PRACTICE TUNE-UP

How you can see more patients, increase revenue, boost staff efficiency
Primary end point: A1C change from baseline at week 26

<table>
<thead>
<tr>
<th></th>
<th>Placebo</th>
<th>STEGLATRO 5 mg</th>
<th>STEGLATRO 15 mg</th>
</tr>
</thead>
<tbody>
<tr>
<td>N, BL</td>
<td>N=152; BL=8.0%</td>
<td>N=155; BL=8.1%</td>
<td>N=152; BL=8.0%</td>
</tr>
<tr>
<td>DIFFERENCE FROM PLACEBO, %</td>
<td>–0.2 (P&lt;0.001)</td>
<td>–0.7 (P&lt;0.001)</td>
<td>–0.8 (P&lt;0.001)</td>
</tr>
</tbody>
</table>

* N includes all randomized and treated patients with a baseline measurement of the outcome variable. At week 26, the primary A1C end point was missing for 10%, 11%, and 7% of patients, and during the trial, rescue medication was initiated by 16%, 1%, and 2% of patients randomized to placebo, STEGLATRO 5 mg, and STEGLATRO 15 mg, respectively. Missing week 26 measurements were imputed using multiple imputation with a mean equal to the baseline value of the patient. Results include measurements collected after initiation of rescue medication. For those patients who did not receive rescue medication and had values measured at 26 weeks, the mean changes from baseline for A1C were –0.2%, –0.8%, and –0.9% for placebo, STEGLATRO 5 mg, and STEGLATRO 15 mg, respectively.

** Intent-to-treat analysis using ANCOVA adjusted for baseline value, prior antihyperglycemic medication, and baseline estimated glomerular filtration rate (eGFR).

ANCOVA=analysis of covariance; BL=baseline; LS=least squares.
Study design: 463 adults with type 2 diabetes, inadequately controlled (A1C between 7% and 10.5%) on metformin (≥1500 mg/day for ≥8 weeks) and sitagliptin 100 mg once daily participated in a randomized, double-blind, multicenter, 26-week, placebo-controlled study to evaluate the efficacy and safety of STEGLATRO. Study subjects were randomized to STEGLATRO 5 mg, STEGLATRO 15 mg, or placebo administered once daily in addition to continuation of background metformin and sitagliptin therapy. The primary efficacy end point was the change from baseline in A1C at week 26.

STEGLATRO is indicated as an adjunct to diet and exercise for appropriate adults with type 2 diabetes. STEGLATRO is not recommended in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis.

SELECTED SAFETY INFORMATION

Contraindications: STEGLATRO is contraindicated in patients with severe renal impairment, end-stage renal disease, or on dialysis, and/or a history of a serious hypersensitivity reaction to ertugliflozin.

Hypotension: STEGLATRO causes intravascular volume contraction. Symptomatic hypotension may occur after initiating STEGLATRO, particularly in patients with impaired renal function (estimated glomerular filtration rate [eGFR] less than 60 mL/min/1.73 m²), elderly patients (≥65 years), patients with low systolic blood pressure, or patients on diuretics. Before initiating STEGLATRO, volume status should be assessed and corrected if indicated. Monitor for signs and symptoms after initiating therapy.

Ketoacidosis: Ketoacidosis, a serious life-threatening condition requiring urgent hospitalization, has been reported in patients with type 1 and type 2 diabetes receiving sodium glucose co-transporter 2 (SGLT2) inhibitors, including STEGLATRO. Some cases were fatal. Assess patients with signs and symptoms of metabolic acidosis for ketoacidosis, regardless of blood glucose level. If ketoacidosis is suspected, STEGLATRO should be discontinued, patients should be evaluated, and prompt treatment should be instituted. Before initiating STEGLATRO, consider risk factors for ketoacidosis, including pancreatic insulin deficiency from any cause, caloric restriction, and alcohol abuse. In patients treated with STEGLATRO, consider monitoring for ketoacidosis and temporarily discontinuing STEGLATRO in clinical situations known to predispose to ketoacidosis (eg, prolonged fasting due to acute illness or surgery).

Additional Selected Safety Information on next page.
STEGLATRO™ (ertugliflozin) for appropriate adults with type 2 diabetes

STEGLATRO is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. STEGLATRO is not recommended in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis.

SELECTED SAFETY INFORMATION (continued)

Acute Kidney Injury and Impairment in Renal Function: STEGLATRO causes intravascular volume contraction and can cause renal impairment. There have been postmarketing reports of acute kidney injury, some requiring hospitalization and dialysis, in patients receiving SGLT2 inhibitors. Before initiating STEGLATRO, consider factors that may predispose patients to acute kidney injury. Consider temporarily discontinuing STEGLATRO in any setting of reduced oral intake or fluid losses; monitor patients for signs and symptoms of acute kidney injury. If acute kidney injury occurs, discontinue STEGLATRO promptly and institute treatment. STEGLATRO increases serum creatinine and decreases eGFR. Patients with moderate renal impairment (eGFR 30 to less than 60 mL/min/1.73 m²) may be more susceptible to these changes. Renal function abnormalities can occur after initiating STEGLATRO. Renal function should be evaluated prior to initiating STEGLATRO and periodically thereafter. Use of STEGLATRO is not recommended when eGFR is persistently between 30 and less than 60 mL/min/1.73 m² and is contraindicated in patients with an eGFR less than 30 mL/min/1.73 m².

Urosepsis and Pyelonephritis: There have been postmarketing reports of serious urinary tract infections, including urosepsis and pyelonephritis, requiring hospitalization in patients receiving SGLT2 inhibitors. Cases of pyelonephritis also have been reported in patients treated with STEGLATRO in clinical trials. Treatment with SGLT2 inhibitors increases the risk for urinary tract infections. Evaluate patients for signs and symptoms of urinary tract infections and treat promptly, if indicated.

Lower Limb Amputations: An increased risk for lower limb amputation has been observed in clinical studies with another SGLT2 inhibitor. Across seven Phase 3 clinical trials with STEGLATRO, nontraumatic lower limb amputations were reported in 1 (0.1%) patient in the comparator group, 3 (0.2%) patients in the STEGLATRO 5-mg group, and 8 (0.5%) patients in the STEGLATRO 15-mg group. A causal association between STEGLATRO and lower limb amputation has not been definitively established. Before initiating STEGLATRO, consider factors that may predispose patients to the need for amputations. Monitor patients and discontinue STEGLATRO if complications occur. Counsel patients about the importance of routine preventative foot care.

Hypoglycemia With Concomitant Use With Insulin and Insulin Secretagogues: Insulin and insulin secretagogues (eg, sulfonylurea) are known to cause hypoglycemia. STEGLATRO may increase the risk of hypoglycemia when used in combination with insulin and/or an insulin secretagogue. Therefore, a lower dose of insulin or insulin secretagogue may be required to minimize the risk of hypoglycemia when used in combination with STEGLATRO.

Necrotizing Fasciitis of the Perineum (Fournier’s Gangrene): A rare but serious and life-threatening necrotizing infection requiring urgent surgical intervention has been reported in postmarketing surveillance in females and males with diabetes mellitus receiving SGLT2 inhibitors. Serious outcomes have included hospitalization, multiple surgeries, and death. Patients treated with STEGLATRO presenting with pain or tenderness, erythema, or swelling in the genital or perineal area, along with fever or malaise, should be assessed for necrotizing fasciitis. If suspected, start treatment immediately with broad-spectrum antibiotics and, if necessary, surgical debridement. Discontinue STEGLATRO, closely monitor blood glucose levels, and provide appropriate alternative therapy for glycemic control.

Genital Mycotic Infections: STEGLATRO increases the risk of genital mycotic infections. Patients who have a history of genital mycotic infections or who are uncircumcised are more likely to develop genital mycotic infections. Monitor and treat appropriately.

Increases in Low-Density Lipoprotein Cholesterol (LDL-C): Dose-related increases in LDL-C can occur with STEGLATRO. Monitor and treat as appropriate.

Macrovascular Outcomes: There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with STEGLATRO.

The most common adverse reactions associated with STEGLATRO (≥5%) were female genital mycotic infections.

Please read the adjacent Brief Summary of the Prescribing Information.
INDICATIONS AND USAGE
STEGLATRO™ (ertugliflozin) 5 mg, 15 mg tablets

Brief Summary of the Prescribing Information

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

Limitations of Use
• STEGLATRO is not recommended in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis.

DOSEAGE AND ADMINISTRATION

Recommended Dosage. The recommended starting dose of STEGLATRO is 5 mg once daily, taken in the morning, with or without food. In patients tolerating STEGLATRO 5 mg once daily, the dose may be increased to a maximum recommended dose of 15 mg once daily if additional glycemic control is needed. In patients with volume depletion, correct this condition prior to initiation of STEGLATRO (see Warnings and Precautions).

Patients with Renal Impairment. Assess renal function prior to initiation of STEGLATRO and periodically thereafter (see Warnings and Precautions). STEGLATRO is contraindicated in patients with an eGFR less than 30 mL/minute/1.73 m² (see Contraindications). Initiation of STEGLATRO is not recommended in patients with an eGFR of 30 mL/minute/1.73 m² to less than 60 mL/minute/1.73 m² (see Warnings and Precautions and Use in Specific Populations). Continued use of STEGLATRO is not recommended when eGFR is persistently between 30 and less than 60 mL/minute/1.73 m². No dose adjustment is needed in patients with mild renal impairment.

CONTRAINDICATIONS
• Severe renal impairment, end-stage renal disease (ESRD), or dialysis (see Warnings and Precautions and Use in Specific Populations).
• History of a serious hypersensitivity reaction to STEGLATRO.

WARNINGS AND PRECAUTIONS

Hypotension. STEGLATRO causes intravascular volume contraction. Therefore, symptomatic hypotension may occur after initiating STEGLATRO (see Adverse Reactions) particularly in patients with impaired renal function (eGFR less than 60 mL/min/1.73 m²) (see Use in Specific Populations), elderly patients (≥65 years), in patients with low systolic blood pressure, and in patients on diuretics. Before initiating STEGLATRO, volume status should be assessed and corrected if indicated. Monitor for signs and symptoms of hypotension after initiating therapy.

Ketoacidosis. Reports of ketoacidosis, a serious life-threatening condition requiring urgent hospitalization, have been identified in clinical trials and postmarketing surveillance in patients with type 1 and type 2 diabetes mellitus receiving sodium glucose co-transporter-2 (SGLT2) inhibitors and cases have been reported in STEGLATRO-treated patients in clinical trials. Across the clinical program, ketoacidosis was identified in 3 of 3,409 (0.1%) of STEGLATRO-treated patients and 0% of comparator-treated patients. Fatal cases of ketoacidosis have been reported in patients taking SGLT2 inhibitors. STEGLATRO is not indicated for the treatment of patients with type 1 diabetes mellitus (see Indications and Usage).

Patients treated with STEGLATRO who present with signs and symptoms consistent with severe metabolic acidosis should be assessed for ketoacidosis regardless of presenting blood glucose levels, as ketoacidosis associated with STEGLATRO may be present even if blood glucose levels are less than 250 mg/dL. If ketoacidosis is suspected, STEGLATRO should be discontinued, patient should be evaluated, and prompt treatment should be instituted. Treatment of ketoacidosis may require insulin, fluid and carbohydrate replacement.

In many of the reported cases, and particularly in patients with type 1 diabetes, the presence of ketoacidosis was not immediately recognized and institution of treatment was delayed because presenting blood glucose levels were below those typically expected for diabetic ketoacidosis (often less than 250 mg/dL). Signs and symptoms at presentation were consistent with dehydration and severe metabolic acidosis and included nausea, vomiting, abdominal pain, generalized malaise, and shortness of breath. In some but not all cases, factors predisposing to ketoacidosis such as insulin dose reduction, acute febrile illness, reduced caloric intake due to illness or surgery, pancreatic disorders suggesting insulin deficiency (e.g., type 1 diabetes, history of pancreatitis or pancreatic surgery), and alcohol abuse were identified.

