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VOLUME 23 | NUMBER 10

GlaxoSmithKline

For your members with COPD (chronic obstructive pulmonary disease)

The only once-daily ICS/LABA (inhaled corticosteroid/long-acting beta$_2$-agonist) for the maintenance treatment of COPD.

Contact your GlaxoSmithKline Account Manager to schedule a presentation.

Indications

- BREO ELLIPTA is a combination inhaled corticosteroid/long-acting beta$_2$-adrenergic agonist (ICS/LABA) indicated for the long-term, once-daily, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema. BREO ELLIPTA is also indicated to reduce exacerbations of COPD in patients with a history of exacerbations.
- BREO ELLIPTA is NOT indicated for the relief of acute bronchospasm or for the treatment of asthma.

Important Safety Information for BREO ELLIPTA

WARNING: ASTHMA-RELATED DEATH

- **Long-acting beta$_2$-adrenergic agonists (LABAs), such as vilanterol, one of the active ingredients in BREO ELLIPTA, increase the risk of asthma-related death. A placebo-controlled trial with another LABA (salmeterol) showed an increase in asthma-related deaths in subjects receiving salmeterol. This finding with salmeterol is considered a class effect of all LABAs, including vilanterol.**
- **The safety and efficacy of BREO ELLIPTA in patients with asthma have not been established. BREO ELLIPTA is not indicated for the treatment of asthma.**

CONTRAINDICATIONS

- BREO ELLIPTA is contraindicated in patients with severe hypersensitivity to milk proteins or who have demonstrated hypersensitivity to either fluticasone furoate, vilanterol, or any of the excipients.

WARNINGS AND PRECAUTIONS

- BREO ELLIPTA should not be initiated in patients during rapidly deteriorating or potentially life-threatening episodes of COPD.
- BREO ELLIPTA should not be used for the relief of acute symptoms, i.e., as rescue therapy for the treatment of acute episodes of bronchospasm. Acute symptoms should be treated with an inhaled, short-acting beta$_2$-agonist.
- BREO ELLIPTA should not be used more often than recommended, at higher doses than recommended, or in conjunction with other medications containing LABAs, as an overdose may result. Clinically significant cardiovascular effects and fatalities have been reported in association with excessive use of inhaled sympathomimetic drugs. Patients using BREO ELLIPTA should not use another medicine containing a LABA (e.g., salmeterol, formoterol fumarate, arformoterol tartrate, indacaterol) for any reason.
- Oropharyngeal candidiasis has occurred in patients treated with BREO ELLIPTA. Advise patients to rinse the mouth without swallowing following inhalation to help reduce the risk of oropharyngeal candidiasis.
- An increase in the incidence of pneumonia has been observed in subjects with COPD receiving BREO ELLIPTA. There was also an increased incidence of pneumonias resulting in hospitalization. In some incidences these pneumonia events were fatal.
  - In replicate 12-month studies of 3255 subjects with COPD who had experienced a COPD exacerbation in the previous year, there was a higher incidence of pneumonia reported in subjects receiving BREO ELLIPTA 100/25 mcg (6% [51 of 806 subjects]), fluticasone furoate (FF)/vilanterol (VI) 50/25 mcg (6% [48 of 820 subjects]), and FF/VI 200/25 mcg (7% [55 of 811 subjects]) than in subjects receiving VI 25 mcg (3% [27 of 818 subjects]). There was no fatal pneumonia in subjects receiving VI or FF/VI 50/25 mcg. There was fatal pneumonia in 1 subject receiving BREO ELLIPTA at the approved strength (100/25 mcg) and in 7 subjects receiving FF/VI 200/25 mcg (<1% for each treatment group).
- Physicians should remain vigilant for the possible development of pneumonia in patients with COPD, as the clinical features of such infections overlap with the symptoms of COPD exacerbations.
- Patients who use corticosteroids are at risk for potential worsening of existing tuberculosis; fungal, bacterial, viral, or parasitic infections; or ocular herpes simplex. A more serious or even fatal course of chickenpox or measles may occur in susceptible patients. Use caution in patients with the above because of the potential for worsening of these infections.
- Particular care is needed for patients who have been transferred from systemically active corticosteroids to inhaled corticosteroids because deaths due to adrenal insufficiency have occurred in patients with asthma during and after transfer from systemic corticosteroids to less systemically available inhaled corticosteroids. Taper patients slowly from systemic corticosteroids if transferring to BREO ELLIPTA.
- Hypercorticism and adrenal suppression may occur with very high dosages or at the regular dosage of inhaled corticosteroids in susceptible individuals. If such changes occur, discontinue BREO ELLIPTA slowly.

BREO™ ELLIPTA™ (fluticasone furoate 100 mcg and vilanterol 25 mcg inhalation powder)

Important Safety Information for BREO ELLIPTA (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

- Caution should be exercised when considering the coadministration of BREO ELLIPTA with long-term ketoconazole and other known strong CYP3A4 inhibitors (e.g., ritonavir, clarithromycin, conivaptan, indinavir, itraconazole, lopinavir, nefazodone, nelfinavir, saquinavir, telithromycin, troleandomycin, voriconazole) because increased systemic corticosteroid and cardiovascular adverse effects may occur.
- If paradoxical bronchospasm occurs, discontinue BREO ELLIPTA and institute alternative therapy.
- Vilanterol can produce clinically significant cardiovascular effects in some patients as measured by increases in pulse rate, systolic or diastolic blood pressure, and also cardiac arrhythmias, such as supraventricular tachycardia and extrasystoles. If such effects occur, BREO ELLIPTA may need to be discontinued. BREO ELLIPTA should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension.
- Decreases in bone mineral density (BMD) have been observed with long-term administration of products containing inhaled corticosteroids. Patients with major risk factors for decreased bone mineral content, such as prolonged immobilization, family history of osteoporosis, postmenopausal status, tobacco use, advanced age, poor nutrition, or chronic use of drugs that can reduce bone mass (e.g., anticonvulsants, oral corticosteroids) should be monitored and treated with established standards of care. Since patients with COPD often have multiple risk factors for reduced BMD, assessment of BMD is recommended prior to initiating BREO ELLIPTA and periodically thereafter.
- Glaucoma, increased intraocular pressure, and cataracts have been reported in patients with COPD following the long-term administration of inhaled corticosteroids. Therefore, close monitoring is warranted in patients with a change in vision or with a history of increased intraocular pressure, glaucoma, and/or cataracts.
- Use with caution in patients with convulsive disorders, thyrotoxicosis, diabetes mellitus, ketoacidosis, and in patients who are unusually responsive to sympathomimetic amines.
- Be alert to hypokalemia and hyperglycemia.

ADVERSE REACTIONS

- The most common adverse reactions (≥3% and more common than placebo) reported in two 6-month clinical trials with BREO ELLIPTA (and placebo) were nasopharyngitis, 9% (8%); upper respiratory tract infection, 7% (3%); headache, 7% (5%); and oral candidiasis, 5% (2%).
- In addition to the events reported in the 6-month studies, adverse reactions occurring in ≥3% of the subjects treated with BREO ELLIPTA in two 1-year studies included COPD, back pain, pneumonia, bronchitis, sinusitis, cough, oropharyngeal pain, arthralgia, hypertension, influenza, pharyngitis, diarrhea, peripheral edema, and pyrexia.

DRUG INTERACTIONS

- Caution should be exercised when considering the coadministration of BREO ELLIPTA with long-term ketoconazole and other known strong CYP3A4 inhibitors (e.g., ritonavir, clarithromycin, conivaptan, indinavir, itraconazole, lopinavir, nefazodone, nelfinavir, saquinavir, telithromycin, troleandomycin, voriconazole) because increased systemic corticosteroid and cardiovascular adverse effects may occur.
- BREO ELLIPTA should be administered with extreme caution to patients being treated with monoamine oxidase inhibitors, tricyclic antidepressants, or drugs known to prolong the QTc interval, or within 2 weeks of discontinuation of such agents, because the effect of adrenergic agonists, such as vilanterol, on the cardiovascular system may be potentiated by these agents.
- Use beta-blockers with caution as they not only block the pulmonary effect of beta-agonists, such as vilanterol, but may produce severe bronchospasm in patients with reversible obstructive airways disease.
- Use with caution in patients taking non–potassium-sparing diuretics, as electrocardiographic changes and/or hypokalemia associated with non–potassium-sparing diuretics may worsen with concomitant beta-agonists.

USE IN SPECIFIC POPULATIONS

- Use BREO ELLIPTA with caution in patients with moderate or severe hepatic impairment. Fluticasone furoate exposure may increase in these patients. Monitor for systemic corticosteroid effects.

Please see Brief Summary of Prescribing Information, including Boxed Warning, for BREO ELLIPTA on the following pages.

BREO ELLIPTA was developed in collaboration with Theravance

BREO™ ELLIPTA™ (fluticasone furoate 100 mcg and vilanterol 25 mcg inhalation powder)

BRIEF SUMMARY

BREO™ ELLIPTA™
(fluticasone furoate and vilanterol inhalation powder)
FOR ORAL INHALATION USE

The following is a brief summary only; see full prescribing information for complete product information

WARNING: ASTHMA-RELATED DEATH

Long-acting beta$_2$-adrenergic agonists (LABA) increase the risk of asthma-related death. Data from a large placebo-controlled US trial that compared the safety of another LABA (salmeterol) with placebo added to usual asthma therapy showed an increase in asthma-related deaths in subjects receiving salmeterol. This finding with salmeterol is considered a class effect of LABA, including vilanterol, an active ingredient in BREO ELLIPTA *[see Warnings and Precautions (5.1)]*.

The safety and efficacy of BREO ELLIPTA in patients with asthma have not been established. BREO ELLIPTA is not indicated for the treatment of asthma.

1 INDICATIONS AND USAGE

BREO ELLIPTA is a combination inhaled corticosteroid/long-acting beta$_2$-adrenergic agonist (ICS/LABA) indicated for the long-term, once-daily, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema. BREO ELLIPTA is also indicated to reduce exacerbations of COPD in patients with a history of exacerbations.

Important Limitations of Use: BREO ELLIPTA is NOT indicated for the relief of acute bronchospasm or for the treatment of asthma.

4 CONTRAINDICATIONS

The use of BREO ELLIPTA is contraindicated in patients with severe hypersensitivity to milk proteins or who have demonstrated hypersensitivity to either fluticasone furoate, vilanterol, or any of the excipients *[see Warnings and Precautions (5.11), Description (11) of full prescribing information]*.

5 WARNINGS AND PRECAUTIONS

5.1 Asthma-Related Death Data from a large placebo-controlled trial in subjects with asthma showed that LABA may increase the risk of asthma-related death. Data are not available to determine whether the rate of death in patients with COPD is increased by LABA. A 28-week, placebo-controlled, US trial comparing the safety of another LABA (salmeterol) with placebo, each added to usual asthma therapy, showed an increase in asthma-related deaths in subjects receiving salmeterol (13/13,176 in subjects treated with salmeterol vs 3/13,179 in subjects treated with placebo; relative risk: 4.37 [95% CI: 1.25, 15.34]). The increased risk of asthma-related death is considered a class effect of LABA, including vilanterol, one of the active ingredients in BREO ELLIPTA. No study adequate to determine whether the rate of asthma-related death is increased in subjects treated with BREO ELLIPTA has been conducted. The safety and efficacy of BREO ELLIPTA in patients with asthma have not been established. BREO ELLIPTA is not indicated for the treatment of asthma.

5.2 Deterioration of Disease and Acute Episodes BREO ELLIPTA should not be initiated in patients during rapidly deteriorating or potentially life-threatening episodes of COPD. BREO ELLIPTA has not been studied in patients with acutely deteriorating COPD. The initiation of BREO ELLIPTA in this setting is not appropriate. BREO ELLIPTA should not be used for the relief of acute symptoms, i.e., as rescue therapy for the treatment of acute episodes of bronchospasm. BREO ELLIPTA has not been studied in the relief of acute symptoms and extra doses should not be used for that purpose. Acute symptoms should be treated with an inhaled, short-acting beta$_2$-agonist. When beginning treatment with BREO ELLIPTA, patients who have been taking oral or inhaled, short-acting beta$_2$-agonists on a regular basis (e.g., 4 times a day) should be instructed to discontinue the regular use of these drugs and to use them only for symptomatic relief of acute respiratory symptoms. When prescribing BREO ELLIPTA, the healthcare provider should also prescribe an inhaled, short-acting beta$_2$-agonist and instruct the patient on how it should be used. Increasing inhaled, short-acting beta$_2$-agonist use is a signal of deteriorating disease for which prompt medical attention is indicated. COPD may deteriorate acutely over a period of hours or chronically over several days or longer. If BREO ELLIPTA no longer controls symptoms of bronchoconstriction; the patient's inhaled, short-acting, beta$_2$-agonist becomes less effective; or the patient needs more short-acting beta$_2$-agonist than usual, these may be markers of deterioration of disease. In this setting a re-evaluation of the patient and the COPD treatment regimen should be undertaken at once. Increasing the daily dose of BREO ELLIPTA beyond the recommended dose is not appropriate in this situation.

5.3 Excessive Use of BREO ELLIPTA and Use With Other Long-Acting Beta$_2$-Agonists BREO ELLIPTA should not be used more often than recommended, at higher doses than recommended, or in conjunction with other medicines containing LABA, as an overdose may result. Clinically significant cardiovascular effects and fatalities have been reported in association with excessive use of inhaled sympathomimetic drugs. Patients using BREO ELLIPTA should not use another medicine containing a LABA (e.g., salmeterol, formoterol fumarate, arformoterol tartrate, indacaterol) for any reason.

5.4 Local Effects of Inhaled Corticosteroids In clinical trials, the development of localized infections of the mouth and pharynx with *Candida albicans* has occurred in subjects treated with BREO ELLIPTA. When such an infection develops, it should be treated with appropriate local or systemic (i.e., oral) antifungal therapy while treatment with BREO ELLIPTA continues, but at times therapy with BREO ELLIPTA may need to be interrupted. Advise the patient to rinse his/her mouth without swallowing following inhalation to help reduce the risk of oropharyngeal candidiasis.

5.5 Pneumonia An increase in the incidence of pneumonia has been observed in subjects with COPD receiving the fluticasone furoate/vilanterol combination, including BREO ELLIPTA 100 mcg/25 mcg, in clinical trials. There was also an increased incidence of pneumonias resulting in hospitalization. In some incidences these pneumonia events were fatal. Physicians should remain vigilant for the possible development of pneumonia in patients with COPD as the clinical features of such infections overlap with the symptoms of COPD exacerbations. In replicate 12-month trials in 3,255 subjects with COPD who had experienced a COPD exacerbation in the previous year, there was a higher incidence of pneumonia reported in subjects receiving the fluticasone furoate/vilanterol combination (50 mcg/25 mcg: 6% [48 of 820 subjects]; 100 mcg/25 mcg: 6% [51 of 806 subjects]; or 200 mcg/25 mcg: 7% [55 of 811 subjects]) than in subjects receiving vilanterol 25 mcg (3% [27 of 818 subjects]). There was no fatal pneumonia in subjects receiving vilanterol or fluticasone furoate/vilanterol 50 mcg/25 mcg. There was fatal pneumonia in 1 subject receiving fluticasone furoate/vilanterol 100 mcg/25 mcg and in 7 subjects receiving fluticasone furoate/vilanterol 200 mcg/25 mcg (less than 1% for each treatment group).

5.6 Immunosuppression Persons who are using drugs that suppress the immune system are more susceptible to infections than healthy individuals. Chickenpox and measles, for example, can have a more serious or even fatal course in susceptible children or adults using corticosteroids. In such children or adults who have not had these diseases or been properly immunized, particular care should be taken to avoid exposure. How the dose, route, and duration of corticosteroid administration affect the risk of developing a disseminated infection is not known. The contribution of the underlying disease and/or prior corticosteroid treatment to the risk is also not known. If a patient is exposed to chickenpox, prophylaxis with varicella zoster immune globulin (VZIG) may be indicated. If a patient is exposed to measles, prophylaxis with pooled intramuscular immunoglobulin (IG) may be indicated. (See the respective package inserts for complete VZIG and IG prescribing information.) If chickenpox develops, treatment with antiviral agents may be considered. Inhaled corticosteroids should be used with caution, if at all, in patients with active or quiescent tuberculosis infections of the respiratory tract; systemic fungal, bacterial, viral, or parasitic infections; or ocular herpes simplex.

