NEBULIZER MEDICAL POLICY
(continued)

at the higher allowance, whereas the other drug(s) (i.e., those billed with the KQ modifier) will be reimbursed at the same allowance as the concentrate. (See Coding Guidelines section for explanation of the KO, KP, and KQ modifiers).

A monthly dispensing fee (Q0132) for each covered drug or combination of drugs used in a nebulizer will be paid in addition to payment for the drug or drugs. This dispensing fee will be based on the drug dispensed, and not on the number of unit dose vials dispensed. Also, if two or more drugs are combined in single unit dose vials only one dispensing fee will be paid per drug combination per month. The dispensing fee(s) must be billed on the same claim as the dispensed inhalation drug(s).

Charges for the drugs, diluent, and dispensing fees may only be billed by the entity that actually dispenses the drug to the Medicare beneficiary and that entity must be permitted under all applicable federal, state, and local laws and regulations to dispense drugs. Only pharmacies licensed in the state where they are physically located may bill the DMERC for nebulizer drugs with a date of service on or after December 1, 1996.

Aerosol compressors and ultrasonic generators will be grandfathered according to the provisions of the general DMERC Grandfathering policy, Sections A and B if the approval did not conflict with national Medicare policy. In addition, equipment which was approved by the DMERC before the effective date of the policy will be handled similarly. Accessories, supplies, and drugs will be covered if the equipment had been approved by the local carrier or the DMERC and the approval did not conflict with national policy. However, even though coverage is continued, the frequency parameters listed in the policy will be applied. Also, coding for inhalation drugs and resulting reimbursement will be according to the DMERC policy.

Coding guidelines

The billing unit for most inhalation drugs is per milligram (mg.) of the drug dispensed. The billing unit of K0511, K0523 and K0524 is per 10 milligrams (10 mg) of the drug dispensed. The billing unit of K0503 is per gram (gm.) of the drug dispensed. The billing unit of J2545 is per 300 milligrams (300 mg) of the drug dispensed.

When inhalation drugs are dispensed as a single drug formulation, the coding of a unit dose form or a concentrated form (see Definitions section) is determined by the formulation of the drug as it is dispensed to the patient. If a pharmacist takes a concentrated form of a single inhalation drug (e.g., 0.5% albuterol) and dilutes it to a ready-to-use concentration (e.g., 0.083% albuterol) which is then dispensed to the patient in single-dose bottles/ vials/ ampules, the inhalation solution is billed as the unit dose form, not the concentrated form.

When there is a single drug in a unit dose container, the KO modifier is added to the unit dose form code. When two or more drugs are combined by a pharmacist and dispensed to the patient in the same unit dose container, all of the drugs are billed using the unit dose form code. However, the KP modifier is added to only one of the unit dose form codes and the KQ modifier is added to the other unit dose code(s). When two or more drugs are combined, the use of the KP and KQ modifiers should result in a combination that yields the lower cost to the beneficiary.

Whenever a unit dose form code is billed, it must have either a KO, KP or KQ modifier. If a unit dose code does not have one of these modifiers, it will be denied as an invalid code. The KO, KP and KQ modifiers are not used with the concentrated form codes.

The concentration of the drug in the dispensed solution can be converted to mg or gm as follows: A solution with a labeled concentration of 1% has ten (10) mg of drug in each milliliter (ml) of solution. Therefore, a 0.083% albuterol solution has 0.83 mg of albuterol in each ml of solution. Since albuterol 0.083% solution typically comes in a 3 ml vial/ ampule, each vial/ ampule contains 2.5 mg of albuterol (3 x .83 = 2.5). If a supplier provides 120 ampules of 0.083% albuterol solution each


**Nebulizer Medical Policy**

(continued)

containing 3 ml, the billed units of service would be 300 (2.5 x 120) units (1 unit = 1 mg) of code K0505K0. One unit of Q0132 would be billed, which would represent the dispensing fee for the albuterol for the entire month.

When billing unit dose solutions which combine two or more drugs in a single container, each drug must be listed on a separate claim line. For example, if a supplier provides 120 ampules of a solution containing a combination of 2.5 mg of albuterol and 20 mg of cromolyn in each 3 ml ampule, the supplier would bill K0505KQ 300 units for the albuterol (2.5 mg x 120 doses = 300) (1 unit = 1 mg) and K0511KP (unit dose cromolyn) 240 units (20 mg/amp ÷ 10 mg/unit x 120 = 240) (1 unit = 10 mg) for the cromolyn. One unit of Q0132 would be billed which represents the dispensing fee for the combined solution for the entire month. There should be no separate billing for saline diluent.