Before initiating STEGLATRO, consider factors in the patient history that may predispose to ketoacidosis, including pancreatic insulin deficiency from any cause, caloric restriction, and alcohol abuse. In patients treated with STEGLATRO consider monitoring for ketoacidosis and temporarily discontinuing STEGLATRO in clinical situations known to predispose to ketoacidosis (e.g., prolonged fasting due to acute illness or surgery).

Acute Kidney Injury and Impairment in Renal Function. STEGLATRO causes intravascular volume contraction and can cause renal impairment (see Adverse Reactions). There have been postmarketing reports of acute kidney injury requiring hospitalization and dialysis in patients receiving SGLT2 inhibitors.

Before initiating STEGLATRO, consider factors that may predispose patients to acute kidney injury including prerenal, chronic renal disease, congestive heart failure and other cardiovascular medications (diuretics, ACE inhibitors, ARBs, NSAIDs). Consider temporarily discontinuing STEGLATRO in any setting of reduced oral intake (such as acute illness or fasting) or fluid losses (such as gastrointestinal illness or excessive heat exposure); monitor patients for signs and symptoms of acute kidney injury. If acute kidney injury occurs, discontinue STEGLATRO promptly and institute treatment.

STEGLATRO increases serum creatinine and decreases eGFR. Patients with moderate renal impairment (eGFR 30 to less than 60 mL/min/1.73 m²) may be more susceptible to these changes. Renal function abnormalities can occur after initiating STEGLATRO (see Adverse Reactions). Renal function should be evaluated prior to initiating STEGLATRO and periodically thereafter. Use of STEGLATRO is not recommended when eGFR is persistently between 30 and less than 60 mL/min/1.73 m² and is contraindicated in patients with an eGFR less than 30 mL/min/1.73 m² (see Dosage and Administration, Contraindications, and Use in Specific Populations).

Urosepsis and Pyelonephritis. There have been postmarketing reports of serious urinary tract infections, including urosepsis and pyelonephritis, requiring hospitalization in patients receiving SGLT2 inhibitors. Cases of pyelonephritis also have been reported in STEGLATRO-treated patients in clinical trials. Treatment with SGLT2 inhibitors increases the risk for urinary tract infections. Evaluate patients for signs and symptoms of urinary tract infections and treat promptly, if indicated (see Adverse Reactions).

Lower Limb Amputation. An increased risk for lower limb amputation (primarily of the toe) has been observed in clinical studies with another SGLT2 inhibitor. Across seven Phase 3 clinical trials in the STEGLATRO development program, non-traumatic lower limb amputations were reported in 1.0% of patients in the comparator group, 3.0% of patients in the STEGLATRO 5 mg group, and 3.5% of patients in the STEGLATRO 15 mg group. A causal association between STEGLATRO and lower limb amputation has not been definitively established.

Before initiating STEGLATRO, consider factors in the patient history that may predispose them to the need for amputations, such as a history of prior amputation, peripheral vascular disease, neuropathy and diabetic foot ulcers. Counsel patients about the importance of routine preventive foot care. Monitor patients receiving STEGLATRO for signs and symptoms of infection (including osteomyelitis), new pain or tenderness, sores or ulcers involving the lower limbs, and discontinue STEGLATRO if these complications occur.

Hypoglycemia with Concomitant Use with Insulin and Insulin Secretagogues. Insulin and insulin secretagogues (e.g., sulfonylureas) are known to cause hypoglycemia. STEGLATRO may increase the risk of hypoglycemia when used in combination with insulin and/or an insulin secretagogue (see Adverse Reactions). Therefore, a lower dose of insulin or insulin secretagogue may be required to minimize the risk of hypoglycemia when used in combination with STEGLATRO.

Necrotizing Fasciitis of the Perineum (Fournier’s Gangrene). Reports of necrotizing fasciitis of the perineum (Fournier’s gangrene), a rare but serious and life-threatening necrotizing infection requiring urgent surgical intervention, have been identified in postmarketing surveillance in patients with diabetes mellitus receiving SGLT2 inhibitors. Cases have been reported in females and males. Serious outcomes have included hospitalization, multiple surgeries, and death.

Patients treated with STEGLATRO presenting with pain or tenderness, erythema, or swelling in the genital or perineal area, along with fever or malaise, should be assessed for necrotizing fasciitis. If suspected, prompt treatment immediately with broad-spectrum antibiotics and, if necessary, surgical debridement. Discontinue STEGLATRO, closely monitor blood glucose levels, and provide appropriate alternative therapy for glycometabolic control.

Genital Mycotic Infections. STEGLATRO increases the risk of genital mycotic infections. Patients who have a history of genital mycotic infections or who are uncircumcised are more likely to develop genital mycotic infections (see Adverse Reactions). Monitor and treat appropriately.

Increases in Low-Density Lipoprotein Cholesterol (LDL-C). Dose-related increases in LDL-C can occur with STEGLATRO (see Adverse Reactions). Monitor and treat as appropriate.

Macrovascular Outcomes. There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with STEGLATRO.

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. Pool of Placebo-Controlled Trials Evaluating STEGLATRO 5 and 15 mg. The data in Table 1 are derived from a pool of three 26-week, placebo-controlled trials. STEGLATRO was used as monotherapy in one trial and as add-on therapy in two trials. These data reflect exposure of 1,029 patients to STEGLATRO with a mean exposure duration of approximately 25 weeks. Patients received STEGLATRO 5 mg (N=519), STEGLATRO 15 mg (N=510), or placebo (N=515) once daily. The mean age of the population was 57 years and 2% were older than 75 years of age. Fifty-three percent (53%) of the population was male and 73% were Caucasian; 15% were Asian, and 7% were Black or African American. At baseline the population had diabetes for an average of 7.5 years, had a mean HbA1c of 8.1%, and 19.4% had established microvascular complications of diabetes. Baseline renal function (mean eGFR 88.9 mL/min/1.73 m²) was normal or mildly impaired in 97% of patients and moderately impaired in 3% of patients.
Table 1: Adverse Reactions Reported in ≥2% of Patients with Type 2 Diabetes Mellitus Treated with STEGLATRO® and Greater than Placebo in POLED Placebo-Controlled Clinical Studies of STEGLATRO Monotherapy or Combination Therapy

<table>
<thead>
<tr>
<th>Number (%) of Patients</th>
<th>Placebo N = 515</th>
<th>STEGLATRO 5 mg N = 519</th>
<th>STEGLATRO 15 mg N = 510</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female genital mycotic infections</td>
<td>3.0%</td>
<td>9.1%</td>
<td>12.2%</td>
</tr>
<tr>
<td>Male genital mycotic infections</td>
<td>0.4%</td>
<td>3.7%</td>
<td>4.2%</td>
</tr>
<tr>
<td>Urinary tract infections</td>
<td>3.9%</td>
<td>4.0%</td>
<td>4.1%</td>
</tr>
<tr>
<td>Headache</td>
<td>2.3%</td>
<td>3.5%</td>
<td>2.9%</td>
</tr>
<tr>
<td>Vaginal pruritus</td>
<td>0.4%</td>
<td>2.8%</td>
<td>2.4%</td>
</tr>
<tr>
<td>Increased emotion</td>
<td>1.0%</td>
<td>2.7%</td>
<td>2.4%</td>
</tr>
<tr>
<td>Nasopharyngitis</td>
<td>2.3%</td>
<td>2.5%</td>
<td>2.0%</td>
</tr>
<tr>
<td>Back pain</td>
<td>2.3%</td>
<td>1.7%</td>
<td>2.5%</td>
</tr>
<tr>
<td>Weight decreased</td>
<td>1.0%</td>
<td>1.2%</td>
<td>2.4%</td>
</tr>
<tr>
<td>Thyroid</td>
<td>0.6%</td>
<td>2.7%</td>
<td>1.4%</td>
</tr>
</tbody>
</table>

* The three placebo-controlled studies included one monotherapy trial and two add-on combination trials with metformin or with metformin and sitagliptin.

† Includes: genital candidiasis, genital infection fungal, vaginal infection, vulvitis, vulvovaginal conditions, vulvovaginal mycotic infection, and vulvovaginitis. Percentages calculated with the number of female patients in each group as denominator: placebo (N=235), STEGLATRO 5 mg (N=252), STEGLATRO 15 mg (N=245).

‡ Includes: balanitis candida, balanoposthitis, genital infection, and genital infection fungal. Percentages calculated with the number of male patients in each group as denominator: placebo (N=280), STEGLATRO 5 mg (N=267), STEGLATRO 15 mg (N=265).

§ Includes: cystitis, dysuria, streptococcal urinary tract infection, urethritis, urinary tract infection.

¶ Includes: vulvovaginal pruritus and pruritus genital. Percentages calculated with the number of female patients in each group as denominator: placebo (N=154), STEGLATRO 5 mg (N=158), STEGLATRO 15 mg (N=155).

Volume Depletion. STEGLATRO causes an osmotic diuresis, which may lead to intravascular volume contraction and adverse reactions related to volume depletion, particularly in patients with impaired renal function (eGFR less than 60 mL/min/1.73 m²). In patients with moderate renal impairment, adverse reactions related to volume depletion (e.g., dehydration, dizziness postural, presyncope, syncope, hypotension, and orthostatic hypotension) were reported in 1%, 4.4%, and 1.9% of patients treated with placebo, STEGLATRO 5 mg, and STEGLATRO 15 mg, respectively. STEGLATRO may also increase the risk of hypotension in other patients at risk for volume contraction (see Use in Specific Populations).

Ketoacidosis. Across the clinical program, ketoacidosis was identified in 3 of 3,409 (0.1%) eptugliflozin-treated patients and 0.0% of comparator-treated patients (see Warnings and Precautions).

Impairment in Renal Function. Treatment with STEGLATRO was associated with increases in serum creatinine and decreases in eGFR (see Table 2). Patients with moderate renal impairment at baseline had larger mean changes. In a study in patients with moderate renal impairment, these abnormal laboratory findings were observed to reverse after treatment discontinuation (see Use in Specific Populations).

Renal-related adverse reactions (e.g., acute kidney injury, renal impairment, acute prerenal failure) may occur in patients treated with STEGLATRO, particularly in patients with moderate renal impairment where the incidence of renal-related adverse reactions was 0.6%, 2.5%, and 1.3% in patients treated with placebo, STEGLATRO 5 mg, and STEGLATRO 15 mg, respectively.

Lower Limb Amputation. Across seven Phase 3 clinical trials in which STEGLATRO was studied as monotherapy and in combination with other antihyperglycemic agents, non-traumatic lower limb amputations occurred in 1 of 1,450 (0.1%) in the non-STEGLATRO group, 3 of 1,716 (0.2%) in the STEGLATRO monotherapy group, and 8 of 1,693 (0.5%) in the STEGLATRO 5 mg group, and 8 of 1,693 (0.5%) in the STEGLATRO 15 mg group.

Hypoglycemia. The incidence of hypoglycemia by study is shown in Table 3.
Genital Mycotic Infections. In the pool of three placebo-controlled clinical trials, the incidence of female genital mycotic infections (e.g., balanitis candidiasis, balanitis xerotica, vaginal infection, vulvovaginal vaginitis, vulvovaginal mycotic infection, vulvovaginal infections) occurred in 3%, 9.1%, and 12.2% of females treated with placebo, STEGLATRO™ (ertugliflozin) 5 mg, and STEGLATRO 15 mg, respectively (see Table 1). In females, discontinuations due to genital mycotic infections occurred in 0% and 0.6% of patients treated with placebo and STEGLATRO, respectively.