5.7 Transferring Patients From Systemic Corticosteroid Therapy Particular care is needed for patients who have been transferred from systemically active corticosteroids to inhaled corticosteroids because deaths due to adrenal insufficiency have occurred in patients with asthma during and after transfer from systemic corticosteroids to less systemically available inhaled corticosteroids. After withdrawal from systemic corticosteroids, a number of months are required for recovery of hypothalamic-pituitary-adrenal (HPA) function. Patients who have been previously maintained on 20 mg or more of prednisone (or its equivalent) may be most susceptible, particularly when their systemic corticosteroids have been almost completely withdrawn. During this period of HPA suppression, patients may exhibit signs and symptoms of adrenal insufficiency when exposed to trauma, surgery, or infection (particularly gastroenteritis) or other conditions associated with severe electrolyte loss. Although BREO ELLIPTA may control COPD symptoms during these episodes, in recommended doses it supplies less than normal physiological amount of glucocorticoid systemically and does NOT provide the mineralocorticoid activity that is necessary for coping with these emergencies. During periods of stress or a severe COPD exacerbation, patients who have been withdrawn from systemic corticosteroids should be instructed to resume oral corticosteroids (in large doses) immediately and to contact their physicians for further instruction. These patients should also be instructed to carry a warning card indicating that they may need supplementary systemic corticosteroids during periods of stress or severe COPD exacerbation. Patients requiring oral corticosteroids should be weaned slowly from systemic corticosteroid use after transferring to BREO ELLIPTA. Prednisone reduction can be accomplished by reducing the daily prednisone dose by 2.5 mg on a weekly basis during therapy with BREO ELLIPTA. Lung function (mean forced expiratory volume in 1 second [FEV_1]), beta-agonist use, and COPD symptoms should be carefully monitored during withdrawal of oral corticosteroids. In addition, patients should be observed for signs and symptoms of adrenal insufficiency, such as fatigue, lassitude, weakness, nausea and vomiting, and hypotension. Transfer of patients from systemic corticosteroid therapy to BREO ELLIPTA may unmask allergic conditions previously suppressed by the systemic corticosteroid therapy (e.g., rhinitis, conjunctivitis, eczema, arthritis, eosinophilic conditions). During withdrawal from oral corticosteroids, some patients may experience symptoms of systemically active corticosteroid withdrawal (e.g., joint and/or muscular pain, lassitude, and depression) despite maintenance or even improvement of respiratory function.

5.8 Hypercorticism and Adrenal Suppression Inhaled fluticasone furoate is absorbed into the circulation and can be systemically active. Effects of fluticasone furoate on the HPA axis are not observed with the therapeutic dose of BREO ELLIPTA. However, exceeding the recommended dosage or coadministration with a strong cytochrome P450 3A4 (CYP3A4) inhibitor may result in HPA dysfunction *[see Warnings and Precautions (5.9), Drug Interactions (7.1)]*. Because of the possibility of significant systemic absorption of inhaled corticosteroids in sensitive patients, patients treated with BREO ELLIPTA should be observed carefully for any evidence of systemic corticosteroid effects. Particular care should be taken in observing patients postoperatively or during periods of stress for evidence of inadequate adrenal response. It is possible that systemic corticosteroid effects such as hypercorticism and adrenal suppression (including adrenal crisis) may appear in a small number of patients who are sensitive to these effects. If such effects occur, BREO ELLIPTA should be reduced slowly, consistent with accepted procedures for reducing systemic corticosteroids, and other treatments for management of COPD symptoms should be considered.

5.9 Drug Interactions With Strong Cytochrome P450 3A4 Inhibitors Caution should be exercised when considering the coadministration of BREO ELLIPTA with long-term ketoconazole and other known strong CYP3A4 inhibitors (e.g., ritonavir, clarithromycin, conivaptan, indinavir, itraconazole, lopinavir, nefazodone, nelfinavir, saquinavir, telithromycin, troleandomycin, voriconazole) because increased systemic corticosteroid and increased cardiovascular adverse effects may occur *[see Drug Interactions (7.1), Clinical Pharmacology (12.3) of full prescribing information]*.

5.10 Paradoxical Bronchospasm As with other inhaled medicines, BREO ELLIPTA

can produce paradoxical bronchospasm, which may be life threatening. If paradoxical bronchospasm occurs following dosing with BREO ELLIPTA, it should be treated immediately with an inhaled, short-acting bronchodilator; BREO ELLIPTA should be discontinued immediately; and alternative therapy should be instituted.

5.11 Hypersensitivity Reactions Hypersensitivity reactions may occur after administration of BREO ELLIPTA. There have been reports of anaphylactic reactions in patients with severe milk protein allergy after inhalation of other powder products containing lactose; therefore, patients with severe milk protein allergy should not take BREO ELLIPTA *[see Contraindications (4)]*.

5.12 Cardiovascular Effects Vilanterol, like other beta$_2$-agonists, can produce a clinically significant cardiovascular effect in some patients as measured by increases in pulse rate, systolic or diastolic blood pressure, and also cardiac arrhythmias, such as supraventricular tachycardia and extrasystoles. If such effects occur, BREO ELLIPTA may need to be discontinued. In addition, beta-agonists have been reported to produce electrocardiographic changes, such as flattening of the T wave, prolongation of the QTc interval, and ST segment depression, although the clinical significance of these findings is unknown. In healthy subjects, large doses of inhaled fluticasone furoate/vilanterol (4 times the recommended dose of vilanterol, representing a 12-fold higher systemic exposure than seen in patients with COPD) have been associated with clinically significant prolongation of the QTc interval, which has the potential for producing ventricular arrhythmias. Therefore, BREO ELLIPTA, like other sympathomimetic amines, should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension.

5.13 Reduction in Bone Mineral Density Decreases in bone mineral density (BMD) have been observed with long-term administration of products containing inhaled corticosteroids. The clinical significance of small changes in BMD with regard to long-term consequences such as fracture is unknown. Patients with major risk factors for decreased bone mineral content, such as prolonged immobilization, family history of osteoporosis, postmenopausal status, tobacco use, advanced age, poor nutrition, or chronic use of drugs that can reduce bone mass (e.g., anticonvulsants, oral corticosteroids) should be monitored and treated with established standards of care. Since patients with COPD often have multiple risk factors for reduced BMD, assessment of BMD is recommended prior to initiating BREO ELLIPTA and periodically thereafter. If significant reductions in BMD are seen and BREO ELLIPTA is still considered medically important for that patient's COPD therapy, use of medicine to treat or prevent osteoporosis should be strongly considered. In replicate 12-month trials in 3,255 subjects with COPD, bone fractures were reported by 2% of subjects receiving the fluticasone furoate/vilanterol combination (50 mcg/25 mcg: 2% [14 of 820 subjects]; 100 mcg/25 mcg: 2% [19 of 806 subjects]; or 200 mcg/25 mcg: 2% [14 of 811 subjects]) than in subjects receiving vilanterol 25 mcg alone (less than 1% [8 of 818 subjects]).

5.14 Glaucoma and Cataracts Glaucoma, increased intraocular pressure, and cataracts have been reported in patients with COPD following the long-term administration of inhaled corticosteroids. Therefore, close monitoring is warranted in patients with a change in vision or with a history of increased intraocular pressure, glaucoma, and/or cataracts. In replicate 12-month trials in 3,255 subjects with COPD, similar incidences of ocular effects (including glaucoma and cataracts) were reported in subjects receiving the fluticasone furoate/vilanterol combination (50 mcg/25 mcg: less than 1% [7 of 820 subjects]; 100 mcg/25 mcg: 1% [12 of 806 subjects]; 200 mcg/25 mcg: less than 1% [7 of 811 subjects]) as those receiving vilanterol 25 mcg alone (1% [9 of 818 subjects]).

5.15 Coexisting Conditions BREO ELLIPTA, like all medicines containing sympathomimetic amines, should be used with caution in patients with convulsive disorders or thyrotoxicosis and in those who are unusually responsive to sympathomimetic amines. Doses of the related beta$_2$-adrenoceptor agonist albuterol, when administered intravenously, have been reported to aggravate preexisting diabetes mellitus and ketoacidosis.

5.16 Hypokalemia and Hyperglycemia Beta-adrenergic agonist medicines may produce significant hypokalemia in some patients, possibly through intracellular shunting, which has the potential to produce adverse cardiovascular effects. The decrease in serum potassium is usually transient, not requiring supplementation. Beta-agonist medications may produce transient hyperglycemia in some patients. In 4 clinical trials of 6- and 12-month duration evaluating BREO ELLIPTA in subjects with COPD, there was no evidence of a treatment effect on serum glucose or potassium.

6 ADVERSE REACTIONS

LABA, such as vilanterol, one of the active ingredients in BREO ELLIPTA, increase the risk of asthma-related death. BREO ELLIPTA is not indicated for the treatment of asthma. *[See Boxed Warnings and Warnings and Precautions (5.1).]* Systemic and local corticosteroid use may result in the following: Increased risk of pneumonia in COPD *[see Warnings and Precautions (5.5)]*; Increased risk for decrease in bone mineral density *[see Warnings and Precautions (5.13)]*.

6.1 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 with rates in the clinical trials of another drug and may not reflect the rates observed in practice. The clinical program for BREO ELLIPTA included 7,700 subjects with COPD in two 6-month lung function trials, two 12-month exacerbation trials, and 6 other trials of shorter duration. A total of 2,034 subjects have received at least 1 dose of BREO ELLIPTA 100 mcg/25 mcg, and 1,087 subjects have received higher doses of fluticasone furoate/vilanterol. The safety data described below are based on the confirmatory 6-month and 12-month trials. Adverse reactions observed in the other trials were similar to those observed in the confirmatory trials.

6-Month Trials: The incidence of adverse reactions associated with BREO ELLIPTA in Table 1 is based on 2 placebo-controlled, 6-month clinical trials (Trials 1 and 2; n = 1,224 and n = 1,030, respectively). Of the 2,254 subjects, 70% were male and 84% were Caucasian. They had a mean age of 62 years and an average smoking history of 44 pack years, with 54% identified as current smokers. At screening, the mean postbronchodilator percent predicted FEV_1 was 48% (range: 14% to 87%), the mean postbronchodilator FEV_1/forced vital capacity (FVC) ratio was 47% (range: 17% to 88%), and the mean percent reversibility was 14% (range: -41% to 152%). Subjects received 1 inhalation once daily of the following: BREO ELLIPTA 100 mcg/25 mcg, fluticasone furoate/vilanterol 50 mcg/25 mcg, fluticasone furoate/vilanterol 200 mcg/25 mcg, fluticasone furoate 100 mcg, fluticasone furoate 200 mcg, vilanterol 25 mcg, or placebo.

Table 1. Adverse Reactions With ≥3% Incidence and More Common Than Placebo With BREO ELLIPTA in Subjects With Chronic Obstructive Pulmonary Disease

Adverse Event	BREO ELLIPTA 100 mcg/25 mcg (n = 410) %	Vilanterol 25 mcg (n = 408) %	Fluticasone Furoate 100 mcg (n = 410) %	Placebo (n = 412) %
Infections and infestations				
Nasopharyngitis	9	10	8	8
Upper respiratory tract infection	7	5	4	3
Oropharyngeal candidiasis[a]	5	2	3	2
Nervous system disorders				
Headache	7	9	7	5

[a] Includes terms oral candidiasis, oropharyngeal candidiasis, candidiasis, and oropharyngitis fungal.

12-Month Trials: Long-term safety data is based on two 12-month trials (Trials 3 and 4; n = 1,633 and n = 1,622, respectively). Trials 3 and 4 included 3,255 subjects, of which 57% were male and 85% were Caucasian. They had a mean age of 64 years and an average smoking history of 46 pack years, with 44% identified as current smokers. At screening, the mean postbronchodilator percent predicted FEV_1 was 45% (range: 12% to 91%), and the mean postbronchodilator FEV_1/FVC ratio was 46% (range: 17% to 81%), indicating that the subject population had moderate to very severely impaired airflow obstruction. Subjects received 1 inhalation once daily of the following: BREO ELLIPTA 100 mcg/25 mcg, fluticasone furoate/vilanterol 50 mcg/25 mcg, fluticasone furoate/vilanterol 200 mcg/25 mcg, or vilanterol 25 mcg. In addition to the events shown in Table 1, adverse reactions occurring in greater than or equal to 3% of the subjects treated with BREO ELLIPTA (N = 806) for 12 months included COPD, back pain, pneumonia *[see Warnings and Precautions (5.5)]*, bronchitis, sinusitis, cough, oropharyngeal pain, arthralgia, hypertension, influenza, pharyngitis, diarrhea, peripheral edema, and pyrexia.

7 DRUG INTERACTIONS

7.1 Inhibitors of Cytochrome P450 3A4 Fluticasone furoate and vilanterol, the individual components of BREO ELLIPTA, are both substrates of CYP3A4. Concomitant administration of the potent CYP3A4 inhibitor ketoconazole increases the systemic exposure to fluticasone furoate and vilanterol. Caution should be exercised when considering the coadministration of BREO ELLIPTA with long-term ketoconazole and other known strong CYP3A4 inhibitors (e.g., ritonavir, clarithromycin, conivaptan, indinavir, itraconazole, lopinavir, nefazodone, nelfinavir, saquinavir, telithromycin, troleandomycin, voriconazole) *[see Warnings and Precautions (5.9) and Clinical Pharmacology (12.3) of full prescribing information]*.

7.2 Monoamine Oxidase Inhibitors and Tricyclic Antidepressants Vilanterol, like other beta$_2$-agonists, should be administered with extreme caution to patients being treated with monoamine oxidase inhibitors, tricyclic antidepressants, or drugs known to prolong the QTc interval or within 2 weeks of discontinuation of such agents, because the effect of adrenergic agonists on the cardiovascular system may be potentiated by these agents. Drugs that are known to prolong the QTc interval have an increased risk of ventricular arrhythmias.

7.3 Beta Adrenergic Receptor Blocking Agents Beta-blockers not only block the pulmonary effect of beta-agonists, such as vilanterol, a component of BREO ELLIPTA, but may produce severe bronchospasm in patients with reversible obstructive airways disease. Therefore, patients with COPD should not normally be treated with beta-blockers. However, under certain circumstances, there may be no acceptable alternatives to the use of beta-adrenergic blocking agents for these patients; cardioselective beta-blockers could be considered, although they should be administered with caution.

7.4 Non–Potassium-Sparing Diuretics The electrocardiographic changes and/or hypokalemia that may result from the administration of non-potassium-sparing diuretics (such as loop or thiazide diuretics) can be acutely worsened by beta-agonists, especially when the recommended dose of the beta-agonist is exceeded. Although the clinical significance of these effects is not known, caution is advised in the coadministration of beta-agonists with non–potassium-sparing diuretics.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy Teratogenic Effects: Pregnancy Category C. There are no adequate and well-controlled trials with BREO ELLIPTA in pregnant women. Corticosteroids and beta$_2$-agonists have been shown to be teratogenic in laboratory animals when administered systemically at relatively low dosage levels. Because animal studies are not always predictive of human response, BREO ELLIPTA should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Women should be advised to contact their physicians if they become pregnant while

taking BREO ELLIPTA. *Fluticasone Furoate and Vilanterol:* There was no evidence of teratogenic interactions between fluticasone furoate and vilanterol in rats at approximately 9 and 40 times, respectively, the maximum recommended human daily inhalation dose (MRHDID) in adults (on a mcg/m^2 basis at maternal inhaled doses of fluticasone furoate and vilanterol, alone or in combination, up to approximately 95 mcg/kg/day). *Fluticasone Furoate:* There were no teratogenic effects in rats and rabbits at approximately 9 and 2 times, respectively, the MRHDID in adults (on a mcg/m^2 basis at maternal inhaled doses up to 91 and 8 mcg/kg/day in rats and rabbits, respectively). There were no effects on perinatal and postnatal development in rats at approximately 3 times the MRHDID in adults (on a mcg/m^2 basis at maternal doses up to 27 mcg/kg/day). *Vilanterol:* There were no teratogenic effects in rats and rabbits at approximately 13,000 and 160 times, respectively, the MRHDID in adults (on a mcg/m^2 basis at maternal inhaled doses up to 33,700 mcg/kg/day in rats and on an AUC basis at maternal inhaled doses up to 591 mcg/kg/day in rabbits). However, fetal skeletal variations were observed in rabbits at approximately 1,000 times the MRHDID in adults (on an AUC basis at maternal inhaled or subcutaneous doses of 5,740 or 300 mcg/kg/day, respectively). The skeletal variations included decreased or absent ossification in cervical vertebral centrum and metacarpals. There were no effects on perinatal and postnatal development in rats at approximately 3,900 times the MRHDID in adults (on a mcg/m^2 basis at maternal oral doses up to 10,000 mcg/kg/day).

Nonteratogenic Effects: Hypoadrenalism may occur in infants born of mothers receiving corticosteroids during pregnancy. Such infants should be carefully monitored.

8.2 Labor and Delivery There are no adequate and well-controlled human trials that have investigated the effects of BREO ELLIPTA during labor and delivery. Because beta-agonists may potentially interfere with uterine contractility, BREO ELLIPTA should be used during labor only if the potential benefit justifies the potential risk.

8.3 Nursing Mothers It is not known whether fluticasone furoate or vilanterol are excreted in human breast milk. However, other corticosteroids and $beta_2$-agonists have been detected in human milk. Since there are no data from controlled trials on the use of BREO ELLIPTA by nursing mothers, caution should be exercised when it is administered to a nursing woman.

