selection of these products results in the less frequent dressing changes which they are designed to allow. An example of an inappropriate combination is the use of a specialty absorptive dressing on top of non-impregnated gauze being used as a primary dressing.*

j. *Dressing size must be based on and appropriate to the size of the wound. For wound covers, the pad size is usually about 2 inches greater than the dimensions of the wound. For example, a 5 cm x 5 cm (2 in. x 2 in.) wound requires a 4 in. x 4 in. pad size.*

k. *The quantity and type of dressings dispensed at any one time must take into account the current status of the wound(s), the likelihood of change, and the recent use of dressings.*

2. **Documentation Guidelines**

a. *Dressing needs may change frequently (e.g., weekly) in the early phases of wound treatment and/or with heavily draining wounds. Suppliers are also expected to have a mechanism for determining the quantity of dressings that the patient is actually using and to adjust their provision of dressings accordingly. No more than a one month's supply of dressings may be provided at one time, unless there is documentation to support the necessity of greater quantities in the home setting in an individual case. An even smaller quantity may be appropriate in the situations described above.*

b. *Surgical dressings must be tailored to the specific needs of an individual patient. When surgical dressings are provided in kits, only those components of the kit that meet the definition of a surgical dressing, that are ordered by the physician, and that are medically necessary are covered.*

c. *The following are some specific coverage guidelines for individual products when the products themselves are necessary in the individual patient. The medical necessity for more frequent change of dressing must be documented in the patient's medical record and submitted with the claim to the DMERC (see Documentation section).*

B. <u>A6209-A6215</u>: Foam Dressings

1. *Foam dressings are covered when used on full thickness wounds (e.g., stage III or IV ulcers) with moderate to heavy exudate. Usual dressing change for a foam wound cover used as a primary dressing is up to 3 times per week. When a foam wound cover is used as a secondary dressing for wounds with very heavy exudate, dressing change may be up to 3 times per week. Usual dressing change for foam wound fillers is up to once per day.*

2. **Coding**
    a. HCPCS
        i. ***A1*** *– Dressing for one wound*
        ii. ***A2*** *– Dressing for two wounds*
        iii. ***A3*** *– Dressing for three wounds*
        iv. ***A4*** *– Dressing for four wounds*
        v. ***A5*** *– Dressing for five wounds*
        vi. ***A6*** *– Dressing for six wounds*
        vii. ***A7*** *– Dressing for seven wounds*
        viii. ***A8*** *– Dressing for eight wounds*
        ix. ***A9*** *– Dressing for nine wounds*
        x. ***AW*** *– Item furnished in conjunction with a surgical dressing*
        xi. ***EY*** *– No physician or other licensed health care provider order for this item or service*
        xii. ***GY*** *– Item or service statutorily non-covered or does not meet the definition of any Medicare benefit*
        xiii. ***LT*** *– Left side*
        xiv. ***RT*** *– Right side*
    b. **HCPCS Code A6212**
        i. Foam dressing, wound cover, pad size 16 sq. in. or less, any size adhesive border each
        ii. **ICD-9 codes that support medical necessity** – not specified
        iii. **Diagnoses that support medical necessity** – not specified
        iv. **ICD-9 codes that DO NOT support medical necessity** – not specified
        v. **Diagnoses that DO NOT support medical necessity** – not specified
3. **Non-Medical Necessity Coverage and Payment Rules**
    a. *Surgical dressings are covered when either of the following criteria are met:*
        i. *They are required for the treatment of a wound caused by, or treated by, a surgical procedure; or*
        ii. *They are required after debridement of a wound.*
    b. *Surgical dressings include both primary dressings (i.e., therapeutic or protective coverings applied directly to wounds or lesions either on the skin or caused by an opening to the skin) and secondary dressings (i.e., materials that serve a therapeutic or protective function and that are needed to secure a primary dressing).*
    c. *The surgical procedure or debridement must be performed by a physician or other healthcare professional to the extent permissible under State law. Debridement of a wound may be any type of debridement (examples given are not all-inclusive): surgical (e.g., sharp instrument or laser), mechanical (e.g., irrigation or wet-to-dry dressings), chemical (e.g., topical application of enzymes), or autolytic (e.g., application of occlusive dressings to an open wound). Dressings used for mechanical debridement, to cover chemical debriding agents, or to cover wounds to allow for autolytic debridement are covered although the agents themselves are non-covered.*

