

New Payment Method Piloted by Nonprofit Group

BY JANE M. ANDERSON

Contributing Writer

WASHINGTON — Prometheus Payment Inc., a nonprofit group seeking to implement a better way to pay providers, intends to launch pilot projects this year that will test a new form of payment featuring a negotiated flat fee for guideline-based care of patients with specific conditions.

The program, supported by a 3-year, \$6-million Robert Wood Johnson Founda-

tion grant, will be piloted in Minneapolis, Rockford, Ill., as well as at two other sites that have not yet been announced by Prometheus.

The developers believe that it could represent the basis of a payment system that moves beyond pay for performance to integrate evidence-based medicine, said Alice Gosfield, a Philadelphia-based attorney and a past chairwoman of the National Committee for Quality Assurance, who heads the effort.

The intent of the Prometheus payment system is to get beyond pay for performance, “which is not going to be sustainable,” Ms. Gosfield said at the annual meeting of the American College of Physicians.

Pay for performance “is not sustainable because if the whole class gets an A in diabetes, what happens next? Do we take that money and put it on asthma? If so, what happens to diabetes performance?” Ms. Gosfield asked. “If we add more mon-

ey for asthma, how is that going to keep costs down?”

She also said that physicians are suspicious of where pay-for-performance money comes from. “They believe that either the money comes from what could be paid to other doctors, or it is money that isn’t being paid to increase fee schedules,” she said.

In addition, some of the documentation required for pay for performance wastes time.

Dr. Keith Michl, a general internist in Manchester Center, Vt., who has been involved in the development of Prometheus, said that the system would reward primary care physicians for saving money by keeping people healthier.

Under the Prometheus system, he said, case rates are standardized, and physicians who provide good care consistently will see a profit.

“This provides a powerful incentive to develop new systems of cost-effective care with much more validation than is provided by current pay-for-performance methods,” he added.

The Prometheus group held its first meeting in December 2004 and has met monthly since. The Commonwealth Fund provided some of the initial funding to develop the group’s evidence-informed case rates (ECRs), which are used as the foundation of the payment system.

The system aims to create regionally adjusted ECRs for patients with specific conditions, such as controlled diabetes. Providers will be asked to take responsibility for well-defined parts of the care for such patients.

For example, if a provider group agrees to be responsible for 70% of a patient’s care, that group would receive 70% of the ECR, Ms. Gosfield said.

The ECRs would replace any other payments to providers, and once the ECR has been negotiated, physicians would be free to manage the patient in any way they deem appropriate.

“The amount of the payment is derived from taking a good clinical practice guideline and deriving from it the amount of money it would take to deliver care,” she said.

Providers negotiate which part of the care budget they can cover, she said. Obviously, a one- or two-physician practice would be able to handle less of the “global care budget” than would a large, integrated delivery system, she said.

“The evidence-informed case rate encompasses all providers treating the patient for that condition and is allocated among them in accordance with that portion of the clinical practice guideline they negotiate to deliver,” she said.

Although this may sound like capitation, Ms. Gosfield said it differs in several ways. First, the payment model avoids the problems inherent in capitation by constructing the payment rates in a way that reflects the cost of what is clinically relevant to the patient’s condition, and, second, by adjusting ECRs to account for relative severity of patients’ cases, she said.

YAZ® (drospirenone and ethinyl estradiol) Tablets

Brief Summary of Prescribing Information

CONTRAINDICATIONS: YAZ® should not be used in women who have the following: •Renal insufficiency •Hepatic dysfunction •Adrenal insufficiency •Thrombophlebitis or thromboembolic disorders •A past history of deep-vein thrombophlebitis or thromboembolic disorders •Cerebral-vascular or coronary-artery disease (during or shortly after) •Heart disease with thrombotic complications •Severe hypertension •Diabetes mellitus •Known or suspected cancer •Major surgery with prolonged immobilization •Known or suspected carcinoma of the breast •Carcinoma of the endometrium or other known or suspected estrogen-dependent neoplasia •Undiagnosed abnormal genital bleeding •Cholestatic jaundice of pregnancy or jaundice with prior pill use •Known or suspected pregnancy •Liver tumor (benign or malignant) or active liver disease •Heavy smoking (>15 cigarettes per day) and over age 35 •Hypersensitivity to any component of this product. **WARNINGS:**

Cigarette smoking increases the risk of serious cardiovascular side effects from oral contraceptive use. This risk increases with age and with heavy smoking (15 or more cigarettes per day) and is quite marked in women over 35 years of age. Women who use oral contraceptives should be strongly advised not to smoke.

