

Value-Based Competition: Health Care's Future?

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Contributing Writer

WASHINGTON — Schemes measuring the quality of health care services against price will emerge in some local markets for several procedures in the next 2 years, Secretary of Health and Human Services Mike Leavitt said at a meeting on health information technology sponsored by eHealth Initiative and Bridges to Excellence.

Within 5 years, Mr. Leavitt said, the term

“value” will become part of the health care lexicon. “Within 10 years, value-based competition will have truly emerged.”

Working toward that goal are six pilot projects being conducted by the Ambulatory Care Quality Alliance (AQA), Mr. Leavitt said. Supported by the Centers for Medicare and Medicaid Services and the Agency for Health Care Research and Quality (AHRQ), the pilot projects are testing approaches to aggregating and reporting both public and private data on

physician performance. According to AQA, the programs “will not only measure quality, but will identify those high quality providers who are able to deliver efficient care to patients, avoiding unnecessary complications and cost.”

Dr. Carolyn Clancy, AHRQ director, expanded on the purpose of the projects. “These pilots will begin to pave the way for showing how we can use the same set of measures ... to try to figure out how can we report publicly on performance and, at

least as important although probably not as rapidly, how do we get that information back to providers so they can improve.” She added that other sites would be added to project shortly.

“We expect that when completed, the knowledge we develop through the AQA pilots will provide a comprehensive national framework for performance measurement and public reporting,” she said.

While measurement will be conducted locally, Dr. Clancy said, it’s important to have one set of measures used nationally. “If we’re competing on different types of measures, we’re not going to make any progress,” she said.

AQA is a national coalition of 125 physician, consumer, business, insurer, and government organizations that are working to develop strategies for measuring, reporting, and improving performance at the physician level. The group developed a “starter set” of 26 standard performance measures last year that AQA says is “now being incorporated in physician contracts and implemented around the country.” Measurements for hospital care are being developed by the Hospital Quality Alliance.

Mr. Leavitt said that, in addition to those two national alliances, he knows of 29 community-based quality measurement efforts, driven not only by businesses but also by physicians.

“The force that I believe must drive quality will be those who provide it, and the force that I have seen learning to measure quality [is] the physicians,” he said. “This cannot simply be the MBAs ganging up on the MDs. This has got to be a collaborative effort because in every case where quality has been measured by one side without the other, it’s been ineffective and less efficient.”

Measuring quality is a key component of the Bush administration’s policy to increase transparency and value in health care purchasing and delivery. The policy requires federal health care purchasers, including Medicare, Medicaid, and the Department of Veterans Affairs, to encourage the use of health information technology, share information about procedure prices, develop quality of care measures, and develop and identify approaches that facilitate high quality and efficient care. Part of the effort is to define “episode of care” units for frequent procedures in order to compare costs among providers.

“The important thing is that insurance companies and larger payers like the government are able to present their information in a form that the data can, in a privacy-protected way, be assembled into episodes of care for comparison,” Mr. Leavitt said. “What is a hip replacement? What expense ought to be put into that bucket so we can compare one hospital or one physician to another?”

“During the next several months, we’re going to see a tremendous push to combine the purchasing clout of the federal government with the health care buying power of the top 100 private employers in America—a public-private partnership on a scale we’ve never seen before to help health care consumers make more informed decisions about health care,” Dr. Clancy said. ■

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Verdeso™
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Foam, 0.05%
Easy to use, easy to like.™

BRIEF SUMMARY

Rx Only

**FOR TOPICAL USE ONLY
NOT FOR OPHTHALMIC, ORAL OR INTRAVAGINAL USE**

INDICATIONS AND USAGE

Verdeso Foam is indicated for the treatment of mild to moderate atopic dermatitis in patients 3 months of age and older.

Patients should be instructed to use Verdeso Foam for the minimum amount of time necessary to achieve the desired results because of the potential for Verdeso Foam to suppress the hypothalamic-pituitary-adrenal (HPA) axis (see PRECAUTIONS). Treatment should not exceed 4 consecutive weeks.

CONTRAINDICATIONS

The use of Verdeso Foam is contraindicated in patients who are hypersensitive to desonide or to any ingredient in this preparation.