d. *Examples of situations in which dressings are non-covered under the Surgical Dressings benefit are:*
    i. *Drainage from a cutaneous fistula which has not been caused by or treated by a surgical procedure; or*
    ii. *A Stage I pressure ulcer; or*
    iii. *A first degree burn; or*
    iv. *Wounds caused by trauma which do not require surgical closure or debridement – e.g., skin tear or abrasion; or*
    v. *A venipuncture or arterial puncture site (e.g., blood sample) other than the site of an indwelling catheter or needle.*
e. *Surgical dressing codes billed without modifiers A1-A9 (see Coding Guidelines) are non-covered under the Surgical Dressings benefit. Certain dressings may be covered under other benefits.*
f. *A silicone gel sheet (A6025) used for the treatment of keloids or other scars does not meet the definition of the surgical dressing benefit and will be denied as non-covered.*
g. *If a physician applies surgical dressings as part of a professional service that is billed to Medicare, the surgical dressings are considered incident to the professional services of the health care practitioner and are not separately payable. Claims for these dressings must not be submitted to the DMERC. Claims for the professional service which includes the dressings must be submitted to the local carrier or intermediary. If dressing changes are sent home with the patient, claims for these dressings may be submitted to the DMERC. In this situation, use the place of service corresponding to the patient's residence; Place of Service Office (POS=11) must not be used.*
h. *The following are examples of wound care items which are non-covered under the surgical dressing benefit: skin sealants or barriers (A6250), wound cleansers (A6260) or irrigating solutions, solutions used to moisten gauze (e.g., saline), silicone gel sheets, topical antiseptics, topical antibiotics, enzymatic debriding agents, gauze or other dressings used to cleanse or debride a wound but not left on the wound. Also, any item listed in the latest edition of the Orange Book (e.g., an antibiotic-impregnated dressing which requires a prescription) is considered a drug and is non-covered under the Surgical Dressings benefit.*

4. **Documentation**
    a. *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.*
    b. *An order for each item billed must be signed and dated by the treating 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.*
    c. *The order must specify (a) the type of dressing (e.g., hydrocolloid wound cover, hydrogel wound filler, etc.), (b) the size of the dressing (if appropriate), (c) the number/amount to be used at one time (if more than one), (d) the frequency of dressing change, and (e) the expected duration of need.*

d. *A new order is needed if a new dressing is added or if the quantity of an existing dressing to be used is increased. A new order is not routinely needed if the quantity of dressings used is decreased. However a new order is required at least every 3 months for each dressing being used even if the quantity used has remained the same or decreased.*

e. *Information defining the number of surgical/debrided wounds being treated with a dressing, the reason for dressing use (e.g., surgical wound, debrided wound, etc.), and whether the dressing is being used as a primary or secondary dressing or for some non-covered use (e.g., wound cleansing) must be obtained from the physician, nursing home, or home care nurse. The source of that information and date obtained must be documented in the supplier's records.*

f. *Current clinical information which supports the reasonableness and necessity of the type and quantity of surgical dressings provided must be present in the patient's medical records. Evaluation of a patient's wound(s) must be performed at least on a monthly basis unless there is documentation in the medical record which justifies why an evaluation could not be done within this timeframe and what other monitoring methods were used to evaluate the patient's need for dressings. Evaluation is expected on a more frequent basis (e.g., weekly) in patients in a nursing facility or in patients with heavily draining or infected wounds. The evaluation may be performed by a nurse, physician or other health care professional. This evaluation must include the type of each wound (e.g., surgical wound, pressure ulcer, burn, etc.), its location, its size (length x width in cm) and depth, the amount of drainage, and any other relevant information. This information does not have to be routinely submitted with each claim. However a brief statement documenting the medical necessity of any quantity billed which exceeds the quantity needed for the usual dressing change frequency stated in the policy must be submitted with the claim. This statement may be attached to a hard copy claim or entered in the HA0 record of an electronic claim.*