In the same pool, male genital mycotic infections (e.g., balanitis candidiasis, balanoposthitis, genital infection, genital infection fungal) occurred in 0.4%, 3.7%, and 4.2% of males treated with placebo, STEGLATRO 5 mg, and STEGLATRO 15 mg, respectively (see Table 1). Male genital mycotic infections occurred more commonly in uncircumcised males. In males, discontinuations due to genital mycotic infections occurred in 0% and 0.2% of patients treated with placebo and STEGLATRO, respectively. Phimosis was reported in 8 of 1729 (0.5%) male ertugliflozin-treated patients, of which four required circumcision.

Laboratory Tests. Increases in Low-Density Lipoprotein Cholesterol (LDL-C). In the pool of three placebo-controlled trials, dose-related increases in LDL-C were observed in patients treated with STEGLATRO. Mean percent changes from baseline to Week 26 in LDL-C relative to placebo were 2.6% and 5.4% with STEGLATRO 5 mg and STEGLATRO 15 mg, respectively. The range of mean baseline LDL-C was 96.6 to 97.7 mg/dl across treatment groups (see Warnings and Precautions).

Increases in Hemoglobin. In the pool of three placebo-controlled trials, mean changes (percent changes) from baseline to Week 26 in hemoglobin were -0.21 g/dl (-1.4%) with placebo, 0.46 g/dl (3.5%) with STEGLATRO 5 mg, and 0.48 g/dl (3.5%) with STEGLATRO 15 mg. The range of mean baseline hemoglobin was 13.90 to 14.00 g/dl across treatment groups. At the end of treatment, 0.7%, 0.3%, and 0.4% of patients treated with placebo, STEGLATRO 5 mg, and STEGLATRO 15 mg, respectively, had a hemoglobin increase greater than 2 g/dl and above the upper limit of normal.

Increases in Serum Phosphate. In the pool of three placebo-controlled trials, mean changes (percent changes) from baseline in serum phosphate were 0.04 mg/dl (1.9%) with placebo, 0.21 mg/dl (6.8%) with STEGLATRO 5 mg, and 0.26 mg/dl (8.5%) with STEGLATRO 15 mg. The range of mean baseline serum phosphate was 3.53 to 3.54 mg/dl across treatment groups. In a clinical trial of patients with moderate renal impairment, mean changes (percent changes) from baseline at Week 26 in serum phosphate were -0.01 mg/dl (0.8%) with placebo, 0.29 mg/dl (9.7%) with STEGLATRO 5 mg, and 0.24 mg/dl (7.8%) with STEGLATRO 15 mg.

DRUG INTERACTIONS

Concomitant Use with Insulin and Insulin Secretagogues. STEGLATRO may increase the risk of hypoglycemia when used in combination with insulin and/or an insulin secretagogue (see Adverse Reactions). Therefore, a lower dose of insulin or insulin secretagogue may be required to minimize the risk of hypoglycemia when used in combination with STEGLATRO (see Warnings and Precautions).

Positive Urine Glucose Test. Monitoring glycomic control with urine glucose tests is not recommended in patients taking SGLT2 inhibitors as SGLT2 inhibitors increase urinary glucose excretion and will lead to positive urine glucose tests. Use alternative methods to monitor glycomic control.

Interference with 1,5-anhydroglucitol (1,5-AG) Assay. Monitoring glycomic control with 1,5-AG assay is not recommended as measurements of 1,5-AG are unreliable in assessing glycomic control in patients taking SGLT2 inhibitors. Use alternative methods to monitor glycomic control.

USE IN SPECIFIC POPULATIONS

Pregnancy.

Risk Summary. Based on animal data showing adverse renal effects, STEGLATRO is not recommended during the second and third trimesters of pregnancy. The limited available data with STEGLATRO in pregnant women are not sufficient to determine a drug-associated risk of adverse developmental outcomes. There are risks to the mother and fetus associated with poorly controlled diabetes in pregnancy (see Clinical Considerations).

In animal studies, adverse renal changes were observed in rats when ertugliflozin was administered during a period of renal development corresponding to the late second and third trimesters of human pregnancy. Dose approximately 13 times the maximum clinical dose caused renal pelvic and tubule dilatations and renal mineralization that were not fully reversible. There was no evidence of fetal harm in rats or rabbits at exposures of ertugliflozin approximately 300 times higher than the maximal clinical dose of 15 mg/day when administered during organogenesis (see Data). The estimated background risk of major birth defects is 6-10% in women with pre-gestational diabetes with a HbA1c >7 and has been reported to be as high as 20-25% in women with HbA1c <10. The estimated background risk of miscarriage for the indicated population is unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.

Clinical Considerations.

Disease-Associated Maternal and/or Embryo/Fetal Risk. Poorly-controlled diabetes in pregnancy increases the maternal risk for diabetic ketoacidosis, pre-eclampsia, spontaneous abortions, preterm delivery, stillbirth, and delivery complications. Poorly controlled diabetes increases the fetal risk for major birth defects, stillbirth, and macrosomia related morbidity.
A recent article in *Health Affairs* draws an important distinction between patient-centered care and patients as consumers. We need to retire the concept of patient-as-consumer.

The authors, from the Hastings Center, cite the absence of a true market, the lack of sufficient knowledge and time to make informed choices, and the erosion of physicians’ professionalism as reasons to retire the idea. While these alone are sufficient reasons to do so, we would take it one step further. We believe that positioning the patient as a “consumer” and the physician as “provider” erodes the trusting relationship between physician and patient, which is the cornerstone of healthcare, and in so doing, contributes to the moral injury of healthcare.

When the patient is a consumer there is a shift in the implied power dynamic. Rather than presenting to the physician seeking his or her expert advice and counsel, the interaction becomes a transactional one in which the physician provides a service and the patient pays for it. In this type of dynamic, the patient-customer is “never wrong,” according to Cesar Ritz’s well-known edict, broadly adopted in the hospitality industry.

This has led to the bizarre situation where rooming staff in clinics now sometimes ask the patient what he or she expects from the visit before the patient has had the benefit of any expert guidance. An MRI? An injection? A prescription? Most of them, answering thoughtfully, would probably say, “I want to feel better, whatever that takes.” But often, web searches or marketing campaigns have already set patients’ expectations, and they want specific diagnostic or therapeutic interventions, before they even receive a differential diagnosis.

“**When the patient is a consumer there is a shift in the implied power dynamic ... the interaction becomes a transactional one.”**

When physicians become customer service reps, whose reimbursements and incomes are tied to their patient satisfaction scores, the implications for care are subtle, but important. Physicians might no longer initiate difficult conversations, giving feedback patients do not want to hear about their weight, their smoking, or their substance use, because they fear patients will score them poorly. In addition, patients may come to their appointment with expectations of testing or medication, so physicians may over-test or over-prescribe if there is any way to justify it, to avoid an angry reaction.

But physicians know this is not good care. They know it may lead to delayed prevention measures, and they know when patients don’t need the care they demand. But physicians are caught between doing what’s best for the patient—having the hard conversations, declining testing or a prescription—and protecting themselves.

Much of the business of medicine, curiously enough, seems to assume patient capabilities on par with fully functioning, knowledgeable, and healthy doctors. It assumes patients have the time, energy, focus and mental acuity to consider all their treatment options dispassionately. It assumes they can shop around and have equal access to other options (i.e., that their insurance covers other entities equally). And it assumes they can walk away without purchasing care in the moment.

Medicine used to be overly paternalistic to patients. But we must be vigilant about over-correcting in the other direction, requiring patients and families to assume responsibilities they are not equipped to manage. Sometimes, we just need to take care of patients when they are ill and ask for a partner when they are better.

Wendy Dean, MD is senior medical officer at the Henry M. Jackson Foundation for the Advancement of Military Medicine. Simon G. Talbot, MD, is a reconstructive plastic surgeon at Brigham and Women’s Hospital and associate professor of surgery at Harvard Medical School.
Practice Tune-up

See more patients, increase revenue, boost efficiency  PAGE 12

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Understanding the “Internet of Medical Things”
The Centers for Medicare & Medicaid Services (CMS) is proposing changes to the Medicare Physician Fee Schedule (PFS) and the Quality Payment Program as part of its effort to reduce provider burden. “Clinicians are drowning in paperwork and reporting requirements caused by cumbersome government rules and regulations,” said CMS Administrator Seema Verma in a press release. “These administrative costs add to the total cost of delivering healthcare, which means physicians often have to hire extra staff and spend more time complying with requirements instead of with their patients.”

The proposed changes for 2020 are as follows:

- The PFS conversion factor for RVUs would increase from $36.04 to $36.09, and three codes would be added for telehealth services that treat opioid abuse disorders.
- In addition, CMS is proposing that CPT coding retain five levels of coding for established patients, reduces to four the number of levels for office/outpatient E/M visits for new patients and revises the code definitions.
- The proposed CPT changes also revise the times and medical decision-making process for all of the codes and requires performance history and exam only as medically appropriate. In addition, the changes would allow clinicians to choose the E/M visit level based on either medical decision-making or time.
- CMS is proposing to adopt the AMA Relative Value Scale Update Committee’s recommended values for the office/outpatient E/M visit codes for 2021 and the new add-on CPT code for prolonged service time. The recommended values would increase payments for office/outpatient E/M visits.
- Also under consideration is consolidating the Medicare-specific add-on code for office/outpatient E/M visits for primary care and non-procedural specialty care that was finalized in the 2019 PFS final rule for implementation in 2021. These will be consolidated into a single code describing the work associated with visits that are part of ongoing care related to a chronic condition.

"Despite a relatively rosy economic picture with low unemployment, a healthy stock market, and solid housing gains, many of the nation’s most compensated workers are often struggling.”

—Michael Miller, assistant vice president for disability insurance, UNUM

“Wearables are evolving beyond smartwatches and into medical-first applications. Physicians at Johns Hopkins University designed an app to coach heart attack survivors through the recovery process.”

—Marc Fischer, CEO and co-founder, Dogtown Media

**CMS proposes physician fee schedule changes**

MedicalEconomics.com

Slideshow spotlight

**Top 13 reasons for claim denials**

Practices that can eliminate these common reasons will find greater financial success.

*To view, visit bit.ly/13-reasons-for-claim-denials*

**Topic Resource Center**

**SEXUAL HEALTH**

- 5 ways primary care physicians can make their practices LGBTQ+ friendly
- Seniors need sexual healthcare too
- Understanding recurrent miscarriage

*For more, visit bit.ly/MEC-sexual-health*

**Bloggers**

"Despite a relatively rosy economic picture with low unemployment, a healthy stock market, and solid housing gains, many of the nation’s most compensated workers are often struggling.”

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Expanding the roles of NPs and PAs will make primary care more desirable

Senior editor Jeffrey Benedict’s comments in “Non-physician providers can help lower care costs for complex patients” (July 25, 2019 issue) will be met with derision by some primary care doctors. Why? For two reasons.

First, some primary care physicians feel that their incomes will suffer if nurse practitioners and physician assistants provide primary care services. Second, others consider it demeaning that non-physician providers are considered capable of providing primary care despite their fewer years of training.

But the traditional training of primary care doctors—4 years of pre-med, 4-5 years of med school, and three years of residency—turns out physicians who are over-trained for what is required.

Primary care doctors no longer take care of hospital patients or nursing home patients. They don’t treat patients in the emergency room; and they rarely do gynecology or office surgery.

Most of their work includes treating upper respiratory diseases, hypertension, diabetes and coordinating care with specialists—not to mention the time-consuming, frustrating, administrative work that drains their energy and mental stamina and makes many feel like medical drudges.

One way to solve this predicament is to encourage nurse practitioners and physician assistants to join the primary care workforce, and provide the services for which they were trained. This will reduce the workload per provider, reduce burnout, reduce frustration—it may even make a career in primary care desirable.

Although many practice in a collaborative role with physicians, in many states nurse practitioners are licensed to practice independently.