8.5 Geriatric Use Based on available data, no adjustment of the dosage of BREO ELLIPTA in geriatric patients is necessary, but greater sensitivity in some older individuals cannot be ruled out. Clinical trials of BREO ELLIPTA for COPD included 2,508 subjects aged 65 and older and 564 subjects aged 75 and older. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger subjects.

8.6 Hepatic Impairment Fluticasone furoate systemic exposure increased by up to 3-fold in subjects with hepatic impairment compared with healthy subjects. Hepatic impairment had no effect on vilanterol systemic exposure. Use BREO ELLIPTA with caution in patients with moderate or severe hepatic impairment. Monitor patients for corticosteroid-related side effects *[see Clinical Pharmacology (12.3) of full prescribing information]*.

8.7 Renal Impairment There were no significant increases in either fluticasone furoate or vilanterol exposure in subjects with severe renal impairment (CrCl<30 mL/min) compared with healthy subjects. No dosage adjustment is required in patients with renal impairment *[see Clinical Pharmacology (12.3) of full prescribing information]*.

10 OVERDOSAGE

No human overdosage data has been reported for BREO ELLIPTA. BREO ELLIPTA contains both fluticasone furoate and vilanterol; therefore, the risks associated with overdosage for the individual components described below apply to BREO ELLIPTA.

10.1 Fluticasone Furoate Because of low systemic bioavailability (15.2%) and an absence of acute drug-related systemic findings in clinical trials, overdosage of fluticasone furoate is unlikely to require any treatment other than observation. If used at excessive doses for prolonged periods, systemic effects such as hypercorticism may occur *[see Warnings and Precautions (5.8)]*. Single- and repeat-dose trials of fluticasone furoate at doses of 50 to 4,000 mcg have been studied in human subjects. Decreases in mean serum cortisol were observed at dosages of 500 mcg or higher given once daily for 14 days.

10.2 Vilanterol The expected signs and symptoms with overdosage of vilanterol are those of excessive beta-adrenergic stimulation and/or occurrence or exaggeration of any of the signs and symptoms of beta-adrenergic stimulation (e.g., angina, hypertension or hypotension, tachycardia with rates up to 200 beats/min, arrhythmias, nervousness, headache, tremor, seizures, muscle cramps, dry mouth, palpitation, nausea, dizziness, fatigue, malaise, insomnia, hyperglycemia, hypokalemia, metabolic acidosis). As with all inhaled sympathomimetic medicines, cardiac arrest and even death may be associated with an overdose of vilanterol. Treatment of overdosage consists of discontinuation of BREO ELLIPTA together with institution of appropriate symptomatic and/or supportive therapy. The judicious use of a cardioselective beta-receptor blocker may be considered, bearing in mind that such medicine can produce bronchospasm. Cardiac monitoring is recommended in cases of overdosage.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

BREO ELLIPTA: No studies of carcinogenicity, mutagenicity, or impairment of fertility were conducted with BREO ELLIPTA; however, studies are available for the individual components, fluticasone furoate and vilanterol, as described below.

Fluticasone Furoate: Fluticasone furoate produced no treatment-related increases in the incidence of tumors in 2-year inhalation studies in rats and mice at inhaled doses up to 9 and 19 mcg/kg/day, respectively (approximately equal to the MRHDID in adults on a mcg/m^2 basis). Fluticasone furoate did not induce gene mutation in bacteria or chromosomal damage in a mammalian cell mutation test in mouse lymphoma L5178Y cells in vitro. There was also no evidence of genotoxicity in the in vivo micronucleus test in rats. No evidence of impairment of fertility was observed in male and female rats at inhaled fluticasone furoate doses up to 29 and 91 mcg/kg/day, respectively (approximately 3 and 9 times, respectively, the MRHDID in adults on a mcg/m^2 basis).

Vilanterol: In a 2-year carcinogenicity study in mice, vilanterol caused a statistically significant increase in ovarian tubulostromal adenomas in females at an inhalation dose of 29,500 mcg/kg/day (approximately 8,750 times the MRHDID in adults on an AUC basis). No increase in tumors was seen at an inhalation dose of 615 mcg/kg/day (approximately 530 times the MRHDID in adults on an AUC basis). In a 2-year carcinogenicity study in rats, vilanterol caused statistically significant increases in mesovarian leiomyomas in females and shortening of the latency of pituitary tumors at inhalation doses greater than or equal to 84.4 mcg/kg/day (greater than or equal to approximately 45 times the MRHDID in adults on an AUC basis). No tumors were seen at an inhalation dose of 10.5 mcg/kg/day (approximately 2 times the MRHDID in adults on an AUC basis). These tumor findings in rodents are similar to those reported previously for other beta-adrenergic agonist drugs. The relevance of these findings to human use is unknown. Vilanterol tested negative in the following genotoxicity assays: the in vitro Ames assay, in vivo rat bone marrow micronucleus assay, in vivo rat unscheduled DNA synthesis (UDS) assay, and in vitro Syrian hamster embryo (SHE) cell assay. Vilanterol tested equivocal in the in vitro mouse lymphoma assay. No evidence of impairment of fertility was observed in reproductive studies conducted in male and female rats at inhaled vilanterol doses up to 31,500 and 37,100 mcg/kg/day, respectively (approximately 12,000 and 14,000 times, respectively, the MRHDID in adults on a mcg/m^2 basis).

17 PATIENT COUNSELING INFORMATION

See FDA-approved patient labeling (Medication Guide and Instructions for Use)

17.1 Asthma-Related Death Patients should be informed that LABA, such as vilanterol, one of the active ingredients in BREO ELLIPTA, increase the risk of asthma-related death. BREO ELLIPTA is not indicated for the treatment of asthma.

17.2 Not for Acute Symptoms BREO ELLIPTA is not meant to relieve acute symptoms of COPD and extra doses should not be used for that purpose. Acute symptoms should be treated with a rescue inhaler such as albuterol. The physician should provide the patient with such medicine and instruct the patient in how it should be used. Patients should be instructed to notify their physicians immediately if they experience any of the following: Symptoms get worse; Need for more inhalations than usual of their rescue inhaler; Significant decrease in lung function as outlined by the physician. Patients should not stop therapy with BREO ELLIPTA without physician/provider guidance since symptoms may recur after discontinuation.

17.3 Do Not Use Additional Long-Acting $Beta_2$-Agonists When patients are prescribed BREO ELLIPTA, other medicines containing a LABA should not be used.

17.4 Risks Associated With Corticosteroid Therapy

Local Effects: Patients should be advised that localized infections with *Candida albicans* occurred in the mouth and pharynx in some patients. If oropharyngeal candidiasis develops, it should be treated with appropriate local or systemic (i.e., oral) antifungal therapy while still continuing therapy with BREO ELLIPTA, but at times therapy with BREO ELLIPTA may need to be temporarily interrupted under close medical supervision. Rinsing the mouth without swallowing after inhalation is advised to help reduce the risk of thrush.

Pneumonia: Patients with COPD who have received BREO ELLIPTA have a higher risk of pneumonia and should be instructed to contact their healthcare providers if they develop symptoms of pneumonia (e.g., fever, chills, change in sputum color, increase in breathing problems).

Immunosuppression: Patients who are on immunosuppressant doses of corticosteroids should be warned to avoid exposure to chickenpox or measles and, if exposed, to consult their physicians without delay. Patients should be informed of potential worsening of existing tuberculosis, fungal, bacterial, viral, or parasitic infections, or ocular herpes simplex.

Hypercorticism and Adrenal Suppression: Patients should be advised that BREO ELLIPTA may cause systemic corticosteroid effects of hypercorticism and adrenal suppression. Additionally, patients should be instructed that deaths due to adrenal insufficiency have occurred during and after transfer from systemic corticosteroids.

Reduction in Bone Mineral Density: Patients who are at an increased risk for decreased BMD should be advised that the use of corticosteroids may pose an additional risk.

Ocular Effects: Long-term use of inhaled corticosteroids may increase the risk of some eye problems (cataracts or glaucoma); regular eye examinations should be considered.

17.5 Risks Associated With Beta-Agonist Therapy Patients should be informed of adverse effects associated with $beta_2$-agonists, such as palpitations, chest pain, rapid heart rate, tremor, or nervousness.

BREO ELLIPTA was developed in collaboration with Theravance

GlaxoSmithKline
Research Triangle Park, NC 27709

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Keeping up with PPACA worth the time investment

Convenient sound bites do not take the place of true intelligence

BY JULIE MILLER

Julie Miller is editor-in-chief of MANAGED HEALTHCARE EXECUTIVE. She can be reached at julie.miller@advanstar.com

And so it begins! The enormous gears of the Patient Protection and Affordable Care Act (PPACA) are locking in their pointy teeth and transmitting the torque of one of the most aggressive healthcare policies in the history of the United States.

We now have less and less justification for the excuse that we "don't know" what will happen within the giant machinery of health reform. It's happening right now, today, as the state insurance exchange marketplaces open and thousands of Americans sign up for coverage.

Industry leaders must make a special effort to analyze the daily reform updates over the next several months, even though it's a time-consuming task. Your business success in 2014 will depend on being extremely nimble, and constantly watching the trends as they develop is the only way to figure out your next move.

WHAT YOU DON'T KNOW

I am always surprised by the number of "don't know" responses we receive in our annual MANAGED HEALTHCARE EXECUTIVE State of the Industry survey. This year, we specifically asked readers how well they personally understand PPACA. More than 17% said "not well." The majority of respondents, however, said they at least know the major provisions, and it was good to see that more than 28% said they know PPACA rather well.

But once in a while, a reader will use the open-ended question field on our survey form to leave a comment indicating the multiple-choice questions we ask are too difficult to answer. That excuse is no longer valid in my book. Make the effort. Get the updates. Understand the nuances.

Paul Keckley, who retired from Deloitte last month and is the only person I know who actually read PPACA from beginning to end, made a great point in one of his final blogs:

"Most in the health care industry are busy, so we default to time-savers—PowerPoint presentations with speaker notes prepared by others, talking points that make good sound bites, trade associations' legislative summaries and so on. Though helpful, they sometimes mask lack of personal knowledge about this full scope of this industry—the issues, challenges, innovations and constraints facing sectors other than our own. It takes ongoing, persistent personal study, nothing less."

Hopefully the 2014 State of the Industry forecast that we're presenting this month will be a starting point for you to consider exploring new ideas or researching ongoing trends.

For example, half of our more than 300 reader respondents believe over the next five years, newly enrolled health plan members will come into the system in worse health than current members. But a study in the September *Annals of Family Medicine* seems to indicate otherwise. If you're operating in the exchange market, you at least have some risk protection and reinsurance to back you up if needed. Even so, adverse selection will be an issue indefinitely.

Consumer interaction—as I'm sure you've already noticed—has become more integral to daily business. It's not just about marketing campaigns to retain and attract members either. Your call centers and even your network providers will become the face of your health plan brand.

Some day, when you look back on the journey of PPACA, I hope you will be able to consider yourself a leader who took the time to know and understand its implications. **MHE**

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Pros and cons of retail clinics

Retail clinics are rising in popularity, but their overall quality and impact on care coordination is still in dispute. Many say they stand in the way of patient-physician relationships.

by Morgan Lewis, Jr.

DEPARTMENTS

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COMMENTARY

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Location more critical than income level

Even low-income families have advantages in top-performing states

JULIE MILLER | EDITOR IN CHIEF

NATIONAL REPORTS — For healthcare consumers, low household income need not condemn them to low quality, but high income is not the panacea either. A scorecard released in September by the Commonwealth Fund indicates that the wide differences in healthcare experiences found in a state-by-state comparison often put high-income as well as low-income families at risk.

It all depends on where you live, according to study authors.

"Lack of insurance is probably one factor and, therefore, implementation of the Affordable Care Act can help to alleviate these differences," says David Blumenthal, MD, president of the Commonwealth Fund.

The report finds that higher-income people living in states with poor ratings on quality and access are often worse off than low-income people in states that rank at the top of the scorecard.

For example, low-income Medicare beneficiaries in top-ranking Connecticut and Wisconsin are less likely to receive medications that are known to cause health risks than are higher-income elderly in Louisiana and Alabama.

On most indicators, the experiences of low-income individuals in top-performing states exceeded the national average for all incomes, according to the report.

"Where low income individuals have insurance, they look more like their high-income counterparts," says Cathy Schoen, senior vice president. "Insurance begins to close the income gap."

Schoen says that the low-income group represents as much as 50% of the population in states such as Louisiana, Arkansas and New Mexico—three of the lowest-ranking states in the scorecard. With such a significant share of the population at risk, even small gains would potentially lower costs of healthcare. For high-poverty states, federal resources to expand coverage and invest in local health systems offer new opportunities to improve under the Patient Protection and Affordable Care Act (PPACA).

She says the potential gain could amount to millions of lives improved if all the states rose to benchmark levels.

ROOM TO IMPROVE

All states have room to improve, even top-ranking Hawaii and Wisconsin. The organization measured 30 indicators of access, prevention and quality, potentially avoidable hospital use, and health outcomes, but no state was in the top quartile for all 30. In fact, nine of the 10 top-ranked states overall had at least four indicators in the bottom half of the distribution.

"All states need to do better on preventive care," Schoen says.

Under PPACA, accountable care is being reinforced with provider bonus payment and innovation grants. Schoen says even low-ranking states like Texas have provider systems that want to improve and use measurement data to find opportunities for better care delivery. For example, Blue Cross Blue Shield of Texas recently partnered with the Memorial Hermann Physician Network to form an accountable care organization for 100,000 members.

Dr. Blumenthal is particularly concerned about states that aren't going to expand Medicaid eligibility in the near future. In areas with a gap between Medicaid and subsidized exchange coverage, there are fewer opportunities to narrow the healthcare quality and access disparities among higher and lower incomes.

"Medicaid is a lifesaver for low income Americans with poor health status," he says.

The Commonwealth Fund recommendations include expanding insurance—including Medicaid—and creating policies to hold insurers accountable for fostering timely access to provider networks and quality care. **MHE**

TOP 10 STATES
HEALTH SYSTEM PERFORMANCE FOR LOW-INCOME POPULATIONS

- Hawaii
- Wisconsin
- Vermont
- Minnesota
- Massachusetts
- Connecticut
- Rhode Island
- South Dakota
- Iowa
- Maine

Source: The Commonwealth Fund

INDICATION

BELVIQ is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of:

- 30 kg/m^2 or greater (obese), or
- 27 kg/m^2 or greater (overweight) in the presence of at least one weight-related comorbid condition (eg, hypertension, dyslipidemia, type 2 diabetes).

Limitations of Use

- The safety and efficacy of coadministration of BELVIQ with other products intended for weight loss, including prescription drugs (eg, phentermine), over-the-counter drugs, and herbal preparations, have not been established.
- The effect of BELVIQ on cardiovascular morbidity and mortality has not been established.

IMPORTANT SAFETY INFORMATION

Contraindication

- BELVIQ should not be taken during pregnancy or by women who are planning to become pregnant.

Warnings and Precautions

- BELVIQ is a serotonergic drug. The development of potentially life-threatening serotonin syndrome or Neuroleptic Malignant Syndrome (NMS)-like reactions have been reported during use of serotonergic drugs, including, but not limited to, selective serotonin-norepinephrine reuptake inhibitors, and selective serotonin reuptake inhibitors, tricyclic antidepressants, bupropion, triptans, dietary supplements such as St. John's Wort and tryptophan, drugs that impair metabolism of serotonin (including monoamine oxidase inhibitors), dextromethorphan, lithium, tramadol, antipsychotics or other dopamine antagonists,

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- Currently, 69% of adults aged 20 years or older in the United States are overweight or obese[1]

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particularly when used in combination. Patients should be monitored for the emergence of serotonin syndrome symptoms or NMS-like reactions, including agitation, hallucinations, coma, tachycardia, labile blood pressure, hyperthermia, hyperreflexia, incoordination, nausea, vomiting, diarrhea, and muscle rigidity. Treatment with BELVIQ and any concomitant serotonergic or antidopaminergic agents should be discontinued immediately if the above events occur, and supportive symptomatic treatment should be initiated.