g. *When surgical dressings are billed, the appropriate modifier (A1-A9, AW, EY, or GY) must be added to the code when applicable. If A9 is used, information must be submitted with the claim indicating the number of wounds. If GY is used, a brief description of the reason for non-coverage (e.g., "A6216GY – used for wound cleansing") must be included. These statements must be included with a hard copy claim or entered in the narrative field of an electronic claim.*

h. *The staging of pressure ulcers used in this policy is as follows:*
   i. *<u>Stage I</u> – Observable pressure-related alteration of intact skin whose indicators, as compared to the adjacent or opposite area on the body, may include changes in one of more of the following: skin temperature (warmth or coolness), tissue consistency (firm or boggy feel) and/or sensation (pain, itching). The ulcer appears as a defined area of persistent redness in lightly pigmented skin, whereas in darker skin tones, the ulcer may appear with persistent red, blue, or purple hues.*
   ii. *<u>Stage II</u> – Partial thickness skin loss involving epidermis, dermis, or both. The ulcer is superficial and presents clinically as an abrasion, blister, or shallow crater.*
   iii. *<u>Stage III</u> – Full thickness skin loss involving damage to, or necrosis of, subcutaneous tissue that may extend down to, but not through, underlying fascia. The ulcer presents clinically as a deep crater with or without undermining of adjacent tissue.*
   iv. *<u>Stage IV</u> – Full thickness skin loss with extensive destruction, tissue necrosis, or damage*

C. A6248 is defined by HCPCS as "Hydrogel dressing, wound filler, gel, per fluid oz."

1. *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.*
2. *If the coverage criteria described below are not met, the claim will be denied as not medically necessary.*
3. *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 without first receiving the completed order, the item will be denied as not medically necessary.*
4. *Surgical dressings are covered for as long as they are medically necessary. Dressings over a percutaneous catheter or tube (e.g., intravascular, epidural, nephrostomy, etc.) are covered as long as the catheter or tube remains in place and after removal until the wound heals.*
5. *Surgical dressings used in conjunction with investigational wound healing therapy (e.g., platelet derived wound healing formula) may be covered if all applicable coverage criteria are met based on the number and type of surgical dressings that are appropriate to treat the wound if the investigational therapy were not being used.*
6. *When a wound cover with an adhesive border is being used, no other dressing is needed on top of it and additional tape is usually not required. Reasons for use of additional tape must be well-documented. An adhesive border is usually more binding than that obtained with separate taping and is therefore indicated for use with wounds requiring less frequent dressing changes.*
7. *Use of more than one type of wound filler or more than one type of wound cover in a single wound is rarely medically necessary and the reasons must be well-documented. An exception is an alginate or other fiber gelling dressing wound cover or a saline, water, or hydrogel impregnated gauze dressing which might need an additional wound cover.*
8. *It may not be appropriate to use some combinations of a hydrating dressing on the same wound at the same time as an absorptive dressing (e.g., hydrogel and alginate).*
9. *Because composite dressings, foam and hydrocolloid wound covers, and transparent film, when used as secondary dressings, are meant to be changed at frequencies less than daily, appropriate clinical judgment should be used to avoid their use with primary dressings which require more frequent dressing changes. When claims are submitted for these dressings for changes greater than once every other day, the quantity in excess of that amount will be denied as not medically necessary. While a highly exudative wound might require such a combination initially, with continued proper management the wound usually progresses to a point where the appropriate selection of these products results in the less frequent dressing changes which they are designed to allow. An example of an inappropriate combination is the use of a specialty absorptive dressing on top of non-impregnated gauze being used as a primary dressing.*
10. *Dressing size must be based on and appropriate to the size of the wound. For wound covers, the pad size is usually about 2 inches greater than the dimensions of the wound. For example, a 5 cm x 5 cm (2 in. x 2 in.) wound requires a 4 in. x 4 in. pad size.*
11. *The quantity and type of dressings dispensed at any one time must take into account the current status of the wound(s), the likelihood of change, and the recent use of dressings.*

