

centage of patients with myocardial infarction who are given fibrinolytic medication within 30 minutes of arrival at the hospital.

To evaluate patient satisfaction, a random sample of discharged patients will be surveyed about their perceptions, including physician and nurse communication, hospital staff responsiveness, pain management, discharge instructions, and hospital cleanliness. A complete list of the measures is available at <http://www.healthcare.gov/news/factsheets/valuebasedpurchasing04292011b.html>.

The measures have been endorsed by

such national panels as the National Quality Forum, and hospitals have already been reporting their performance on them through Medicare’s Hospital Compare website. The measures are weighted so that 70% of the payment is based on the quality measures and 30% is based on patient evaluations.

Over time, CMS officials plan to add measures focused on patient outcomes, including prevention of hospital-acquired conditions. And measures will be phased out over time if hospitals achieve consistently high compliance scores, Dr. Berwick said.

The new value-based purchasing initiative is only one way that hospital payments will be tied to quality of care. Starting in 2013, Medicare will reduce payments to hospitals if they have excess 30-day readmissions for patients who suffer heart attacks, heart failure, and pneumonia. And in 2015, hospitals could see their payments cut if they have high rates of certain hospital-acquired conditions.

The final rule on hospital value-based purchasing will be published in the Federal Register in May and becomes final on July 1. ■

E-Prescribing Rules May Be Eased by CMS

BY ALICIA AULT

The Centers for Medicare and Medicaid Services has proposed modifying the rules for e-prescribing so more physicians could claim exemptions from the criteria and therefore avoid being penalized in 2012.

In a conference call, agency officials said the change was in response to indications from providers and professional societies that many prescribers might not be able to meet the requirements of the current incentive program.

“Today’s rule demonstrates that CMS is willing to work cooperatively with the medical professional community to encourage participation in electronic prescribing,” Dr. Patrick Conway, chief medical officer at CMS and director of the agency’s Office of Clinical Standards and Quality, said in a statement.

Under the current incentive program, eligible prescribers were due to get a 1% bonus payment for 2011 and 2012 and a 0.5% bonus in 2013. For prescribers who did not meet the criteria, there would be a penalty imposed in 2012. The penalty would escalate in 2013 and 2014.

The final Medicare Physician Fee Schedule for 2011 contains exceptions, along with two hardship exemptions. Practices are exempt if they are in a rural area without high-speed internet access or an area without enough available pharmacies for electronic prescribing.

Under the proposed rule, prescribers who use certified EHRs can now claim this as a “qualified” e-prescribing system. This move was designed to more closely align the e-prescribing program with the program that offers incentives for meaningful use of electronic health records. The proposed rule would also create four additional hardship exemption categories.

Prescribers also would be granted an extension, until Oct. 1, 2011, to apply for the hardship exemption. ■

Table 4 – Adverse Drug Reactions from Post approval Experience of FORTESTA by System Organ Class

System Organ Class	MedDRA Preferred Term
Blood and lymphatic system disorders	Polycythemia
Eye disorders	Vitreous detachment
Gastrointestinal disorders	Abdominal symptoms
General disorders and administrative site conditions	Application site erythema, irritation, pruritus, and swelling; fatigue, influenza like illness, and malaise
Investigations	Decreased serum testosterone, increased hematocrit and hemoglobin
Musculoskeletal and connective tissue disorders	Pain in extremity
Nervous system disorders	Dizziness, headache, and migraine
Reproductive system and breast disorders	Erectile dysfunction and priapism
Skin and subcutaneous tissue disorders	Allergic dermatitis, erythema, rash, and papular rash

Secondary Exposure to Testosterone in Children

Cases of secondary exposure to testosterone resulting in virilization of children have been reported in postmarketing surveillance of testosterone gel products. Signs and symptoms of these reported cases have included enlargement of the clitoris (with surgical intervention) or the penis, development of pubic hair, increased erections and libido, aggressive behavior, and advanced bone age. In most cases with a reported outcome, these signs and symptoms were reported to have regressed with removal of the testosterone gel exposure. In a few cases, however, enlarged genitalia did not fully return to age appropriate normal size, and bone age remained modestly greater than chronological age. In some of the cases, direct contact with the sites of application on the skin of men using testosterone gel was reported. In at least one reported case, the reporter considered the possibility of secondary exposure from items such as the testosterone gel user's shirts and/or other fabric, such as towels and sheets [see Warnings and Precautions].

