

Reaching the Underserved With a Preventorium

Health clinic effectively bridges cultures to offer at-risk group a proactive approach to health care.

BY GINA SHAW
Contributing Writer

NEW YORK — When Elmer E. Huerta, M.D., left his oncology practice in Peru to come to the Washington, D.C., area in 1987, “I thought I was going to the heavens,” he recalls. In Peru, 85% of breast and cervical cancers are found at stage III or IV, he told physicians at a cancer symposium.

But when he arrived in the United States, Dr. Huerta found pockets of poverty and lack of access, where people were horribly underserved and where diagnosis of disease came much too late, just as it did in Peru. He treated women with breasts horribly swollen and disfigured by tumors, who hadn’t sought care until their symptoms were overwhelming, and their cancers so far advanced that they were almost untreatable.

“I saw women who could not bring themselves to do breast self-exams, because their mothers and grandmothers told them never to touch their breasts,” Dr. Huerta said at the symposium, which

was sponsored by New York University and the Lynne Cohen Foundation for Ovarian Cancer Research.

Dr. Huerta realized that cultural barriers—as well as unfamiliarity with the health care system, a lack of insurance coverage, and linguistic isolation—were keeping many Hispanic men and women in the United States from seeking preventive health care. Many would go to the doctor only when they were sick, which meant that diseases that could have been caught and treated early were being diagnosed in late, deadly stages. “The challenge I faced was how to convince people to seek care when they had no symptoms,” he said.

The answer came through television and radio. He asked a patient with an advanced case of cervical cancer why she had not had a Pap smear before, and she responded, “What’s that?” Seeking to lighten the mood during the same visit, he asked her what she thought of the goings-on on a popular soap opera appearing on a Spanish-language television network. She

was instantly engaged, telling him what she thought the characters would do next. So, “I thought, why can’t we sell health like we sell shoes—through the media?”

In 1989, Dr. Huerta created his first radio program, “Cuidando Su Salud [Taking Care of Your Health],” selling not pills, potions, and products, but prevention. The show has run daily ever since, and now Dr. Huerta has added a weekly, nationally syndicated call-in talk show and a local live television program to his roster. Together, the programs are estimated to reach 90% of Hispanics in the United States.

In 1993, a health clinic in Maryland’s Montgomery County learned about the power of Dr. Huerta’s message. In an average quarter, the clinic saw perhaps 20 Hispanic women for mammograms and Pap smears. During the first quarter of 1993, for example, 23 Hispanic women came to the clinic. But in the following 3 months, that number skyrocketed to 118—more than 5 times as many Hispanic patients as the clinic had seen in any quarter.

Dr. Huerta also persuaded his listeners to participate in clinical trials, which have struggled with low rates of accrual in the Spanish-speaking community. When he

promoted one National Institutes of Health-sponsored trial on the radio, 325 listeners signed up, compared with no Hispanic participants in the previous month. He broadcasts clear, easy to understand information on topics such as how clinical trials work, why men should examine their testicles regularly, and the importance of wearing seat belts.

Once people got the message about preventive care and screening, they were left to seek affordable care. This is one reason Dr. Huerta founded the Cancer Preventorium more than a decade ago at the Washington (D.C.) Hospital Center. The affordable clinic allows low-income people to go for screening tests and get referrals for treatment. It’s the opposite of the sanatoriums that sprang up in the early part of the 20th century, which hosted people with long-term illnesses. You don’t go to the Preventorium if you’re sick, he says. You go because you’re well and want to stay that way.

Three weeks after its opening, the Preventorium had appointments booked through the end of the year. Patients pay \$64 a visit, and the collection rate is almost 100%. “Even poor people will pay if you give them something of value,” he said. ■

Rx ONLY Ovace® (Sodium Sulfacetamide 10%) Cream, Foam, Gel, Wash

FOR DERMATOLOGIC USE ONLY—NOT FOR OPHTHALMIC USE

DESCRIPTION:

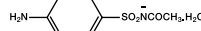
Each gram of Ovace® (sodium sulfacetamide 10%) Wash contains 100 mg of sulfacetamide sodium USP in a vehicle consisting of purified water, sodium laureth sulfate, cocamidopropyl betaine, PEG-150 pentaerythritol tetrastearate, PEG-6 caprylic/capric glycolides, PEG-60 almond triglycerides, methylparaben, edetate disodium, and sodium thiosulfate.