Suppliers should note that the correct concentration figure must be used to determine the number of mg of drug dispensed. For example, if a pharmacist takes 0.5 ml of a concentrated 0.5% albuterol solution and dilutes it with 2.5 ml of saline to give a 3 ml unit dose solution which is dispensed to the patient, each vial contains 2.5 mg of albuterol (0.5 ml x 5.0 mg/ml = 2.5 mg), not 15 mg (3 x 5.0).

When a drug is provided in a concentration which is dilute enough that it may be administered to a patient without adding any separate diluent in a multidose container, use code J7699.

Code J7699 is also used for an inhalation drug administered by a nebulizer which does not have a valid specific J or K code. If two or more drugs are combined in the same unit dose container, bill specific J or K codes when possible and J7699 only for individual drugs which do not have a specific J or K code. Claims for drugs that are incorrectly coded J7699 instead of the appropriate specific J or K codes will be denied for invalid coding.

Code E0585 is used when a heavy duty aerosol compressor (E0565), durable bottle type large volume nebulizer (K0530), and immersion heater (E1372) are provided at the same time. If all three items are not provided initially, the separate codes for the components would be used for billing. Code K0530 is billed for a durable, bottle type nebulizer when it is used with a K0269 compressor or a separately billed E0565 compressor. Code K0530 would not be separately billed when an E0585 system was also being billed. Code E0580 (Nebulizer, durable, glass or autoclavable plastic, bottle type, for use with regulator or flow meter) describes the same piece of equipment as K0530, but should only be billed when this type of nebulizer is used with a beneficiary-owned oxygen system.

Codes K0503 - K0529 are valid for dates of service on or after 4/1/97. Codes J7610 - J7675, describing drugs used in nebulizers, are valid for dates of service prior to 4/1/97.

Codes K0269, K0501 and K0530 are valid for dates of service on or after 4/1/97.

Code E1375 (Nebulizer, portable with small compressor, with limited flow) is not valid for claim submission to the DMERC. Use code E0570 or K0501 instead.

Code A4323 (Sterile saline irrigation solution, 1000 ml) is not valid for saline solutions used with nebulizers.

Code XX001 (Sterile saline) should not be billed to the DMERC; use code J7051 instead.

**Documentation**

An order for all equipment, accessories, drugs, and other supplies related to nebulizer therapy must be signed and dated by the ordering physician and kept on file by the supplier. The order for any drug must clearly specify the type of solution to be dispensed to the patient and the administration instructions for that solution. The type of solution is described by a combination of (a) the name of the drug and the concentration of the drug in the dispensed solution and the volume of solution in each
**NEBULIZER MEDICAL POLICY**  
(continued)

container, or (b) the name of the drug and the number of milligrams/grams of drug in the dispensed solution and the volume of solution in that container. Examples of (a) would be: albuterol 0.083% 3 ml; or albuterol 0.5% 20 ml; or cromolyn 20 mg/2 ml. Examples of (b) would be: albuterol 1.25 mg in 3 ml saline; or albuterol 2.5 mg and cromolyn 20 mg in 3 ml saline. Administration instructions must specify the amount of solution and frequency of use. Examples would be: 3 ml qid and prn - max 6 doses/24 hr; or one ampule q 4 hr prn; or 0.5 ml diluted with saline to 3.0 ml tid and prn. A new order is required if there is a change in the type of solution dispensed or the administration instructions. For all inhalation drugs, a new order is required at least every 12 months even if the prescription has not changed.

A narrative diagnosis and/or an ICD-9 diagnosis code describing the condition must be present on each order. An ICD-9 code describing the condition which necessitates nebulizer therapy must be included on each claim for equipment, accessories, and/or drugs.

The patient's medical record must contain information which supports the medical necessity for all equipment, accessories, drugs, and other supplies that are ordered. Except for the situations described below, this information does not have to be submitted with the claim but should be available to the DMERC on request.

Claims for K0501 must be accompanied by documentation of the need for the battery feature.

When billing for quantities of nebulized inhalation drugs or nebulizer accessories and supplies greater than those described in the policy as the usual maximum amounts, each claim must be accompanied by a copy of the prescription(s) and physician documentation supporting the medical necessity for the higher utilization.

When billing for nebulized inhalation drugs or nebulizer accessories and the related compressor/generator is not billed on the same claim, indicate on the claim the HCPCS code of the compressor/generator with which the drugs or accessories are used.

