6) any medications used that might impair GI tolerance to enteral feedings (e.g. anticholinergics, opiates, tricyclics, phenothiazines, etc.) or that might interfere with test results (e.g. mineral oil, etc.) and a statement explaining the need for these medications.

Any other information which supports the medical necessity for parenteral nutrition may also be included.

For the Initial Certification and for Revised Certifications or Recertification involving a change in the order, there must be additional documentation to support the medical necessity of the following orders, if applicable.

1) the need for special nutrients (B5000-B5200),
2) the need for dextrose concentration less than 10%,
3) the need for lipids more than 15 units of a 20% solution or 30 units of a 10% solution per month.

After the Initial Certification of parenteral nutrition items, Recertification is required after 6 months of therapy to document the patient's continued need for therapy. After the recertification at 6 months, further routine recertifications will not generally be required. However, additional recertifications may be requested on an individual basis at the discretion of the DMERC.

For patients who have had their initial certification and at least one routine recertification approved by the DMERC prior to 7/1/96, no further routine recertification will be required.

A Revised Certification would be required when (1) nutrients billed with a different code are ordered, or (2) the number of days per week administered is decreased. A Revised Certification does not change the schedule for the required Recertification.

A new Initial Certification would be required when parenteral nutrition services are resumed when they are not required for two consecutive months. In this situation the required recertification schedule would start again.

The 6 month recertification must include a physician's statement describing the continued need for parenteral nutrition. For situations E-H, the recertification must include the results of the most recent serum albumin (within 2 weeks of recertification) and the patient's most recent weight with the date of each. If the results indicate malnutrition, there should be a physician's statement describing the continued need for parenteral nutrition and any changes to the therapeutic regimen that are planned.

When a certification is required, the claim must include a copy of the CMN if filed hard copy. If the claim is filed electronically, the information on the CMN must be transcribed exactly into the GUØ record. (See DMEPOS National Standard Format Matrix for details.) The HAØ record can be used for additional narrative documentation that will not fit on the GUØ record.

When code B9999 is billed, the claim must include a clear description of the item, the quantity provided, and the medical necessity of the item for the patient.

Refer to the Supplier Manual for more information on orders, CMN's, medical records, and supplier documentation.

**EFFECTIVE DATE:** Claims received by the DMERC on or after July 1, 1996.

This is a revision to a previously published policy.
The following Grandfathering PEN Update to Section E of the DMERC Grandfathering Policy published in the July 1995 issue of the Region C DMERC DMEPOS Supplier Manual replaces all previously published versions of the PEN section (Section E) of the Grandfathering Policy.

This update will be included in the next Region C DMERC DMEPOS Supplier Manual revision.

E) Parenteral/Enteral Nutrition

For parenteral nutrition, if it had been approved by the prior regional carrier, consistent with the then existing policy, before transition to the DMERC, payment will be continued as long as it is ordered by the physician. When parenteral nutrition therapy is grandfathered, further routine recertifications with a fully completed CMN will not be required, though revised certifications should continue to be submitted as required in the Parenteral Nutrition policy.

For enteral nutrition, if it had been approved by the prior regional carrier before transition to the DMERC, payment will be continued for as long as it is ordered by the physician. When enteral nutrition therapy is grandfathered, further routine recertifications with a fully completed CMN will not be required, though revised certifications should continue to be submitted as required in the Enteral Nutrition policy.

When enteral nutrition coverage is grandfathered, payment for the specific enteral product that the patient was on at the time of transition will be continued if it had been approved by the prior carrier. This payment will continue until such time as revised national coverage policy for special enteral formulae becomes effective. If the patient is subsequently changed to a different specialty formula, the DMERC policy for the specialty formula applies.
EXTERNAL INFUSION PUMPS

REGION C DMERC REGIONAL MEDICAL REVIEW POLICY

SUBJECT: External Infusion Pumps

HCPCS CODES:

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

Equipment:

E0781 - Ambulatory infusion pump, single or multiple channels, with administrative equipment, worn by patient
E0782 - Infusion pump, implantable
E0791 - Parenteral infusion pump, stationary, single or multichannel
E0776 - IV pole
E1399 - Durable medical equipment miscellaneous
K0284 - External infusion pump, mechanical, reusable, for extended drug infusion
K0417 - External infusion pump, mechanical, reusable, for extended drug infusion

Supplies:

A4305 - Disposable drug delivery system, flow rate of 50 ml or greater per hour
A4306 - Disposable drug delivery system, flow rate of 5 ml or less per hour
A9270 - Noncovered item or service
K0110 - Supplies for the maintenance of a drug infusion catheter, per week
K0111 - Supplies for external drug infusion pump, per cassette or bag

Drugs:

J0895 - Injection, deferoxamine mesylate, 500 mg per 5 cc
J1170 - Injection, hydromorphone, up to 4 mg
J1250 - Injection, dobutamine hydrochloride, per 250 mg
J1455 - Injection, foscarnet sodium, per 1000 mg
J1570 - Injection, ganciclovir sodium, 500 mg
J2175 - Injection, meperidine, per 100 mg
J2250 - Injection, milrinone lactate, per 5 ml
J2270 - Injection, morphine sulfate, up to 10 mg
J2275 - Injection, morphine sulfate (preservative-free sterile solution), per 10 mg
J3010 - Injection, fentanyl citrate, up to 2 ml
J3370 - Injection, Vancomycin HCL, up to 500 mg
J7799 - NOC drugs, other than inhalation drugs, administered through DME
J9000 - Doxorubicin HCL, 10 mg
J9010 - Doxorubicin HCL, 50 mg
J9040 - Bleomycin sulfate, 15 units
J9065 - Injection, cladribine, per 1 mg
J9100 - Cytarabine, 100 mg
J9110 - Cytarabine, 500 mg
J9190 - Fluorouracil, 500 mg
J9200 - Floxuridine, 500 mg
J9360 - Vinblastine sulfate, 1 mg
J9370 - Vincristine sulfate, 1 mg
J9375 - Vincristine sulfate, 2 mg
J9380 - Vincristine sulfate, 5 mg
XX009 - Dobutamine, 250 mg

BENEFITS CATEGORY: Durable Medical Equipment

REFERENCE: Coverage Issues Manual 60-14
DEFINITIONS:

An ambulatory infusion pump (E0781) is an electrical device which is used to deliver solutions containing parenteral medication under pressure at a regulated flow rate. It is small, portable and designed to be carried by the patient.

A stationary infusion pump (E0791) is an electrical device which serves the same purpose as an ambulatory pump but is larger and typically mounted on a pole.

An infusion controller (E1399) is an electrical device which regulates the flow of parenteral solutions under gravity pressure.

A reusable mechanical infusion pump (K0284) is a device used to deliver solutions containing parenteral medication under pressure at a constant flow rate determined by the tubing with which it is used. It is small, portable and designed to be carried by the patient. It must be capable of a single infusion cycle of at least 8 hours.

Code K0417 describes a mechanical infusion pump which is similar to a K0284 pump, but which is only capable of a single infusion cycle of less than 8 hours.

A disposable drug delivery system (A4305, A4306) is a device used to deliver solutions containing parenteral medication under pressure generated from the elastic properties of the container. It is commonly called an elastomeric infusion pump.

Code K0110 includes dressings for the catheter site and flush solutions not directly related to drug infusion. The catheter site may be a peripheral intravenous line, a peripherally inserted central catheter (PICC), a centrally inserted intravenous line with either an external or subcutaneous port, or an epidural catheter.

Code K0111 includes the cassette or bag, diluting solutions, tubing and other administration supplies, port cap changes, compounding charges, and preparation charges.

COVERAGE AND PAYMENT RULES:

An infusion pump is indicated for the administration of parenteral medication in the home setting when both of the following criteria are met:

1. Parenteral administration of the medication in the home is reasonable and necessary, and
2. An infusion pump is necessary to safely administer the medication.

An external infusion pump is covered for the following indications:

1. In the administration of deferoxamine for the treatment of chronic iron overload.
2. Chemotherapy for the treatment of primary hepatocellular carcinoma or colorectal cancer where this disease is unresectable or where the patient refuses surgical excision of the tumor.