- Patients should not take BELVIQ in combination with drugs that have been associated with valvular heart disease (eg, cabergoline). In clinical trials, 2.4% of patients taking BELVIQ and 2.0% of patients taking placebo developed valvular regurgitation: none of these patients were symptomatic. BELVIQ should be used with caution in patients with congestive heart failure (CHF). Patients who develop signs and symptoms of valvular heart disease, including dyspnea, dependent edema, CHF, or a new cardiac murmur, should be evaluated and discontinuation of BELVIQ should be considered.
- Impairment in attention, memory, somnolence, confusion, and fatigue, have been reported in patients taking BELVIQ. Patients should not drive a car or operate heavy machinery until they know how BELVIQ affects them.
- The recommended dose of 10 mg twice daily should not be exceeded, as higher doses may cause euphoria, hallucination, and dissociation. Monitor patients for the development or worsening of depression, suicidal thoughts or behaviors, and/or any changes in mood. Discontinue BELVIQ in patients who develop suicidal thoughts or behaviors.
- Weight loss may increase the risk of hypoglycemia in patients with type 2 diabetes mellitus who are being treated with antidiabetic medications, so measurement of blood sugar levels before and during treatment with BELVIQ is recommended. Decreases in doses of antidiabetic medications or changes in medication regimen should be considered.
- Men who experience priapism should immediately discontinue BELVIQ and seek emergency medical attention. BELVIQ should be used with caution with erectile dysfunction medications. BELVIQ should be used with caution in men who have conditions that might predispose them to priapism (eg, sickle cell anemia, multiple myeloma, or leukemia), or in men with anatomical deformation of the penis (eg, angulation, cavernosal fibrosis, or Peyronie's disease).
- Because BELVIQ may cause a slow heartbeat, it should be used with caution in patients with a history of bradycardia or heart block greater than first degree.
- Consider monitoring for CBC changes, prolactin excess, and pulmonary hypertension.

Most Common Adverse Reactions

- In patients without diabetes: headache (17%), dizziness (9%), fatigue (7%), nausea (8%), dry mouth (5%), and constipation (6%).
- In patients with diabetes: hypoglycemia (29%), headache (15%), back pain (12%), cough (8%), and fatigue (7%).

Nursing Mothers

- BELVIQ should not be taken by women who are nursing.

BELVIQ is a federally controlled substance (CIV) because it may be abused or lead to drug dependence.

Please see Brief Summary of Prescribing Information and references on adjacent pages.

BELVIQ® (lorcaserin HCl) IV

Eisai

BELVIQ®
(lorcaserin HCl) IV

BRIEF SUMMARY:
For prescribing information, see package insert.

INDICATIONS AND USAGE
BELVIQ is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adult patients with an initial body mass index (BMI) of:
- 30 kg/m^2 or greater (obese), or
- 27 kg/m^2 or greater (overweight) in the presence of at least one weight related comorbid condition (e.g., hypertension, dyslipidemia, type 2 diabetes)

Limitations of Use:
- The safety and efficacy of coadministration of BELVIQ with other products intended for weight loss including prescription drugs (e.g., phentermine), over-the-counter drugs, and herbal preparations have not been established
- The effect of BELVIQ on cardiovascular morbidity and mortality has not been established

DOSAGE AND ADMINISTRATION
The recommended dose of BELVIQ is 10 mg administered orally twice daily. Do not exceed recommended dose. BELVIQ can be taken with or without food. Response to therapy should be evaluated by week 12. If a patient has not lost at least 5% of baseline body weight, discontinue BELVIQ, as it is unlikely that the patient will achieve and sustain clinically meaningful weight loss with continued treatment.

CONTRAINDICATION
- Pregnancy

WARNINGS AND PRECAUTIONS
Serotonin Syndrome or Neuroleptic Malignant Syndrome (NMS)-like Reactions. BELVIQ is a serotonergic drug. The development of a potentially life-threatening serotonin syndrome or Neuroleptic Malignant Syndrome (NMS)-like reactions have been reported during use of serotonergic drugs, including, but not limited to, selective serotonin-norepinephrine reuptake inhibitors (SNRIs) and selective serotonin reuptake inhibitors (SSRIs), tricyclic antidepressants (TCAs), bupropion, triptans, dietary supplements such as St. John's Wort and tryptophan, drugs that impair metabolism of serotonin (including monoamine oxidase inhibitors [MAOIs]), dextromethorphan, lithium, tramadol, antipsychotics or other dopamine antagonists, particularly when used in combination.
Serotonin syndrome symptoms may include mental status changes (e.g., agitation, hallucinations, coma), autonomic instability (e.g., tachycardia, labile blood pressure, hyperthermia), neuromuscular aberrations (e.g., hyperreflexia, incoordination) and/or gastrointestinal symptoms (e.g., nausea, vomiting, diarrhea). Serotonin syndrome, in its most severe form, can resemble neuroleptic malignant syndrome, which includes hyperthermia, muscle rigidity, autonomic instability with possible rapid fluctuation of vital signs, and mental status changes. Patients should be monitored for the emergence of serotonin syndrome or NMS-like signs and symptoms.
The safety of BELVIQ when coadministered with other serotonergic or antidopaminergic agents, including antipsychotics, or drugs that impair metabolism of serotonin, including MAOIs, has not been systematically evaluated and has not been established.
If concomitant administration of BELVIQ with an agent that affects the serotonergic neurotransmitter system is clinically warranted, extreme caution and careful observation of the patient is advised, particularly during treatment initiation and dose increases. Treatment with BELVIQ and any concomitant serotonergic or antidopaminergic agents, including antipsychotics, should be discontinued immediately if the above events occur and supportive symptomatic treatment should be initiated.
Valvular Heart Disease. Regurgitant cardiac valvular disease, primarily affecting the mitral and/or aortic valves, has been reported in patients who took serotonergic drugs with 5-HT$_{2B}$ receptor agonist activity. The etiology of the regurgitant valvular disease is thought to be activation of 5-HT$_{2B}$ receptors on cardiac interstitial cells. At therapeutic concentrations, BELVIQ is selective for 5-HT$_{2C}$ receptors as compared to 5-HT$_{2B}$ receptors. In clinical trials of 1-year duration, 2.4% of patients receiving BELVIQ and 2.0% of patients receiving placebo developed echocardiographic criteria for valvular regurgitation at one year (mild or greater aortic regurgitation and/or moderate or greater mitral regurgitation): none of these patients was symptomatic.
BELVIQ has not been studied in patients with congestive heart failure or hemodynamically-significant valvular heart disease. Preliminary data suggest that 5HT$_{2B}$ receptors may be overexpressed in congestive heart failure. Therefore, BELVIQ should be used with caution in patients with congestive heart failure.
BELVIQ should not be used in combination with serotonergic and dopaminergic drugs that are potent 5-HT$_{2B}$ receptor agonists and are known to increase the risk for cardiac valvulopathy (e.g., cabergoline).
Patients who develop signs or symptoms of valvular heart disease, including dyspnea, dependent edema, congestive heart failure, or a new cardiac murmur while being treated with BELVIQ should be evaluated and discontinuation of BELVIQ should be considered.
Cognitive Impairment. In clinical trials of at least one year in duration, impairments in attention and memory were reported adverse reactions associated with 1.9% of patients treated with BELVIQ and 0.5% of patients treated with placebo, and led to discontinuation in 0.3% and 0.1% of these patients, respectively. Other reported adverse reactions associated with BELVIQ in clinical trials included confusion, somnolence, and fatigue.
Since BELVIQ has the potential to impair cognitive function, patients should be cautioned about operating hazardous machinery, including automobiles, until they are reasonably certain that BELVIQ therapy does not affect them adversely.
Psychiatric Disorders. Events of euphoria, hallucination, and dissociation were seen with BELVIQ at supratherapeutic doses in short-term studies. In clinical trials of at least 1-year in duration, 6 patients (0.2%) treated with BELVIQ developed euphoria, as compared with 1 patient (<0.1%) treated with placebo. Doses of BELVIQ should not exceed 10 mg twice a day.
Some drugs that target the central nervous system have been associated with depression or suicidal ideation. Patients treated with BELVIQ should be monitored for the emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior. Discontinue BELVIQ in patients who experience suicidal thoughts or behaviors.
Potential Risk of Hypoglycemia in Patients with Type 2 Diabetes Mellitus on Anti-diabetic Therapy. Weight loss may increase the risk of hypoglycemia in patients with type 2 diabetes mellitus treated with insulin and/or insulin secretagogues (e.g., sulfonylureas); hypoglycemia was observed in clinical trials with BELVIQ. BELVIQ has not been studied in combination with insulin. Measurement of blood glucose levels prior to starting BELVIQ and during BELVIQ treatment is recommended in patients with type 2 diabetes. Decreases in medication doses for anti-diabetic medications which are non-glucose-dependent should be considered to mitigate the risk of hypoglycemia. If a patient develops hypoglycemia after starting BELVIQ, appropriate changes should be made to the anti-diabetic drug regimen.
Priapism. Priapism (painful erections greater than 6 hours in duration) is a potential effect of 5-HT$_{2C}$ receptor agonism.
If not treated promptly, priapism can result in irreversible damage to the erectile tissue. Men who have an erection lasting greater than 4 hours, whether painful or not, should immediately discontinue the drug and seek emergency medical attention.
BELVIQ should be used with caution in men who have conditions that might predispose them to priapism (e.g., sickle cell anemia, multiple myeloma, or leukemia), or in men with anatomical deformation of the penis (e.g., angulation, cavernosal fibrosis, or Peyronie's disease). There is limited experience with the combination of BELVIQ and medication indicated for erectile dysfunction (e.g., phosphodiesterase type 5 inhibitors). Therefore, the combination of BELVIQ and these medications should be used with caution.
Heart Rate Decreases. In clinical trials of at least 1-year in duration, the mean change in heart rate (HR) was -1.2 beats per minute (bpm) in BELVIQ and -0.4 bpm in placebo-treated patients without diabetes and -2.0 beats per minute (bpm) in BELVIQ and -0.4 bpm in placebo-treated patients with type 2 diabetes. The incidence of HR less than 50 bpm was 5.3% in BELVIQ and 3.2% in placebo-treated patients without diabetes and 3.6% in BELVIQ and 2.0% in placebo-treated patients with type 2 diabetes. In the combined population, adverse reactions of bradycardia occurred in 0.3% of BELVIQ and 0.1% of placebo-treated patients. Use with caution in patients with bradycardia or a history of heart block greater than first degree.
Hematological Changes. In clinical trials of at least one year in duration, adverse reactions of decreases in white blood cell count (including leukopenia, lymphopenia, neutropenia, and decreased white cell count) were reported in 0.4% of patients treated with BELVIQ as compared to 0.2% of patients treated with placebo. Adverse reactions of decreases in red blood cell count (including anemia and decreases in hemoglobin and hematocrit) were reported by 1.3% of patients treated with BELVIQ as compared to 1.2% treated with placebo. Consider periodic monitoring of complete blood count during treatment with BELVIQ.
Prolactin Elevation. Lorcaserin moderately elevates prolactin levels. In a subset of placebo-controlled clinical trials of at least one year in duration, elevations of prolactin greater than the upper limit of normal, two times the upper limit of normal, and five times the upper limit of normal, measured both before and 2 hours after dosing, occurred in 6.7%, 1.7%, and 0.1% of BELVIQ-treated patients and 4.8%, 0.8%, and 0.0% of placebo-treated patients, respectively. Prolactin should be measured when symptoms and signs of prolactin excess are suspected (e.g., galactorrhea, gynecomastia). There was one patient treated with BELVIQ who developed a prolactinoma during the trial. The relationship of BELVIQ to the prolactinoma in this patient is unknown.
Pulmonary Hypertension. Certain centrally-acting weight loss agents that act on the serotonin system have been associated with pulmonary hypertension, a rare but lethal disease. Because of the low incidence of this disease, the clinical trial experience with BELVIQ is inadequate to determine if BELVIQ increases the risk for pulmonary hypertension.

ADVERSE REACTIONS
Clinical Trials Experience. In the BELVIQ placebo-controlled clinical database of trials of at least one year in duration, of 6888 patients (3451 BELVIQ vs. 3437 placebo; age range 18-66 years, 79.3% women, 66.6% Caucasians, 19.2% Blacks, 11.8% Hispanics, 2.4% other, 7.4% type 2 diabetics), a total of 1969 patients were exposed to BELVIQ 10 mg twice daily for 1 year and 426 patients were exposed for 2 years.
In clinical trials of at least one year in duration, 8.6% of patients treated with BELVIQ prematurely discontinued treatment due to adverse reactions, compared with 6.7% of placebo-treated patients. The most common adverse reactions leading to discontinuation more often among BELVIQ treated patients than placebo were headache (1.3% vs. 0.8%), depression (0.9% vs. 0.5%) and dizziness (0.7% vs. 0.2%).

Most Common Adverse Reactions

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.
The most common adverse reactions for non-diabetic patients (greater than 5% and more commonly than placebo) treated with BELVIQ compared to placebo were headache, dizziness, fatigue, nausea, dry mouth, and constipation. The most common adverse reactions for diabetic patients were hypoglycemia, headache, back pain, cough, and fatigue. Adverse reactions that were reported by greater than or equal to 2% of patients and were more frequently reported by patients taking BELVIQ compared to placebo are summarized in Table 1 (non-diabetic subjects) and Table 2 (subjects with type 2 diabetes mellitus).

Table 1. Adverse Reactions Reported by Greater Than or Equal to 2% of BELVIQ Patients and More Commonly than with Placebo in Patients without Diabetes Mellitus

	Number of Patients (%)	
Adverse Reaction	**BELVIQ 10 mg BID N=3195**	**Placebo N=3185**
Gastrointestinal Disorders		
Nausea	264 (8.3)	170 (5.3)
Diarrhea	207 (6.5)	179 (5.6)
Constipation	186 (5.8)	125 (3.9)
Dry mouth	169 (5.3)	74 (2.3)
Vomiting	122 (3.8)	83 (2.6)
General Disorders And Administration Site Conditions		
Fatigue	229 (7.2)	114 (3.6)
Infections And Infestations		
Upper respiratory tract infection	439 (13.7)	391 (12.3)
Nasopharyngitis	414 (13.0)	381 (12.0)
Urinary tract infection	207 (6.5)	171 (5.4)
Musculoskeletal And Connective Tissue Disorders		
Back pain	201 (6.3)	178 (5.6)
Musculoskeletal pain	65 (2.0)	43 (1.4)
Nervous System Disorders		
Headache	537 (16.8)	321 (10.1)
Dizziness	270 (8.5)	122 (3.8)
Respiratory, Thoracic And Mediastinal Disorders		
Cough	136 (4.3)	109 (3.4)
Oropharyngeal pain	111 (3.5)	80 (2.5)
Sinus congestion	93 (2.9)	78 (2.4)
Skin And Subcutaneous Tissue Disorders		
Rash	67 (2.1)	58 (1.8)

Table 2. Adverse Reactions Reported by Greater Than or Equal to 2% of BELVIQ Patients and More Commonly than with Placebo in Patients with Type 2 Diabetes Mellitus

	Number of Patients (%)	
Adverse Reaction	**BELVIQ 10 mg BID N=256**	**Placebo N=252**
Gastrointestinal Disorders		
Nausea	24 (9.4)	20 (7.9)
Toothache	7 (2.7)	0

(Table continues)

Table 2. (cont'd.)

Adverse Reaction	Number of Patients (%)	
	BELVIQ 10 mg BID N=256	Placebo N=252
General Disorders And Administration Site Conditions		
Fatigue	19 (7.4)	10 (4.0)
Peripheral edema	12 (4.7)	6 (2.4)
Immune System Disorders		
Seasonal allergy	8 (3.1)	2 (0.8)
Infections And Infestations		
Nasopharyngitis	29 (11.3)	25 (9.9)
Urinary tract infection	23 (9.0)	15 (6.0)
Gastroenteritis	8 (3.1)	5 (2.0)
Metabolism And Nutrition Disorders		
Hypoglycemia	75 (29.3)	53 (21.0)
Worsening of diabetes mellitus	7 (2.7)	2 (0.8)
Decreased appetite	6 (2.3)	1 (0.4)
Musculoskeletal And Connective Tissue Disorders		
Back pain	30 (11.7)	20 (7.9)
Muscle spasms	12 (4.7)	9 (3.6)
Nervous System Disorders		
Headache	37 (14.5)	18 (7.1)
Dizziness	18 (7.0)	16 (6.3)
Psychiatric Disorders		
Anxiety	9 (3.5)	8 (3.2)
Insomnia	9 (3.5)	6 (2.4)
Stress	7 (2.7)	3 (1.2)
Depression	6 (2.3)	5 (2.0)
Respiratory, Thoracic And Mediastinal Disorders		
Cough	21 (8.2)	11 (4.4)
Vascular Disorders		
Hypertension	13 (5.1)	8 (3.2)

Other Adverse Reactions

Serotonin-associated Adverse Reactions. SSRIs, SNRIs, bupropion, tricyclic antidepressants, and MAOIs were excluded from the BELVIQ trials. Triptans and dextromethorphan were permitted: 2% and 15%, respectively, of patients without diabetes and 1% and 12%, respectively, of patients with type 2 diabetes experienced concomitant use at some point during the trials. Two patients treated with BELVIQ in the clinical program experienced a constellation of symptoms and signs consistent with serotonergic excess, including one patient on concomitant dextromethorphan who reported an event of serotonin syndrome. Some symptoms of possible serotonergic etiology that are included in the criteria for serotonin syndrome were reported by patients treated with BELVIQ and placebo during clinical trials of at least 1 year in duration. In both groups, chills were the most frequent of these events (1.0% vs. 0.2%, respectively), followed by tremor (0.3% vs. 0.2%), confusional state (0.2% vs. less than 0.1%), disorientation (0.1% vs. 0.1%) and hyperhidrosis (0.1% vs. 0.2%). Because serotonin syndrome has a very low incidence, an association between BELVIQ and serotonin syndrome cannot be excluded on the basis of clinical trial results.