Each gram of Ovace® (sodium sulfacetamide 10%) Foam contains 100 mg of sodium sulfacetamide USP in a vehicle consisting of purified water, PVP/DMAEA acrylates copolymer, polydione, cocamidopropyl betaine, methylparaben, disodium EDTA, sodium thiosulfate, glycerin, quaternium 26/propylene glycol and lactic acid and is dispensed from an aluminum can pressurized with a hydrocarbon propellant (propane/butane).

Each gram of Ovace® (sodium sulfacetamide 10%) Cream contains 100 mg of sodium sulfacetamide USP in a vehicle consisting of purified water, glycerin, mineral oil, cetearyl alcohol/ceteareth 20, cetyl alcohol, glyceryl stearate, PEG-100 stearate, phenoxethanol, dimethicone, methylparaben, disodium EDTA, sodium thiosulfate, quaternium-26 and propylene glycol, propylparaben, and lactic acid.

Each gram of Ovace® (sodium sulfacetamide 10%) Gel contains 100 mg of sodium sulfacetamide USP in a vehicle consisting of purified water, glycerin, xanthan gum, methylparaben, disodium EDTA, sodium thiosulfate, quaternium-26 and propylene glycol, and lactic acid.

Sulfacetamide sodium is C₈H₉N₃NaO₂S₂H₂O with a molecular weight of 254.24. Chemically, it is Acetamide N-(4-aminophenyl)sulfonyl-, monosodium salt, monohydrate, with the following structural formula:



Sulfacetamide sodium is an odorless, white, crystalline powder with a bitter taste. It is freely soluble in water, sparingly soluble in alcohol, while practically insoluble in benzene, in chloroform, and in ether.

CLINICAL PHARMACOLOGY: Sulfacetamide sodium exerts a bacteriostatic effect against sulfonamide sensitive Gram-positive and Gram-negative microorganisms commonly isolated from secondary cutaneous pyogenic infections. It acts by restricting the synthesis of folic acid required by bacteria for growth, by its competition with para-aminobenzoic acid. There are no clinical data available on the degree and rate of systemic absorption of Ovace® when applied to the skin or scalp. However, significant absorption of sulfacetamide sodium through the skin has been reported.

The following *in vitro* data are available but their clinical significance is unknown. Organisms which show susceptibility to sulfacetamide sodium are: *Streptococci*, *Staphylococci*, *E. coli*, *Klebsiella pneumoniae*, *Pseudomonas pyocyanea*, *Salmonella*, *Proteus vulgaris*, *Nocardia* and *Actinomyces*.

INDICATIONS AND USAGE: Ovace® is intended for topical application in the following scaling dermatoses: seborrheic dermatitis and seborrhea sicca (dandruff). It also is indicated for the treatment of secondary bacterial infections of the skin due to organisms susceptible to sulfonamides.

CONTRAINDICATIONS: Ovace® is contraindicated in persons with known or suspected hypersensitivity to sulfonamides or to any of the ingredients of the product.

WARNINGS: Sulfonamides are known to cause Stevens-Johnson syndrome in hypersensitive individuals. Stevens-Johnson syndrome also has been reported following the use of sulfacetamide sodium topically. Cases of drug-induced systemic lupus erythematosus from topical sulfacetamide also have been reported. In one of these cases, there was a fatal outcome.

PRECAUTIONS:

For external use only

General: Nonsusceptible organisms, including fungi, may proliferate with the use of this preparation. Hypersensitivity reactions may recur when a sulfonamide is readministered, irrespective of the route of administration, and cross hypersensitivity between different sulfonamides may occur. If Ovace® produces signs of hypersensitivity or other untoward reactions, discontinuance of the preparation. Systemic absorption of topical sulfonamides is greater following application to large, infected, abraded, denuded, or severely burned areas. Under these circumstances, potentially any of the adverse effects produced by the systemic administration of these agents could occur and appropriate observations and laboratory determinations should be performed.