Additional uses of an infusion pump are covered for the administration of parenteral medication in the home setting if the patient meets:

a) criteria 1, 2, and 3, or
b) criteria 1, 4, and 5

Criteria:

1) Parenteral administration of the medication in the home is reasonable and necessary.
2) The drug is administered by a prolonged infusion of at least 8 hours because of proven improved clinical efficacy.
3) The therapeutic regimen is proven or generally accepted to have significant advantages over (a) intermittent bolus administration regimens or (b) infusions lasting less than 8 hours.
4) The drug is administered by intermittent infusion (each episode of infusion lasting less than 8 hours) which does not require the patient to return to the physician’s office prior to the beginning of each infusion.
5) Systemic toxicity or adverse effects of the drug is unavoidable without infusing it at a strictly controlled rate as indicated in the Physicians Desk Reference, American Medical Association’s Drug Evaluations, or the U.S. Pharmacopeia Drug Information.
The criteria for additional uses of infusion pumps as described in a) and b) above are met in the following situations:

A. Administration of cladribine, fluorouracil, cytarabine, bleomycin, floxuridine, doxorubicin, vincristine or vinblastine by continuous infusion over at least 8 hours when the regimen is proven or generally accepted to have significant advantages over intermittent administration regimens. This does not apply to primary hepatocellular carcinoma or liver metastases from colorectal carcinoma.

B. Administration of narcotic analgesics (except meperidine) in place of morphine to a patient with intractable pain caused by cancer who has not responded to an adequate oral/transdermal therapeutic regimen and/or cannot tolerate oral/transdermal narcotic analgesics.

C. Administration of the following antibiotics or antiviral drugs: fosfamet, amphotericin B, Vancomycin, acyclovir, and ganciclovir.

D. Administration of parenteral inotropic therapy, using the drugs dobutamine, milrinone and/or dopamine for patients with congestive heart failure and depressed cardiac function if a patient has all of the following conditions:

1) Dyspnea at rest despite treatment with maximum or near maximum tolerated doses of digoxin, a loop diuretic, and an angiotensin converting enzyme inhibitor or another vasodilator (e.g., hydralazine or isosorbide dinitrate), used simultaneously (unless allergic or intolerant), and

2) Doses are within the following ranges (lower doses will be covered only if part of a weaning or tapering protocol from higher dose levels):
   a) Dobutamine 2.5 - 10 mcg/kg/min
   b) Milrinone 0.375 - 0.750 mcg/kg/min
   c) Dopamine < 2 mcg/kg/min, and

3) Invasive hemodynamic studies performed within 6 months prior to the initiation of home inotropic therapy show (a) cardiac index (CI) is less than or equal to 2.2 liters/min/meter squared and/or pulmonary capillary wedge pressure (PCWP) is greater than or equal to 20 mm Hg before inotropic infusion on maximum medical management and (b) at least a 20% increase in CI and/or at least a 20% decrease in PCWP during inotropic infusion at the dose initially prescribed for home infusion, and

4) An improvement in patient well being, (less dyspnea, improved diuresis, improved renal function and/or reduction in weight) with the absence of dyspnea at rest at the time of discharge and the capability of outpatient evaluation by the prescribing physician at least monthly, and

5) In the case of continuous infusion, there is documented deterioration in clinical status when the drug(s) is tapered or discontinued under observation in a hospital, or

   In the case of intermittent infusions, there is documentation of repeated hospitalizations for congestive heart failure despite maximum medical management, and

6) Any life threatening arrhythmia is controlled prior to hospital discharge and there is no need for routine electrocardiographic monitoring at home, and

7) The patient is maintained on the lowest practical dose and efforts to decrease the dose of the drug(s) or the frequency/duration of infusion are documented during the first 3 months of therapy, and

8) The patient’s cardiac symptoms, vital signs, weight, lab values, and response to therapy are routinely assessed and documented in the patient’s medical record.

External infusion pumps and related drugs and supplies will be denied as not medically necessary when these criteria are not met unless there is documentation justifying medical necessity in the individual case.

When an infusion pump is covered, the medication necessitating the use of the pump and necessary supplies are also covered. When a pump has been purchased by the Medicare program, other insurer, or the patient, or the rental cap has been reached, the medication necessitating the use of the pump, and supplies are covered as long as the coverage criteria for the pump are met.

Disposable drug delivery systems, including elastomeric infusion pumps (A4305, A4306) are noncovered devices because they do not meet the Medicare definition of durable medical equipment. Medication and supplies used with disposable drug delivery systems are also noncovered items.
An external infusion pump and related medication and supplies will be denied as not medically necessary in the home setting in the following situations:

1. Heparin for the treatment of thromboembolic disease and/or pulmonary embolism,
2. Insulin for the treatment of diabetes mellitus.

An infusion controller device (E1399) is not medically necessary.

An IV pole (E0776) is covered only when a stationary infusion pump (E0791) is covered. It is considered not medically necessary if it is billed with an ambulatory infusion pump (E0781).

