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MARCH 25, 2013

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Sunshine Act Communication will prevent you from getting burned PAGE 64

MU2

2013's Interoperability Challenge

Connectivity barriers remain as physicians try to move from EHR implementation to meaningful data exchange, communication PAGE 18

Plus

ACOs redefine relationships with specialists PAGE 47

Credit lines can be lifelines PAGE 52

Can immunization services protect your business? PAGE 59

ADVANSTAR MEDICAL COMMUNICATIONS GROUP

VOL. 90 NO. 6

FOR ADULT PATIENTS WITH TYPE 2 DIABETES

TRADJENTA® (LINAGLIPTIN) TABLETS: THE ONLY SINGLE-STRENGTH DPP-4 INHIBITOR

Focusing on what matters

Improving glycemic control for adult patients with type 2 diabetes

Indication and Important Limitations of Use

TRADJENTA is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

TRADJENTA should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis.

Important Safety Information

CONTRAINDICATIONS

TRADJENTA is contraindicated in patients with a history of hypersensitivity reaction to linagliptin, such as urticaria, angioedema or bronchial hyperreactivity.

WARNINGS AND PRECAUTIONS

Use with Medications Known to Cause Hypoglycemia
Insulin secretagogues and insulin are known to cause hypoglycemia. The use of TRADJENTA in combination with an insulin secretagogue (e.g., sulfonylurea) was associated with a higher rate of hypoglycemia compared with placebo in a clinical trial. Therefore, a lower dose of the insulin secretagogue or insulin may be required to reduce the risk of hypoglycemia when used in combination with TRADJENTA.

Macrovascular Outcomes
There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with TRADJENTA or any other antidiabetic drug.

ADVERSE REACTIONS

Adverse reactions reported in ≥5% of patients treated with TRADJENTA and more commonly than in patients treated with placebo included nasopharyngitis.

Hypoglycemia was more commonly reported in patients treated with the combination of TRADJENTA and sulfonylurea compared with those treated with the combination of placebo and sulfonylurea. When TRADJENTA was administered in combination with metformin and a sulfonylurea, 181 of 792 (22.9%) patients reported hypoglycemia compared with 39 of 263 (14.8%) patients administered placebo in combination with metformin and a sulfonylurea. In patients receiving

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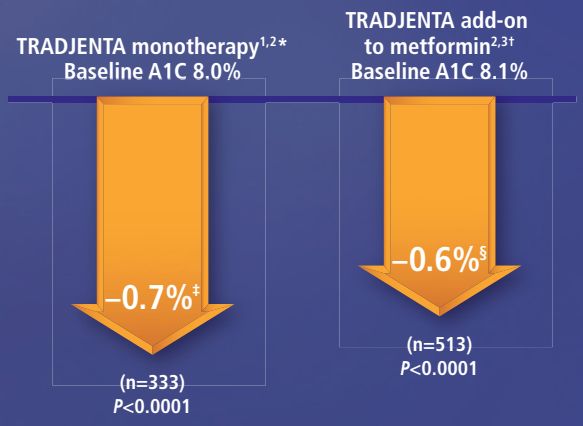
TRADJENTA delivers proven glycemic control

Placebo-adjusted difference in A1C with oral mono- and dual therapy at 24 weeks (%)



*A randomized, multicenter, double-blind, placebo-controlled study of adult patients with type 2 diabetes (aged 18-80) who were randomized to TRADJENTA 5 mg/day (n=336; mean baseline A1C=8.0%) or placebo (n=167; mean baseline A1C=8.0%) for 24 weeks. Primary endpoint was change from baseline in A1C at 24 weeks. 20.9% of patients in the placebo group required rescue therapy vs 10.2% of patients in the TRADJENTA group. Full analysis population using last observation on study.

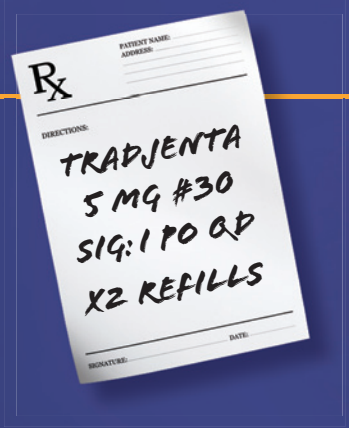
†A randomized, double-blind, placebo-controlled, parallel-group study of adult patients with type 2 diabetes (aged 18-80) with insufficient glycemic control despite metformin therapy who were randomized to TRADJENTA 5 mg/day (n=524; mean baseline A1C=8.1%) or placebo (n=177; mean baseline A1C=8.0%) in combination with metformin ≥1500 mg/day for 24 weeks. Primary endpoint was change from baseline in A1C at 24 weeks. 18.9% of patients in the placebo group required rescue therapy vs 7.8% of patients in the TRADJENTA group. Full analysis population using last observation on study.

‡0.3% adjusted mean increase from baseline A1C 8.0% with placebo (n=163).[2]

§0.15% adjusted mean increase from baseline A1C 8.0% with placebo plus metformin (n=175).[2]

TRADJENTA: A single-strength DPP-4 inhibitor

- No dose adjustment required regardless of declining renal function or hepatic impairment
- TRADJENTA is primarily nonrenally excreted with 80% eliminated via the bile and gut and 5% eliminated via the kidney within 4 days of dosing
- TRADJENTA has a demonstrated safety profile evaluated in more than 6000 patients



TRADJENTA as add-on therapy to a stable dose of insulin, severe hypoglycemic events were reported in 11 (1.7%) patients compared with 7 (1.1%) for placebo.

In the clinical trial program, pancreatitis was reported in 15.2 cases per 10,000 patient-years of exposure while being treated with TRADJENTA compared with 3.7 cases per 10,000 patient-years of exposure while being treated with comparator (placebo and active comparator, sulfonylurea). Three additional cases of pancreatitis were reported following the last administered dose of linagliptin.

DRUG INTERACTIONS

The efficacy of TRADJENTA may be reduced when administered in combination with a strong P-glycoprotein or CYP3A4 inducer (e.g., rifampin). Therefore, use of alternative treatments to TRADJENTA is strongly recommended.

USE IN SPECIFIC POPULATIONS

There are no adequate and well-controlled studies in pregnant women. Therefore, TRADJENTA should be used during pregnancy only if clearly needed.

It is not known whether linagliptin is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when TRADJENTA is administered to a nursing woman.

The safety and effectiveness of TRADJENTA in patients below the age of 18 have not been established.

TJ PROF ISI Sept 28 2012

References: 1. Del Prato S, Barnett AH, Huisman H, et al. Effect of linagliptin monotherapy on glycaemic control and markers of β-cell function in patients with inadequately controlled type 2 diabetes: a randomized controlled trial. *Diabetes Obes Metab.* 2011;13:258-267. **2.** Data on file. Boehringer Ingelheim Pharmaceuticals, Inc. **3.** Taskinen M-R, Rosenstock J, Tamminen I, et al. Safety and efficacy of linagliptin as add-on therapy to metformin in patients with type 2 diabetes: a randomized, double-blind, placebo-controlled study. *Diabetes Obes Metab.* 2011;13:65-74.

Please see brief summary of full Prescribing Information on adjacent page.

Tradjenta®
(linagliptin) tablets 5 mg

Find out more about TRADJENTA and the Savings Card program at www.tradjenta.com

Lilly

Tradjenta® (linagliptin) tablets

BRIEF SUMMARY OF PRESCRIBING INFORMATION R_x only

Please see package insert for full Prescribing Information.

INDICATIONS AND USAGE

Monotherapy and Combination Therapy: TRADJENTA tablets are indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. **Important Limitations of Use:** TRADJENTA should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis, as it would not be effective in these settings.

CONTRAINDICATIONS

TRADJENTA is contraindicated in patients with a history of a hypersensitivity reaction to linagliptin, such as urticaria, angioedema, or bronchial hyperreactivity.

WARNINGS AND PRECAUTIONS

Use with Medications Known to Cause Hypoglycemia: Insulin secretagogues and insulin are known to cause hypoglycemia. The use of TRADJENTA in combination with an insulin secretagogue (e.g., sulfonylurea) was associated with a higher rate of hypoglycemia compared with placebo in a clinical trial. The use of TRADJENTA in combination with insulin in subjects with severe renal impairment was associated with a higher rate of hypoglycemia. Therefore, a lower dose of the insulin secretagogue or insulin may be required to reduce the risk of hypoglycemia when used in combination with TRADJENTA. **Macrovascular Outcomes:** There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with TRADJENTA tablets or any other antidiabetic drug.

ADVERSE REACTIONS

Clinical Trials Experience: 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 the clinical trials of another drug and may not reflect the rates observed in practice. The safety evaluation of TRADJENTA 5 mg once daily in patients with type 2 diabetes is based on 14 placebo-controlled trials, 1 active-controlled study, and one study in patients with severe renal impairment. In the 14 placebo-controlled studies, a total of 3625 patients were randomized and treated with TRADJENTA 5 mg daily and 2176 with placebo. The mean exposure in patients treated with TRADJENTA across studies was 29.6 weeks. The maximum follow-up was 78 weeks. TRADJENTA 5 mg once daily was studied as monotherapy in three placebo-controlled trials of 18 and 24 weeks' duration and in five additional placebo-controlled studies lasting ≤18 weeks. The use of TRADJENTA in combination with other antihyperglycemic agents was studied in six placebo-controlled trials: two with metformin (12 and 24 weeks' treatment duration); one with a sulfonylurea (18 weeks' treatment duration); one with metformin and sulfonylurea (24 weeks' treatment duration); one with pioglitazone (24 weeks' treatment duration); and one with insulin (primary endpoint at 24 weeks). In a pooled dataset of 14 placebo-controlled clinical trials, adverse reactions that occurred in ≥2% of patients receiving TRADJENTA (n = 3625) and more commonly than in patients given placebo (n = 2176), are shown in Table 1. The overall incidence of adverse events with TRADJENTA were similar to placebo.

Table 1 Adverse Reactions Reported in ≥2% of Patients Treated with TRADJENTA and Greater than Placebo in Placebo-Controlled Clinical Studies of TRADJENTA Monotherapy or Combination Therapy

	Number (%) of Patients	
	TRADJENTA 5 mg n = 3625	Placebo n = 2176
Nasopharyngitis	254 (7.0)	132 (6.1)
Diarrhea	119 (3.3)	65 (3.0)
Cough	76 (2.1)	30 (1.4)

Rates for other adverse reactions for TRADJENTA 5 mg versus placebo when TRADJENTA was used in combination with specific anti-diabetic agents were: urinary tract infection (3.1% vs 0%) and hypertriglyceridemia (2.4% vs 0%) when TRADJENTA was used as add-on to sulfonylurea; hyperlipidemia (2.7% vs 0.8%) and weight increased (2.3% vs 0.8%) when TRADJENTA was used as add-on to pioglitazone; and constipation (2.1% vs 1%) when TRADJENTA was used as add-on to basal insulin therapy. Following 104 weeks' treatment in a controlled study comparing TRADJENTA with glimepiride in which all patients were also receiving metformin, adverse reactions reported in ≥5% of patients treated with TRADJENTA (n = 776) and more frequently than in patients treated with a sulfonylurea (n = 775) were back pain (9.1% vs 8.4%), arthralgia (8.1% vs 6.1%), upper respiratory tract infection (8.0% vs 7.6%), headache (6.4% vs 5.2%), cough (6.1% vs 4.9%), and pain in extremity (5.3% vs 3.9%). Other adverse reactions reported in clinical studies with treatment of TRADJENTA were hypersensitivity (e.g., urticaria, angioedema, localized skin exfoliation, or bronchial hyperreactivity), and myalgia. In the clinical trial program, pancreatitis was reported in 15.2 cases per 10,000 patient year exposure while being treated with TRADJENTA compared with 3.7 cases per 10,000 patient year exposure while being treated with comparator (placebo and active comparator, sulfonylurea). Three additional cases of pancreatitis were reported following the last administered dose of linagliptin. *Hypoglycemia:* In the placebo-controlled studies, 199 (6.6%) of the total 2994 patients treated with TRADJENTA 5 mg reported hypoglycemia compared to 56 patients (3.6%) of 1546 placebo-treated patients. The incidence of hypoglycemia was similar to placebo when TRADJENTA was administered as monotherapy or in combination with metformin, or with pioglitazone. When TRADJENTA was administered in combination with metformin and a sulfonylurea, 181 of 792 (22.9%) patients reported hypoglycemia compared with 39 of 263 (14.8%) patients administered placebo in combination with metformin and a sulfonylurea. Adverse reactions of hypoglycemia were based on all reports of hypoglycemia. A concurrent glucose measurement was not required or was normal in some patients. Therefore, it is not possible to conclusively determine that all these reports reflect true hypoglycemia. In the study of patients receiving TRADJENTA as add-on therapy to a stable dose of insulin for up to 52 weeks (n=1261), no significant difference in the incidence of investigator reported hypoglycemia, defined as all symptomatic or asymptomatic episodes with a self measured blood glucose ≤70 mg/dL, was noted between the TRADJENTA (31.4%) and placebo (32.9%) treated groups. During the same time period, severe hypoglycemic events, defined as requiring the assistance of another person to actively administer carbohydrate, glucagon or other resuscitative actions, were reported in 11 (1.7%) of TRADJENTA treated patients and 7 (1.1%) of placebo treated patients. Events that were considered life-threatening or required hospitalization were reported in 3 (0.5%) patients on TRADJENTA and 1 (0.2%) on placebo. *Use in Renal Impairment:* TRADJENTA was compared to placebo as add-on to pre-existing antidiabetic therapy over 52 weeks in 133 patients with severe renal impairment (estimated GFR <30 mL/min). For the initial 12 weeks of the study, background antidiabetic therapy was kept stable and included insulin, sulfonylurea, glinides, and pioglitazone. For the remainder of the trial, dose adjustments in antidiabetic background therapy were allowed. In general, the incidence of adverse events including severe hypoglycemia was similar to those reported in other TRADJENTA trials. The observed incidence of hypoglycemia was higher (TRADJENTA, 63% compared to placebo, 49%) due to an increase in asymptomatic hypoglycemic events especially during the first 12 weeks when background glycemic therapies were kept stable. Ten TRADJENTA treated patients (15%) and 11 placebo-treated patients (17%) reported at least one episode of confirmed symptomatic hypoglycemia (accompanying finger stick glucose ≤54 mg/dL). During the same time period, severe hypoglycemic events, defined as an event requiring the assistance of another person to actively administer carbohydrate, glucagon or other resuscitative actions, were reported in 3 (4.4%) TRADJENTA treated patients and 3 (4.6%) placebo treated patients. Events that were considered life-threatening or required hospitalization were reported in 2 (2.9%) patients on TRADJENTA and 1 (1.5%) on placebo. Renal function as measured by mean eGFR and creatinine clearance did not change over 52 weeks treatment compared to placebo. *Laboratory Tests:* Changes in laboratory findings were similar in patients treated with TRADJENTA 5 mg compared to patients treated with placebo. Changes in laboratory values that occurred more frequently in the TRADJENTA group and ≥1% more than in the placebo group were increases in uric acid (1.3% in the placebo group, 2.7% in the TRADJENTA group). No clinically meaningful changes in vital signs were observed in patients treated with TRADJENTA.

DRUG INTERACTIONS

Inducers of P-glycoprotein or CYP3A4 Enzymes: Rifampin decreased linagliptin exposure suggesting that the efficacy of TRADJENTA may be reduced when administered in combination with a strong P-gp or CYP3A4 inducer. Therefore, use of alternative treatments is strongly recommended when linagliptin is to be administered with a strong P-gp or CYP3A4 inducer.

USE IN SPECIFIC POPULATIONS

Pregnancy: *Pregnancy Category B.* Reproduction studies have been performed in rats and rabbits. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed. Linagliptin administered during the period of organogenesis was not teratogenic at doses up to 30 mg/kg in the rat and 150 mg/kg in the rabbit, or approximately 49 and 1943 times the clinical dose based on AUC exposure. Doses of linagliptin causing maternal toxicity in the rat and the rabbit also caused developmental delays in skeletal ossification and slightly increased embryofetal loss in rat (1000 times the clinical dose) and increased fetal resorptions and visceral and skeletal variations in the rabbit (1943 times the clinical dose). Linagliptin administered to female rats from gestation day 6 to lactation day 21 resulted in decreased body weight and delays in physical and behavioral development in male and female offspring at maternally toxic doses (exposures >1000 times the clinical dose). No functional, behavioral, or reproductive toxicity was observed in offspring of rats exposed to 49 times the clinical dose. Linagliptin crossed the placenta into the fetus following oral dosing in pregnant rats and rabbits. **Nursing Mothers:** Available animal data have shown excretion of linagliptin in milk at a milk-to-plasma ratio of 4:1. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when TRADJENTA is administered to a nursing woman. **Pediatric Use:** Safety and effectiveness of TRADJENTA in pediatric patients have not been established. **Geriatric Use:** There were 4040 type 2 diabetes patients treated with linagliptin 5 mg from 15 clinical trials of TRADJENTA; 1085 (27%) were 65 years and over, while 131 (3%) were 75 years and over. Of these patients, 2566 were enrolled in 12 double-blind placebo-controlled studies; 591 (23%) were 65 years and over, while 82 (3%) were 75 years and over. No overall differences in safety or effectiveness were observed between patients 65 years and over and younger patients. Therefore, no dose adjustment is recommended in the elderly population. While clinical studies of linagliptin have not identified differences in response between the elderly and younger patients, greater sensitivity of some older individuals cannot be ruled out. **Renal Impairment:** No dose adjustment is recommended for patients with renal impairment. **Hepatic Impairment:** No dose adjustment is recommended for patients with hepatic impairment.

OVERDOSAGE

In the event of an overdose with TRADJENTA, contact the Poison Control Center. Employ the usual supportive measures (e.g., remove unabsorbed material from the gastrointestinal tract, employ clinical monitoring, and institute supportive treatment) as dictated by the patient's clinical status. Removal of linagliptin by hemodialysis or peritoneal dialysis is unlikely. During controlled clinical trials in healthy subjects, with single doses of up to 600 mg of TRADJENTA (equivalent to 120 times the recommended daily dose) there were no dose-related clinical adverse drug reactions. There is no experience with doses above 600 mg in humans.

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PAGE 52

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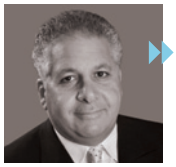

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MARCH 25, 2013

Volume 90
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COLUMNS

51 CODING INSIGHTS

Maxine Lewis,
CMM, CPC, CPC-I
Complex care coordination

58 FINANCIAL STRATEGIES

Marissa Manley
Funding retirement through practice property equity

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STARTS ON PAGE
18

MEANINGFUL USE 2: 2013'S INTEROPERABILITY CHALLENGE

COVER STORY | TECH

Connectivity barriers remain as physicians move from EHR implementation to data exchange, communication

STARTS ON PAGE 18

- Meaningful use stage 2 objectives
- Interoperability is goal of EHR vendor alliance
- 4 tips to help you exchange health information with other providers
- Health information exchange pilot to begin soon

IN DEPTH

Tech

Operations

Money

Trends

Policy

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When Patients **RAISE** *Concerns About Cholesterol Treatment…*

INDICATIONS AND USAGE

Drug therapy should be one component of multiple-risk-factor intervention in individuals who require modifications of their lipid profile. Lipid-altering agents should be used in addition to a diet restricted in saturated fat and cholesterol only when the response to diet and other nonpharmacological measures has been inadequate.

PRIMARY HYPERLIPIDEMIA AND MIXED DYSLIPIDEMIA

LIVALO® (pitavastatin) is indicated as an adjunctive therapy to diet to reduce elevated total cholesterol (TC), low-density lipoprotein cholesterol (LDL-C), apolipoprotein B (Apo B), triglycerides (TG), and to increase high-density lipoprotein cholesterol (HDL-C) in adult patients with primary hyperlipidemia or mixed dyslipidemia.

LIMITATIONS OF USE

- Doses of LIVALO greater than 4 mg once daily were associated with an increased risk for severe myopathy in premarketing clinical studies. Do not exceed 4-mg, once-daily dosing of LIVALO
- The effect of LIVALO on cardiovascular morbidity and mortality has not been determined
- LIVALO has not been studied in Fredrickson Type I, III, and V dyslipidemias

LIV-RA-0037 PS73368 08/2011

IMPORTANT SAFETY INFORMATION FOR LIVALO (pitavastatin) tablets

CONTRAINDICATIONS

LIVALO is contraindicated in patients with a known hypersensitivity to product components, in patients with active liver disease (which may include unexplained persistent elevations in hepatic transaminase levels), in women who are pregnant or may become pregnant, in nursing mothers, or in co-administration with cyclosporine.

Please see additional Important Safety Information for LIVALO on the adjacent page.
LIVALO is available in 1-mg, 2-mg, and 4-mg tablets.

Try LIVALO® to Lower LDL-C and Improve Other Lipid Parameters

IMPORTANT SAFETY INFORMATION FOR LIVALO (pitavastatin) tablets (continued)

WARNINGS AND PRECAUTIONS

Skeletal Muscle Effects

Cases of myopathy and rhabdomyolysis with acute renal failure secondary to myoglobinuria have been reported with HMG-CoA reductase inhibitors, including LIVALO.

- The risk of skeletal muscle effects (e.g., myopathy and rhabdomyolysis) increases in a dose-dependent manner with advanced age (≥65 years), renal impairment, inadequately treated hypothyroidism, and in combination use with fibrates or lipid-modifying doses of niacin (≥1 g/day)
- Concomitant administration of LIVALO with gemfibrozil should be avoided
- LIVALO therapy should be discontinued if markedly elevated CK levels occur or myopathy is diagnosed or suspected. LIVALO therapy should also be temporarily withheld in any patient with an acute, serious condition suggestive of myopathy or predisposing to the development of renal failure secondary to rhabdomyolysis (e.g., sepsis; hypotension; dehydration; major surgery; trauma; severe metabolic, endocrine, and electrolyte disorders; or uncontrolled seizures)
- Advise patients to promptly report unexplained muscle pain, tenderness, or weakness, particularly if accompanied by malaise or fever, and to discontinue LIVALO if these signs or symptoms appear
- There have been rare reports of immune-mediated necrotizing myopathy (IMNM), an autoimmune myopathy, associated with statin use. IMNM is characterized by: proximal muscle weakness and elevated serum creatine kinase, which persist despite discontinuation of statin treatment; muscle biopsy showing necrotizing myopathy without significant inflammation; improvement with immunosuppressive agents. IMNM has not been reported with LIVALO therapy
- Advise patients to promptly report if muscle signs and symptoms persist after discontinuing LIVALO as this may be a sign of IMNM requiring immediate medical attention

Liver Enzyme Abnormalities

Increases in serum transaminases have been reported with HMG-CoA reductase inhibitors, including LIVALO.

- It is recommended that liver enzyme tests be performed before the initiation of LIVALO and if signs or symptoms of liver injury occur
- There have been rare postmarketing reports of fatal and non-fatal hepatic failure in patients taking statins, including pitavastatin. If serious liver injury with clinical symptoms and/or hyperbilirubinemia or jaundice occurs during treatment with LIVALO, promptly interrupt therapy. If an alternate etiology is not found do not restart LIVALO
- Advise patients to promptly report any symptoms that may indicate liver injury, including fatigue, anorexia, right upper abdominal discomfort, dark urine or jaundice
- LIVALO should be used with caution in patients who consume substantial quantities of alcohol and/or have a history of chronic liver disease

Endocrine Function

Increases in HbA1c and fasting serum glucose levels have been reported with HMG-CoA reductase inhibitors, including LIVALO.

ADVERSE REACTIONS

In short-term controlled studies, the most frequent adverse reactions reported by ≥2% of patients treated with LIVALO 1 mg, 2 mg, and 4 mg, respectively, and at a rate ≥ placebo were back pain (3.9%, 1.8%, 1.4% vs 2.9%), constipation (3.6%, 1.5%, 2.2% vs 1.9%), diarrhea (2.6%, 1.5%, 1.9% vs 1.9%), myalgia (1.9%, 2.8%, 3.1% vs 1.4%), and pain in extremity (2.3%, 0.6%, 0.9% vs 1.9%). This is not a complete listing of all reported adverse events.

For additional information please see the full Prescribing Information provided, or visit www.LivaloRx.com.

LIV-RA-0050 PS81391 10/2012

Please see brief summary of full Prescribing Information on the following page.

Livalo®
(pitavastatin) tablets

Kowa Lilly

LIVALO® (pitavastatin) tablets

BRIEF SUMMARY: The following is a brief summary only. Before prescribing, see full Prescribing Information*.

INDICATIONS AND USAGE

LIVALO is a HMG-CoA reductase inhibitor indicated as an adjunctive therapy to diet to reduce elevated total cholesterol (TC), low-density lipoprotein cholesterol (LDL-C), apolipoprotein B (Apo B), triglycerides (TG), and to increase high-density lipoprotein cholesterol (HDL-C) in adult patients with primary hyperlipidemia or mixed dyslipidemia.

Limitations of Use: Doses of LIVALO greater than 4 mg once daily were associated with an increased risk for severe myopathy in premarketing clinical studies. Do not exceed 4 mg once daily dosing of LIVALO. The effect of LIVALO on cardiovascular morbidity and mortality has not been determined. LIVALO has not been studied in Fredrickson Type I, III, and V dyslipidemias.

General Dosing Information: The dose range for LIVALO is 1 to 4 mg orally once daily at any time of the day with or without food. The recommended starting dose is 2 mg and the maximum dose is 4 mg. The starting dose and maintenance doses of LIVALO should be individualized according to patient characteristics, such as goal of therapy and response. After initiation or upon titration of LIVALO, lipid levels should be analyzed after 4 weeks and the dosage adjusted accordingly.

Dosage in Patients with Renal Impairment: Patients with moderate and severe renal impairment (glomerular filtration rate 30 – 59 mL/min/1.73 m^2 and 15 – 29 mL/min/1.73 m^2 not receiving hemodialysis, respectively) as well as end-stage renal disease receiving hemodialysis should receive a starting dose of LIVALO 1 mg once daily and a maximum dose of LIVALO 2 mg once daily.

Use with Erythromycin or Rifampin: In patients taking erythromycin, a dose of LIVALO 1 mg once daily should not be exceeded. In patients taking rifampin, a dose of LIVALO 2 mg once daily should not be exceeded.

CONTRAINDICATIONS

The use of LIVALO is contraindicated in the following conditions:

- Known hypersensitivity to product components
- Active liver disease, which may include unexplained persistent elevations in hepatic transaminase levels
- Women who are pregnant or may become pregnant
- Nursing mothers
- Co-administration with cyclosporine

*See **CONTRAINDICATIONS (4)** in full Prescribing Information**.*

WARNINGS AND PRECAUTIONS

Skeletal Muscle Effects: Cases of myopathy and rhabdomyolysis with acute renal failure secondary to myoglobinuria have been reported with HMG-CoA reductase inhibitors, including LIVALO. These risks can occur at any dose level, but increase in a dose-dependent manner. LIVALO should be prescribed with caution in patients with predisposing factors for myopathy. These factors include advanced age (≥65 years), renal impairment, and inadequately treated hypothyroidism. The risk of myopathy may also be increased with concurrent administration of fibrates or lipid-modifying doses of niacin. LIVALO should be administered with caution in patients with impaired renal function, in elderly patients, or when used concomitantly with fibrates or lipid-modifying doses of niacin (≥1 g/day). Concomitant administration of LIVALO with gemfibrozil should be avoided. There have been rare reports of immune-mediated necrotizing myopathy (IMNM), an autoimmune myopathy, associated with statin use. IMNM is characterized by: proximal muscle weakness and elevated serum creatine kinase, which persist despite discontinuation of statin treatment; muscle biopsy showing necrotizing myopathy without significant inflammation; improvement with immunosuppressive agents. LIVALO therapy should be discontinued if markedly elevated creatine kinase (CK) levels occur or myopathy is diagnosed or suspected. LIVALO therapy should also be temporarily withheld in any patient with an acute, serious condition suggestive of myopathy or predisposing to the development of renal failure secondary to rhabdomyolysis (e.g., sepsis, hypotension, dehydration, major surgery, trauma, severe metabolic, endocrine, and electrolyte disorders, or uncontrolled seizures). All patients should be advised to promptly report unexplained muscle pain, tenderness, or weakness, particularly if accompanied by malaise or fever or if muscle signs and symptoms persist after discontinuing LIVALO.

Liver Enzyme Abnormalities: Increases in serum transaminases (aspartate aminotransferase [AST]/serum glutamic-oxaloacetic transaminase, or alanine aminotransferase [ALT]/serum glutamic-pyruvic transaminase) have been reported with HMG-CoA reductase inhibitors, including LIVALO. In most cases, the elevations were transient and resolved or improved on continued therapy or after a brief interruption in therapy. In placebo-controlled Phase 2 studies, ALT >3 times the upper limit of normal was not observed in the placebo, LIVALO 1 mg, or LIVALO 2 mg groups. One out of 202 patients (0.5%) administered LIVALO 4 mg had ALT >3 times the upper limit of normal.

It is recommended that liver enzyme tests be performed before the initiation of LIVALO and if signs or symptoms of liver injury occur.

There have been rare postmarketing reports of fatal and non-fatal hepatic failure in patients taking statins, including pitavastatin. If serious liver injury with clinical symptoms and/or hyperbilirubinemia or jaundice occurs during treatment with LIVALO, promptly interrupt therapy. If an alternate etiology is not found do not restart LIVALO.

As with other HMG-CoA reductase inhibitors, LIVALO should be used with caution in patients who consume substantial quantities of alcohol. Active liver disease, which may include unexplained persistent transaminase elevations, is a contraindication to the use of LIVALO.

Endocrine Function

Increases in HbA1c and fasting serum glucose levels have been reported with HMG-CoA reductase inhibitors, including LIVALO.

ADVERSE REACTIONS:

Serious Adverse Reactions: The following adverse reactions are discussed in detail in the full prescribing information*: rhabdomyolysis with myoglobinuria and acute renal failure and myopathy (including myositis); and liver enzyme abnormalities.