12. *Dressing needs may change frequently (e.g., weekly) in the early phases of wound treatment and/or with heavily draining wounds. Suppliers are also expected to have a mechanism for determining the quantity of dressings that the patient is actually using and to adjust their provision of dressings accordingly. No more than a one month's supply of dressings may be provided at one time, unless there is documentation to support the necessity of greater quantities in the home setting in an individual case. An even smaller quantity may be appropriate in the situations described above.*
13. *Surgical dressings must be tailored to the specific needs of an individual patient. When surgical dressings are provided in kits, only those components of the kit that meet the definition of a surgical dressing, that are ordered by the physician, and that are medically necessary are covered.*
14. *The following are some specific coverage guidelines for individual products when the products themselves are necessary in the individual patient. The medical necessity for more frequent change of dressing must be documented in the patient's medical record and submitted with the claim to the DMERC (see Documentation section).*

D. A6231-A6233, A6242-A6248: Hydrogel Dressing

1. *Hydrogel dressings are covered when used on full thickness wounds with minimal or no exudate (e.g., stage III or IV ulcers). Hydrogel dressings are not usually medically necessary for stage II ulcers. Documentation must substantiate the medical necessity for use of hydrogel dressings for stage II ulcers (e.g., location of ulcer is sacro-coccygeal area). Usual dressing change for hydrogel wound covers without adhesive border or hydrogel wound fillers is up to once per day. Usual dressing change for hydrogel wound covers with adhesive border is up to 3 times per week.*
2. *The quantity of hydrogel filler used for each wound must not exceed the amount needed to line the surface of the wound. Additional amounts used to fill a cavity are not medically necessary. Documentation must substantiate the medical necessity for code A6248 billed in excess of 3 units (fluid ounces) per wound in 30 days.*
3. *Use of more than one type of hydrogel dressing (filler, cover, or impregnated gauze) on the same wound at the same time is not medically necessary.*
4. **Coding**
    a. The appearance of a code in this section does not necessarily indicate coverage.
    b. HCPCS
        i. ***A1*** *– Dressing for one wound*
        ii. ***A2*** *– Dressing for two wounds*
        iii. ***A3*** *– Dressing for three wounds*
        iv. ***A4*** *– Dressing for four wounds*
        v. ***A5*** *– Dressing for five wounds*
        vi. ***A6*** *– Dressing for six wounds*
        vii. ***A7*** *– Dressing for seven wounds*
        viii. ***A8*** *– Dressing for eight wounds*
        ix. ***A9*** *– Dressing for nine wounds*
        x. ***AW*** *– Item furnished in conjunction with a surgical dressing*
        xi. ***EY*** *– No physician or other licensed health care provider order for this item or service*
        xii. ***GY*** *– Item or service statutorily non-covered or does not meet the definition of any Medicare benefit*
        xiii. ***LT*** *– Left side*
        xiv. ***RT*** *– Right side*

c. **HCPCS Code A6248**
   i. Hydrogel dressing, wound filler, gel, per fluid ounce
   ii. **ICD-9 codes that support medical necessity** – not specified
   iii. **Diagnoses that support medical necessity** – not specified
   iv. **ICD-9 codes that DO NOT support medical necessity** – not specified
   v. **Diagnoses that DO NOT support medical necessity** – not specified

