

CMS Proposes 30% Physician Pay Cut for 2012

BY ALICIA AULT

FROM THE FEDERAL REGISTER

The Centers for Medicare and Medicaid Services proposed that physician fees for 2012 would be reduced by 29.5%, even as the head of the agency vowed that the cuts would not occur. The proposed rule was released in the Federal Register July 1.

The reduction is required by the Sustainable Growth Rate (SGR) formula that was part of the Balanced Budget Act of 1997. But Dr. Donald M. Berwick, CMS administrator, said in a statement that the agency is hoping to find a way to avoid the statutory decrease.

"This payment cut would have serious consequences and we cannot and will not allow it to happen," Dr. Berwick said. "We need a permanent SGR fix to solve this problem once and for all. That's why the president's budget and his fiscal framework call for averting these cuts and why we are determined to pass and implement a permanent and sustainable fix."

Dr. Peter W. Carmel, president of the American Medical Association, said the reductions called for by the SGR formula are a constant threat to physicians' stability. "We are pleased that there is support from the administration and bi-partisan members of congress for permanent reform of this broken system, but agreement is not enough," said Dr. Carmel, in a statement.

The AMA has been seeking a review and revision of the Medicare Economic Index (MEI), a measure of cost increases that affect physician practices. Dr. Carmel said that such a review was promised in the 2011 Medicare Physician Fee Schedule final rule, but the newly released proposed rule for 2012 shows it has not yet begun. "Revisions in the MEI could significantly reduce the legislative cost of permanent reform of the Medicare physician payment formula," said Dr. Carmel.

The reductions could be deeper for some specialties – including cardiology – based on the impact of the Physician Practice Information Survey. The changes would reflect the third year of a 4-year transition to new practice expense relative value units. American College of Cardiology CEO Jack Lewin put this in perspective: "The 2010 payment rule was devastatingly bad. The 2011 rule was nowhere near as bad as that, and this one

for 2012 is not full of apparent surprises. The 2012 rule has the third year of residual cuts that originated in 2010, but the impact next year averages out about negative 1%. The big impact would be the SGR cut of 29.5% if it were not waived – which it will be for a year at least I presume," he wrote in his ACCinTouch blog.

And more payment changes may be looming. The CMS said in a statement that it is proposing to continue its efforts

to identify what it calls "potentially mis-valued codes." As part of those efforts, it will be taking a look at all evaluation and management (E/M) codes to determine if they are undervalued. The agency also proposes to examine the highest non-E/M expenditure codes for each specialty to see if they are overvalued.

The agency will be looking at three cardiology codes that are potentially mis-valued: data for cardiovascular stress test

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Important Safety Information

MULTAQ is contraindicated in patients with NYHA Class IV heart failure, or NYHA Class II–III heart failure with a recent decompensation requiring hospitalization or referral to a specialized heart failure clinic. In the ANDROMEDA Study, a greater than two-fold increase in mortality was observed in this unstable population (see full boxed WARNING).

Important Update: Hepatocellular liver injury, including acute liver failure requiring transplant, has been reported in patients treated with MULTAQ in the postmarketing setting. A liver injury section has been added to the Important Safety Information.

Please see additional Important Safety Information and brief summary of Prescribing Information, including boxed WARNING, on adjacent pages.

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(93015), extracranial study (93880), and complete ECG (93000). According to ACC, these will be reviewed by the RUC for presentation to CMS before July 2012.

The agency said that the reviews will improve payment accuracy, in particular ensuring that primary care services are appropriately reimbursed. It's the first time the agency has looked across all specialties, according to the CMS.

Diagnostic imaging has been a target for Medicare, and it is again in this proposal. The agency wants to extend the multiple procedure payment reduction (MPPR) policy to the professional com-

ponent of advanced imaging services, which includes CT scans, MRI, and ultrasound. The agency said the reduction would affect about 100 types of services. It is also the first time that the CMS has taken aim at the professional component of these services. That component would be reduced by 50% for subsequent procedures furnished to the same patient, on the same day, in the same session, resulting in an estimated \$200 million in savings, according to the CMS.

For the first time, the agency is proposing quality and cost measures to be used in setting incentive payments for

physicians who provide higher quality and more efficient care. That lays the groundwork for 2015, when the Affordable Care Act requires the CMS to begin making payment adjustments for certain physicians and physician groups. The requirement goes into effect for all physicians in 2017. The agency is proposing to use 2013 as the initial performance year.

In other issues addressed by the proposed rule, CMS seeks to add smoking cessation to the list of services that can be provided through telehealth. In the future, new services would be examined according to the clinical benefit

they provide rather than on whether they are equivalent to a corresponding in-person service.

Finally, the CMS proposed some changes to the Physician Quality Reporting System, the ePrescribing Incentive Program, and the Electronic Health Records Incentive Program. The agency, for instance, is expanding the ways physicians can qualify for incentive payments under the meaningful use criteria.

Comments to the proposed rule can be submitted until Aug. 30 at www.regulations.gov; a final rule is expected by Nov. 1. ■

Important Safety Information for MULTAQ®

Contraindications

WARNING: HEART FAILURE

MULTAQ is contraindicated in patients with NYHA Class IV heart failure, or NYHA Class II–III heart failure with a recent decompensation requiring hospitalization or referral to a specialized heart failure clinic.