Supplies for the maintenance of a parenteral drug infusion catheter (K0110) are covered during the period of covered use of an infusion pump. They are also covered for the weeks in between covered infusion pump use, not to exceed 4 weeks per episode.

Supplies used with an external infusion pump, K0111, are covered. Allowance is based on the number of cassettes or bags prepared. For intermittent infusions, no more than one cassette or bag is covered for each dose of medication. For continuous infusion, the concentration of the drug and the size of the cassette or bag should be maximized to result in the fewest cassettes or bags in keeping with good pharmacologic and medical practice. Medications and supplies that are dispensed but not used for completely unforeseen circumstances (e.g., emergency admission to hospital, drug toxicity, etc.) are covered. Suppliers are expected to anticipate changing needs for drugs (e.g. planned hospital admissions, drug level testing with possible dosage change, etc.) in their drug and supply preparation and delivery schedule.

The DMERC does not process claims for implantable infusion pumps or medications and supplies used in conjunction with implantable infusion pumps. Claims for these items must be submitted to the local carrier.

RELATED CLINICAL INFORMATION

The Center for Disease Control and Prevention (CDC) has determined that use of Vancomycin may increase the possibility of emergence of Vancomycin-resistant staphylococci and enterococci. Since the presence of these organisms has a significant negative public health impact, use of Vancomycin should be limited to those situations in which it is clearly necessary. The CDC outlined appropriate and inappropriate uses of Vancomycin. Of the appropriate uses listed, use of Vancomycin administered through an infusion pump in the home setting would usually be limited to the following:

1. Treatment of serious infections due to beta-lactam resistant gram positive microorganisms
2. Treatment of infections due to gram positive microorganisms in patients with serious allergy to beta-lactam antimicrobials

CODING GUIDELINES:

Supplies (including dressings) used in conjunction with a durable infusion pump (E0781, E0791, K0284, K0417) are included in codes K0110 or K0111. Other codes should not be used for the separate billing of these supplies.

Use codes K0110 and K0111 only for supplies related to durable infusion pumps. Charges for supplies for noncovered infusion therapy via disposable pump or without a pump may be billed under code A9270.

Medication used in a durable infusion pump should be coded using the appropriate HCPCS codes. If the medication does not have a distinct code, then use the unclassified drug code J7799. Do not use codes A4610 or J9999. If there is no distinct HCPCS code for the drug billed, and the drug is not administered via an infusion pump, use code A9270.

Use code J2275 only for morphine sulfate that is labeled "preservative free." Morphine sulfate that is not labeled "preservative free" must be coded J2270.

For disposable drug delivery systems (e.g. elastomeric) with a flow rate of more than 5 ml per hour and less than 50 ml per hour, use code A9270.

Code XX009 is invalid for claims with dates of service on or after 1/1/96; code J1250 should be used instead.

Code K0417 is valid for claims with dates of service on or after 4/1/96.
DOCUMENTATION:

An order for the item which has been signed and dated by the ordering physician and a certificate of medical necessity (CMN) which has been filled out, signed and dated by the ordering physician must be kept on file by the supplier. The CMN for external infusion pumps is DMERC 09.

The initial claim must include a copy of the CMN if filed hard copy. If the claim is filed electronically, the information on the CMN must be transcribed exactly into the GUØ record. (See DMEPOS National Standard Format Matrix for details.) If additional medical necessity information is included, it must be transcribed into the HAØ record.

If an inotropic drug is ordered, the initial claim must include a copy of the order (prescription and documentation from the ordering physician) which includes information relating to each of the criteria (D1-D8) defined in the Coverage and Payment Rules section. This must include the before and after inotropic drug infusion values defined in D3. A suggested form for collecting this information is attached. Questions pertaining to medical necessity on any form used to collect this information may not be completed by the supplier or by anyone in a financial relationship with the supplier. If coverage criteria stated in the policy are not met, the claim should be accompanied by a copy of a letter from the physician giving details of the patient’s history (e.g. dates of past hospitalization for heart failure, prior use of parenteral inotropics and the results, etc.) If invasive hemodynamic studies were not performed, the claim should be accompanied by a letter from the attending physician explaining the rationale for not performing the tests accompanied by any other documentation deemed appropriate to explain this exception.

Refer to the Supplier Manual for more information on orders, CMNs, medical records and supplier documentation.

