

POLICY & PRACTICE

2006 Outlook

This year, officials at the American College of Obstetricians and Gynecologists say that they plan to continue work on a number of the society's top priorities from last year. These ongoing issues include medical liability reform, in particular caps on noneconomic damage; Medicare physician payment and pay for performance; imaging; and preserving access to reproductive health services. ACOG officials said that the organization will formally decide on its 2006 legislative and regulatory agenda in February.

Medical Liability Reform

Passage of medical liability reform legislation, particularly caps on noneconomic damages, once again failed to gain traction in the Senate in 2005 despite passage of a bill (H.R. 5) in the House. Shifting priorities in the wake of Hurricane Katrina may have contributed to the lack of attention paid to the issue, said an ACOG government affairs spokesperson. But ACOG officials expect to see a Senate vote this year. The college also will continue to support alternative remedies that don't deal directly with caps such as the Fair and Reli-

able Medical Justice Act (S. 1337), which was introduced this summer. That bill proposes to fund state demonstration programs to evaluate alternatives to the current medical tort system.

Physician Pay and P4P

At press time, physicians were anticipating a 4.3% cut in Medicare payments in 2006. ACOG officials said the college remains opposed to the pay cut and supports a permanent change to the Sustainable Growth Rate (SGR) formula used to pay physicians under Medicare. If no changes are made to the current formula, physicians can expect to see their

Medicare payments cut by about 25% by 2011 while seeing their office expenses increase by 19% over the same time period, according to ACOG. This means that physicians won't have any capital to make investments in information technology and other changes that could improve care. ACOG also opposes pay-for-performance proposals that are tied to the SGR formula, which they consider inadequate. ACOG supports a reasonable pay-for-performance plan but it must be based on a payment formula that reflects the actual cost of medical care, an ACOG government affairs spokesperson said.

Imaging

Another hot topic carrying on into 2006 is who can perform and be paid for imaging. ACOG plans to push for ob.gyns. to continue to provide imaging to patients and to be paid for that service. Some radiology organizations want to restrict who can provide imaging services.

Reproductive Health Access

Access to reproductive health services—in particular, providing information on and access to emergency contraception—also continues to be a top priority at ACOG. Most notably, ACOG continues to support over-the-counter status for the emergency contraceptive Plan B and has condemned the Food and Drug Administration for delaying its decision on the product. The college also is continuing to support access to emergency contraception for rape victims. The Compassionate Assistance for Rape Emergencies Act (H.R. 2928/S. 1264), which was introduced last summer, directs hospitals to provide information on emergency contraception to all sexual assault victims and to offer emergency contraception regardless of the patient's ability to pay.

FDA's Unusual Plan B Review

The FDA's decision in 2004 not to approve the emergency contraception product Plan B for over-the-counter sale was not typical of the 67 other prescription-to-OTC switch decisions made by the agency between 1994 and 2004, according to a report from the Government Accountability Office (GAO). The FDA denied an application to approve Plan B for OTC sale in May 2004 saying that officials had safety concerns about the use of the product in women aged under 16 years. Among the differences is that FDA officials took the rare step of not approving the Rx-to-OTC switch against the advice of its agency's own advisory committee, which had voted to recommend approval of the application. GAO's review also found that the FDA has placed no age-related marketing restrictions for safety reasons on any prescription or OTC contraceptive. But the FDA questioned the integrity of the GAO's investigative process. "The report mischaracterizes facts and does not appear to take into consideration the input provided by the FDA," an FDA spokesperson said in a statement. "We stand by the original decision to issue a Not Approvable letter to Barr Labs for OTC Plan B." The FDA is still considering an application by the Plan B manufacturer, Barr Pharmaceuticals Inc., to market Plan B OTC only for women aged 16 and older.

—Mary Ellen Schneider

ZOVIRAX® (acyclovir) Ointment 5% Soothes at the Site to Heal Herpes Fast

Soothing Relief, Proven Efficacy¹

Duration with first episode of primary genital herpes	ZOVIRAX® Ointment (duration in days)	Placebo (duration in days)
Itching	3.6 (P<0.01 vs placebo)	8.0
Pain	5.2 (P<0.05 vs placebo)	7.0
Viral shedding from lesions	2.3 (P<0.001 vs placebo)	5.6

- 68% of patients treated with ZOVIRAX® Ointment were no longer shedding HSV after 2 days*¹

*Duration of viral shedding from external genital lesions in a comparison among patients with primary first episode genital herpes between topical acyclovir and placebo-treated patients (topical acyclovir 68% vs placebo 30%).

Reference: 1. Corey L, Benedetti JK, Critchlow CW, et al. Double-blind controlled trial of topical acyclovir in genital herpes simplex virus infections. *Am J Med.* 1982;73:326-334.

ZOVIRAX®
(acyclovir)
Ointment 5%

INDICATIONS AND USAGE

ZOVIRAX (acyclovir) Ointment 5% is indicated in the management of initial genital herpes and in limited non-life-threatening mucocutaneous Herpes simplex virus infections in immunocompromised patients.

