EXTERNAL INFUSION PUMPS MEDICAL POLICY  
(continued)

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, flouxuridine, 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 antifungal or antiviral drugs: foscarinet, amphotericin B, 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, and
   c) Dopamine < 2 mcg/kg/min;

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 inotrope infusion at the dose initially prescribed for home infusion.

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,

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 MEDICAL POLICY (continued)

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 also are 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 non-covered devices because they do not meet the Medicare definition of durable medical equipment. Medication and supplies used with disposable drug delivery systems are also non-covered 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, and
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 a 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.

Coding guidelines

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

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

Medication used in a durable infusion pump should be coded using the appropriate HCPCS code. If the medication does not have a distinct HCPCS code, then use the unclassified drug HCPCS code J7799. Do not use HCPCS 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 HCPCS code A9270.
EXTERNAL INFUSION PUMPS MEDICAL POLICY
(continued)

Use HCPCS 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 HCPCS code A9270.

HCPCS code J1250 is valid for dates of service on or after January 1, 1996.

HCPCS code K0417 is valid for claims with dates of service on or after April 1, 1996.

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 GUI record. (See DMEPOS National Standard Format Matrix for details.) If additional medical necessity information is included, it must be transcribed into the HA90 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 DMEPOS Supplier Manual for further information on orders, CMNs, medical records and supplier documentation.

Effective date

Claims with dates of service on or after September 1, 1996.

This is a revision to a previously published policy.
SUCTION PUMPS MEDICAL POLICY

Subject: Suction pumps

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

- E0600–Suction pump, home model, portable
- E1399–Durable medical equipment, miscellaneous
- A4214–Sterile saline or water, 30 cc vial
- A4323–Sterile saline irrigation solution, 1000 ml
- A4624–Tracheal suction catheter, any type, each
- A4628–Oropharyngeal suction catheter, each
- K0190–Canister, disposable, used with suction pump
- K0191–Canister, non-disposable, used with suction pump
- K0192–Tubing, used with suction pump

Benefit category
Durable Medical Equipment

Reference
Coverage Issues Manual 60-9

Definition
A portable home model suction pump is a lightweight, compact, electric aspirator designed for upper respiratory oral pharyngeal and tracheal suction for use in the home. Use of the device does not require technical or professional supervision.

Coverage and payment rules
Use of a home model suction machine is covered for patients who have difficulty raising and clearing secretions secondary to:

1. cancer or surgery of the throat or mouth,
2. dysfunction of the swallowing muscles,
3. unconsciousness or obtunded state, and
4. tracheostomy (ICD-9 V44.0).

When a suction pump is covered, tracheal suction catheters (A4624) are separately payable supplies. In most cases, in the home setting, sterile catheters are medically necessary only for tracheostomy suctioning. Three suction catheters per day are covered for medically necessary tracheostomy suctioning, unless additional documentation is provided. When a tracheal suction catheter is used in the oropharynx, which is not sterile, the catheter can be reused if properly cleansed and/or disinfected. In this situation the medical necessity for more than three catheters (A4624) per week would require additional documentation.

Sterile saline solution (A4214, A4323) is covered and separately payable when used to clear a suction catheter after tracheostomy suctioning. It is not usually medically necessary for oropharyngeal suctioning. Saline used for tracheal lavage is a non-covered supply.
SUCTION PUMPS MEDICAL POLICY
(continued)

Tracheal suction catheters (A4624) and sterile saline used for suctioning (A4214, A4323) are considered supplies for durable medical equipment. Therefore, when supplied to beneficiaries in nursing facilities, Place of Service Codes 31 and 32, they will be denied as non-covered.

Supplies (A4628, K0190-K0192) are covered and are separately payable when they are medically necessary and used with a medically necessary suction pump in a covered setting.

When a suction pump is used for tracheal suctioning, other supplies (e.g. cups, basins, gloves, solutions, etc.) are included in the tracheal care kit HCPCS code (A4625). (Refer to the Tracheostomy Care Supplies policy for details.) When a suction pump is used for oropharyngeal suctioning, these other supplies are not medically necessary.

Coding guidelines

HCPCS code E0600 would not be used for a suction pump used with nasogastric tubes. This would be coded E1399.

HCPCS code A4628 is valid for claims with dates of service on or after January 1, 1996.