EFFECTIVE DATE: Claims received by the DMERC on or after April 1, 1996.

This is a revision to a previously published policy.

NOTE: Infusion Pump - New Code

A new code has been established for a mechanical infusion pump.

K0417 External infusion pump, mechanical, reusable, for short term drug infusion.

This code is valid for dates of service on or after 4/1/96. This code is in the inexpensive or routinely purchased DME payment category. An Infusion Pump CMN (DMERC 09) is required with the initial claim.

Code K0417 describes a reusable device used to deliver solutions containing parenteral medication under pressure at a constant flow rate determined by the tubing with which it is used. It is small, portable, and designed to be carried by the patient. It is distinguished from code K0284 by the fact that it is only capable of a single infusion cycle of less than 8 hours.

At the present time, the only product known to be described by this code is the Sidekick pump by I-Flow Corporation. If a supplier or manufacturer thinks that another product meets the definition of this code, they should contact the Statistical Analysis DME Regional Carrier (SADMERC) for a coding determination.

Statistical Analysis DMERC
HCPCS Help-Line (803) 736-6809
OSTEOGENESIS STIMULATORS

REGION C DMERC REGIONAL MEDICAL REVIEW POLICY

SUBJECT: Osteogenesis Stimulators

HCPCS CODES:

E0747  -  Osteogenesis stimulator, noninvasive, other than spinal applications
E0748  -  Osteogenesis stimulator, noninvasive, spinal applications

BENEFIT CATEGORY: Durable Medical Equipment

REFERENCE: Coverage Issues Manual 35-48

DEFINITIONS:

An osteogenesis stimulator is a device that provides electrical stimulation to augment bone repair. A noninvasive stimulator is characterized by an external power source which is attached to a coil or electrodes placed on the skin or on a cast or brace over a fracture or fusion site.

A multilevel spinal fusion is one which involves 3 or more vertebrae (e.g. L3-L5, L4-S1, etc).

COVERAGE AND PAYMENT RULES:

A nonspinal osteogenesis stimulator (E0747) is covered if any of the following criteria are met:

1) Nonunion of a long bone fracture after six months have elapsed without healing of the fracture, or
2) Failed fusion of a joint other than in the spine where a minimum of nine months has elapsed since the last surgery, or
3) Congenital pseudarthrosis.

A spinal osteogenesis stimulator (E0748) is covered if any of the following criteria are met:

1) Failed spinal fusion where a minimum of nine months has elapsed since the last surgery, or
2) Following a multilevel spinal fusion surgery, or
3) Following spinal fusion surgery where there is a history of a previously failed spinal fusion.

An osteogenesis stimulator will usually be denied as not medically necessary if none of the criteria above are met.

The DMERC does not process claims for an invasive osteogenesis stimulator.

CODING GUIDELINES:

Code E0748 is valid for claims with dates of service on or after 1/1/96. Revised wording for code E0747 became effective for dates of service on or after 1/1/96. For dates of service prior to 1/1/96, code E0747 was used for either nonspinal or spinal noninvasive stimulators.

DOCUMENTATION:

An order for the item which has been signed and dated by the ordering physician and a certificate of medical necessity (CMN) which has been signed and dated by the ordering physician must be kept on file by the supplier. The CMN for osteogenesis stimulators is DMERC 04.

The initial claim must include a copy of the CMN if filed hard copy. If the claim is filed electronically, the information on the CMN must be transcribed exactly into the GU0 record. (See DMEPOS National Standard Format Matrix for details.) If additional medical necessity information is included, it must be transcribed into the HA0 record.
Additional documentation is required in the following situations. If a spinal stimulator is ordered following a multilevel spinal fusion, the claim must include the date of the surgery and level of the fusion. If a spinal stimulator is ordered when there is a history of a previously failed spinal fusion, the claim must include the date and level of the previous fusion and that fact that the fusion failed. This additional documentation should be attached to a hard copy claim or entered in the HAØ record of an electronic claim.

Refer to the Supplier Manual for more information on orders, CMNs, medical records and supplier documentation.