Clinical Studies Experience: Because clinical studies are conducted in varying study populations and study designs, the frequency of adverse reactions observed in the clinical studies of LIVALO cannot be directly compared with that in the clinical studies of other HMG-CoA reductase inhibitors and may not reflect the frequency of adverse reactions observed in clinical practice. Adverse reactions reported in ≥2% of patients in controlled clinical studies and at a rate greater than or equal to placebo are shown in the Table below.

Adverse Reactions by MedDRA preferred term reported by ≥2.0% of Patients Treated with LIVALO and > Placebo in Short-Term (up to 12 weeks) Controlled Studies

Adverse Reactions	Placebo N= 208	LIVALO 1 mg N=309	LIVALO 2 mg N=951	LIVALO 4 mg N=1540
Back Pain	2.9%	3.9%	1.8%	1.4%
Constipation	1.9%	3.6%	1.5%	2.2%
Diarrhea	1.9%	2.6%	1.5%	1.9%
Myalgia	1.4%	1.9%	2.8%	3.1%
Pain in extremity	1.9%	2.3%	0.6%	0.9%

Other adverse reactions reported from clinical studies were arthralgia, headache, influenza, and nasopharyngitis. Laboratory abnormalities were also reported including elevated creatine phosphokinase, transaminases, alkaline phosphatase, bilirubin, and glucose. In controlled clinical studies and their open-label extensions, 3.9% (1 mg), 3.3% (2 mg), and 3.7% (4 mg) of pitavastatin-treated patients were discontinued due to adverse reactions. The most common adverse reactions that led to treatment discontinuation were: elevated creatine phosphokinase (0.6% on 4 mg) and myalgia (0.5% on 4 mg). Hypersensitivity reactions including rash, pruritus, and urticaria have been reported with LIVALO.

Postmarketing Experience: The following adverse reactions have been identified during postapproval use of LIVALO. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Adverse reactions associated with LIVALO therapy reported since market introduction, regardless of causality assessment, include the following: abdominal discomfort, abdominal pain, dyspepsia, nausea, asthenia, fatigue, malaise, hepatitis, jaundice, fatal and non-fatal hepatic failure, dizziness, hypoesthesia, insomnia, depression, interstitial lung disease, erectile dysfunction and muscle spasms.

There have been rare postmarketing reports of cognitive impairment (e.g., memory loss, forgetfulness, amnesia, memory impairment, confusion) associated with statin use. These cognitive issues have been reported for all statins. The reports are generally nonserious, and reversible upon statin discontinuation, with variable times to symptom onset (1 day to years) and symptom resolution (median of 3 weeks).

There have been rare reports of immune-mediated necrotizing myopathy associated with statin use.

DRUG INTERACTIONS:

Consult the full prescribing information* regarding suggested dose reductions or avoidance of LIVALO therapy when co-adminstration of any of the following is being considered:

- LIVALO should not be used with cyclosporine.
- LIVALO dose reduction is indicated when using erythromycin and rifampin.
- LIVALO co-administration with gemfibrozil should be avoided.
- LIVALO should be administered with caution when used concomitantly with other fibrates.
- LIVALO dose reduction may be indicated when using lipid-modifying doses (≥1g/day) of niacin.
- LIVALO had no significant effect on prothrombin time (PT) and international normalized ratio (INR) when administered to patients receiving chronic warfarin treatment *[see Clinical Pharmacology (12.3)]*. However, patients receiving warfarin should have their PT and INR monitored when pitavastatin is added to their therapy.

*See **Pharmacokinetics (12.3)** in full Prescribing Information* for additional drug interaction information.*

HOW SUPPLIED

LIVALO tablets for oral administration are provided as white, film-coated tablets that contain 1 mg, 2 mg, or 4 mg of pitavastatin. Each tablet has "KC" debossed on one side and a code number specific to the tablet strength (1, 2, or 4) on the other.

Storage: Store at room temperature between 15°C and 30°C (59° to 86°F) [see USP]. Protect from light.

PATIENT COUNSELING INFORMATION

See **PATIENT COUNSELING INFORMATION (17)** *in full Prescribing Information**.

LIVALO® is a trademark of the Kowa group of companies.

Manufactured under license from: Kowa Company, Limited Tokyo 103-8433 Japan
Product of Japan

Manufactured into tablets by: Patheon, Inc. Cincinnati, OH 45237 USA or
by Kowa Company, LTD Nagoya, 462-0024 Japan

Marketed by: Kowa Pharmaceuticals America, Inc. Montgomery, AL 36117 USA,
and Lilly USA, LLC. Indianapolis, IN 46285 USA

* The full Prescribing Information for LIVALO (pitavastatin) tablets is available at www.LivaloRx.com.

LIV-RA-0051 PS81390 10/2012

LIVALO® (pitavastatin) tablets LIV-RA-0051 PS81390 10/2012

from the Trenches

thoughts from **LOIS A. BOWERS, MA, EDITOR-IN-CHIEF**

THE NEW AND IMPROVED *MEDICAL ECONOMICS*

Notice anything different?

With this issue, *Medical Economics* is unveiling a redesign that features a new look and the presentation of information by topic area rather than by dividing content into sections of features and columns or "departments" such as question-and-answer pieces. So this issue and future ones will look a little different than what you're used to seeing. We hope you like it as much as we do, because we made the change with you in mind.

Medical Economics is producing its 90th volume this year. Over that time, both the practice of medicine and the look of the print publication have changed to reflect the times—and in the case of our publication, your needs. You've told us how pressed for time you are, how important the business information we convey is to you as you face financial and other pressures. With this redesign, we are able to present this information to you in an energetic, easy-to-navigate package.

The general areas into which you'll find content divided:

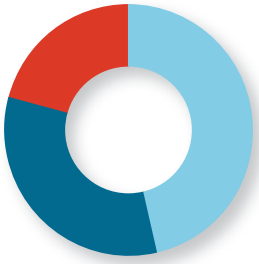
- **Money**—topics related to practice finances, payers, and payment systems.
- **Policy**—information about government actions that affect your livelihood as well as new approaches to the practice of medicine.
- **Operations**—subject matter related to efficient management of your practice so that you maximize your human and financial resources.
- **Technology**—keeping you up-to-date on meaningful use requirements and other technology-related news and information.
- **Trends**—information that may transcend any one category while relaying the latest data and thought leadership on particular issues.
- **Out of office**—the place where your colleagues will share professional experiences that have left an impression on them, as well as issues such as professional/personal life balance, volunteer pursuits, and other activities in which you engage when you're not at work or that affect your personal life.

"PLEASE SHARE YOUR THOUGHTS WITH US. WE WANT YOU TO BE PART OF THE PROCESS."

Some of your favorite columns and departments now have new names or present information in a slightly different way. A new offering will feature new drugs, devices, and technology and other products of interest to you (see page 46). And in this space, From the Trenches, you'll typically find thoughts from your fellow physicians. You'll notice more information about social media and other online offerings, too.

Our redesign is a work in progress that I'm sure we'll be redefining as we progress. Please share your thoughts with us—we want you to be part of the process. Our goal is to help you be successful in your professional endeavors, so please let us know how we can best do that. Send me an email message at lbowers@advanstar.com.

Are you a family or internal medicine physician accepting new patients?



Yes, I am accepting any type of patient

Yes, but I am accepting only patients who have private insurance or pay cash

I am not accepting new patients

"This may change to only accepting private pay/insurance if further cuts to government insurance happen."

"Medicaid is my best friend right now; turn around time is 1 week, and less rejections, way better than any other normal insurance providers."

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> As a solo family physician for more than 30 years, the cost to implement ICD-10...is estimated to be $83,290. Couple that with the $250,000 average first-year cost for an electronic health record system, and you can understand why I have gone to a cash practice, accepting no insurance."
>
> **Gary Yarborough, MD,** PARSONS, KANSAS

APPROACH OF ICD-11 MAKES TRANSITION TO ICD-10 UNNECESSARY

In his article "ICD-10: Can physicians stave off or delay implementation?" (February 10, 2013), Senior Editor Jeffrey Bendix, MA, outlines the mandate by the government to use ICD-10, and that the deadline has been pushed from 2013 back to 2014. He points out the opposition by medical groups related to cost and changes needed, and that payers and others are moving ahead. He points out that the ICD-10 has been used in Europe for 10 years, which implies that we Americans are and have been backward for not using ICD-10 also. The implication is that our government is helping our country out by mandating the same system the rest of the world uses.

Mr. Bendix does not say that ICD-11 comes out in 2015 and will correct many of the problems of ICD-10. So why go to all that expense and trouble now? The "rest of the world" that uses ICD-10 will switch to ICD-11, as they did from ICD-9 to ICD-10.

The AMA and some other physician groups are fighting ICD-10 with the goal of skipping over ICD-10 and going straight to ICD-11 in 2015. At a time when so much is changing (Mr. Bendix covered this very well), why make everyone learn a new coding language and style of documenting medical care that is already dead and being replaced in a year?

Stanley Sharp, MD
KANSAS CITY, MISSOURI

ICD-10 WON'T IMPROVE PATIENT CARE

Jeffrey Bendix's article on ICD-10 actually makes a case for not implementing it. He mentions that European countries have been using ICD-10 since the 1980s. They have documented no decreases in morbidity or mortality solely related to ICD-10 implementation, however.

Mr. Bendix's article points out that a finger fracture now has to be coded not only as to which finger but to which phalanx of that finger. Such extreme specificity will not result in improved quality of care for that fracture; after all, no one has ever healed or improved just because their coding was more specific.

Mr. Bendix also inadvertently points out that there will be a huge increase in the cost of care delivery, costs that eventually will be paid by our patients. In my case, as a solo family physician for more than 30 years, the cost to implement ICD-10, according to the article, is estimated to be $83,290. Couple that with the $250,000 average first-year cost for installing an electronic health record [system], and you can understand why I have gone to a cash practice, accepting no insurance.

Now I once again work just for my patients by eliminating all the leaches sucking money out of healthcare and driving up costs.

Gary Yarborough, MD
PARSONS, KANSAS

TELL US

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Or mail to:
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the Vitals

Examining the news affecting the busines of medicine

ONE SIZE DOESN'T FIT ALL

A "one-size-fits-all" approach is at the heart of a key management problem facing primary care practices today, according to a new study in *Health Affairs*.

Unless primary care is redefined and organized in a different way—one in which it can "deliver and demonstrate measured value"—the field will remain marginalized, according to study authors Michael Porter, MBA, PhD, a Harvard business professor; Erika Pabo, MD, MBA, a clinical fellow at Harvard Medical School; and Thomas Lee, MD, Msc, network president at Partners HealthCare in Boston.

The key to redefining primary care lies in shifting it to what the authors call "value-based patient subgroup management."

The authors cite "five essential elements" to this approach:

- **Base primary care on patients' needs.** This involves designing care delivery processes and outcome measures around a small number of subgroups of patients with similar needs and challenges.
- **Integrate delivery models by subgroup.** Develop teams focused on care delivery and improvement for each patient subgroup.
- **Measure value for each patient subgroup.** Identify multiple outcomes that matter to patients. Outcomes are factors such as quality of life, timeliness of care, total costs, and specific measures for specific diseases.
- **Align payment with value.** Time-based bundled payments are an example.
- **Integrate teams and specialty care.** The mix will vary, but the main idea is that providers of both types must function as members of a joint team.

SEQUESTRATION CUTS INFLICT NEW PHYSICIAN PAIN, GROUPS SAY

Cuts to Medicare and other services will not only cost healthcare jobs; they also are putting more financial pressure on doctors, according to statements issued by two prominent physician groups.

Jeremy A. Lazarus, MD, president of the American Medical Association (AMA), reports, "Our lawmakers have failed to act, and Medicare patients and physicians will now feel real pain in the form of new cuts that come at an already difficult time for the nation's economy."

A report released jointly by the AMA, the American Hospital Association, and the American Nurses Association found that up to 766,000 healthcare and related jobs could be lost by 2021 as a result of the 2% cut in Medicare resulting from sequestration," Lazarus contends.

"The across-the-board cut will hit physicians particularly hard because of the fundamentally flawed Medicare physician payment system. Since 2001, Medicare payments for physician services have only increased by 4%, while the cost of caring for patients has gone up by more than 20%. A 2% cut widens the already enormous gap between what Medicare pays and the actual cost of caring for seniors," he says.

Jeffrey Cain, MD, president of the American Academy of Family Physicians, agrees. "As small businesses operating on a razor-thin margin, family physicians will face a stark choice between putting their practices at risk or reducing the number of elderly and disabled patients they can see. Rather than rein in costs, sequestration payment cuts to healthcare providers will reduce access to needed care, increase the risk that preventable health conditions will develop or will worsen, and increase the chance that patients will ultimately require more intensive and expensive care."

Thinkstock/Hemera

EHR satisfaction scores slide, survey says

A NEW SURVEY released by the American College of Physicians (ACP) and AmericanEHR Partners reports that overall user satisfaction with electronic health record (EHR) systems slid by 12% from 2010 to 2012.

Users reporting being "very dissatisfied" increased 10% during the same time period.

The ACP and AmericanEHR Partners reported the findings at the recently concluded 2013 Health Information and Management Systems Society annual meeting in New Orleans, Louisiana.

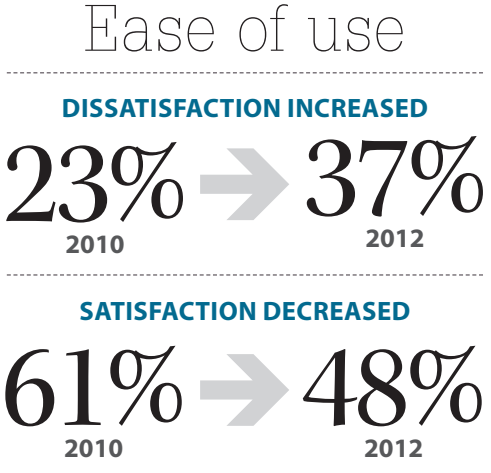
"Dissatisfaction is increasing regardless of practice type or EHR system," says Michael S. Barr, MD, MBA, FACP, who leads ACP's medical practice, professionalism, and quality division. "These findings highlight the need for the meaningful use program and EHR manufacturers to focus on improving EHR features and usability to help reduce inefficient work flows, improve error rates and patient care, and for practices to recognize the importance of ongoing training at all stages of EHR adoption."

The findings are from 4,279 responses to multiple surveys developed and analyzed by the ACP and AmericanEHR Partners between March 2010 and December 2012. Of the clinicians who responded to the surveys, 71% were in practices of 10 or fewer physicians and 82% of respondents intend to participate in the government's meaningful use incentive programs, up from 65% in 2010.

Additional key findings from the surveys:

- **The percentage of clinicians who would not recommend their EHR to a colleague increased from 24% in 2010 to 39% in 2012.**
- **Clinicians who were "very satisfied" with the ability of their EHR to improve care dropped by 6% compared with 2010, whereas those who were "very dissatisfied" increased 10%. (Surgical specialists were the least satisfied group. Primary care physicians were more satisfied than medical subspecialists.)**
- **34% of users were "very dissatisfied" with the ability of their EHR to decrease workload, an increase from 19% in 2010.**
- **Survey responses also indicated that it is becoming more difficult to return to pre-EHR implementation productivity. In 2012, 32% of the responders had not returned to normal productivity, compared with 20% in 2010.**

AmericanEHR Partners provides information to help clinicians select and use EHRs to improve healthcare delivery. It was founded by ACP and Cientis Technologies. More findings based on the surveys are available at www.americanehr.com.



ACP TO STUDY QUALITY OUTCOMES RELATED TO DIABETES, CARDIO CARE

A pilot to test the effects of a technology-based quality improvement program on physician participation, value to practices, rapid-cycle learning, and patient outcomes has been launched by the American College of Physicians (ACP) in collaboration with CECity, developer of a social, cloud-based performance improvement platform called MedConcert.

The 1-year pilot program, "Improving the Quality of Diabetes Care," will tailor MedConcert with diabetes and cardiovascular disease prevention content.

"This initiative will provide important data to help us determine the feasibility of recruiting physician offices to participate in an integrated, technology-based quality improvement program," says Michael S. Barr, MD, MBA, FACP, senior vice president of ACP's medical practice, professionalism, and quality division.

Up to 50 internal medicine practices in three states will have access to the following Web-based tools:

- **the ACP diabetes registry based on the 2013 Physician Quality Reporting System Diabetes Measure Group and related data elements;**
- **patient surveys to provide feedback on system and provider performance, including information about coordination of care; and**
- **the ACP's Medical Home Builder 2.0, which provides practice teams with a self-assessment tool designed to to improve patient care, streamline fundamental business operations, and implement key features of the Patient-Centered Medical Home.**

A report on the results of the pilot program is expected by the end of the year.

Important Safety Information

- COLCRYS is contraindicated in patients with renal or hepatic impairment who are currently prescribed P-gp inhibitors or strong inhibitors of CYP3A4. In these patients, life-threatening and fatal colchicine toxicity has been reported with colchicine taken in therapeutic doses. Dose adjustments of COLCRYS may be required when co-administered with P-gp or CYP3A4 inhibitors in patients with normal renal and hepatic function.
- Fatal overdoses, both accidental and intentional, have been reported in adults and children who have ingested colchicine. Keep COLCRYS out of the reach of children.
- Blood dyscrasias such as myelosuppression, leukopenia, granulocytopenia, thrombocytopenia, pancytopenia, and aplastic anemia have been reported in patients taking colchicine at therapeutic doses.

References:
1. COLCRYS (colchicine, USP) full prescribing information, June 2012.
2. Zhu Y, Pandya BJ, Choi HK. Prevalence of gout and hyperuricemia in the US general population: the National Health and Nutrition Examination Survey 2007-2008. *Arthritis Rheum.* 2011;63:3136-3141.

Takeda

Takeda GoutCare

If your patients are experiencing gout flares, consider COLCRYS (colchicine, USP)

Low-dose COLCRYS is indicated to treat acute attacks of gout, a common form of arthritis.[1,2]

Indications

COLCRYS (colchicine, USP) 0.6 mg tablets are indicated in adults for the prophylaxis of gout flares and treatment of acute gout flares when taken at the first sign of a flare.

COLCRYS is not an analgesic medication and should not be used to treat pain from other causes.

- Colchicine-induced neuromuscular toxicity and rhabdomyolysis have been reported with chronic treatment in therapeutic doses, especially when colchicine is prescribed in combination with other drugs known to cause this effect. Patients with renal dysfunction and elderly patients, even those with normal renal and hepatic function, are at increased risk.
- Monitor for toxicity and if present consider temporary interruption or discontinuation of colchicine.
- The most common adverse reactions in clinical trials were diarrhea (23%) and pharyngolaryngeal pain (3%).

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

Colcrys®
(colchicine, USP) tablets

SIGN UP TO LEARN MORE AT GoutRx.com

BRIEF SUMMARY OF FULL PRESCRIBING INFORMATION
COLCRYS (colchicine, USP) tablets for Oral use

INDICATIONS AND USAGE

Gout Flares
COLCRYS (colchicine, USP) tablets are indicated in adults for prophylaxis and the treatment of acute gout flares.

Prophylaxis of Gout Flares:
COLCRYS is indicated for prophylaxis of gout flares.

Treatment of Gout Flares:
COLCRYS tablets are indicated for treatment of acute gout flares when taken at the first sign of a flare.

Familial Mediterranean fever (FMF)
COLCRYS (colchicine, USP) tablets are indicated in adults and children 4 years or older for treatment of familial Mediterranean fever (FMF).

COLCRYS is not an analgesic medication and should not be used to treat pain from other causes.

CONTRAINDICATIONS

Patients with renal or hepatic impairment should not be given COLCRYS in conjunction with P-gp or strong CYP3A4 inhibitors (this includes all protease inhibitors, except fosamprenavir). In these patients, life-threatening and fatal colchicine toxicity has been reported with colchicine taken in therapeutic doses.

WARNINGS AND PRECAUTIONS

Fatal Overdose
Fatal overdoses, both accidental and intentional, have been reported in adults and children who have ingested colchicine [*see OVERDOSAGE*]. COLCRYS should be kept out of the reach of children.

Blood Dyscrasias
Myelosuppression, leukopenia, granulocytopenia, thrombocytopenia, pancytopenia, and aplastic anemia have been reported with colchicine used in therapeutic doses.

Drug Interactions
Colchicine is a P-gp and CYP3A4 substrate. Life-threatening and fatal drug interactions have been reported in patients treated with colchicine given with P-gp and strong CYP3A4 inhibitors. If treatment with a P-gp or strong CYP3A4 inhibitor is required in patients with normal renal and hepatic function, the patient's dose of colchicine may need to be reduced or interrupted [*see DRUG INTERACTIONS*]. Use of COLCRYS in conjunction with P-gp or strong CYP3A4 inhibitors (this includes all protease inhibitors, except fosamprenavir) is contraindicated in patients with renal or hepatic impairment [*see CONTRAINDICATIONS*].

Neuromuscular Toxicity
Colchicine-induced neuromuscular toxicity and rhabdomyolysis have been reported with chronic treatment in therapeutic doses. Patients with renal dysfunction and elderly patients, even those with normal renal and hepatic function, are at increased risk. Concomitant use of atorvastatin, simvastatin, pravastatin, fluvastatin, lovastatin, gemfibrozil, fenofibrate, fenofibric acid, or benzafibrate (themselves associated with myotoxicity) or cyclosporine with COLCRYS may potentiate the development of myopathy [*see DRUG INTERACTIONS*]. Once colchicine is stopped, the symptoms generally resolve within 1 week to several months.

ADVERSE REACTIONS

Prophylaxis of Gout Flares:
The most commonly reported adverse reaction in clinical trials of colchicine for the prophylaxis of gout was diarrhea.

Treatment of Gout Flares:
The most common adverse reactions reported in the clinical trial with COLCRYS for treatment of gout flares were diarrhea (23%) and pharyngolaryngeal pain (3%).

FMF:
Gastrointestinal tract adverse effects are the most frequent side effects in patients initiating COLCRYS, usually presenting within 24 hours, and occurring in up to 20% of patients given therapeutic doses. Typical symptoms include cramping, nausea, diarrhea, abdominal pain, and vomiting. These events should be viewed as dose-limiting if severe as they can herald the onset of more significant toxicity.

Clinical Trials Experience in Gout
Because clinical studies are conducted under widely varying and controlled conditions, adverse reaction rates observed in clinical studies of a drug cannot be directly compared to rates in the clinical studies of another drug, and may not predict the rates observed in a broader patient population in clinical practice.

In a randomized, double-blind, placebo-controlled trial in patients with a gout flare, gastrointestinal adverse reactions occurred in 26% of patients using the recommended dose (1.8 mg over 1 hour) of COLCRYS compared to 77% of patients taking a non-recommended high-dose (4.8 mg over 6 hours) of colchicine and 20% of patients taking placebo. Diarrhea was the most commonly reported drug-related gastrointestinal adverse event. As shown in Table 3, diarrhea is associated with COLCRYS treatment. Diarrhea was more likely to occur in patients taking the high-dose regimen than the low-dose regimen. Severe diarrhea occurred in 19% and vomiting occurred in 17% of patients taking the non-recommended high-dose colchicine regimen but did not occur in the recommended low-dose COLCRYS regimen.

Table 3
Number (%) of Patients with at Least One Drug-Related Treatment Emergent Adverse Events with an Incidence of ≥ 2% of Patients in Any Treatment Group

MedDRA System Organ Class MedDRA Preferred Term	COLCRYS Dose		Placebo (N=59) n (%)
	High (N=52) n (%)	Low (N=74) n (%)	
Number of Patients with at Least One Drug-Related TEAE	40 (77)	27 (37)	16 (27)
Gastrointestinal Disorders	40 (77)	19 (26)	12 (20)
Diarrhea	40 (77)	17 (23)	8 (14)
Nausea	9 (17)	3 (4)	3 (5)
Vomiting	9 (17)	0	0
Abdominal Discomfort	0	0	2 (3)
General Disorders and Administration Site Conditions	4 (8)	1 (1)	1 (2)
Fatigue	2 (4)	1 (1)	1 (2)
Metabolic and Nutrition Disorders	0	3 (4)	2 (3)
Gout	0	3 (4)	1 (2)
Nervous System Disorders	1 (2)	1 (1.4)	2 (3)
Headache	1 (2)	1 (1)	2 (3)
Respiratory Thoracic Mediastinal Disorders	1 (2)	2 (3)	0
Pharyngolaryngeal Pain	1 (2)	2 (3)	0

Postmarketing Experience
Serious toxic manifestations associated with colchicine include myelosuppression, disseminated intravascular coagulation, and injury to cells in the renal, hepatic, circulatory, and central nervous systems.

These most often occur with excessive accumulation or overdosage [*see OVERDOSAGE*].

The following adverse reactions have been reported with colchicine. These have been generally reversible upon temporarily interrupting treatment or lowering the dose of colchicine.

Neurological: sensory motor neuropathy

Dermatological: alopecia, maculopapular rash, purpura, rash

Digestive: abdominal cramping, abdominal pain, diarrhea, lactose intolerance, nausea, vomiting

Hematological: leukopenia, granulocytopenia, thrombocytopenia, pancytopenia, aplastic anemia

Hepatobiliary: elevated AST, elevated ALT

Musculoskeletal: myopathy, elevated CPK, myotonia, muscle weakness, muscle pain, rhabdomyolysis

Reproductive: azoospermia, oligospermia

DRUG INTERACTIONS

COLCRYS (colchicine) is a substrate of the efflux transporter P-glycoprotein (P-gp). Of the cytochrome P450 enzymes tested, CYP3A4 was mainly involved in the metabolism of colchicine. If COLCRYS is administered with drugs that inhibit P-gp, most of which also inhibit CYP3A4, increased concentrations of colchicine are likely. Fatal drug interactions have been reported.

Physicians should ensure that patients are suitable candidates for treatment with COLCRYS and remain alert for signs and symptoms of toxicities related to increased colchicine exposure as a result of a drug interaction. Signs and symptoms of COLCRYS toxicity should be evaluated promptly and, if toxicity is suspected, COLCRYS should be discontinued immediately.

Table 4 provides recommendations as a result of other potentially significant drug interactions. Table 1 provides recommendations for strong and moderate CYP3A4 inhibitors and P-gp inhibitors.

Table 4
Other Potentially Significant Drug Interactions

Concomitant Drug Class or Food	Noted or anticipated Outcome	Clinical Comment
HMG-Co A Reductase Inhibitors: atorvastatin, fluvastatin, lovastatin, pravastatin, simvastatin	Pharmacokinetic and/or pharmacodynamic interaction: the addition of one drug to a stable long-term regimen of the other has resulted in myopathy and rhabdomyolysis (including a fatality)	Weigh the potential benefits and risks and carefully monitor patients for any signs or symptoms of muscle pain, tenderness, or weakness, particularly during initial therapy; monitoring CPK (creatine phosphokinase) will not necessarily prevent the occurrence of severe myopathy.
Other Lipid Lowering Drugs: fibrates, gemfibrozil		
Digitalis Glycosides: digoxin	P-gp substrate; rhabdomyolysis has been reported	

USE IN SPECIFIC POPULATIONS

Pregnancy
Pregnancy Category C

There are no adequate and well-controlled studies with colchicine in pregnant women. Colchicine crosses the human placenta. While not studied in the treatment of gout flares, data from a limited number of published studies found no evidence of an increased risk of miscarriage, stillbirth, or teratogenic effects among pregnant women using colchicine to treat familial Mediterranean fever (FMF). Although animal reproductive and developmental studies were not conducted with COLCRYS, published animal reproduction and development studies indicate that colchicine causes embryofetal toxicity, teratogenicity, and altered postnatal development at exposures within or above the clinical therapeutic range. COLCRYS should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Labor and Delivery
The effect of colchicine on labor and delivery is unknown.

Nursing Mothers
Colchicine is excreted into human milk. Limited information suggests that exclusively breast-fed infants receive less than 10 percent of the maternal weight-adjusted dose. While there are no published reports of adverse effects in breast-feeding infants of mothers taking colchicine, colchicine can affect gastrointestinal cell renewal and permeability. Caution should be exercised and breast-feeding infants should be observed for adverse effects when COLCRYS is administered to a nursing woman.

Pediatric Use
The safety and efficacy of colchicine in children of all ages with FMF has been evaluated in uncontrolled studies. There does not appear to be an adverse effect on growth in children with FMF treated long-term with colchicine. Gout is rare in pediatric patients, safety and effectiveness of colchicine in pediatric patients has not been established.

Geriatric Use
Clinical studies with colchicine for prophylaxis and treatment of gout flares and for treatment of FMF did not include sufficient numbers of patients aged 65 years and older to determine whether they respond differently from younger patients. In general, dose selection for an elderly patient with gout should be cautious, reflecting the greater frequency of decreased renal function, concomitant disease, or other drug therapy.

Renal Impairment
Colchicine is significantly excreted in urine in healthy subjects. Clearance of colchicine is decreased in patients with impaired renal function. Total body clearance of colchicine was reduced by 75% in patients with end-stage renal disease undergoing dialysis.

Prophylaxis of Gout Flares:
For prophylaxis of gout flares in patients with mild (estimated creatinine clearance Clcr 50 – 80 mL/min) to moderate (Clcr 30 – 50 mL/min) renal function impairment, adjustment of the recommended dose is not required, but patients should be monitored closely for adverse effects of colchicine. However, in patients with severe impairment, the starting dose should be 0.3 mg per day and any increase in dose should be done with close monitoring. For the prophylaxis of gout flares in patients undergoing dialysis, the starting doses should be 0.3 mg given twice a week with close monitoring.

Treatment of Gout Flares:
For treatment of gout flares in patients with mild (Clcr 50 – 80 mL/min) to moderate (Clcr 30 – 50 mL/min) renal function impairment, adjustment of the recommended dose is not required, but patients should be monitored closely for adverse effects of COLCRYS. However, in patients with severe impairment, while the dose does not need to be adjusted for the treatment of gout flares, a treatment course should be repeated no more than once every 2 weeks. For patients with gout flares requiring repeated courses consideration should be given to alternate therapy. For patients undergoing dialysis, the total recommended dose for the treatment of gout flares should be reduced to a single dose of 0.6 mg (1 tablet). For these patients, the treatment course should not be repeated more than once every 2 weeks.