Documentation

An order for the item, which has been signed and dated by the ordering physician, must be kept on file by the supplier. When billing HCPCS code A4624 for patients with a tracheostomy, ICD-9 code V44.0 should be entered on the claim form.

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

Effective date

Claims with dates of service on or after November 1, 1996.

This is a revision to a previously published policy.

TRACHEOSTOMY CARE SUPPLIES MEDICAL POLICY

Subject: Tracheostomy care supplies

HCPCS codes

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

- A4625–Tracheostomy care kit for a new tracheostomy
- A4626–Tracheostomy cleaning brush, each
- A4629–Tracheostomy care kit for established tracheostomy

Benefit category

Prosthetic Devices
TRACHEOSTOMY CARE SUPPLIES MEDICAL POLICY
(continued)

Definition

A tracheostomy care or cleaning starter kit (A4625) contains the following:

1) 1 plastic tray, 6) 1 pre-cut tracheostomy dressing,  
2) 1 basin, 7) 1 roll of gauze,  
3) 1 pair of sterile gloves, 8) 4 x 4 sponges,  
4) tube brush, 9) 2 cotton tip applicators,  
5) 3 pipe cleaners, 10) 30 inches twill tape.

A tracheostomy care kit for an established tracheostomy (A4629) contains the following:

1) 1 tube brush,  
2) 2 pipe cleaners,  
3) 2 cotton tip applicators,  
4) 30" twill tape, and  
5) 2 x 4 sponge

Coverage and payment rules

A tracheostomy care kit is covered for a patient following an open surgical tracheostomy which has been open or is expected to remain open for at least three months.

A tracheostomy care or cleaning starter kit (A4625) is covered for the first two weeks following an open surgical tracheostomy. Beginning two weeks postoperatively, HCPCS code A4625 is no longer medically necessary and, if that HCPCS code is billed, payment is based on the least costly alternative, HCPCS code A4629.

One tracheostomy care kit (A4625, A4629) per day is considered necessary for routine care of a tracheostomy. Claims for additional kits for non-routine tracheostomy care must be accompanied by substantiating documentation.

For information on tracheal suction catheters and related supplies, see the Suction Pump policy.

Coding guidelines

A Column II HCPCS code is included in the allowance for the corresponding Column I HCPCS code when provided at the same time.

<table>
<thead>
<tr>
<th>Column I</th>
<th>Column II</th>
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<tbody>
<tr>
<td>A4625</td>
<td>A4626</td>
</tr>
<tr>
<td>A4629</td>
<td>A4626</td>
</tr>
</tbody>
</table>

Tracheostomy care kits provided in the first two postoperative weeks should be coded as A4625. Tracheostomy care kits provided after the first two postoperative weeks should be coded as A4629.

Documentation

An order for tracheostomy care supplies, which is signed and dated by the ordering physician, must be kept on file by the supplier. The physician's records must contain information which supports the medical necessity of the item ordered.
**Tracheostomy Care Supplies Medical Policy**
*(continued)*

When billing for more than one tracheostomy care kit (A4625, A4629) per day, documentation must be submitted with the claim explaining the medical necessity for the greater amount.

See the DMEPOS Supplier Manual for more information on orders, medical records and supplier documentation.

**Effective date**

Claims with dates of service on or after November 1, 1996.

This is a revision to a previously published policy.

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**Home Blood Glucose Monitors Medical Policy**

**Subject: Home blood glucose monitors**

**HCPCS codes**

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

- E0607–Home blood glucose monitor
- E0609–Blood glucose monitor with special features (e.g. voice synthesizers, automatic timers, etc.)
- A4244–Alcohol or peroxide, per pint
- A4245–Alcohol wipes, per box
- A4246–Betadine or pHisoHex solution, per pint
- A4247–Betadine or iodine swabs/wipes, per box
- A4250–Urine test or reagent strips or tablets (100 tablets or strips)
- A4253–Blood glucose test or reagent strips for home blood glucose monitor, per 50 strips
- A4254–Replacement battery, any type, for use with medically necessary home blood glucose monitor owned by patient, each
- A4256–Normal, low and high calibrator solution/chips
- A4258–Spring-powered device for lancet, each
- A4259–Lancets, per box of 100
- A9270–Non-covered item or service
- XX003–Platforms for home blood glucose monitor, 50 per box

**HCPCS modifiers**

ZX – Specific requirements found in the Documentation section of the medical policy have been met, and evidence of this is available in the supplier's records.

