

# Broader HIV Screening Faces Payment Obstacles

BY MIRIAM E. TUCKER  
Senior Writer

WASHINGTON — Reimbursement for routine, universal HIV screening will prove challenging in both the private and public sectors, Dr. Michael Horberg and Christine Lubinski said in separate presentations at a meeting on HIV diagnosis and prevention and access to care.

Last year, the Centers for Disease Control and Prevention recommended that

diagnostic HIV testing and “opt-out” HIV screening be made a part of routine clinical care in all health care settings for patients aged 13-64 years (MMWR 2006;55[RR-14]). Kaiser Permanente, which is the country’s largest staff-model HMO, is “grappling with this now. We have to look at the implications,” said Dr. Horberg, director of HIV/AIDS Policy, Quality Improvement, and Research at Kaiser.

“We have the capacity to do it, and we

have the will to do it. But it is a lot of money,” said Dr. Horberg.

As for the public sector, “There are significant roadblocks. ... The Centers for Medicare and Medicaid Services and the [Bush] administration have little commitment to expand the federal contribution to the Medicaid program in any way, shape, or form,” said Ms. Lubinski, executive director of the HIV Medicine Association. This association is a multidisciplinary arm of the Infectious Diseases Society of

America that represents medical professionals involved in HIV care.

However, a few states—most notably New Jersey—have committed their Medicaid funds to cover broad-based HIV testing for low-income beneficiaries, Ms. Lubinski noted.

The Kaiser Permanente/Group Health Cooperative system covers approximately 3% of the entire U.S. population, including more than 16,000 active HIV-infected patients. The numbers vary widely by region, from about 180 patients in Ohio to nearly 5,500 in California.

Currently, nearly two-thirds of HIV-infected patients within Kaiser are not diagnosed until they meet AIDS criteria, “which means our case-finding is not very good,” Dr. Horberg remarked. However, more than 90% of patients who are diagnosed enter into care within 120 days of diagnosis. Last year, more than 70% of those patients were on highly active antiretroviral therapy, he said.

Kaiser has been performing about 340,000 HIV antibody tests a year, which account for 15% of its target population

**Rozerem™**  
ramelteon 8-mg tablets

Brief Summary of Prescribing Information  
05-1114

**ROZEREM™**  
(ramelteon) Tablets

**INDICATIONS AND USAGE**

ROZEREM is indicated for the treatment of insomnia characterized by difficulty with sleep onset.

**CONTRAINDICATIONS**

ROZEREM is contraindicated in patients with a hypersensitivity to ramelteon or any components of the ROZEREM formulation.

**WARNINGS**

Since sleep disturbances may be the presenting manifestation of a physical and/or psychiatric disorder, symptomatic treatment of insomnia should be initiated only after a careful evaluation of the patient. The failure of insomnia to remit after a reasonable period of treatment may indicate the presence of a primary psychiatric and/or medical illness that should be evaluated. Worsening of insomnia, or the emergence of new cognitive or behavioral abnormalities, may be the result of an unrecognized underlying psychiatric or physical disorder and requires further evaluation of the patient. As with other hypnotics, exacerbation of insomnia and emergence of cognitive and behavioral abnormalities were seen with ROZEREM during the clinical development program.

ROZEREM should not be used by patients with severe hepatic impairment.

ROZEREM should not be used in combination with fluvoxamine (see PRECAUTIONS: Drug Interactions).

A variety of cognitive and behavior changes have been reported to occur in association with the use of hypnotics. In primarily depressed patients, worsening of depression, including suicidal ideation, has been reported in association with the use of hypnotics.

Patients should avoid engaging in hazardous activities that require concentration (such as operating a motor vehicle or heavy machinery) after taking ROZEREM.

After taking ROZEREM, patients should confine their activities to those necessary to prepare for bed.

**PRECAUTIONS**

**General**

ROZEREM has not been studied in subjects with severe sleep apnea or severe COPD and is not recommended for use in those populations.