In a placebo-controlled study in patients with severe heart failure requiring recent hospitalization or referral to a specialized heart failure clinic for worsening symptoms (the ANDROMEDA Study), patients given MULTAQ had a greater than two-fold increase in mortality. Such patients should not be given MULTAQ.

- MULTAQ is also contraindicated in patients with second- or third-degree atrioventricular (AV) block or sick sinus syndrome (except when used in conjunction with a functioning pacemaker), bradycardia <50 bpm, QTc Bazett interval \geq 500 msec or PR interval >280 msec, and severe hepatic impairment
- MULTAQ should not be given to patients who are or may become pregnant (Category X) or nursing. MULTAQ may cause fetal harm when administered to a pregnant woman
- MULTAQ should not be coadministered with strong CYP 3A inhibitors, such as ketoconazole, itraconazole, voriconazole, cyclosporine, telithromycin, clarithromycin, nefazodone, ritonavir, or drugs or herbal products that prolong the QT interval and might increase the risk of Torsade de Pointes, such as phenothiazine antipsychotics, tricyclic antidepressants, certain macrolide antibiotics, and Class I and III antiarrhythmics

New or Worsening Heart Failure

Postmarketing cases of new onset and worsening heart failure have been reported during treatment with MULTAQ. Advise patients to consult a physician if they develop signs and symptoms of heart failure, such as weight gain, dependent edema, or increasing shortness of breath. If heart failure develops or worsens, consider the suspension or discontinuation of MULTAQ.

Liver Injury

Hepatocellular liver injury, including acute liver failure requiring transplant, has been reported in patients treated with MULTAQ in the postmarketing setting. Advise patients treated with MULTAQ to report immediately symptoms suggesting hepatic injury (such as anorexia, nausea, vomiting, fever, malaise, fatigue, right upper quadrant pain, jaundice, dark urine, or itching).

Consider obtaining periodic hepatic serum enzymes, especially during the first 6 months of treatment. It is not known whether routine periodic monitoring of serum enzymes will prevent the development of severe liver injury. If hepatic injury is suspected, promptly discontinue MULTAQ and test serum enzymes, aspartate aminotransferase (AST), alanine aminotransferase (ALT), and alkaline phosphatase, as well as serum bilirubin, to establish whether there is liver injury. If liver injury is found, institute appropriate treatment and investigate the probable cause. Do not restart MULTAQ in patients without another explanation for the observed liver injury.

Hypokalemia and Hypomagnesemia with Potassium-Depleting Diuretics

Hypokalemia and hypomagnesemia may occur with concomitant administration of potassium-depleting diuretics. Potassium levels should be within the normal range prior to administration of MULTAQ and maintained in the normal range during administration of MULTAQ.

QT Interval Prolongation

MULTAQ induces a moderate (average of about 10 msec but much greater effects have been observed) QTc (Bazett) prolongation. If the QTc Bazett interval is \geq 500 msec, MULTAQ should be stopped.

Increase in Creatinine

Serum creatinine levels increase by about 0.1 mg/dL following MULTAQ treatment initiation. The elevation has a rapid onset, reaches a plateau after 7 days and is reversible after discontinuation. If an increase in serum creatinine occurs and plateaus, this increased value should be used as the patient's new baseline. The change in creatinine levels has been shown to be the result of an inhibition of creatinine's tubular secretion, with no effect upon the glomerular filtration rate.

Drug-Drug Interactions

- Treatment with Class I or III antiarrhythmics or drugs that are strong inhibitors of CYP 3A must be stopped before starting MULTAQ (see Contraindications)
- Patients should be instructed to avoid grapefruit juice beverages while taking MULTAQ
- Calcium channel blockers and beta-blockers could potentiate the effects of MULTAQ on conduction
- Increased digoxin levels and gastrointestinal disorders have been observed when MULTAQ was coadministered with digoxin. Digoxin can also potentiate the electrophysiologic effects of MULTAQ (such as decreased AV-node conduction); the need for digoxin therapy should be reconsidered when prescribing MULTAQ. If digoxin treatment is continued, halve the dose of digoxin, monitor serum levels closely, and observe for toxicity
- Postmarketing cases of increased INR with or without bleeding events have been reported in warfarin-treated patients initiated with MULTAQ. Monitor INR after initiating MULTAQ in patients taking warfarin

Adverse Reactions

In studies, the most common adverse reactions observed with MULTAQ were diarrhea, nausea, abdominal pain, vomiting, and asthenia.

Please see brief summary of Prescribing Information, including boxed WARNING, on adjacent pages.

References: 1. Singh BN, Connolly SJ, Crijns HJGM, et al; for the EURIDIS and ADONIS Investigators. Dronedaron for maintenance of sinus rhythm in atrial fibrillation or flutter. *N Engl J Med.* 2007;357:987-999. 2. MULTAQ® (dronedaron) Prescribing Information. Sanofi-aventis U.S. LLC; 2011, Bridgewater, NJ. 3. Hohnloser SH, Crijns HJGM, van Eickels M, et al; for the ATHENA Investigators. Effect of dronedaron on cardiovascular events in atrial fibrillation. *N Engl J Med.* 2009;360:668-678.