FMF
Although, pharmacokinetics of colchicine in patients with mild (Clcr 50 – 80 mL/min) and moderate (Clcr 30 – 50 mL/min) renal impairment is not known, these patients should be monitored closely for adverse effects of colchicine. Dose reduction may be necessary. In patients with severe renal failure (Clcr less than 30 mL/minute) and end-stage renal disease requiring dialysis, COLCRYS may be started at the dose of 0.3 mg/day. Any increase in dose should be done with adequate monitoring of the patient for adverse effects of COLCRYS.

Hepatic Impairment
The clearance of colchicine may be significantly reduced and plasma half-life prolonged in patients with chronic hepatic impairment, compared to healthy subjects.

Prophylaxis of Gout Flares:
For prophylaxis of gout flares in patients with mild to moderate hepatic function impairment, adjustment of the recommended dose is not required, but patients should be monitored closely for adverse effects of colchicine. Dose reduction should be considered for the prophylaxis of gout flares in patients with severe hepatic impairment.

Treatment of Gout Flares:
For treatment of gout flares in patients with mild to moderate hepatic function impairment, adjustment of the recommended COLCRYS dose is not required, but patients should be monitored closely for adverse effects of COLCRYS. However, for the treatment of gout flares in patients with severe impairment while the dose does not need to be adjusted, the treatment course should be repeated no more than once every 2 weeks. For these patients, requiring repeated courses for the treatment of gout flares, consideration should be given to alternate therapy.

FMF
In patients with severe hepatic disease, dose reduction should be considered with careful monitoring.

OVERDOSAGE
The exact dose of colchicine that produces significant toxicity is unknown. Fatalities have occurred after ingestion of a dose as low as 7 mg over a 4-day period, while other patients have survived after ingesting more than 60 mg. A review of 150 patients who overdosed on colchicine found that those who ingested less than 0.5 mg/kg survived and tended to have milder toxicities, such as gastrointestinal symptoms, whereas those who took 0.5 to 0.8 mg/kg had more severe reactions, such as myelosuppression. There was 100% mortality in those who ingested more than 0.8 mg/kg.

The first stage of acute colchicine toxicity typically begins within 24 hours of ingestion and includes gastrointestinal symptoms, such as abdominal pain, nausea, vomiting, diarrhea, and significant fluid loss, leading to volume depletion. Peripheral leukocytosis may also be seen. Life-threatening complications occur during the second stage, which occurs 24 to 72 hours after drug administration, attributed to multi-organ failure and its consequences. Death is usually a result of respiratory depression and cardiovascular collapse. If the patient survives, recovery of multi-organ injury may be accompanied by rebound leukocytosis and alopecia starting about 1 week after the initial ingestion.

Treatment of colchicine poisoning should begin with gastric lavage and measures to prevent shock. Otherwise, treatment is symptomatic and supportive. No specific antidote is known. Colchicine is not effectively removed by dialysis.

Distributed by:
Takeda Pharmaceuticals America, Inc.
Deerfield, IL 60015

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For more detailed information, see the complete prescribing information for COLCRYS (colchicine, USP) tablets at Colcrys.com or contact Takeda Pharmaceuticals America, Inc. at 1-877-825-3327. L-ECH-0612-1

Meaningful use 2:

2013's interoperability challenge

Connectivity barriers remain as physicians move from EHR implementation to data exchange, communication

by **JEFFREY BENDIX, MA,** *Senior Editor*

HIGHLIGHTS

01 Disparate electronic health record systems find it difficult to communicate directly with each other, leaving physicians with fewer options for meeting the information exchange requirements of the second stage of meaningful use.

02 Encrypting data, installing firewalls, and frequently changing access passwords are steps doctors and their staff members should take to ensure the security of patients' health information.

With stage 2 of the financial incentive program for meaningful use of electronic health records (EHRs) just over the horizon, 2013 is shaping up as a crucial year for meeting the biggest challenge to meaningful use compliance: the ability to exchange patient health information among providers.

THE REASON IS SIMPLE. Currently, wide-scale interoperability challenges exist, leaving primary care physicians and other providers with few options for meeting the health information exchange objectives included in meaningful use 2 (MU2). EHR vendors, along with the federal government and the states, are taking steps to address the interoperability issue and provide doctors with the tools to meet the MU2 requirements, but it is unclear how many of the proposed remedies will be available by the start of 2014 when MU2 attestation begins.

The rush to meet the MU2 interoperability requirements comes at a time when close to two-thirds of the nation's family physicians have implemented EHR systems, yet a recent survey of 17,000 doctors revealed that nearly 25% of them are considering changing EHR systems because of dissatisfaction with their current systems.

The weakness of EHR interoperability has not gone unnoticed in Congress, either. In October, four powerful Republican members of the U.S. House of Representatives' Ways and Means Committee wrote to Kath-

leen Sebelius, secretary of the U.S. Department of Health and Human Services (HHS), expressing "serious concern" that MU2 rules "fail to achieve comprehensive interoperability in a timely manner, leaving our healthcare system trapped in information silos." The letter urged Sebelius to suspend incentive payments and delay penalties until HHS promulgates universal interoperable standards.

The health information exchange requirements are among the 17 "core" objectives physicians must meet to qualify for MU2 under the program's final rule, which the Centers for Medicare and Medicaid Services (CMS) issued in August. (The rule also includes six "menu" objectives, from which providers must choose three to meet.) Doctors who began meaningful use in 2011 or 2012 will have to begin meeting the MU2 objectives in 2014. (See "MU2 objectives.")

Although many of the MU2 objectives are similar to those in stage 1, MU2 includes key differences in the areas of health information exchange, patient access to information, and securing patient information. In health information exchange, physicians must:

- provide a summary of care record for more than 50% of the patients they refer to another provider or transition to another care setting,
- supply the summary of care record electronically for more than 10% of those referrals or transitions, and
- conduct at least one successful electronic exchange of a summary of care with a recipient who uses a different EHR system.

In the area of patient access to information, doctors must:

- provide their patients with the ability to view online, download, and transmit their health information within 4 business days of the information being available to the physician, and
- have at least 5% of a practice's patients access their information online.

In the area of data security, physicians are required to protect electronic health information created or maintained by certified EHR technology.

For most doctors, especially ➔24

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MU2 objectives

As was the case with stage 1 of the meaningful use program, stage 2 consists of a set of core objectives that all electronic health record (EHR) users are required to meet. In addition, users must choose three from a set of six "menu" objectives.

CORE OBJECTIVES:

- use computerized order entry for medication, laboratory, and radiology orders;
- generate and transmit permissible prescriptions electronically;
- record demographic information;
- record and chart changes in vital signs;
- record smoking status for patients 13 years or older;
- use clinical decision support to improve performance on high-priority health conditions;
- protect electronic health information created or maintained by certified EHR technology;
- incorporate clinical lab test results into certified EHR technology;
- generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research, or outreach;
- use clinically relevant information to identify patients who should receive reminders for preventive/follow-up care;
- use certified EHR technology to identify patient-specific education resources;
- perform medication reconciliation;
- provide a summary of care record for each transition of care or referral;
- submit electronic data to immunization registries; and
- use secure electronic messaging to communicate with patients on relevant health information.

MENU OBJECTIVES:

- submit electronic syndromic surveillance data to public health agencies,
- record electronic notes in patient records,
- have imaging results available through certified EHR technology,
- record patient family health history,
- identify and report cancer cases to a state cancer registry, and
- identify and repot specific cases to a specialized registry (other than a cancer registry).

OxyContin® CII
(OXYCODONE HCl CONTROLLED-RELEASE) TABLETS

Not actual patients.

WARNING: ABUSE POTENTIAL, LIFE-THREATENING RESPIRATORY DEPRESSION, and ACCIDENTAL EXPOSURE

Abuse Potential

OxyContin® contains oxycodone, an opioid agonist and Schedule II controlled substance with an abuse liability similar to other opioid agonists, legal or illicit *[see Warnings and Precautions (5.1)]*. Assess each patient's risk for opioid abuse or addiction prior to prescribing OxyContin. The risk for opioid abuse is increased in patients with a personal or family history of substance abuse (including drug or alcohol abuse or addiction) or mental illness (e.g., major depressive disorder). Routinely monitor all patients receiving OxyContin for signs of misuse, abuse, and addiction during treatment *[see Drug Abuse and Dependence (9)]*.

Life-Threatening Respiratory Depression

Respiratory depression, including fatal cases, may occur with use of OxyContin, even when the drug has been used as recommended and not misused or abused *[see Warnings and Precautions (5.2)]*. Proper dosing and titration are essential and OxyContin should be prescribed only by healthcare professionals who are knowledgeable in the use of potent opioids for the management of chronic pain. Monitor for respiratory depression, especially during initiation of OxyContin or following a dose increase. Instruct patients to swallow OxyContin tablets intact. Crushing, dissolving, or chewing the tablet can cause rapid release and absorption of a potentially fatal dose of oxycodone.

Accidental Exposure

Accidental ingestion of OxyContin, especially in children, can result in a fatal overdose of oxycodone *[see Warnings and Precautions (5.3)]*.

Please read Brief Summary of Full Prescribing Information on the following pages, including Boxed Warning.

For eligible OxyContin patients

Broad formulary coverage and a savings program you can offer your patients

OxyContin is covered* on ~90% of lives, and is on a preferred branded tier for ~82% of lives nationally†

- Inclusion on formulary does not imply superior clinical efficacy or safety

The OxyContin Savings Program provides 2 convenient ways to access up to $90 in potential savings

The OxyContin Savings Card—printable online

- After paying the first $25, eligible patients can save up to $90 on each prescription by providing the pharmacist with a savings card

or

The eVoucherRx™ program

- After paying the first $25, eligible patients can save up to $90 on each prescription through an e-coupon that automatically applies savings at participating pharmacies' point of sale

Eligibility requirements: This card cannot be used if prescriptions are covered by: (i) any federal or state healthcare program, including a state medical or pharmaceutical assistance program (Medicare, Medicaid, Medigap, VA, DOD, TRICARE, etc); (ii) Medicare Prescription Drug Program (Part D Program); (iii) insurance in states that have an "all payer" anti-kickback law or insurance that is paying the entire cost of the prescription. Card use must comply with all Terms and Conditions. The patient is responsible for the first $25 out-of-pocket expense on each prescription. Other restrictions may apply.

Print patient savings cards at PurdueHCP.com/SavingsProgram

Indications and Usage

OxyContin is indicated for the management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time.

Limitations of Use

OxyContin is not for use:

- As an as-needed (prn) analgesic
- For pain that is mild or not expected to persist for an extended period of time
- For acute pain
- In the immediate postoperative period (the first 24 hours following surgery) for patients not previously taking the drug, because its safety in this setting has not been established
- For postoperative pain unless the patient is already receiving chronic opioid therapy prior to surgery, or if the postoperative pain is expected to be moderate to severe and persist for an extended period of time

OxyContin 60 mg and 80 mg tablets, a single dose greater than 40 mg, or a total daily dose greater than 80 mg are only for patients in whom tolerance to an opioid of comparable potency is established. Patients considered opioid tolerant are those who are taking at least 60 mg oral morphine/day, 25 mcg transdermal fentanyl/hour, 30 mg oral oxycodone/day, 8 mg oral hydromorphone/day, 25 mg oral oxymorphone/day, or an equianalgesic dose of another opioid for one week or longer.

Contraindications

OxyContin is contraindicated in patients with:

- Significant respiratory depression
- Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment
- Known or suspected paralytic ileus and gastrointestinal obstruction
- Hypersensitivity (e.g., anaphylaxis) to oxycodone

The eVoucherRx program for OxyContin is

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**Covered* represents on formulary (on any tier, with or without restrictions) and may include quantity limits, prior authorizations, and/or step edit restrictions.

†Source: Fingertip Formulary®–database represents 95%-98% of commercial, Medicare, and Medicaid covered lives in the U.S. (11/14/12). Please check with the health plan directly to confirm coverage for individual patients. Patient costs may vary among plans.

OXYCONTIN® CII
(OXYCODONE HCl CONTROLLED-RELEASE) TABLETS

OxyContin® CII

(OXYCODONE HCl CONTROLLED-RELEASE) TABLETS

10 mg | 15 mg | 20 mg | 30 mg

40 mg | 60 mg* | 80 mg*

***60 mg and 80 mg tablets for use in opioid-tolerant patients only**

BRIEF SUMMARY OF PRESCRIBING INFORMATION (For complete details please see the Full Prescribing Information and Medication Guide.)

WARNING: ABUSE POTENTIAL, LIFE-THREATENING RESPIRATORY DEPRESSION, and ACCIDENTAL EXPOSURE

Abuse Potential

OxyContin® contains oxycodone, an opioid agonist and Schedule II controlled substance with an abuse liability similar to other opioid agonists, legal or illicit *[see Warnings and Precautions (5.1)]*. Assess each patient's risk for opioid abuse or addiction prior to prescribing OxyContin. The risk for opioid abuse is increased in patients with a personal or family history of substance abuse (including drug or alcohol abuse or addiction) or mental illness (e.g., major depressive disorder). Routinely monitor all patients receiving OxyContin for signs of misuse, abuse, and addiction during treatment *[see Drug Abuse and Dependence (9)]*.

Life-Threatening Respiratory Depression

Respiratory depression, including fatal cases, may occur with use of OxyContin, even when the drug has been used as recommended and not misused or abused *[see Warnings and Precautions (5.2)]*. Proper dosing and titration are essential and OxyContin should be prescribed only by healthcare professionals who are knowledgeable in the use of potent opioids for the management of chronic pain. Monitor for respiratory depression, especially during initiation of OxyContin or following a dose increase. Instruct patients to swallow OxyContin tablets intact. Crushing, dissolving, or chewing the tablet can cause rapid release and absorption of a potentially fatal dose of oxycodone.

Accidental Exposure

Accidental ingestion of OxyContin, especially in children, can result in a fatal overdose of oxycodone *[see Warnings and Precautions (5.3)]*.

1 INDICATIONS AND USAGE OxyContin is indicated for the management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time. *Limitations of Use* OxyContin is not for use: • As an as-needed (prn) analgesic • For pain that is mild or not expected to persist for an extended period of time • For acute pain • In the immediate postoperative period (the first 24 hours following surgery) for patients not previously taking the drug, because its safety in this setting has not been established. • For postoperative pain unless the patient is already receiving chronic opioid therapy prior to surgery, or if the postoperative pain is expected to be moderate to severe and persist for an extended period of time. OxyContin 60 mg and 80 mg tablets, a single dose greater than 40 mg, or a total daily dose greater than 80 mg are only for patients in whom tolerance to an opioid of comparable potency is established. Patients considered opioid tolerant are those who are taking at least 60 mg oral morphine/day, 25 mcg transdermal fentanyl/hour, 30 mg oral oxycodone/day, 8 mg oral hydromorphone/day, 25 mg oral oxymorphone/day, or an equianalgesic dose of another opioid for one week or longer.

4 CONTRAINDICATIONS OxyContin is contraindicated in patients with: • Significant respiratory depression • Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment • Known or suspected paralytic ileus and gastrointestinal obstruction • Hypersensitivity (e.g., anaphylaxis) to oxycodone *[see Adverse Reactions (6.2)]*

5 WARNINGS AND PRECAUTIONS **5.1 Abuse Potential** OxyContin contains oxycodone, an opioid agonist and a Schedule II controlled substance. Oxycodone can be abused in a manner similar to other opioid agonists legal or illicit. Opioid agonists are sought by drug abusers and people with addiction disorders and are subject to criminal diversion. Consider these risks when prescribing or dispensing OxyContin in situations where there is concern about increased risks of misuse, abuse, or diversion. Concerns about abuse, addiction, and diversion should not, however, prevent the proper management of pain. Assess each patient's risk for opioid abuse or addiction prior to prescribing OxyContin. The risk for opioid abuse is increased in patients with a personal or family history of substance abuse (including drug or alcohol abuse or addiction) or mental illness (e.g., major depression). Patients at increased risk may still be appropriately treated with modified-release opioid formulations; however these patients will require intensive monitoring for signs of misuse, abuse, or addiction. Routinely monitor all patients receiving opioids for signs of misuse, abuse, and addiction because these drugs carry a risk for addiction even under appropriate medical use. Misuse or abuse of OxyContin by crushing, chewing, snorting, or injecting the dissolved product will result in the uncontrolled delivery of the opioid and pose a significant risk that could result in overdose and death *[see Overdosage (10)]*. Contact local state professional licensing board or state controlled substances authority for information on how to prevent and detect abuse or diversion of this product. **5.2 Life-Threatening Respiratory Depression** Respiratory depression is the chief hazard of opioid agonists, including OxyContin. Respiratory depression if not immediately recognized and treated, may lead to respiratory arrest and death. Respiratory depression from opioids is manifested by a reduced urge to breathe and a decreased rate of respiration, often associated with a "sighing" pattern of breathing (deep breaths separated by abnormally long pauses). Carbon dioxide (CO_2) retention from opioid-induced respiratory depression can exacerbate the sedating effects of opioids. Management of respiratory depression may include close observation, supportive measures, and use of opioid antagonists, depending on the patient's clinical status *[see Overdosage (10)]*. While serious, life-threatening, or fatal respiratory depression can occur at any time during the use of OxyContin, the risk is greatest during the initiation of therapy or following a dose increase. Closely monitor patients for respiratory depression when initiating therapy with OxyContin and following dose increases. Instruct patients against use by individuals other than the patient for whom OxyContin was prescribed and to keep OxyContin out of the reach of children, as such inappropriate use may result in fatal respiratory depression. To reduce the risk of respiratory depression, proper dosing and titration of OxyContin are essential *[see Dosage and Administration (2)]*. Overestimating the OxyContin dose when converting patients from another opioid product can result in fatal overdose with the first dose. Respiratory depression has also been reported with use of modified-release opioids when used as recommended and not misused or abused. To further reduce the risk of respiratory depression, consider the following: • Proper dosing and titration are essential and OxyContin should only be prescribed by healthcare professionals who are knowledgeable in the use of potent opioids for the management of chronic pain. • OxyContin 60 mg and 80 mg tablets are for use in opioid-tolerant patients only. Ingestion of these strengths of OxyContin tablets may cause fatal respiratory depression when administered to patients not already tolerant to high doses of opioids. • Instruct patients to swallow OxyContin tablets intact. The tablets are not to be crushed, dissolved, or chewed. The resulting oxycodone dose may be fatal, particularly in opioid-naïve individuals. • OxyContin is contraindicated in patients with respiratory depression and in patients with conditions that increase the risk of life-threatening respiratory depression *[see Contraindications (4)]*. **5.3 Accidental Exposure** Accidental ingestion of OxyContin, especially in children, can result in a fatal overdose of oxycodone. **5.4 Elderly, Cachectic, and Debilitated Patients** Respiratory depression is more likely to occur in elderly, cachectic, or debilitated patients as they may have altered pharmacokinetics or altered clearance compared to younger, healthier patients. Therefore, monitor such patients closely, particularly when initiating and titrating OxyContin and when OxyContin is given concomitantly with other drugs that depress respiration *[see Warnings and Precautions (5.2)]*. **5.5 Use in Patients with Chronic Pulmonary Disease** Monitor patients with significant chronic obstructive pulmonary disease or cor pulmonale, and patients having a substantially decreased respiratory reserve, hypoxia, hypercapnia, or pre-existing respiratory depression for respiratory depression, particularly when initiating therapy and titrating with OxyContin, as in these patients, even usual therapeutic doses of OxyContin may decrease respiratory drive to the point of apnea *[see Warnings and Precautions (5.2)]*. Consider the use of alternative non-opioid analgesics in these patients if possible. **5.6 Interactions with Alcohol, CNS Depressants, and Illicit Drugs** Hypotension, and profound sedation, coma or respiratory depression may result if OxyContin is used concomitantly with other CNS depressants (e.g., sedatives, anxiolytics, hypnotics, neuroleptics, muscle relaxants, other opioids). When considering the use of OxyContin in a patient taking a CNS depressant, assess the duration of use of the CNS depressant and the patient's response, including the degree of tolerance that has developed to CNS depression. Additionally, consider the patient's use, if any, of alcohol and/or illicit drugs that can cause CNS depression. If OxyContin therapy is to be initiated in a patient taking a CNS depressant, start with a lower OxyContin dose than usual and monitor patients for signs of sedation and respiratory depression and consider using a lower dose of the concomitant CNS depressant *[see Drug Interactions (7.1)]*. **5.7 Hypotensive Effects** OxyContin may cause severe hypotension including orthostatic hypotension and syncope in ambulatory patients. There is an increased risk in patients whose ability to maintain blood pressure has already been compromised by a reduced blood volume or concurrent administration of certain CNS depressant drugs (e.g., phenothiazines or general anesthetics) *[see Drug Interactions (7.1)]*. Monitor these patients for signs of hypotension after initiating or titrating the dose of OxyContin. In patients with circulatory shock, OxyContin may cause vasodilation that can further reduce cardiac output and blood pressure. Avoid the use of OxyContin in patients with circulatory shock. **5.8 Use in Patients with Head Injury or Increased Intracranial Pressure** Monitor patients taking OxyContin who may be susceptible to the intracranial effects of CO_2 retention (e.g., those with evidence of increased intracranial pressure or brain tumors) for signs of sedation and respiratory depression, particularly when initiating therapy with OxyContin. OxyContin may reduce respiratory drive, and the resultant CO_2 retention can further increase intracranial pressure. Opioids may also obscure the clinical course in a patient with a head injury. Avoid the use of OxyContin in patients with impaired consciousness or coma. **5.9 Difficulty in Swallowing and Risk for Obstruction in Patients at Risk for a Small Gastrointestinal Lumen** There have been post-marketing reports of difficulty in swallowing OxyContin tablets. These reports included choking, gagging, regurgitation and tablets stuck in the throat. Instruct patients not to pre-soak, lick or otherwise wet OxyContin tablets prior to placing in the mouth, and to take one tablet at a time with enough water to ensure complete swallowing immediately after placing in the mouth. There have been rare post-marketing reports of cases of intestinal obstruction, and exacerbation of diverticulitis, some of which have required medical intervention to remove the tablet. Patients with underlying GI disorders such as esophageal cancer or colon cancer with a small gastrointestinal lumen are at greater risk of developing these complications. Consider use of an alternative analgesic in patients who have difficulty swallowing and patients at risk for underlying GI disorders resulting in a small gastrointestinal lumen. **5.10 Use in Patients with Gastrointestinal Conditions** OxyContin is contraindicated in patients with GI obstruction, including paralytic ileus. The oxycodone in OxyContin may cause spasm of the sphincter of Oddi. Monitor patients with biliary tract disease, including acute pancreatitis, for worsening symptoms. Opioids may cause increases in the serum amylase. **5.11 Use in Patients with Convulsive or Seizure Disorders** The oxycodone in OxyContin may aggravate convulsions in patients with convulsive disorders, and may induce or aggravate seizures in some clinical settings. Monitor patients with a history of seizure disorders for worsened seizure control during OxyContin therapy. **5.12 Avoidance of Withdrawal** Avoid the use of mixed agonist/antagonist analgesics (i.e., pentazocine, nalbuphine, and butorphanol) in patients who have received or are receiving a course of therapy with a full opioid agonist analgesic, including OxyContin. In these patients, mixed agonist/antagonist analgesics may reduce the analgesic effect and/or may precipitate withdrawal symptoms. When discontinuing OxyContin, gradually taper the dose *[see Dosage and Administration (2.4)]*. Do not abruptly discontinue OxyContin. **5.13 Driving and Operating Machinery** OxyContin may impair the mental or physical abilities needed to perform potentially hazardous activities such as driving a car or operating machinery. Warn patients not to drive or operate dangerous machinery unless they are tolerant to the effects of OxyContin and know how they will react to the medication. **5.14 Cytochrome P450 3A4 Inhibitors and Inducers** Since the CYP3A4 isoenzyme plays a major role in the metabolism of OxyContin, drugs that alter CYP3A4 activity may cause changes in clearance of oxycodone which could lead to changes in oxycodone plasma concentrations. Inhibition of CYP3A4 activity by its inhibitors, such as macrolide antibiotics (e.g., erythromycin), azole-antifungal agents (e.g., ketoconazole), and protease inhibitors (e.g., ritonavir), may increase plasma concentrations of oxycodone and prolong opioid effects. CYP450 inducers, such as rifampin, carbamazepine, and phenytoin, may induce the metabolism of oxycodone and, therefore, may cause increased clearance of the drug which could lead to a decrease in oxycodone plasma concentrations, lack of efficacy or, possibly, development of an abstinence syndrome in a patient who had developed physical dependence to oxycodone. If co-administration is necessary, caution is advised when initiating OxyContin treatment in patients currently taking, or discontinuing, CYP3A4 inhibitors or inducers. Evaluate these patients at frequent intervals and consider dose adjustments until stable drug effects are achieved *[see Drug Interactions (7.3), and Clinical Pharmacology (12.3)]*. **5.15 Laboratory Monitoring** Not every urine drug test for "opioids" or "opiates" detects oxycodone reliably, especially those designed for in-office use. Further, many laboratories will report urine drug concentrations below a specified "cut-off" value as "negative". Therefore, if urine testing for oxycodone is considered in the clinical management of an individual patient, ensure that the sensitivity and specificity of the assay is appropriate, and consider the limitations of the testing used when interpreting results.

6 ADVERSE REACTIONS The following adverse reactions described elsewhere in the labeling include: • Respiratory depression *[see Boxed Warning, Warnings and Precautions (5.2, 5.5), and Overdosage (10)]* • CNS depression *[see Drug Interactions (7.1), and Overdosage (10)]* • Hypotensive effects *[see Warnings and Precautions (5.7), and Overdosage (10)]* • Drug abuse, addiction, and dependence *[see Drug Abuse and Dependence (9.2, 9.3)]* • Gastrointestinal Effects *[see Warnings and Precautions (5.9, 5.10)]* • Seizures *[see Warnings and Precautions (5.11)]* **6.1 Clinical Trial Experience** 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 the clinical trials of another drug and may not reflect the rates observed in practice. The safety of OxyContin was evaluated in double-blind clinical trials involving 713 patients with moderate to severe pain of various etiologies. In open-label studies of cancer pain, 187 patients received OxyContin in total daily doses ranging from 20 mg to 640 mg per day. The average total daily dose was approximately 105 mg per day. OxyContin may increase the risk of serious adverse reactions such as those observed with other opioid analgesics, including respiratory depression, apnea, respiratory arrest, circulatory depression, hypotension, or shock *[see Overdosage (10)]*. The most common adverse reactions (>5%) reported by patients in clinical trials comparing OxyContin with placebo are shown in Table 1 below:

TABLE 1: Common Adverse Reactions (>5%)

Adverse Reaction	OxyContin (n=227)	Placebo (n=45)
	(%)	(%)
Constipation	(23)	(7)
Nausea	(23)	(11)
Somnolence	(23)	(4)
Dizziness	(13)	(9)
Pruritus	(13)	(2)
Vomiting	(12)	(7)
Headache	(7)	(7)
Dry Mouth	(6)	(2)
Asthenia	(6)	—
Sweating	(5)	(2)

In clinical trials, the following adverse reactions were reported in patients treated with OxyContin with an incidence between 1% and 5%: **Gastrointestinal disorders:** abdominal pain, diarrhea, dyspepsia, gastritis **General disorders and administration site conditions:** chills, fever **Metabolism and nutrition disorders:** anorexia **Musculoskeletal and connective tissue disorders:** twitching **Psychiatric disorders:** abnormal dreams, anxiety, confusion, dysphoria, euphoria, insomnia, nervousness, thought abnormalities **Respiratory, thoracic and mediastinal disorders:** dyspnea, hiccups **Skin and subcutaneous tissue disorders:** rash **Vascular disorders:** postural hypotension The following adverse reactions occurred **in less than 1% of patients** involved in clinical trials: **Blood and lymphatic system disorders:** lymphadenopathy **Ear and labyrinth disorders:** tinnitus **Eye disorders:** abnormal vision **Gastrointestinal disorders:** dysphagia, eructation, flatulence, gastrointestinal disorder, increased appetite, stomatitis **General disorders and administration site conditions:** withdrawal syndrome (with and without seizures), edema, peripheral edema, thirst, malaise, chest pain, facial edema **Injury, poisoning and procedural complications:** accidental injury **Investigations:** ST depression **Metabolism and nutrition disorders:** dehydration **Nervous system disorders:** syncope, migraine, abnormal gait, amnesia, hyperkinesia, hypesthesia, hypotonia, paresthesia, speech disorder, stupor, tremor, vertigo, taste perversion **Psychiatric disorders:** depression, agitation, depersonalization, emotional lability, hallucination **Renal and urinary disorders:** dysuria, hematuria, polyuria, urinary retention **Reproductive system and breast disorders:** impotence **Respiratory, thoracic and mediastinal disorders:** cough increased, voice alteration **Skin and subcutaneous tissue disorders:** dry skin, exfoliative dermatitis **6.2 Postmarketing Experience** The following adverse reactions have been identified during post-approval use of controlled-release oxycodone: abuse, addiction, amenorrhea, cholestasis, death, dental caries, increased hepatic enzymes, hyperalgesia, hyponatremia, ileus, muscular hypertonia, overdose, palpitations (in the context of withdrawal), seizures, syndrome of inappropriate antidiuretic hormone secretion,

and urticaria. Anaphylaxis has been reported with ingredients contained in OxyContin. Advise patients how to recognize such a reaction and when to seek medical attention. In addition to the events listed above, the following have also been reported, potentially due to the swelling and hydrogelling property of the tablet: choking, gagging, regurgitation, tablets stuck in the throat and difficulty swallowing the tablet.