PRECAUTIONS

General: Systemic absorption of topical corticosteroids has produced reversible HPA axis suppression, manifestations of Cushing’s syndrome, hyperglycemia, and glucosuria in some patients.

Conditions which augment systemic absorption include the application of topical corticosteroids over large body surface areas, prolonged use, or the addition of occlusive dressings. Therefore, patients applying a topical corticosteroid to a large body surface area or to areas under occlusion should be evaluated periodically for evidence of HPA axis suppression (see Laboratory 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 upon discontinuation of topical corticosteroids. Infrequently, signs and symptoms of glucocorticosteroid insufficiency may occur requiring supplemental systemic corticosteroids. For information on systemic corticosteroid supplementation, see prescribing information for those products.

The effect of Verdeso Foam on HPA axis function was investigated in pediatric patients in one study. In this study, patients with atopic dermatitis covering at least 25% of their body applied Verdeso Foam twice daily for 4 weeks. Three out of 75 patients (4%) displayed adrenal suppression after 4 weeks of use based on the cosyntropin stimulation test. The laboratory suppression was transient; all subjects had returned to normal when tested 4 weeks post treatment.

Pediatric patients may be more susceptible to systemic toxicity from equivalent doses because of their larger skin surface area to body mass ratios (see PRECAUTIONS – Pediatric Use).

If irritation develops, Verdeso Foam should be discontinued and appropriate therapy instituted. Allergic contact dermatitis with corticosteroids is usually diagnosed by observing a failure to heal rather than noticing a clinical exacerbation, as with most products not containing corticosteroids. Such an observation should be corroborated with appropriate diagnostic patch testing.

If concomitant skin infections are present or develop, the use of an appropriate antifungal, antibacterial or antiviral agent should be instituted. If a favorable response does not occur promptly, use of Verdeso Foam should be discontinued until the infection has been adequately controlled.

Information for Patients: 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 or other mucous membranes. The medication should not be dispensed directly onto the face. Dispense in hands and gently massage into the affected areas of the face until the medication disappears. For areas other than the face, the medication may be dispensed directly on the affected area. Wash hands after use.
2. This medication should not be used for any disorder other than that for which it was prescribed.
3. The treated skin area should not be bandaged, otherwise covered, or wrapped so as to be occlusive unless directed by the physician.
4. Patients should report any signs of local or systemic adverse reactions to the physician.
5. Patients should inform their physicians that they are using Verdeso Foam if surgery is contemplated.
6. As with other corticosteroids, therapy should be discontinued when control is achieved. If no improvement is seen within 4 weeks, contact the physician.

Laboratory Tests: The cosyntropin (ACTH₁₋₂₄) stimulation test may be helpful in evaluating patients for HPA axis suppression.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Long-term animal studies have not been performed to evaluate the carcinogenic or photoco-carcinogenic potential of Verdeso Foam or the effect on fertility of desonide.

Desonide revealed no evidence of mutagenic potential based on the results of two in vitro genotoxicity tests (Ames assay, mouse lymphoma cell assay) and an in vivo genotoxicity test (mouse micronucleus assay).

Pregnancy: Teratogenic Effects. Pregnancy Category C: Corticosteroids have been shown to be teratogenic in laboratory animals when administered systemically at relatively low dosage levels. Some corticosteroids have been shown to be teratogenic after dermal application in laboratory animals.

There are no adequate and well-controlled studies of Verdeso Foam in pregnant women. Therefore, Verdeso Foam should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

No long-term reproductive studies in animals have been performed with Verdeso Foam. Dermal embryofetal development studies were conducted in rats and rabbits with a desonide cream, 0.05% formulation. Topical doses of 0.2, 0.6 and 2.0 g cream/kg/day of a desonide cream, 0.05% formulation or 2.0 g/kg of the cream base were administered topically to pregnant rats (gestational days 6-15) and pregnant rabbits (gestational days 6-18). Maternal body weight loss was noted at all dose levels of the desonide cream, 0.05% formulation in rats and rabbits. Teratogenic effects characteristic of corticosteroids were noted in both species. The desonide cream, 0.05% formulation was teratogenic in rats at topical doses of 0.6 and 2.0 g cream/kg/day and in rabbits at a topical dose of 2.0 g cream/kg/day. No teratogenic effects were noted for the desonide cream, 0.05% formulation at a topical dose of 0.2 g cream/kg/day in rats

and at a topical dose of 0.6 g cream/kg/day in rabbits. These doses (0.2 g cream/kg/day in rats and 0.6 g cream/kg/day in rabbits) are similar to the maximum recommended human dose based on body surface area comparisons.