Hypoglycemia in Patients with Type 2 Diabetes. In a clinical trial of patients with type 2 diabetes mellitus, hypoglycemia requiring the assistance of another person occurred in 4 (1.6%) of BELVIQ-treated patients and in 1 (0.4%) placebo-treated patient. Of these 4 BELVIQ-treated patients, all were concomitantly using a sulfonylurea (with or without metformin). BELVIQ has not been studied in patients taking insulin. Hypoglycemia defined as blood sugar less than or equal to 65 mg/dL and with symptoms occurred in 19 (7.4%) BELVIQ-treated patients and 16 (6.3%) placebo-treated patients.

Cognitive Impairment. In clinical trials of at least 1-year duration, adverse reactions related to cognitive impairment (e.g., difficulty with concentration/attention, difficulty with memory, and confusion) occurred in 2.3% of patients taking BELVIQ and 0.7% of patients taking placebo.

Psychiatric Disorders. Psychiatric disorders leading to hospitalization or drug withdrawal occurred more frequently in patients treated with BELVIQ (2.2%) as compared to placebo (1.1%) in non-diabetic patients.

Euphoria. In short-term studies with healthy individuals, the incidence of euphoric mood following supratherapeutic doses of BELVIQ (40 and 60 mg) was increased as compared to placebo. In clinical trials of at least 1-year duration in obese patients, euphoria was observed in 0.17% of patients taking BELVIQ and 0.03% taking placebo.

Depression and Suicidality. In trials of at least one year in duration, reports of depression/mood problems occurred in 2.6% BELVIQ-treated vs. 2.4% placebo-treated and suicidal ideation occurred in 0.6% BELVIQ-treated vs. 0.4% placebo-treated patients. 1.3% of BELVIQ patients vs. 0.6% of placebo patients discontinued drug due to depression-, mood-, or suicidal ideation-related events.

Laboratory Abnormalities. *Lymphocyte and Neutrophil Counts.* In clinical trials of at least 1-year duration, lymphocyte counts were below the lower limit of normal in 12.2% of patients taking BELVIQ and 9.0% taking placebo, and neutrophil counts were low in 5.6% and 4.3%, respectively.

Hemoglobin. In clinical trials of at least 1-year duration, 10.4% of patients taking BELVIQ and 9.3% taking placebo had hemoglobin below the lower limit of normal at some point during the trials.

Prolactin. In clinical trials, elevations of prolactin greater than the upper limit of normal, two times the upper limit of normal, and five times the upper limit of normal, occurred in 6.7%, 1.7%, and 0.1% of BELVIQ-treated patients and 4.8%, 0.8%, and 0.0% of placebo-treated patients, respectively.

Eye Disorders. More patients on BELVIQ reported an eye disorder than patients on placebo in clinical trials of patients without diabetes (4.5% vs. 3.0%) and with type 2 diabetes (6.3% vs. 1.6%). In the population without diabetes, events of blurred vision, dry eye, and visual impairment occurred in BELVIQ-treated patients at an incidence greater than that of placebo. In the population with type 2 diabetes, visual disorders, conjunctival infections, irritations, and inflammations, ocular sensation disorders, and cataract conditions occurred in BELVIQ-treated patients at an incidence greater than placebo.

Echocardiographic Safety Assessments

The possible occurrence of regurgitant cardiac valve disease was prospectively evaluated in 7794 patients in three clinical trials of at least one year in duration, 3451 of whom took BELVIQ 10 mg twice daily. The primary echocardiographic safety parameter was the proportion of patients who developed echocardiographic criteria of mild or greater aortic insufficiency and/or moderate or greater mitral insufficiency from baseline to 1 year. At 1 year, 2.4% of patients who received BELVIQ and 2.0% of patients who received placebo developed valvular regurgitation. The relative risk for valvulopathy with BELVIQ is summarized in Table 3. BELVIQ was not studied in patients with congestive heart failure or hemodynamically-significant valvular heart disease.

Table 3. Incidence of FDA-Defined Valvulopathy at Week 52 by Treatment Group[1]

	Study 1		Study 2		Study 3	
	BELVIQ N=1278	Placebo N=1191	BELVIQ N=1208	Placebo N=1153	BELVIQ N=210	Placebo N=209
FDA-defined Valvulopathy, n (%)	34 (2.7)	28 (2.4)	24 (2.0)	23 (2.0)	6 (2.9)	1 (0.5)
Relative Risk (95% CI)	1.13 (0.69, 1.85)		1.00 (0.57, 1.75)		5.97 (0.73, 49.17)	
Pooled RR (95% CI)	**1.16 (0.81, 1.67)**					

[1] Patients without valvulopathy at baseline who received study medication and had a post-baseline echocardiogram; ITT-intention-to-treat; LOCF-last observation carried forward.

DRUG INTERACTIONS

Use with Other Agents that Affect Serotonin Pathways. Based on the mechanism of action of BELVIQ and the theoretical potential for serotonin syndrome, use with extreme caution in combination with other drugs that may affect the serotonergic neurotransmitter systems, including, but not limited to, triptans, monoamine oxidase inhibitors (MAOIs, including linezolid, an antibiotic which is a reversible non-selective MAOI), selective serotonin reuptake inhibitors (SSRIs), selective serotonin-norepinephrine reuptake inhibitors (SNRIs), dextromethorphan, tricyclic antidepressants (TCAs), bupropion, lithium, tramadol, tryptophan, and St. John's Wort.

Cytochrome P450 (2D6) substrates. Use caution when administering BELVIQ together with drugs that are CYP 2D6 substrates, as BELVIQ can increase exposure of these drugs.

USE IN SPECIFIC POPULATIONS

Pregnancy. Pregnancy Category X.

Risk Summary. BELVIQ is contraindicated during pregnancy, because weight loss offers no potential benefit to a pregnant woman and may result in fetal harm. Maternal exposure to lorcaserin in late pregnancy in rats resulted in lower body weight in offspring which persisted to adulthood. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard of maternal weight loss to the fetus.

Clinical Considerations. A minimum weight gain, and no weight loss, is currently recommended for all pregnant women, including those who are already overweight or obese, due to the obligatory weight gain that occurs in maternal tissues during pregnancy.

Animal Data. Reproduction studies were performed in pregnant rats and rabbits that were administered lorcaserin during the period of embryofetal organogenesis. Plasma exposures up to 44 and 19 times human exposure in rats and rabbits, respectively, did not reveal evidence of teratogenicity or embryolethality with lorcaserin hydrochloride.

In a pre- and postnatal development study, maternal rats were dosed from gestation through post-natal day 21 at 5, 15, and 50mg/kg lorcaserin; pups were indirectly exposed in utero and throughout lactation. The highest dose (~44 times human exposure) resulted in stillborns and lower pup viability. All doses lowered pup body weight similarly at birth which persisted to adulthood; however, no developmental abnormalities were observed and reproductive performance was not affected at any dose.

Nursing Mothers. It is not known whether BELVIQ is excreted in human milk. Because many drugs are excreted in human milk, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use. The safety and effectiveness of BELVIQ in pediatric patients below the age of 18 have not been established and the use of BELVIQ is not recommended in pediatric patients.

Geriatric Use. In the BELVIQ clinical trials, a total of 135 (2.5%) of the patients were 65 years of age and older. Clinical studies of BELVIQ did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects, but greater sensitivity of some older individuals cannot be ruled out.

Since elderly patients have a higher incidence of renal impairment, use of BELVIQ in the elderly should be made on the basis of renal function. Elderly patients with normal renal function should require no dose adjustment.

Renal Impairment. No dose adjustment of BELVIQ is required in patients with mild renal impairment. Use BELVIQ with caution in patients with moderate renal impairment. Use of BELVIQ in patients with severe renal impairment or end stage renal disease is not recommended.

Hepatic Impairment. Dose adjustment is not required for patients with mild hepatic impairment (Child-Pugh score 5-6) to moderate hepatic impairment (Child-Pugh score 7-9). The effect of severe hepatic impairment on lorcaserin was not evaluated. Use lorcaserin with caution in patients with severe hepatic impairment.

DRUG ABUSE AND DEPENDENCE

Controlled Substance. BELVIQ is listed in Schedule IV of the Controlled Substances Act.

Abuse. In a human abuse potential study in recreational drug abusers, supratherapeutic oral doses of lorcaserin (40 and 60 mg) produced up to two- to six-fold increases on measures of "High", "Good Drug Effects", "Hallucinations" and "Sedation" compared to placebo. These responses were similar to those produced by oral administration of the positive control drugs, zolpidem (15 and 30 mg) and ketamine (100 mg). In this study, the incidence of the adverse reaction of euphoria following lorcaserin administration (40 and 60 mg; 19%) is similar to the incidence following zolpidem administration (13-16%), but less than the incidence following ketamine administration (50%). The duration of euphoria following lorcaserin administration persisted longer (> 9 hours) than that following zolpidem (1.5 hours) or ketamine (2.5 hours) administration.

Overall, in short-term studies with healthy individuals, the rate of euphoria following oral administration of lorcaserin was 16% following 40 mg (n = 11 of 70) and 19% following 60 mg (n = 6 of 31). However, in clinical studies with obese patients with durations of 4 weeks to 2 years, the incidence of euphoria and hallucinations following oral doses of lorcaserin up to 40 mg was low (< 1.0%).

Dependence. There are no data from well-conducted animal or human studies that evaluate whether lorcaserin can induce physical dependence, as evidenced by a withdrawal syndrome. However, the ability of lorcaserin to produce hallucinations, euphoria, and positive subjective responses at supratherapeutic doses suggests that lorcaserin may produce psychic dependence.

OVERDOSAGE

No experience with overdose of BELVIQ is available. In clinical studies that used doses that were higher than the recommended dose, the most frequent adverse reactions associated with BELVIQ were headache, nausea, abdominal discomfort, and dizziness. Single 40- and 60-mg doses of BELVIQ caused euphoria, altered mood, and hallucination in some subjects. Treatment of overdose should consist of BELVIQ discontinuation and general supportive measures in the management of overdosage. BELVIQ is not eliminated to a therapeutically significant degree by hemodialysis.

References: 1. Flegal KM, Carroll MD, Kit BK, Ogden CL. Prevalence of obesity and trends in the distribution of body mass index among US adults, 1999-2010. *JAMA.* 2012;307(5):491-497. **2.** BELVIQ [package insert]. Woodcliff Lake, NJ: Eisai Inc; 2012.

Eisai

Role of EMRs slowly shifting from data vessel to decision tool

Patients have new demand for open access to their medical records

JULIE MILLER
EDITOR IN CHIEF

NATIONAL REPORTS — While the use of electronic medical records (EMRs) is rising, observers are examining the ultimate value and ideal use of health IT systems. A global study by Accenture recently found that U.S. physicians agree that health IT is beneficial, but cost remains a barrier to adoption.

As part of the American Recovery and Reinvestment Act of 2009, the federal government began offering financial assistance to providers that adopted health IT and put it to meaningful use. The Centers for Medicare and Medicaid Services has handed out $9.5 billion to Medicare providers and $6 billion to Medicaid providers in incentive payments as of July.

Kaveh Safavi JD, MD, managing director of Accenture's North America health business, says use of health IT has increased 32% since 2012, even with the cost concerns. And the benefits are broad enough to justify the investment.

"It's worth noting that the Meaningful Use mandates introduced an unintentional benefit for EMRs," Dr. Safavi says. "The role of an EMR has shifted from a mere clinical repository to a platform for shared decision-making among patients and doctors. This matters because when consumers are part of the record-keeping process, it can increase their understanding of conditions, improve motivation and serve as a clear differentiator for clinical care."

Providers have long been resistant to allowing patient access to medical records for a variety of reasons, including the risk of misunderstanding, which could cause undue anxiety for patients. Dr. Safavi says a Robert Wood Johnson Foundation study last year found that patients who were able to review open medical notes reported a better understanding of their health conditions, felt more in control of their care and improved their engagement.

"Currently, four out of five consumers—84%—believe they should have full access to their EMR, while only one-third—31%—of doctors share this belief," he says.

Patients tend to have the most access to their physicians' healthcare IT capabilities in Singapore, the United States and Spain, according to the Accenture study. For instance, the United States reports 43% of consumers are able to access their electronic medical records, 48% refill prescriptions electronically, and 36% email physicians.

U.S. physicians increasingly use systems for patient-information record-keeping, alerts and reminders. For example, 78% of respondents say they used health IT to enter patient notes in 2012, as opposed to just 58% in 2011. The trend for use of administrative e-tools, however, declined from 61% in 2011 to 55% in 2012.

Top benefits of health IT for physicians include reduced medical errors and improved diagnostic decisions. Fewer physicians believe health IT helps them see more patients, however.

LATENT DEMAND

The most surprising finding of the Accenture study was that 41% of U.S. consumers would be willing to switch doctors to gain access to their electronic medical records, according to Dr. Safavi.

"This finding suggests a latent demand that we expect will become more evident in the market as capabilities emerge to help support decisions and information management," he says. "The reality is that consumers have the ability to self-manage many areas of their lives, and we expect that an EMR will soon have an integral role in patient engagement." **MHE**

Kentucky co-op leverages outreach

JOANNE SAMMER
MHE CONTRIBUTOR

LOUISVILLE, KY — As a new health plan, Kentucky Health Cooperative needs to be all things to all people—on a budget. As the state gets ready for the first year of operation for its "kynect" health insurance exchange, Kentucky Health Cooperative (KHC) is preparing to insure "tens of thousands" of individuals and families.

Leaders for the cooperative are not sure where it will rank relative to the rest of the market in terms of enrollment and premium costs.

"However, we do think that we will be very competitive," says Janie Miller, Kentucky Health Cooperative's CEO. "We expect a large percentage of the uninsured and underinsured populations to be eligible to receive a premium subsidy."

The organization began with a federal loan agreement signed in June 2012, which provides $11.9 million of start-up

*See **Kentucky** on pg. 16*

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Kentucky *from pg. 14*

funding that is made available as the plan achieves specific milestones in the development process, as well as $46.8 million in solvency funding. The loan letter of agreement was signed before the federal government cut new funding for the program overall.

KHC itself was established as a result of actions by "business and community leaders, particularly those involved with primary care and federally qualified health centers throughout Kentucky, who are very familiar with the issues of the uninsured and the lack of access to health coverage," says Miller.

What is also clear is that, given the state's population, the co-op's enrollees are likely to include many individuals with cardiovascular disease, cancer, smoking-related conditions, obesity and other serious and chronic conditions. For that reason, the plan is preparing to help consumers to navigate the healthcare system and to deal with pent-up demand.

"We will be reaching out to those members and helping them to identify a medical home where they can obtain needed care," says Miller.

The outreach could extend to helping individuals to make their first appointment with a physician.

Because the co-op cannot use loan funds for marketing, it has no marketing budget to begin open enrollment season. Therefore, outreach and education is the best way to attract members. **MHE**

PERCEPTION OF CO-OPS IN THE NEXT 3 TO 5 YEARS

Survey Answer	Percentage of Respondents
Significant players in the market	33%
Not significant players in the market	21.6%
Don't know	45.4%

Source: MHE State of the Industry Survey, August 2013

MemorialCare's new plan manages state coordination demo

Seaside health plan hits the ground running with service contracts

JOANNE SAMMER
MHE CONTRIBUTOR

NATIONAL REPORTS — On September 1, MemorialCare Health System, a not-for-profit integrated delivery system with six hospitals, launched its Seaside Health Plan as perhaps a hedge against the ongoing uncertainty surrounding the future of healthcare.

"We are now moving from a being a system of hospitals to becoming a fully integrated health system," says Barry Arbuckle, PhD, MemorialCare Health System president and CEO. "The addition of a health plan license will be useful in the immediate term but also has some potential longer-term strategic value."

MANAGING RISK

As payers move from traditional fee-for-service to risk-based reimbursement, Arbuckle notes that many physicians believe that they can better serve the community by "being in a position to own and operate the health plan that allows them to make some utilization decisions, rather than having some other middle person doing so."

Rather than building its own infrastructure to support the plan, Seaside began by acquiring the assets of Universal Care in November 2012. The deal included the retention of certain key staff members with experience in health plan operations, as well as plan-to-plan contracts to be serviced by assignment of agreements with Universal Care's contracted providers and MemorialCare's primary care physician network.

The plan-to-plan contracts allow Seaside to operate like a health plan but partner with other health plans for certain services, including claims processing and marketing.