7 DRUG INTERACTIONS **7.1 CNS Depressants** Concurrent use of OxyContin and other central nervous system (CNS) depressants including sedatives or hypnotics, general anesthetics, phenothiazines, tranquilizers, and alcohol can increase the risk of respiratory depression, hypotension, profound sedation or coma. Monitor patients receiving CNS depressants and OxyContin for signs of respiratory depression and hypotension. When such combined therapy is contemplated, start OxyContin at 1/3 to 1/2 of the usual dosage and consider using a lower dose of the concomitant CNS depressant. **7.2 Muscle Relaxants** Oxycodone may enhance the neuromuscular blocking action of true skeletal muscle relaxants and produce an increased degree of respiratory depression. Monitor patients receiving muscle relaxants and OxyContin for signs of respiratory depression that may be greater than otherwise expected. **7.3 Agents Affecting Cytochrome P450 Isoenzymes** *Inhibitors of CYP3A4* Co-administration of a strong CYP3A4 inhibitor ketoconazole, with OxyContin, significantly increased the plasma concentrations of oxycodone. Inhibition of CYP3A4 activity by its inhibitors, such as macrolide antibiotics (e.g., erythromycin), azole-antifungal agents (e.g., ketoconazole), and protease inhibitors (e.g., ritonavir), may prolong opioid effects. If co-administration is necessary, caution is advised when initiating therapy with, currently taking, or discontinuing CYP3A4 inhibitors. Evaluate these patients at frequent intervals and consider dose adjustments until stable drug effects are achieved *[see Clinical Pharmacology (12.3)]*. *Inducers of CYP3A4* A published study showed that the co-administration of rifampin, a drug metabolizing enzyme inducer, significantly decreased plasma oxycodone concentrations. CYP450 inducers, such as rifampin, carbamazepine, and phenytoin, may induce the metabolism of oxycodone and, therefore, may cause increased clearance of the drug which could lead to a decrease in oxycodone plasma concentrations, lack of efficacy or, possibly, development of an abstinence syndrome in a patient who had developed physical dependence to oxycodone. If co-administration with OxyContin is necessary, caution is advised when initiating therapy with, currently taking, or discontinuing CYP3A4 inducers. Evaluate these patients at frequent intervals and consider dose adjustments until stable drug effects are achieved *[see Clinical Pharmacology (12.3)]*. *Inhibitors of CYP2D6* Oxycodone is metabolized in part to oxymorphone via CYP2D6. While this pathway may be blocked by a variety of drugs such as certain cardiovascular drugs (e.g., quinidine) and antidepressants (e.g., fluoxetine), such blockade has not been shown to be of clinical significance during oxycodone treatment. However, clinicians should be aware of this possible interaction. **7.4 Mixed Agonist/Antagonist Opioid Analgesics** Mixed agonist/antagonist analgesics (i.e., pentazocine, nalbuphine, and butorphanol) should generally not be administered to a patient who has received or is receiving a course of therapy with a pure opioid agonist analgesic such as OxyContin. In this situation, mixed agonist/antagonist analgesics may reduce the analgesic effect of oxycodone and may precipitate withdrawal symptoms in these patients. **7.5 Diuretics** Opioids can reduce the efficacy of diuretics by inducing the release of antidiuretic hormone. Opioids may also lead to acute retention of urine by causing spasm of the sphincter of the bladder, particularly in men with enlarged prostates. **7.6 Anticholinergics** Anticholinergics or other medications with anticholinergic activity when used concurrently with opioid analgesics may result in increased risk of urinary retention and/or severe constipation, which may lead to paralytic ileus. Monitor patients for signs of urinary retention or reduced gastric motility when OxyContin is used concurrently with anticholinergic drugs.

8 USE IN SPECIFIC POPULATIONS **8.1 Pregnancy** *Pregnancy Category B* There are no adequate and well-controlled studies of oxycodone use during pregnancy. Based on limited human data in the literature, oxycodone does not appear to increase the risk of congenital malformations. In animal reproduction and developmental toxicology studies, no evidence of fetal harm was observed. Because animal reproduction studies are not always predictive of human response, oxycodone should be used during pregnancy only if clearly needed. *Teratogenic Effects* The effect of oxycodone in human reproduction has not been adequately studied. Studies with oral doses of oxycodone hydrochloride in rats up to 8 mg/kg/day and rabbits up to 125 mg/kg/day, equivalent to 0.5 and 2.0 times an adult human dose of 160 mg/day, respectively on a mg/m^2 basis, did not reveal evidence of harm to the fetus due to oxycodone. In a pre- and postnatal toxicity study, female rats received oxycodone during gestation and lactation. There were no long-term developmental or reproductive effects in the pups *[see Nonclinical Toxicology (13.1)]*. *Non-Teratogenic Effects* Oxycodone hydrochloride was administered orally to female rats during gestation and lactation in a pre- and postnatal toxicity study. There were no drug-related effects on reproductive performance in these females or any long-term developmental or reproductive effects in pups born to these rats. Decreased body weight was found during lactation and the early post-weaning phase in pups nursed by mothers given the highest dose used (6 mg/kg/day, equivalent to approximately 0.4-times an adult human dose of 160 mg/day, on a mg/m^2 basis). However, body weight of these pups recovered. **8.2 Labor and Delivery** Opioids cross the placenta and may produce respiratory depression and psycho-physiologic effects in neonates. OxyContin is not recommended for use in women immediately prior to and during labor, when use of shorter-acting analgesics or other analgesic techniques are more appropriate. Occasionally, opioid analgesics may prolong labor through actions which temporarily reduce the strength, duration and frequency of uterine contractions. However this effect is not consistent and may be offset by an increased rate of cervical dilatation, which tends to shorten labor. Closely observe neonates whose mothers received opioid analgesics during labor for signs of respiratory depression. Have a specific opioid antagonist, such as naloxone or nalmefene, available for reversal of opioid-induced respiratory depression in the neonate. **8.3 Nursing Mothers** Oxycodone has been detected in breast milk. Instruct patients not to undertake nursing while receiving OxyContin. Do not initiate OxyContin therapy while nursing because of the possibility of sedation or respiratory depression in the infant. Withdrawal signs can occur in breast-fed infants when maternal administration of an opioid analgesic is stopped, or when breast-feeding is stopped. **8.4 Pediatric Use** Safety and effectiveness of OxyContin in pediatric patients below the age of 18 years have not been established. **8.5 Geriatric Use** In controlled pharmacokinetic studies in elderly subjects (greater than 65 years) the clearance of oxycodone was slightly reduced. Compared to young adults, the plasma concentrations of oxycodone were increased approximately 15% *[see Clinical Pharmacology (12.3)]*. Of the total number of subjects (445) in clinical studies of oxycodone hydrochloride controlled-release tablets, 148 (33.3%) were age 65 and older (including those age 75 and older) while 40 (9.0%) were age 75 and older. In clinical trials with appropriate initiation of therapy and dose titration, no untoward or unexpected adverse reactions were seen in the elderly patients who received oxycodone hydrochloride controlled-release tablets. Thus, the usual doses and dosing intervals may be appropriate for elderly patients. However, reduce the starting dose to 1/3 to 1/2 the usual dosage in debilitated, non-opioid-tolerant patients. Respiratory depression is the chief risk in elderly or debilitated patients, usually the result of large initial doses in patients who are not tolerant to opioids, or when opioids are given in conjunction with other agents that depress respiration. Titrate the dose of OxyContin cautiously in these patients. **8.6 Hepatic Impairment** A study of OxyContin in patients with hepatic impairment demonstrated greater plasma concentrations than those seen at equivalent doses in persons with normal hepatic function. Therefore, in the setting of hepatic impairment, start dosing patients at 1/3 to 1/2 the usual starting dose followed by careful dose titration *[see Clinical Pharmacology (12.3)]*. **8.7 Renal Impairment** In patients with renal impairment, as evidenced by decreased creatinine clearance (<60 mL/min), the concentrations of oxycodone in the plasma are approximately 50% higher than in subjects with normal renal function. Follow a conservative approach to dose initiation and adjust according to the clinical situation *[see Clinical Pharmacology (12.3)]*. **8.8 Gender Differences** In pharmacokinetic studies with OxyContin, opioid-naïve females demonstrate up to 25% higher average plasma concentrations and greater frequency of typical opioid adverse events than males, even after adjustment for body weight. The clinical relevance of a difference of this magnitude is low for a drug intended for chronic usage at individualized dosages, and there was no male/female difference detected for efficacy or adverse events in clinical trials. **8.9 Neonatal Opioid Withdrawal Syndrome** Chronic maternal use of oxycodone during pregnancy can affect the fetus with subsequent withdrawal signs. Neonatal withdrawal syndrome presents as irritability, hyperactivity and abnormal sleep pattern, high pitched cry, tremor, vomiting, diarrhea and failure to gain weight. The onset, duration and severity of neonatal withdrawal syndrome vary based on the drug used, duration of use, the dose of last maternal use, and rate of elimination of drug by the newborn. Neonatal opioid withdrawal syndrome, unlike opioid withdrawal syndrome in adults, may be life-threatening and should be treated according to protocols developed by neonatology experts.

9 DRUG ABUSE AND DEPENDENCE **9.1 Controlled Substance** OxyContin contains oxycodone, a Schedule II controlled substance with a high potential for abuse similar to other opioids including fentanyl, hydromorphone, methadone, oxycodone, and oxymorphone. OxyContin can be abused and is subject to misuse, addiction, and criminal diversion *[see Warnings and Precautions (5.1)]*. The high drug content in extended-release formulations adds to the risk of adverse outcomes from abuse and misuse. **9.2 Abuse** Abuse of OxyContin poses a hazard of overdose and death. This risk is increased with compromising the tablet and with concurrent abuse of alcohol or other substances. All patients treated with opioids require careful monitoring for signs of abuse and addiction, since use of opioid analgesic products carries the risk of addiction even under appropriate medical use. Drug addiction is a treatable disease, utilizing a multidisciplinary approach, but relapse is common. Drug abuse is the intentional non-therapeutic use of an over-the-counter or prescription drug, even once, for its rewarding psychological or physiological effects. Drug abuse includes, but is not limited to, the following examples: the use of a prescription or over-the-counter drug to get "high", or the use of steroids for performance enhancement and muscle build up. Drug addiction is a cluster of behavioral, cognitive, and physiological phenomena that develop after repeated substance use and include: a strong desire to take the drug, difficulties in controlling its use, persisting in its use despite harmful consequences, a higher priority given to drug use than to other activities and obligations, increased tolerance, and sometimes a physical withdrawal. "Drug-seeking" behavior is very common to addicts and drug abusers. Drug-seeking tactics include emergency calls or visits near the end of office hours, refusal to undergo appropriate examination, testing or referral, repeated claims of loss of prescriptions, tampering with prescriptions and reluctance to provide prior medical records or contact information for other treating physician(s). "Doctor shopping" (visiting multiple prescribers) to obtain additional prescriptions is common among drug abusers and people suffering from untreated addiction. Preoccupation with achieving adequate pain relief can be appropriate behavior in a patient with poor pain control. Abuse and addiction are separate and distinct from physical dependence and tolerance. Physicians should be aware that addiction may not be accompanied by concurrent tolerance and symptoms of physical dependence in all addicts. In addition, abuse of opioids can occur in the absence of true addiction. OxyContin, like other opioids, can be diverted for non-medical use into illicit channels of distribution. Careful recordkeeping of prescribing information, including quantity, frequency, and renewal requests as required by state law, is strongly advised. Proper assessment of the patient, proper prescribing practices, periodic reevaluation of therapy, and proper dispensing and storage are appropriate measures that help to reduce abuse of opioid drugs. *Risks Specific to Abuse of OxyContin* OxyContin is for oral use only. Abuse of OxyContin poses a risk of overdose and death. This risk is increased with concurrent abuse of OxyContin with alcohol and other substances. Taking cut, broken, chewed, crushed, or dissolved OxyContin enhances drug release and increases the risk of overdose and death. Abuse may occur by taking intact tablets without legitimate purpose, by crushing and chewing or snorting the crushed formulation, or by injecting a solution made from the crushed formulation. With parenteral abuse, the tablet excipients can result in death, local tissue necrosis, infection, pulmonary granulomas, and increased risk of endocarditis and valvular heart injury. Parenteral drug abuse is commonly associated with transmission of infectious diseases, such as hepatitis and HIV. **9.3 Dependence** Both tolerance and physical dependence can develop during chronic opioid therapy. Tolerance is the need for increasing doses of opioids to maintain a defined effect such as analgesia (in the absence of disease progression or other external factors). Tolerance may occur to both the desired and undesired effects of drugs, and may develop at different rates for different effects. Physical dependence results in withdrawal symptoms after abrupt discontinuation or a significant dose reduction of a drug. Withdrawal also may be precipitated through the administration of drugs with opioid antagonist activity, e.g., naloxone, nalmefene, or mixed agonist/antagonist analgesics (pentazocine, butorphanol, nalbuphine). Physical dependence may not occur to a clinically significant degree until after several days to weeks of continued opioid usage. OxyContin should not be abruptly discontinued *[see Dosage and Administration (2.4)]*. If OxyContin is abruptly discontinued in a physically-dependent patient, an abstinence syndrome may occur. Some or all of the following can characterize this syndrome: restlessness, lacrimation, rhinorrhea, yawning, perspiration, chills, myalgia, and mydriasis. Other signs and symptoms also may develop, including: irritability, anxiety, backache, joint pain, weakness, abdominal cramps, insomnia, nausea, anorexia, vomiting, diarrhea, or increased blood pressure, respiratory rate, or heart rate. Infants born to mothers physically dependent on opioids will also be physically dependent and may exhibit respiratory difficulties and withdrawal signs *[see Use in Specific Populations (8.9)]*.

10 OVERDOSAGE ***Clinical Presentation*** Acute overdosage with OxyContin can be manifested by respiratory depression, somnolence progressing to stupor or coma, skeletal muscle flaccidity, cold and clammy skin, constricted pupils, and in some cases, pulmonary edema, bradycardia, hypotension, partial or complete airway obstruction, atypical snoring and death. Marked mydriasis rather than miosis may be seen due to severe hypoxia in overdose situations. ***Treatment of Overdose*** In case of overdose, priorities are the reestablishment of a patent and protected airway and institution of assisted or controlled ventilation if needed. Employ other supportive measures (including oxygen, vasopressors) in the management of circulatory shock and pulmonary edema as indicated. Cardiac arrest or arrhythmias will require advanced life support techniques. The opioid antagonists, naloxone or nalmefene, are specific antidotes to respiratory depression resulting from opioid overdose. Opioid antagonists should not be administered in the absence of clinically significant respiratory or circulatory depression secondary to oxycodone overdose. Such agents should be administered cautiously to persons who are known, or suspected to be physically dependent on OxyContin. In such cases, an abrupt or complete reversal of opioid effects may precipitate an acute withdrawal syndrome. Because the duration of reversal would be expected to be less than the duration of action of oxycodone in OxyContin, carefully monitor the patient until spontaneous respiration is reliably reestablished. OxyContin will continue to release oxycodone and add to the oxycodone load for 24 to 48 hours or longer following ingestion, necessitating prolonged monitoring. If the response to opioid antagonists is suboptimal or not sustained, additional antagonist should be administered as directed in the product's prescribing information. In an individual physically dependent on opioids, administration of the usual dose of the antagonist will precipitate an acute withdrawal syndrome. The severity of the withdrawal symptoms experienced will depend on the degree of physical dependence and the dose of the antagonist administered. If a decision is made to treat serious respiratory depression in the physically dependent patient, administration of the antagonist should be begun with care and by titration with smaller than usual doses of the antagonist.

CAUTION DEA FORM REQUIRED

17 PATIENT COUNSELING INFORMATION *See FDA-approved patient labeling (Medication Guide)* *Abuse Potential* Inform patients that OxyContin contains oxycodone, a Schedule II controlled substance that is subject to abuse. Instruct patients not to share OxyContin with others and to take steps to protect OxyContin from theft or misuse. *Life-Threatening Respiratory Depression* Discuss the risk of respiratory depression with patients, explaining that the risk is greatest when starting OxyContin or when the dose is increased. Advise patients how to recognize respiratory depression and to seek medical attention if they are experiencing breathing difficulties. *Accidental Exposure* Instruct patients to take steps to store OxyContin securely. Accidental exposure, especially in children, may result in serious harm or death. Advise patients to dispose of unused OxyContin by flushing the tablets down the toilet. *Risks from Concomitant Use of Alcohol and other CNS Depressants* Inform patients that the concomitant use of alcohol with OxyContin can increase the risk of life-threatening respiratory depression. Instruct patients not to consume alcoholic beverages, as well as prescription and over-the-counter drug products that contain alcohol, during treatment with OxyContin. Inform patients that potentially serious additive effects may occur if OxyContin is used with other CNS depressants, and not to use such drugs unless supervised by a health care provider. *Important Administration Instructions* Instruct patients how to properly take OxyContin, including the following: • OxyContin is designed to work properly only if swallowed intact. Taking cut, broken, chewed, crushed, or dissolved OxyContin tablets can result in a fatal overdose. • OxyContin tablets should be taken one tablet at a time. • Do not pre-soak, lick or otherwise wet the tablet prior to placing in the mouth. • Take each tablet with enough water to ensure complete swallowing immediately after placing in the mouth. *Hypotension* Inform patients that OxyContin may cause orthostatic hypotension and syncope. Instruct patients how to recognize symptoms of low blood pressure and how to reduce the risk of serious consequences should hypotension occur (e.g., sit or lie down, carefully rise from a sitting or lying position). *Driving or Operating Heavy Machinery* Inform patients that OxyContin may impair the ability to perform potentially hazardous activities such as driving a car or operating heavy machinery. Advise patients not to perform such tasks until they know how they will react to the medication. *Constipation* Advise patients of the potential for severe constipation, including management instructions and when to seek medical attention. *Anaphylaxis* Inform patients that anaphylaxis has been reported with ingredients contained in OxyContin. Advise patients how to recognize such a reaction and when to seek medical attention. *Pregnancy* Advise female patients that OxyContin can cause fetal harm and to inform the prescriber if they are pregnant or plan to become pregnant. Healthcare professionals can telephone Purdue Pharma's Medical Services Department (1-888-726-7535) for information on this product.

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"WE'RE REALLY TRYING TO MOVE MEANINGFUL USE IN THE DIRECTION OF GETTING INFORMATION ACROSS BOUNDARIES, SO DOCTORS CAN COORDINATE PATIENT CARE AMONG MULTIPLE SITES OF CARE."

ROBERT ANTHONY, DEPUTY DIRECTOR OF THE HEALTH INFORMATION TECHNOLOGY INITIATIVES GROUP IN THE CMS OFFICE OF E-HEALTH STANDARDS AND SERVICES

Interoperability is goal of EHR vendor alliance

Healthcare information technology (HIT) companies Cerner, McKesson, Allscripts, athenahealth, Greenway Medical Technologies, and RelayHealth have launched the CommonWell Health Alliance, planned to be an independent, not-for-profit organization that will support universal, trusted access to healthcare data through seamless interoperability. This effort is aimed at improving the quality of care delivery while working to lower costs for care providers, patients, and the industry as a whole.

The alliance will define, promote, and certify a national infrastructure with common platforms and policies, says John Hammergren, chairman and chief executive officer (CEO), McKesson Corp., and will ensure that HIT products displaying the alliance seal are certified to work on the national infrastructure.

"If we can rise to the challenge as an industry, we have a chance to deliver a golden era of healthcare," says Neal Patterson, co-founder, chairman, CEO, and president, Cerner. "It is a system where consumers not only have a right to their data, but also have the ability to mobilize [them] in the pursuit of better health. This alliance is about setting aside the admittedly tough politics of this issue to do what is right for the healthcare consumer."

Elements of the alliance's national infrastructure will be tested in a local pilot within the next year, according to the group. Early components will include the following core services:

- **cross-entity patient linking and matching services to help developers and providers link and match patients as they transition through care facilities, regardless of the underlying software system;**
- **patient consent and data access management to foster Health Insurance Portability and Accountability Act-compliant and simple patient-centered management of data sharing consents and authorizations; and**
- **patient record locator and directed query services to help providers deliver a history of recent patient care encounters, and, with appropriate authorization, patient data across multiple providers and episodes of care.**

➔19 independent practitioners, the biggest challenge posed by MU2 will be the health information exchange requirements, for the simple reason that the EHR systems of various vendors currently are able to communicate with one another (several vendors have formed a new organization designed to address that issue, however; see "Interoperability is goal of EHR vendor alliance"). That need to promote greater interoperability among systems was the impetus for including the information exchange objectives, according to Robert Anthony, deputy director of the health information technology (IT) initiatives group in the CMS Office of e-Health Standards and Services.

"At base, there really isn't a business motivation for vendors to make that information sharable. In fact, there's sometimes a case to be made for doing the opposite," Anthony says. "So we're really trying to move meaningful use in the direction of getting information across boundaries, so doctors can coordinate patient care among multiple sites of care."

GOALS OF INFORMATION EXCHANGE

The ability to improve patient care by moving patient information seamlessly among providers is one of the goals of health information exchange, Anthony says. Other goals he cites:

- **reducing costs by avoiding duplication of tests and other services, and facilitating the operations of practices using alternative payment models such as the accountable care organization and the Patient-Centered Medical Home;**
- **being able to examine various patient populations with a view toward improving public health and controlling chronic diseases; and**
- **improving clinical quality measurements.**

"Within the different medical organizational structures, be it a hospital system or integrated practice, the existing EHR tools work pretty well at addressing internal work flows," says Robert Rowley, MD, a family physician with Hayward Family Care in Hayward, California, a healthcare IT consultant, and author of the blog RobertRowleyMD.com, says. "But each system handles data so differently from each other that, without standards—which is what MU2 is really designed to promote—there's really no way to send information from one place to another."

OPTIONS FOR MEETING EXCHANGE OBJECTIVES

So what can you do when you need to send patient information to meet the MU2 requirements but can't find another provider with the ability to accept the information electronically? Depending on where you practice, one solution may lie in becoming part of a health information exchange network. Among other services, networks provide a set of common standards to their members for sending and receiving healthcare data electronically. Many integrated healthcare networks, and even some smaller hospital systems, already have developed their own proprietary networks for use among their affiliated providers.

Along with the private exchange networks, states are establishing regional and statewide network groups for use by providers, organizations, and payers, although these vary in their degrees of robustness.

"What I tell physicians is that they have to get to know what's going on around them," says Pamela Matthews, RN, MBA, senior director of regional affairs for the Healthcare Information and Management Systems Society (HIMSS). "They need to inform themselves about all the [health information exchange] players at their state and local level, because every situation is unique. The market forces are different, the demographics are different. The physician needs to find out what's available or being planned for their

4 tips to help you exchange health information with other providers

Health information exchanges tie together patient data between medical practices, health centers, and hospitals. But as the exchanges move further into the public eye, one important question remains: Will doctors in small, private practices be involved?

If you really want to succeed, you want primary care providers to be involved," said Chris Hobson, MBA, MB ChB, a former internist who is now chief medical officer for health information exchange software provider Orion Health.

That's the same opinion held by Laura Kolkman, RN, MS, and Bob Brown, authors of *The Health Information Exchange Formation Guide: The Authoritative Guide for Planning and Forming an HIE in Your State, Region, or Community*, which was named 2012 HIMSS Book of the Year. The two also write a monthly column in the HIMSS HIELights newsletter.

In an exclusive interview with *Medical Economics*, they offer four tips to help small practices with the process of exchanging health information:

1. Implement an electronic health record [EHR] system and use it. Health information exchanges operate by pulling and aggregating data provided by many different EHRs. By making your practice's system part of your daily workflow now, you'll be able to make better use of health information exchange in the future, Kolkman explains, adding, "Otherwise, we find people don't use it because it's an extra step and too much trouble." (Hobson adds that some health information exchanges, including those using Orion products, provide a "light" form of the EHR software, allowing practices that don't have their own systems to enter data manually as they go so they can participate.)

2. Find out all you can about health information exchanges and the pros and cons of participating in them. The pros, Kolkman says, include the ability to get a more complete picture of the patient's health status by accessing data from other providers and the fact that participation in accountable care organizations and other types of bundled payment arrangements depend on seamless information exchange. The main downside of participation is the cost, which Kolkman says can run in the thousands of dollars, even for small practices Also important: ensuring that data obtained through the exchange can be easily integrated into your practice's workflow. "That's an absolute must for any chance of success," she says.

Good sources of information about exchanges, Kolkman says, include regional extension centers, state and local medical societies, and local hospitals or health systems. Once you contact an exchange, it will provide information regarding service agreements, privacy standards, interoperability standards, and costs. And don't forget to notify your EHR vendor that you will be participating in an exchange, so that the vendor can provide the necessary interface between your EHR and the exchange.

3. Look for incentives for participation. Up front, it may be "difficult to find a return on investment because it is costly to invest in the software," Kolkman says. So look for meaningful use incentives from the government or quality incentives from private payers.

4. Be proactive in influencing how health information exchanges are developed and run in your area. Brown suggests that primary care doctors ask themselves: Do my patients ever interact with other physicians or providers? Do they ever go to the hospital? "If that's the case, they're going to want to get involved in health information exchange to make sure they're providing the information and that they have the information" they need, he says.

"EACH SYSTEM HANDLES DATA SO DIFFERENTLY FROM EACH OTHER THAT... THERE'S REALLY NO WAY TO SEND INFORMATION FROM ONE PLACE TO ANOTHER."

ROBERT ROWLEY, MD, FAMILY PHYSICIAN AND HEALTHCARE INFORMATION TECHNOLOGY CONSULTANT

area so he or she can take advantage of it." (See "4 tips to help you exchange health information with other providers.")

States with robust statewide or regional exchanges, she says, include Colorado, Florida, Indiana, Michigan, New Mexico, New Yor, Texas, and Virginia. Doctors seeking information about exchanges, she adds, should contact their state medical society, state healthcare agency, or the IT staff of the local hospital. More information about regional and state-wide exchanges is available on the HIMSS Web site at http://apps.himss.org/StateDashboard//.

Another possibility for undertaking health information exchange is by using point-to-point communication protocols being developed by the Direct Project, a consortium of EHR vendors, medical organizations, government agencies, and consultants working to develop secure ways of sending encrypted health information between providers. Direct Project protocols will be embedded in EHRs certified for MU2 and are expected to become available to doctors and other providers in 2014.

In addition, CMS says it is establishing an EHR test site that physicians who can't find another provider to receive information electronically can use to meet the information exchange objective. The site is scheduled to go live early in 2014.

ENCOURAGING PATIENT ENGAGEMENT

A second challenge physicians will face in meeting the MU2 requirements is in the area of patient engagement; specifically, persuading patients to access and transmit their health information via online patient portals.

"A lot of the patients just aren't there yet in terms of their computer skills," says Cindy Blain, CPA, FACMPE, director of SS&G healthcare services in Akron, Ohio. "I think it will get better with time and efforts to increase patient involvement."

In the meantime, Blain recommends that doctors and practice staff members constantly remind patients of the benefits of online portals.

"It's telling patients, 'You can get that information on our portal,' or 'Please fill out these forms on our portal before you come in,'" she says. Also important: Getting patients' email addresses so you can send them reminders and links via electronically.

The key to getting patients to use portals, Rowley says, is having information and services on it that patients value.

"Most of the stuff people will want to get are lab results, or [they want to] know they can make an appointment when they think of it at 11 at night," he says. "If it includes functionality that gives them value, then people will use it."

Doctors and staff members in Rowley's practice give patients information about the practice's portal when they come in. Posters in the exam rooms communicate the portal's URL and information about services available on it. Rowley also has suggested to the practice's EHR vendor that it should automatically e-mail patients every time the patient puts something new on the portal.

Dean Sorensen, principal consultant and chief executive officer with Sorensen Informatics Inc. in Lombard, Illinois, suggests that physicians who have practice newsletters include portal links in them. Posting information about the portal on a practice Facebook page also a useful. Overall, however, Sorensen is skeptical about the ability of practices, especially those with a large proportion of elderly patients, to attain the patient engagement objectives.

"I can guarantee you that doctors in a gerontology or rheumatology practice won't get anywhere with a patient portal. Most of those [patients] don't even have computers," he points out. In those cases, Sorensen says, doctors' only option is to try to engage a family member or other caregiver on behalf of the patient.

PROTECTING PATIENT INFORMATION

A third additional challenge posed by MU2 is ensuring the security of patients' health information when it is stored and transmitted electronically. In general, experts and consultants recommend using the same security techniques as those used to comply with the Health Insurance Portability and Accountability Act, such as:

- encrypting data,
- installing and maintaining antivirus software,
- using robust passwords that are changed regularly,
- installing strong firewalls that also alert the practice when breach attempts take place, and
- using software that tracks log-in attempts.

Health information exchange pilot to begin soon

The Certification Commission for Health Information Technology (CCHIT) announced March 4 that it will launch the pilot phase of a new health information exchange compliance testing program that will involve more than 50% of the U.S. population through a collaboration of states, public agencies, federally funded exchanges and health information technology (HIT) companies. A related certification program is set to begin in the spring.

The program's components:

- **HIE Certified Community**—for electronic health records (EHRs) and other HIT systems that will enable state-wide patient data inquiry allowing clinicians to query an health information exchange for information on specific patients;
- **HIE Certified Direct**—a way for providers to send secure health information directly to trusted recipients, including patients, over the Internet; and
- **HIE Certified Network**—for exchange-to-exchange connectivity and for connection to the eHealth Exchange.

The pilot program is for the HIE Certified Network. Healtheway, the public-private partnership of the eHealth Exchange, and the EHR/health information exchange Interoperability Workgroup, a consortium of states and vendors, established the program to test and certify EHRs and other forms of health information technology to enable reliable transfer of data within and across organizational and state boundaries. The partnership selected CCHIT as the compliance testing body.

Certification will be technology-specific and will include testing of commercially available products, healthcare provider participants, and health information exchanges.

"For the first time, providers and purchasers of EHR systems and health information exchange will have a simple way of assuring their system has all the capabilities required for plug and play interoperability," says Dave Whitlinger, executive director of the New York eHealth Collaborative. "In New York, vendors will be required to pass the compliance testing program...to connect to [the Statewide Health Information of New York].

