

# Equipment Suppliers to Face Big Changes Next Year

BY ALICIA AULT

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Starting in April 2008, retailers and suppliers in 10 metropolitan areas that sell certain durable medical equipment will have to become accredited and enter a competitive bidding process, according to a final rule issued by the Centers for Medicare and Medicaid Services.

Unlike other entities, physicians may opt out of competitive bidding and accreditation, but they will still have to accept a single payment for the durable medical equipment (DME) item instead of a fee schedule-based payment, Acting CMS Administrator Leslie Norwalk said in a briefing with reporters.

The new competitive bidding program was developed to reduce Medicare's substantial DME expenditures and to decrease the out-of-pocket burden for beneficiaries, who are liable for copayments of 20%.

"The final rule we are announcing today is focused on improving both service delivery and the quality of care, while getting savings for beneficiaries and taxpayers," Ms. Norwalk said in a statement.

She estimated that Medicare could shave

\$1 billion a year off its DME tab by the time the program is fully implemented in 2010.

The final rule will apply initially only to 10 categories of supplies and only to suppliers in 10 competitive bidding areas (CBA) that have been established by CMS. Physicians, hospitals, and other entities that sell DME, prosthetics, orthotics, and certain other supplies will be required to submit bids to CMS proposing charges for the items.

Bidding will probably be open until late June. CMS will evaluate the bids and then, probably in December, the agency will award contracts to a certain number of bidders in each CBA, Ms. Norwalk said in the briefing.

Beginning in April 2008, Medicare will pay a single amount for each item in those areas instead of basing payments on a fee schedule, as it has in the past.

CMS will expand the program to 70 bidding areas in 2009, and to more CBAs, and to cover more DME items after that, Ms. Norwalk said.

The new process was required by the Medicare Prescription Drug Improvement and Modernization Act of 2003. CMS outlined its intentions in a proposed rule in August 2006. It also gathered data from

two pilot studies that ran from 1999 to 2002 in San Antonio and in Polk County, Fla., Ms. Norwalk said. After incorporating public comments and experience from the pilot, CMS published the final rule in the Federal Register.

Suppliers in the following 10 areas will be the first subject to the new requirements: Charlotte-Gastonia-Concord, N.C./S.C.; Cincinnati-Middletown, Ohio/Ky./Ind.; Cleveland-Elyria-Mentor, Ohio; Dallas-Fort Worth-Arlington, Tex.; Kansas City, Mo./Kans.; Miami-Fort Lauderdale-Miami Beach, Fla.; Orlando-Kissimmee, Fla.; Pittsburgh; Riverside-San Bernardino-Ontario, Calif.; and San Juan-Caguas-Guaynabo, Puerto Rico.

The locations were selected because they are 10 of the largest Metropolitan Statistical Areas in the United States and because each area had high costs and/or high utilization of DME items in the 10 focus categories. Although New York, Los Angeles, and Chicago are among the largest Metropolitan Statistical Areas and have high costs and utilization, CMS decided to exclude those areas initially to simplify the process, Ms. Norwalk said.

The 10 categories include: oxygen supplies and equipment; standard power wheelchairs, scooters, and accessories; complex rehabilitative power wheelchairs and accessories; mail-order diabetes supplies; enteral nutrients, equipment, and supplies; continuous positive airway pressure (CPAP) devices; respiratory assist devices and supplies and accessories; hospital beds and accessories; negative pressure wound therapy pumps and supplies and accessories; walkers and related acces-

sories; and support surfaces (group 2 and 3 mattresses and overlays).

In most CBAs, only nine categories will be subject to bidding in 2008. All 10 will be covered in the Miami and the San Juan areas.

Since 60% of diabetic supplies are delivered through mail-order, CMS decided to require those suppliers to be subject to

**Medicare could cut \$1 billion per year from its DME bill by 2010, when the new competitive bidding program should be fully implemented.**

competitive bidding. Thus, patients with diabetes will continue to have the option of mail-order and it should be less costly, according to CMS. Payment for supplies obtained at a pharmacy or elsewhere will still be covered

under the old Medicare fee schedule, even in the 10 CBAs, the agency said.

Blood glucose monitors are not subject to competitive bidding.

To qualify to bid, suppliers have to be accredited by 1 of 10 agencies certified by CMS. Those include the Joint Commission on Accreditation of Healthcare Organizations, the Board of Orthotist/Prosthetist Certification, and the Accreditation Commission for Health Care Inc.

Generally, bidders also have to be in good standing with Medicare, have an active National Supplier Clearinghouse number, and agree to service an entire bidding area, regardless of where a beneficiary may be located.