If more than one beta-adrenergic or more than one anticholinergic inhalation drug are billed during the same month, each claim must be accompanied by a copy of the prescription(s) and physician documentation supporting the medical necessity of concurrent use.

When code E1399 is billed for miscellaneous equipment or accessories, the claim must be accompanied by a clear description of the item including the manufacturer, the model name/number if applicable, and the medical necessity of the item for that patient. When code J7699 is billed for miscellaneous inhalation drugs, the claim must be accompanied by the detailed order information described above, a clear statement of the number of ampules/bottles of solution dispensed and documentation of the medical necessity of the drug for that patient.

In all of the situations listed above, the documentation should be attached to each hard copy claim (as when physician documentation is required) or entered in the HA0 record of each electronic claim.

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

**Effective date**

For claims with dates of service on or after April 1, 1997.
INTERIM POLICY FOR COLD THERAPY INTRODUCED

A new HCPCS code, E0218—water circulating cold pad with pump, is effective for dates of service on or after January 1, 1997. This code is used for equipment which has an electric pump.

A device in which ice water is put in a reservoir and then circulated through a pad by means of gravity is not considered durable medical equipment. It should be coded HCPCS A9270 and will be denied as a noncovered item.

A interim policy for these devices, which will be effective for claims with dates of service on or after April 1, 1997, is printed on the following page. The policy is based on a determination by the DMERCs that the medical necessity of an E0218 device rather than use of ice packs or other non-DME coded modalities has not been established. The DMERCs invite comments on this proposed policy. Comments to the Region C DMERC should be submitted no later than March 1, 1997, to: Paul Metzger, M.D., Medical Director, Region C DMERC, Palmetto GBA, PO Box 100141, Columbia SC 29202-3141. If you disagree with the policy, you should offer an alternative position, provide a clinical rationale for your position and, if possible, include references from standard textbooks and/or peer-reviewed journals. We would also encourage a written response if you agree with the policy. If, based on comments received, the DMERCs decide to revise this policy, the revision will be published in a future DMERC Medicare Advisory.

HCPCS code E0218 is in the capped rental payment category. Until the policy which follows becomes effective, when HCPCS code E0218 is billed, the claim for the first month’s rental must be accompanied by documentation of medical necessity. This documentation should include, but is not limited to:

♦ the diagnosis for the condition requiring use of the cold therapy pump,
♦ the area to which the pad is applied, and
♦ the type and date of surgery, if applicable.

If the pump is provided for more than one month, (that is, if a subsequent month’s claim is billed), the claim must be accompanied by a detailed explanation of the extended use of the device. Documentation should be put in the HAO record of an electronic claim or attached to a paper claim.
INTERIM MEDICAL POLICY RELEASED

Subject: Cold therapy

HCPCS codes

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

E0218—Water circulating cold pad with pump
A9270—Noncovered item or service

Benefit category

Durable Medical Equipment

Definition

Code E0218 describes a device which has an electric pump that circulates cold water through a pad.

Coverage and payment rules

A water circulating cold pad with pump (E0218) will be denied as not medically necessary. Other non-DME cooling devices (see Coding guidelines) will be denied as noncovered.

Coding guidelines

A device in which ice water is put in a reservoir and then circulated through a pad by means of gravity is not considered durable medical equipment (DME). Other devices (not all-inclusive) which are also not considered to be DME are: single use packs which generate cold temperature by a chemical reaction; packs which contain gel or other material which can be repeatedly frozen; simple containers into which ice water can be placed. All of these types of devices must be coded A9270 if claims are submitted to the DMERC.

A supplier wanting a coding determination for a particular product should contact the SADMERC.

Documentation

An order for the device which is signed and dated by the ordering physician must be kept on file by the supplier.

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

Effective date

Claims with dates of service on or after April 1, 1997.

MEDICAL POLICY REVISIONS

Revisions to the following medical DMERC Medical Policies are found in the enclosed December 1996 DMEPOS Supplier Manual Revisions. Replace these updated medical policies in your DMEPOS Supplier Manual using the instructions provided with the revision.

- Lower limb protheses
- Ostomy supplies
- Surgical dressings
Hip abduction devices used to treat contractures in adults are correctly billed using HCPCS code L2999. Unlisted procedures for lower extremity orthosis. These items typically consist of cuffs which are placed around each thigh and are connected by a device which can be adjusted to vary the distance between the two cuffs. Examples (not all inclusive) of this type device are: Comfy Hip and Knee Abductor Orthosis (Lenjoy Engineering); Hip and Knee Abductor (Restorative Care of America); Oscar HKO (Orthosis Corrective Systems); Safe Hip Abductor System (Restorative Medical); Therapy Concepts Hip-Knee-Orthosis (Therapy Concepts); Vari-Duct Hip and Knee Orthosis (Orthotic Rehab). **Other specific L HCPCS codes must not be used at this time for these devices.** Claims for these devices must be accompanied by the manufacturer's name and brand name of the product. The DMERC has determined that the medical necessity of this type device has not been established and, therefore, claims for these items will be denied.