Patients should be advised to exercise caution if they consume alcohol in combination with ROZEREM.

**Use in Adolescents and Children**

ROZEREM has been associated with an effect on reproductive hormones in adults, e.g. decreased testosterone levels and increased prolactin levels. It is not known what effect chronic or even chronic intermittent use of ROZEREM may have on the reproductive axis in developing humans (see Pediatric Use).

**Information for Patients**

Patients should be advised to take ROZEREM within 30 minutes prior to going to bed and should confine their activities to those necessary to prepare for bed.

Patients should be advised to avoid engaging in hazardous activities (such as operating a motor vehicle or heavy machinery) after taking ROZEREM.

Patients should be advised that they should not take ROZEREM with or immediately after a high fat meal.

Patients should be advised to consult their health care provider if they experience worsening of insomnia or any new behavioral signs or symptoms of concern.

Patients should consult their health care provider if they experience one of the following: cessation of menses or galactorrhea in females, decreased libido, or problems with fertility.

**Laboratory Tests**

No *in vitro* monitoring is required.

For patients presenting with unexplained amenorrhea, galactorrhea, decreased libido, or problems with fertility, assessment of prolactin levels and testosterone levels should be considered as appropriate.

**Drug Interactions**

ROZEREM has a highly variable inter-subject pharmacokinetic profile (approximately 100% coefficient of variation in  $C_{max}$  and AUC). As noted above, CYP1A2 is the major isozyme involved in the metabolism of ROZEREM; the CYP2C subfamily and CYP3A4 isozymes are also involved to a minor degree.

**Effects of Other Drugs on ROZEREM Metabolism**

**Fluvoxamine (strong CYP1A2 inhibitor):** When fluvoxamine 100 mg twice daily was administered for 3 days prior to single-dose co-administration of ROZEREM 16 mg and fluvoxamine, the  $AUC_{0-12}$  for ramelteon increased approximately 190-fold, and the  $C_{max}$  increased approximately 70-fold, compared to ROZEREM administered alone. ROZEREM should not be used in combination with fluvoxamine (see WARNINGS). Other less potent CYP1A2 inhibitors have not been adequately studied. ROZEREM should be administered with caution to patients taking less strong CYP1A2 inhibitors.

**Rifampin (strong CYP enzyme inducer):** Administration of rifampin 600 mg once daily for 11 days resulted in a mean decrease of approximately 80% (40% to 90%) in total exposure to ramelteon and metabolite M-II, (both  $AUC_{0-12}$  and  $C_{max}$ ) after a single 32 mg dose of ROZEREM. Efficacy may be reduced when ROZEREM is used in combination with strong CYP enzyme inducers such as rifampin.

**Ketoconazole (strong CYP3A4 inhibitor):** The  $AUC_{0-12}$  and  $C_{max}$  of ramelteon increased by approximately 84% and 36%, respectively, when a single 16 mg dose of ROZEREM was administered on the fourth day of ketoconazole 200 mg twice daily administration, compared to administration of ROZEREM alone. Similar increases were seen in M-II pharmacokinetic variables. ROZEREM should be administered with caution in subjects taking strong CYP3A4 inhibitors such as ketoconazole.

**Fluconazole (strong CYP2C9 inhibitor):** The total and peak systemic exposure ( $AUC_{0-12}$  and  $C_{max}$ ) of ramelteon after a single 16 mg dose of ROZEREM was increased by approximately 150% when administered with fluconazole. Similar increases were also seen in M-II exposure. ROZEREM should be administered with caution in subjects taking strong CYP2C9 inhibitors such as fluconazole.

Interaction studies of concomitant administration of ROZEREM with fluoxetine (CYP2D6 inhibitor), omeprazole (CYP1A2 inducer/CYP2C19 inhibitor), theophylline (CYP1A2 substrate), and dextromethorphan (CYP2D6 substrate) did not produce clinically meaningful changes in either peak or total exposures to ramelteon or the M-II metabolite.