Edward Volpintesta, MD
Bethel, Conn.

Patients demanding convenience means trade-offs

In response to the article “Patients Demand Convenience” (June 25, 2019 cover story):

There is a sign in my nurses’ work area that says the following: “We offer three kinds of services: Good, cheap or fast. But you can choose only two! Choose Wisely!”

Cheap and fast won’t be good. Fast and good won’t be cheap and good and cheap won’t be fast.

I first saw this in a non-medical office 30 years ago. It still applies today, in any business—including medicine.

Choose wisely, indeed!

Jon Ahrendsen, MD
Clarion, Iowa
Do Americans trust physicians?

Americans report an overall positive attitude toward medical doctors, and most say they trust physicians to do a good job, according to a recent survey conducted by the Pew Research Center. But there are a few areas where the American public is less trusting of physicians, the survey shows. Here is a snapshot of the results:

**Americans largely trust their doctors**

74% of Americans have a positive view of medical doctors. (*Older Americans are more trusting of physicians than younger Americans.*)

**Younger, minority Americans have less trust in physicians**

- Younger participants, blacks and Hispanics believe doctors only provide accurate treatment 42% of the time.
- 71% of blacks and 63% of Hispanics expressed levels of concern over professional misconduct.
- 43% of whites saw professional misconduct as a problem.

**Most believe doctors care about their patients**

Medical doctors care about the best interests of their patients…

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**Doctors provide accurate info and good recommendations**

Doctors do a good job providing recommendations…

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**The public does not think physicians are transparent about conflicts of interest**

Physicians are transparent about conflicts of interest…

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**The public does not think physicians take responsibility for their mistakes**

Doctors admit mistakes and take responsibility…

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*Numbers have been rounded and may not precisely reflect absolute figures*
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How to rev up practice productivity

by JEFFREY BENDIX Senior Editor

**HIGHLIGHTS**

- Practices should put in place processes to ensure they receive all the revenue they are owed from payers and patients.
- Wellness visits serve an important revenue-related function. Reviewing patients’ records prior to their visits sometimes reveals services for which they are due, or overdue.

A recent AMA study found that in 2018, for the first time, employed doctors outnumbered those that owned, or had an ownership stake in, a practice. For independent practices, this milestone highlights the importance of operating as efficiently as possible. That’s because financial difficulties are among the main reasons practice owners cite in giving up their independence by selling or merging their practice.

The good news, according to practice management experts, is that many independent practices can find ways to grow revenue and reduce overhead costs. And while doing so requires planning and sometimes making difficult changes, for practices that want to continue operating independently the effort often pays off.

“In some cases even small improvements in revenues and operating efficiencies can make the difference between staying independent and selling or merging a practice,” says Reed Tinsley, CPA, CFP, a medical practice consultant based in Houston, Texas.

**SEE MORE PATIENTS**

Often, the most direct route to bolstering revenue is by seeing more patients. “In this era of declining reimbursements, you’ve got to add patient volume, and you do that by adding appointment slots,” Tinsley says.

Finding ways to see additional patients often is easier said than done, Tinsley acknowledges. Some doctors work more slowly than others, or want to spend more time with patients. Sometimes nurse practitioners and physician assistants balk at the idea of seeing more patients during the day. Still, says Tinsley, “I tell my clients, ‘I don’t care how you do it, it just needs to get done. Even if it’s two a day per provider, over the course of a year that’s going to add some nice revenue to the bottom line.”

Two common methods for scheduling additional patients are to extend appointment hours and to double-book appointments with the expectation of no-shows. And while the latter technique carries the risk of some patients having to wait longer if there aren’t any no-shows, “it just takes a very good front desk staff to communicate to patients why the doctor is running behind,” Tinsley says.
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we’ll cure the inefficiencies.

The athenahealth network is designed to help medical practices of all sizes work more efficiently. We help you get paid the money you’re owed, while keeping schedules full and increasing provider productivity. It’s all about giving you time back so that you can focus on what really matters.
5 tips to boost EHR productivity

By Mary K. Pratt Contributing author

Many doctors complain that one of the main efficiency drains on their practices is their EHRs. Health IT experts say doctors can take these six steps to reduce technology strain and boost productivity.

Avoid typing
Physicians say typing information into EHRs takes too much time and draws attention away from patients. John W. Beasley, MD, former coordinator of I-PrACTISE (Improving Primary Care Through Industrial Systems Engineering), has found that physicians can save about six hours a week by dictating notes for medical assistants to edit and enter into EHRs. Jeff Weil, chief information officer of District Medical Group of Arizona Inc., says his organization is using speech recognition software in a pilot project.

Configure the EHR to match workflow
Ann Meehan, RHIA, director of information governance for AHIMA, recommends physicians work with their EHR vendors or IT consultants to configure their software to match their workflow processes. She says too many clinicians settle for default settings that have them scrolling or clicking through extra screens. Some physicians have successfully streamlined their work processes, further boosting their efficiencies as a result.

Optimize your system
Clinicians who invest in training for themselves and their staff learn shortcuts and macros to speed through routine tasks, says Andrew Gettinger, MD, a chief clinical officer at the Office of the National Coordinator. For example, most doctors typically prescribe the same few dozen medications, so they can save time by preformatting those in their EHR.

Involve patients in the process
Asking patients to handle some tasks can also boost productivity, says Steven D. Weinman, MBA, a principal at healthcare consulting firm FOHC Associates in Gainesville, Florida. Physicians can have patients use in-office tablets to enter basic information needed for their visits, such as current prescriptions, with that information configured to populate the patient’s electronic record. He says doctors even can have patients do the same tasks through patient portals prior to visits. This way, doctors can quickly review and verify information during the visit.

Put collected data to better use
EHRs collect and analyze information in ways that aren’t possible with paper charts, so Weinman advises physicians to take advantage of that capability by hiring companies that use the data to perform specific tasks, such as coding visits, streamlining referrals or handling chronic care.

1. Another technique is to take a strategic approach to appointment scheduling. Some appointments may be getting more time than they need, says Laurie Morgan, MBA, a partner in the San Francisco-based medical practice consulting firm Capko & Morgan.

“Look at the schedule over the past six months, and see if you can determine whether certain types of appointments that have always been booked for, say, half an hour, are only taking 20 minutes the vast majority of times. You may be able to recapture some time by doing that type of analysis,” she advises.

Along with seeing more patients, Tinsley emphasizes the value of good customer service. “I often say to my clients, ‘are you a referable medical practice?’” he says. “It’s an intangible way to add revenue, by becoming the kind of practice where patients want to come, and refer their friends and family and coworkers to,” he says.

Improving Billing and Coding
A second way practices can increase revenue is by ensuring they receive all the money they are owed and to which they are entitled—in other words, by being efficient and up-to-date in their billing, coding, and collections.

“Understanding all the codes available to you and using them appropriately and regularly is extremely important because it improves your reimbursement from payers,” says Ripley Hollister, MD, president of the Physicians Foundation and owner of Dynamic Healthcare Team, a family practice in Colorado Springs, Col.

Dynamic Healthcare recently hired a “patient navigator,” whose responsibilities include tracking and following up with patients so that the practice can bill Medicare’s transitional care and chronic care management codes. In addition, Hollister says, the practice’s coder/biller learned that Medicare has codes for time spent discussing advance directives and living wills during annual wellness visits, so he has started billing for those.

The wellness visits serve another important revenue-related function, Hollister says. Reviewing patients’ records prior to their visits sometimes reveals services for which they are due, or overdue. “This lady isn’t getting her mammograms, that patient needs...
their pneumonia vaccine, this guy hasn't had a colonoscopy in 11 years, it all pops up," he says. "They help keep patients healthy and many of them are services we can bill for."

Along the same lines, Tinsley encourages clients to put in place a recall system for tracking when patients are due for a needed service and notifying them to come in. He recommends starting by printing out a diagnosis frequency report for the practice's patients, and identifying which diagnoses require regular visits to manage or treat.

The next step, Tinsley says, is to "data-mine your system for every patient you've billed one of those diagnoses to and determine whether they need to come back in. Then bombard them with messages reminding them why they need to come in and to make an appointment."

"It's low-hanging fruit and it's just crazy to let it sit there without taking advantage of the revenue opportunity," Tinsley says.

Billing and collecting from patients are other areas where practices often can find more revenue with little or no additional investment. For example, Tinsley recommends keeping patients' credit card numbers on file to ensure that copays and self-pays are collected promptly.

"Think about the time and money you waste when a bill ends up in the receivables process. It's a total waste," he says.

Some practices, he adds, go as far as requiring non-emergent patients to reschedule if they can't pay what they owe the day of their appointment.

TECHNOLOGY CAN HELP
Morgan urges her clients to bill and collect electronically, via a patient portal. "From my perspective, the biggest thing practices can do is to enable patients to receive their statements and pay online," she says, since that's how people increasingly are accustomed to—and usually prefer—paying bills. Moreover, having to mail a statement to the patient and wait for the patient to mail payment slows the revenue cycle.

"Automating those processes is a real win-win because the practice gets paid faster and at lower cost, and the patient is happier," she says. "We've worked with practices where they've turned on the payment portal and that night they started getting new payments from patients. It's a really nice thing to come in in the morning and see that you got money while you were sleeping."

Effective portal use can also help bolster revenue in less direct ways, by enabling providers and staff members to use their time more efficiently, says Margo Williams, MHA, CMPE, senior associate for practice management at the American College of Physicians.

Practices that encourage patients to use the portal generally see a reduction in phone calls, she says, and spend less time playing phone tag with patients. Also, many of the queries that come via the portal are routine and can be handled by someone other than a physician. "If someone just wants to know their lab results, as long as they're normal, a nurse can usually respond," she says.

"The overarching thing to remember is that practice efficiency isn't rocket science," she adds. "It's just a constant process of looking at each step and asking, 'what can we do to make it better? What can we do to address snags in the system?'"

THE STAFFING QUESTION
Turning to the expense side of the equation, the biggest overhead costs most practices incur are in staffing, and here an easy target
Financial reports physicians need to see monthly

By Cheryl Toth, MBA, Contributing author

**PROFIT AND LOSS (P&L) STATEMENT**

The P&L, as it’s typically called, is a tally of revenue and expenses for a given period, and includes key financial indicators such as gross revenue, net revenue, and overhead. A well-developed P&L displays dollars and percentages for each revenue and expense line item, and compares them against previous periods and budget amounts.

When reviewing the P&L, start with revenue. How does revenue this month compare to the same month last year? Is the practice on track to meet projections?

Then scrutinize expenses. Are they within budget? Comparable to the same period last year? In line with industry data for your specialty? If expenses seem high, investigate instead of hastily slashing them. We’ve watched many physicians cut staff to save money, only to see overtime rise and collections drop because there weren’t enough people to cover key tasks.

**AGED ACCOUNTS RECEIVABLE (A/R)**

The A/R report summarizes your practice’s lifeblood: the potential revenue from payers and patients for services you’ve rendered. That’s right: potential — because any number of things can hinder (or halt) payments. And that’s precisely why physicians must review their A/R on a monthly basis.

Start with “days in A/R,” which indicates the average number of days it takes to collect on an account. [Total A/R ÷ annual gross charges ÷ 365]. “Days” of 30 or less is good. “Days” of 50 or more is not so good. And look at the percentage of total A/R in each aging category. More than 10 percent to 15 percent in the 120+ days indicates a problem.

If the indicators signal trouble, analyze further. For instance, review A/R by individual payer to determine if specific companies are slow to pay, and identify why by analyzing explanation of benefits (EOB) for denial patterns such as non-covered service, applied to deductible, patient ineligible, or wrong modifier. If necessary, adjust your operations or train staff accordingly to minimize denials.

