

POLICY & PRACTICE

Alefcept for Sale

Biogen Idec, which markets alefacept (Amevive), has announced plans to sell its global alefacept business franchise. The company plans to focus instead on other products in the oncology, immunology, and neurology fields. At press time, the company was in discussions with potential buyers. John Palmer, senior vice president of the immunology business unit at Biogen Idec, noted that the pending sale will not impact delivery of the drug. During this interim period, the product supply will remain available through normal distribution channels and the company will continue to provide customer service and medical support, according to a letter from Biogen Idec to doctors who prescribe the drug. In addition, ongoing clinical studies and associated activities will be continued, the letter said. "The dermatology community and psoriasis patients deserve the best support available and we are committed to finding a company that ensures ongoing support and development of Amevive," the letter said. Physicians with questions can call the company at 866-263-8483.

Salary Affects Specialty Choice

When it comes to choosing a specialty, U.S. medical graduates are more concerned with earning power than medical liability

costs, according to a study published in the September issue of *Obstetrics and Gynecology*. Procedure-based and hospital-based specialties, generally associated with higher incomes, are the most likely to have residency positions filled by U.S. medical graduates, the researchers found, even when the specialty had higher professional liability costs. For example, U.S. medical students filled more than 90% of the residency positions in neurosurgery and orthopedic surgery, where liability insurance costs are high, but so are incomes. But the researchers noted that students also may be attracted to high-earning fields because of the technical challenges or the ability to have a more controllable lifestyle. The results are based on data from the 2004 National Resident Matching Program, the American Medical Association, the Medical Group Management Association, and a major Massachusetts liability insurer.

Part B Premiums on the Rise

Monthly Medicare Part B premiums will be \$88.50 in 2006, an increase of \$10.30 from the current \$78.20 premium, the Centers for Medicare and Medicaid Services announced. The agency cited continued rapid growth in the intensity and utilization of Part B services as the primary reason for the premium increase. "This

growth is seen in physician office visits, lab tests, minor procedures, and physician-administered drugs. It also includes rapid growth in hospital outpatient services," the agency said in a statement. Part of the premium increase is necessary to increase funds held, for accounting purposes, in the Part B trust fund. Though premiums are rising, most Medicare beneficiaries will see significantly lower out-of-pocket health care costs in 2006 because of the savings in drug costs from the new Medicare prescription drug benefit, the agency claimed. About 25% of beneficiaries can receive assistance that pays for their entire Part B premium, and about 33% can receive assistance for their Part D premium.

Health IT Standards

The National Committee for Quality Assurance (NCQA) is planning to make changes to its 2-year-old program that recognizes physicians for using clinical information and technology to improve patient care. The Physician Practice Connections (PPC) program was launched in 2004 with nine modules. The new version attempts to streamline those modules into eight standards as part of a single program. The eight elements include patient tracking and registry functions, care management, patient self-management support, electronic prescribing, tracking of laboratory and radiology tests, referral

tracking, performance reporting and improvement, and interconnectivity. Currently 80 practices, representing nearly 700 physicians, are recognized under the NCQA program. For more information, visit www.ncqa.org/ppc. The revised standards will be published early next year.

Research Fraud Investigation

Key members of the House Energy and Commerce Committee are calling for an investigation into the alleged misuse of millions of dollars in government research funds at top U.S. universities. Committee chairman Rep. Joe Barton (R-Tex.) and Rep. Ed Whitfield (R-Ky.), chairman of the committee's oversight and investigations subcommittee, have asked the Department of Health and Human Services' Office of Inspector General to audit some of the largest research grants from the National Institutes of Health to compare the number of research activities projected to the NIH and the number actually performed. They cited recent settlements between NIH university grantees and the Department of Justice over allegations that federal grant funds were misused. "The alleged misuse of NIH grant funds raises serious public policy concerns of waste, effectiveness, and integrity of taxpayer-support research programs," the congressmen said in a letter to the inspector general.

—Mary Ellen Schneider

Rx ONLY

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

FOR DERMATOLOGIC USE ONLY—NOT FOR OPHTHALMIC USE

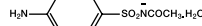
DESCRIPTION:

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, povidone, 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, phenoxyethanol, 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 $C_8H_9N_3NaO_5 \cdot H_2O$ 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, discontinue use 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 precipitation of sulfate crystals in the renal tubules and the urinary tract. For treatment contact local Poison Control Center.

DOSAGE 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 to 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 reinstated 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)

HEALTEPOINT®

137124-0904 Marketed by: Manufactured by:
PATENT PENDING Healthpoint, Ltd. DPT Laboratories, Ltd.
REORDER NO. Fort Worth, TX 76107 San Antonio, TX 78215
1-800-441-8227

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)

Premium Increases Could Hurt Medicaid Enrollment

BY MARY ELLEN SCHNEIDER
Senior Writer

NASHVILLE, TENN. — Proposals to increase cost sharing for Medicaid beneficiaries could reduce enrollment in the program, according to the preliminary results of a study presented at the annual conference of the National Academy for State Health Policy.

Genevieve Kenney, principal research associate at the Urban Institute, and her colleagues examined the impact of premium increases in the State Children's Health Insurance Program (CHIP) as a way to inform policy changes under Medicaid.

More than 30 states have premiums for some children whose incomes are above the federal poverty level. No existing Medicaid program charges premiums for children below poverty, Ms. Kenney said.

However, proposals, such as one from the National Governors' Association, would permit states to charge up to \$480 annually per child to low-income families.

The research, which was funded by the David and Lucile Packard Foundation, looked at enrollment and disenrollment patterns in three states that increased premiums in 2003—Kansas, Kentucky, and New Hampshire.

SCHIP officials in Kansas increased premiums from \$10 to \$30 per family in February 2003 for families between 151% and 175% of the federal poverty level. The state then decreased the premiums to \$20 in July 2003. For families between 176% and 200% of poverty, the premium was increased from \$15 to \$45 and then decreased to \$30.

The total caseload growth rate 6 months before the premium increase in Kansas was 14.6%. Six months after the increase the growth rate had fallen to -4.2%, Ms. Kenney reported. Although there was an initial drop in enrollment, the caseload picked up over time, and there has been healthy growth, she said.

The results were similar in New Hampshire, where SCHIP officials increased the premiums from \$20 to \$25 per child in January 2003 for families between 185% and 249% of poverty. For families between 250% and 300% of poverty, the premium was increased from \$40 to \$45.

But in Kentucky, which instituted a premium for the first time, the decline in caseload was more dramatic. Officials there initiated a \$20 premium for families between 151% and 200% of poverty in December 2003. Six months before the change, the total caseload growth rate was -0.2%. Six months after the new premium was instituted, the growth rate fell to -17.4%. The premium increases there also had a stronger disenrollment effect than in the other two states.

These findings add to a growing body of evidence that increased premiums appear to reduce enrollment and increase disenrollment, Ms. Kenney said, though the impact is different among subgroups.

The largest effects occur when new premiums are imposed, especially on lower-income beneficiaries. The availability and cost of employer-sponsored insurance and other public premium policies, such as sanction policies for nonpayment of premiums, may also play a role, she said. ■