**Effects of ROZEREM on Metabolism of Other Drugs**

Concomitant administration of ROZEREM with omeprazole (CYP2C19 substrate), dextromethorphan (CYP2D6 substrate), midazolam (CYP3A4 substrate), theophylline (CYP1A2 substrate), digoxin (p-glycoprotein substrate), and warfarin (CYP2C9 [S]/CYP1A2 [R] substrate) did not produce clinically meaningful changes in peak and total exposures to these drugs.

**Effect of Alcohol on Rozerem**

Alcohol: With single-dose, daytime co-administration of ROZEREM 32 mg and alcohol (0.6 g/kg), there were no clinically meaningful or statistically sig-

nificant effects on peak or total exposure to ROZEREM. However, an additive effect was seen on some measures of psychomotor performance (i.e., the Digit Symbol Substitution Test, the Psychomotor Vigilance Task Test, and a Visual Analog Scale of sedation) at some post-dose time points. No additive effect was seen on the Delayed Word Recognition Test. Because alcohol by itself impairs performance, and the intended effect of ROZEREM is to promote sleep, patients should be cautioned not to consume alcohol when using ROZEREM.

**Drug/Laboratory Test Interactions**

ROZEREM is not known to interfere with commonly used clinical laboratory tests. In addition, *in vitro* data indicate that ramelteon does not cause false-positive results for benzodiazepines, opiates, barbiturates, cocaine, cannabinoids, or amphetamines in two standard urine drug screening methods *in vitro*.

**Carcinogenesis, Mutagenesis, and Impairment of Fertility**

**Carcinogenesis**  
In a two-year carcinogenicity study, B6C3F<sub>1</sub> mice were administered ramelteon at doses of 0, 30, 100, 300, or 1000 mg/kg/day by oral gavage. Male mice exhibited a dose-related increase in the incidence of hepatic tumors at dose levels  $\geq 100$  mg/kg/day including hepatic adenoma, hepatic carcinoma, and hepatoblastoma. Female mice developed a dose-related increase in the incidence of hepatic adenomas at dose levels  $\geq 300$  mg/kg/day and hepatic carcinoma at the 1000 mg/kg/day dose level. The no-effect level for hepatic tumors in male mice was 30 mg/kg/day (103-times and 3-times the therapeutic exposure to ramelteon and the active metabolite M-II, respectively, at the maximum recommended human dose [MRHD] based on an area-under-the-curve [AUC] comparison). The no-effect level for hepatic tumors in female mice was 100 mg/kg/day (327-times and 12-times the therapeutic exposure to ramelteon and M-II, respectively, at the MRHD based on AUC).

In a two-year carcinogenicity study conducted in the Sprague-Dawley rat, male and female rats were administered ramelteon at doses of 0, 15, 60, 250 or 1000 mg/kg/day by oral gavage. Male rats exhibited a dose-related increase in the incidence of hepatic adenoma and benign Leydig cell tumors of the testis at dose levels  $\geq 250$  mg/kg/day and hepatic carcinoma at the 1000 mg/kg/day dose level. Female rats exhibited a dose-related increase in the incidence of hepatic adenoma at dose levels  $\geq 60$  mg/kg/day and hepatic carcinoma at the 1000 mg/kg/day dose level. The no-effect level for hepatic tumors and benign Leydig cell tumors in male rats was 60 mg/kg/day (1,429-times and 12-times the therapeutic exposure to ramelteon and M-II, respectively, at the MRHD based on AUC). The no-effect level for hepatic tumors in female rats was 15 mg/kg/day (472-times and 16-times the therapeutic exposure to ramelteon and M-II, respectively, at the MRHD based on AUC).