**ADJUSTMENTS**

Also known as “write offs;” adjustments are the detailed categories to which staff post the amount between an actual payment and
**Purchasing Options**

Another area practices can look for savings is in practice-related equipment and services. Here there are no shortcuts; instead, it’s a matter of monitoring expenses and looking for ways to trim them without harming productivity, experts say.

A good place to start is with physician societies, some of which offer savings to their members. For example, the American Osteopathic Association provides discounts on medical and office supplies, as well as vaccines, through its group purchasing organization, AOA Purchase Power.

“Vaccines are a significant upfront expense for physicians in private practice” says Matthew Kremke, vice president of the American Osteopathic Information Association. “In busy practices, it isn’t uncommon for our members to incur out-of-pocket costs of $10,000 a month or more.”

Outsourcing vaccine-related services can be another way to reduce their costs, according to Ripley. VaxCare, the company his practice uses, handles all vaccine billing and manages the practice’s inventory. “They know what we have on hand at any given time and send the stuff they know we need. And if it goes out of date, they take it back,” he says.

Ripley recommends that practices regularly shop around for lower prices on services such as telephone and internet, as well as office supplies and equipment. For the latter, he suggests wholesale clubs such as Costco and Sam’s Club. “I’m not above dropping by Sam’s to pick up some c-fold towels or whatever,” he says.

“If it’s something that you absolutely need, then of course you have to make sure you get it,” says Morgan. “But if you can get it at a lower cost then that’s always a good idea.”

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**Credit Balances**

Credit balances are a financial liability. If they are accurate, you must pay them back to patients or insurers. A six-doctor group thought they could avoid this “unless someone asked,” so they did not run a credit balance report for years. When they finally did, it was 65 pages long and had about $74,000 in credit balances—all of which had to be researched, verified, and refunded.

Review and approve the credit balances that staff have researched and verified every month. This report should be as close to zero dollars as possible.

**Patient Balance “Trio Pack”**

Historically, patient revenue has been fairly minor compared to insurance revenue. So if collections slipped, it was not going to put you out of business. Now that patient financial responsibilities are much larger, they need greater focus. Assess the status of patient receivables using a trio of reports:

- **Patient A/R.** Generate this by patient account in descending balance order, not alphabetically, so that the biggest balances will be on page one. Ask for a monthly status update on the top 10 accounts. Train staff to call patients, not just send statements and letters, and establish payment plans using automated, recurring, payment-plan software. Be sure front-desk staff ask for past-due balances when patients come in for their appointment.

- **Payment Plan Status.** Be aware of which patients are current and which are not. Train staff how to speak with and assist patients who are not current in their payments.

- **Accounts Recommended for Collection or Bad Debt.** Some patients simply can’t or won’t pay. Keeping them on the books for years is foolish financial management and frustrating for staff. Ask staff to prepare their recommendations on which patient accounts should be sent collections, and ask them to provide back-up details. Approve the accounts for bad debt or send them to collections, but get them out of A/R.
Dealing with the shortage of rural physicians

How can the healthcare industry better encourage doctors to practice in rural settings?

by KAYT SUKEL Contributing author

HIGHLIGHTS

- Monetary investments in training and recruitment may offer significant gains in addressing the rural physician shortage.

- Relying on physician assistants and nurse practitioners to do more primary care could help fill some gaps, but even so, there will remain a need for physicians.

Natalie King, MD, a family medicine practitioner, trained in Toledo, Ohio, an inner-city environment less than two hours away from the family farm where she grew up. That residency training prepared her to work in under-resourced urban areas. But when she was offered a job at a community health clinic in Jellico, Tennessee—population 2,217—she didn’t hesitate. “Having grown up in a rural setting, moving to a small town didn’t faze me,” she explains. “As a physician, I was inspired to find ways to engage with more vulnerable populations. And practicing full secondary family medicine, where I could provide real care continuity for my patients, was something I wanted to do.”

Yet, after four years in Jellico, King decided to return to Toledo. “There are so many different challenges involved with practicing in a rural setting, from lack of insurance to just the distance a patient has to travel to get care,” she says. “I found the work really satisfying, but it was hard, as a single woman, to live in the middle of nowhere. When the hospital where I worked changed hands, and they closed down the obstetrics department, it changed the dynamic for me and I decided to head back north.”
A SHORTAGE OF DOCTORS

According to the Centers for Disease Control and Prevention (CDC), more than 46 million Americans, about 15 percent of the entire U.S. population, live in sparsely populated areas with low housing density, often hours from urban centers. Numerous studies have demonstrated a significant gap in health outcomes between individuals who reside in urban areas and those in rural ones.

"Generally, people who live in rural America are sicker, older, and come from a lower socioeconomic level," says David Schmitz, MD, chair of the Department of Family and Community Medicine at the University of North Dakota and past president of the National Rural Health Association. "They are less well insured and tend to suffer from a lot of chronic diseases. And, by nature of where they are, it's often difficult for them to access healthcare, even basic primary care."

While primary care physicians are in short supply everywhere in the country, the lack of providers in rural settings is more acute. The Health Resources and Services Administration has designated 7,200 regions across the country as Health Professional Shortage Areas. Nearly 60 percent of those shortage areas are located in rural regions. Because healthcare access is widely recognized as a key determinant of health outcomes, these statistics highlight a large and growing issue.

"Provider shortages, like those seen in rural regions in both the U.S. and Australia, are associated with delayed healthcare seeking, reduced continuity of care, increased travel burdens, higher healthcare costs, poorer prognoses, and poorer adherence to care plans," says Matthew McGrail, Ph.D., a member of the Rural Clinical School at the University of Queensland in Australia.

Yet the very factors that tend to make rural patients sicker are also those that make it difficult to recruit and retain healthcare providers for those areas, says Amitabh Chandra, director of health policy research at Harvard University's John F. Kennedy School of Government.

"There are likely a lack of jobs in many of these places, as well as lower quality schools and housing," he says. "Doctors know better than anyone the importance of good healthcare to a thriving community. Will they be comfortable moving to an area, and raising a family, in a place where you can't get great hospital care—or perhaps any hospital care at all within a hundred miles?"

EMBRACING A RURAL PRACTICE

The lack of primary care physicians in rural areas has led the healthcare industry to consider what can be done to better encourage doctors to practice outside of metropolitan areas. While the most straightforward approach may seem like finding ways to make it more lucrative for physicians to practice in a rural area, Chandra says simply throwing money at the problem is not the answer.

"Rural medicine is very rewarding. It's a lot of hard work, and as a provider, you are going to find yourself wearing many hats, but it feels like you are doing something really meaningful. I wish more people could see that."

— AMITABH CHANDRA, PHD, DIRECTOR OF HEALTH POLICY RESEARCH, HARVARD UNIVERSITY'S JOHN F. KENNEDY SCHOOL OF GOVERNMENT

"The amount of money that you'd need to try and make up for what these doctors could make in the city would be cost-prohibitive," he explains. "We aren't talking about the state or other agencies adding 5 percent in extra wages but more like 40, 50, maybe even 60 percent to make up the difference.

Instead of focusing on salary, we need to think more creatively about how we can make rural America more attractive to doctors and their families."

That said, investments in training and recruitment may bring more progress in addressing the rural physician shortage. Relying on physician assistants and nurse practitioners to do more primary care could help fill some gaps, but even so, the need will remain for physicians to help oversee their work and deal with more complex patient cases.
Physician Careers

The physician shortage

“Generally, people who live in rural America are sicker, older, and come from a lower socioeconomic level. They are less well insured and tend to suffer from a lot of chronic diseases. And, by nature of where they are, it’s often difficult for them to access healthcare, even basic primary care.”

—DAVID SCHMITZ, MD, CHAIR, DEPARTMENT OF FAMILY AND COMMUNITY MEDICINE, UNIVERSITY OF NORTH DAKOTA

Shannon Brownlee, MSc, senior vice president of the Lown Institute, a non-profit organization working to create a more equitable healthcare system, says that in an age of mergers and acquisitions, she would like to see more health systems making greater investments in their rural facilities.

Rural hospitals are reducing their services, even shutting down completely, at an unprecedented rate. Such changes were part of the reason why King decided to move back to Toledo.

Beyond investing in those facilities, Brownlee says subsidizing medical school for those willing to go into primary care and practice in rural areas could also be beneficial.

“Some countries in Europe have invested in primary care education because they see physicians as public servants that offer a common good to society,” she says. “We already pay for residency training in the United States. What if we also paid for basic medical education and primary care training for doctors who are willing to stay in the field and work in areas with primary care shortages?”

King, having grown up in a rural area herself, believes that targeted recruitment programs that reach out to students in rural areas as early as high school, should also be considered. Brownlee agrees.

“Some people who live in these communities are just looking for a way out. But many are looking for ways to stay and serve,” she says. “We can put forth a concerted effort to recruit people from these underserved areas and show them that a career in medicine is not only possible but possible to pursue in their hometowns.”

Changes to medical education are also important. The addition of rural residency programs, where doctors can be trained in rural hospitals or other rural care settings, should be a vital part of this effort, says Schmitz. Doctors who train in these resource-limited environments can gain both the competence and confidence to thrive in a rural environment, making it much more likely that they’ll stay after they complete their programs.

“People go to medical school for all kinds of different reasons,” he says. “But if the reason is to make a real difference, there are very few opportunities that offer as many ways to make a real difference as rural medicine. You just won’t know that until you actually practice it.”

Finally, Chandra says, there is an opportunity for telehealth technologies to provide additional support and expand healthcare access for underserved rural communities, at least for diagnostic purposes.

“In terms of providing better care to communities, telemedicine is a great idea,” he says. “You can connect someone who lives in rural Maine to one of the best physicians in Boston for evaluation. But, unfortunately, no matter how good a telehealth technology is, it’s just not going to be a solution if a patient needs a basic procedure or hospital care.”

King says telehealth does offer much-needed support for physicians, allowing those who work in rural areas to consult with specialists when needed. But given that access to high-speed internet—and sometimes any internet—can often be spotty in many remote regions, larger urban hospitals sending...
Reduce your risk as a rural physician with key takeaways in our whitepaper “A Rural Physician’s Guide to Mitigating Risks.” Such strategies include broadening services, expanding access, outsourcing house calls and leveraging technology. Download it at www.ismie.com/mitigatingrisks
The physician shortage

Physician Careers

specialists to rural community health clinics to see patients on a monthly basis could be more effective.

“If we could have gotten a cardiologist to come in every month for a day to see my patients back in Jellico, it would have made a huge difference,” King says. “Something as simple as that can help us manage that distance barrier that keeps patients from getting to those specialty appointments that they so need.”

Chandra says that the rural physician shortage is a complex issue, resulting from many factors. And effectively addressing it will require a multi-pronged approach. When asked if she can see herself returning to rural practice, King says she’d be glad to. But, if she does, she believes rural Ohio, where she grew up, may be a better fit.

“Rural medicine is very rewarding,” she says. “It’s a lot of hard work, and as a provider, you are going to find yourself wearing many hats, but it feels like you are doing something really meaningful. I wish more people could see that.”

Chandra says that doctors, like King, who serve rural communities really are the unsung heroes of modern American medicine.

“They’re not publishing papers in the New England Journal of Medicine or developing new innovative medical devices, for the most part,” he says. “But they are providing care to patients who, historically, have been systematically underserved and, for many reasons, are really hurting. These providers are not only doctors, but they are social workers, counselors, and advocates for their patients. They do it all. We don’t praise them enough.”

The U.S. Department of Health and Human Services (HHS) has awarded nearly $20 million in Rural Residency Planning and Development Program (RRPD) grants to develop new residency programs in rural areas.

The funds, awarded through the Health Resources and Services Administration (HRSA), will help set up 27 new residency programs across 21 states. The residency programs will focus on primary care, including internal medicine and family medicine, and psychiatry.

These grants are part of a multi-year initiative to improve conditions in rural hospitals, schools of medicine, and health centers operated by the Indian Health Service—all of which are experiencing a shortage of physicians and other healthcare providers.