"We wanted to be able to hit the ground running with greater success and less expense," says Arbuckle.

Seaside will not be participating in the California health insurance exchange in 2014 and it is evaluating whether to participate in 2015.

A key initiative for Seaside Health Plan is the demonstration project it is operating for California Children's Services. The project is one of five in the state designed to create a managed care environment for children with certain chronic conditions that will require lifelong care.

"These kids typically see multiple specialists for a lifetime," says Arbuckle. "The care for these patients has historically been quite uncoordinated and paid on a fee-for-service basis. The demonstration project is moving that care back to more of a managed care, fully coordinated mode."

The project has the added benefit of being able to move children out of the demonstration project and into the Seaside Health Plan under Medi-Cal if they qualify when they turn 18 years old.

"Because we are a health plan, we can continue to cover them, and we have the systems necessary to hand them off seamlessly," says Arbuckle.

Seaside was approved with a Knox Keene health plan license earlier this year. It currently contracts with certain partner health plans that include Health Net, L.A. Care Health Plan, Anthem Blue Cross, Blue Shield of California and Care 1st Health Plan. **MHE**

PPOs remain most favored plan among employer populations

HMOs continue to lose ground while high-deductible plans level off

JULIE MILLER
EDITOR IN CHIEF

NATIONAL REPORTS — PPO health plans remain the top choice among workers, according to the 2013 Kaiser Family Foundation/Health Research and Educational Trust (KFF/HRET) annual survey. In fact, PPOs cover more than half of all workers who report receiving health benefits.

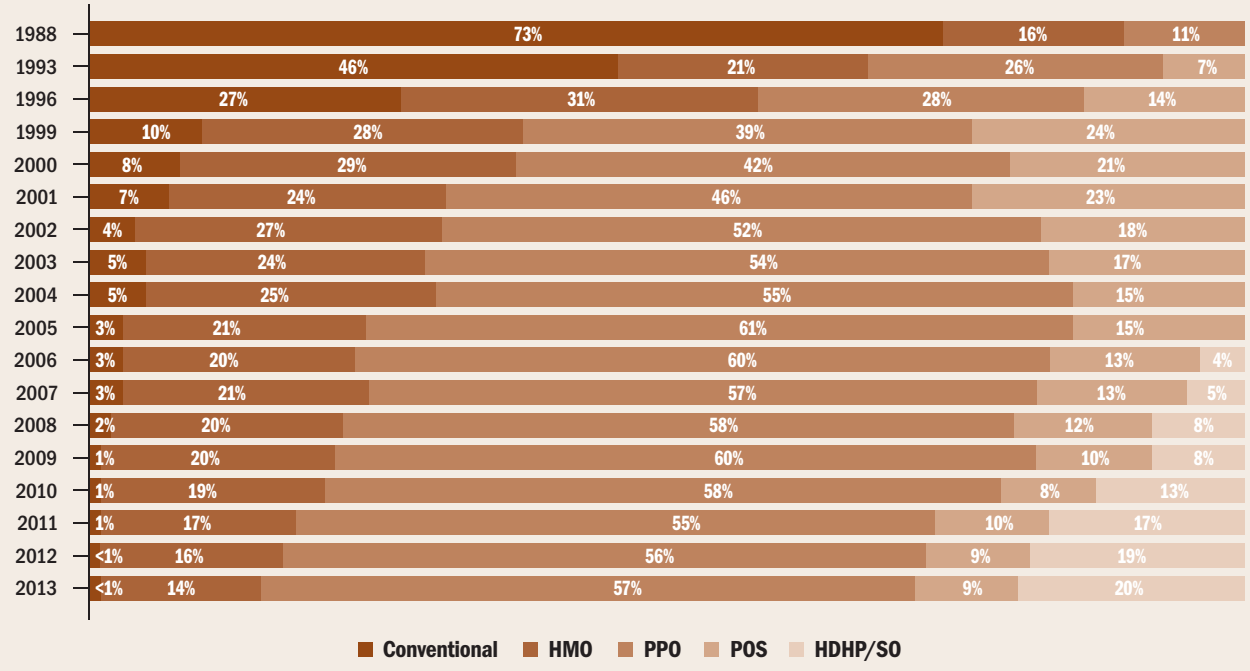
Fifty-seven percent of covered workers are enrolled in PPOs, followed by high-deductible health plans (20%), HMOs (14%), POS plans (9%) and conventional plans (<1%).

Historically, HMOs peaked in 1996 with 31% of covered workers enrolled, but the trend shows a continuous decline. In 2013, only 14% of workers were covered by HMO plans.

According to KFF/HRET, enrollment in high-deductible health plans (HDHP)—which emerged in 2006 on the survey—has leveled off after several years of increases. Workers in the Midwest are more likely to be enrolled in such plans. Average premiums for high-deductible health plans with a savings option (SO) are lower than the overall average for all plan types for both single and family coverage, at $5,306 and $15,227, respectively.

The savings option—often a tax-advantaged Health Savings Account—can only be used to pay qualified medical expenses. Balances roll over. For 2013, federal law allows account contributions up to $3,250 for a single person and $6,450 for a family, however, rules also allow those over the age of 55 to contribute more. **MHE**

DISTRIBUTION OF HEALTH PLAN ENROLLMENT FOR COVERED WORKERS, BY PLAN TYPE, 1988-2013



NOTE: Information was not obtained for POS plans in 1988. A portion of the change in plan type enrollment for 2005 is likely attributable to incorporating more recent Census Bureau estimates of the number of state and local government workers and removing federal workers from the weights. See the Survey Design and Methods section from the 2005 Kaiser/HRET Survey of Employer-Sponsored Health Benefits for additional information.

Source: Kaiser/HRET Survey of Employer-Sponsored Health Benefits, 1999-2013; KPMG Survey of Employer-Sponsored Health Benefits, 1993, 1996; The Health Insurance Association of America (HIAA), 1988.

Health reform erodes revenue for insurers

While HHS touts big savings for consumers, insurers feel the pinch on prices

BY JILL WECHSLER

Jill Wechsler, a veteran reporter, has been covering Capitol Hill since 1994.

The Department of Health and Human Services (HHS) rolled out reports documenting big gains for consumers from health reform last month. In addition to promising affordable coverage rates, the Obama administration highlighted savings already achieved under the Patient Protection and Affordable Care Act (PPACA).

According to HHS, the premium rate review program established by PPACA saved consumers $1.2 billion in 2012 by pressuring insurers to lower proposed increases. Insurance companies also paid $500 million in rebates under new rules limiting the medical loss ratios (MLR) on health plans, bringing the savings from these two provisions up to $1.7 billion.

Furthermore, HHS calculates that the MLR rule saved consumers another $3.4 billion by compelling insurers to reduce premiums and "operate more efficiently."

While these programs may cut costs for consumers in the short run, they also erode insurer revenues and profits.

The cuts from rate review were most notable in the small group market, where "high" (over 10%) rate change requests dropped from 16% to 9.7%, according the HHS assistant secretary for policy and evaluation (ASPE). This pushed the average rate change down by 19% (from 5.8% to 4.7%), saving 3.4 million consumers about $866 million.

Similarly, high rate-change requests in the individual market dropped from 14% to 12%, reducing premium increases by $311 million. Total savings thus added up to $1.2 billion.

ASPE also concludes that insurers were much less likely to request rate increases of 10% or more in 2012 than previously, knowing that hefty hikes would be scrutinized closely by state regulators and HHS. In 2012, 26% of rate increases in the individual market exceeded 10%, compared to 43% of rate hikes proposed in 2011.

The analysis by ASPE, though, doesn't highlight the fact that HHS approved most high rate increase requests. Only 28% of requests for high rate increases in 2012 were rejected by regulators or modified by the issuer.

LOWER MARGINS

Meanwhile, the MLR policy had a noticeable impact on insurer profitability, a development seen as beneficial or troubling, depending on one's viewpoint. Insurers reduced administrative costs and lowered premiums to meet the new spending standards, as published in the September 2013 issue of *Health Affairs*.

The data indicates that in 2011, the first year the MLR policy was in effect, insurers in the individual market saw MLRs rise 5.5% overall. This had an impact on the bottom line, as operating margins dropped 1.3% for all insurers, and 2.2% at for-profit firms.

The lesser impact on non-profit firms is evidence, according to the authors, that these insurers already were spending more on healthcare services and keeping profits low, so they didn't have to make big adjustments. Changes in spending and margins also were less notable in the small- and large-group markets, where administrative costs and premiums generally are lower for all insurers.

The larger issue is whether insurers can offer high-quality affordable healthcare coverage, especially in the individual market, and meet all the PPACA requirements. The premiums and benefits provided through exchanges will provide some answers. **MHE**

Navigator role still raises valid questions

Will the 34 federally facilitated and state-partnership marketplace Navigator programs be sufficient?

J. RYAN WILLIAMS, ESQ.

J. Ryan Williams, Esq. is a partner in the Health Care & Bioscience Practice Group of Cleveland-based Walter | Haverfield, LLP.

One resource carved out in the Patient Protection and Affordable Care Act is "Navigators." Federally facilitated, state-partnership and state-based marketplaces are all required to set up a Navigator program. They will primarily provide in-person and impartial information to consumers about the different Qualified Health Plans, walk consumers through the selection process, and conduct public outreach and education efforts.

Although the Act stipulates the availability of Navigators, it does not spell out how and when these programs will be implemented. The answer to this question is only beginning to emerge. On August 15, the U.S. Department of Health and Human Services (HHS) awarded $67 million to 105 Navigator grant applicants. The grant recipients can share their awards with organizations to hire and train individual Navigators, or they can hire and train Navigators themselves.

While $67 million may seem like a lot to allocate toward the programs, some marketplaces received less than others. For example, Texas received the largest total award with $10.9 million, but more than 10 marketplaces received less than $1 million to implement a Navigator program.

However, these numbers really begin to raise questions of capability when you consider how much money marketplaces are allocating toward their own programs. Maryland will be spending $24 million to dispatch more than 325 Navigators, Colorado will spend more than $17 million on 400 Navigators, and New York will spend $27 million.

These figures raise a number of questions. How many Navigators will be needed to assist consumers? Are state-based marketplaces spending too much? Will the 34 federally facilitated and state-partnership marketplace programs be insufficient? Will the Navigators be trained and available in time?

On top of this, several of the grantees were forced to quickly respond to a Congressional inquiry. While some have said the inquiry is nothing more than partisan politics, the inquiry appeared to divert attention away from the Navigator grantees' necessary work—preparing for the launch of the marketplaces. With all of these questions and uncertainties, all interested parties—not just consumers—should keep an active eye on the developments of the Navigator programs.

ROLE OF THE BROKER

In addition, another option that HHS views as a "critical" resource is agents or brokers. HHS requires that agents or brokers wishing to work on the marketplace complete an online marketplace-specific training program and register for specific IDs.

Agents and brokers will continue to be hired by insurance issuers, and their compensation arrangements will be negotiated with the insurance issuer.

They will not be required to provide impartial information like Navigators. HHS recognizes that they will provide consumers information specific to the plans of the insurer that hired them. However, HHS does expect agents and brokers to inform the consumer that they can directly access their marketplace's website, which lists all available Qualified Health Plans.

Like Navigators, it is unclear how many marketplace brokers or agents will be needed to serve as the "critical" resource HHS expects that they will serve. **MHE**

This column is written for informational purposes only and should not be construed as legal advice.

Engagement drives use of preventive services

Health plans are supporting providers by offering outcomes-driven engagement programs for members

BY JORAN DOLIN

Jordan Dolin is co-founder of Emmi Solutions, a healthcare communications company that builds technology-focused patient empowerment solutions.

New models of care, including accountable care organizations and medical homes, are looking for the most cost-effective and efficient way to manage the health of large populations. This is a major challenge, and patient engagement is the ideal way to address the issue, especially when it comes to preventive care.

Take, for example, colonoscopies. Despite colorectal cancer being the second-leading cause of cancer-related deaths in the United States, and one of the most preventable, only 53% of people 50 years and older follow recommendations for screenings.

On the surface, the new preventive services provision under the Patient Protection and Affordable Care Act (PPACA) should help address this issue, as the screenings are one of many preventive services that insurers must now cover without cost-sharing.

With an estimated 71 million Americans now eligible for copay-free colonoscopies, what remains to be seen is the level at which patients will take advantage of this benefit. That's why forward-thinking health plans are supporting providers by offering outcomes-driven engagement programs that close gaps and inspire members to take action.

Consider the fact that access, plus affordability, plus engagement, equals prevention.

These engagement strategies are powerful ways to increase utilization of preventive services, such as colonoscopies, while also boosting member satisfaction and loyalty:

Multi-modal communication: Increasingly, we are learning that there is no one-size-fits-all approach to messaging. Programs must be offered in multi-modal ways (Web-based, automated interactive phone calls, email, text messaging and mail). If the goal is to put patients at the center of care, then engagement efforts need to be designed with their convenience in mind. Patients need tools that allow them to be engaged on their terms, when and where they choose, and on the devices they already own.

Customized contact: Tools that gauge individual members' ability and interest in managing their own health and healthcare, such as the Patient Activation Measure (PAM), can be used to meet patients where they are, tailor engagement strategies and increase activation levels.

Web-based interactive programs: These initiatives can increase the bandwidth of providers, while also freeing up more of their time to deliver care. Web-based programs can be leveraged not only to motivate members to schedule colorectal cancer screenings and other types of preventive care, but also to follow through. Surveys show that only 23% to 58% of patients who schedule colonoscopies keep those appointments. This wastes resources, increases costs and extends the waiting time for others seeking an appointment.

In a study that was presented last year at Digestive Disease Week, researchers found that patients who viewed a 30-minute online instructional video were 40% more likely than people who didn't watch the video to keep their colonoscopy appointments and arrive prepared for the procedure.

Financial incentives: Financial incentives and wellness programs can be great motivators—if members know about them. Effective programs engage patients not only about the health benefits of preventive care, but also the more tangible ones, such as insurance premium reductions for adherence to scheduled screenings.

Empowering patients isn't just good for their health—it's good for disease management and the business of managed care. **MHE**

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2014 EXCLUSIVE SURVEY

STATE OF THE INDUSTRY

Healthcare leaders take note of future trends

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Clearly 2014 will be the pivotal year in health reform. While designing plan products and pricing them correctly was a huge task in 2013, measuring the market response to rates and benefits will be just as much of a challenge throughout 2014.

And leading managed care organizations will be remiss if they don't seriously consider the evolving competitive landscape. Unique payer/provider partnerships have created new health plans, and Consumer Oriented and Operated Plans (CO-OPs) are actively signing up members. Each market will emerge from 2014 with a distinctly different health reform story to tell.

Ever since the Patient Protection and Affordable Care Act (PPACA) was signed into law, observers from all corners of the country have made predictions on everything from the ultimate cost of reform to the percentage of the uninsured. There's a mix of optimism and pessimism. What's striking though is the opportunity to compare their predictions to reality.

A few weeks ago, MANAGED HEALTHCARE EXECUTIVE polled readers on their forecast for 2014 and beyond. Nearly 350 readers responded.

This is the sixth year of our survey, and it's interesting to take a look back.

For example, 26 states are currently opting out of Medicaid expansion. In last year's survey, 27% of respondents correctly predicted a range of 21 to 30 states opting out. Yet, more readers (31%) predicted just 11 to 20 states would opt out—quite a bit lower than the actual total. But states can change their minds and expand Medicaid at a later date, so there's more to come on this issue.

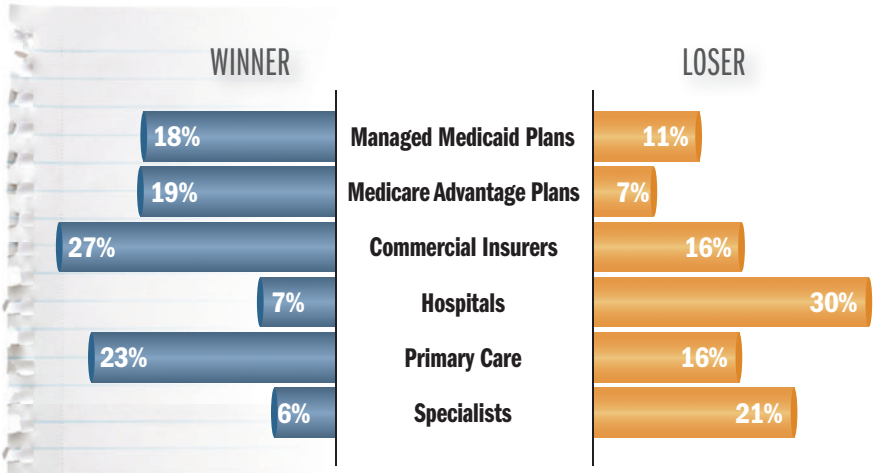
Also in last year's survey, the majority of respondents (78%) predicted state exchanges would not be ready in time for the October 2013 launch and that implementation would be delayed. The administration did indeed carry on with exchanges, even those operated by the federal government.