Of the winning contract slots, 30% are set aside for small suppliers—those with gross revenue of \$3.5 million or less per year.

*A list of the accrediting bodies, bidding criteria, and other details can be found online at [www.cms.hhs.gov/CompetitiveAcqforDMEPOS](http://www.cms.hhs.gov/CompetitiveAcqforDMEPOS).*

## Rx Only

### Cloderm Cream, 0.1% (clocortolone pivalate)

FOR TOPICAL DERMATOLOGIC USE ONLY—NOT FOR OPHTHALMIC, ORAL, OR INTRAVAGINAL USE. WARNING: KEEP OUT OF REACH OF CHILDREN

#### DESCRIPTION:

Cloderm Cream 0.1% contains the medium potency topical corticosteroid, clocortolone pivalate, in a specially formulated water-washable emollient cream base consisting of purified water, white petrolatum, mineral oil, stearyl alcohol, polyoxyl 40 stearate, carbomer 934P, edetate disodium, sodium hydroxide, with methylparaben and propylparaben as preservatives.

Chemically, clocortolone pivalate is

9-chloro-6 $\alpha$ -fluoro-11 $\beta$ , 21-dihydroxy-16 $\alpha$ -methylpregna-1, 4-diene-3, 20-dione 21-pivalate.

Its structure is as follows:

#### CLINICAL PHARMACOLOGY:

Topical corticosteroids share anti-inflammatory, antipruritic and vasoconstrictive actions.

The mechanism of anti-inflammatory activity of the topical corticosteroids is unclear. Various laboratory methods, including vasoconstrictor assays, are used to compare and predict potencies and/or clinical efficacies of the topical corticosteroids. There is some evidence to suggest that a recognizable correlation exists between vasoconstrictor potency and therapeutic efficacy in man.

**Pharmacokinetics:** The extent of percutaneous absorption of topical corticosteroids is determined by many factors including the vehicle, the integrity of the epidermal barrier, and the use of occlusive dressings.

Topical corticosteroids can be absorbed from normal intact skin. Inflammation and/or other disease processes in the skin increase percutaneous absorption. Occlusive dressings substantially increase the percutaneous absorption of topical corticosteroids. Thus, occlusive dressings may be a valuable therapeutic adjunct for treatment of resistant dermatoses. (See **DOSE AND ADMINISTRATION**).

Once absorbed through the skin, topical corticosteroids are handled through pharmacokinetic pathways similar to systemically administered corticosteroids. Corticosteroids are bound to plasma proteins in varying degrees. Corticosteroids are metabolized primarily in the liver and are then excreted by the kidneys. Some of the topical corticosteroids and their metabolites are also excreted into the bile.

#### INDICATIONS AND USAGE:

Topical corticosteroids are indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

#### CONTRAINDICATIONS:

Topical corticosteroids are contraindicated in those patients with a history of hypersensitivity to any of the components of the preparation.

#### PRECAUTIONS:

**General:** Systemic absorption of topical corticosteroids has produced reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, manifestations of Cushing's syndrome, hyperglycemia, and glucosuria in some patients.

Conditions which augment systemic absorption include the application of the more potent steroids, use over large surface areas, prolonged use, and the addition of occlusive dressings.

Therefore, patients receiving a large dose of a potent topical steroid applied to a large surface area or under an occlusive dressing should be evaluated periodically for evidence of HPA axis suppression by using the urinary free cortisol and ACTH stimulation tests. If HPA axis suppression is noted, an attempt should be made to withdraw the drug, to reduce the frequency of application, or to substitute a less potent steroid.

Recovery of HPA axis function is generally prompt and complete upon discontinuation of the drug. Infrequently, signs and symptoms of steroid withdrawal may occur, requiring supplemental systemic corticosteroids.

Children may absorb proportionally larger amounts of topical corticosteroids and thus be more susceptible to systemic toxicity. (See **PRECAUTIONS—Pediatric Use**).

If irritation develops, topical corticosteroids should be discontinued and appropriate therapy instituted. In the presence of dermatological infections, the use of an appropriate antifungal or antibacterial agent should be instituted. If a favorable response does not occur promptly, the corticosteroid should be discontinued until the infection has been adequately controlled.

**Information for the Patient:** Patients using topical corticosteroids should receive the following information and instructions:

1. This medication is to be used as directed by the physician. It is for external use only. Avoid contact with the eyes.

2. Patients should be advised not to use this medication for any disorder other than for which it was prescribed.

3. The treated skin area should not be bandaged or otherwise covered or wrapped as to be occlusive unless directed by the physician.