DRUG INTERACTIONS

Insulin

Changes in insulin sensitivity or glycemic control may occur in patients treated with androgens. In diabetic patients, the metabolic effects of androgens may decrease blood glucose and, therefore, may decrease insulin requirements.

Oral Anticoagulants

Changes in anticoagulant activity may be seen with androgens, therefore more frequent monitoring of international normalized ratio (INR) and prothrombin time are recommended in patients taking anticoagulants, especially at the initiation and termination of androgen therapy.

Corticosteroids

The concurrent administration of testosterone with adrenocorticotrophic hormone (ACTH) or corticosteroids may result in increased fluid retention and requires careful monitoring particularly in patients with cardiac, renal or hepatic disease.

USE IN SPECIFIC POPULATIONS

Pregnancy

Pregnancy Category X [see Contraindications]. – FORTESTA is contraindicated during pregnancy or in women who may become pregnant. Testosterone is teratogenic and may cause fetal harm. Exposure of a female fetus to androgens may result in varying degrees of virilization. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be made aware of the potential hazard to the fetus.

Nursing Mothers

Although it is not known how much testosterone transfers into human milk, FORTESTA is contraindicated in nursing women because of the potential for serious adverse reactions in nursing infants. Testosterone and other androgens may adversely affect lactation [see Contraindications].

Pediatric Use

The safety and efficacy of FORTESTA in pediatric patients <18 years old has not been established. Improper use may result in acceleration of bone age and premature closure of epiphyses.

Geriatric Use

There have not been sufficient numbers of geriatric patients involved in controlled clinical studies utilizing FORTESTA to determine whether efficacy in those over 65 years of age differs from younger subjects. Of the 149 patients enrolled in the pivotal clinical study utilizing FORTESTA, 20 were over 65 years of age. Additionally, there are insufficient long-term safety data in geriatric patients to assess the potential risks of cardiovascular disease and prostate cancer. Geriatric patients treated with androgens may also be at risk for worsening of signs and symptoms of BPH.

Renal Impairment

No studies were conducted in patients with renal impairment.

Hepatic Impairment

No studies were conducted in patients with hepatic impairment.

DRUG ABUSE AND DEPENDENCE

Controlled Substance

FORTESTA contains testosterone, a Schedule III controlled substance as defined under the Anabolics Steroid Control Act.

Abuse

Anabolic steroids, such as testosterone, are abused. Abuse is often associated with adverse physical and psychological effects.

Dependence

Although drug dependence is not documented in individuals using therapeutic doses of anabolic steroids for approved indications, dependence is observed in some individuals abusing high doses of anabolic steroids. In general, anabolic steroid dependence is characterized by any three of the following:

- Taking more drug than intended
- Continued drug use despite medical and social problems
- Significant time spent in obtaining adequate amounts of drug
- Desire for anabolic steroids when supplies of the drugs are interrupted
- Difficulty in discontinuing use of the drug despite desires and attempts to do so
- Experience of a withdrawal syndrome upon discontinuation of anabolic steroid use

OVERDOSAGE

There is a single report of acute overdose after parenteral administration of an approved testosterone product in the literature. This subject had serum testosterone concentrations of up to 11,400 ng/dL, which were implicated in a cerebrovascular accident. There were no reports of overdose in the FORTESTA clinical trial.

Treatment of overdose would consist of discontinuation of FORTESTA, washing the application site with soap and water, and appropriate symptomatic and supportive care.

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