Devices which consist of a set of cushioned plastic pads which are designed to protect the hip from fracture in the event of a fall are **not** considered orthoses/braces. These items are correctly coded with code A9270, Noncovered item or service, and will be denied. An example (not all-inclusive) of this type device is Hipguard (Othoquest).

Coding questions concerning other devices should be referred to the Statistical Analysis DMERC (SADMERC).

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Seating systems

A recent HCFA ruling has clarified the distinction between orthotics and durable medical equipment under Medicare Part B. This is particularly important in the area of seating systems where some suppliers have claimed that certain support or positioning components of wheelchairs or other seating systems are orthoses rather than durable medical equipment. The distinction impacts payment for items provided to patients in nursing facilities in which orthoses are covered but durable medical equipment is not covered under Medicare Part B.

The ruling says that the orthotics benefit in section 1861 (s)(9) of the Act, in so far as braces are concerned, is limited to leg, arm, back, and neck braces that are used independently rather than in conjunction with, or as components of other medical or non-medical equipment. It also clarifies that accessories used in conjunction with, and necessary for the full functioning of, durable medical equipment fall under the durable medical equipment benefits category.

Suppliers must not use L codes, other than L3964-L3974, to bill for items that are components of, or used in conjunction with, wheelchairs or other seating systems. These items are billed using K HCPCS codes for wheelchair options or accessories or using HCPCS codes K0114-K0116. Specific coding questions should be directed to the Statistical Analysis DMERC (SADMERC).

Codes K0114 and L3964-3974 are considered durable medical equipment. Effective with dates of services on or after January 1, 1997, an NU, RR or UE modifier must be added to the codes, as appropriate.
National Medicare policy (Coverage Issues Manual 60-17) covers use of Continuous Positive Airway Pressure (CPAP) for obstructive sleep apnea (OSA). There is no coverage in national policy, nor in the regional DMERC policy, for the use of CPAP for central sleep apnea (CSA). In OSA, the sleeping patient's normal attempts at inspiration are anatomically obstructed by the posterior soft palate at the level of the upper airway. CSA involves the patient's failure, during sleep, to even attempt inspiration because of other underlying cardiopulmonary or neurological conditions. Because OSA does not involve lapses in respirations, per se, there is no need for timed, mechanically produced inspirations (also known as intermittent mandatory ventilation, or a "back-up" ventilatory rate), as is found on a true ventilator.

If a patient has OSA, as diagnosed according to the criteria in DMERC regional policy, a CPAP device may be used and billed to the DMERC. However, if OSA is the condition being treated, there is no reason to use or bill a therapeutic ventilator, even one which is suitable for use 12 hours or less per day (HCPCS code E0453).

If HCPCS code E0453 is submitted to the DMERC there must be a statement on the claim declaring "This item is being issued for the treatment of a condition other than obstructive sleep apnea." If this statement is not included on claims received on or after January 15, 1997, claims for HCPCS code E0453 will be denied for lack of medical necessity documentation.

The DMERC revised RMRP for Lower Limb Prostheses which became effective on December 1, 1995, indicated which knee HCPCS codes were covered for patients with a Level 3 functional status or above.

HCPCS codes L5611 and L5616 were included in that list of codes. Since these are both friction control knees and do not offer variable cadence comfortably, these codes will now be covered for patients with functional Level 1 or above.

The policy section on knees has been revised and applies to claims with dates of service on or after January 1, 1997, and reads as follows:

A determination of the type of knee for the prosthesis will be made by the prescribing physician and/or the prosthetist, based upon the functional needs of the patient. Basic lower extremity prostheses include a single axis, constant friction knee. Prosthetic knees are considered for coverage based upon functional classification.

Fluid and pneumatic knees (HCPCS codes L5610, L5613, L5614, L5722-L5780, L5822-L5840) are covered for patients with a functional Level 3 or above.

Other knee systems (HCPCS codes L5611, L5616, L5710-L5718, L5810-L5818) are covered for patients with a functional Level 1 or above.

Coverage is extended only if there is sufficient clinical documentation or functional need for the technologic design feature of a given type of knee. This information must be retained in the physician's or prosthetist's files.