"We're creating a robust, highly automated testing program using an open-source version of the AEGIS Developers Integration Lab tool that relies on a set of specifications created by the partnership. Our aim is to enable true 'plug and play' connectivity to simplify HIT development and reduce the cost of interface development," says Alisa Ray, executive director and chief executive officer, CCHIT. "This will help health IT developers get their technology to market quickly and prepare provider and health information exchange participants share information more efficiently."

In addition, Sorensen recommends to his clients the use of software or outside security firms that can regularly scan browsers and software for vulnerabilities and provide patches for them.

SS&G's Blain suggests to her clients that when other physicians request patient information, they provide nothing beyond the specific information requested.

"If a specialist wants results of a particular test, don't give them the whole chart," she says. Blain also emphasizes the importance of disaster recovery plans.

"Most private practices don't have one. They say, 'We'll just revert to paper,' but there's a lot more involved. You can't lose protected health information," she says.

"IF A SPECIALIST WANTS RESULTS OF A PARTICULAR TEST, DON'T GIVE THEM THE WHOLE CHART."

CINDY BLAIN, CPA, FACMPE, DIRECTOR OF SS&G HEALTHCARE SERVICES

"It's huge to access patient data through Greenway's PrimeSUITE EHR — to do it in real time, at night or on the weekend from wherever I am."

David Savage, MD
Orthopedic Surgeon
Texas Orthopedics, Sports and Rehabilitation Associates
Austin, TX

Healthcare revolves around data and reporting, so building a connected community is a no-brainer. But how? Greenway provides a solution that your affiliate staff will embrace, that provides the right clinical analytics, uses standards-based interoperability with acute care systems, and is backed by customer service that's the envy of the industry. We believe that building a smarter healthcare system can begin today. How can we help you?

"Finally, we have a solution in Greenway for patients to get what they need, with the security that everyone needs."

Michele A. Kettles, MD, MSPH
Chief Operations Officer
Cooper Clinic
Dallas, TX

"With PrimeSUITE, the data's there and I don't have to worry about shuffling through a chart. I spend my time talking to the patient about how we're going to use this to improve things."

W. Reese Baxter, MD
Medical Director
COMCARE, P.A.
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"It's unbelievable the timesaving that we're able to do just by setting it up. Ease of use is a huge, huge timesaver."

Twyla Fuertes
Chief Business Officer
Texas Orthopedics, Sports and Rehabilitation Associates
Austin, TX

"We have no regrets. It's been an amazing journey."

Mona S. Engle, RN
Practice Administrator
Doctors May•Grant Associates
Lancaster, PA

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Physicians make inroads in EHR use

Significant hurdles remain, however, as operations 'normalize'

by **DANIEL R. VERDON,** *Group Editor, Primary Care*

HIGHLIGHTS

01 Although physicians in the 2-year Medical Economics EHR Best Practices Study report progress toward meaningful use, they are working more hours to accomplish it.

02 Indirect costs associated with electronic health record (EHR) implementation and use have been steadily climbing for nearly a year. The average of $7,610 for hardware, peripherals, and other equipment (outside of the cost of the EHR system/software) may be even greater, one study participant says.

Progress can be painful. And although that observation has been well-documented when implementing an electronic health record (EHR) system, physicians participating in *Medical Economics* EHR Best Practices Study are making inroads.

According to data recently gathered as part of the study, the majority of the 29 solo practice doctors participating in the 2-year study have made progress as measured by the core objectives associated with Centers for Medicare and Medicaid Services (CMS) meaningful use EHR incentive programs.

To date, more than 90% of the participating physicians have implemented EHR systems since the start of the study in January 2012. Seven of the doctors in the study have attested for meaningful use.

Here are survey results as they relate to meaningful use objectives after nearly 1 year (full tabulations are itemized in the table on the next page):

Computerized provider order entry:
March 2012: **11%**
February 2013: **52%**

Drug-drug; drug-allergy interaction checks:
March 2012: **26%**
February 2013: **57%**

Maintain an up-to-date problem list of current and active diagnoses
March 2012: **33%**
February 2013: **91%**

E-prescribing
March 2012: **52%**
February 2013: **86%**

Maintain active medication list
March 2012: **52%**
February 2013: **100%**

Maintain active medication allergy list
March 2012: **48%**
February 2013: **100%**

Record demographics
March 2012: **44%**
February 2013: **95%**

Record and chart changes in vital signs
March 2012: **52%**
February 2013: **86%**

Record smoking status for patients 13 or older
March 2012: **48%**
February 2013: **100%**

Report ambulatory clinical quality measures to CMS/states
March 2012: **15%**
February 2013: **38%**

Implement one clinical decision support rule
March 2012: **15%**
February 2013: **48%**

MAKING PROGRESS TOWARD MEANINGFUL USE OBJECTIVES

For which of the following activities has your practice made reasonable progress toward stage 1 meaningful use requirements? (reported in percentages)

	March 2012	May 2012	July 2012	October 2012	February 2013
Computerized provider order entry:	11.1	37.5	40.7	42.3	52.4
Drug-drug; drug-allergy interaction checks	25.7	37.5	63	53.8	57.1
Maintain an up-to-date problem list of current and active diagnoses	33.3	54.2	74.1	76.9	90.5
E-prescribing	51.9	62.5	81.5	76.9	85.7
Maintain active medication list	51.9	62.5	74.1	76.9	100
Maintain active medication allergy list	48.1	62.5	77.8	69.2	100
Record demographics	44.4	66.7	77.8	84.6	95.2
Record and chart changes in vital signs	51.9	58.3	70.4	73.1	85.7
Record smoking status for patients aged 13 or older	48.1	58.3	77.8	76.9	100
Report ambulatory clinical quality measures to CMS/states	14.8	12.5	29.6	26.9	38.1
Implement one clinical decision support rule	14.8	12.5	18.5	26.9	47.6
Provide patients with an electronic copy of their health information upon request	11.1	20.8	48.1	53.8	61.9
Provide clinical summaries for patients for each office visit	7.4	20.8	40.7	57.7	66.7
Capability to exchange key clinical information among providers of care and patient- authorized entities electronically	3.7	8.3	7.4	23.1	23.8
Protect electronic health records	29.6	58.3	59.3	50	81
Incorporate clinical lab test results as structured data	11.1	41.7	40.7	38.5	61.9
Provide patients timely electronic access to their health information	3.7	33.3	25.9	34.6	57.1
Medication reconciliation	29.6	41.7	40.7	53.8	57.1
Summary of care record for each transition of care/referrals	3.7	20.8	25.9	30.8	38.1

Source: Medical Economics EHR Best Practices Study

Note: Data gathered from 29 physicians participating in the 2-year study

"ALTHOUGH PROGRESS TOWARD MEANINGFUL USE HAS BEEN SIGNIFICANT, PHYSICIANS REPORT WORKING MORE HOURS EACH DAY TO ACCOMPLISH IT."

Provide patients with an electronic copy of their health information on request
March 2012: **11%**
February 2013: **62%**

Provide clinical summaries for patients for each office visit
March 2012: **7%**
February 2013: **67%**

Capability to exchange key clinical information among providers of care and patient-authorized entities electronically
March 2012: **3%**
February 2013: **24%**

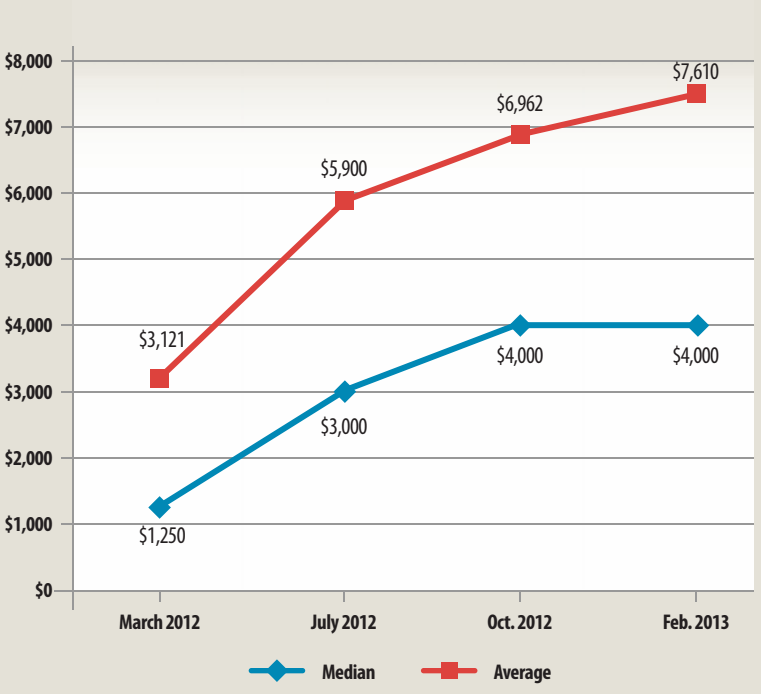
Protect electronic health records
March 2012: **30%**
February 2013: **81%**

Incorporate clinical lab test results as structured data
March 2012: **11%**
February 2013: **62%**

Provide patients timely electronic access to their health information
March 2012: **4%**
February 2013: **57%**

Medication reconciliation
March 2012: **30%**
February 2013: **57%**

Unanticipated costs related to EHR implementation



Source: Medical Economics EHR Best Practices Study
Data gathered from 29 physicians participating in 2-year study

*Note: Costs do not reflect expenditures related to EHR software, but for other equipment associated with its implementation, including hardware, peripherals, service, etc.

Summary of care record for each transition of care/referrals
March 2012: **4%**
February 2013: **38%**

OTHER FACTORS

Although the progress toward meaningful use has been significant, physicians in the study report working more hours each day to accomplish it. In March 2012, doctor-participants reported a median 40-hour work week, and that number has been steadily climbing to a February 2013 high of 50 hours per week.

Conversely, a significant change in the numbers of total direct patient contact hours per week in the office has not occurred, according to the survey.

The group posted a significant drop in the numbers of patient visits during the timeframe, especially notable as many of the participants began implementation. Also, a steady decline was reported in the average number of new patient office visits from March to October 2012. The February 2013 survey denotes the first increase since March 2012, however. (See the table on page 39.)

Many physicians in the study report being frustrated by the inability to see as many patients each day as usual, at least for the first few months following an implementation.

One of the physicians in the study reports that ➔39

32 it took four to 6 months of using the system and entering enough patient data for the practice to return to patient volumes experienced before implementation.

"The ability to see patients in a timely manner was dramatically affected. It was very difficult getting patients into the system," one physician adds.

"We had a 50% reduced schedule for 2 to 3 weeks, then we had 75% of normal schedule for the next 2 weeks," one study participant notes.

RELATED COSTS

What has increased are indirect costs associated with the EHR implementation and use. Indirect costs (excluding expenses for the EHR software system) might include computer hardware, peripherals, Internet services, or related supplies.

Although initial surveys in March 2012 noted average expenditures of $3,121, the costs have been steadily climbing to an average of $7,610 as of February 2013.

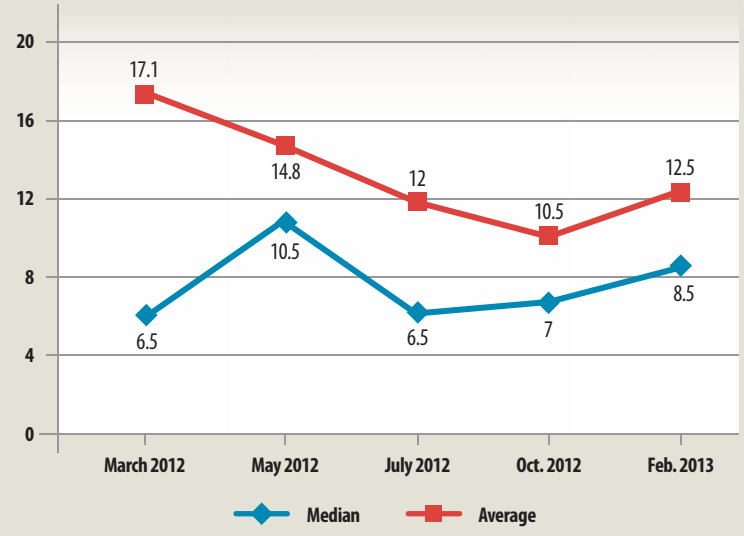
Andrew Garner, MD, a family medicine physician in Glens Falls, New York, who is participating in the study, reports that dollar figure could even be higher. In fact, his practice spent tens of thousands of dollars setting up his practice's computer system and related infrastructure to support use of the EHR, he says.

Garner also suggests that physicians closely consider, monitor, and budget those costs when implementing an EHR system for the first time.

Vendors participating in the *Medical Economics* EHR Best Practices Study include:

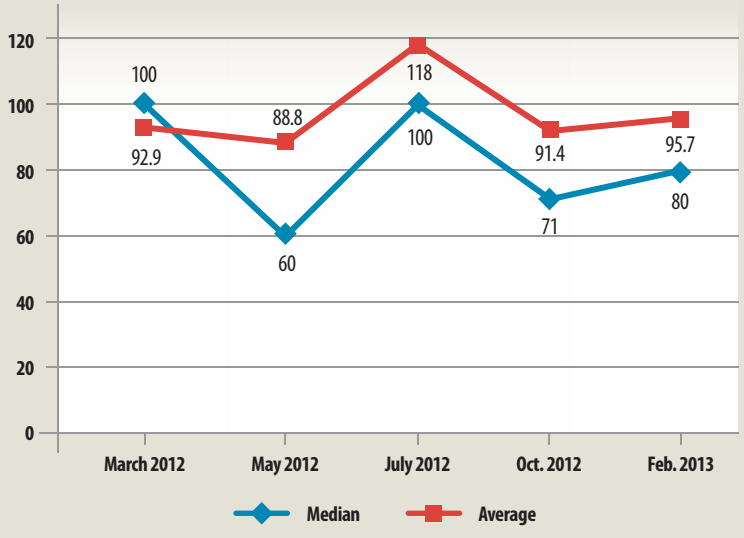
- ABEL Medical
- Amazing Charts
- Aprima
- athenahealth
- CureMD
- McKesson
- MedNet Medical Solutions
- Practice Fusion
- Vitera

New patient office visits per week



Source: Medical Economics EHR Practice Study
Data gathered from 29 physicians participating in 2-year study

Total established-patient office visits per week



Source: Medical Economics EHR Best Practices Study
Data gathered from 29 physicians participating in 2-year study

Tech Talk

BE PREPARED FOR BREACHES OF PROTECTED PATIENT INFORMATION

Q More and more of our practice's patient data are in electronic form, and I keep hearing about the growing numbers of data breaches. What should I do if our protected information is breached?

IF YOUR PATIENTS' PROTECTED HEALTH INFORMATION IS BREACHED, your first requirements are to notify the individuals whose data have been accessed illegally within 60 days of discovering the breach, and to log the event. The log should include:

- **the date of the breach,**
- **the date that you discovered the breach,**
- **the number of persons affected by the breach, and**
- **how affected individuals were notified.**

If fewer than 500 individuals were affected by the breach, you must include the incident as part of required annual reporting to the U.S. Department of Health and Human Services (HHS). If the number affected is 500 or more, you need to notify HHS and media outlets in your area. Examples of logs and notifications are available at www.hhs.gov/ocr/privacy/hipaa/administrative/breachnotificationrule/postedbreaches.html.

You can minimize the chances of a data breach occurring by encrypting patient data, having firewalls in place, and making sure that all data are password-protected and that passwords are changed regularly.

In addition, develop a written response plan that addresses the following questions:

How did the breach occur? Most breaches are the result of lost or stolen mobile devices, such as smart phones, tablets, and laptop computers, on which patient information has been stored.

What information was breached? Not every breach involves protected patient information. If the information is not protected, you don't have to notify HHS.

Can the breach be mitigated? If the protected information is locked and can be wiped within 24 hours, it is not considered a breach.

Who must be notified? Include a list of individuals and organizations (the Centers for Medicare and Medicaid Services, hospitals, payers, law enforcement, news media) to notify, along with assigned notification responsibilities among staff members.

It's worth noting that a recent HHS ruling extended liability for breaches to business associates, a category that includes anyone with access to your patients' data, with penalties ranging from $100 to $50,000 per violation, capped at $1.5 million per calendar year, and criminal penalties of up to 10 years' imprisonment.

Incidentally, you are correct that breaches are occurring more frequently, and not just among small practices. For example, an employee of Emory Healthcare in Georgia recently misplaced 10 backup disks containing information for more than 315,000 patients.

You can find additional advice and resources for data breach preparations at:

- **www.cms.gov**
- **www.nist.gov**
- **www.sans.org**
- **www.himss.org**
- **www.ahima.org**

The answer to our reader's question was provided by Dean Sorensen, MBA, CPHMS, principal consultant and chief executive officer of Sorensen Informatics in Lombard, Illinois. Send your technology-related questions to ***medec@advanstar.com****.*

Med Ec Tech

TOO MANY EHR ALERTS RAISE PATIENT SAFETY CONCERNS

You may be bombarded with so many alerts from your electronic health record (EHR) system that you are in danger of overlooking important test results, creating potential patient safety issues, according to a new study.

"OUR DATA SUGGEST that primary care physicians (PCPs) using comprehensive EHRs are vulnerable to information overload, which might lead them to miss important information," states a research letter published in *JAMA Internal Medicine*. The study was driven by the results of a survey that was answered by about 2,600 PCPs in the U.S. Department of Veterans Affairs (VA).

In the VA, abnormal test result alerts are generated automatically for pre-specified abnormal laboratory values.

And PCPs in the VA get large numbers of those alerts every day. The median number per physician per day was 63, according to the study.

Nearly 87% of the physicians surveyed said they receive an "excessive" number of alerts every day, and 70% said they receive more alerts per day than they can effectively manage.

Nearly 56% of responding physicians said that their EHR systems as currently implemented made it possible for them to miss patient test results, and nearly 30% reported missing results that led to delays in care, according to the study.

So what's the solution to information overload? Efforts to improve usability should be tied to an overall "real-world" context that factors in broader "sociotechnical" aspects of the primary care work environment, the authors say.

"An isolated reduction in alert numbers without attention to the broader PCP experience related to information overload might be insufficient to improve outcomes," they write.

More broadly, concerns about workflow problems caused by EHRs are nothing new to most physicians. In a *Medical Economics* survey of 500 physicians last year, one-third said the greatest challenge associated with EHR adoption was the disruption to practice productivity they cause during the process of implementation.

Study: Practice changes needed to recoup costs of EHR adoption

Doctors who adopt electronic health record (EHR) systems but don't make additional changes in the practice to enhance revenue and cut costs stand to lose money, a University of Michigan researcher and her colleagues found. And a $44,000 federal incentive to encourage conversion to EHRs may not be enough to prevent losses, particularly for small practices.

In an article published in the March issue of the journal *Health Affairs,* Julia Adler-Milstein, PhD, assistant professor in the University of Michigan School of Information and School of Public Health, reported on a study of 49 community practices in a large EHR pilot program. Adler-Milstein found that the average physician lost $43,743 over 5 years, and only 27% of practices showed a positive return on their investments.

"OUR DATA SUGGEST THAT PCPs USING COMPREHENSIVE EHRs ARE VULNERABLE TO INFORMATION OVERLOAD, WHICH MIGHT LEAD THEM TO MISS IMPORTANT INFORMATION,"

"What our research shows is that a substantial fraction of physicians who adopt these systems don't make the additional changes in the practice that they need to recoup the cost of adoption," Adler-Milstein said.

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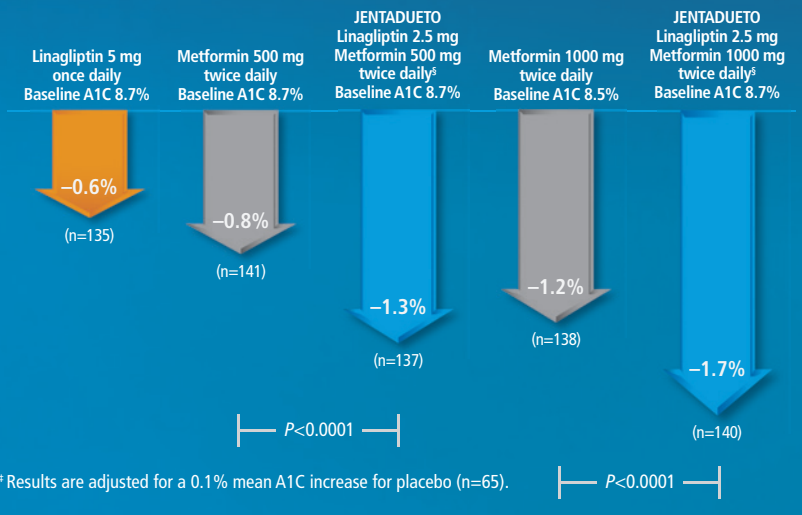
(linagliptin / metformin HCl) tablets

2.5 mg/500 mg, 2.5 mg/850 mg, 2.5 mg/1000 mg

Significant A1C reductions (placebo-adjusted) at 24 weeks[1*†‡]



‡ Results are adjusted for a 0.1% mean A1C increase for placebo (n=65).

- JENTADUETO was approved based on clinical trials that evaluated linagliptin and metformin as separate tablets. Bioequivalence of JENTADUETO to linagliptin and metformin coadministered as individual tablets was demonstrated in healthy subjects

*A randomized, double-blind, placebo-controlled, parallel-group study of drug-naïve or previously treated (4 weeks washout and 2 weeks placebo run-in) adult patients with type 2 diabetes and insufficient glycemic control (aged 18-80) who were randomized to placebo (n=72), linagliptin 5 mg once daily (n=142), metformin 500 mg twice daily (n=144), linagliptin 2.5 mg twice daily + metformin 500 mg twice daily (n=143), metformin 1000 mg twice daily (n=147), or linagliptin 2.5 mg twice daily + metformin 1000 mg twice daily (n=143). Primary endpoint was change from baseline A1C at 24 weeks. Results adjusted for 0.1% mean A1C increase for placebo. 29.2% of patients in the placebo group required use of rescue therapy vs 11.1% of patients receiving linagliptin 5 mg once daily, 13.5% of patients receiving metformin 500 mg twice daily, 8.0% of patients receiving metformin 1000 mg twice daily, 7.3% of patients receiving linagliptin 2.5 mg twice daily + metformin 500 mg twice daily, and 4.3% of patients receiving linagliptin 2.5 mg twice daily + metformin 1000 mg twice daily. Full analysis population using last observation on study.

† Superiority of both free-combination therapies, consisting of the twice-daily administration of linagliptin 2.5 mg and metformin (500 mg or 1000 mg), was shown over the individual metformin components (500 mg and 1000 mg, both BID) and over linagliptin 5 mg QD for the change in A1C from baseline at Week 24. Linagliptin 2.5 mg BID + metformin 1000 mg BID was superior to metformin 1000 mg BID ($P<0.0001$); linagliptin 2.5 mg BID + metformin 1000 mg BID was superior to linagliptin 5 mg QD ($P<0.0001$); linagliptin 2.5 mg BID + metformin 500 mg BID was superior to metformin 500 mg BID ($P<0.0001$); linagliptin 2.5 mg BID + metformin 500 mg BID was superior to linagliptin 5 mg QD ($P<0.0001$).

§ JENTADUETO studied as coadministered linagliptin and metformin tablets; total daily dose of linagliptin was equal to 5 mg.

INDICATION AND IMPORTANT LIMITATIONS OF USE

JENTADUETO tablets are indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both linagliptin and metformin is appropriate.

JENTADUETO should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis, and has not been studied in combination with insulin.

IMPORTANT SAFETY INFORMATION

WARNING: RISK OF LACTIC ACIDOSIS

Lactic acidosis is a rare, but serious, complication that can occur due to metformin accumulation. The risk increases with conditions such as renal impairment, sepsis, dehydration, excess alcohol intake, hepatic impairment, and acute congestive heart failure.

The onset is often subtle, accompanied only by nonspecific symptoms such as malaise, myalgias, respiratory distress, increasing somnolence, and nonspecific abdominal distress.

Laboratory abnormalities include low pH, increased anion gap, and elevated blood lactate.

If acidosis is suspected, JENTADUETO should be discontinued and the patient hospitalized immediately.

CONTRAINDICATIONS

JENTADUETO is contraindicated in patients with:

- Renal impairment (e.g., serum creatinine ≥1.5 mg/dL for men or ≥1.4 mg/dL for women, or abnormal creatinine clearance).
- Acute or chronic metabolic acidosis, including diabetic ketoacidosis.
- History of hypersensitivity reaction to linagliptin (such as urticaria, angioedema, or bronchial hyperreactivity) or metformin.

WARNINGS AND PRECAUTIONS

Lactic Acidosis

- Lactic acidosis is a serious, metabolic complication that can occur due to metformin accumulation during treatment with JENTADUETO and is fatal in approximately 50% of cases.
- The reported incidence of lactic acidosis in patients receiving metformin is approximately 0.03 cases/1000 patient-years, with approximately 0.015 fatal cases/1000 patient-years. Reported cases have occurred primarily in diabetic patients with significant renal impairment, including both intrinsic renal disease and renal hypoperfusion, often in the setting of multiple concomitant medical/surgical problems and multiple concomitant medications.
- Patients with congestive heart failure requiring pharmacologic management, particularly when accompanied by hypoperfusion and hypoxemia due to unstable or acute failure, are at increased risk of lactic acidosis.

Boehringer Ingelheim

- The risk of lactic acidosis increases with the degree of renal impairment and the patient's age. The risk of lactic acidosis may be significantly decreased by regular monitoring of renal function in patients taking metformin. Treatment of the elderly should be accompanied by careful monitoring of renal function. Metformin treatment should not be initiated in any patients unless measurement of creatinine clearance demonstrates that renal function is not reduced.
- Metformin should be promptly withheld in the presence of any condition associated with hypoxemia, dehydration, or sepsis.

Monitoring of Renal Function
Before initiation of therapy with JENTADUETO and at least annually thereafter, renal function should be assessed and verified as normal. In patients in whom development of renal impairment is anticipated (e.g., elderly), renal function should be assessed more frequently and JENTADUETO discontinued if evidence of renal impairment is present.

Radiological studies and surgical procedures: JENTADUETO should be temporarily discontinued prior to any intravascular radiocontrast study and for any surgical procedure necessitating restricted intake of food or fluids, and withheld for 48 hours subsequent to the procedure and reinstituted only after renal function has been confirmed to be normal.

Impaired Hepatic Function
Impaired hepatic function has been associated with cases of lactic acidosis with metformin therapy. JENTADUETO tablets should generally be avoided in patients with clinical or laboratory evidence of hepatic impairment.

Hypoglycemia
Insulin secretagogues are known to cause hypoglycemia. The use of linagliptin in combination with an insulin secretagogue (e.g., sulfonylurea) was associated with a higher rate of hypoglycemia compared with placebo in a clinical trial. A lower dose of the insulin secretagogue may be required to reduce the risk of hypoglycemia when used in combination with JENTADUETO.

Vitamin B_{12} Levels
Vitamin B_{12} deficiency: Metformin may lower Vitamin B_{12} levels. Monitor hematologic parameters annually.

Alcohol Intake
Alcohol is known to potentiate the effect of metformin on lactate metabolism. Patients should be warned against excessive alcohol intake while receiving JENTADUETO.

Hypoxic States
Cardiovascular collapse (shock) from whatever cause (e.g., acute congestive heart failure, acute myocardial infarction, and other conditions characterized by hypoxemia) has been associated with lactic acidosis and may also cause prerenal azotemia. When such events occur in patients on JENTADUETO therapy, the drug should be promptly discontinued.

Macrovascular Outcomes
There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with JENTADUETO or any other antidiabetic drug.

ADVERSE REACTIONS

- In a 24-week factorial design study, adverse reactions reported in ≥5% of patients treated with JENTADUETO and more commonly than in patients treated with placebo were nasopharyngitis and diarrhea.
- In a 24-week factorial design study, hypoglycemia was reported in 4 (1.4%) of 286 subjects treated with linagliptin + metformin, 6 (2.1%) of 291 subjects treated with metformin and 1 (1.4%) of 72 subjects treated with placebo. In the placebo-controlled studies, hypoglycemia was more commonly reported in patients treated with the combination of linagliptin and metformin with SU (22.9%) compared with those treated with the combination of placebo and metformin with SU (14.8%).
- Pancreatitis was reported more often in patients randomized to linagliptin (1 per 538 person-years versus 0 in 433 person-years for comparator).

DRUG INTERACTIONS

- Because cationic drugs eliminated by renal tubular secretion theoretically have the potential for interaction with metformin by competing for common renal tubular transport systems, careful patient monitoring and dose adjustment of JENTADUETO and/or the interfering drug is recommended in patients who are taking cationic medications that are excreted via the proximal renal tubular secretory system.
- The efficacy of JENTADUETO may be reduced when administered in combination with a strong P-glycoprotein inducer and CYP3A4 inducer (e.g., rifampin). Use of alternative treatments is strongly recommended.
- The concomitant use of carbonic anhydrase inhibitors (e.g., topiramate) and metformin may induce metabolic acidosis. Use these drugs with caution in patients treated with JENTADUETO, as the risk of lactic acidosis may increase.

USE IN SPECIFIC POPULATIONS

- As there are no adequate and well-controlled studies in pregnant women, the safety of JENTADUETO in pregnant women is not known. JENTADUETO should be used during pregnancy only if clearly needed.
- It is not known whether linagliptin is excreted in human milk. Metformin is excreted in human milk in low concentrations. Because the potential for hypoglycemia in nursing infants may exist, a decision should be made whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.
- The safety and effectiveness of JENTADUETO in patients below the age of 18 have not been established.
- JENTADUETO should be used with caution as age increases, as aging can be associated with reduced renal function.

JD PROF ISI MAR152012

Reference: 1. Data on file. Boehringer Ingelheim Pharmaceuticals, Inc.

Please see adjacent pages for brief summary of full Prescribing Information and Boxed Warning regarding the risk of lactic acidosis.