Information For Patients: Patients should discontinue Ovace® if the condition becomes worse, or if a rash develops in the area being treated or elsewhere. Ovace® also should be discontinued promptly and the physician notified if any arthritis, fever, or sores in the mouth develop.

Drug Interactions: Ovace® is incompatible with silver preparations. **Pharmacology:** Ovace® has a bacteriostatic effect against Gram-positive and Gram-negative microorganisms commonly isolated from secondary cutaneous pyogenic infections.

Carcinogenesis, Mutagenesis, and Impairment of Fertility: Long-term animal studies for carcinogenic potential have not been performed on Ovace® to date. Studies on reproduction and fertility also have not been performed. One author detected chromosomal nondisjunction in the yeast, *Saccharomyces cerevisiae*, following application of sulfacetamide sodium. The significance of this finding to the topical use of sulfacetamide sodium in the human is unknown.

Pregnancy Category C: Animal reproduction studies have not been conducted with Ovace®. It also is not known whether Ovace® can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Ovace® should be used by a pregnant woman only if clearly needed or when potential benefits outweigh potential hazards to the fetus.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Ovace® is administered to a nursing woman.

Pediatric Use: Safety and effectiveness in children under the age of 12 years have not been established.

ADVERSE REACTIONS: Reports of irritation and hypersensitivity to sulfacetamide sodium are uncommon. The following adverse reactions, reported after administration of sterile ophthalmic sulfacetamide sodium, are noteworthy: instances of Stevens-Johnson syndrome and instances of local hypersensitivity which progressed to a syndrome resembling systemic lupus erythematosus; in one case a fatal outcome has been reported. (See **WARNINGS**.)

OVERDOSAGE: The oral LD₅₀ of sulfacetamide in mice is 16.5 g/kg. The LD₅₀ for topical administration of sulfacetamide has not been determined. Oral overdosage may cause nausea and vomiting. Large oral overdosage may cause hematuria, crystalluria, and renal shutdown due to the precipitation of sulfite crystals in the renal tubules and the urinary tract. For treatment, contact local Poison Control Center.

DOSE AND ADMINISTRATION:

Seborrheic dermatitis including seborrhea sicca—
Ovace® Wash: Wash affected areas twice daily (morning and evening), or as directed by your physician. Avoid contact with eyes or mucous membranes. Wet skin and liberally apply areas to be cleaned, massage gently into skin working into a full lather, rinse thoroughly and pat dry. Rinsing with plain water will remove any excess medication. Repeat application as described for eight to ten days. If skin dryness occurs it may be controlled by rinsing cleanser off sooner or using less frequently. Regular shampooing following Ovace® Wash is not necessary, but the hair should be shampooed at least once a week.

Ovace® Foam: For proper dispensing of foam, can must be inverted. Shake well before use. Remove clear cap. Gently break the tiny plastic piece where the back of the nozzle connects to the top. Invert can and dispense small amount of Ovace® Foam onto hand. The exact amount needed will vary according to the size of the affected area. Hair should be towel-dried or dry before applying to scalp. With fingers, gently massage Ovace® Foam into affected areas of the scalp until foam disappears. Use twice daily or as directed by your physician. Wash your hands after applying the foam. Allow the treated area to air dry. Do not wash the treated area immediately after applying the foam. Hair styling products can be used as usual after the foam has been applied. Repeat application as described for 8-10 days.

Ovace® Cream and Gel: Apply to affected areas twice daily (morning and evening), or as directed by your physician. Avoid contact with eyes or mucous membranes. Repeat application as described for eight to ten days. As the condition subsides, the interval between applications may be lengthened. Applications once or twice weekly or every other week may prevent recurrence. Should the condition recur after stopping therapy, the application of Ovace® should be reinitiated as at the beginning of treatment.

Secondary Cutaneous Bacterial Infections— Apply up to four times daily if necessary. See above directions for use.

Occasionally, a slight yellowish discoloration may occur when an excessive amount of the product is used and comes in contact with white fabrics. This discoloration, however, presents no problem, as it is readily removed by ordinary laundering without bleaches.

HOW SUPPLIED:

Ovace® Wash is available in a 6 oz. (170 mL) (NDC 0064-4000-06) and a 12 oz. (340 mL) (NDC 0064-4000-12) bottle.