**Benefit category**

Durable Medical Equipment
HOME BLOOD GLUCOSE MONITORS MEDICAL POLICY
(continued)

Reference

Coverage Issues Manual 60-11

Definition

Insulin-treated means the patient is receiving insulin injections to treat their diabetes. Insulin does not exist in an oral form and therefore patients taking oral medication to treat their diabetes are NOT insulin-treated.

Coverage and payment rules

Home blood glucose monitors are covered for patients who are insulin-treated diabetics and who can better control their blood glucose levels by frequently checking these levels and appropriately contacting their attending physician for advice and treatment.

A blood glucose monitor with special features is covered for patients who additionally have severe visual impairment (20/200).

Coverage of home blood glucose monitors is limited to patients meeting the following conditions:

1. The patient must be an insulin-treated diabetic,
2. The patient’s physician states the patient is capable of being trained to use the particular device prescribed in an appropriate manner. In some cases, the patient may not be able to perform this function, but a responsible individual can be trained to use the equipment and monitor the patient to assure the intended effect is achieved. This is permissible if the record is properly documented by the patient’s physician, and
3. The device is designed for home rather than clinical use.

Blood glucose monitors with features such as voice synthesizers, automatic timers and specially designed arrangements of supplies and materials to enable the visually-impaired to use the equipment without assistance (E0609) are covered when the following conditions are met:

1. The patient and device meet the three conditions listed above for coverage of standard home blood glucose monitors, and
2. The patient’s physician certifies he or she has a visual impairment severe enough to require use of this special monitoring system.

Lancets (A4259) and blood glucose test, reagent strips (A4253) and spring powered device for lancets (A4258) are covered for patients for whom the glucose monitor is covered. More than one spring powered device (A4258) per 6 months will rarely be medically necessary. More than 100 test strips (A4253) and 100 lancets (A4259) per month will rarely be medically necessary. The need for more than these amounts should be documented in the physician's record and noted on the order kept on file by the supplier.

Alcohol or peroxide (A4244, A4245) and Betadine or pHisoHex (A4246, A4247) are non-covered since these items are not required for the proper functioning of the device.

Urine test reagent strips or tablets (A4250) are non-covered since they are not related to this equipment.

Glucose monitors and related supplies billed without a ZX modifier (see Documentation section) will be denied as not medically necessary.
HOME BLOOD GLUCOSE MONITORS MEDICAL POLICY
(continued)

Coding guidelines

HCPCS codes A4254 and A4258 are valid only for dates of service on or after January 1, 1996.

Blood glucose test or reagent strips that utilize a visual reading and are not used in a glucose monitor should be coded A9270. Do not use HCPCS code A4253 for these items.

Documentation

An order for the billed equipment/supplies which has been signed and dated by the ordering physician must be kept on file by the supplier. The physician’s order must include a statement indicating whether the patient is a diabetic and whether the patient is being treated with insulin injections. If the order indicates the patient is diabetic and is being treated with insulin injections, the ZX modifier should be added to the HCPCS code for the monitor, and each related supply on every claim submitted. The ZX modifier may only be used when these requirements are met.

In addition, the medical necessity for E0609 must be documented by a narrative statement from the physician which includes the patient’s visual acuity. If the claim is filed hard-copy, this could be noted in field 21 of the HCFA 1500 claim form or as a separate attachment. If the claim is filed electronically, it could be transcribed into the HAØ record.

When billing for quantities of supplies greater than those described as the usual replacement frequency (e.g. more than 100 test strips or lancets per month), the claim must include documentation supporting the medical necessity for the higher utilization. This information should be attached to a hard-copy claim or entered in the HAØ record of an electronic claim.

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

Effective date

Claims with dates of service on or after November 1, 1996.

This is a revision to a previously published policy.