Find out more about JENTADUETO and the Savings Card program at www.jentadueto.com

Lilly

Jentadueto™ (linagliptin and metformin hydrochloride) tablets

BRIEF SUMMARY OF PRESCRIBING INFORMATION

Please see package insert for full Prescribing Information.

WARNING: RISK OF LACTIC ACIDOSIS

Lactic acidosis is a rare, but serious, complication that can occur due to metformin accumulation. The risk increases with conditions such as renal impairment, sepsis, dehydration, excess alcohol intake, hepatic impairment, and acute congestive heart failure.

The onset is often subtle, accompanied only by nonspecific symptoms such as malaise, myalgias, respiratory distress, increasing somnolence, and nonspecific abdominal distress.

Laboratory abnormalities include low pH, increased anion gap, and elevated blood lactate.

If acidosis is suspected, JENTADUETO should be discontinued and the patient hospitalized immediately.

INDICATIONS AND USAGE: Indication: JENTADUETO tablets are indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both linagliptin and metformin is appropriate. **Important Limitations of Use:** JENTADUETO should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis, as it would not be effective in these settings. JENTADUETO has not been studied in combination with insulin.

CONTRAINDICATIONS: JENTADUETO is contraindicated in patients with:

- Renal impairment (e.g., serum creatinine ≥1.5 mg/dL for men, ≥1.4 mg/dL for women, or abnormal creatinine clearance) which may also result from conditions such as cardiovascular collapse (shock), acute myocardial infarction, and septicemia *[see Warnings and Precautions]*
- Acute or chronic metabolic acidosis, including diabetic ketoacidosis. Diabetic ketoacidosis should be treated with insulin *[see Warnings and Precautions]*
- A history of hypersensitivity reaction to linagliptin (such as urticaria, angioedema, or bronchial hyperreactivity) or metformin *[see Adverse Reactions]*

WARNINGS AND PRECAUTIONS: Lactic Acidosis: *Metformin:* Lactic acidosis is a serious, metabolic complication that can occur due to metformin accumulation during treatment with JENTADUETO and is fatal in approximately 50% of cases. Lactic acidosis may also occur in association with a number of pathophysiologic conditions, including diabetes mellitus, and whenever there is significant tissue hypoperfusion and hypoxemia. Lactic acidosis is characterized by elevated blood lactate levels (>5 mmol/L), decreased blood pH, electrolyte disturbances with an increased anion gap, and an increased lactate/pyruvate ratio. When metformin is implicated as the cause of lactic acidosis, metformin plasma levels of >5 µg/mL are generally found. The reported incidence of lactic acidosis in patients receiving metformin is approximately 0.03 cases/1000 patient-years, (with approximately 0.015 fatal cases/1000 patient-years). In more than 20,000 patient-years exposure to metformin in clinical trials, there were no reports of lactic acidosis. Reported cases have occurred primarily in diabetic patients with significant renal impairment, including both intrinsic renal disease and renal hypoperfusion, often in the setting of multiple concomitant medical/surgical problems and multiple concomitant medications. Patients with congestive heart failure requiring pharmacologic management, particularly when accompanied by hypoperfusion and hypoxemia due to unstable or acute failure, are at increased risk of lactic acidosis. The risk of lactic acidosis increases with the degree of renal impairment and the patient's age. The risk of lactic acidosis may, therefore, be significantly decreased by regular monitoring of renal function in patients taking metformin. In particular, treatment of the elderly should be accompanied by careful monitoring of renal function. Metformin treatment should not be initiated in any patients unless measurement of creatinine clearance demonstrates that renal function is not reduced. In addition, metformin should be promptly withheld in the presence of any condition associated with hypoxemia, dehydration, or sepsis. Because impaired hepatic function may significantly limit the ability to clear lactate, metformin should be avoided in patients with clinical or laboratory evidence of hepatic impairment. Patients should be cautioned against excessive alcohol intake when taking metformin, since alcohol potentiates the effects of metformin on lactate metabolism. In addition, metformin should be temporarily discontinued prior to any intravascular radiocontrast study and for any surgical procedure necessitating restricted intake of food or fluids. Use of topiramate, a carbonic anhydrase inhibitor, in epilepsy and migraine prophylaxis may cause dose-dependent metabolic acidosis and may exacerbate the risk of metformin-induced lactic acidosis *[see Drug Interactions]*. The onset of lactic acidosis is often subtle, and accompanied by nonspecific symptoms such as malaise, myalgias, respiratory distress, increasing somnolence, and nonspecific abdominal distress. More severe acidosis may be associated with signs such as hypothermia, hypotension, and resistant bradyarrhythmias. Patients should be educated to recognize and promptly report these symptoms. If present, JENTADUETO should be discontinued until lactic acidosis is ruled out. Gastrointestinal symptoms, which are commonly reported during initiation of metformin therapy are less frequently observed in subjects on a chronic, stable, dose of metformin. Gastrointestinal symptoms in subjects on chronic, stable, dose of metformin could be caused by lactic acidosis or other serious disease. To rule out lactic acidosis, serum electrolytes, ketones, blood glucose, blood pH, lactate levels, and blood metformin levels may be useful. Levels of fasting venous plasma lactate above the upper limit of normal but less than 5 mmol/L in patients taking metformin do not necessarily indicate impending lactic acidosis and may be due to other mechanisms, such as poorly-controlled diabetes or obesity, vigorous physical activity, or technical problems in sample handling. Lactic acidosis should be suspected in any diabetic patient with metabolic acidosis lacking evidence of ketoacidosis (ketonuria and ketonemia). Lactic acidosis is a medical emergency that must be treated in a hospital setting. In a patient with lactic acidosis who is taking metformin, the drug should be discontinued immediately and supportive measures promptly instituted. Metformin is dialyzable (clearance of up to 170 mL/min under good hemodynamic conditions) and prompt hemodialysis is recommended to remove the accumulated metformin and correct the metabolic acidosis. Such management often results in prompt reversal of symptoms and recovery *[see Boxed Warning]*.

Monitoring of Renal Function: Although linagliptin undergoes minimal renal excretion, metformin is known to be substantially excreted by the kidney. The risk of metformin accumulation and lactic acidosis increases with the degree of renal impairment. Therefore, JENTADUETO is contraindicated in patients with renal impairment. Before initiation of therapy with JENTADUETO and at least annually thereafter, renal function should be assessed and verified to be normal. In patients in whom development of renal impairment is anticipated (e.g., elderly), renal function should be assessed more frequently and JENTADUETO discontinued if evidence of renal impairment is present. Linagliptin may be continued as a single entity tablet at the same total daily dose of 5 mg if JENTADUETO is discontinued due to evidence of renal impairment. No dose adjustment of linagliptin is recommended in patients with renal impairment.

Use of concomitant medications that may affect renal function or metformin disposition: Concomitant medication(s) that may affect renal function or result in significant hemodynamic change or interfere with the disposition of metformin should be used with caution *[see Drug Interactions]*. ***Radiological studies and surgical procedures:*** Radiologic studies involving the use of intravascular iodinated contrast materials (e.g., intravenous urogram, intravenous cholangiography, angiography, and computed tomography) can lead to acute alteration of renal function and have been associated with lactic acidosis in patients receiving metformin. Therefore, in patients in whom any such study is planned, JENTADUETO should be temporarily discontinued at the time of or prior to the procedure, and withheld for 48 hours subsequent to the procedure and reinstituted only after renal function has been confirmed to be normal. JENTADUETO should be temporarily discontinued for any surgical procedure (except minor procedures not associated with restricted intake of food and fluids) and should not be restarted until the patient's oral intake has resumed and renal function has been evaluated as normal. **Impaired Hepatic Function:** Because impaired hepatic function has been associated with some cases of lactic acidosis with metformin therapy, JENTADUETO should generally be avoided in patients with clinical or laboratory evidence of hepatic disease *[see Warnings and Precautions]*. **Hypoglycemia:** *Linagliptin:* Insulin secretagogues are known to cause hypoglycemia. The use of linagliptin in combination with an insulin secretagogue (e.g., sulfonylurea) was associated with a higher rate of hypoglycemia compared with placebo in a clinical trial *[see Adverse Reactions]*. Therefore, a lower dose of the insulin secretagogue may be required to reduce the risk of hypoglycemia when used in combination with JENTADUETO. *Metformin:* Hypoglycemia does not occur in patients receiving metformin alone under usual circumstances of use, but could occur when caloric intake is deficient, when strenuous exercise is not compensated by caloric supplementation, or during concomitant use with other glucose-lowering agents (such as SUs and insulin) or ethanol. Elderly, debilitated, or malnourished patients, and those with adrenal or pituitary insufficiency or alcohol intoxication are particularly susceptible to hypoglycemic effects. Hypoglycemia may be difficult to recognize in the elderly, and in people who are taking β-adrenergic blocking drugs. **Vitamin B_{12} Levels:** In controlled, 29-week clinical trials of metformin, a decrease to subnormal levels of previously normal serum vitamin B_{12} levels, without clinical manifestations, was observed in approximately 7% of metformin-treated patients. Such decrease, possibly due to interference with B_{12} absorption from the B_{12}-intrinsic factor complex, is, however, very rarely associated with anemia or neurologic manifestations due to the short duration (<1 year) of the clinical trials. This risk may be more relevant to patients receiving long-term treatment with metformin, and adverse hematologic and neurologic reactions have been reported postmarketing. The decrease in vitamin B_{12} levels appears to be rapidly reversible with discontinuation of metformin or vitamin B_{12} supplementation. Measurement of hematologic parameters on an annual basis is advised in patients on JENTADUETO and any apparent abnormalities should be appropriately investigated and managed. Certain individuals (those with inadequate vitamin B_{12} or calcium intake or absorption) appear to be predisposed to developing subnormal vitamin B_{12} levels. In these patients, routine serum vitamin B_{12} measurement at 2- to 3-year intervals may be useful. **Alcohol Intake:** Alcohol is known to potentiate the effect of metformin on lactate metabolism. Patients, therefore, should be warned against excessive alcohol intake while receiving JENTADUETO *[see Warnings and Precautions]*. **Hypoxic States:** Cardiovascular collapse (shock) from whatever cause (e.g., acute congestive heart failure, acute myocardial infarction, and other conditions characterized by hypoxemia) have been associated with lactic acidosis and may also cause prerenal azotemia. When such events occur in patients on JENTADUETO therapy, the drug should be promptly discontinued *[see Warnings and Precautions]*. **Macrovascular Outcomes:** There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with linagliptin or metformin or any other antidiabetic drug.

ADVERSE REACTIONS: Clinical Trials Experience: 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 the clinical trials of another drug and may not reflect the rates observed in clinical practice. *Linagliptin/Metformin:* The safety of concomitantly administered linagliptin (daily dose 5 mg) and metformin (mean daily dose of approximately 1800 mg) has been evaluated in 2816 patients with type 2 diabetes mellitus treated for ≥12 weeks in clinical trials. Three placebo-controlled studies with linagliptin + metformin were conducted: 2 studies were 24 weeks in duration, 1 study was 12 weeks in duration. In the 3 placebo-controlled clinical studies, adverse events which occurred in ≥5% of patients receiving linagliptin + metformin (n=875) and were more common than in patients given placebo + metformin (n=539) included nasopharyngitis (5.7% vs 4.3%). In a 24-week factorial design study, adverse events reported in ≥5% of patients receiving linagliptin + metformin and were more common than in patients given placebo are shown in Table 1.

Table 1 Adverse Reactions Reported in ≥5% of Patients Treated with Linagliptin + Metformin and Greater than with Placebo in a 24-week Factorial-Design Study

	Placebo n=72	Linagliptin Monotherapy n=142	Metformin Monotherapy n=291	Combination of Linagliptin with Metformin n=286
	n (%)	n (%)	n (%)	n (%)
Nasopharyngitis	1 (1.4)	8 (5.6)	8 (2.7)	18 (6.3)
Diarrhea	2 (2.8)	5 (3.5)	11 (3.8)	18 (6.3)

Other adverse reactions reported in clinical studies with treatment of linagliptin + metformin were hypersensitivity (e.g., urticaria, angioedema, or bronchial hyperactivity), cough, decreased appetite, nausea, vomiting, pruritus, and pancreatitis. *Linagliptin Monotherapy:* Nasopharyngitis was reported in ≥5% of patients treated with linagliptin and more commonly than in patients treated with placebo (5.8% vs 5.5%). In the clinical trial program, pancreatitis was reported in 8 of 4687 patients (4311 patient-years of exposure) while being treated with TRADJENTA compared with 0 of 1183 patients (433 patient-years of exposure) treated with placebo. Three additional cases of pancreatitis were reported following the last administered dose of linagliptin. Other adverse reactions reported in clinical studies with treatment of linagliptin monotherapy were hypersensitivity (e.g., urticaria, angioedema, localized skin exfoliation, or bronchial hyperactivity) and myalgia. *Metformin Monotherapy:* The most common adverse reactions due to initiation of metformin are diarrhea, nausea/vomiting, flatulence, asthenia, indigestion, abdominal discomfort, and headache. Long-term treatment with metformin has been associated with a decrease in vitamin B_{12} absorption which may very rarely result in clinically significant vitamin B_{12} deficiency (e.g., megaloblastic anemia) *[see Warnings and Precautions]*. *Hypoglycemia:* In a 24-week factorial design study, hypoglycemia was reported in 4 (1.4%) of 286 subjects treated with linagliptin + metformin, 6 (2.1%) of 291 subjects treated with metformin, and 1 (1.4%) of 72 subjects treated with placebo. When linagliptin was administered in combination with metformin and a sulfonylurea, 181 (22.9%) of 792 patients reported hypoglycemia compared with 39 (14.8%) of 263 patients administered placebo in combination with metformin and sulfonylurea. *Laboratory Tests:* Changes in laboratory findings were similar in patients treated with linagliptin + metformin compared to patients treated with placebo + metformin. Changes in laboratory values that occurred more frequently in the linagliptin + metformin group and ≥1% more than in the placebo group were not detected. No clinically meaningful changes in vital signs were observed in patients treated with linagliptin.

DRUG INTERACTIONS: Drug Interactions with Metformin: *Cationic Drugs:* Cationic drugs (e.g., amiloride, digoxin, morphine, procainamide, quinidine, quinine, ranitidine, triamterene, trimethoprim, or vancomycin) that are eliminated by renal tubular secretion theoretically have the potential for interaction with metformin by competing for common renal tubular transport systems. Although such interactions remain theoretical (except for cimetidine), careful patient monitoring and dose adjustment of JENTADUETO and/or the interfering drug is recommended in patients who are taking cationic medications that are excreted via the proximal renal tubular secretory system *[see Warnings and Precautions]*. *Carbonic Anhydrase Inhibitors:* Topiramate or other carbonic anhydrase inhibitors (e.g., zonisamide, acetazolamide or dichlorphenamide) frequently decrease serum bicarbonate and induce non-anion gap, hyperchloremic metabolic acidosis. Concomitant use of these drugs may induce metabolic acidosis. Use these drugs with caution in patients treated with JENTADUETO, as the risk of lactic acidosis may increase *[see Warnings and Precautions]*. **Drug Interactions With Linagliptin:** *Inducers of P-glycoprotein and CYP3A4 Enzymes:* Rifampin decreased linagliptin exposure, suggesting that the efficacy of linagliptin may be reduced when administered in combination with a strong P-gp inducer or CYP 3A4 inducer. As JENTADUETO is a fixed-dose combination of linagliptin and metformin, use of alternative treatments (not containing linagliptin) is strongly recommended when concomitant treatment with a strong P-gp or CYP 3A4 inducer is necessary. **Drugs Affecting Glycemic Control:** Certain drugs tend to produce hyperglycemia and may lead to loss of glycemic control. These drugs include the thiazides and other diuretics, corticosteroids, phenothiazines, thyroid products, estrogens, oral contraceptives, phenytoin, nicotinic acid, sympathomimetics, calcium channel blocking drugs, and isoniazid. When such drugs are administered to a patient receiving JENTADUETO, the patient should be closely observed to maintain adequate glycemic control. When such drugs are withdrawn from a patient receiving JENTADUETO, the patient should be observed closely for hypoglycemia.

USE IN SPECIFIC POPULATIONS: Pregnancy: *Pregnancy Category B: JENTADUETO:* There are no adequate and well controlled studies in pregnant women with JENTADUETO or its individual components, and some clinical data is available for metformin which indicate that the risk for major malformations was not increased when metformin is taken during the first trimester in pregnancy. In addition, metformin was not associated with increased perinatal complications. Nevertheless, because these clinical data cannot rule out the possibility of harm, JENTADUETO should be used during pregnancy only if clearly needed. JENTADUETO was not teratogenic when administered to Wistar Han rats during the period of organogenesis at doses similar to clinical exposure. At higher maternally toxic doses (9 and 23 times the clinical dose based on exposure), the metformin component of the combination was associated with an increased incidence of fetal rib and scapula malformations. *Linagliptin:* Linagliptin was not teratogenic when administered to pregnant Wistar Han rats and Himalayan rabbits during the period of organogenesis at doses up to 240 mg/kg and 150 mg/kg, respectively. These doses represent approximately 943 times the clinical dose in rats and 1943 times the clinical dose in rabbits, based on exposure. No functional, behavioral, or reproductive toxicity was observed in offspring of female Wistar Han rats when administered linagliptin from gestation day 6 to lactation day 21 at a dose 49 times the maximum recommended human dose, based on exposure. Linagliptin crosses the placenta into the fetus following oral dosing in pregnant rats and rabbits. *Metformin Hydrochloride:* Metformin has been studied for embryofetal effects in 2 rat strains and in rabbits. Metformin was not teratogenic in Sprague Dawley rats up to 600 mg/kg or in Wistar Han rats up to 200 mg/kg (2-3 times the clinical dose based on body surface area or exposure, respectively). At higher maternally toxic doses (9 and 23 times the clinical dose based on exposure), an increased incidence of rib and scapula skeletal malformations was observed in the Wistar Han strain. Metformin was not teratogenic in rabbits at doses up to 140 mg/kg (similar to clinical dose based on body surface area). Metformin administered to female Sprague Dawley rats from gestation day 6 to lactation day 21 up to 600 mg/kg/day (2 times the maximum clinical dose based on body surface area) had no effect on prenatal or postnatal development of offspring. Metformin crosses the placenta into the fetus in rats and humans. **Nursing Mothers:** No studies in lactating animals have been conducted with the combined components of JENTADUETO. In studies performed with the individual components, both linagliptin and metformin were secreted in the milk of lactating rats. It is not known whether linagliptin is excreted in human milk. Metformin is excreted in human milk in low concentrations. Because the potential for hypoglycemia in nursing infants may exist, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother. **Pediatric Use:** Safety and effectiveness of JENTADUETO in pediatric patients have not been established. **Geriatric Use:** Linagliptin is minimally excreted by the kidney; however, metformin is substantially excreted by the kidney. Considering that aging can be associated with reduced renal function, JENTADUETO should be used with caution as age increases *[see Warnings and Precautions]*. *Linagliptin:* Of the total number of patients (n=4040) in clinical studies of linagliptin, 1085 patients were 65 years and over, while 131 patients were 75 years and over. No overall differences in safety or effectiveness were observed between patients 65 years and over and younger patients. Therefore, no dose adjustment is recommended in the elderly population. While clinical studies of linagliptin have not identified differences in response between the elderly and younger patients, greater sensitivity of some older individuals cannot be ruled out. *Metformin:* Controlled clinical studies of metformin did not include sufficient numbers of elderly patients to determine whether they respond differently from younger patients, although other reported clinical experience has not identified differences in responses between the elderly and young patients. The initial and maintenance dosing of metformin should be conservative in patients with advanced age, due to the potential for decreased renal function in this population. Any dose adjustment should be based on a careful assessment of renal function *[see Contraindications and Warnings and Precautions]*.

OVERDOSAGE: In the event of an overdose with JENTADUETO, employ the usual supportive measures (e.g., remove unabsorbed material from the gastrointestinal tract, employ clinical monitoring, and institute supportive treatment) as dictated by the patient's clinical status. Removal of linagliptin by hemodialysis or peritoneal dialysis is unlikely. However, metformin is dialyzable with a clearance of up to 170 mL/min under good hemodynamic conditions. Therefore, hemodialysis may be useful partly for removal of accumulated metformin from patients in whom JENTADUETO overdosage is suspected. *Linagliptin:* During controlled clinical trials in healthy subjects, with single doses of up to 600 mg of linagliptin (equivalent to 120 times the recommended daily dose), there were no dose-related clinical adverse drug reactions. There is no experience with doses above 600 mg in humans. *Metformin:* Overdose of metformin has occurred, including ingestion of amounts greater than 50 grams. Hypoglycemia was reported in approximately 10% of cases, but no causal association with metformin has been established. Lactic acidosis has been reported in approximately 32% of metformin overdose cases *[see Boxed Warning and Warnings and Precautions]*.

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Doctor's Bag

SNAP PRACTICE USES iPAD FOR OFFICE VISITS

Interfaceware and Seamless Medical Systems demonstrated their mobile patient engagement solutions for the iPad at this year's Health Information and Management Systems Society annual meeting. Snap Practice, Seamless Medical's cloud-based enterprise platform is designed to be used by patients throughout an office visit, starting with registration and moving to the delivery of health and wellness information and continuing into the exam room.

Patient data from Snap Practice can be transferred to electronic health records or an organization's practice management system with Interfaceware's interface engine.

Available in two models, Snap Express and Snap Enterprise, the iPad-based platform includes a standard form for primary care and internal medicine, among other specialties. The platform is not only Health Insurance Accountability and Portability Act-compliant but also offers digital signage capture, pre-populating and auto-formatting data field logic, and structured data output to practice systems. Patients also can access customized wellness information from the Mayo Clinic with SnapEdu.

The platform is designed to save time, money, and errors associated with paper-based registration forms and the re-keying of information involved. Its electronic information transfer can occur without replacing existing technologies or redesigning existing systems. The software also connects healthcare systems to new technologies, such as cloud computing, with a single Web-based interface.

Interfaceware (888) 824-6785 | www.interfaceware.com | www.snappractice.com

ONLINE TOOL ALLOWS EFT ENROLLMENT WITH MULTIPLE PAYERS THROUGH SINGLE PROCESS

In 2014, payers must offer electronic funds transfer (EFT) under the requirements of the Affordable Care Act, and Medicare will reimburse providers only through EFT.

CAQH has released a universal EFT enrollment tool that aims to create efficiencies and cost savings by eliminating the need for providers to sign up for EFT capabilities separately for each plan in which they participate. It also can reduce paperwork and time spent on printing, mailing, and receiving checks; lower lockbox fees; and enable tighter security on transactions.

Participating payers, such as Aetna and Cigna, support the operations of the service through an annual participation fee, so use of the service comes at no cost to providers.

CAQH (202) 861-1492 | solutions.caqh.org

DOCUSIGN SOLUTION DESIGNED TO STREAMLINE PATIENT REGISTRATION

DocuSign announced an electronic signature solution to help eliminate paper from the patient registration process at this year's Health Information and Management Systems Society annual meeting. The product allows providers and patients to complete consent, history, and registration forms from any electronic device before an appointment.

Designed by Kryptiq using DocuSign's electronic signature platform, the product aims to have patients see the physician more quickly and simplify and eliminate errors from the registration process. Practices receive all patient forms and signatures electronically and can update patient data via integration with existing systems. Staff members can eliminate the process of printing forms, manually entering data, scanning, and shredding, saving time and money while ensuring accuracy.

DocuSign
(877) 720-2040
www.kryptiq.com/docusign

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CODING INSIGHTS
How to get paid for complex care coordination [51]

Operations

ACOs redefine relationships with specialists

Everyone's goal is to keep quality up, costs down

by **BETH THOMAS HERTZ**

HIGHLIGHTS

01 In an accountable care organization (ACO), a primary care physician can be hurt financially if a specialist does not treat appropriately, so pay special attention to what happens to your patients once you refer them.

02 Reimbursement will shift from being volume-based to being value-based as ACOs try to break the cycle of sick people showing up in the emergency department because they had no other access to care.

03 Moving toward a Patient-Centered Medical Home model is a recommended step on the path to becoming an ACO.

Accountable care organizations (ACOs), with their overriding goal of getting patients the right care at the right time in an efficient way, might be the vehicle that finally elevates primary care to a status equal to specialty care, because primary care is the key to ensuring ACO revenue streams.

"YOU ALWAYS HEAR about people building a new heart tower, but no one builds primary care towers," quips Bruce Bagley, MD, interim president and chief executive officer of TransforMED, a subsidiary of the American Academy of Family Physicians. "Maybe that is about to change."

TransforMED was created after studies showed that primary care was going to be strangled unless change occurred.

"We need to hold up our successes to show how a redesign of the system requires primary care to have a central role," Bagley says.

He predicts that ACOs, and the changes they bring, represent the future of healthcare.

"Value-based purchasing requires a very different structure for how payments are distributed," he says. "There are currently no incentives for clinicians to take shared responsibility for cost and quality. ACOs will require us to manage global payments in a way that is antithetical to fee-for-service."

CHANGING INTERACTIONS WITH SPECIALISTS

ACOs also are expected to redefine the relationships between primary care physicians (PCPs) and specialists.

ACOs across the United States

In January, the Centers for Medicare and Medicaid Services (CMS) announced 106 new accountable care organizations (ACOs).

They include a diverse cross-section of physician practices throughout the country, according to CMS. Roughly half are physician-led organizations that serve fewer than 10,000 beneficiaries. Approximately 20% of ACOs include community health centers, rural health clinics, and critical access hospitals that serve low-income and rural communities

These 106 organizations bring the total number of CMS-approved ACOs to 252, according to the agency. Although many of these are shared savings programs, other alternatives are available:

Advance payment model. According to CMS, 35 of these ACOs are functioning under the advance payment model. Through this model, participants receive upfront and monthly payments that they can use to make important investments in their care coordination infrastructure. This arrangement is meant to help smaller ACOs with less access to capital. These organizations will receive an advance on the shared savings they are expected to earn.

Pioneer ACOs. CMS says 32 ACOs are participating using the Pioneer ACO model. This model is designed for health care organizations and providers who already are experienced in coordinating care for patients across care settings. It will allow them to move more rapidly from a shared savings payment model to a population-based payment model on a track consistent with, but separate from, the Medicare Shared Services Program. It is designed to work in coordination with private payers by aligning provider incentives, which aim to improve quality and health outcomes for patients across the ACO and achieve cost savings for Medicare, employers, and patients.

"We need to hold up our successes to show how a redesign of the system requires primary care to have a central role."

BRUCE BAGLEY, MD, INTERIM PRESIDENT AND CHIEF EXECUTIVE OFFICER, TRANSFORMED

"All players will have to start to have a conversation about how to accomplish good patient care in a more effective way," Bagley says. "[PCPs] and specialists will be required to work together to achieve these goals. We need to discuss each other's role, such as what a [PCP] can do to get a patient ready to see a specialist."

Such conversations sometimes occur in multispecialty group practices in which physicians are salaried, but they are more rare when doctors work separately, he says.

"We need a shared understanding of how to handle common conditions and have a team approach to efficient diagnoses and treatment regimens. If the ACO model is working well, primary care should be the central focus that sends patients to the right place at the right time," Bagley says.

Neil Kirschner, PhD, senior associate of regulatory and insurer affairs at the American College of Physicians, says that ACOs will make it more important than ever for PCPs to be aware of what is happening with the patients they refer to specialists.

"The [PCP] can be hurt financially if the specialist isn't doing [his or her] job correctly," he says.

Part of this process is making sure the right information is given to the specialist from the start. Ensuring that test results get to the specialist in a timely way, for example, will reduce costly redundancies.

Although Bagley stresses that the restructuring that will come with ACOs is not about putting more money in doctors' pockets, he does predict that primary care ultimately will be rewarded because it will be better able to contribute to the overall process of delivering appropriate care.

Part of keeping all of the members of an ACO "on their toes," however, may be allowing PCPs to refer to outside providers if they do not believe certain ones in an ACO are operating efficiently, he says. Bagley acknowledges, however, that some ACOs will resist offering such an ability.

Catherine Leape, assistant director of recognition programs at the National Committee for Quality Assurance (NCQA), predicts that as ACOs transcend healthcare delivery from "site" care to "population health" care, it will be good for all physicians.

"Our current delivery system works in silos, and ACOs break down those barriers so that care management, coordination, and transitions from one provider to another are seamless. This has a very positive effect for all providers by promoting continuity of care and reducing duplicative tests or procedures," she says.

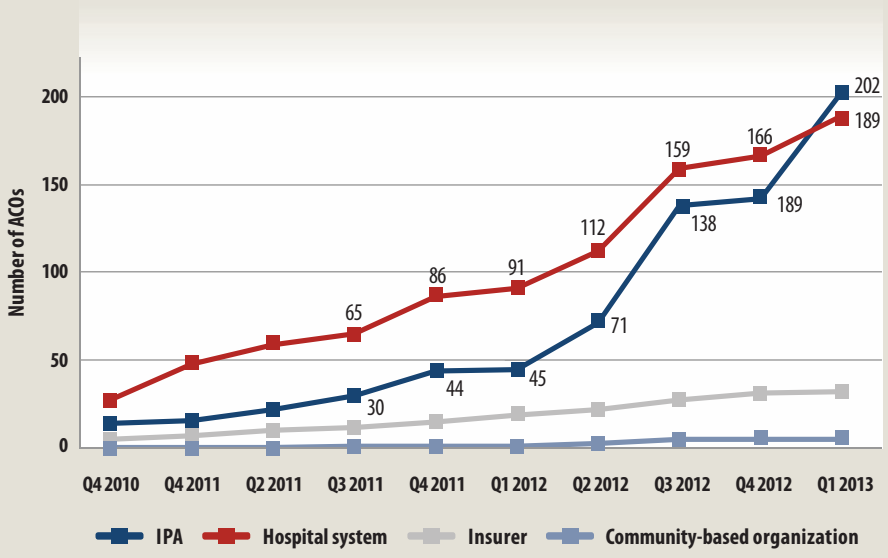
The NCQA offers an ACO accreditation program to assist organizations in making the transition to integrated care. "As primary care is of the utmost importance, we were sure to align our accreditation program with our Patient-Centered Medical Home (PCMH) recognition, a program that recognizes excellence in primary care," she says.