Ovace® Foam is available in 100 gram (NDC 0064-4101-00) and 50 gram (NDC 0064-4100-50) aluminum cans.

Ovace® Cream is available in 30 gram (NDC 0064-4300-30) and 60 gram (NDC 0064-4300-60) tubes.

Ovace® Gel is available in 30 gram (NDC 0064-4200-30) and 60 gram (NDC 0064-4200-60) tubes.

Store at controlled room temperature 20°-25°C (68°-77°F). Do not freeze.

Ovace® Wash: Protect from freezing and excessive heat. Ovace® Wash may tend to darken slightly on storage. Slight discoloration does not impair the efficacy or safety of the product.

Ovace® Foam: WARNING: FLAMMABLE. AVOID FIRE, FLAME OR SMOKING DURING USE. Keep out of reach of children. Contents under pressure. Do not puncture or incinerate container. Do not expose to heat or store at temperatures above 49°C (120°F).

HEALTHPOINT®

137124-0904 Marketed by: Healthpoint, Ltd.
PATENT PENDING Fort Worth, TX 76107
REORDER NO. 1-800-441-8227

Manufactured by: DPT Laboratories, Ltd.
San Antonio, TX 78215

Ovace® Wash 0064-4000-06 (6 oz. bottle) and 0064-4000-12 (12 oz. bottle)

Ovace® Foam 0064-4101-00 (100 gm can) and 0064-4100-50 (50 gm can)

Ovace® Cream 0064-4300-30 (30 g tube) and 0064-4300-60 (60 g tube)

Ovace® Gel 0064-4200-30 (30 g tube) and 0064-4200-60 (60 g tube)

Medicare Part D Benefit May Facilitate Formulary Appeals

BY JENNIFER SILVERMAN
Associate Editor, Practice Trends

WASHINGTON — Patients may find it easier to appeal denials of payment for medications under Medicare’s new Part D prescription drug benefit than they do under other health programs, an analyst said during a meeting of the Medicare Payment Advisory Commission.

Specifically, the new benefit offers quicker alternatives to getting formulary exceptions for nonpreferred drugs than private plans or Medicaid, Joan Sokolovsky, Ph.D., a MedPAC senior analyst indicated. The new prescription drug benefit, a part of the Medicare Modernization Act of 2003, goes into effect in January.

MedPAC analysts reviewed the appeals processes in several private plans and in Medicaid to see how they compare with the upcoming Part D prescription drug benefit. The commission queried a number of stakeholders in these markets, including physicians, pharmacists, consumer advocates, health plan representatives, and pharmacy benefit manager representatives.

While Medicare’s regulations on appeals generally support the processes of Medicaid and private health plans, MedPAC did find some fundamental differences, Dr. Sokolovsky said.

More situations are considered “coverage determinations” under the Part D benefit and may be appealed, she said. For example, Medicare beneficiaries will be able to appeal an increased copayment if they are prescribed a nonpreferred drug as opposed to a preferred drug. Dr.

Sokolovsky said that private plans reported having little experience with this kind of adjustment.

The time frame for handling exception requests is also shorter under Part D, Dr. Sokolovsky continued. “If under an urgent request for an exception, a [Medicare Part D] plan must handle these determinations within 24 hours. That’s typically faster than required for most [private insurers] now.”

Shorter, expedited time frames and the ability to appeal copays, however, may lead to an increased volume of appeals, and possibly higher premiums, she said.

To minimize appeals, Part D plans may put fewer restrictions on separate, tiered cost sharing on nonpreferred drugs.

In some cases, physicians under Part D must get prior approval or authorization before nonpreferred drugs are covered.

From interviews with stakeholders, MedPAC learned prior authorization often creates burdens for beneficiaries and providers in commercial and Medicaid plans.

Prior authorization should ideally take place before the prescription is written—but often doesn’t, Dr. Sokolovsky said.

“Physicians frequently don’t know what the drugs are on their patients’ formularies, or which ones require prior authorization.” Patients often become aware of the need for prior authorization when the pharmacist tries to process the prescription and gets a notice the drug is not covered, but lists others that would be covered.

Private plans tend to keep detailed information on the disposition of exception requests; however, some information never comes back to a plan, she said. ■