Soon, we'll have the initial findings of health reform's impact on the country, but until then, we'll continue to predict and analyze based on the information we do have available.

Winners and losers

Which stakeholder will fare best under reform?

Marie Rosenthal



Source: *Managed Healthcare Executive* original research, October 2013

Commercial insurers have an opportunity to attract previously uninsured lives and become dominant in the exchange markets, so on the surface, they look like the group that would fare best under PPACA.

"On the other hand, if providers bear the risk under capitated arrangements or bundled payments, under any system where payments are made directly to providers, one has to ask: What is the role for that insurer?" asks David B. Muhlestein, PhD, JD, director of research at Leavitt Partners LLC.

"There are people who say that insurers as we know them now will not exist in 10 years," he says. "I'm not sure I agree with that, but I do think the role of the insurer will change."

The lines between provider and insurer are blurring. Think Kaiser Permanente, which is both the payer and provider. There is also a trend among health systems launching their own health-plan products.

But these entities will need to acquire new expertise to reimburse and pay for care, as well as deliver quality care if they are to be successful.

In the past, MCOs would manage care based on utilization review. Now, they are measuring and incentivizing how that care is delivered, rather than just deciding whether to pay for it.

That is one of the advantages of today's managed Medicaid and Medicare Advantage plans—more control over how and where care is delivered.

"When you have a defined network, you are more aware of when and where someone is receiving care," says Muhlestein. "You have more relationships with those providers, and you can better manage that care. This gives the organization much better control over risk and monitoring those populations."

Who will fare best under PPACA might depend on the success or failure of accountable care organizations (ACOs). People are looking at ACOs from a business and a care perspective: What they are doing in terms of payment arrangements, how they will bear and allocate risk between the organization and the individual provider, what populations they are covering, and how they are coordinating care.

"If they are successful, you can expect this payment trend to continue. If they are not successful, you can expect the fee-for-service-trend to continue," according to Muhlestein.

Right now, doctors and hospitals are living in two worlds. They aren't able to operate in a fee-for-service system one day and a value-based plan the next.

In the short term, they need revenue centers, and those revenue centers will continue to be specialists and hospitals. "Under a value-based payment world, those would be considered cost centers," he says, and primary care becomes more important.

"In the longer term—at the end of 10 years, if this trend continues, then hospitals and specialists will be worse off because they will be viewed as cost centers. But in the short term, they are still bringing in the revenue," he says.

To improve the quality of care while controlling costs will require a good primary care system.

"Many organizations that see success are starting at that primary care level, focusing on preventing illness as opposed to trying to treat illness down the road," he says.

The systems that will fare best will assure that a patient is treated by the correct person at the correct level.

"You will see changes, but the entire system will not be completely different in 10 years," he says.

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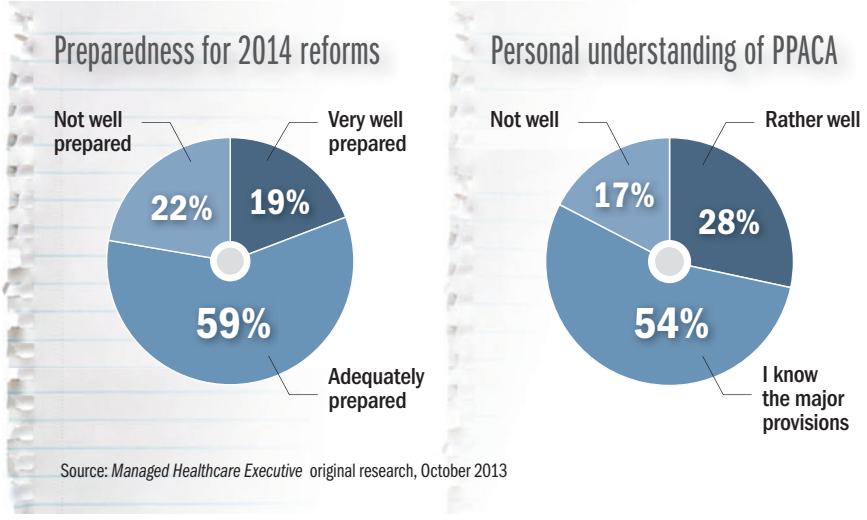
Preparedness for PPACA

Expect a few missteps as provisions phase in over time

Marie Rosenthal



One of the biggest challenges facing insurers as they implement PPACA will be moving from a wholesale, business-to-business model to a retail, direct-to-consumer model.

"It won't happen overnight," says Ceci Connolly, managing director of PwC Health Research Institute. "I don't mean to suggest that in 2014 the employer market disappears, because it doesn't, but over time that is how Americans will purchase their healthcare."

To prepare, insurers must develop a sophisticated understanding of these customers and the types of products and services they want, as well as how they want those services delivered. Some people might want wellness plans and gym memberships, while others will want purely medical procedure coverage with high deductible levels.

> **"It will be important to understand the different slices of the population and how you reach them."**
>
> —**Ceci Connolly**, PwC

"It will be important to understand the different slices of the population and how you reach them, enroll them and engage them," she says.

Traditional insurers must also prepare for the stiff competition they face, as other entities move into the arena.

"We at PwC see opportunity for many organizations," Connolly says. "There will be millions of new customers shopping for healthcare with federal subsidies. We estimate that 86% of the exchange customers will have subsidies. So, there is real money to be made from this newly insured population.

"At the same time, there will be challenges. We don't yet know the details of their health status. We don't yet know how hard it will be to get them to engage in their own health and wellness. These are some of the big unknowns," she continues.

There could be an initial spike in provider visits for individuals who have not received medical care for some time, but that should settle out as people learn to manage their conditions. Since there was a decline in office visits in recent years with the recession, some providers will welcome new patients.

"The median age of the exchange population in our analysis is age 33, and the average 33-year-old still does not have monumental medical problems," she says. "The more important thing for that age group will be getting them in for checkups and screenings to see what could be percolating, so they can monitor it as they go forward."

Insurers will also need to manage the sicker outliers, so they want to attract the "young invincibles"—young, healthy adults—into the pool to spread the financial risk.

Many business owners, who have spent the last few years navigating their companies through tough financial times, aren't prepared for PPACA and educating them will be a challenge.

"Health reform felt far off, but now it is almost here, so this is the time to focus in on these things," she says. "The good news is there are a lot of resources available, and there is still time to put in place the smart strategies."

If there are a few missteps, Connolly believes that enforcement will ramp up slowly, because the government recognizes that it will take time to enact all of the provisions.

"I don't think there will be an emphasis on punishing someone who is in good faith trying to navigate this brand new, complicated, confusing law," she says. "The idea is to help everyone understand it and navigate it."

CUBICIN IS IN THE 2010 IDSA GUIDELINES FOR MRSA cSSSI AND BACTEREMIA[1]

For suspected MRSA cSSSI or bacteremia, consider CUBICIN first

- Rapid bactericidal activity against MRSA *in vitro**
- Over 99% of *Staphylococcus aureus* isolates are susceptible to CUBICIN *in vitro** according to U.S. surveillance studies[2]
- More than 1.6 million patients have been treated with CUBICIN[2]
- Does not require drug-level monitoring; monitor CPK levels
- Once-a-day, 2-minute IV injection or 30-minute IV infusion

2 MINUTE IV INJECTION

*Clinical relevance of *in vitro* data has not been established.

Indications and Important Safety Information

INDICATIONS

- CUBICIN® (daptomycin for injection) is indicated for the following infections:

  Complicated skin and skin structure infections (cSSSI) caused by susceptible isolates of the following Gram-positive bacteria: *Staphylococcus aureus* (including methicillin-resistant isolates), *Streptococcus pyogenes*, *Streptococcus agalactiae*, *Streptococcus dysgalactiae* subspecies *equisimilis*, and *Enterococcus faecalis* (vancomycin-susceptible isolates only).

  S. aureus bloodstream infections (bacteremia), including those with right-sided infective endocarditis, caused by methicillin-susceptible and methicillin-resistant isolates.

LIMITATIONS OF USE

- CUBICIN is not indicated for the treatment of left-sided infective endocarditis due to *S. aureus*. The clinical trial of CUBICIN in patients with *S. aureus* bloodstream infections included limited data from patients with left-sided infective endocarditis; outcomes in these patients were poor. CUBICIN has not been studied in patients with prosthetic valve endocarditis.
- CUBICIN is not indicated for the treatment of pneumonia.

WARNINGS AND PRECAUTIONS

- Anaphylaxis/hypersensitivity reactions have been reported with the use of antibacterial agents, including CUBICIN, and may be life-threatening. If an allergic reaction to CUBICIN occurs, discontinue the drug and institute appropriate therapy.
- Myopathy, defined as muscle aching or muscle weakness in conjunction with increases in creatine phosphokinase (CPK) values to greater than 10 times the upper limit of normal (ULN), has been reported with the use of CUBICIN. Rhabdomyolysis, with or without acute renal failure, has been reported. Patients receiving CUBICIN should be monitored for the development of muscle pain or weakness, particularly of the distal extremities. In patients who receive CUBICIN, CPK levels should be monitored weekly, and more frequently in patients who received recent prior or concomitant therapy with an HMG-CoA reductase inhibitor or in whom elevations in CPK occur during treatment with CUBICIN. In patients with renal impairment, both renal function and CPK should be monitored more frequently than once weekly. In Phase 1 studies and Phase 2 clinical trials, CPK elevations appeared to be more frequent when CUBICIN was dosed more than once daily. Therefore, CUBICIN should not be dosed more frequently than once a day. CUBICIN should be discontinued in patients with unexplained signs and symptoms of myopathy in conjunction with CPK elevations to levels >1,000 U/L (~5× ULN), and in patients without reported symptoms who have marked elevations in CPK, with levels >2,000 U/L (≥10× ULN). In addition, consideration should be given to suspending agents associated with rhabdomyolysis, such as HMG-CoA reductase inhibitors, temporarily in patients receiving CUBICIN.
- Eosinophilic pneumonia has been reported in patients receiving CUBICIN. In reported cases associated with CUBICIN, patients developed fever, dyspnea with hypoxic respiratory insufficiency, and diffuse pulmonary infiltrates. In general, patients developed eosinophilic pneumonia 2 to 4 weeks after starting CUBICIN and improved when CUBICIN was discontinued and steroid therapy was initiated. Recurrence of eosinophilic pneumonia upon re-exposure has been reported. Patients who develop these signs and symptoms while receiving CUBICIN should undergo prompt medical evaluation, and CUBICIN should be discontinued immediately. Treatment with systemic steroids is recommended.
- Cases of peripheral neuropathy have been reported during the CUBICIN postmarketing experience. Therefore, physicians should be alert to signs and symptoms of peripheral neuropathy in patients receiving CUBICIN.
- *Clostridium difficile*–associated diarrhea (CDAD) has been reported with the use of nearly all systemic antibacterial agents, including CUBICIN, and may range in severity from mild diarrhea to fatal colitis. CDAD must be considered in all patients who present with diarrhea following antibacterial use. Careful medical history is necessary because CDAD has been reported to occur more than 2 months after the administration of antibacterial agents.
- Patients with persisting or relapsing *S. aureus* bacteremia/endocarditis or poor clinical response should have repeat blood cultures. If a blood culture is positive for *S. aureus*, minimum inhibitory concentration (MIC) susceptibility testing of the isolate should be performed using a standardized procedure, and diagnostic evaluation of the patient should be performed to rule out sequestered foci of infection. Appropriate surgical intervention (e.g., debridement, removal of prosthetic devices, valve replacement surgery) and/or consideration of a change in antibacterial regimen may be required. Failure of treatment due to persisting or relapsing *S. aureus* bacteremia/endocarditis may be due to reduced daptomycin susceptibility (as evidenced by increasing MIC of the *S. aureus* isolate).
- There are limited data available from the cSSSI clinical trials regarding the clinical efficacy of CUBICIN treatment in patients with creatinine clearance (CrCL) <50 mL/min; only 6% (31/534) patients treated with CUBICIN in the intent-to-treat (ITT) population had a baseline CrCL <50 mL/min. The clinical success rates in CUBICIN (4 mg/kg q24h)-treated patients with CrCL 50-70 mL/min and CrCL 30-<50 mL/min were 66% (25/38) and 47% (7/15), respectively. The clinical success rates in comparator-treated patients with CrCL 50-70 mL/min and CrCL 30-<50 mL/min were 63% (30/48) and 57% (20/35), respectively. In a subgroup analysis of the ITT population in the *S. aureus* bacteremia/endocarditis trial, clinical success rates in the CUBICIN-treated patients were lower in patients with baseline CrCL <50 mL/min.

ADVERSE REACTIONS

- The most clinically significant adverse reactions observed with CUBICIN 4 mg/kg (cSSSI trials) and 6 mg/kg (*S. aureus* bacteremia/endocarditis trial) were abnormal liver function tests, elevated CPK, and dyspnea.

References: 1. Liu C, Bayer A, Cosgrove SE, et al. Clinical practice guidelines by the Infectious Diseases Society of America for the treatment of methicillin-resistant *Staphylococcus aureus* infections in adults and children. *CID.* 2011;52:e18-e55. **2.** Data on file. Cubist Pharmaceuticals, Inc.

Please see Brief Summary of Prescribing Information on adjacent page.

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5158101912 November 2012

Once-A-Day CUBICIN® (daptomycin for injection)

CUBICIN® (daptomycin for injection)

Brief Summary of Prescribing Information

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CONTRAINDICATIONS CUBICIN is contraindicated in patients with known hypersensitivity to daptomycin.