TENS MEDICAL POLICY

Subject: Transcutaneous electrical nerve stimulators

HCPCS codes

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

- E0720–TENS, two lead, localized stimulation
- E0730–TENS, four lead, larger area/multiple nerve stimulation
- E0731–Form fitting conductive garment for delivery of TENS or NMES (with conductive fibers separated from the patient’s skin by layers of fabric)
- A4556–Electrodes (e.g. apnea monitor)
- A4557–Lead wires (e.g. apnea monitor)
- A4558–Conductive paste or gel
**TENS Medical Policy**

*continued*

A4595—TENS supplies, 2 lead, per month
A4630—Replacement batteries, medically necessary TENS owned by patient

**Benefit Category**

Durable Medical Equipment

**References**

Coverage Issues Manual 35-46, 45-19, 45-25, 60-20

**Definition**

A Transcutaneous Electrical Nerve Stimulator (TENS) (E0720, E0730) is a device which utilizes electrical current delivered through electrodes placed on the surface of the skin to decrease the patient's perception of pain by inhibiting the transmission of afferent pain nerve impulses and/or stimulating the release of endorphins. A TENS unit must be distinguished from other electrical stimulators (e.g., neuromuscular stimulators) which are used to directly stimulate muscles and/or motor nerves. A TENS supply allowance (A4595) includes electrodes (any type), conductive paste or gel (if needed, depending on the type of electrode), tape or other adhesive (if needed, depending on the type of electrode), adhesive remover, skin preparation materials, batteries (9 volt or AA, single use or rechargeable) and a battery charger (if rechargeable batteries are used).

**Coverage and Payment Rules**

A Transcutaneous Electrical Nerve Stimulator (TENS) is covered for the treatment of patients with chronic, intractable pain or acute postoperative pain who meet the coverage rules listed below.

When a TENS unit is used for acute postoperative pain, the medical necessity is usually limited to 30 days from the day of surgery. Payment for more than one month is determined by individual consideration based upon supportive documentation provided by the attending physician. Payment will be made only as a rental. A TENS unit will be denied as not medically necessary for acute pain (less than three months duration) other than postoperative pain.

For chronic pain, the medical record must document the location of the pain, the duration of time the patient has had the pain and the presumed etiology of the pain. The pain must have been present for at least three months. Other appropriate treatment modalities must have been tried and failed, and the medical record must document what treatment modalities have been used (including the names and dosage of medication), the length of time each type of treatment was used and the results.

The presumed etiology of the pain must be a type that is accepted as responding to TENS therapy. Examples of conditions for which a TENS unit are not considered to be medically necessary are (not all-inclusive): headache, visceral abdominal pain, pelvic pain and temporomandibular joint (TMJ) pain.

When used for the treatment of chronic, intractable pain, the TENS unit must be used by the patient on a trial basis for a minimum of one month (30 days), but not to exceed two months. The trial period will be paid as a rental. The trial period must be monitored by the physician to determine the effectiveness of the TENS unit in modulating the pain. For coverage of a purchase, the physician must determine that the patient is likely to derive significant therapeutic benefit from continuous use of the unit over a long period of time. The physician's records must document a reevaluation of the patient at the end of the trial period, must indicate how often the patient used the TENS unit, the typical duration of use each time and the results.
TENS MEDICAL POLICY
(continued)

A 4 lead TENS unit may be used with either 2 leads or 4 leads, depending on the characteristics of the patient's pain. If it is ordered for use with 4 leads, the medical record must document why 2 leads are insufficient to meet the patient's needs.

During the rental of a TENS unit, supplies for the unit are included in the rental allowance; there is no additional allowance for electrodes, lead wires, batteries, etc. If a TENS unit (E0720, E0730) is purchased, the allowance includes lead wires and one month's supply of electrodes, conductive paste or gel (if needed) and batteries.

Separate allowance will be made for replacement supplies when they are medically necessary and are used with a TENS unit that has been purchased and/or approved by Medicare. If 2 TENS leads are medically necessary, then a maximum of one unit of HCPCS code A4595 would be allowed per month; if 4 TENS leads are necessary, a maximum of two units per month would be allowed. If the use of the TENS unit is less than daily, the frequency of billing for the TENS supply HCPCS code should be reduced proportionally.

There should be no billing and there will be no separate allowance for replacement electrodes (A4556), conductive paste or gel (A4558), replacement batteries (A4630) or a battery charger used with a TENS unit.

Replacement of lead wires (A4557) will be covered when they are inoperative due to damage and the TENS unit is still medically necessary. Replacement more often than every 12 months would rarely be medically necessary.