YAZ contains 3 mg of the progestin drospirenone that has antimineralocorticoid activity, including the potential for hyperkalemia in high-risk patients, comparable to a 25 mg dose of spironolactone. YAZ should not be used in patients with conditions that predispose to hyperkalemia (i.e., renal insufficiency, hepatic dysfunction and adrenal insufficiency). Women receiving daily, long-term treatment for chronic conditions or diseases with medications that may increase serum potassium should have their serum potassium level checked during the first treatment cycle. Medications that may increase serum potassium include ACE inhibitors, angiotensin II receptor antagonists, potassium-sparing diuretics, potassium supplementation, hepatic enzyme antagonists. The use of oral contraceptives is associated with increased risks of several serious conditions including venous and arterial thrombotic and thromboembolic events (such as myocardial infarction, thromboembolism, stroke), hepatic neoplasia, gallbladder disease, and hypertension. The risk of serious morbidity or mortality is very small in healthy women without underlying risk factors. The risk of morbidity and mortality increases significantly in the presence of other underlying risk factors such as hypertension, hyperlipidemias, obesity and diabetes. Practitioners prescribing oral contraceptives should be familiar with the following information relating to these risks. The information contained in this package insert is based principally on studies carried out in patients who used oral contraceptives with higher hormonal potency and progestins than those in common use today. The effect of long-term use of oral contraceptives with low formulations of both estrogens and progestogens remains to be determined. Throughout this labeling, epidemiologic studies reported are of two types: retrospective or case control studies and prospective or cohort studies. Case control studies provide a measure of the relative risk of a disease, namely, a ratio of the incidence of a disease among oral contraceptive users to that among nonusers. The relative risk does not provide information on the actual clinical occurrence of a disease. Cohort studies provide a measure of attributable risk, which is the difference in the incidence of disease between oral contraceptive users and nonusers. The attributable risk does provide information about the actual occurrence of a disease in the population. For further information, the reader is referred to a text on epidemiologic methods. 1. THROMBOEMBOLIC DISORDERS AND OTHER VASCULAR PROBLEMS: a. Myocardial infarction: An increased risk of myocardial infarction has been attributed to oral contraceptive use. This risk is primarily in smokers with other underlying risk factors for coronary-artery disease such as hypertension, hypercholesterolemia, morbid obesity, and diabetes. The relative risk of heart attack for current oral contraceptive users has been estimated to be two to six. The risk is very low under the age of 30. Smoking in combination with oral contraceptive use has been shown to contribute substantially to the incidence of myocardial infarctions in women in their mid-thirties or older with smoking accounting for the majority of excess cases. Mortality rates associated with circulatory disease have been shown to increase substantially in smokers over the age of 35 and nonsmokers over the age of 40 among women who use oral contraceptives. Oral contraceptives may compound the effects of well-known risk factors, such as hypertension, diabetes, hyperlipidemias, age and obesity. In general, the use of oral contraceptives is known to decrease HDL cholesterol and cause glucose intolerance, while estrogens may create a state of hyperinsulinism. Oral contraceptives have been shown to increase blood pressure among users (see section 9 in WARNINGS). Similar effects on risk factors have been associated with an increased risk of heart disease. Oral contraceptives must be used with caution in women with cardiovascular disease risk factors. b. Thromboembolism: An increased risk of thromboembolic and thrombotic disease associated with the use of oral contraceptives is well established. Case control studies have found the relative risk of users compared to nonusers to be 3 for the first episode of superficial venous thrombosis, 4 to 11 for deep vein thrombosis or pulmonary embolism, and 1.5 to 6 for women with predisposing conditions for venous thromboembolic disease. Cohort studies have shown the relative risk to be somewhat lower, about 1 for new cases and about 1.5 for recurrent cases. The risk of thromboembolic disease increases with age and with increasing duration of use. The relative risk increases with age and disappears after pill use is stopped. a. Two- to four-fold increase in the relative risk of post-operative thromboembolic complications has been reported with the use of oral contraceptives. The relative risk of venous thrombosis in women who have predisposing conditions is twice that of women without such medical conditions. If feasible, oral contraceptives should be discontinued from at least four weeks prior to and for two weeks after elective surgery of a type associated with an increase in risk of thromboembolism and during and following prolonged immobilization. Since the immediate postpartum period is also associated with an increased risk of thromboembolism, combined oral contraceptives should be started no earlier than 4 to 6 weeks after delivery and at that time only in women who elect not to breast feed. c. Cerebrovascular diseases: Oral contraceptives have been shown to increase both the relative and attributable risks of cerebrovascular events (thrombotic and hemorrhagic