

## POLICY & PRACTICE

### Steady Surgery Growth

Nearly 5 million skin surgery procedures were performed in the United States this year, with minimally invasive procedures fueling the steady growth since 2001, according to a survey from the American Society for Dermatologic Surgery (ASDS). The 4.8 million procedures in 2005 represent a 20% increase over 2003 and a 32% increase from 2001, ASDS said. Since 2003, some of the largest increases in minimally invasive procedures have been in dermal filler injections, laser and light treatment, nonablative skin rejuvenation, resurfacing, and botulinum toxin injections. "In-office, minimally invasive treatments are driving the growth of skin surgery, primarily because the procedures are very safe and require minimal recovery time," ASDS President Rhoda Narins, M.D., said in a statement. "As a result, more and more patients are willing to undergo convenient outpatient surgery for both medically necessary and cosmetic purposes." The survey is based on a random sample of 1,200 ASDS members. The data were then projected to reflect the procedures done by the entire membership for a single complete year.

### Alternative Medicine Centers

The National Center for Complementary

and Alternative Medicine (NCCAM) is funding five new research centers to study complementary and alternative approaches to HIV/AIDS, arthritis, asthma, and pain. Three of the new centers will focus on therapies used in traditional Chinese medicine, such as acupuncture and Chinese herbal mixtures. The other centers will study millimeter wave therapy—a type of energy medicine—and botanical therapies used by traditional healers in Africa. For example, NCCAM has awarded more than \$1 million in first-year funding to the Center for Mechanisms Underlying Millimeter Wave Therapy at Temple University in Philadelphia. Researchers there will examine the mechanisms of action of millimeter wave therapy for a variety of diseases and conditions, and will look at the therapy's use in animal models of pruritis and chronic neuropathic pain. NCCAM is part of the National Institutes of Health.

### The Research Pipeline

Drug researchers are currently developing 446 medicines aimed at the diseases that disproportionately affect women in the United States, according to a report from the Pharmaceutical Research and Manufacturers of America (PhRMA). Forty-seven medicines are in the pipeline

for autoimmune disorders, including 13 that are being developed for the treatment of psoriasis. These medicines are either in clinical trials or awaiting approval by the Food and Drug Administration. PhRMA estimates that autoimmune diseases collectively affect 23.5 million Americans, most of them women.

### HHS Mulls Investigation

The Department of Health and Human Services' Office of Inspector General is looking into the circumstances surrounding the resignation of former FDA Commissioner Lester M. Crawford, D.V.M., Ph.D., to determine if an investigation should be opened, an OIG spokeswoman said. In a response to a query from Rep. Maurice Hinchey (D-N.Y.), HHS Inspector General Daniel R. Levinson said that the OIG is doing an initial review of the facts, not an investigation in any regulatory sense, according to the spokeswoman. "After reviewing the facts, the OIG will determine if an investigation is formally launched," she said. "Dr. Crawford's departure, a mere 2 months after confirmation to his position, raises significant questions," Rep. Hinchey and several fellow members of Congress wrote in their request. Dr. Crawford had resigned his position after a 30-year career with the agency.

### Humana Settles Class Action Suit

Humana and representatives of more than 700,000 physicians settled a nationwide class action suit that had been pending in U.S. District Court for the Southern District of Florida for more than 6 years. The original lawsuit alleged a conspiracy between Humana and other HMOs against physicians, "to manipulate software to

cheat the doctor out of getting paid money due for services rendered," Archie Lamb, lead co-counsel for the physicians, said in an interview. Pursuant to the settlement, Humana has agreed to pay \$40 million to physicians, as well as modify its software system to make it more fair and efficient for physicians—changes worth more than \$75 million. "Humana should be commended for joining the growing list of health insurance companies that have settled with the nation's physicians," Mr. Lamb said. Those companies include Aetna, Cigna, Prudential, and HealthNet.

### Resident Work Hours

Resident work-hour restrictions have improved residents' satisfaction with their personal lives but not with their work, according to a study published online in the September issue of the Journal of Reproductive Medicine. Researchers surveyed a total of 10 current and 25 graduated ob.gyn. residents at a Cleveland medical center that implemented resident work hour changes a full year before the requirement went into effect in 2003. Current and former residents reported that their sleep while not on call did not change with the reforms, suggesting that residents were spending the extra 6 hours each week on other outside activities. In addition, residents reported sleeping an average of 1 hour less (from 3 to 2 hours) while on call. "While employers clearly have no control over employees' amount of sleep outside work, residents should be informed of the evidence of how fatigue affects performance and should be encouraged to obtain enough sleep when not on duty," the authors wrote.

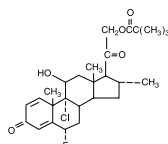
—Mary Ellen Schneider

## Cloderm<sup>®</sup> (clocortolone pivalate) Cream, 0.1%

### For Topical Use Only

**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, polyoxy 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, anti-pruritic 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:

- This medication is to be used as directed by the physician. It is for external use only. Avoid contact with the eyes.
- Patients should be advised not to use this medication for any disorder other than for which it was prescribed.
- The treated skin area should not be bandaged or otherwise covered or wrapped as to be occlusive unless directed by the physician.
- 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 papilloedema.**

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

Miliaria

**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 anti-microbial 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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## New Medicare Part D Benefit Will Provoke Many Patient Questions

SAN DIEGO — Physicians will face many questions about the new Medicare Part D benefit as patients decide whether to enroll and which plan to select in the voluntary prescription drug program, Elizabeth Carder-Thompson said at the annual meeting of the American Health Lawyers Association.

CMS has begun posting informational resources on its Web site, and additional materials will become available. The best resource at this time is the "Outreach Toolkit," available by download or on CD-ROM, said Ms. Carder-Thompson, a lawyer with Reed Smith LLP.

"The Outreach Toolkit doesn't answer all the questions we want answered, but it's a good start," she said.

Enrollment for Part D began on Nov. 15, 2005, and patients must enroll by May 15, 2006, or face a financial penalty when they do. The new coverage goes into effect Jan. 1, 2006, and the interim discount drug card program ends at that time. This means Medicare beneficiaries will need to make fairly complicated choices within a short time. There will be at least two Part D prescription drug plans available in each geographic area, and possibly several subplans.

A Kaiser Family Foundation survey, conducted March/April 2005, found that seniors are more likely to turn to their doc-

tor (49%) or pharmacist (33%) for help in making these decisions, rather than to Medicare information sources (23%). About two-thirds (68%) of those surveyed said they did not have a good understanding of the new benefit.

In October, Part D started sending marketing materials. CMS distributed its "Medicare and You," handbook to all beneficiaries via mail, with a description of the new benefit. A "Plan Comparison Web Tool" and "Medicare Personal Plan Finder" are posted at www.medicare.gov, and there have been special mailings for low income beneficiaries.

According to Robert J. Hill, also of Reed Smith LLP, the CMS marketing guidelines on Part D include a great deal of material that will affect physicians. For example, enrollment cannot be taken at the point of care, such as a physician's office. If physicians offer their patients information on any Part D plan then they must offer information on all available Part D plans.

Once Part D becomes effective, doctors will face a different set of concerns, Ms. Carder-Thompson said. When a plan doesn't cover a prescribed drug, physicians will need to provide supporting statements in order to get an exception, but many details are not clear at this time.

—Elaine Zablocki