Other supplies, including but not limited to the following, will not be separately allowed: adapters (snap, banana, alligator, tab, button, clip), belt clips, adhesive remover, additional connecting cable for lead wires, carrying pouch, or covers.

A conductive garment (E0731) used with a TENS unit is rarely medically necessary, but may be covered if all of the following conditions are met:

1. it has been prescribed by a physician for use in delivering covered TENS treatment, and
2. one of the medical indications outlined below is met:
   a) the patient cannot manage without the conductive garment because there is such a large area or so many sites to be stimulated and the stimulation would have to be delivered so frequently that it is not feasible to use conventional electrodes, adhesive tapes and lead wires,
   b) the patient cannot manage without the conductive garment for the treatment of chronic intractable pain because the areas or sites to be stimulated are inaccessible with the use of conventional electrodes, adhesive tapes and lead wires,
   c) the patient has a documented medical condition, such as skin problems, that preclude the application of conventional electrodes, adhesive tapes and lead wires, or
   d) the patient requires electrical stimulation beneath a cast to treat chronic intractable pain.

A conductive garment is not covered for use with a TENS device during the trial period unless:

1. the patient has a documented skin problem prior to the start of the trial period, and
2. the item is medically necessary for the patient.

The physician ordering the TENS unit must be the attending physician or a consulting physician for the disease or condition resulting in the need for the TENS unit.
TENS MEDICAL POLICY
(continued)

Coding guidelines

HCPCS codes A4556, A4558 and A4630 are not valid for supplies used with a TENS unit; A4595 should be used instead.

A4595 is valid only for dates of service on or after January 1, 1996.

For HCPCS code A4557, one unit of service is for lead wires going to two electrodes. If all the lead wires of a 4 lead TENS unit needed to be replaced, billing would be for two units of service.

Documentation

An order for the TENS unit and related supplies, which has been signed and dated by the ordering physician, and a Certificate of Medical Necessity (CMN), which has been completed, signed and dated by the ordering physician, must be kept on file by the supplier. The CMN for TENS is HCFA form 848. The written order for a TENS unit must be obtained prior to delivery.

The claim for the first month's rental 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 the DMEPOS National Standard Format Matrix for details.) If additional medical necessity information is included, it would be transcribed into the HAØ record.

Purchase (not rental) of a TENS unit may be prior authorized. (See Prior Authorization section for more information.) In order to obtain Prior Authorization, a copy of the CMN, which has been completed, signed and dated by the ordering physician, must be sent to the DMERC on hard-copy.

If purchase of a TENS unit has been prior authorized, the claim does not have to include a copy of the CMN. If prior authorization has not been obtained, the claim for the purchase of a TENS unit must include a copy of a new, initial CMN, if filed hard-copy, or transmission of the CMN, if filed electronically.

A claim for HCPCS code E0731 must be accompanied by the brand name and model number of the conductive garment and a detailed statement justifying the medical necessity of the garment for the patient.

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

Effective date

Claims with dates of service on or after November 1, 1996.

This is a revision to a previously published policy.
EXTERNAL BREAST PROSTHESES MEDICAL POLICY

Subject: External breast prostheses

HCPCS codes

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

- L8000–Breast prosthesis, mastectomy bra
- L8010–Breast prosthesis, mastectomy sleeve
- L8020–Breast prosthesis, mastectomy form
- L8030–Breast prosthesis, silicone or equal
- K0400–Adhesive skin support attachment for use with an external breast prosthesis, each

Benefit category

Prosthetic Device

Coverage and payment rules

A breast prosthesis is covered for a patient who has had a mastectomy.

A mastectomy sleeve (L8010) is denied as non-covered, since it does not meet the definition of a prosthesis.

Coding guidelines

The right (RT) and left (LT) modifiers should be used with these HCPCS codes. When the same HCPCS code for two breast prostheses are billed for both breasts on the same date, the items (RT and LT) should be entered on the same line of the claim form using the RTLT modifier and two units of service.

K0400 is valid for dates of service on or after October 1, 1995.

Documentation

An order for the breast prosthesis, which shows the type of prosthesis, and which is signed and dated by the ordering physician, must be kept on file by the supplier.

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

Effective date

Claims with dates of service on or after November 1, 1996.

This is a revision to a previously published policy.