The development of hepatic tumors in rodents following chronic treatment with non-genotoxic compounds may be secondary to microsomal enzyme induction, a mechanism for tumor generation not thought to occur in humans. Leydig cell tumor development following treatment with non-genotoxic compounds in rodents has been linked to reduction in circulating testosterone levels with compensatory increases in luteinizing hormone release, which is a known proliferative stimulus to Leydig cells in the rat testis. Rat Leydig cells are more sensitive to the stimulatory effects of luteinizing hormone than human Leydig cells. In mechanistic studies conducted in the rat, daily ramelteon administration at 250 and 1000 mg/kg/day for 4 weeks was associated with a reduction in plasma testosterone levels. In the same study, luteinizing hormone levels were elevated over a 24 hour period after the last ramelteon dose up to 600 mg/kg/day (7.6-times higher than the MRHD on a mg/m<sup>2</sup> basis). Irregular estrus cycles, reduction in the number of implants, and reduction in the number of live embryos were noted with dosing females at  $\geq 60$  mg/kg/day (79-times higher than the MRHD on a mg/m<sup>2</sup> basis). A reduction in the number of corpora lutea occurred at the 600 mg/kg/day dose level. Administration of ramelteon up to 600 mg/kg/day to male rats for 7 weeks had no effect on sperm quality and when the treated male rats were mated with untreated female rats there was no effect on implants or embryos. In a repeat of this study using oral administration of ramelteon at 20, 60 or 200 mg/kg/day for the same study duration, females demonstrated irregular estrus cycles with doses  $\geq 60$  mg/kg/day, but no effects were seen on implantation or embryo viability. The no-effect dose for fertility endpoints was 20 mg/kg/day in females (26-times the MRHD on a mg/m<sup>2</sup> basis) and 600 mg/kg/day in males (786-times higher than the MRHD on a mg/m<sup>2</sup> basis) when considering all studies.

Although the rodent tumors observed following ramelteon treatment occurred at plasma levels of ramelteon and M-II in excess of mean clinical plasma concentrations at the MRHD, the relevance of both rodent hepatic tumors and benign rat Leydig cell tumors to humans is not known.

**Mutagenesis**

Ramelteon was not genotoxic in the following: *in vitro* bacterial reverse mutation (Ames) assay; *in vitro* mammalian cell gene mutation assay using the mouse lymphoma TK<sup>+</sup> cell line; *in vivo/in vitro* unscheduled DNA synthesis assay in rat hepatocytes; and *in vivo* micronucleus assays conducted in mouse and rat. Ramelteon was positive in the chromosomal aberration assay in Chinese hamster lung cells in the presence of S9 metabolic activation.

Separate studies indicated that the concentration of the M-II metabolite formed by the rat liver S9 fraction used in the *in vitro* genetic toxicology studies described above, exceeded the concentration of ramelteon; therefore, the genotoxic potential of the M-II metabolite was also assessed in these studies.

**Impairment of Fertility**

Ramelteon was administered to male and female Sprague-Dawley rats in an initial fertility and early embryonic development study at dose levels of 6, 60, or 600 mg/kg/day. No effects on male or female mating or fertility were observed with a ramelteon dose up to 600 mg/kg/day (7.6-times higher than the MRHD on a mg/m<sup>2</sup> basis). Irregular estrus cycles, reduction in the number of implants, and reduction in the number of live embryos were noted with dosing females at  $\geq 60$  mg/kg/day (79-times higher than the MRHD on a mg/m<sup>2</sup> basis). A reduction in the number of corpora lutea occurred at the 600 mg/kg/day dose level. Administration of ramelteon up to 600 mg/kg/day to male rats for 7 weeks had no effect on sperm quality and when the treated male rats were mated with untreated female rats there was no effect on implants or embryos. In a repeat of this study using oral administration of ramelteon at 20, 60 or 200 mg/kg/day for the same study duration, females demonstrated irregular estrus cycles with doses  $\geq 60$  mg/kg/day, but no effects were seen on implantation or embryo viability. The no-effect dose for fertility endpoints was 20 mg/kg/day in females (26-times the MRHD on a mg/m<sup>2</sup> basis) and 600 mg/kg/day in males (786-times higher than the MRHD on a mg/m<sup>2</sup> basis) when considering all studies.