strokes), although, in general, the risk is greatest among older (>35 years), hypertensive women who also smoke. Hypertension was found to be a risk factor, for both users and nonusers, for both types of strokes, while smoking interacted to increase the risk for hemorrhagic strokes. In a large study, the relative risk of thrombotic strokes has been shown to range from 3 for nonusers to 14 for users with severe hypertension. The relative risk of hemorrhagic stroke is reported to be 1.2 for nonsmokers who used oral contraceptives, 2.6 for smokers who did not use oral contraceptives, 7.6 for smokers who used oral contraceptives, 1.8 for nonusers and 25.7 for users with severe hypertension. The attributable risk is also greater in older women. Oral contraceptives also increase the risk for stroke in women with other underlying risk factors such as certain inherited or acquired thrombophilias. d. Dose-related risk of vascular disease from oral contraceptives: A positive association has been observed between the amount of estrogen and progestogen in oral contraceptives and the risk of vascular disease. A decline in serum high-density lipoproteins (HDL) has been reported with many progestational agents. A decline in serum high-density lipoproteins has been associated with an increased incidence of ischemic heart disease. Because estrogens increase HDL cholesterol, the net effect of an oral contraceptive depends on a balance achieved between doses of estrogen and progestogen and the nature and absolute amount of progestogen used in the contraceptive. The amount of both hormones should be considered in the choice of an oral contraceptive. Minimal risk exposure to estrogen and progestogen is in keeping with good principles of therapeutics. For any particular estrogen/progestogen combination, the dosage regimen prescribed should be one which contains the least amount of estrogen and progestogen that is compatible with a low failure rate and the needs of the individual patient. New acceptors of oral contraceptive agents should be started on preparations containing the lowest estrogen content that is judged appropriate for the individual patient. e. Persistence of risk of vascular disease: There are two studies which have shown persistence of risk of vascular disease for ever-users of oral contraceptives. In a study in the United States, the risk of developing myocardial infarction after discontinuing oral contraceptives persists for at least 9 years for women aged 40 to 49 years who had used oral contraceptives for five or more years, but this increased risk was not demonstrated in other age groups. In another study in Great Britain, the risk of developing cerebrovascular disease persisted for at least 6 years after discontinuation of oral contraceptives, although excess risk was very small. However, both studies were performed with oral contraceptive users who used low-dose formulations containing 50 micrograms or higher of estrogens. 2. ESTIMATES OF MORTALITY FROM CONTRACEPTIVE USE: One study gathered data from a variety of sources which have estimated the mortality rate associated with different methods of contraception at different ages. These estimates include the combined risk of death associated with contraceptive methods plus the risk attributable to pregnancy in the event of method failure. Each method of contraception has its specific benefits and risks. The study concluded that with the exception of oral contraceptive users 35 and older who smoke and 40 and older who do not smoke, mortality associated with all methods of birth control is below that associated with natural fertility. The observation of a possible increase in risk of mortality with age for oral contraceptive users is based on data gathered in the 1970's but not reported until 1983. However, current clinical practice involves the use of lower estrogen dose formulations combined with careful restriction of oral contraceptive use to women who do not have the various risk factors listed in this labeling. Because of these changes in practice and also, because of some limited new data which suggest that the risk of cardiovascular disease with the use of oral contraceptives may now be less than previously observed, the Fertility and Maternal Health Drugs Advisory Committee was asked to review the topic in 1989. The Committee concluded that although cardiovascular disease risks may be increased with oral contraceptive use after age 40 in healthy nonsmoking women (even with the newer low-dose formulations), there are greater potential health risks associated with pregnancy in older women and with the alternative surgical and medical procedures which may be necessary if such women do not have access to effective and acceptable means of contraception. Therefore, the Committee recommended that the benefits of oral contraceptive use by healthy nonsmoking women over 40 may outweigh the possible risks. Of course, women of all ages who take oral contraceptives should take the lowest possible dose formulation that is effective. 3. CARCINOMA OF THE REPRODUCTIVE ORGANS AND BREASTS: Numerous epidemiological studies have been performed on the incidence of breast, endometrial, ovarian and cervical cancer in women using oral contraceptives. Although the risk of having breast cancer diagnosed may be slightly increased among current and recent users of combined oral contraceptives (RR=1.24), this excess risk decreases over time after combination oral contraceptive discontinuation and after 10 years the attributable risk of breast cancer is not increased. The recent findings of minimal risk and no consistent relationships have been found with dose or type of steroid. 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