The grant is one part of an effort by policymakers to address the nationwide physician shortage, especially in rural communities.

Physicians who learn in rural settings are more likely to stay, according to HHS.

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By Logan Lutton, assistant editor

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“Training residents in rural areas is one strategy shown to successfully encourage graduates to practice in rural settings,” HRSA Associate Administrator for FORHP Tom Morris said in a news release.

More physicians practicing in rural areas will eventually lead to greater overall health for those communities, research shows.

“Rural communities are more likely to have a shortage of health professionals,” Luis Padilla, MD, a family physician and HRSA Associate Administrator for the Bureau of Health Workforce, said in a news release. “The rural residency grants are one more way HRSA is helping to expand the health workforce and increase access to quality healthcare for these communities.”
HIPAA has been around since 1996, and the HITECH Act since 2009. So the requirement to maintain the confidentiality, availability and integrity of protected health information (PHI) isn’t new.

But now smart assistants such as Google’s Assistant, Amazon’s Alexa and Apple’s Siri, which use voice recognition and AI, add new concerns.

Physicians and providers need to ascertain whether the smart assistant meets the Security Rule’s technical, administrative and physical safeguards. They need to make sure that the recorded audio and the privacy statements are not being shared with third parties.

They must also ensure that the privacy statements meet the requirements of state, federal and international laws.

In April, Amazon announced the rollout of six new HIPAA-compliant skills from Express Scripts, Cigna, Livongo, Atrium Health, Providence St. Joseph Health and Boston Children’s Hospital.

However, whether smart assistants are HIPAA-compliant remains unclear.

Recently, Google learned that a state’s law may also create liability and that data transfers differ from the sharing or selling of the audio to a third party. In July, a class action was filed against Google for violations of the Illinois Biometric Information Privacy Act (IBIPA).

In essence, the plaintiffs allege that Google violated the IBIPA by sharing audio that was recorded from their Google Assistant-enabled devices with third parties.

The July 15, 2019, pleading alleges that "Google disregards these statutorily imposed obligations and fails to inform persons that a biometric identifier or biometric information is being collected or stored and fails to secure written releases executed by the subject or the subject’s legally authorized representative."

This statement alone raises a myriad of issues for providers to consider.

Here are six questions to ask yourself before using any smart assistant:

❚ What do the privacy statements say, and what is being agreed to?
❚ Has a risk analysis been done, and are the Privacy Rule and Security Rule requirements being met?
❚ Can recorded items be subpoenaed in a legal proceeding? (The answer is yes.)
❚ Has the patient given consent to be recorded?

As healthcare technology and the legal landscape become increasingly complex, providers should take a deep breath and consider the basics. Conducting an annual risk analysis along with adequate due diligence on products and business associates/subcontractors can mitigate risk and enable a doctor to make an informed decision while complying with a variety of applicable laws.

Artificial intelligence has great potential in healthcare. When in doubt about its legality, explain the device to patients, how it is being utilized and get their consent.

Rachel V. Rose, JD, MBA, advises clients on compliance and transactions in healthcare, cybersecurity, corporate and securities law. Send your legal questions to medec@mmhgroup.com
Recruiting for clinical trials: Finding a better way

A better process for recruiting patients to the right clinical trials is deceptively simple: produce a single source for massive quantities of comprehensive, quality data and sophisticated trial algorithms. The hard part is that it can only be achieved by long, hard, detailed work that doesn’t skip a single step.

It begins with deeply understanding the patient population, it requires identifying the patients of tomorrow and it means finding the right sites where the patient populations can be found for the specific clinical trials that will produce the discoveries we need to take giant leaps forward in the quality of care.

RECRUITMENT

Here’s how it works. The right data and tools can help researchers improve the scale and precision of clinical trial recruitment.

While the number of available clinical trials is increasing, the reality is that about 50 percent of trials do not meet recruitment goals. Proper adoption of a clinical workflow based on new digital tools with the right data can ameliorate this challenge, but simply being data-driven is not enough. The core value of putting patients over process must rule the day so that the industry migrates efforts toward drug development tailored to patient population.

“The most time-consuming element is knowing which patients to review for matching to the eligibility requirements of the clinical trial, which is often a manual process that can take a significant amount of work and time.”

The goal is to use real-world data (RWD) to improve clinical trial design, as well as to find consistent and predictable methods to accelerate clinical trial recruitment. This means that sponsors and their clinical research organizations (CROs) must use digital tools to decipher which patients should be enrolled and where clinical trials should be opened.

We need to focus on helping to find eligible patients faster, today. We need to provide early insights to broaden or enrich a trial’s patient population with the use of specific EHR data fields like diagnosis codes, histologies, treatment pathways to trial, laboratory tests around the time of trial availability, and comorbidities at and before trial availability.

All of this information is currently spread out among many different clinical settings and systems – hospital EHRs, practice management systems, lab information systems, biobanks, and registries. Centralizing this information into one repository is one way to get one source of truth, where researchers can draw evidence-based insight to help design better inclusion and exclusion criteria.

Patient recruiting can be improved through the use of digital technology and automation to identify and match eligible patients. Automation and technology can help clinical site personnel discover much more information about the uniqueness of the patient population in terms of geographic location, as well as the patient’s age, gender, type and stage of a disease, treatment history, and other medical conditions that affect the patient’s ability to participate in a clinical trial.

The right technology can help provide insight and harness knowledge to dramatically improve this process for everyone, from sponsors to patients. It is essential that the recruitment process be a collaborative partnership between healthcare providers, sponsors, CROs, and patient advocacy.
Second Opinion

groups—all working from a central clinical trial enablement platform to bring lasting solutions to cancer and other critical illnesses that can improve the standard of care for patients everywhere. It must be a shared mission to ensure that every patient has access to the best treatment option, which can be a clinical trial. Technology at scale and invested with comprehensive detail can help enable such a mission.

IDENTIFYING TOMORROW’S PATIENTS

Participating in trials as a clinical research site can be difficult. Screening for eligible trial patients can be a tedious and error-prone process for sites, akin to finding specific snowflakes in a storm. The most time-consuming element is knowing which patients to review for matching to the eligibility requirements of the clinical trial, which is often a manual process that can take a significant amount of work and time. And more complex eligibility criteria make it even more difficult to find patients who qualify and want to participate. The search process requires an automated method to sift through thousands of patients who may not be right for the trial, so researchers can concentrate on the ones who are.

Identifying patients who could be eligible for a trial tomorrow can accelerate research. A powerful single source of truth can reach out and help watch patients who could be eligible once the current treatment is no longer working, so that they would move to be eligible—for example, if they meet all criteria for a trial. Perhaps the latest treatment hasn’t failed yet.

Once we learn that it has failed, then that patient automatically becomes eligible and the site is made aware of it so that the physician has a comfortable workflow to move the patient to a trial. The research staff can discuss the trial as the next treatment option with that patient at their next appointment.

The research and data to propel new therapies is there. We just need a single source of truth with the detail and capacity that can guide us into new frontiers in care.

Carla Balch is CEO of Inteliquet, a maker of software for matching cancer patients to clinical trials. Previously, Carla was President and CEO of Altos Solutions, now Flatiron Health.
Coding for revenue:
Focus on accurate billing to drive and retain revenue

By LISA A. ERAMO, MA
Contributing author

Physicians work hard to generate revenue, and with slim operating margins, they don’t want to contend with costly recoupments. Compliant coding and billing helps them avoid the focus of a pre- or post-payment audit.

This article discusses four services that physicians say pose payment challenges along with general tips for coding compliance.

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Annual wellness visits vs. physicals:

**Know Medicare requirements**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>2019 national Medicare payment</th>
<th>Medicare coverage</th>
</tr>
</thead>
<tbody>
<tr>
<td>G0402</td>
<td>Initial preventive physical exam (IPPE)</td>
<td>$169.02</td>
<td>Covered once within 12 months of Part B enrollment</td>
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<tr>
<td>G0403</td>
<td>Routine electrocardiogram (ECG) with 12 leads performed as a screening for the IPPE with interpretation and report</td>
<td>$17.30</td>
<td>Covered once within 12 months of Part B enrollment</td>
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<tr>
<td>G0404</td>
<td>Routine ECG with 12 leads, tracing only, performed as a screening for the IPPE</td>
<td>$8.65</td>
<td>Covered once within 12 months of Part B enrollment</td>
</tr>
<tr>
<td>G0405</td>
<td>Routine ECG with 12 leads, interpretation and report only, performed as a screening for the IPPE</td>
<td>$8.65</td>
<td>Covered once within 12 months of Part B enrollment</td>
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<tr>
<td>G0438</td>
<td>Annual wellness visit (AWV), initial visit</td>
<td>$174.43</td>
<td>Covered once every 12 months</td>
</tr>
<tr>
<td>G0439</td>
<td>AWV, subsequent visit</td>
<td>$118.21</td>
<td>Covered for medically necessary services</td>
</tr>
<tr>
<td>99387</td>
<td>Comprehensive preventive medicine visit, initial visit 65 years and older</td>
<td>$0</td>
<td>Not covered (patient pays 100% out of pocket—obtain an ABN)*</td>
</tr>
<tr>
<td>99397</td>
<td>Comprehensive preventive medicine visit, periodic visit, 65 years and older</td>
<td>$0</td>
<td>Not covered (patient pays 100% out of pocket—obtain an ABN)*</td>
</tr>
</tbody>
</table>

*Most private payers accept these codes unless they follow Medicare guidelines in which case they require G0402-G0405 and G0438-G0439.

It’s easy to confuse the AWV and Initial Preventive Physical Exam (IPPE) because both are Medicare-covered services for preventive health. However, there are some notable differences, says Sonal Patel, CPMA, CPC, a coding and compliance consultant with Nexsen Pruet LLC, a business law firm in Charleston, S.C. Patel provides these tips for compliant billing:

1. Know what’s included in the AWV visit vs. the IPPE. Visit the CMS website to learn more about specific requirements for the AWV (including subsequent AWV visits) and IPPE. Documentation should reflect each of these services, says Patel.

2. Report the IPPE, otherwise known as the ‘Welcome to Medicare exam,’ only once within 12 months of Part B enrollment. The patient is ineligible for this service after 12 months post-enrollment, says Patel.

3. Once the 12 months post-enrollment have elapsed, physicians can bill an AWV once every 11 months thereafter for the patient’s annual AWV. The physician must perform and document all components of the AWV or IPPE, including any updates since the last visit. However, they can’t bill an AWV and IPPE during the same 12 months, says Patel. If the patient needs to be seen after the IPPE but before they’re eligible for the AWV, the physician must bill another appropriate service for which the patient may owe a co-pay or deductible. With the AWV and IPPE, the beneficiary owes nothing. ☑
Telemedicine:
Know your codes and modifiers

Telemedicine increases access, convenience and patient satisfaction, but it can cause headaches in terms of getting paid, says Jamie Claypool, CPC, CPMA, practice management consultant at J. Claypool Associates Inc. in Spicewood, Tex. Follow these four tips to avoid denials:

1. Know what codes are acceptable to report as telemedicine. CMS provides a complete list of eligible CPT/HCPCS codes for calendar year 2019 (see pp. 6-9). For example, via telemedicine, physicians can report:

- office visits
- smoking cessation services
- annual depression screenings
- transitional care management
- advance care planning
- prolonged services
- annual wellness visits, and more.

Payment for services rendered via telemedicine is no different from those rendered in the office setting, says Claypool. She adds that commercial payers may or may not allow physicians to report these same services via telemedicine.

2. Report place of service (POS) code 02. POS 02 indicates the physician furnished the service as a professional telehealth service from a distant site. Physicians should not report POS 11 (office) when billing these services, says Joette Derricks, healthcare compliance and revenue integrity consultant in Baltimore.