5. **Non-Medical Necessity Coverage and Payment Rules**
   a. *Surgical dressings are covered when either of the following criteria are met:*
      i. *They are required for the treatment of a wound caused by, or treated by, a surgical procedure; or*
      ii. *They are required after debridement of a wound.*
   b. *Surgical dressings include both primary dressings (i.e., therapeutic or protective coverings applied directly to wounds or lesions either on the skin or caused by an opening to the skin) and secondary dressings (i.e., materials that serve a therapeutic or protective function and that are needed to secure a primary dressing).*
   c. *The surgical procedure or debridement must be performed by a physician or other healthcare professional to the extent permissible under State law. Debridement of a wound may be any type of debridement (examples given are not all-inclusive): surgical (e.g., sharp instrument or laser), mechanical (e.g., irrigation or wet-to-dry dressings), chemical (e.g., topical application of enzymes), or autolytic (e.g., application of occlusive dressings to an open wound). Dressings used for mechanical debridement, to cover chemical debriding agents, or to cover wounds to allow for autolytic debridement are covered although the agents themselves are non-covered.*
   d. *Examples of situations in which dressings are non-covered under the Surgical Dressings benefit are:*
      i. *Drainage from a cutaneous fistula which has not been caused by or treated by a surgical procedure; or*
      ii. *A Stage I pressure ulcer; or*
      iii. *A first degree burn; or*
      iv. *Wounds caused by trauma which do not require surgical closure or debridement – e.g., skin tear or abrasion; or*
      v. *A venipuncture or arterial puncture site (e.g., blood sample) other than the site of an indwelling catheter or needle.*
   e. *Surgical dressing codes billed without modifiers A1-A9 (see Coding Guidelines) are non-covered under the Surgical Dressings benefit. Certain dressings may be covered under other benefits.*
   f. *A silicone gel sheet (A6025) used for the treatment of keloids or other scars does not meet the definition of the surgical dressing benefit and will be denied as non-covered.*
   g. *If a physician applies surgical dressings as part of a professional service that is billed to Medicare, the surgical dressings are considered incident to the professional services of the health care practitioner and are not separately payable. Claims for these dressings must not be submitted to the DMERC. Claims for the professional service which includes the dressings must be submitted to the local carrier or intermediary. If dressing changes are sent home with the patient, claims for these dressings may be submitted to the DMERC. In this situation, use the place of service corresponding to the patient's residence; Place of Service Office (POS=11) must not be used.*

h. *The following are examples of wound care items which are non-covered under the surgical dressing benefit: skin sealants or barriers (A6250), wound cleansers (A6260) or irrigating solutions, solutions used to moisten gauze (e.g., saline), silicone gel sheets, topical antiseptics, topical antibiotics, enzymatic debriding agents, gauze or other dressings used to cleanse or debride a wound but not left on the wound. Also, any item listed in the latest edition of the Orange Book (e.g., an antibiotic-impregnated dressing which requires a prescription) is considered a drug and is non-covered under the Surgical Dressings benefit.*

6. **Documentation**
   a. *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.*
   b. *An order for each item billed must be signed and dated by the treating 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.*
   c. *The order must specify (a) the type of dressing (e.g., hydrocolloid wound cover, hydrogel wound filler, etc.), (b) the size of the dressing (if appropriate), (c) the number/amount to be used at one time (if more than one), (d) the frequency of dressing change, and (e) the expected duration of need.*
   d. *A new order is needed if a new dressing is added or if the quantity of an existing dressing to be used is increased. A new order is not routinely needed if the quantity of dressings used is decreased. However a new order is required at least every 3 months for each dressing being used even if the quantity used has remained the same or decreased.*
   e. *Information defining the number of surgical/debrided wounds being treated with a dressing, the reason for dressing use (e.g., surgical wound, debrided wound, etc.), and whether the dressing is being used as a primary or secondary dressing or for some non-covered use (e.g., wound cleansing) must be obtained from the physician, nursing home, or home care nurse. The source of that information and date obtained must be documented in the supplier's records.*

f. *Current clinical information which supports the reasonableness and necessity of the type and quantity of surgical dressings provided must be present in the patient's medical records. Evaluation of a patient's wound(s) must be performed at least on a monthly basis unless there is documentation in the medical record which justifies why an evaluation could not be done within this timeframe and what other monitoring methods were used to evaluate the patient's need for dressings. Evaluation is expected on a more frequent basis (e.g., weekly) in patients in a nursing facility or in patients with heavily draining or infected wounds. The evaluation may be performed by a nurse, physician or other health care professional. This evaluation must include the type of each wound (e.g., surgical wound, pressure ulcer, burn, etc.), its location, its size (length x width in cm) and depth, the amount of drainage, and any other relevant information. This information does not have to be routinely submitted with each claim. However a brief statement documenting the medical necessity of any quantity billed which exceeds the quantity needed for the usual dressing change frequency stated in the policy must be submitted with the claim. This statement may be attached to a hard copy claim or entered in the HA0 record of an electronic claim.*

g. *When surgical dressings are billed, the appropriate modifier (A1-A9, AW, EY, or GY) must be added to the code when applicable. If A9 is used, information must be submitted with the claim indicating the number of wounds. If GY is used, a brief description of the reason for non-coverage (e.g., "A6216GY – used for wound cleansing") must be included. These statements must be included with a hard copy claim or entered in the narrative field of an electronic claim.*