**Pregnancy: Pregnancy Category C**

Ramelteon has been shown to be a developmental teratogen in the rat when given in doses 197 times higher than the maximum recommended human dose [MRHD] on a mg/m<sup>2</sup> basis. There are no adequate and well-controlled studies in pregnant women. Ramelteon should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

The effects of ramelteon on embryo-fetal development were assessed in both the rat and rabbit. Pregnant rats were administered ramelteon by oral gavage at doses of 0, 10, 40, 150, or 600 mg/kg/day during gestation days 6-17, which is the period of organogenesis in this species. Evidence of maternal toxicity and fetal teratogenicity was observed at doses greater than or equal to 150 mg/kg/day. Maternal toxicity was chiefly characterized by decreased body weight and, at 600 mg/kg/day, ataxia and decreased spontaneous movement. At maternally toxic doses (150 mg/kg/day or greater), the fetuses demonstrated visceral malformations consisting of diaphragmatic hernia and minor anatomical variations of the skeleton (irregularly shaped scapula). At 600 mg/kg/day, reductions in fetal body weights and malformations including cysts on the external genitalia were additionally observed. The no-effect level for teratogenicity in this study was 40 mg/kg/day (1,892-times and 45-times higher than the therapeutic exposure to ramelteon and the active metabolite M-II, respectively, at the MRHD based on an area-under-the-curve [AUC] comparison). Pregnant rabbits were administered ramelteon by oral gavage at doses of 0, 12, 60, or 300 mg/kg/day during gestation days 6-18, which is the period of organogenesis in this species. Although maternal toxicity was apparent with a ramelteon dose of 300 mg/kg/day, no evidence of fetal effects or teratogenicity was associated with any dose level. The no-effect level for teratogenicity was, therefore, 300 mg/kg/day (11,862-times and 99-times

higher than the therapeutic exposure to ramelteon and M-II, respectively, at the MRHD based on AUC).

The effects of ramelteon on pre- and post-natal development in the rat were studied by administration of ramelteon to the pregnant rat by oral gavage at doses of 0, 30, 100, or 300 mg/kg/day from day 6 of gestation through parturition to postnatal (lactation) day 21, at which time offspring were weaned. Maternal toxicity was noted at doses of 100 mg/kg/day or greater and consisted of reduced body weight gain and increased adrenal gland weight.

Reduced body weight during the post-weaning period was also noticed in the offspring of the groups given 100 mg/kg/day and higher. Offspring in the 300 mg/kg/day group also showed evidence of diaphragmatic hernia, a finding observed in the embryo-fetal development study previously described. There were no effects on the reproductive capacity of offspring and the resulting progeny were not different from those of vehicle-treated offspring. The no-effect level for pre- and postnatal development in this study was 30 mg/kg/day (39-times higher than the MRHD on a mg/m<sup>2</sup> basis).

**Labor and Delivery**

The potential effects of ROZEREM on the duration of labor and/or delivery, for either the mother or the fetus, have not been studied. ROZEREM has no established use in labor and delivery.

**Nursing Mothers**

Ramelteon is secreted into the milk of lactating rats. It is not known whether this drug is excreted in human milk. No clinical studies in nursing mothers have been performed. The use of ROZEREM in nursing mothers is not recommended.

**Pediatric Use**

Safety and effectiveness of ROZEREM in pediatric patients have not been established. Further study is needed prior to determining that this product may be used safely in pre-pubescent and pubescent patients.

**Geriatric Use**

A total of 654 subjects in double-blind, placebo-controlled, efficacy trials who received ROZEREM were at least 65 years of age; of these, 199 were 75 years of age or older. No overall differences in safety or efficacy were observed between elderly and younger adult subjects.

**ADVERSE REACTIONS**

**Overview**

The data described in this section reflect exposure to ROZEREM in 4251 subjects, including 346 exposed for 6 months or longer, and 473 subjects for one year.

