

Medicare Sets Bonuses for Intensive Primary Care

BY ALICIA AULT

Medicare will begin rewarding primary care physicians for spending more time with patients and offering services such as late hours and intensive care management beginning next summer, under a new program unveiled Sept. 28.

The Primary Care Initiative aims to pay primary care physicians for services that

they currently might not have time to provide or aren't getting paid for, such as creating a care plan, reviewing test results on the phone, or helping patients closely manage cholesterol or weight, Dr. Richard Baron, director of the seamless care models group at the Centers for Medicare and Medicaid Services (CMS), said during a telephone briefing with reporters.

Some physician groups welcomed the announcement. The initiative "offers

enormous potential to promote the kind of personalized and coordinated care that patients seek and that physicians want to deliver," Dr. Steven Weinberger, executive vice president and chief executive officer of the American College of Physicians, said in a statement. The program "will provide primary care physicians with the support needed to work hand-in-hand with patients toward a shared goal of ensuring high-quality

care while making the most efficient use of health care resources."

The initiative is being funded by the Affordable Care Act, Dr. Baron said.

"Instead of being paid for doing more procedures and squeezing more patients into each day, primary care practices will receive payments for being accessible after hours or using electronic health records to make sure care is well coordinated," Health and Human Services

For the management of fibromyalgia

Savella relieves symptoms of fibromyalgia

- Delivers simultaneous improvements on 3 measures of fibromyalgia¹
 - Pain reduction
 - Improvement in patient global fibromyalgia assessment
 - Improvement in physical function
- Decrease in pain as early as week 1 of treatment with a stable dose in some patients who reported global improvement¹
 - Primary endpoint was assessed at week 15
- Low potential for pharmacokinetic drug-drug interactions¹
 - Clinically important interactions may occur with MAOIs, serotonergic drugs (including other SSRIs, SNRIs, lithium, tryptophan, antipsychotics, and dopamine antagonists), triptans, catecholamines (epinephrine and norepinephrine), CNS-active drugs (including clomipramine), and select cardiovascular agents (digoxin and clonidine)
- A dual reuptake inhibitor that blocks the uptake of norepinephrine over serotonin with approximately 3 times greater potency in vitro¹
 - The clinical significance of in vitro data is unknown
- Widely available on managed care formularies²

Savella 
 milnacipran HCl
 12.5 mg, 25 mg, 50 mg, 100 mg tablets
 For the management of fibromyalgia

IMPORTANT SAFETY INFORMATION

Savella is a selective serotonin and norepinephrine reuptake inhibitor (SNRI), similar to some drugs used for the treatment of depression and other psychiatric disorders. Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders. Anyone considering the use of such drugs in a child, adolescent, or young adult must balance this risk with the clinical need. Short-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24; there was a reduction in risk with antidepressants compared to placebo in adults aged 65 and older. Depression and certain other psychiatric disorders are themselves associated with increases in the risk of suicide. Patients of all ages who are started on Savella should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior, especially during the initial few months of drug therapy or at times of dose changes, either increases or decreases. Families and caregivers should be advised of the need for close observation and communication with the prescriber. Savella is not approved for use in the treatment of major depressive disorder. Savella is not approved for use in pediatric patients.

References: 1. Savella (milnacipran HCl) prescribing information. Forest Pharmaceuticals, Inc. St Louis, MO. 2. MediMedia Database as of April 2011 for Savella.

Secretary Kathleen Sebelius said during the briefing. "For patients, it means valuable extra time with their doctors, to understand their conditions and talk about how to lead healthier lives."

The program aims to recognize the ability of primary care to lower costs and improve health outcomes, Dr. Baron said. Some insurers and self-insured companies have started making similar payments for enhanced primary care services.

Dick Wilkerson, chairman and president of Michelin North America, said that his company has seen a huge decrease in health costs by covering 100%

of preventive care services and 100% of care for people with chronic conditions, as well as making primary care services available on-site at two of its major facilities. Primary care physicians are required to spend a minimum of 20 minutes with each Michelin patient, he said.

The company has had a big reduction in emergency department visits, hospitalizations, and high-cost claims, he said.

WellPoint has also been testing bonus payments and coordinated care models in nine of its Blue Cross Blue Shield plans, said Dr. Sam Nussbaum, WellPoint chief medical officer. Participating

medical practices offer on-site care managers and 24/7 access for members. There has been a 4%-6% reduction in hospitalizations, rehospitalizations, and emergency department visits, he said.

The agency is seeking letters of intent from private insurers and other payers by Nov. 15; final applications are due by Jan. 17. After the CMS has identified the markets where there will be a critical mass of Medicare and private pay patients covered by the incentives, the agency will solicit participation from primary care physicians. The aim is to be in five to seven markets with 75 physician

practices participating.