h. *The staging of pressure ulcers used in this policy is as follows:*

i. *<u>Stage I</u> – Observable pressure-related alteration of intact skin whose indicators, as compared to the adjacent or opposite area on the body, may include changes in one of more of the following: skin temperature (warmth or coolness), tissue consistency (firm or boggy feel) and/or sensation (pain, itching). The ulcer appears as a defined area of persistent redness in lightly pigmented skin, whereas in darker skin tones, the ulcer may appear with persistent red, blue, or purple hues.*

ii. *<u>Stage II</u> – Partial thickness skin loss involving epidermis, dermis, or both. The ulcer is superficial and presents clinically as an abrasion, blister, or shallow crater.*

iii. *<u>Stage III</u> – Full thickness skin loss involving damage to, or necrosis of, subcutaneous tissue that may extend down to, but not through, underlying fascia. The ulcer presents clinically as a deep crater with or without undermining of adjacent tissue.*

iv. *<u>Stage IV</u> – Full thickness skin loss with extensive destruction, tissue necrosis, or damage to muscle, bone, or supporting structures (e.g., tendon, joint capsule). Undermining and sinus tracts also may be associated with Stage IV pressure ulcers.*

E. <u>A6021</u> is defined by HCPCS as "collagen dressing, pad size 16 sq. in. or less, each."

1. **Definitions**

a. *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.*

b. *If the coverage criteria described below are not met, the claim will be denied as not medically necessary.*
c. *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 without first receiving the completed order, the item will be denied as not medically necessary.*
d. *Surgical dressings are covered for as long as they are medically necessary. Dressings over a percutaneous catheter or tube (e.g., intravascular, epidural, nephrostomy, etc.) are covered as long as the catheter or tube remains in place and after removal until the wound heals.*
e. *Surgical dressings used in conjunction with investigational wound healing therapy (e.g., platelet derived wound healing formula) may be covered if all applicable coverage criteria are met based on the number and type of surgical dressings that are appropriate to treat the wound if the investigational therapy were not being used*
f. *When a wound cover with an adhesive border is being used, no other dressing is needed on top of it and additional tape is usually not required. Reasons for use of additional tape must be well-documented. An adhesive border is usually more binding than that obtained with separate taping and is therefore indicated for use with wounds requiring less frequent dressing changes.*
g. *Use of more than one type of wound filler or more than one type of wound cover in a single wound is rarely medically necessary and the reasons must be well-documented. An exception is an alginate or other fiber gelling dressing wound cover or a saline, water, or hydrogel impregnated gauze dressing which might need an additional wound cover.*
h. *It may not be appropriate to use some combinations of a hydrating dressing on the same wound at the same time as an absorptive dressing (e.g., hydrogel and alginate).*
i. *Because composite dressings, foam and hydrocolloid wound covers, and transparent film, when used as secondary dressings, are meant to be changed at frequencies less than daily, appropriate clinical judgment should be used to avoid their use with primary dressings which require more frequent dressing changes. When claims are submitted for these dressings for changes greater than once every other day, the quantity in excess of that amount will be denied as not medically necessary. While a highly exudative wound might require such a combination initially, with continued proper management the wound usually progresses to a point where the appropriate selection of these products results in the less frequent dressing changes which they are designed to allow. An example of an inappropriate combination is the use of a specialty absorptive dressing on top of non-impregnated gauze being used as a primary dressing.*
j. *Dressing size must be based on and appropriate to the size of the wound. For wound covers, the pad size is usually about 2 inches greater than the dimensions of the wound. For example, a 5 cm x 5 cm (2 in. x 2 in.) wound requires a 4 in. x 4 in. pad size.*
k. *The quantity and type of dressings dispensed at any one time must take into account the current status of the wound(s), the likelihood of change, and the recent use of dressings.*

l. *Dressing needs may change frequently (e.g., weekly) in the early phases of wound treatment and/or with heavily draining wounds. Suppliers are also expected to have a mechanism for determining the quantity of dressings that the patient is actually using and to adjust their provision of dressings accordingly. No more than a one month's supply of dressings may be provided at one time, unless there is documentation to support the necessity of greater quantities in the home setting in an individual case. An even smaller quantity may be appropriate in the situations described above.*

m. *Surgical dressings must be tailored to the specific needs of an individual patient. When surgical dressings are provided in kits, only those components of the kit that meet the definition of a surgical dressing, that are ordered by the physician, and that are medically necessary are covered.*

n. *The following are some specific coverage guidelines for individual products when the products themselves are necessary in the individual patient. The medical necessity for more frequent change of dressing must be documented in the patient's medical record and submitted with the claim to the DMERC (see Documentation section).*