CHANGING DYNAMICS

The ACOs that succeed will be the ones that break the cycle of sick people

Accountable care organizations over time

Accountable care organizations (ACOs) have expanded dramatically, more than doubling in number since the start of 2011. Physician groups are now the largest backers of ACOs, with hospital systems a close second.



Source: Leavitt Partners Center for Accountable Care Intelligence

showing up in the emergency department because they had no other access to care.

In the process, the reimbursement focus will shift from being volume-based to being value-based, Kirschner says. "Payments will be weighted toward quality and efficiency."

Practices will receive a budget—likely a generous one, he says—to care for a population. The better the job they do at keeping quality high and costs down, the more they will be rewarded.

Several models exist in which this can happen through Medicare (see "ACOs across the United States"), and private payers are likely to follow suit, he says. Some of the models require no risk for the providers if they do not meet their saving targets.

"The government knows this is a major change and is trying to make it as easy as possible," Kirschner says.

The only upfront costs some practices will need to face will be those related to implementing procedures to succeed in these new models, he says. Examples could be offering extended office hours, having a person good at triage take after-hours calls, and making sure patients are seen quickly and treated appropriately after being hospitalized.

"Once you get good at these things, you can start to assume some risk" and eventually move into more of a "capitated" model, Kirschner says.

According to TransforMED, primary care provides access, disease prevention, disease management, and care coordination services that leverage overall cost savings for the system. Other components of an ACO could include specialty care, imaging, laboratory services, hospital care, and information technology support.

"Each component must be integrated and coordinated and contribute to the overall efficiency of the ACO enterprise," Bagley says.

He predicts that the ACOs that will achieve the best results are ones that are already mastering clinical integration. That is why moving toward a PCMH model is a recommended step on the path to becoming an ACO. It also lets you demonstrate your quality and efficiency to any ACO in your community seeking primary care services, he adds.

TransforMED recommends that, for the time being, PCPs keep seeing patients to optimize their revenue in the current payment environment. Mastering proper coding,

What to ask

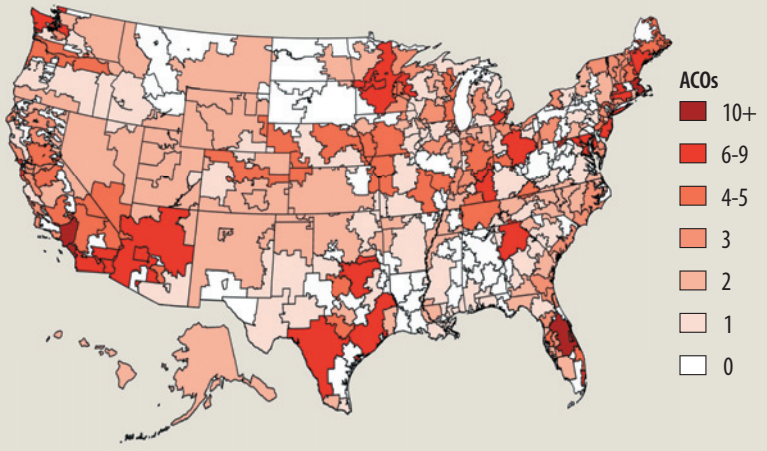
Ask these questions when considering joining an accountable care organization (ACO).

- What are the ACO's by-laws, and do they protect my interests?
- What representation will I have on the ACO's governing body?
- What are the administrative and organizational requirements to participate (for instance, pertaining to data submission, committee participation, etc.)?
- What practice transformation changes will be required to participate (for instance, use of an electronic health record system, 24/7 access or triage, provision of case management)?
- What financial or "in kind" assistance can I expect from the ACO to implement and maintain any required practice transformation?
- What are reasonable estimates of shared savings or extra payments that the ACO can earn?
- How will any earned shared savings or extra payments be distributed?
- Is there any potential for accrued loses and participation in a "pay back" to the payer?
- Is the ACO adequately protected from relevant federal and state penalties (related to anti-trust and anti-kickback statutes)?
- What are the advantages and disadvantages of ACO participation versus establishing an independent service contract with the ACO, particularly for subspecialty physicians?

Source: American College of Physicians

Accountable care organization growth by hospital referral region

An estimated 428 accountable care organizations (ACOs) now exist in 49 states. As of February 20, Delaware was the only state in the country without an ACO, although entities in the state are engaged in ongoing discussions about creating one, and ACOs in neighboring states may cover some Delaware residents. The Medicare Pioneer ACO and Shared Savings Programs account for more than 250 ACOs and cover up to 4 million Medicare beneficiaries. Private ACOs make up the remainder of ACOs.



Sources: Leavitt Partners Center for Accountable Care Intelligence

Advice from the field

In a recent Web seminar offered by the National Committee for Quality Assurance and titled "Lessons from the first accredited ACOs," participants represented organizations that had voluntarily submitted their accountable care organizations (ACOs) for accreditation by the organization.

Some advice offered by these early adopters:

Hal Teitelbaum, MD, JD, managing partner and chief executive officer of Crystal Run Healthcare: Change your mindset. You are no longer selling office visits. You are selling good outcomes. With time, this will lead to lower costs.

If you are torn between value and volume because your patients have a variety of payer situations, choose a value-based approach for all, and partner with like-minded payers, providers, and suppliers.

Trude Haecker, MD, medical director, quality improvement department patient safety officer at the Children's Hospital of Philadelphia Care Network: The Patient-Centered Medical Home model is a crucial framework from which to launch an ACO formation process. Also, use the ACO creation process to open dialogues with specialists on how you all can use electronic health record systems in new ways to improve outcomes.

Spencer R. Berthelsen, MD, chairman and managing director of Kelsey-Seybold Clinic: Do not minimize the value of having good medical leadership.

Douglas Carr, MD, medical director of education and system initiatives, Billings Clinic: An independent accreditation process is a useful way to review and improve your internal processes.

> "Payments will be weighted toward quality and efficiency."
>
> NEIL KIRSCHNER, PHD, SENIOR ASSOCIATE OF REGULATORY AND INSURER AFFAIRS, AMERICAN COLLEGE OF PHYSICIANS

having good billing procedures, and paying attention to accounts receivable also are critical to being able to respond quickly as the incentives change.

"Pay attention to what is happening in your market, and determine which players seem to value primary care as more than just a referral hub for hospitals and specialists," Bagley says.

Kirschner also recommends that physicians stay up to date in areas such as contracts and the use of data to improve outcomes. "Providers need to be knowledgeable about many more things," he says.

ANTI-KICKBACK LAWS

Another area in which physicians need to become more knowledgeable is anti-trust laws. As providers collaborate to provide care, they need to adhere to legal guidelines.

Consolidation of healthcare services within a market carries a high risk of monopolistic behaviors with resulting higher costs and controlled access. According to TransforMED, on the same day that CMS published the proposed rules for ACOs, the Department of Justice and the Federal Trade Commission also published rules that allow a certain level of consolidation and market share for health care organizations.

Kirschner says that physicians should be fully aware of those rules, because following them will offer substantial protection. Although professional legal advice on this topic has no substitute, practices should ask questions to identify potential problems. (See "What to ask.")

Coding Insights

HOW TO GET PAID FOR COMPLEX CARE COORDINATION

While reviewing the 2013 Current Procedural Terminology book, I came across new codes for complex chronic care coordination services. Can you explain those codes to me?

THESE NEW CODES were designed to incentivize care coordination and improve healthcare delivery to patients with chronic diseases. The Centers for Medicare and Medicaid Services considers these services as bundled into the services to which they are incident-to, however, not separately payable.

The codes cover services provided to an individual residing in a home, domiciliary, or assisted living facility and are addressed by multiple disciplines and community service agencies. The reporting individual provider is the one who directs the management and/or coordination of services as needed for all medical conditions, psychosocial needs, and activities of daily living.

Care coordination may include:

- **communication with the patient, family members, and caregiver decision-makers regarding aspects of care;**
- **communication with agencies serving the patient;**
- **patient and/or family education to support self-management;**
- **identification of community resources;**
- **facilitating access to care as needed; and**
- **development and maintenance of a comprehensive plan of care directed by the physician or qualified healthcare professional.**

THREE CODES

The new codes:

99487: Complex chronic coordination services; first hour of clinical staff time directed by a physician or other qualified healthcare professional with no face-to-face visit, (once) per calendar month.

99488: First hour of clinical staff time directed by a physician or other qualified healthcare professional with one face-to-face visit, per calendar month.

99589: Each additional 30 minutes of clinical staff time directed by a physician or other qualified healthcare professional, per calendar month (list separately in addition to code for primary procedure).

The first hour of time is defined as 31 to 74 minutes. Time is not recorded on the day the patient has an evaluation/management visit with the provider.

These codes can be used when doctors of different specialties confer to treat patients with one or more chronic diseases. Care coordination includes services such as **care plan oversight** (99339–99340), **prolonged services without direct face-to-face contact** (99358–99359), **anticoagulant management** (99363–99364), **analysis of data** (99090–99091), **medical team conferences** (99366–99368), **education and training** (99360–98962, 99071), **telephone services** (98966–98968), **online medical evaluation** (98969, 98944), **preparation of special reports** (99080) **transitional care management** (99495-99496), **medication therapy management** (99605–99607), **and end-stage renal disease services** (90951–90970); if performed these services may not be reported separately in the month for which 99487–99489 are reported.

The American Medical Association/Specialty Society Relative Value Scale Update Committee, commonly known as the RUC, has recommended work relative value units (wRVUs) as follows:

99487: Work RVU = 1.00
99488: Work RVU = 2.50
99489: Work RVU = 0.5

*Answers to readers' questions were provided by **Maxine Lewis, CMM, CPC, CPC-I, CCS-P**, president of Medical Coding and Reimbursement in Cincinnati, Ohio. Send your primary care-related coding questions to **medec@advanstar.com**.*

FINANCIAL STRATEGIES
Don't count on real estate to fund your retirement [58]

Money

Credit line can be lifeline for your practice

Interest rates are low, so consider establishing this resource to help you handle irregular or cyclical cash flow issues

by **DAVID BENNETT**

HIGHLIGHTS

01 Your practice's size, specialty, and practice cash flow needs and trends will determine the amount of credit to apply for.

02 During underwriting, your practice's tangible net worth, debt-to-worth ratio, and available liquidity will be evaluated.

03 Consider closing a credit line if you have not used it in more than 3 years, especially if you are paying annual fees.

Because your practice's cash flow is threatened by an array of economic realities, from reduced Medicare reimbursements to higher technology costs, most financial experts agree that a solid line of credit is an essential tool to have. **But where should you start?**

FIRST OF ALL, a credit line can be defined as an available amount of money that can be tapped at the borrower's discretion, says Michael La Penna, principal of the La Penna Group Inc., Grand Rapids, Michigan.

Generally, if you are looking to finance big-ticket items, you will want to seek out a business line of credit. If, on the other hand, you wish to fund smaller business purchases such as office supplies, you will want a revolving line of credit, such as a credit card. When you use either will depend in part on your preferences. Some practices establish a line of credit, or revolving credit, for emergencies, and others regularly use one or the other types of lines.

"A credit line is an open access resource to a physician practice that can be used on an episodic basis. It's generally in place for private physician practices, and it is a useful tool for any business that has a cash flow that can be irregular or cyclical," La Penna adds. "It should never be used for standard financing. Generally, the size [of the line] is a function that is determined by business planning and business trends. It's generally agreed on between the bank and the practice. It's at a variable [floating] interest rate, and it is re-qualified annually." More on the appropriate amount of credit to seek later.

THE RIGHT STRATEGY?

So how can a solo or small practice determine whether opening a credit line is the right strategy?

Marc Lion CPA, CFP, founding ➔54

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Financial checklist

If applying for a credit line, **Marc Lion** CPA, CFP, founding member of Lion and Co. CPAs LLP in Syosset, New York,

recommends bringing these items with you:

- ☑ 2 years of personal tax returns;
- ☑ 2 years of business tax returns;
- ☑ financial statements for the current year;
- ☑ 3 months of current personal and business bank statements;
- ☑ 3 months of current brokerage statements (regular and retirement), if applicable;
- ☑ copies of 2 years of any K-1s that may appearing on the return on schedule E;
- ☑ with respect to number 6, if any of the K-1s are related to businesses that a significant ownership position may exist, be prepared to provide 2 years of copies of those tax returns as well; and
- ☑ if a business owner, a letter from your certified public accountant indicating that if any funds from the business are to be used toward the purchase or the refinancing, it will not hurt business operations.

➔52 member of Lion and Co. CPAs LLP in Syosset, New York, says a credit line is a good resource to have all of the time, especially now, when interest rates are extremely low.

"I usually advise my clients, 'Even if you don't need a [credit line] today, let's go ahead and apply for something just so you will have it,' " he says, adding that despite the low interest rates, he has not seen an influx of physicians seeking counsel regarding credit-line implementation.

Lion, who oversees his firm's healthcare advisory group, working with providers on tax, personal finance, and practice management issues, says practices should aim for an interest rate one or two points above the prime rate, a commonly used benchmark easily obtained online. He's also the outgoing president of the National CPA Health Care Advisors Association.

> "I USUALLY ADVISE MY CLIENTS, 'EVEN IF YOU DON'T NEED A [CREDIT LINE] TODAY, LET'S GO AHEAD AND APPLY FOR SOMETHING JUST SO YOU WILL HAVE IT.' "
>
> MARC LION CPA, CFP, FOUNDING MEMBER OF LION AND CO. CPAs LLP

CREDIT COVERAGE

If you commit to applying for a line of credit, it's important to calculate the proper amount to establish and maintain. Barry Oliver, CPA, CPS, of Thomas, Wirig & Co., advises to base the size of a credit line on the necessity of the practice—and then some.

The need for credit is likely to be greater in newer, seasonal, and transitioning practices, which are more likely to have uneven cash flows, as well as in practices adding a partner, staff member, or location or merging with another practice. Regardless, La Penna says, "Doctors should have a realistic assessment of their actual 'in the door' cash and be able to predict how and when they can...pay down the line."

Oliver, an editorial consultant to *Medical Economics*, says, "In today's environment, many doctors will take more than they need, because credit lines don't come as easy as they once did." For physicians, outstanding student loan debt may complicate matters, La Penna notes.

A practice's legal structure may necessitate a credit line, Oliver says. "Many C-corporations will need one immediately following their year-end so they can make their payroll in the first part of the year," he adds.

Lion recommends to his clients that they maintain a credit line of avt least $100,000, although he says a larger line of $250,000 can cover most budgetary goals, including expansion plans, significant equipment upgrades, or even buying out a partner. The respective amount of credit needed also will depend on the size of the practice and specialty, he adds.

Cash flow needs and trends within the practice will dictate additional factors to consider, Le Penna says.

"A practice with seasonal trends may require a more robust line of credit," he says.

"Consultation with a banker or a financial consultant over the practice performance is the first step. Traditionally, banks will look at [accounts receivable (AR)] and approve some line of credit that is a function of the existing AR—like one half of the AR or some other ratio that is standard within their reference set."

Lion recommends that physicians maintain credit lines regardless of their practices' financial health, in case situations should arise that interrupt practice cash flow. He points to the effect that Superstorm Sandy had on medical practices in New York and New Jersey this past October.

"Some specialists have big war chests. Family practitioners? Not so much," he says. "All the insurance companies have to do is jam you up 3 or 4 weeks and all of the sudden, you are falling behind and now you are in a cash crunch. That's where the credit line comes into play."

"FOR THE LOCAL PHYSICIAN PRACTICE AND FOR OTHER PREMIUM CUSTOMERS WITH SOLID BUSINESS AND REVENUE HISTORY, BANKS ARE EAGER TO CONNECT."

MICHAEL LA PENNA, PRINCIPAL, THE LA PENNA GROUP INC.

SHOP AROUND

The experts who spoke with *Medical Economics* recommend shopping around, because the marketplace is competitive.

Lion includes credit card companies, banks, and financial services firms in his list of credit line providers. Financial services firm often charge more interest compared with regular banks but often can process a credit line request more rapidly—saving time but not necessarily money, he adds.

La Penna advises limiting your choices, however. "The only option that should be considered should be a credit line with a bank that handles the practice assets and checking and banking services," he says. "Credit cards are too expensive and should never be used. Financial services companies charge too much."

Other factors to consider when shopping for credit, according to La Penna, include terms that define your ability to change any aspect of the credit agreement, and the structure and nature of the security for any credit or loan as related to guarantees for the credit line.

Lion says that national or regional banks are granting credit according to stricter underwriting standards that dictate how banks and other financial institution assess the eligibility of a customer for a credit line. The more stringent underwriting guidelines stem from the financial incidents of a few years ago, when the nation's banking system came under intense scrutiny, he adds.

"Key factors that contributed to the rise in product and portfolio credit risk were the weakening economy, rising energy costs, turbulence in the secondary credit markets, the downturn in the housing market, and the anticipated impact of relaxed underwriting standards over the past few years on payment performance," La Penna says.

During the business underwriting process, the institution evaluates the financial information provided by the practice, including analyzing the practice's balance sheet of tangible net worth, the ratio of debt to worth (leverage), and available liquidity (current ratio). The more solid a practice's balance sheet, the more likely the institution will grant a line of credit.

ESTABLISH A RELATIONSHIP

When it comes to seeking a credit line for your practice, the experts advise taking the same action you would to position yourself well as a consumer: make sure your financial statements are in order, complete, accurate, and up-to-date. (See "Financial checklist.") And approach establishing a line of credit with the same business acumen as any professional dealing, says Bruce Bagley, MD, interim president and chief executive officer of TransforMED, a wholly owned subsidiary of the American Academy of Family Physicians (AAFP).

Develop good rapport with your bank first, however.

"Probably the best advice is that a physician's practice is no different than any small business in terms of cash flow and capital needs," Bagley says. "They should have an established banking relationship that is responsive to business needs."

The CAPLine program

The U.S. Small Business Administration (SBA) continues to expand is the CAPLine loan program, an umbrella program under which it helps small businesses meet their short-term and cyclical working-capital needs. Key benefits of the program, according to the SBA:

- Small businesses can pledge accounts receivable, inventory, contracts, and purchase orders to secure an SBA revolving line of credit. For example, when fulfilling a purchase order request, that same order can be used as collateral to obtain an SBA-guaranteed line of credit to hire more workers and buy more materials.
- Small business subcontractors can obtain an SBA-guaranteed line of credit to finance their work on a contract with a federal prime contractor.
- The SBA no longer requires small-business owners without buildings or equipment to use their personal assets as collateral to secure working capital.
- Small businesses working on a contract that requires surety bonding can obtain an SBA-guaranteed line of credit.

In addition, small businesses that use CAPLine can take advantage of an increased SBA 7(a) loan limit of $5 million, which went into effect with the Small Business Jobs Act of 2010.

"IN TODAY'S ENVIRONMENT, MANY DOCTORS WILL TAKE MORE THAN THEY NEED, BECAUSE CREDIT LINES DON'T COME AS EASILY AS THEY ONCE DID."

BARRY OLIVER, CPA, CPS, THOMAS, WIRIG & CO.

"A PHYSICIAN'S PRACTICE IS NO DIFFERENT THAN ANY SMALL BUSINESS IN TERMS OF CASH FLOW AND CAPITAL NEEDS."

BRUCE BAGLEY, MD, INTERIM PRESIDENT AND CHIEF EXECUTIVE OFFICER OF TRANSFORMED

Once you are on a solid footing with your bank, the groundwork for securing a line of credit is mostly done, according to La Penna.

"Processes for underwriting on all credit are more stringent, but a line of credit is typically constructed with a local bank that has a depository relationship with the practice [the practice is an ongoing client], and there may be many linkages," La Penna says. "We do not see mature practices with local connections and solid business histories having a problem with accessing lines of credit.

"For the local physician practice and for other premium customers with solid business and revenue history, banks are eager to connect," he continues. "One way to connect is at the point of deposits, and the other is to fulfill standard credit needs. Property loans, leases, lines of credit, etc., will never have lower standards in the future, but banks will be seeking the 'right customers' for their products, and many doctors would be considered [to be] in this category."

Find independent banks in your area by using the bank locator tool from the Independent Banks of America at www.icba.org.

ALLY ORGANIZATIONS

Most physician organizations, such as the AAFP, have access to financial advisers that can assist with the questions a practice might have. Also, your local bank likely is connected with the medical community or works with many medical practices.

And government-backed organizations assist physician practices directly. One organization expanding its credit line offerings in the past few years, for instance, is the U.S. Small Business Administration (SBA).

Dianna Seaborn, SBA's policy program chief of Basic 7(a) Loan Program, Office of Portfolio Management, says one successful program that the administration continues to expand is the CAPLine loan program, an umbrella program under which the SBA helps small businesses meet their short-term and cyclical working-capital needs.

"We do a reasonable number of medical practices, providing capital for equipment [and] capital for expansion of a building," she says.

Seaborn says that the number of lending institutions nationwide that participate in CAPLine has grown incrementally, providing physician practices a wider canvas with which to take advantage of the loan program. (See "The CAPLine program.") In fiscal year 2012, SBA's loan programs posted the second-largest dollar volume ever, according to the agency's annual report. The year was surpassed only by the 2011 fiscal year, which was greatly influenced by the loan incentives offered under the Small Business Jobs Act of 2010.

TO CLOSE OR NOT TO CLOSE?

In Lion's opinion, if a practice is using a line of credit appropriately and for the purpose for which it was sought, then the credit line can remain open indefinitely. If a credit line is being used for purposes that aren't appropriate, however, or if it hasn't been tapped in more than 3 years, then the practice should consider closing it. For instance, he adds, "If the practice's cash is not flowing sufficiently to pay the owners/partners, then it's time to 'check under the hood' of the practice to identify where the profit leaks are." The same advice holds true if you tire of paying annual fees for a line of credit that you're not tapping into, Lion says.

As the borrower, when you close a line, you may be required to pay an "unused line fee," often an annualized percentage fee on the money not withdrawn. You will pay interest, which can be written off on your taxes, only on amount of money actually withdrawn.

Weigh the act of closing a credit carefully, Oliver says.

"Because credit lines are difficult to come by, most [practices] won't close [them] for fear of being denied if they apply for a new one," he adds.

WHAT THE FUTURE HOLDS

According to La Penna, market-influenced changes in the healthcare industry will continue to trickle down to practicing solo and small-practice physicians, who, in turn, must remain flexible and aware so they can continue to keep their businesses operating in the black.

"Healthcare reform will change many local marketplaces, and referral sources will change as accountable care organizations and insurance exchanges mature," he says. "These factors will cause uncertainty in some medical markets, and any doctor who is independent will have to be vigilant concerning how these factors might impact their business—and their access to credit."

Richard E. Anderson, MD, FACP
Chairman and CEO, The Doctors Company

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Financial Strategies

DON'T COUNT ON REAL ESTATE TO FUND YOUR RETIREMENT

BY MARISSA MANLEY

Some doctors dream of funding a comfortable retirement by acquiring real estate for their practices and then selling it for a profit when they are ready to retire. Although it sounds good, remember that buying and selling real estate often depends on market conditions and, very importantly, the location of the property.

IF YOUR GOAL is to fund your retirement from the equity of the practice's property using its increasing market value, then you will need a sound entry/exit strategy and be willing to face the challenges of ownership. Here are three issues you will need to consider before you begin looking for property to acquire.

Location: Fundamental market conditions—such as population density, the physical attractiveness of the building and the surrounding neighborhood, and the supply of and demand for the particular type of space will be key in determining the ultimate value of the real estate you purchase.

The size and type of building. If you are thinking of purchasing a small, stand-alone property suitable for housing a solo practice, an important consideration should be who will buy it from you. A growing number of physicians are working for hospitals rather than going into independent practice, so candidates to purchase such properties are declining.

Because this segment of the real estate market is shrinking, you might have to sell the property to an entity other than a medical practice. If so, you may incur costs for removing equipment not needed by a non-medical business.

What if you decide to purchase an office building or strip mall to house your practice and become a landlord? If so, you will need to determine whether ownership responsibilities will compete with your role as a physician.

If your practice is managing a mixed-use property, you may encounter non-medical issues such as renovation, heating, ventilating, and air conditioning, security, snow removal, and parking lot maintenance, to name just a few considerations.

BUUYING AND SELLING REAL ESTATE OFTEN DEPENDS ON THE EBB AND FLOW OF UNPREDICTABLE MARKET CONDITIONS AND, VERY IMPORTANTLY, THE LOCATION OF THE PROPERTY.

Despite the management challenges, however, tackling them offers potential benefits to solo practitioners. When you close your practice and eventually sell the property, the proceeds will be yours. That leads to the third issue to consider:

The roles and responsibilities of partners in the practice when it comes to real estate. As a solo practitioner, you do not have to share in decision-making—or profits—when it comes time to sell. If you have partners, however, things become more complicated. For example:

- Will each partner own an equal share of the real estate?
- What happens if a partner does not wish to participate in real estate ownership?
- What if a new partner wants to buy in to the property? How will you arrive at an appropriate price for the buy-in?

Clearly, owning your own medical building takes careful planning to ensure that you can retire someday on your profits from real estate. You can improve your chances of being successful by being aware of the pitfalls, exercising caution, and seeking professional advice before embarking on any deal.

The author is president of Healthcare Real Estate Advisors, a nationwide real estate consulting and advisory firm based in New York, New York. Send your practice finance-related questions to ***medec@advanstar.com****.*

Trends*

Push for wellness continues

Economics of immunization services could improve, but need exists to better adult vaccination rates, physician/pharmacy reporting

by **DANIEL R. VERDON,** *Group Editor, Primary Care*

HIGHLIGHTS

01 To either consider offering immunization as a service or evaluate it as an existing service, first assess the need, access for patients in the community, and, very importantly, the costs associated with the service.

02 Beyond business considerations, the main issue is removing barriers to make sure people are protected from preventable diseases.

Immunization rates are so low for adults, the situation has hastened new calls from the Centers for Disease Control and Prevention (CDC) for physicians to assess patient vaccination histories and intervene when appropriate to increase adherence.

THE ISSUE is clearly about improving public health, according to new guidelines from the CDC's Advisory Committee on Immunization Practices, which released its updated guidelines for 2013 recently in an effort to increase adult vaccination rates and offer recommendations for physicians.

In a healthcare system that is shifting toward wellness and prevention as a means of reducing runaway healthcare costs, some work remains when it comes to improving vaccination rates, physicians say.

According to new CDC data, pneumococcal vaccination coverage among adults aged 19 to 64 years at high risk was just 20% overall. Nearly 16% of adults received herpes zoster (shingles) vaccination in 2011, whereas tetanus vaccination is estimated at 64.5% for adults aged 19 to 49 years over a 10-year period.

Although the goal, according to physicians interviewed by *Medical Economics,* is to make certain patients are protected from the health threats of influenza, pneumococcal, shingles, Tdap, diphtheria, and others, every practice must answer very real business questions. For instance, can you receive adequate reimbursement to make an immunization service viable, and how can you use vaccine administration as a way to

By the numbers

123
MILLION DOSES
…the number of influenza vaccine doses delivered to providers as of mid-November 2012 for the 2012–2013 season

15.8%
OF ADULTS
aged ≥60 years reported receiving herpes zoster vaccination to prevent shingles.

PNEUMOCOCCAL VACCINATION
Pneumococcal vaccination coverage among adults aged 19 to 64 years at high risk was 20.1% overall.

IN 2011,
the proportion of adults receiving any tetanus toxoid–containing vaccination (for instance, Td or Tdap) during the past 10 years was 64.5% for adults aged 19 to 49 years.

HEPATITIS A
vaccination coverage (≥2 doses) increased among adults aged 19 to 49 years (by 1.8 percentage points to 12.5%) but remained low.

HEPATITIS B
vaccination coverage (≥3 doses) among all adults aged 19 to 49 years was 35.9%.

29.5%
OF WOMEN
aged 19 to 26 years reported receiving ≥1 dose of HPV vaccine in 2011.

Source: Centers for Disease Control and Prevention

engage adults and families about a very serious health threat?

Donna K. Knapp, a practice management consultant with MGMA Consulting, says that physicians simply need to recognize that not many CPT codes command 100% reimbursement from some commercial payers as do immunization services, and it underscores the important role immunizations play in keeping adults and children healthy.

Vaccinations, Knapp says, always will be a necessary service for patients, and they remain a key component to prevention strategies. But assessing their economic viability is another question entirely. Some signs for optimism among public and private payers exist, however.

Over the past few years, improvements in reimbursement of children's immunizations also have given a boost to the financial realities for family physicians and pediatricians in providing this service, says Jamie Loehr, MD, a family physician at Cayuga Medical Center in Ithaca, New York. In fact, work by the American Academy of Family Physicians and the American Academy of Pediatrics added CPT codes 90460 and 90461, which allow for reimbursement by vaccine components. It means a five-part combination vaccine is reimbursing for five administration codes.

But not every practice or patient panel is alike, experts say, and a service that might be successful for one specialty can be a loss leader for another.

THE BUSINESS OF IMMUNIZATION

To either consider offering immunization as a service or evaluate it as an existing service, first assess the need, access for patients in the community, and, very importantly, the costs associated with the service.

The list actually can be quite long, Knapp says. You definitely will need to factor costs for rent, space, labor (including staff benefits, retirement), utilities, vaccine acquisition, equipment, medical and non-medical supplies, storage, and insurance, to name a few.

The practice also will need to evaluate any costs related to special events during the year. She is aware of some primary care practices that conduct Saturday clinics to administer influenza vaccinations. The costs associated with an event might include its promotion, patient scheduling, overtime, etc. The point? Paint a true picture of your practice costs, and then evaluate the level of reimbursement based on your contracts.

So, is it worth it?

It largely depends on the practice and the need of the patient population for immunizations.