4. Patients should report any signs of local adverse reactions especially under occlusive dressing.

5. Parents of pediatric patients should be advised not to use tight-fitting diapers or plastic pants on a child being treated in the diaper area, as these garments may constitute occlusive dressings.

**Laboratory Tests:** The following tests may be helpful in evaluating the HPA axis suppression:

Urinary free cortisol test

ACTH stimulation test

**Carcinogenesis, Mutagenesis, and Impairment of Fertility:** Long-term animal studies have not been performed to evaluate the carcinogenic potential or the effect on fertility of topical corticosteroids.

**Studies to determine mutagenicity with prednisolone and hydrocortisone have revealed negative results.**

**Pregnancy Category C:** Corticosteroids are generally teratogenic in laboratory animals when administered systemically at relatively low dosage levels. The more potent corticosteroids have been shown to be teratogenic after dermal application in laboratory animals. There are no adequate and well-controlled studies in pregnant women on teratogenic effects from topically applied corticosteroids. Therefore, topical corticosteroids should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Drugs of this class should not be used extensively on pregnant patients, in large amounts, or for prolonged periods of time.

**Nursing Mothers:** It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Systemically administered corticosteroids are secreted into breast milk in quantities not likely to have deleterious effect on the infant. Nevertheless, caution should be exercised when topical corticosteroids are administered to a nursing woman.

**Pediatric Use:** Pediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced HPA axis suppression and Cushing's syndrome than mature patients because of a larger skin surface area/body weight ratio.

Hypothalamic-pituitary-adrenal (HPA) axis suppression, Cushing's syndrome, and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children include linear growth retardation,

delayed weight gain, low plasma cortisol levels, and absence of response to ACTH stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilledema.

Administration of topical corticosteroids to children should be limited to the least amount compatible with an effective therapeutic regimen. Chronic corticosteroid therapy may interfere with the growth and development of children.

#### ADVERSE REACTIONS:

The following local adverse reactions are reported infrequently with topical corticosteroids, but may occur more frequently with the use of occlusive dressings. These reactions are listed in an approximate decreasing order of occurrence:

Burning  
Itching  
Irritation  
Dryness  
Folliculitis  
Hypertrichosis  
Acneiform eruptions  
Hypopigmentation  
Perioral dermatitis  
Allergic contact dermatitis  
Maceration of the skin  
Secondary infection  
Skin atrophy  
Striae  
Milium

#### OVERDOSAGE:

Topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects (see **PRECAUTIONS**).

#### DOSE AND ADMINISTRATION:

Apply Cloderm (clocortolone pivalate) Cream 0.1% sparingly to the affected areas three times a day and rub in gently.

Occlusive dressings may be used for the management of psoriasis or recalcitrant conditions.

If an infection develops, the use of occlusive dressings should be discontinued and appropriate antimicrobial therapy instituted.

#### HOW SUPPLIED:

Cloderm (clocortolone pivalate) Cream 0.1% is supplied in 15 gram, 45 gram and 90 gram tubes.

Store Cloderm Cream between 15° and 30° C (59° and 86° F). Avoid freezing.

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## Derms Fall Short When It Comes to Knowing Physician Extenders Scope

WASHINGTON — Dermatologists are not very knowledgeable about the training requirements and scope of practice of nurse-practitioners and physician assistants, according to a poster presented at the annual meeting of the American Academy of Dermatology.

The poster presented results of a survey given to 150 participants at a forum on physician extenders held at last year's annual AAD meeting. A total of 83 surveys (55%) were returned, according to Dr. Marianna Blyumin and her colleagues at Massachusetts General Hospital, Boston.

Forty percent of the respondents were female, 83% held a medical degree, and 82% were board-certified dermatologists. Almost all practiced in the United States.

Specifically, the survey questioned physicians about extenders' scope of practice, pay, how scope of practice is determined (by state or federal authorities), whether they practice independently of the physician, and how much training

was required for nurse-practitioners.

None of those polled answered all of the questions correctly; on average, 44% of answers were correct. Knowledge was not influenced by age, gender, board certification, practice location, or whether the respondent had worked with the non-physician practitioners in the past, according to the authors.

On average, physicians rated their past experiences with NPs as neutral and their experiences with PAs as positive.

Interestingly, more than 50% of the physicians said they viewed both NPs and PAs as potential partners in the future. A smaller number (20%-30%) said they viewed them as subordinates, and a few reported viewing extenders as potential competition.

Despite limited knowledge of these extenders currently, the larger view of them as future partners was encouraging, concluded the authors.

—Alicia Ault