2. **Coding**
   a. The appearance of a code in this section does not necessarily indicate coverage.
   b. HCPCS
      i. ***A1*** *– Dressing for one wound*
      ii. ***A2*** *– Dressing for two wounds*
      iii. ***A3*** *– Dressing for three wounds*
      iv. ***A4*** *– Dressing for four wounds*
      v. ***A5*** *– Dressing for five wounds*
      vi. ***A6*** *– Dressing for six wounds*
      vii. ***A7*** *– Dressing for seven wounds*
      viii. ***A8*** *– Dressing for eight wounds*
      ix. ***A9*** *– Dressing for nine wounds*
      x. ***AW*** *– Item furnished in conjunction with a surgical dressing*
      xi. ***EY*** *– No physician or other licensed health care provider order for this item or service*
      xii. ***GY*** *– Item or service statutorily non-covered or does not meet the definition of any Medicare benefit*
      xiii. ***LT*** *– Left side*
      xiv. ***RT*** *– Right side*
   c. **HCPCS Code A6021**
      i. Collagen dressing, pad size 16 sq. in. or less, each
      ii. **ICD-9 codes that support medical necessity** – not specified
      iii. **Diagnoses that support medical necessity** – not specified
      iv. **ICD-9 codes that DO NOT support medical necessity** – not specified
      v. **Diagnoses that DO NOT support medical necessity** – not specified
3. **Non-Medical Necessity Coverage and Payment Rules**
   a. *Surgical dressings are covered when either of the following criteria are met:*
      i. *They are required for the treatment of a wound caused by, or treated by, a surgical procedure; or*
      ii. *They are required after debridement of a wound.*
   b. *Surgical dressings include both primary dressings (i.e., therapeutic or protective coverings applied directly to wounds or lesions either on the skin or caused by an opening to the skin) and secondary dressings (i.e., materials that serve a therapeutic or protective function and that are needed to secure a primary dressing).*

c. *The surgical procedure or debridement must be performed by a physician or other healthcare professional to the extent permissible under State law. Debridement of a wound may be any type of debridement (examples given are not all-inclusive): surgical (e.g., sharp instrument or laser), mechanical (e.g., irrigation or wet-to-dry dressings), chemical (e.g., topical application of enzymes), or autolytic (e.g., application of occlusive dressings to an open wound). Dressings used for mechanical debridement, to cover chemical debriding agents, or to cover wounds to allow for autolytic debridement are covered although the agents themselves are non-covered.*
   i. *Drainage from a cutaneous fistula which has not been caused by or treated by a surgical procedure; or*
   ii. *A Stage I pressure ulcer; or*
   iii. *A first degree burn; or*
   iv. *Wounds caused by trauma which do not require surgical closure or debridement – e.g. skin tear or abrasion; or*
   v. *A venipuncture or arterial puncture site (e.g., blood sample) other than the site of an indwelling catheter or needle.*

d. *Surgical dressing codes billed without modifiers A1-A9 (see Coding Guidelines) are non-covered under the Surgical Dressings benefit. Certain dressings may be covered under other benefits.*

e. *A silicone gel sheet (A6025) used for the treatment of keloids or other scars does not meet the definition of the surgical dressing benefit and will be denied as non-covered.*

f. *If a physician applies surgical dressings as part of a professional service that is billed to Medicare, the surgical dressings are considered incident to the professional services of the health care practitioner and are not separately payable. Claims for these dressings must not be submitted to the DMERC. Claims for the professional service which includes the dressings must be submitted to the local carrier or intermediary. If dressing changes are sent home with the patient, claims for these dressings may be submitted to the DMERC. In this situation, use the place of service corresponding to the patient's residence; Place of Service Office (POS=11) must not be used.*

g. *The following are examples of wound care items which are non-covered under the surgical dressing benefit: skin sealants or barriers (A6250), wound cleansers (A6260) or irrigating solutions, solutions used to moisten gauze (e.g., saline), silicone gel sheets, topical antiseptics, topical antibiotics, enzymatic debriding agents, gauze or other dressings used to cleanse or debride a wound but not left on the wound. Also, any item listed in the latest edition of the Orange Book (e.g., an antibiotic-impregnated dressing which requires a prescription) is considered a drug and is non-covered under the Surgical Dressings benefit.*