Nursing Mothers: Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in human milk. Because many drugs are excreted in human milk, caution should be exercised when Verdeso Foam is administered to a nursing woman.

Pediatric Use: Because of a higher ratio of skin surface area to body mass, pediatric patients are at a greater risk than adults of HPA axis suppression and Cushing’s syndrome when they are treated with topical corticosteroids. They are therefore also at greater risk of adrenal insufficiency during and/or after withdrawal of treatment. Adverse effects including striae have been reported with inappropriate use of topical corticosteroids in infants and children. HPA axis suppression, Cushing’s syndrome, linear growth retardation, delayed weight gain, and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children include low plasma cortisol levels and an 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.

The effect of Verdeso Foam on HPA axis function was investigated in pediatric patients, ages 6 months to 17 years of age in one study. In this study, patients with atopic dermatitis covering at least 25% of their body applied Verdeso Foam twice daily for 4 weeks. Three out of 75 patients (4%) displayed adrenal suppression after 4 weeks of use based on the ACTH stimulation test. The suppression was transient; all subjects’ cortisol levels had returned to normal when tested 4 weeks post treatment.

Safety of Verdeso Foam has not been evaluated in pediatric patients below the age of 3 months.

Geriatric Use: Clinical studies of Verdeso Foam did not include any subjects aged 65 or older to determine whether they respond differently from younger subjects. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

ADVERSE REACTIONS

In a controlled clinical study of 581 patients 3 months to 17 years of age, adverse events occurred at the application site in 6% of subjects treated with Verdeso Foam and 14% of subjects treated with vehicle foam. Other commonly reported adverse events for Verdeso Foam and vehicle foam are noted in Table 1 (see full prescribing information).

Elevated blood pressure was observed in 6 (2%) subjects receiving Verdeso Foam and 1 (1%) subject receiving vehicle foam. Other local adverse events occurred at rates less than 1.0%. The majority of adverse events were transient and mild to moderate in severity, and they were not affected by age, race or gender. The following additional local adverse reactions have been reported with topical corticosteroids. They may occur more frequently with the use of occlusive dressings and higher potency corticosteroids. These reactions are listed in an approximate decreasing order of occurrence: folliculitis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, secondary infection, striae and miliaria.

OVERDOSAGE

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

DOSAGE AND ADMINISTRATION

A thin layer of Verdeso Foam should be applied to the affected area(s) twice daily. Shake the can before use. Verdeso Foam should be dispensed by inverting the can (upright actuation will cause loss of the propellant, which may affect product delivery). Dispense the smallest amount of foam necessary to adequately cover the affected area(s) with a thin layer.

The medication should not be dispensed directly on the face. Dispense in hands and gently massage into affected areas of the face until the medication disappears. For areas other than the face, the medication may be dispensed directly onto the affected area. Take care to avoid contact with the eyes or other mucous membranes.

Therapy should be discontinued when control is achieved. If no improvement is seen within 4 weeks, reassessment of diagnosis may be necessary. Treatment should not exceed 4 consecutive weeks.

Unless directed by a physician, Verdeso Foam should not be used with occlusive dressings.

HOW SUPPLIED

Verdeso Foam is supplied in 100 g (NDC 63032-111-00) and 50 g (NDC 63032-111-50) aluminum cans. Store at controlled room temperature 68°F–77°F (20°C–25°C).

WARNING: FLAMMABLE. AVOID FIRE, FLAME OR SMOKING DURING AND IMMEDIATELY FOLLOWING APPLICATION. Contents under pressure. Do not puncture or incinerate. Do not expose to heat or store at temperatures above 120°F (49°C). Avoid contact with eyes or other mucous membranes. Keep out of reach of children.

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For additional information, visit www.verdeso.com.



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Reference: 1. Data on file [010], Connetics Corporation.