**Adverse Reactions Resulting in Discontinuation of Treatment**

Five percent of the 3594 individual subjects exposed to ROZEREM in clinical studies discontinued treatment owing to an adverse event, compared with 2% of the 1370 subjects receiving placebo. The most frequent adverse events leading to discontinuation in subjects receiving ROZEREM were somnolence (0.8%), dizziness (0.5%), nausea (0.3%), fatigue (0.3%), headache (0.3%), and insomnia (0.3%).

**ROZEREM Most Commonly Observed Adverse Events in Phase 1-3 trials**

The incidence of adverse events during the Phase 1 through 3 trials (% placebo, n=1370; % ramelteon [8 mg], n=1250) were: headache NOS (7%, 7%), somnolence (3%, 5%), fatigue (2%, 4%), dizziness (3%, 5%), nausea (2%, 3%), insomnia exacerbated (2%, 3%), upper respiratory tract infection NOS (2%, 3%), diarrhea NOS (2%, 2%), myalgia (1%, 2%), depression (1%, 2%), dysgeusia (1%, 2%), arthralgia (1%, 2%), influenza (0, 1%), blood cortisol decreased (0, 1%).

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in clinical trials of other drugs, and may not reflect the rates observed in practice. The adverse reaction information from clinical trials does, however, provide a basis for identifying the adverse events that appear to be related to drug use and for approximating rates.

**DRUG ABUSE AND DEPENDENCE**

ROZEREM is not a controlled substance.

**Human Data: See the CLINICAL TRIALS section, Studies Pertinent to Safety Concerns for Sleep-Promoting Agents in the Complete Prescribing Information.**

**Animal Data:** Ramelteon did not produce any signals from animal behavioral studies indicating that the drug produces rewarding effects. Monkeys did not self-administer ramelteon and the drug did not induce a conditioned place preference in rats. There was no generalization between ramelteon and midazolam. Ramelteon did not affect rotarod performance, an indicator of disruption of motor function, and it did not potentiate the ability of diazepam to interfere with rotarod performance.

Discontinuation of ramelteon in animals or in humans after chronic administration did not produce withdrawal signs. Ramelteon does not appear to produce physical dependence.

**OVERDOSAGE**

**Signs and Symptoms**

No cases of ROZEREM overdose have been reported during clinical development. ROZEREM was administered in single doses up to 160 mg in an abuse liability trial. No safety or tolerability concerns were seen.

**Recommended Treatment**  
General symptomatic and supportive measures should be used, along with immediate gastric lavage where appropriate. Intravenous fluids should be administered as needed. As in all cases of drug overdose, respiration, pulse, blood pressure, and other appropriate vital signs should be monitored, and general supportive measures employed.

Hemodialysis does not effectively reduce exposure to ROZEREM. Therefore, the use of dialysis in the treatment of overdose is not appropriate.

**Poison Control Center**

As with the management of all overdoses, the possibility of multiple drug ingestion should be considered. The physician may contact a poison control center for current information on the management of overdose.

**Rx only**

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**References:** 1. Rozerem package insert, Takeda Pharmaceuticals America, Inc. 2. Johnson MW, Suess PE, Griffiths RR. Ramelteon: a novel hypnotic lacking abuse liability and sedative side effects. *Arch Gen Psychiatry.* In press.



**“We have the capacity to do [routine, universal HIV screening], and we have the will to do it. But it is a lot of money.”**

DR. HORBERG

aged 13-65 years. The majority are pregnant women, of whom more than 90% are currently tested. If Kaiser were to adopt the CDC guidelines, it would mean about 5 million more tests—and 1,773 newly identified cases—at a cost of at least \$26,599,450 annually.

Aside from cost, other potential barriers to expanded HIV screening in managed care include the fact that many managed care organizations follow recommendations from the U.S. Preventive Services Task Force, not the CDC, in determining what type of tests to cover. The USPSTF has not yet issued guidelines on universal HIV screening.

Although most managed care organizations do support targeted screening for pregnant women and for individuals with high-risk behavior, they have not yet generated broader screening policies. “Most are probably waiting for the USPSTF,” Dr. Horberg said.

