

Medicare Targets Infusion Fraud

Medicare officials have launched a 2-year demonstration project aimed at preventing infusion fraud schemes in South Florida, where medical fraud has been on the rise.

Under the project, the Centers for Medicare and Medicaid Services is requiring infusion providers operating in several South Florida counties to reapply to be qualified Medicare infusion therapy providers. Those who fail to reapply within 30 days will have their Medicare billing privileges revoked.

Infusion therapy providers also will have their billing privileges revoked if they fail to report a change in ownership or have employees or owners who have committed a felony. Even those providers who reapply successfully may face increased scrutiny from CMS, including site visits.

"Prevention is the most important course here as we move to deal with those who are committing fraud against the program," Herb Kuhn, CMS acting deputy administrator, said during a press conference to announce the project.

The project is similar to other fraud prevention efforts recently launched by CMS. The agency is currently conducting demonstrations to root out fraudulent billing by durable medical equipment

suppliers in South Florida and Southern California and among home health agencies in greater Los Angeles and Houston.

Although these projects focus on specific geographic areas, they provide a chance for CMS to test ideas that could be applicable across the country, Mr. Kuhn said, adding that he expects these projects to help the agency develop new tools to catch individuals if they try to relocate fraudulent schemes from one part of the country to another.

South Florida has already been the site of a string of prosecutions this year for fraud involving durable medical equipment and infusion therapy. Since March, the Department of Justice and the assistant U.S. attorneys from the Southern District of Florida have filed 47 indictments against individuals and entities that are alleged to have collectively billed Medicare more than \$345 million in fraudulent charges.

The fraudulent billing comes in various forms. For example, in some cases the billing is done on behalf of fictional clinics or fictional patients. In other cases, patients may be infused with saline or another substance instead of the drug that is being billed to Medicare.

—Mary Ellen Schneider

Tiered Plans Cut Drug Use, But Enrollees Spend More

BY MARY ELLEN SCHNEIDER
New York Bureau

Cost-containment strategies, such as tiered drug plans, reduce overall prescription drug utilization and increase the use of generics, according to an analysis of prescription drug use by Medicare-eligible retirees.

But even with decreased utilization, individuals enrolled in three-tiered drug plans, which charge higher copayments for certain medications, spent more money out of pocket than did individuals enrolled in single-tiered plans.

The study, conducted by researchers at Mathematica Policy Research Inc. and RTI International, included 352,760 Medicare beneficiaries with employer-sponsored drug coverage and dependent spouses aged 65 or older. The researchers analyzed five employer-sponsored drug plans: two with a single copayment tier, and three with a three-tiered structure.

The study is further confirmation that the retiree population is sensitive to price, Boyd H. Gilman, Ph.D., one of the study authors and a senior researcher at the Cambridge, Mass., office of Mathematica, said in an interview.

"They do respond to price, but we don't know what that means in terms of health outcomes," he said.

On average, individuals in single-tiered plans filled 46 prescriptions a year, compared with 38 prescriptions among those enrolled in three-tiered plans. But en-

rollees in single-tiered plans used fewer generics, the researchers found.

Nearly 39% of the drugs purchased under single-tier plans were generics, compared with nearly 44% in three-tiered plans. Both findings were statistically significant.

The average annual expenditures by the drug plan per enrollee were higher in single-tiered plans, whereas enrollee out-of-pocket costs were higher among those enrolled in three-tiered drug plans, despite their lower drug utilization.

Drug plans spent about \$1,943 per individual in single-tiered plans, versus \$1,354 in three-tiered plans. Individuals enrolled in single-tier plans spent about \$245 a year, compared with \$469 spent by individuals enrolled in multitiered plans. These results were also statistically significant.

When they examined trends among individuals who filled prescriptions for chronic conditions, the researchers found that cost containment strategies had less of an effect on prescription drug use. Total expenditures and the number of prescriptions filled were still lower among beneficiaries enrolled in three-tiered plans, but to a lesser extent than when these individuals filled prescriptions for episodic care.

The findings were published online in the journal *Health Services Research* (Health Serv. Res. 2007 Sept. 11 [Epub doi:10.1111/j.1475-6773.2007.00774.x]). The study was funded by an internal grant from RTI International.

Individuals who were enrolled in single-tier drug plans spent about \$245 a year, compared with \$469 spent by individuals enrolled in multitiered plans.

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, stearic alcohol, polyoxyl 40 stearate, carbomer 934P, edetate disodium, sodium hydroxide, with methylparaben and propylparaben as preservatives.

Chemically, clocortolone pivalate is 9-chloro-6 α -fluoro-11 β , 21-dihydroxy-16 α -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.

HOW SUPPLIED: 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
- Acneform 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 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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