

# New Medicare Process: Limited Appeal for Elderly?

BY JOYCE FRIEDEN

Associate Editor, Practice Trends

A new process for appealing Medicare coverage denials is raising concern among some advocates for senior citizens.

"We're concerned about the ability of beneficiaries to get a fair and favorable hearing," said Vicki Gottlich, senior policy attorney at the Center for Medicare Advocacy, a Mansfield, Conn.-based group that helps beneficiaries with the appeals process. Under the new process, which began on July 1, beneficiaries and providers whose claims are denied will be asked to appeal their claims to an administrative law judge (ALJ) via teleconference. Previously, these appeals were made in person.

"Older people and people with disabilities will have problems" with teleconferences, especially if their vision or hearing is impaired, Ms. Gottlich said. And if they ask for an in-person hearing instead, beneficiaries will waive their right to a timely decision if that request is granted. The new process also specifies that there will be three "regions" for hearing cases in person, rather than beneficiaries being allowed to have hearings in their home states.

Department of Health and Human Services spokesman Bill Hall said there are logistical reasons for waiving the right to speedy resolution in the case of an in-person hearing.

"We have to schedule everyone, allow time for them to travel, and set up a facility for the hearing," he said. "So logistics must come in play. That doesn't mean we'll take a year to do it."

Ms. Gottlich noted that the changes were made in the first place in part because members of Congress were dissatisfied with how long it was taking for beneficiaries to make their way through the appeals process.

"The changes are supposed to protect beneficiaries," but the system needs better funding to make sure everyone gets their chance to be heard in a timely way, she said. "There are some cases where teleconferencing could work, but for an individual beneficiary who's gone through the whole inhuman system and wants to see a real person, the system doesn't really work."

Another change in the process places administrative law judges under the jurisdiction of HHS, rather than the Social Security Administration. Further, judges are instructed to place more weight on

Medicare regulations than they were before. "The [law] says the administrative law judge is supposed to be independent of [the Centers for Medicare and Medicaid Services], but now they are supposed to give deference to their rules," Ms. Gottlich said.

Mr. Hall said that his agency "has gone to great lengths to be sure this is a fair process." Questions about how well the new system will work "are virtually impossible to answer because we haven't even heard the first case yet. I think it's a lot more fair to ask these questions a year from now."

The Medical Group Management Association, which represents medical practice managers, is one group that is very interested in how the appeals process plays out. "We have concerns about how effective arbitration or review will be through a distance," said Jennifer Miller, external relations liaison at MGMA's Washington office. "How effective can someone be to advocate their position over teleconference?"

Ms. Miller added that MGMA supports

having the judges hired by HHS rather than the Social Security Administration. and they are not concerned that being hired by HHS will bias the judges too much, she added.

Several senators expressed concern about the changes. A bill, the Justice for Medicare Beneficiaries Act, sponsored by Sens. Christopher Dodd (D-Conn.), Edward M. Kennedy (D-Mass.), John Kerry (D-Mass.), and Jeff Bingaman (D-N.M.) was introduced earlier this summer and would reverse many of the changes.

For instance, the bill says that judges "shall not be required to give substantial deference to local coverage determination, local medical review policies, or Centers for Medicare and Medicaid Services program guidance." The measure also calls for appeal hearings to be in-person "unless such individual requests that the hearing be conducted using tele- or video conference technologies." The bill was referred to the Senate Finance Committee. ■

## Onus on Physicians to Clarify Patients' Part D Drug Benefits

BY NELLIE BRISTOL

Contributing Writer

WASHINGTON — Physician obligation to help patients negotiate the upcoming Medicare Part D outpatient drug benefit will result in "another unfunded mandate" for Medicare providers, Ronald Castellanos, M.D., chairman of the Practicing Physicians Advisory Council said at the group's recent meeting.

Noting that patients are most likely to rely on their physicians for aid in choosing among the new drug plans, Dr. Castellanos said, "Basically what you're doing is putting the burden on physicians in their offices to really educate the Medicare recipient."

PPAC members asked the Centers for Medicare and Medicaid Services to make educational materials as simple as possible, including information on whether beneficiaries are eligible for the low-income portion of the program.

"I really want a lot of information, very digestible," said PPAC member Geraldine O'Shea, D.O., an internist from Jackson, Calif. "Something very easy for them to understand, because I do not want to take time out of my time to do medicine with my patient to say, 'Well, let me see your tax return.'"

"We are trying to make the information available as simple as possible," said Jeffrey Kelman, M.D., medical officer for the CMS Center for Beneficiary Choices.

Council member Barbara McAneny, M.D., an oncologist from Albuquerque, requested that the agency develop a computer program that would allow physicians to type in the drugs a patient is using and come up with the plan that would cover all of them. She also proposed a draft recommendation that would require CMS to develop a reimbursement code for physician time spent on drug plan education,

but it was voted down by the panel, with members saying it wasn't practical.

Walking through the benefit, Dr. Kelman said CMS is getting "much more robust formularies" from drug plans than officials had anticipated. "They're looking like commercial formularies," he said. He added that the formularies would be available on the Web site in October.

All drugs approved by the Food and Drug Administration must be on the formularies, Dr. Kelman said. If a drug is not included, a beneficiary can appeal, based on medical necessity, but "preferably with a physician's help," he said. "All medically necessary drugs that are approved by the FDA with certain exceptions have to be available." However, off-label prescriptions will be covered, Dr. Kelman said.

In a move important to rare drug organizations, Dr. Kelman said if there is only one drug to treat a disease, it must be included in the formulary. Part D also will ensure drugs are available for chronic conditions by "favorably risk adjusting" those diseases, Dr. Kelman said. The plans also will "overadjust" for low-income individuals and nursing homes.

Council member Laura Powers, M.D., a neurologist from Knoxville, Tenn. said she was relieved by Dr. Kelman's comments. "We were so worried that our patients with very expensive drugs were going to be eliminated from all the formularies."

Dr. Kelman urged physicians to begin moving patients to the new formularies before the benefit is effective Jan. 1, 2006. Beneficiaries can enroll in the program from Nov. 15 through May 15.

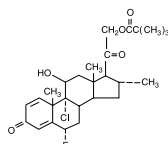
In other issues, Dr. Kelman pointed out that by law, barbiturates and benzodiazepines will not be covered by the plans. Other drugs not covered include cosmetic agents and weight-loss and weight-gain products. ■

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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  
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 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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