The CDC’s provision that prevention counseling should not be required as part of HIV screening is already posing problems in states that require informed consent for HIV testing, including many of the states that Kaiser now serves. Kaiser differentiates between “screening,” defined as testing without counseling, and “testing,” which includes the HIV antibody test, pre- and posttest counseling, and patient education.

“Testing in [Kaiser] is the desired norm. ... We are uncomfortable screening without a proper testing process,” explained Dr. Horberg.

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# Doctors Confront Practical Issues of HIV Testing

*An educational program is being developed to help doctors navigate the challenges of universal screening.*

BY MIRIAM E. TUCKER  
Senior Writer

WASHINGTON — Efforts to make HIV screening an integral part of primary care have created a new set of educational, reimbursement, and workforce challenges for physicians.

In response, the Society of General Internal Medicine (SGIM) is gearing up to help primary care physicians incorporate routine HIV screening into their busy practices, Dr. James M. Sosman said at a meeting on HIV diagnosis and prevention and access to care.

In September, the Centers for Disease Control and Prevention issued recommendations for routine “opt-out” HIV screening of all patients aged 13-64 years. Health care providers should initiate screening unless the prevalence of undiagnosed HIV infection in their patients has been documented to be less than 0.1%. In the absence of such prevalence data, health care providers are advised to initiate voluntary HIV screening until they establish that the diagnostic yield is less than 1/1,000 patients screened, at which point screening is no longer warranted (MMWR 2006;55:RR-14).

Prevention counseling should not be required as part of HIV screening programs, according to the CDC. Although “strongly encouraged” for individuals at high risk for HIV, counseling does not have to be linked to the testing itself, the agency said.

The CDC guidelines have sparked concern that widespread HIV screening will overburden the U.S. health care system by identifying thousands of HIV-positive individuals who will require costly counseling and treatment services. An estimated

252,000-312,000 Americans are unaware that they are HIV-positive.

In anticipation of the guidelines, the SGIM obtained a 3-year grant from the CDC to develop an educational “train the trainer” program aimed at reducing barriers to early diagnosis of HIV infection and increasing patient access to preventive services in primary care settings, Dr. Sosman said at the meeting.

**‘Where will the newly diagnosed patients get their medical care? I don’t foresee the ability of most practitioners to absorb 25%-50% more’ HIV-positive patients.**

Clinician educators will be recruited from medical school and residency programs, and will then “serve as regional trainers, information resources, and role models for other primary care physicians,” said Dr. Sosman, medical director of the Midwest AIDS Training and Education Center, Madison, Wis. Future training sessions and presentations will include collaborations with groups not directly linked with the SGIM, including local and state medical societies, Area Health Education Centers, and other organizations.

The first half of 2007 will be devoted to information gathering. Focus groups and surveys of SGIM members will be used to ascertain current practices and identify potential barriers to implementation of the CDC guidelines. The information will be used to develop educational materials, such as slide sets, case studies, training scripts, and provider tool kits. The sessions themselves are expected to begin around the country in the latter part of the year. They will not be limited to members of SGIM or specifically to internists, said Dr. Sosman, also with the department of general internal medicine at the University of Wisconsin, Madison.

In a separate presentation at the meeting, Dr. Harvey J. Makadon of the department of medicine at Harvard Medical School, Boston, outlined potential operational challenges to incorporation of rou-

tine HIV screening in primary care settings. An informal survey among internists at his hospital revealed “a general sense that routine testing will improve current practices,” but respondents had many questions and concerns, particularly with regard to reimbursement for counseling and the process of counseling itself.

“A lot of doctors have something that they usually say [when counseling patients], and there have been articles written on the topic, but there’s no formal curriculum. We’re not really taught what to talk about with patients regarding HIV prevention,” Dr. Makadon remarked. “What are the best practices?”

There may be potential legal problems as well. In many states, existing laws regarding informed consent for HIV screening appear to conflict with the CDC “opt-out” guidelines, and these laws would likely need to be amended in order for the guidelines to be implemented. Until that happens, the laws supersede public health guidelines, Dr. Sosman noted.