**EFFECTIVE DATE:** Claims with dates of service on or after April 1, 1996.

This is a revision to a previously published policy.
PRESSURE REDUCING SUPPORT SURFACES - GROUP 2

REGION C DMERC REGIONAL MEDICAL REVIEW POLICY

SUBJECT: Pressure Reducing Support Surfaces - Group 2

HCPCS CODES:

E0193 - Powered air flotation bed (low air loss therapy)
E0277 - Alternating pressure mattress
E1399 - Durable medical equipment, miscellaneous
K0413 - Nonpowered adjustable zone pressure-reducing air mattress overlay
K0414 - Powered air overlay for mattress

BENEFIT CATEGORY: Durable Medical Equipment

REFERENCE: Coverage Issues Manual 60-9

DEFINITIONS:

Code E0277 describes a powered pressure reducing mattress (alternating pressure, low air loss, or powered flotation without low air loss) which is characterized by all of the following:

1) An air pump or blower which provides either sequential inflation and deflation of the air cells or a low interface pressure throughout the mattress, and
2) Inflated cell height of the air cells through which air is being circulated is 5 inches or greater, and
3) Height of the air chambers, proximity of the air chambers to one another, frequency of air cycling (for alternating pressure mattresses), and air pressure provide adequate patient lift, reduce pressure and prevent bottoming out, and
4) A surface designed to reduce friction and shear, and
5) Can be placed directly on a hospital bed frame.

Code E0193 describes a semi-electric or total electric hospital bed with a fully integrated powered pressure reducing mattress which has all the characteristics defined above.

Code K0413 describes a nonpowered pressure-reducing mattress overlay which is characterized by all of the following:

1) At least 3 independent sections in which the air pressure is custom adjusted for each patient.
2) Each section contains numerous air cells connected by restrictive manifolding that provides constant force equalization.
3) Each cell is displaceable and low surface tension over the entire body is continually maintained.
4) A surface which reduces friction and shear.
5) Cell height of 3 inches or greater.

Code K0414 describes a powered pressure reducing mattress overlay (low air loss, powered flotation without low air loss, or alternating pressure) which is characterized by all of the following:

1) An air pump or blower which provides either sequential inflation and deflation of the air cells or a low interface pressure throughout the overlay, and
2) Inflated cell height of the air cells through which air is being circulated is 3.5 inches or greater, and
3) Height of the air chambers, proximity of the air chambers to one another, frequency of air cycling (for alternating pressure overlays), and air pressure to provide adequate patient lift, reduce pressure and prevent bottoming out, and
4) A surface designed to reduce friction and shear.

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

Stage I - nonblanchable erythema of intact skin
Stage II - partial thickness skin loss involving epidermis and/or dermis
Stage III - full thickness skin loss involving damage or necrosis of subcutaneous tissue that may extend down to, but not through, underlying fascia
Stage IV - full thickness skin loss with extensive destruction, tissue necrosis or damage to muscle, bone, or supporting structures.

Bottoming out is the finding that an outstretched hand, placed palm up between the undersurface of the mattress and the patient’s bony prominence (coccyx or lateral trochanter), can readily palpate the bony prominence. This bottoming out criterion should be tested with the patient in the supine position with their head flat, in the supine position with their head slightly elevated (no more than 30 degrees), and in the sidelying position.

COVERAGE AND PAYMENT RULES:

A group 2 support surface is covered if the patient meets:

a) criterion 1 and 2 and 3, or
b) criterion 4, or
c) criterion 5 and 6.

1) Multiple stage II pressure ulcers located on the trunk or pelvis.
2) Patient has been on a comprehensive ulcer treatment program for at least the past month which has included the use of an appropriate group 1 support surface.
3) The ulcers have worsened or remained the same over the past month.
4) Large or multiple stage III or IV pressure ulcer(s) on the trunk or pelvis.
5) Recent myocutaneous flap or skin graft for a pressure ulcer on the trunk or pelvis (surgery within the past 60 days).
6) The patient has been on a group 2 or 3 support surface immediately prior to a recent discharge from a hospital or nursing facility (discharge within the past 30 days).

The comprehensive ulcer treatment described in #2 above should generally include:

i) Education of the patient and caregiver on the prevention and/or management of pressure ulcers.
ii) Regular assessment by a nurse, physician, or other licensed healthcare practitioner (usually at least weekly for a patient with a stage III or IV ulcer).
iii) Appropriate turning and positioning.
iv) Appropriate wound care (for a stage II, III, or IV ulcer).
v) Appropriate management of moisture/incontinence.
v) Nutritional assessment and intervention consistent with the overall plan of care.

If the patient is on a group 2 surface, there should be a care plan established by the physician or home care nurse which includes the above elements.

The support surface provided for the patient should be one in which the patient does not “bottom out” (see Definition section).