Physicians who meet the program goals will be eligible to receive \$20 per Medicare beneficiary per month for the first 2 years of the program. The payment will be reduced to \$15 for the second 2 years.

It will be up to the practices to determine how they can best manage patients for that incentive, said Dr. Richard Gilfillan, acting director of the CMS Innovation Center. But, he and Dr. Baron noted that the CMS will be available to help physician practices with data and other support to make the initiative work for them. ■

Contraindications

- Savella is contraindicated in patients taking monoamine oxidase inhibitors (MAOIs) concomitantly or within 14 days of discontinuing treatment with an MAOI. There have been reports of serious, sometimes fatal, reactions in patients started on an MAOI who were receiving or had recently discontinued a serotonin reuptake inhibitor. At least 5 days should be allowed after stopping Savella before starting an MAOI.
- Savella is contraindicated in patients with uncontrolled narrow-angle glaucoma and should be used with caution in patients with controlled narrow-angle glaucoma. In clinical trials, Savella was associated with an increased risk of mydriasis.

Warnings and Precautions

- Prescriptions for Savella should be written for the smallest quantity of tablets, consistent with good patient management, in order to reduce the risk of overdose.
- Development of a potentially life-threatening serotonin syndrome or neuroleptic malignant syndrome (NMS)-like reactions have been reported with SSRIs and SNRIs alone, including Savella, but particularly with concomitant use of serotonergic drugs (including triptans), drugs that impair metabolism of serotonin (including MAOIs), or antipsychotics or other dopamine antagonists. The management of these reactions should include immediate discontinuation of Savella and the concomitant agent and supportive symptomatic treatment. The concomitant use of Savella with serotonin precursors is not recommended.
- SNRIs, including Savella, have been associated with cardiovascular effects, including cases of elevated blood pressure, requiring immediate treatment. In clinical trials, sustained increases in systolic and diastolic blood pressure occurred more frequently in Savella-treated patients compared to placebo. Among patients who were non-hypertensive at baseline, approximately twice as many patients receiving Savella, vs placebo, became hypertensive at the end of the study. Clinically significant increases in pulse (≥ 20 bpm) occurred more frequently in Savella-treated than placebo-treated patients. Blood pressure and heart rate should be monitored prior to initiating treatment with Savella and periodically throughout treatment. Pre-existing hypertension, tachyarrhythmias, and other cardiac diseases should be treated before starting therapy with Savella. Savella should be used with caution in patients with significant hypertension or cardiac disease. Concomitant use of Savella with drugs that increase blood pressure and pulse has not been evaluated, and such combinations should be used with caution. For patients who experience a sustained increase in blood pressure or heart rate while receiving Savella, either dose reduction or discontinuation should be considered.
- Savella should be prescribed with caution in patients with a history of seizure disorder or mania.

- Savella has been associated with mild elevations of ALT and AST (1 to 3 times the upper limit of normal). Rarely, reports of serious liver injury, including fulminant hepatitis, have been reported in patients treated with milnacipran. Savella should be discontinued in patients who develop jaundice or other evidence of liver dysfunction and should not be resumed unless another cause can be established.
- As with other SNRIs and SSRIs, withdrawal symptoms have been observed following discontinuation of milnacipran. A gradual dose reduction is recommended.
- Hyponatremia may occur as a result of treatment with SSRIs and SNRIs, including Savella. Elderly patients may be at greater risk. Discontinuation should be considered for patients with symptomatic hyponatremia.
- SSRIs and SNRIs, including Savella, may increase the risk of bleeding events. Patients should be cautioned regarding the risk of bleeding associated with concomitant use of Savella and NSAIDs, aspirin, warfarin, or other drugs that affect coagulation.
- Savella can affect urethral resistance and micturition. Caution is advised in the use of Savella in patients with a history of dysuria, notably in male patients with a history of obstructive uropathies as these patients may experience higher rates of genitourinary adverse events.
- Savella should ordinarily not be prescribed to patients with substantial alcohol use or evidence of chronic liver disease.

Use in Specific Populations

- There are no adequate and well-controlled studies in pregnant women. Savella should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Adverse Reactions

- In clinical trials, the most frequently occurring adverse reaction was nausea (37% vs 20% for placebo). The most commonly occurring adverse reactions ($\geq 5\%$ and greater than placebo) were headache (18% vs 14%), constipation (16% vs 4%), dizziness (10% vs 6%), insomnia (12% vs 10%), hot flush (12% vs 2%), hyperhidrosis (9% vs 2%), vomiting (7% vs 2%), palpitations (7% vs 2%), heart rate increased (6% vs 1%), dry mouth (5% vs 2%), and hypertension (5% vs 2%).

Please see brief summary of Prescribing Information on the following pages.

Please also see Full Prescribing Information at www.Savella.com.

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