CONTRAINDICATIONS

ZOVIRAX Ointment 5% is contraindicated in patients who develop hypersensitivity to the components of the formulation.

WARNINGS

ZOVIRAX Ointment 5% is intended for cutaneous use only and should not be used in the eye.

PRECAUTIONS

General: The recommended dosage, frequency of applications, and length of treatment should not be exceeded (see DOSAGE AND ADMINISTRATION). There are no data to support the use of ZOVIRAX Ointment 5% to prevent transmission of infection to other persons or prevent recurrent infections when applied in the absence of signs and symptoms. ZOVIRAX Ointment 5% should not be used for the prevention of recurrent HSV infections. Although clinically significant viral resistance associated with the use of ZOVIRAX Ointment 5% has not been observed, this possibility exists.

Drug Interactions: Clinical experience has identified no interactions resulting from topical or systemic administration of other drugs concomitantly with ZOVIRAX Ointment 5%.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Systemic exposure following topical administration of acyclovir is minimal. Dermal carcinogenicity studies were not conducted. Results from the studies of carcinogenesis, mutagenesis, and fertility are not included in the full prescribing information for ZOVIRAX Ointment 5% due to the minimal exposures of acyclovir that result from dermal application. Information on these studies is available in the full prescribing information for ZOVIRAX Capsules, Tablets, and Suspension and ZOVIRAX for Injection.

Pregnancy: Teratogenic Effects: Pregnancy Category B. Acyclovir was not teratogenic in the mouse, rabbit, or rat at exposures greatly in excess of human exposure. There are no adequate and well-controlled studies of systemic acyclovir in pregnant women. A prospective epidemiologic registry of acyclovir use during pregnancy was established in 1984 and completed in April 1999. There

were 749 pregnancies followed in women exposed to systemic acyclovir during the first trimester of pregnancy resulting in 756 outcomes. The occurrence rate of birth defects approximates that found in the general population. However, the small size of the registry is insufficient to evaluate the risk for less common defects or to permit reliable or definitive conclusions regarding the safety of acyclovir in pregnant women and their developing fetuses. Systemic acyclovir should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers: It is not known whether topically applied acyclovir is excreted in breast milk. Systemic exposure following topical administration is minimal. After oral administration of ZOVIRAX, acyclovir concentrations have been documented in breast milk in 2 women and ranged from 0.6 to 4.1 times the corresponding plasma levels. These concentrations would potentially expose the nursing infant to a dose of acyclovir up to 0.3 mg/kg per day. Nursing mothers who have active herpetic lesions near or on the breast should avoid nursing.

Geriatric Use: Clinical studies of ZOVIRAX Ointment did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. Systemic absorption of acyclovir after topical administration is minimal (see CLINICAL PHARMACOLOGY).

Pediatric Use: Safety and effectiveness in pediatric patients have not been established.

ADVERSE REACTIONS

In the controlled clinical trials, mild pain (including transient burning and stinging) was reported by about 30% of patients in both the active and placebo arms; treatment was discontinued in 2 of these patients. Local pruritus occurred in 4% of these patients. In all studies, there was no significant difference between the drug and placebo group in the rate or type of reported adverse reactions nor were there any differences in abnormal clinical laboratory findings.

Observed During Clinical Practice: Based on clinical practice experience in patients treated with ZOVIRAX Ointment in the US, spontaneously reported adverse events are uncommon. Data are insufficient to support an estimate to their incidence or to establish causation. These events may also occur as part of the underlying disease process. Voluntary reports of adverse events that have been received since market introduction include:

General: Edema and/or pain at the application site.

Skin: Pruritus, rash.

OVERDOSAGE

Overdosage by topical application of ZOVIRAX Ointment 5% is unlikely because of limited transcutaneous absorption (see CLINICAL PHARMACOLOGY).

DOSAGE AND ADMINISTRATION

Apply sufficient quantity to adequately cover all lesions every 3 hours, 6 times per day for 7 days. The dose size per application will vary depending upon the total lesion area but should approximate a one-half inch ribbon of ointment per 4 square inches of surface area. A finger cot or rubber glove should be used when applying ZOVIRAX to prevent autoinoculation of other body sites and transmission of infection to other persons. **Therapy should be initiated as early as possible following onset of signs and symptoms.**

HOW SUPPLIED

Each gram of ZOVIRAX Ointment 5% contains 50 mg acyclovir in a polyethylene glycol base.

It is supplied as follows:

15-g tubes (NDC 64455-993-94)

3-g tubes (NDC 64455-993-41).

Store at 15° to 25°C (59° to 77°F) in a dry place.

Manufactured by
GlaxoSmithKline
Research Triangle Park, NC 27709
for

BIOVAIL
Pharmaceuticals, Inc.

Bridgewater, NJ 08807

©2005 GlaxoSmithKline. All rights reserved.

BR-2062

January 2005



ZOVIRAX is a registered trademark of GlaxoSmithKline.
© 2005 Biovail Pharmaceuticals, Inc.

ZOV433A1105

December 2005



Soothes the Outbreak