When a group 2 surface is covered following a myocutaneous flap or skin graft, coverage generally is limited to 60 days from the date of surgery.

When the stated coverage criteria for a group 2 mattress or bed are not met, a claim will be denied as not medically necessary unless there is clear documentation which justifies the medical necessity for the item in the individual case. A group 2 support surface billed without a ZX modifier (see Documentation section) will usually be denied as not medically necessary.

A support surface which does not meet the characteristics specified in the Definition section of the support surface policies will usually be denied as not medically necessary. (See Coding Guidelines and Documentation sections concerning billing of E1399.)

Continued use of a group 2 support surface is covered until the ulcer is healed or, if healing does not continue, there is documentation in the medical record to show that: (1) other aspects of the care plan are being modified to promote healing, or (2) the use of the group 2 support surface is medically necessary for wound management.

Appropriate use of the ZX modifier (see Documentation section) is the responsibility of the supplier billing the DMERC. The supplier should maintain adequate communication on an ongoing basis with the clinician providing the wound care in order
to accurately determine that use of the ZX modifier still reflects the clinical conditions which meet the criteria for coverage of a group 2 support surface, and that adequate documentation exists in the medical record reflecting these conditions. Such documentation should not be submitted with a claim but should be available for review if requested by the DMERC.

In cases where a group 2 product is inappropriate, a group 1 or 3 support surface could be covered if coverage criteria for that group are met.

**CODING GUIDELINES:**

Codes K0413 and K0414 are valid for dates of service on or after 4/1/96.

Group 2 support surfaces which do not meet the characteristics specified in the Definition section should be coded using code E1399.

Either alternating pressure mattresses or low air loss mattresses are coded using code E0277.

Products containing multiple components are categorized according to the clinically predominant component (usually the topmost layer of a multilayer product). For example, a product with 3" powered air cells on top of a 3" foam base would be coded as a powered overlay (code E0180 or E0181) not as a powered mattress (E0277).

A supplier wanting to know which code to use to describe a particular product should contact the Statistical Analysis DME Regional Carrier (SADMERC) - Palmetto Government Benefits Administrators.

**DOCUMENTATION:**

An order for the mattress or bed which is signed and dated by the ordering physician must be kept on file by the supplier. The written order must be obtained prior to the delivery of the item.

The supplier must obtain information concerning which, if any, of criteria 1-6 listed in the Coverage and Payment Rules section of this policy the patient meets in a signed and dated statement from the physician. A suggested form for collecting this information is attached. Questions pertaining to medical necessity on any form used to obtain this information may not be completed by the supplier or anyone in a financial relationship with the supplier. This statement must be supported by information in the patient's medical record which would be available to the DMERC on request. **Do not send this form to the DMERC unless specifically requested.**

When the initial claim for a group 2 support surface is received on or after 1/1/96, if it meets the criteria specified in situation (a), (b), or (c) in the Coverage and Payment Rules section, the ZX modifier should be added to the code on the initial claim. On subsequent claims for situations (a) and (b), the ZX modifier should be added to the code until the ulcer has healed. Once the ulcer has healed, the ZX modifier should not be used. On subsequent claims for situation (c), the ZX modifier may only be added to claims with dates of service within 60 days of the surgery.

When the initial claim for a group 2 support surface was received prior to 1/1/96 and was approved, then for subsequent claims with dates of service on or before 12/31/95, the ZX modifier may be added to the claim. When the initial claim for a group 2 support surface was received prior to 1/1/96 and was approved, then for subsequent claims with dates of service on or after 1/1/96, the ZX modifier may be added to the claim if a stage II, III or IV ulcer on the trunk or pelvis is present on 1/1/96.

**The ZX modifier may only be used when these requirements are met.** If the requirements for the modifier are not met, the supplier can submit additional information with the claim to justify coverage but the ZX modifier should not be used.

If a support surface is billed using code E1399, the claim must include the following information: manufacturer and brand name of product, what support surface group (1, 2, or 3) the supplier considers it to be, why it doesn't fall into an existing code, and why it is necessary for that patient. If the supplier considers the support surface to be a Group 2 surface, the ZX modifier should also be added if the requirements for its use are met.

Refer to the Documentation section of the supplier manual for more information on orders, medical records, and supplier documentation.

**EFFECTIVE DATE:** Claims received by the DMERC on or after April 1, 1996.

This is a revision to a previously published policy.