➔62


It was the first note I ever got in crayon. “Thank you for making my daddy feel better.” I keep it on my desk, where I pore over patient records and cash flow statements. Because even if the medical field seems to be changing by the day, the reasons I practice never do.
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According to Loehr, "It is totally worth it from my perspective." And it is largely based on seeing so many children in his patient panel.

For adult immunizations, Yul Ejnes, MD, immediate past chairman of the American College of Physicians' Board of Regents and a practicing internist in Cranston, Rhode Island, says the business model has been more challenging.

Some physicians gladly would turn over the responsibility to other providers because of the expenses associated with stocking vaccines versus economic realities of reimbursement.

"Other physicians want to offer it because it is their responsibility, or it is a way to get patients back to the office for wellness checks or deal with other health issues," Ejnes adds.

RHODE ISLAND'S MODEL

The state of Rhode Island actually removed multiple barriers as it relates to the acquisition of vaccines, Ejnes says, and the move has made it much easier for physicians to manage immunizations.

How does it work? The state of Rhode Island negotiates and purchases vaccines from a variety of manufacturers, and then state officials settle with commercial insurers based on their proportion of the insured population.

"We basically get the vaccine free from the state of Rhode Island, and all we do is charge the insurer for the administration.

10 proven strategies to improve immunization rates

When it comes to improving immunization rates, what strategies work? The Centers for Disease Control and Prevention (CDC) compiled 10 ways to improve vaccination rates in your practice.

1. STANDING ORDER

This written order stipulates that all persons meeting certain criteria (for instance, age or underlying medical condition) should be vaccinated, thus eliminating the need for individual physician's orders for each patient. How effective is it?

According to the CDC, standing orders are the most consistently effective means for increasing vaccination rates. One hospital study (Crouse, 1994) demonstrated that 40% of inpatients were vaccinated against influenza in hospitals using standing orders compared with 10% of patients in hospitals using physician education only.

2. COMPUTERIZED RECORD REMINDERS

Computerized record reminders can be efficient and inexpensive, the CDC reports. The downside is that they only target your patients with office visits. "In one practice, pneumococcal vaccination rates of high-risk persons increased from 29% before implementation to 86% following implementation of computerized chart reminders (Payne, 1995)," the CDC says.

3. CHART REMINDERS

The ones that require a simple check mark in an electronic or paper record are the most effective way to facilitate the discussion between physician and patient.

"Reviewing health maintenance inventories with patients requires less than 4 minutes with the patients and quickly becomes part of the physician's routine," the CDC states. In one study, influenza vaccination rates increased from 18% before use of a health maintenance flow sheet to 40% with use of the health maintenance flow sheet, the CDC reports.

4. TARGET-BASED PERFORMANCE FEEDBACK

An effective incentive for many physicians is comparing their vaccination rates for a particular patient population with a goal or standard, the CDC adds. "Some practices encourage friendly competition among physicians, which creates an additional incentive to increase vaccination rates," the agency reports. In a study (Buffington, 1991), "the percentage of eligible patients vaccinated against influenza at that practice office was 50%, compared to 34% in a control group that did not use the target-based approach. An additional 16% were vaccinated in public clinics, bringing the total percent of patients vaccinated to 66% among patients

> "WE BASICALLY GET THE VACCINE FROM THE STATE OF RHODE ISLAND, AND ALL WE DO IS CHARGE THE INSURER FOR THE ADMINISTRATION. IT ELIMINATES TWO PROBLEMS—GETTING AHOLD OF THE VACCINE AND DIVERSIFYING THE SUPPLY."

It eliminates two problems—getting ahold of the vaccine and diversifying the supply. If one manufacturer has to shut down production, then we still have the other sources."

Reimbursement rates on vaccines themselves traditionally have been just at cost, and in some cases, below cost, Ejnes adds. So it was becoming a loss leader for many physicians. Loehr advises physicians to shop around for price, and he has found success in working directly with vaccine manufacturers to acquire products.

Although the margins are an important consideration, the issue for doctors should be about removing barriers to make certain people are protected from diseases that can be prevented, Ejnes adds. And that's what it's all about.

whose physicians used the target-based approach compared with 50% among control physicians.

5. HOME VISITS

Home visits modestly increase vaccination and counseling for vaccination, the agency says. In the United Kingdom, Nicholson, et al., documented a higher influenza vaccination rate of 20.4% among older persons immobile at home with a specific vaccination program, compared with similar persons with no specified vaccination program.

6. MAILED/TELEPHONE REMINDERS

Reminder calls to the patient or a postcard/letter reminding the patient that a vaccination is due or overdue (recall) is a common practice and can increase adherence by some 22%, according to studies on the subject.

7. EXPANDING ACCESS

Expanding access to immunizations can include: reducing the distance patients must travel to receive vaccination services, making administration hours more convenient, delivering vaccinations in settings previously not used, and reducing administrative barriers to vaccination (for instance, drop-in clinics or express lane vaccination services).

When combined, expanding access has been very effective, especially when combined with other methods like patient reminders/recall notices, the CDC says.

8. PATIENT EDUCATION

Patient information sheets also are helpful. In fact, they can be distributed in the waiting room. Offer a check-off sheet acknowledging whether they fall into any of the risk groups and whether they wish to receive vaccines during the appointment..

When implemented as a pre-discharge measure in a hospital, pneumococcal and influenza vaccination rates were 75% and 78%, respectively, compared with 0% of patients not given an informational handout (Bloom, 1988). This method also has been used to effectively to increase tetanus toxoid administration (Cates, 1990).

9. PERSONAL HEALTH RECORDS (PHRs)

Studies have shown that access to personal health records have increased pneumococcal vaccination rates by 20.5%,

"The effectiveness may hinge on the physician's attitude toward the PHR and receptiveness to patient-initiated care," the CDC says. "Effectiveness will be maximized when physicians encourage the patients to take initiative, and physicians are willing and able to provide the requested services."

10. OPEN UP LINES OF COMMUNICATION

When it comes to vaccination administration, pharmacies also have taken notice. Every state in the country now allows pharmacists to administer influenza vaccine.

Data from the CDC's National Flu Survey showed that in 2011, nearly 21% of adults were receiving flu shots at a pharmacy, drugstore, or local supermarket.

If you put the competitive questions aside, some questions related to adherence, patient safety, and follow-up communication with physicians need to be addressed, physicians say.

In fact, most doctors simply want to be informed about their patient's status. Although some pharmacies are excellent about communicating vaccination status with the practice, others are not. Ultimately, the secure exchange of electronic health information will solve this issue, but until then, experts say to take it as an opportunity to reach out to your patients and to local pharmacies to communicate the need and document it.

CODING INSIGHTS
Getting paid for complex care coordination [53]

Policy

Sunshine Act: 7 things you need to know

Communication will prevent you from getting burned

by **JULIE E. TREUMANN,** *JD*

HIGHLIGHTS

01 The Physician Payment Sunshine Act contains no reporting requirements or noncompliance penalties for physicians, but you will want to ensure that any manufacturers or group purchasing organizations with which you have a relationship report accurate information about you.

02 Those affected by the act seek to obtain clarification on some of its points.

Q What do you think of the act?
Tell us at www.facebook.com/MedicalEconomics

Having a financial relationship with a manufacturer does not necessarily mean that you or your treatment decisions are influenced by that relationship. As a matter of public perception, however, it is important for you to understand the new Physician Payment Sunshine Act so you can determine what relationships to have with manufacturers and group purchasing organizations going forward.

>> **CONGRESS PASSED** the act as part of the Affordable Care Act to shed light on financial relationships between drug and medical device manufacturers and doctors with the goal of enabling patients to make better and informed decisions when choosing healthcare professionals and deciding about treatments. The law also is meant to deter inappropriate financial relationships that might lead to increased healthcare costs.

Beginning August 1, applicable manufacturers of pharmaceuticals, biologics, and medical devices must collect and track data regarding payments and other transfers of value they make to physicians and teaching hospitals. They must electronically submit such data to CMS by March 31, 2014. Affected manufacturers and group purchasing organizations (GPOs) also will be required to report certain physician ownership or investment interests. CMS will

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➔64 on its Web site by September 30, 2014.

Before then, you will want to familiarize yourself with the act. Here are the answers to some questions you might have.

WHAT IS THE RULE?

Briefly, the rule specifies that if you have a financial relationship with, or an ownership interest or investment interest in, an applicable manufacturer, or if you have an ownership interest or investment interest in a GPO, then the entity is required to collect and report certain information about you and your relationship with it. Similar ownership interests held by an immediate family member of a physician (spouse; parent; child; sibling; stepparent; stepchild; stepsibling; father-, mother-, daughter-, son-, brother-, or sister-in-law; grandparent; or grandchild) also must be reported.

The rule defines "physician" as a doctor of medicine or osteopathy, a dentist, a podiatrist, an optometrist, or a chiropractor who is legally authorized to practice by the state in which he or she works. Advance practice nurses, registered nurses, physician assistants, residents, and pharmacists are

Physician groups welcome transparency

by **LOIS A. BOWERS, MA,** *Editor-in-Chief*

The comprehensive, nationwide effort that the Physician Payment Sunshine Act represents is desperately needed, says Steven Nissen, MD, of the Cleveland Clinic.

Secrecy in a democracy is never a good thing," says the chairman of the Robert and Suzanne Tomsich Department of Cardiovascular Medicine at the institution. "In a democracy, transparency is the best policy."

The Sunshine Act, he adds, is about fairness to patients as well. "If I prescribe an expensive, branded drug to treat your cholesterol, you should know whether or not I have a financial relationship with the company that makes that drug."

Nissen was one of five prominent physicians who sent a letter to then-White House Chief of Staff Jacob Lew in January pressing for an end to the delay in release of the final rule. The Affordable Care Act had required that reporting procedures be established by October 2011, with information collection beginning in January 2012 and data submitted to the Department of Health and Human Services by the end of March 2013. The Centers for Medicare and Medicaid Services (CMS) ultimately published the proposed rule in December 2011, however, and accepted comments until February 2012. In November, CMS submitted a preliminary version of the final rule to the Office of Management and Budget for review by the Office of Information and Regulatory Affairs.

The voices of these physicians joined a chorus of other organizations representing doctors, including the American Medical Association and National Physicians Alliance, calling for release of the final rule, although the proposed act also prompted opposition from those who thought the requirements unnecessary or who were concerned about the burdens of reporting, government involvement, or a possible chilling effect on productive collaborations. Even some groups supporting the overall goal of the act expressed misgivings—for instance, about whether physicians would be adequately protected if disputes occurred. Some corporations tired of waiting to put into effect their advance compliance efforts.

REACTION TO FINAL RULE

The final rule was published in February, and Nissen does not agree with its critics.

The Sunshine Act is "very reasonable," he says. "It doesn't say that physicians can't have relationships; it simply says that they should be a matter of public disclosure."

American Medical Association President Jeremy Lazarus, MD, agrees. "Physicians' relationships with the pharmaceutical industry should be transparent and focused on benefits to patients," he says. "Our feedback during this rulemaking process was aimed at ensuring the new registry will provide a meaningful picture of physician-industry interactions and give physicians an easy way to correct any inaccuracies."

The American Academy of Family Physicians says that CMS addressed some but not all of its concerns before releasing the final rule, ultimately exempting speaker fees for accredited and certified continuing medical education programs.

CMS also agreed with some but not all of the suggestions made by the American College of Physicians, ultimately declining to provide links to professional organizations' relevant ethics/professionalism materials, for instance, and deciding not to distinguish between direct and indirect research payments.

EFFECT ON DOCTORS, PATIENTS

CMS expects 224,425 physicians and 1,100 teaching hospitals to be affected in the first year of the program and 168,319 physicians and 1,100 teaching hospitals to be affected in subsequent years.

Physicians acting ethically should have nothing to fear, Nissen says, and doctors who do not want their names appearing in the database can refuse funding from drug and device manufacturer. But "anybody who says [physicians are] not influenced is simply not being realistic. Studies have shown over and over and over again that physicians *are* influenced," he says. (See www.MedicalEconomics.com/SunshineStudies for examples of recent research on this topic.)

not covered recipients, but payments made to non-physician prescribers to be passed through to a doctor are considered indirect payments to the physician and, therefore, would have to be reported under the name of the doctor.

The manufacturers and GPOs must report annually all ownership and investment interests in their entities that were held by a doctor or an immediate family member of a physician.

WHO HAS TO REPORT?

The final rule defines affected manufacturer, covered drug, device, biological, or medical supply, and payment or transfer of value. Generally, a manufacturer is required to report information if its prescription drugs, biologics, devices, or medical supplies require premarket approval/clearance or notification to the Food and Drug Administration and if payment is available for them under Medicare, Medicaid, or the Children's Health Insurance Program.

Generally, GPOs that operate in the United States and purchase, arrange for, or negotiate the purchase of covered drugs, devices, biologicals, or medical supplies for a group

> "Patients have a right to know what monies their physicians are receiving from commercial entities."
>
> —STEVEN NISSEN, MD, OF THE CLEVELAND CLINIC

When Forbes Insights conducted a survey for Deloitte Touche Tohmatsu in early 2012, 68% of physicians said they were in favor of a public, searchable database of physician-industry relationships, and 27% said they were not, citing privacy concerns. A worry expressed by 54% of those in favor of a database was that patients would not understand how to interpret the data.

But Nissen scoffs at the notion that patients may have difficulty interpreting the reported information.

"Patients are much more educated than they've ever been before," he says. "Most of the patients who come to see me have looked me up on the Web. They know my history. They've looked at my Wikipedia page about me. They've looked at Web sites...that have patients who grade physicians."

In such instances, Nissen says, consumers are applying in the healthcare arena the techniques they use when making other important decisions.

"Before I go out and buy a major appliance, I check *Consumer Reports*, and I see this as no different," he says "Before you see a physician, you may want to know whether that physician has relationships that you think might influence their care of you. It's a basic right for patients to have that information."

CMS expects about 1,150 manufacturers and 420 group purchasing organizations to be required to submit information. They face penalties for noncompliance ranging from $1,000 to $100,000 for each payment reported, with a maximum of $1 million per annual filing.

The Coalition for Healthcare Communication, which has members from organizations and industry united to "prevent interference with the conduct of continuing healthcare education," says it may petition the government to reconsider or clarify parts of the rule and says that further interpretation is needed regarding the definition of education, how to quantify educational transfers of value in promotional settings, how to calculate the per-meal costs at educational programs, and where publication supplements and single-sponsor medical journals fall on the spectrum of covered and noncovered materials.

As the rule contains no reporting requirements or noncompliance penalties for physicians, however, the main issue facing doctors, in addition to ensuring that patients understand reported information, is to ensure that the information released is accurate to begin with. Nissen says the affected drug and device manufacturers with which he is familiar plan to share the information with potentially affected physicians before disclosing it to the government, so that any inaccurate information can be corrected before submission. (See "More tips" on page 69.)

OTHER RESOURCES

Prior to the Sunshine Act's finalization, members of the public had other resources to consult to learn whether physicians have received payments from drug or device manufacturers.

ProPublic's Dollars for Doctors Web site (http://projects.propublica.org/docdollars/), for instance, uses public information, some of it disclosed due to legal settlements, to compile a database of payments from 12 pharmaceutical companies to physicians. Searchable by doctor, affiliated institution, and state, the database currently lists $761 million in payments made by the companies.

And some individual institutions have publicly disclosed physician payments from drug and device makers for several years. The Cleveland Clinic announced its reporting policy in 2008.

"This has caused no problems," Nissen says. "It hasn't caused problems for patients, and it hasn't caused problems for physicians."

The database resulting from the Sunshine Act will be another tool available to help patients make informed decisions, Nissen says.

"I feel strongly about it. I believe, and have believed for many years, that patients have a right to know what monies their physicians are receiving from commercial entities," he says.

Final rule versus proposed rule

The Centers for Medicare and Medicaid Services says the final rule differs from the proposed rule in the following ways, based on feedback the agency receiving during the comment period:

- The definition of applicable manufacturer was revised to specify that manufacturers must be "operating in the United States."
- Common ownership was defined an ownership interest of at least 5%.
- All entities under common ownership are now permitted to submit consolidated reports.
- Applicable manufacturers are now allowed to report multiple associated products for each payment or other transfer of value.
- The instances in which indirect payments or other transfers of value need to be reported was clarified, including the addition of a time period limiting the awareness requirements for reporting indirect payments.
- More information was provided on the nature of payment categories.
- The reporting of payments in the context of medical continuing education was limited.
- Requirements for allocating the costs of group meals were revised.
- The process was revised for reporting research payments to ensure that such payments are not double-counted and do not suggest that the physician principal investigator received the entire research payment amount.
- The process for the review and correction period, including dispute resolution, was clarified.
- A 15-day period after the formal review and correction period was created for applicable manufacturers, applicable group purchasing organizations, physicians, and teaching hospitals to resolve disputes.

Source: Centers for Medicare and Medicaid Services

@ Read the final rule at www.gpo.gov/fdsys/pkg/FR-2013-02-08/pdf/2013-02572.pdf

of individuals or entities also are required to report.

WHAT WILL BE REPORTED ABOUT PHYSICIANS?

Manufacturers must report the following physician information for payments or transfers of value made to doctors:

- The name, business address, national provider identifier (NPI), license number and state of licensure, and specialty of the physician (the NPI must be reported but will not be published on the CMS Web site).
- The amount of payments or other transfers of value.
- The date of payment.
- The form of payment (cash or cash equivalent, in-kind item or service, stock, stock option or any other ownership interest, dividend, profit or other return on investment, or any other form of payment or other transfer of value).
- The nature of payment—consulting fees, compensation for services other than consulting, honoraria, gift, entertainment, food, travel (including the specified destinations), education, research, charitable contribution, royalty or license, current or prospective ownership or investment interest, direct compensation for serving as faculty or as a speaker for a medical education program, grant, or any other nature of the payment or transfer of value.
- The name(s) of related covered drugs, devices, biologicals, or medical supplies.
- Whether the payment or other transfer of value was provided to physician or the immediate family of the physician who holds an ownership interest in the applicable manufacturer.

Manufacturers and GPOs also must report the following physician-related information for ownership interests:

- Whether the physician or the immediate family of the physician held the ownership interest.
- The dollar amount invested by each physician or immediate family member of the physician.
- The value and terms of each ownership interest or investment interest.
- Direct and indirect payments or other transfers of value provided to a physician holding an ownership or investment interest, and direct and indirect payments or other transfers of value provided to a third party at the request of or designated by or on behalf of the physician owner or investor.

Dividends or other profit distribution from, or ownership or investment interest in, a publicly traded security or mutual fund do not have to be reported.

WHAT IF I WAIVE PAYMENT AND HAVE THE MANUFACTURER DONATE TO CHARITY?

The final rule requires that when a physician does not receive a payment or other transfer of value, but the applicable manufacturer provides the payment or other transfer of value to another entity "in the name of" or "on behalf" of the physician, this is still considered to be a payment made to the physician. Thus, to avoid reporting, you must make very clear to manufacturers that you are waiving the payment and that any payment should be made to another entity or individual, not in your name or on behalf of you.

WHAT CAN I ACCEPT FROM A MANUFACTURER WITHOUT BEING REPORTED?

Some exceptions to reporting requirements in the final rule:

- **Food and drink.** If an applicable manufacturer offers buffet meals, snacks, or coffee at conferences or other large-scale events where it would be difficult to definitively establish the identities of physicians who partake in the food, then it does not have to report such offerings where the food is made available to all conference attendees. This exception does not apply to meals provided to select individual attendees at a conference where the sponsoring applicable manufacturer can establish the identities of the attendees.
- ***De minimis* payment.** Currently, small payments or other transfers of value less than $10 do not need to be reported, except when the total annual value of payments or other transfers of value provided to a covered recipient exceeds $100.
- **Discounts and rebates** for covered drugs, devices, biologicals, and medical supplies provided by applicable manufacturers to physicians are excluded from reporting requirements.
- **In-kind items for provision of charity care.** Items provided to a physician for one or more patients who cannot pay for such services or for whom payment would be a significant hardship, where the physician neither receives nor expects to receive payment because of the patient's inability to pay, are excluded from reporting. This exclusion does not cover the provision of in-kind items to a physician, even if the recipient is a charitable organization, for the care of all of the physician's patients (both those who can and cannot pay).
- **Product samples**, including coupons and vouchers that can be used by a patient to obtain samples that are not intended to be sold and are intended for patient use, are excluded from reporting requirements.
- **Educational materials** and items that directly benefit patients or are intended to be used by or with patients, including the value of an applicable manufacturer's services to educate patients regarding a covered drug, device, biological, or medical supply, are excluded are well.
- **Payments related to continuing education programs.** Payments or other transfers of value provided as compensation for speaking at a continuing education program are not required to be reported *if* all the following conditions are met:
  - the event at which the physician is speaking meets the accreditation or certification requirements and standards for continuing education of the Accreditation Council for Continuing Medical Education, the American Academy of Family Physicians, the American Medical Association, the American Osteopathic Association, or the American Dental Association's Continuing Education Recognition Program;
  - the applicable manufacturer does not pay the physician speaker directly; and
  - the applicable manufacturer does not select the physician speaker or provide the third party (such as a continuing education vendor) with a distinct, identifiable set of individuals to be considered as speakers for the continuing education program.

ARE THERE PHYSICIAN PENALTIES FOR NONCOMPLIANCE?

Although the Sunshine Act authorizes civil monetary penalties for applicable manufacturers for failure to report required information on a timely basis in accordance with the final rule, as well as for knowing failures, up to a combined maximum annual total of $1.15 million, there is no reporting requirement of physicians and thus, no penalty to physicians, for the manufacturer's or GPO's noncompliance.

WHAT SHOULD I BE DOING NOW?

So now that the Sunshine Act is law, be sure to take these steps to protect yourself and your practice:

- Assess your relationships with manufacturers and GPOs and ask whether they are subject to the Sunshine Act reporting requirements.
- Decide whether to accept the payments or transfers of value, or maintain the ownership interests, that would result in the financial relationship being made public.
- Each time you are approached or offered a payment or something of value, ask whether acceptance will result in reporting under the Sunshine Act—which the manufacturer and its representatives should know—to be fully informed about how such acceptance will be disclosed and how it could be perceived by patients, employers, and potential purchasers of your practice.

The author is a partner in the healthcare department of Ungaretti & Harris, with offices in Chicago and Springfield, Illinois, as well as Washington, D.C.

More tips

Additional insights from attorneys on steps you can take now that the Physician Payment Sunshine Act has been finalized:

Mark Dahlby, JD, of Hall, Render, Killian, Heath, and Lyman: During contract negotiations with manufacturers and group purchasing organizations (GPOs), discuss how information about you will be used so that you know what you need to monitor. Also, don't just rely on them to keep records; keep track of your own information so you have something to compare with their records. Doing so will aid the appeal process if one is necessary.

Joshua Freemire, JD, of Ober Kaler: Stay informed by reading professional publications such as *Medical Economics* and newsletters from law firms and other entities, and periodically perform an Internet search so you know what information is out there about you.

Joe Wolfe, JD, of Hall, Render, Killian, Heath, and Lyman: Determine whether the rule applies to any entity with which you have a relationship. (Contact the manufacturer/GPO and/or your attorney.) "Keep in touch with vendors, or at least realize that they are now operating in a new world of transparency."

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Q&A

TECHNOLOGY, LIFE ISSUES ALTERING WHAT IT MEANS TO BE A PHYSICIAN

Jay Wolfson, DrPH, JD, is the Distinguished Service Professor of Public Health and Medicine and associate vice president for health law, policy, and safety at the University of South Florida in Tampa. He recently spoke with Medical Economics *Editor-in-Chief Lois A. Bowers, MA, about the ways in which your future colleagues are being educated—and why.*

At the University of South Florida (USF), health professions students in various fields are all together in class at the beginning of their education. How is this preparing them for the changing healthcare environment?

Lack of communication is the single leading cause of adverse events occurring in patient safety problems. This can be improved if you start early, if you get physicians talking to each other, talking to nurses, talking to pharmacists, talking to patients.

USF Health is a combination of the colleges of medicine, public health, nursing, pharmacy, the physical therapy program, and the practice plan, which has 450 physicians. We've brought all of these clinical disciplines together to work, and in doing that, we've developed joint curricula. It's been a special opportunity to integrate across the clinical disciplines at the training level, undergraduate medical education, and the residency programs, and then continuing medical education.

We have to transform the way we structure our medical schools. The physician of 2025 is not going to be the same as the one in 1955, for a whole lot of reasons.

At USF, we collapsed all basic science departments into one, and we're redefining the way we do things functionally in terms of the way we train our students. We're restricted still in terms of what accreditation requirements are demanded of us, but we've also participated extensively in the accreditation process nationally and have been recognized as having some really innovative approaches to undergraduate medical education.

For instance, students used to get one course in pharmacology. Historically, doctors have relied on detail people to tell them which drug to give. That's a thing of the past. We now rely extensively and substantially not just on the Internet but on PharmDs, who are trained to assist and work with doctors.

In the hospital setting, ambulatory setting, and places like the Villages (a large senior community in Florida), they have immediate access to a PharmD online or on the telephone, and we've also created interactive teams with healthcare professionals who care for the whole patient. Technology allows us to do it.

How are the medical students of today different from those in the past? And how will these differences change the field of medicine?

As the 1960s and 1970s-trained cohort of physicians moves toward retirement, the younger physicians are really in a different landscape. More than 50% of my class is now women, and most of my seniors are saying, "I don't want to work 90 hours a week. I want to have a life."

Those are internists, family practitioners, and pediatricians, as well as specialists. So there's a different tone among them.

I continue to have a concern, and in all my courses for medical students, I say, "Be careful not to become technicians. You're not TV repair people."

The professionalism component of what we do is what is more important than anything else. We have to engender trust. If we don't, we've lost what it means to be a physician.

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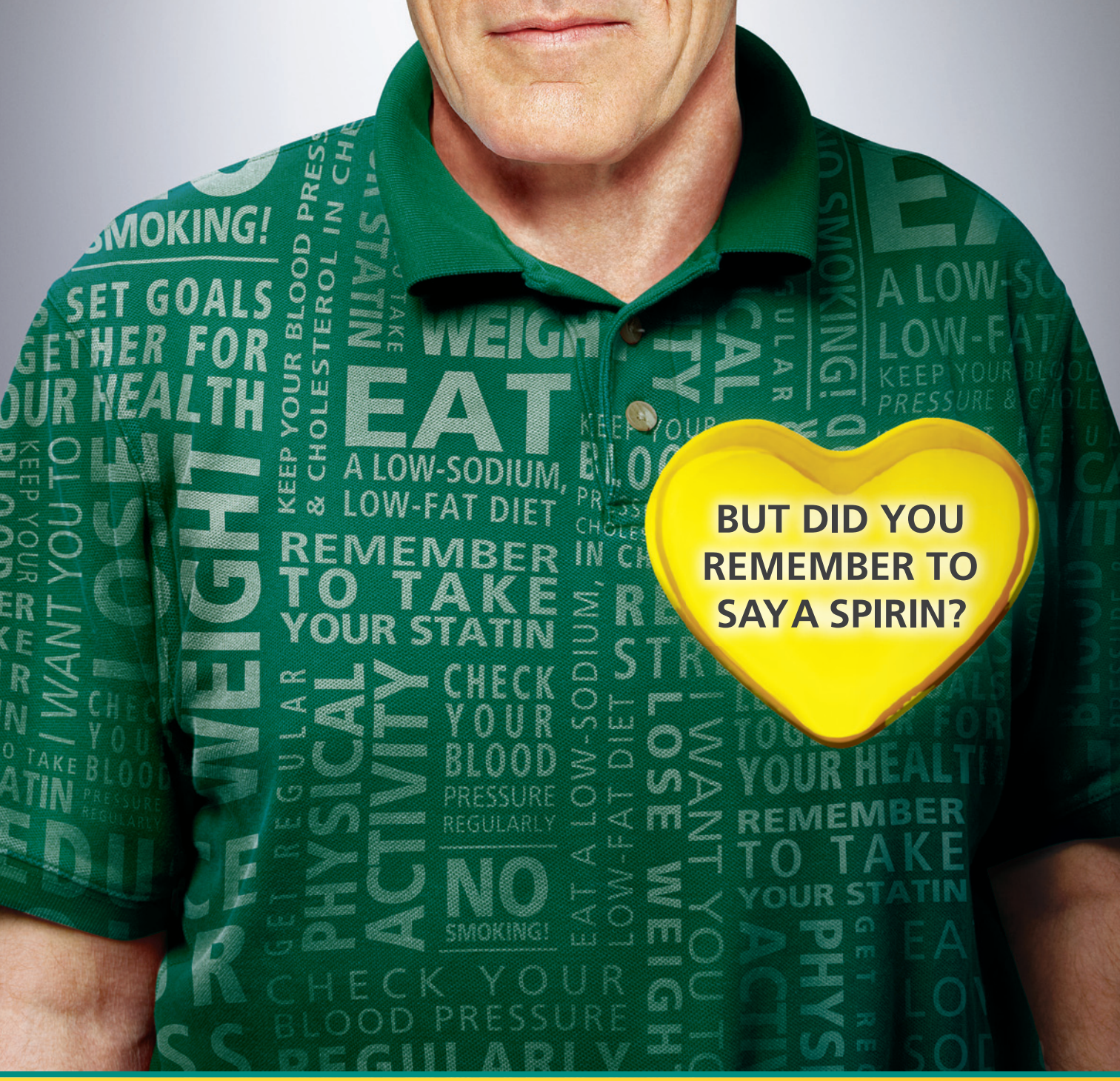

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References: 1. Antithrombotic Trialists' (ATT) Collaboration. Aspirin in the primary and secondary prevention of vascular disease: collaborative meta-analysis of individual participant data from randomised trials. *Lancet.* 2009;373:1849-1860. **2.** Cannon CP, Rhee KE, Califf RM, et al. Current use of aspirin and antithrombotic agents in the United States among outpatients with atherothrombotic disease (from the REduction of Atherothrombosis for Continued Health [REACH] Registry). *Am J Cardiol.* 2010;105:445-452. **3.** Heart disease and stroke statistics—2012 update: a report from the American Heart Association. *Circulation.* 2012;125:e2-e220.

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