3. Apply modifier -95, when applicable. This modifier indicates the physician rendered telemedicine services through a synchronous interactive communication, and some commercial payers may require it for certain codes, says Claypool.

4. Don’t confuse telemedicine with virtual check-ins (G2012) and remote evaluations (G2010). Physicians can bill virtual check-ins when they have a direct conversation in real-time with an established patient to determine whether the patient must come into the office to be evaluated. The only caveat is that it’s not billable when

On the horizon: 3 reimbursement trends to monitor

1. Surprise billing protections.
Twenty-five states have some form of surprise billing protection that prevents physicians from charging patients their out-of-network rates when they go to an in-network hospital or emergency department. President Trump has also vowed to end surprise billing and create more transparency with medical bills. Physicians should keep an eye on this legislation because it could mean they’d take a financial hit for seeing certain patients in the hospital setting, says Tammy Tipton, owner of Appeal Solutions Inc. in Oklahoma City, Okla.

2. Reference-based pricing.
Some commercial payers are moving away from reasonable and customary rates in favor of paying physicians a multiple of the Medicare rate (usually one or two times that rate). However, Medicare often reimburses at cost, leaving a slim profit margin for physicians. Physicians should review their payer contracts, and may need to make some tough decisions (i.e., part ways with some payers), says Tipton.

The ICD-10-CM Coordination and Maintenance Committee has proposed approximately 20 new diagnosis codes that address problems related to education and literacy, employment status, housing and economic circumstances and social environment. Physicians should monitor journals and professional association newsletters to see whether these codes are finalized, says David Vence, MA, RHIA, CPC, assistant vice president of coding and compliance at First Class Solutions Inc. in Maryland Heights, Missouri. The new codes are part of the calendar year 2020 Hospital Inpatient Prospective Payment System Final Rule and would take effect October 1.
the check-in originates from a related E/M service provided within the previous seven days or leads to an E/M service or procedure within the next 24 hours or soonest available appointment. The same caveat is true for remote evaluations during which a physician asynchronously communicates with an established patient (e.g., through the portal) and then speaks with the patient in real time to devise a treatment plan.

CMS doesn’t classify either of these services as telemedicine, which means there are no geographic restrictions, says Derricks. With telemedicine, Medicare will only pay for services when the beneficiary receives the services in an authorized originating site that’s located in a rural Health Professional Shortage Area or a county outside a Metropolitan Statistical Area, she adds. Note that commercial payers don’t accept G2010 and G2012.

### Chronic care management (CCM):

**Avoid common denials**

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<tr>
<th>CPT Code</th>
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<tbody>
<tr>
<td>99490</td>
<td>CCM, 20 minutes</td>
<td>$42.17</td>
</tr>
<tr>
<td>99487</td>
<td>Complex CCM, 60 minutes</td>
<td>$92.98</td>
</tr>
<tr>
<td>99489</td>
<td>Each additional 30 minutes</td>
<td>$46.49</td>
</tr>
</tbody>
</table>

Even though physicians have been able to bill CCM since 2015, they still run in to problems in terms of getting paid, says Kim Garner Huey, CPC, owner of KGG Coding and Reimbursement Consulting in Birmingham, Ala. Here are some common reasons for denials and how to avoid them:

**Reason for denial: Multiple providers bill CCM for the same patient during the same 30 days.**

**How to avoid it:** Communicate with specialists regarding who will bill for the CCM. “This code was really intended for primary care, but it’s not restricted to primary care,” says Huey.

**Reason for denial: Physician bills CCM more than once every 30 days.**

**How to avoid it:** Set up an alert in the practice management system that prevents physicians from reporting CCM before 30 days have elapsed, says Huey.

**Reason for denial: Insufficient documentation.**

**How to avoid it:** This is a problem that tends to surface during post-payment audits, says Huey. Avoid recoupments by ensuring documentation reflects the intent of the code—that is, to manage all of the patient’s chronic conditions. “CMS intended a very personalized, hands-on type of medical management,” she adds. Documentation such as ‘Patient is taking medications as prescribed’ is not sufficient. Instead, she says to document the following:

- List of all of the patient’s conditions with as much specificity as possible
- Why these conditions place the patient at significant risk of death, acute exacerbation/ decompensation, or functional decline
- Comprehensive care plan—What the physician is doing to manage the diagnoses. If a specialist is managing a condition, the primary care physician should note the specialist’s name, the date of the last appointment, and a brief summary of the visit.

For more information about CCM, including patient and practitioner eligibility and the service elements included in the code, visit the CMS web site.
Transitional care management (TCM):
Track patients, comply with requirements

**Physicians can generate revenue by providing TCM, but they must also be prepared to deal with potential denials, says Huey. Here are some common denials and how to avoid them:**

**Reason for denial: Commercial payer rejects the code.**

**How to avoid it:** Bill as an office visit instead, since most commercial payers don’t pay for TCM, says Huey.

**Reason for denial: Interactive contact (telephone, email, or face to face) with the patient did not take place within two business days of discharge.**

**How to avoid it:** With the rise of hospitalists, very few primary care physicians see their own patients in the hospital, making it difficult to track admissions and discharges, says Huey. She says physicians should tell their patients to notify the practice of any hospitalizations as soon as they occur so the physician can help coordinate care. Then appoint someone in the practice (e.g., a medical assistant or care coordinator) to track the date of discharge and call or email the patient within two business days thereafter.

Even when staff call or email within two business days of discharge, they don’t always document it in the medical record, says Claypool. Best practice is to document the date of discharge, the date of the call, and a very brief summary of the interaction, she adds. If two or more attempts to reach the patient within two business days of discharge are unsuccessful, physicians can bill TCM as long as they meet all of the other requirements. However, staff must document their attempts to reach the patient even after the second business day following discharge and should continue trying until they are successful.

**Reason for denial: Documentation doesn’t support high-complexity TCM.**

**How to avoid it:** To report 99496, physicians must perform high-complexity medical decision-making, meaning they must review and document:

- An extensive list of possible diagnoses and/or management options,
- An extensive amount of complex data; and
- High risk of significant complications, morbidity, and/or mortality

Physicians may feel as though they’ve rendered complex TCM because they spent a lot of time talking with a patient, for example, but if the documentation doesn’t reflect the elements listed above, it doesn’t meet the criteria for the code, says Claypool.

For more information about TCM, including TCM components and other resources, visit the CMS Web site.

---

**CPT Code** | **Description** | **2019 national Medicare payment**
---|---|---
99495 | TCM with moderate medical decision complexity and a face-to-face visit within 14 days of discharge | $166.50
99496 | TCM with high-complexity medical decision-making and a face-to-face visit within 7 days of discharge | $234.97
Avoiding denials:

Six general tips to boost coding, billing compliance

Denials are a source of frustration for all physicians. When left unmanaged, they’re also one reason why physicians ultimately sell or close their practices, says Dorothy Steed, CCS, CDIP, revenue cycle consultant in Atlanta. Following are six tips to help practices avoid denials altogether.

1. **Use a claim scrubber.**
   Most practice management systems include a claim scrubber that catches coding errors and omissions before claims are finalized. “Claims have become so complex, you really can’t keep track of all of the codes without some type of technology assistance,” says Tammy Tipton, owner of Appeal Solutions Inc. in Oklahoma City, Okla.
   The claim scrubber can reduce common errors; however, a certified medical coder should still review each claim to ensure it meets payer-specific requirements, says Steed. For example, some payers may accept a certain code or modifier while others don’t. If the coder can’t review 100 percent of cases, they should at least review those that payers frequently deny and/or those for which payers frequently request additional documentation, she adds.

2. **Stay up to date on coding changes.**
   Appoint a staff member to review annual coding changes and ensure that the EHR and/or encounter forms include these changes, says Sally M. Frese, MSN, RN, CPC, coding compliance consultant at First Class Solutions Inc. in Maryland Heights, Missouri.

3. **Hire qualified coders.**
   Require a CPC credential, at least two years of experience, and a 90-day evaluation period, says Steed. If current staff aren’t able or willing to meet these requirements, consider moving them to an alternative role (e.g., the front office). “You could still retain them to perform other office functions, but they won’t have their hands in your finances,” she says. If the practice outsources the coding function, ensure that the vendor only hires credentialed coders, she adds.

4. **Focus on clinical documentation improvement to avoid denials.**
   Physicians should ask coding/billing staff to determine what specific documentation the payer requires so they can provide that information going forward, says Tipton.

5. **Don’t automatically resubmit denied claims.**
   Duplicate claims are one of the most common reasons for denials, says Tipton. Instead of automatically resubmitting the claim, ask coding/billing staff to contact the payer’s customer service to determine why the initial claim was denied, she adds.

6. **Improve the patient experience.**
   Obtaining prior authorizations, for example, should be less of an administrative requirement and more about providing excellent patient care, says Tipton. “There’s so much emphasis now on patient experience, and I think that needs to be expanded beyond clinical staff to include other office staff,” she says. “Front office staff are the front lines, and they can make an impression on patients in terms of paving the way for quality care.”

READ MORE

For our guide to other coding topics, including E/M levels, visit: BIT.LY/MECODINGGUIDE
Diabetes outcomes: Improve your quality scores

Under the 2015 MACRA law, physicians must persuade patients to take care of themselves, says Tina Colangelo, MHA, a consultant specializing in value-based reimbursement. The question is how—especially when it comes to chronic conditions such as diabetes. Here are four tips from the experts to improve diabetes outcomes:

1. **Talk about diabetes management**
   Even when the purpose of the visit is unrelated to diabetes, it should be a topic of conversation during the visit.
   “If it's a priority for the doctor, then it becomes more of a priority for the patient,” says Mary Ann Bauman, MD, an internist in Oklahoma City, Okla.
   Bauman makes a point of asking about exercise, diet and insulin even when patients present for an ailment such as a sore throat or cough. These conversations keep patients engaged in diabetes management and increase the likelihood of a healthy hemoglobin A1C level.

2. **Brush up on communication skills**
   The goal is to keep inspiring patients to take actions that improve outcomes. Here are three tips:
   
   - **Start each visit with an open-ended question.**
     Ask patients to identify what's most difficult in terms of managing their diabetes, says Steven V. Edelman, MD, an endocrinologist and founder of Taking Control of Your Diabetes, an organization that provides diabetes education to patients and physicians. “Then the key is that you have to listen. You can’t interrupt and you also need to have empathy,” he adds.
   
   - **Give positive feedback.**
     Congratulate patients when their hemoglobin A1C has come down or when they’re exercising, says Bauman.
   
   - **Keep an open mind.**
     Don’t make assumptions about patients, advises William Polonsky, Ph.D., president and founder of the Behavioral Diabetes Institute, an organization that provides patient and physician education about diabetes management. For example, he says, there are many reasons why patients don’t take their insulin. Remind patients that many struggle with taking medications and that it’s normal to forget to take medication from time to time.

3. **Focus on care coordination**
   Physicians receive a higher MIPS score when they communicate with specialists and obtain documentation detailing exams or treatments (e.g., diabetic eye exams for retinopathy or neurological screening for neuropathy).
   Ensure that specialists provide copies of their notes. Patients can help by reminding specialists to provide this information to their primary care physician, says Bauman. Enhanced care coordination not only improves outcomes, it also enables physicians to report on additional quality metrics under MIPS.
   Medical assistants can obtain copies of specialists’ notes while patients meet with the primary care physician. In addition, medical assistants can help patients schedule any overdue specialist exams, she adds.

4. **Provide patient education**
   Elizabeth A. Pector, MD, a family physician in Naperville, Ill., educates patients about how blood sugar control reduces the chance of developing small-vessel disease complications such as eye, kidney and nerve damage.
   “I outline basic diet and exercise recommendations, typical follow-up schedule and then refer to our hospital diabetes educators who are excellent resources for initial patient instruction, testing of blood sugar and administration of medication,” she adds.
   When considering patient education, think creatively. “Everybody is a little bit different, and you need to be prepared to give them solutions and strategies that will work best for them,” says Sandra Adamson Fryhofer, MD, an internist in Atlanta.