And then there’s the question of what to do with patients identified as HIV-positive, particularly those who are still healthy and asymptomatic. The number of HIV specialists in the country has re-

mained static since the epidemic began 20 years ago, according to another speaker at the conference, Dr. M. Keith Rawlings.

“Where will the newly diagnosed patients get their medical care? I don’t foresee the ability of most practitioners to absorb 25%-50% more [HIV-positive] individuals. Available resources in the community will have to be identified,” said Dr. Rawlings, medical director of the AIDS Arms Peabody Health Center, Dallas, speaking on behalf of the National Medical Association.

Dr. Sosman noted that a “team approach” to HIV/AIDS care could be implemented in primary care settings, similar to that currently used for patients with diabetes or for smoking cessation. “It works, but it’s expensive,” he remarked.

Dr. Rawlings pointed out that the HIV-positive population is looking more and more like the patients primary care physicians see every day: As antiretroviral medications are allowing patients to live longer, the drugs are also associated with an increased risk for familiar conditions such as dyslipidemia, diabetes, and heart disease. “It’s been a very long time since I’ve seen anybody in my office who has HIV as the only thing wrong with them.” ■



**“We’re not really taught what to talk about with patients regarding HIV prevention,” said Dr. Harvey J. Makadon of the department of medicine at Harvard.**

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However, he added, despite the potential roadblocks, “We are confident that we can handle all new HIV-infected patients identified.”

The public sector is another story. It would take an act of Congress before Medicare, which has only recently begun to cover any preventive health services, would cover HIV screening. Because the upper target age of the CDC recommendation is 64 years, the only people for whom Medicare would cover screening are the 6.8 million current beneficiaries under age 65 who qualify by disability. And that number includes about 100,000 who have already been diagnosed with HIV/AIDS, Ms. Lubinski said.

Thus, the bulk of the reimbursement for HIV screening would fall to Medicaid, which currently provides health coverage

to about half of all people with AIDS in the United States and a significant number of those newly diagnosed with HIV. In an analysis that was done in 25 states, 22% of HIV-infected individuals were already Medicaid eligible at the time of their diagnosis.

Federal law allows HIV screening to be covered by states either under fee-for-service or Medicaid managed care. This service is “optional” and thus depends on the individual state’s policy.

A recent study by researchers at George Washington University’s Center for Health Services Research and Policy found that Medicaid programs in 32 of the 48 states surveyed covered targeted HIV testing and counseling, with 19 of those also covering prenatal and perinatal counseling. A few state programs also covered services such as HIV risk assessment and case management.

But as yet, with the exception of New Jersey, most state Medicaid programs have not adopted routine HIV testing. California has employed a special waiver to provide broad family planning services including HIV testing and counseling for men and women of childbearing age up to 200% of the poverty level. However, that type of waiver is unlikely to be granted elsewhere, she noted.

States could opt to cover HIV screening under a “diagnostic, screening, preventive, and rehabilitative” (DSPR) benefit. The state would need to broaden the definition of medical necessity to allow for preventive services such as HIV screening, as Massachusetts has done.

There, a service is “medically necessary if it is reasonably calculated to prevent, diagnose, prevent the worsening of, alleviate, correct, or cure conditions in the member that endanger life, or cause suf-

fering or pain,” the definition states.

Such definitions could theoretically make HIV testing and counseling eligible for reimbursement, Ms. Lubinski said.

She said she believes that the federal government will need to contribute more to Medicaid for the CDC guidelines to be fully implemented.

“It is absolutely unreasonable to think that the modest amount of discretionary funding through the CDC, Ryan White [Comprehensive AIDS Resources Emergency Act], or state and local health departments is going to be adequate to implement population-based HIV screening. Medicaid, with its significant reach into low-income populations and ethnic and racial minorities, must be part of the financing mix. Federal leadership could and should facilitate coverage of routine screening by state Medicaid programs,” Ms. Lubinski noted. ■