4. **Documentation**

a. *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.*

b. *An order for each item billed must be signed and dated by the treating 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.*
c. *The order must specify (a) the type of dressing (e.g., hydrocolloid wound cover, hydrogel wound filler, etc.), (b) the size of the dressing (if appropriate), (c) the number/amount to be used at one time (if more than one), (d) the frequency of dressing change, and (e) the expected duration of need.*
d. *A new order is needed if a new dressing is added or if the quantity of an existing dressing to be used is increased. A new order is not routinely needed if the quantity of dressings used is decreased. However a new order is required at least every 3 months for each dressing being used even if the quantity used has remained the same or decreased.*
e. *Information defining the number of surgical/debrided wounds being treated with a dressing, the reason for dressing use (e.g., surgical wound, debrided wound, etc.), and whether the dressing is being used as a primary or secondary dressing or for some non-covered use (e.g., wound cleansing) must be obtained from the physician, nursing home, or home care nurse. The source of that information and date obtained must be documented in the supplier's records.*
f. *Current clinical information which supports the reasonableness and necessity of the type and quantity of surgical dressings provided must be present in the patient's medical records. Evaluation of a patient's wound(s) must be performed at least on a monthly basis unless there is documentation in the medical record which justifies why an evaluation could not be done within this timeframe and what other monitoring methods were used to evaluate the patient's need for dressings. Evaluation is expected on a more frequent basis (e.g., weekly) in patients in a nursing facility or in patients with heavily draining or infected wounds. The evaluation may be performed by a nurse, physician or other health care professional. This evaluation must include the type of each wound (e.g., surgical wound, pressure ulcer, burn, etc), its location, its size (length x width in cm.) and depth, the amount of drainage, and any other relevant information. This information does not have to be routinely submitted with each claim. However a brief statement documenting the medical necessity of any quantity billed which exceeds the quantity needed for the usual dressing change frequency stated in the policy must be submitted with the claim. This statement may be attached to a hard copy claim or entered in the HA0 record of an electronic claim.*
g. *When surgical dressings are billed, the appropriate modifier (A1-A9, AW, EY, or GY) must be added to the code when applicable. If A9 is used, information must be submitted with the claim indicating the number of wounds. If GY is used, a brief description of the reason for non-coverage (e.g., "A6216GY – used for wound cleansing") must be included. These statements must be included with a hard copy claim or entered in the narrative field of an electronic claim.*

h. *The staging of pressure ulcers used in this policy is as follows:*
   i. *<u>Stage I</u> – Observable pressure-related alteration of intact skin whose indicators, as compared to the adjacent or opposite area on the body, may include changes in one of more of the following: skin temperature (warmth or coolness), tissue consistency (firm or boggy feel) and/or sensation (pain, itching). The ulcer appears as a defined area of persistent redness in lightly pigmented skin, whereas in darker skin tones, the ulcer may appear with persistent red, blue, or purple hues.*
   ii. *<u>Stage II</u> – Partial thickness skin loss involving epidermis, dermis, or both. The ulcer is superficial and presents clinically as an abrasion, blister, or shallow crater.*
   iii. *<u>Stage III</u> – Full thickness skin loss involving damage to, or necrosis of, subcutaneous tissue that may extend down to, but not through, underlying fascia. The ulcer presents clinically as a deep crater with or without undermining of adjacent tissue.*
   iv. *<u>Stage IV</u> – Full thickness skin loss with extensive destruction, tissue necrosis, or damage to muscle, bone, or supporting structures (e.g., tendon, joint capsule). Undermining and sinus tracts also may be associated with Stage IV pressure ulcers.*