Lisa A. Eramo, MA, is a contributing author. Send your practice management questions to medec@mmhgroup.com
Technology

The Internet of Medical Things

What is it and what does it mean to your practice?

By AVERY HURT CONTRIBUTING AUTHOR

HIGHLIGHTS

- Connected technology can help physicians and patient manage chronic diseases, the most time-consuming and expensive conditions physicians deal with.
- Security is a prime concern. Healthcare data is a major target for hackers, and any internet-connected device poses a risk.

Smart thermostats, home security systems, fitness watches, and other devices that connect with each other and the internet, make up what is called the Internet of Things (IoT). And these devices are ubiquitous these days.

There is another world of internet-connected devices that has not caught on quite so quickly: The Internet of Medical Things (IoMT). Andrew Keller, MD, chief medical officer and chief medical information officer for Western Connecticut Medical Group describes the IoMT as “devices that can collect and exchange data—either with users or other devices—via the internet, and are used to allow doctors to be more aware of a patient’s condition on real-time basis.”

The IoMT could potentially make managing chronic conditions more efficient and more cost-effective. But first physicians have to learn what these devices are and how they can be used safely and effectively.

GAME CHANGER

IoMT technologies cover a wide range of clinical uses. Smart watches and MedicalAlert bracelets can detect falls and call emergency medical services. An implantable pulmonary artery catheter can connect to an external device, such as a mobile phone, and notify the doctor when pressure increases.

Another high-tech device on the IoMT is the “smart pill.” These oral medications have ingestible sensors that, when
activated by stomach acids, transmit messages to a patch on the patient’s arm, which in turn sends a message to a smartphone app. This allows physicians and family members to make sure dementia patients or patients with mental health problems, for example, are taking their medications as prescribed.

Clinical trials are beginning to prove the benefits of some of these devices. A May 2018 study in *JAMA Cardiology* found that an Apple watch with an app called Cardiogram could detect abnormal heart rhythms with close to 97 percent accuracy.

“When this data is transmitted via the internet to the doctor—or someone at the monitoring station—the doctor can adjust medicines or take whatever steps he or she feels necessary,” Keller says.

In an interview with *Cardiology Today*, Jagmeet P. Singh, MD, PhD, *Cardiology Today* editorial board member and associate chief of the cardiology division at Massachusetts General Hospital, described this technology as a “game changer.”

“Since the sensor and its ability to record ECGs and classify the heart rhythm is FDA-approved, it will begin to find its way into clinical practice and potentially into the electronic health record,” he says. “It will certainly create a heightened awareness about rhythm disturbances and atrial fibrillation.”

In a separate editorial, Singh expressed cautious optimism about trends in digital health, writing that “both [artificial intelligence] and digital strategies will make the delivery of care both more patient-centric and cost-effective. The advances in mobile and wearable devices and sensors will help initiate the transition from conventional transactional care to a more continuous form of managing our patients.”

**A PRESCRIPTION FOR VALUE-BASED CARE**

The IoMT could also improve physicians’ bottom line. According to data published in 2017 in the *American Journal of Preventive Medicine*, 86 percent of healthcare expenditures are for people with chronic conditions, including cardiovascular disease, diabetes, obesity, and dementia. And these patients are far more likely than others to end up in the
emergency department. A 2015 study in *American Journal of Managed Care* found that patients with the highest care utilization rates, particularly those with multiple chronic conditions, were five times more likely to visit the emergency department than patients with low utilization rates.

Being able to proactively manage these time- and resource-intensive conditions could save money as well as lives. “A device that signals when the patient’s health is changing and alerts the doctor could make it possible to intervene early and reduce hospitalizations and improve patient outcomes,” says Steven Waldren, MD, vice president and chief medical informatics officer at the American Academy of Family Physicians.

“This technology allows you to manage people with chronic conditions more efficiently and effectively without them having to come into the office,” he says. “As folks are moving toward value-based care, being able to manage patients with chronic conditions at home could help practices be more profitable.”

IoMT technologies can also improve patient engagement. According to Accenture’s 2019 Digital Health Survey, 53 percent of patients surveyed would be more likely to choose a primary care provider who uses remote or telemonitoring devices to monitor and record health indicators. That’s up from 39 percent in 2016, and the trend is more noticeable in younger patients. “There’s a lot of push now for this type of care from a subgroup of patients who want to have their health data themselves,” says Waldren.

Payers are pushing for it, too. “If Medicare will pay doctors to use these technologies, then they’re more likely to use them,” says Waldren. And Medicare is doing just that. The CMS 2019 Fee Schedule includes three additional CPT codes for remote patient monitoring devices. According to the Center for Connected Health Policy 2019 State Telehealth Laws and Reimbursement Policies Report, there has been a slight

“If you’re going to use these devices with your patients, you need to make sure that the devices are HIPAA compliant and being used in a HIPAA-compliant way.”

—RON STERLING, HEALTH IT CONSULTANT

“[The IOMT is] devices that can collect and exchange data—either with users or other devices—via the internet, and are used to allow doctors to be more aware of a patient’s condition on real-time basis.”

—ANDREW KELLER, MD, CHIEF MEDICAL OFFICER AND CHIEF MEDICAL INFORMATION OFFICER, WESTERN CONNECTICUT MEDICAL GROUP
increase in state Medicare programs that reimburse for at least some remote patient monitoring.

**SECURE AND STANDARDIZED**

This world of increased connectivity does pose challenges, however. Healthcare data is a prime target for hackers, and any internet-connected device poses a risk. “If you’re going to use these devices with your patients, you need to make sure that the devices are HIPAA-compliant and being used in a HIPAA-compliant way,” says Ron Sterling, a consultant who specializes in health-care IT.

Consumer-oriented devices—fitness trackers, nutritional programs, and so on—are not necessarily HIPAA compliant, and patients are under no HIPAA obligations. “You must make sure you’re meeting all the HIPAA requirements, but you’re not responsible for what the patient does,” says Sterling. “Devices that you’re prescribing to patients are another matter. You have to stick to the same HIPAA standards and take the same security steps you do with portals, passwords, and so on.”

A physician who is performing due diligence and using FDA-approved devices from trusted vendors should be fine, though. But patients may not be as aware as their doctors of the security risks. When using remote monitoring devices or other IoMT technologies, “the doctor should explain the privacy issue to patients and make sure patients are aware the risks and benefits, and that the benefits do outweigh the risks,” says Keller.

Interoperability and standardization pose additional challenges. As these devices become more widely used, manufacturers and regulators will have to find ways to ensure that devices can communicate easily and securely across a wide range of platforms.

Despite all the potential benefits, it’s important to use these new technologies not only responsibly, but effectively. “Doctors need to understand that just adopting a piece of technology is not that helpful,” says Waldren. “You need to identify a particular problem you have with your patient population and find a solution to address that. Don’t just be enchanted by bright and shiny new tech; make sure it’s something that has clinical value.”

Keller recommends assessing clinical value the same way as any other any treatment. “I would ask the normal questions about sensitivity and specificity,” he says. “There is lots of information available at presentations and sessions at national conventions, and vendors usually have displays set up.”

The IoMT may not be as widespread as the IoT, but it is growing. “The fact of the matter is these devices are here, they’re going to be here, and patients want to use them,” says Sterling. Savvy physicians will be prepared.
Physicians are increasingly being squished. As reimbursement rates decrease or stagnate, many people think the solution is to see more patients. Unfortunately, this just doesn’t work in medicine. Those who tend to see patients as consumers seem to be the same ones who think rushing patients in and out of the office to increase numbers is the answer.

Here are five reasons why seeing more patients is not the solution:

1. Patients are more educated.
Patients often conduct their own internet research on Dr. Google before they come to see us. This does not save time in most cases. Rather, patients come in with many questions that need answers. If we address their concerns up front, they don’t need to call back with questions that weren’t answered at the time of their visit or return to have us look at something that was left unexamined.

2. Patient satisfaction suffers.
When patients feel we don’t spend enough time with them or listen to all their concerns, they are not happy. They come to us when they are worried about a problem, stressed out about life events or just wanting to make the best decisions to stay healthy. We can do much to ease that — if we have time.

When we rush patients in and out to try to increase numbers, we are not able to comfort our patients. Again, this may lead to follow-up calls. Or worse, the patient writes negative reviews about us online or looks for another doctor who can give them 5 extra minutes, both of which can cause our profits to decrease. While we can’t make every patient happy, we should do our best to listen and try to help them find answers.

If we want to improve physician efficiency and productivity, we need to fix our broken healthcare system first.

3. Patients are living longer with more chronic and complicated diseases.
They need more time with physicians and other healthcare providers than ever before. Patients usually have more diseases to monitor and potential complications to watch out for. Additionally, patients are often on more medications, and physicians need more time to discuss potential side effects and interactions. Shortening visits even further means more patients leave the exam room with questions unanswered and conditions undetected. This means taking more time down the road. And it sets the stage for missed diagnoses and unnecessary complications.

4. Documentation suffers.
When we see more patients, we have less time to document, and we are already struggling against an ever-increasing charting burden. We need to report certain metrics to meet MIPS/MACRA requirements. We can’t see more patients and record more data at the same time.

5. More patients equal less time to answer all of patients’ concerns in one visit.
Some doctors now limit the number of problems patients can discuss at one visit. I am a family doctor, and often patients have many disparate concerns that end up being related. For example, a patient may be concerned about why she is so tired and why her legs are swelling. Those are two concerns. However, if we listen to all her concerns, she may also tell us that her hair is falling out and she has trouble swallowing. These added concerns lead me to make the diagnosis of hypothyroidism.

Linda Girgis, MD, is a family physician in private practice in South River, N.J.
Best advice ever given to you by a peer

Maria Young Chandler, MD, MBA
Business of Medicine / Pediatrics
Irvine, Calif.

“Treat your life as a business (Me, Inc.) and you’re the CEO.”

George G. Ellis, Jr., MD
Internal Medicine
Boardman, Ohio

“One of my professors once told me the day you stop learning is the day you hang up your stethoscope.”

Antonio Gamboa, MD, MBA
Internal Medicine / Hospice and Palliative Care
Austin, Texas

“Focus on your family, and don’t let your wife and kids ever feel like they don’t know you anymore.”

Jeffrey M. Kagan, MD
Internal Medicine / Hospice
Newington, Conn.

“The hospital is not your friend.”

Melissa E. Lucarelli MD, FAAFP
Family Medicine
Randolph, Wis.

“Always thank a patient for asking about your family or about your health, and always send a sympathy card when your patient dies.”

Joseph E. Scherger, MD
Family Medicine
La Quinta, Calif.

“Spoken words evaporate. Written words are eternal.”

Salvatore Volpe, MD
Pediatrics/Internal Medicine / Pediatrics
Staten Island, N.Y.

“Slow down.”
“Even small improvements in revenues...can make the difference between staying independent and selling.”

REED TINSLEY, CPA, CFP, PRACTICE MANAGEMENT CONSULTANT, HOUSTON

“Don’t just be enchanted by bright and shiny new tech.”

STEVEN WALDREN, MD, VICE PRESIDENT AND CHIEF MEDICAL INFORMATICS OFFICER, AAFP

$174

Reimbursement amount for an annual wellness visit, initial visit

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“Don’t just be enchanted by bright and shiny new tech.”

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The future of value-based care

Our cover story takes a high-level look at the successes, problems and unanswered questions about the healthcare system’s turn toward value-based care. In this article we will discuss:

- Has value-based care worked as policy makers intended? Is it reducing costs? Is it improving care?
- What challenges have physicians and health systems experienced?
- What new payment models are coming in the future for physicians?

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