WARNINGS AND PRECAUTIONS Anaphylaxis/Hypersensitivity Reactions Anaphylaxis/hypersensitivity reactions have been reported with the use of antibacterial agents, including CUBICIN, and may be life-threatening. If an allergic reaction to CUBICIN occurs, discontinue the drug and institute appropriate therapy [see *Adverse Reactions*]. **Myopathy and Rhabdomyolysis** Myopathy, defined as muscle aching or muscle weakness in conjunction with increases in creatine phosphokinase (CPK) values to greater than 10 times the upper limit of normal (ULN), has been reported with the use of CUBICIN. Rhabdomyolysis, with or without acute renal failure, has been reported [see *Adverse Reactions*]. Patients receiving CUBICIN should be monitored for the development of muscle pain or weakness, particularly of the distal extremities. In patients who receive CUBICIN, CPK levels should be monitored weekly, and more frequently in patients who received recent prior or concomitant therapy with an HMG-CoA reductase inhibitor or in whom elevations in CPK occur during treatment with CUBICIN. In patients with renal impairment, both renal function and CPK should be monitored more frequently than once weekly [see *Use in Specific Populations* in this summary and *Clinical Pharmacology* in full prescribing information]. In Phase 1 studies and Phase 2 clinical trials, CPK elevations appeared to be more frequent when CUBICIN was dosed more than once daily. Therefore, CUBICIN should not be dosed more frequently than once a day. CUBICIN should be discontinued in patients with unexplained signs and symptoms of myopathy in conjunction with CPK elevations to levels >1,000 U/L (~5× ULN), and in patients without reported symptoms who have marked elevations in CPK, with levels >2,000 U/L (≥10× ULN). In addition, consideration should be given to suspending agents associated with rhabdomyolysis, such as HMG-CoA reductase inhibitors, temporarily in patients receiving CUBICIN [see *Drug Interactions*]. **Eosinophilic Pneumonia** Eosinophilic pneumonia has been reported in patients receiving CUBICIN [see *Adverse Reactions*]. In reported cases associated with CUBICIN, patients developed fever, dyspnea with hypoxic respiratory insufficiency, and diffuse pulmonary infiltrates. In general, patients developed eosinophilic pneumonia 2 to 4 weeks after starting CUBICIN and improved when CUBICIN was discontinued and steroid therapy was initiated. Recurrence of eosinophilic pneumonia upon re-exposure has been reported. Patients who develop these signs and symptoms while receiving CUBICIN should undergo prompt medical evaluation, and CUBICIN should be discontinued immediately. Treatment with systemic steroids is recommended. **Peripheral Neuropathy** Cases of peripheral neuropathy have been reported during the CUBICIN postmarketing experience [see *Adverse Reactions*]. Therefore, physicians should be alert to signs and symptoms of peripheral neuropathy in patients receiving CUBICIN. ***Clostridium difficile*–Associated Diarrhea** *Clostridium difficile*–associated diarrhea (CDAD) has been reported with the use of nearly all systemic antibacterial agents, including CUBICIN, and may range in severity from mild diarrhea to fatal colitis [see *Adverse Reactions*]. Treatment with antibacterial agents alters the normal flora of the colon, leading to overgrowth of *C. difficile. C. difficile* produces toxins A and B, which contribute to the development of CDAD. Hypertoxin-producing strains of *C. difficile* cause increased morbidity and mortality, since these infections can be refractory to antimicrobial therapy and may require colectomy. CDAD must be considered in all patients who present with diarrhea following antibacterial use. Careful medical history is necessary because CDAD has been reported to occur more than 2 months after the administration of antibacterial agents. If CDAD is suspected or confirmed, ongoing antibacterial use not directed against *C. difficile* may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibacterial treatment of *C. difficile*, and surgical evaluation should be instituted as clinically indicated. **Persisting or Relapsing *S. aureus* Bacteremia/Endocarditis** Patients with persisting or relapsing *S. aureus* bacteremia/endocarditis or poor clinical response should have repeat blood cultures. If a blood culture is positive for *S. aureus,* minimum inhibitory concentration (MIC) susceptibility testing of the isolate should be performed using a standardized procedure, and diagnostic evaluation of the patient should be performed to rule out sequestered foci of infection. Appropriate surgical intervention (e.g., debridement, removal of prosthetic devices, valve replacement surgery) and/or consideration of a change in antibacterial regimen may be required. Failure of treatment due to persisting or relapsing *S. aureus* bacteremia/endocarditis may be due to reduced daptomycin susceptibility (as evidenced by increasing MIC of the *S. aureus* isolate) [see *Clinical Trials* in full prescribing information]. **Decreased Efficacy in Patients with Moderate Baseline Renal Impairment** Limited data are available from the two Phase 3 complicated skin and skin structure infection (cSSSI) trials regarding clinical efficacy of CUBICIN treatment in patients with creatinine clearance (CL_{CR}) <50 mL/min; only 6% (31/534) patients treated with CUBICIN in the intent-to-treat (ITT) population had a baseline CL_{CR} <50 mL/min. In the ITT population of the Phase 3 cSSSI trials, the clinical success rates in CUBICIN (4 mg/kg q24h)-treated patients with CL_{CR} 50–70 mL/min and CL_{CR} 30–<50 mL/min were 66% (25/38) and 47% (7/15), respectively. The clinical success rates in comparator-treated patients with CL_{CR} 50–70 mL/min and CL_{CR} 30–<50 mL/min were 63% (30/48) and 57% (20/35), respectively. In a subgroup analysis of the ITT population in the Phase 3 *S. aureus* bacteremia/endocarditis trial, clinical success rates, as determined by a treatment-blinded Adjudication Committee [see *Clinical Trials* in full prescribing information], in the CUBICIN-treated patients were lower in patients with baseline CL_{CR} <50 mL/min. A decrease of the following magnitude was not observed in comparator-treated patients. In the ITT population of the *S. aureus* bacteremia/endocarditis trial, the Adjudication Committee clinical success rates at the test-of-cure visit in CUBICIN (6 mg/kg q24h)-treated bacteremia patients with CL_{CR} >80 mL/min, CL_{CR} 50–80 mL/min, and CL_{CR} 30–<50 mL/min were 60% (30/50), 46% (12/26), and 14% (2/14), respectively. The clinical success rates in CUBICIN (6 mg/kg q24h)-treated right-sided infective endocarditis (RIE) patients with CL_{CR} >80 mL/min, CL_{CR} 50–80 mL/min, and CL_{CR} 30–<50 mL/min were 50% (7/14), 25% (1/4), and 0% (0/1), respectively. The clinical success rates in comparator-treated bacteremia patients with CL_{CR} >80 mL/min, CL_{CR} 50–80 mL/min, and CL_{CR} 30–<50 mL/min were 45% (19/42), 42% (13/31), and 41% (7/17), respectively. The clinical success rates in comparator-treated RIE patients with CL_{CR} >80 mL/min, CL_{CR} 50–80 mL/min, and CL_{CR} 30–<50 mL/min were 46% (5/11), 50% (1/2), and 100% (1/1), respectively. Consider these data when selecting antibacterial therapy for use in patients with baseline moderate to severe renal impairment. **Drug-Laboratory Test Interactions** Clinically relevant plasma concentrations of daptomycin have been observed to cause a significant concentration-dependent false prolongation of prothrombin time (PT) and elevation of International Normalized Ratio (INR) when certain recombinant thromboplastin reagents are utilized for the assay [see *Drug-Laboratory Interactions* under DRUG INTERACTIONS below]. **Non-Susceptible Microorganisms** The use of antibacterials may promote the overgrowth of non-susceptible microorganisms. If superinfection occurs during therapy, appropriate measures should be taken. Prescribing CUBICIN in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

ADVERSE REACTIONS The following adverse reactions are described, or described in greater detail, under *Warnings and Precautions:* anaphylaxis/hypersensitivity reactions, myopathy and rhabdomyolysis, eosinophilic pneumonia, peripheral neuropathy. The following adverse reaction is described in greater detail under *Warnings and Precautions* and *Drug-Laboratory Test Interactions* under DRUG INTERACTIONS below*:* increased International Normalized Ratio (INR)/prolonged prothrombin time. Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared with rates in the clinical trials of another drug and may not reflect the rates observed in practice. **Clinical Trials Experience** Clinical trials enrolled 1,864 patients treated with CUBICIN and 1,416 treated with comparator. Complicated Skin and Skin Structure Infection Trials In Phase 3 complicated skin and skin structure infection (cSSSI) trials, CUBICIN was discontinued in 15/534 (2.8%) patients due to an adverse reaction, while comparator was discontinued in 17/558 (3.0%) patients. The incidence (%) of adverse reactions, organized by body system, that occurred in ≥2% of patients in the CUBICIN 4 mg/kg (N=534) treatment group and ≥ the comparator (N=558) treatment group, respectively, in Phase 3 cSSSI trials was as follows [comparators were vancomycin (1 g IV q12h) and anti-staphylococcal semi-synthetic penicillins (i.e., nafcillin, oxacillin, cloxacillin, flucloxacillin; 4 to 12 g/day IV in divided doses)]: *Gastrointestinal disorders:* diarrhea 5.2% and 4.3%; *Nervous system disorders:* headache 5.4% and 5.4%; dizziness 2.2% and 2.0%; *Skin/subcutaneous disorders:* rash 4.3% and 3.8%; *Diagnostic investigations:* abnormal liver function tests 3.0% and 1.6%; elevated CPK 2.8% and 1.8%; *Infections:* urinary tract infections 2.4% and 0.5%; *Vascular disorders:* hypotension 2.4% and 1.4%; *Respiratory disorders:* dyspnea 2.1% and 1.6%. Drug-related adverse reactions (possibly or probably drug-related) that occurred in <1% of patients receiving CUBICIN in the cSSSI trials are as follows: *Body as a Whole:* fatigue, weakness, rigors, flushing, hypersensitivity; *Blood/Lymphatic System:* leukocytosis, thrombocytopenia, thrombocytosis, eosinophilia, increased International Normalized Ratio (INR); *Cardiovascular System:* supraventricular arrhythmia; *Dermatologic System:* eczema; *Digestive System:* abdominal distension, stomatitis, jaundice, increased serum lactate dehydrogenase; *Metabolic/Nutritional System:* hypomagnesemia, increased serum bicarbonate, electrolyte disturbance; *Musculoskeletal System:* myalgia, muscle cramps, muscle weakness, arthralgia; *Nervous System:* vertigo, mental status change, paresthesia; *Special Senses:* taste disturbance, eye irritation. *S. aureus* Bacteremia/Endocarditis Trial In the *S. aureus* bacteremia/endocarditis trial, CUBICIN was

discontinued in 20/120 (16.7%) patients due to an adverse reaction, while comparator was discontinued in 21/116 (18.1%) patients. Serious Gram-negative infections (including bloodstream infections) were reported in 10/120 (8.3%) CUBICIN-treated patients and 0/115 comparator-treated patients. Comparator-treated patients received dual therapy that included initial gentamicin for 4 days. Infections were reported during treatment and during early and late follow-up. Gram-negative infections included cholangitis, alcoholic pancreatitis, sternal osteomyelitis/mediastinitis, bowel infarction, recurrent Crohn's disease, recurrent line sepsis, and recurrent urosepsis caused by a number of different Gram-negative bacteria. The incidence [n (%)] of adverse reactions, organized by System Organ Class (SOC), that occurred in ≥5% of patients in the CUBICIN 6 mg/kg (N=120) treatment group and ≥ the comparator (N=116) treatment group, respectively, in the *S. aureus* bacteremia/endocarditis trial was as follows [comparators were vancomycin (1 g IV q12h) and anti-staphylococcal semi-synthetic penicillins (i.e., nafcillin, oxacillin, cloxacillin, flucloxacillin; 2 g IV q4h), each with initial low-dose gentamicin]: *Infections and infestations:* sepsis not otherwise specified (NOS) 6 (5%) and 3 (3%); bacteremia 6 (5%) and 0 (0%); *Gastrointestinal disorders:* abdominal pain NOS 7 (6%) and 4 (3%); *General disorders and administration site conditions:* chest pain 8 (7%) and 7 (6%); edema NOS 8 (7%) and 5 (4%); *Respiratory, thoracic, and mediastinal disorders:* pharyngolaryngeal pain 10 (8%) and 2 (2%); *Skin and subcutaneous tissue disorders:* pruritus 7 (6%) and 6 (5%); sweating increased 6 (5%) and 0 (0%); *Psychiatric disorders:* insomnia 11 (9%) and 8 (7%); *Investigations:* blood creatine phosphokinase increased 8 (7%) and 1 (1%); *Vascular disorders:* hypertension NOS 7 (6%) and 3 (3%). The following reactions, not included above, were reported as possibly or probably drug-related in the CUBICIN-treated group: *Blood and Lymphatic System Disorders:* eosinophilia, lymphadenopathy, thrombocythemia, thrombocytopenia; *Cardiac Disorders:* atrial fibrillation, atrial flutter, cardiac arrest; *Ear and Labyrinth Disorders:* tinnitus; *Eye Disorders:* vision blurred; *Gastrointestinal Disorders:* dry mouth, epigastric discomfort, gingival pain, hypoesthesia oral; *Infections and Infestations:* candidal infection NOS, vaginal candidiasis, fungemia, oral candidiasis, urinary tract infection fungal; *Investigations:* blood phosphorous increased, blood alkaline phosphatase increased, INR increased, liver function test abnormal, alanine aminotransferase increased, aspartate aminotransferase increased, prothrombin time prolonged; *Metabolism and Nutrition Disorders:* appetite decreased NOS; *Musculoskeletal and Connective Tissue Disorders:* myalgia; *Nervous System Disorders:* dyskinesia, paresthesia; *Psychiatric Disorders:* hallucination NOS; *Renal and Urinary Disorders:* proteinuria, renal impairment NOS; *Skin and Subcutaneous Tissue Disorders:* pruritus generalized, rash vesicular. Other Trials In Phase 3 trials of community-acquired pneumonia (CAP), the death rate and rates of serious cardiorespiratory adverse events were higher in CUBICIN-treated patients than in comparator-treated patients. These differences were due to lack of therapeutic effectiveness of CUBICIN in the treatment of CAP in patients experiencing these adverse events [see *Indications and Usage*]. Laboratory Changes *Complicated Skin and Skin Structure Infection Trials* In Phase 3 cSSSI trials of CUBICIN at a dose of 4 mg/kg, elevations in CPK were reported as clinical adverse events in 15/534 (2.8%) CUBICIN-treated patients, compared with 10/558 (1.8%) comparator-treated patients. Of the 534 patients treated with CUBICIN, 1 (0.2%) had symptoms of muscle pain or weakness associated with CPK elevations to greater than 4 times the upper limit of normal (ULN). The symptoms resolved within 3 days and CPK returned to normal within 7 to 10 days after treatment was discontinued [see *Warnings and Precautions*]. The incidence [n (%)] of CPK elevations from Baseline through End of Therapy, organized by change in CPK, that occurred in all patients in either the CUBICIN 4 mg/kg (N=430) treatment group or the comparator (N=459) treatment group, respectively, in the Phase 3 cSSSI trials was as follows [comparators were vancomycin (1 g IV q12h) and anti-staphylococcal semi-synthetic penicillins (i.e., nafcillin, oxacillin, cloxacillin, flucloxacillin; 4 to 12 g/day IV in divided doses)]: *No increase:* 390 (90.7%) and 418 (91.1%); *Maximum Value >1× Upper Limit of Normal* (ULN; defined as 200 U/L): 40 (9.3%) and 41 (8.9%); *Max Value >2× ULN:* 21 (4.9%) and 22 (4.8%); *Max Value >4× ULN:* 6 (1.4%) and 7 (1.5%); *Max Value >5× ULN:* 6 (1.4%) and 2 (0.4%); *Max Value >10× ULN:* 2 (0.5%) and 1 (0.2%). In patients with normal CPK at baseline, the incidence [n (%)] of CPK elevations, organized by change in CPK, that occurred in either the CUBICIN 4 mg/kg (N=374) treatment group or the comparator (N=392) treatment group, respectively, was as follows: *No increase:* 341 (91.2%) and 357 (91.1%); *Max Value >1× ULN:* 33 (8.8%) and 35 (8.9%); *Max Value >2× ULN:* 14 (3.7%) and 12 (3.1%); *Max Value >4× ULN:* 4 (1.1%) and 4 (1.0%); *Max Value >5× ULN:* 4 (1.1%) and 0 (0.0%); *Max Value >10× ULN:* 1 (0.2%) and 0 (0.0%). Note: Elevations in CPK observed in patients treated with CUBICIN or comparator were not clinically or statistically significantly different. *S. aureus Bacteremia/Endocarditis Trial* In the *S. aureus* bacteremia/endocarditis trial, at a dose of 6 mg/kg, 11/120 (9.2%) CUBICIN-treated patients, including two patients with baseline CPK levels >500 U/L, had CPK elevations to levels >500 U/L, compared with 1/116 (0.9%) comparator-treated patients. Of the 11 CUBICIN-treated patients, 4 had prior or concomitant treatment with an HMG-CoA reductase inhibitor. Three of these 11 CUBICIN-treated patients discontinued therapy due to CPK elevation, while the one comparator-treated patient did not discontinue therapy [see *Warnings and Precautions*]. **Post-Marketing Experience** The following adverse reactions have been identified during postapproval use of CUBICIN. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to estimate their frequency reliably or establish a causal relationship to drug exposure. *Immune System Disorders:* anaphylaxis; hypersensitivity reactions, including angioedema, drug rash with eosinophilia and systemic symptoms (DRESS), pruritus, hives, shortness of breath, difficulty swallowing, truncal erythema, and pulmonary eosinophilia [see *Contraindications* and *Warnings and Precautions*]; *Infections and Infestations: Clostridium difficile*–associated diarrhea [see *Warnings and Precautions*]; *Musculoskeletal Disorders:* myoglobin increased; rhabdomyolysis (some reports involved patients treated concurrently with CUBICIN and HMG-CoA reductase inhibitors) [see *Warnings and Precautions* and *Drug Interactions* in this summary, and *Clinical Pharmacology* in full prescribing information]; *Respiratory, Thoracic, and Mediastinal Disorders:* cough, eosinophilic pneumonia [see *Warnings and Precautions*]; *Nervous System Disorders:* peripheral neuropathy [see *Warnings and Precautions*]; *Skin and Subcutaneous Tissue Disorders:* serious skin reactions, including Stevens-Johnson syndrome and vesiculobullous rash (with or without mucous membrane involvement); *Gastrointestinal Disorders:* nausea, vomiting.

DRUG INTERACTIONS HMG-CoA Reductase Inhibitors In healthy subjects, concomitant administration of CUBICIN and simvastatin had no effect on plasma trough concentrations of simvastatin, and there were no reports of skeletal myopathy [see *Clinical Pharmacology* in full prescribing information]. However, inhibitors of HMG-CoA reductase may cause myopathy, which is manifested as muscle pain or weakness associated with elevated levels of creatine phosphokinase (CPK). In the Phase 3 *S. aureus* bacteremia/endocarditis trial, some patients who received prior or concomitant treatment with an HMG-CoA reductase inhibitor developed elevated CPK [see *Adverse Reactions*]. Experience with the coadministration of HMG-CoA reductase inhibitors and CUBICIN in patients is limited; therefore, consideration should be given to suspending use of HMG-CoA reductase inhibitors temporarily in patients receiving CUBICIN. **Drug-Laboratory Test Interactions** Clinically relevant plasma concentrations of daptomycin have been observed to cause a significant concentration-dependent false prolongation of prothrombin time (PT) and elevation of International Normalized Ratio (INR) when certain recombinant thromboplastin reagents are utilized for the assay. The possibility of an erroneously elevated PT/INR result due to interaction with a recombinant thromboplastin reagent may be minimized by drawing specimens for PT or INR testing near the time of trough plasma concentrations of daptomycin. However, sufficient daptomycin concentrations may be present at trough to cause interaction. If confronted with an abnormally high PT/INR result in a patient being treated with CUBICIN, it is recommended that clinicians: 1. Repeat the assessment of PT/INR, requesting that the specimen be drawn just prior to the next CUBICIN dose (i.e., at trough concentration). If the PT/INR value obtained at trough remains substantially elevated above what would otherwise be expected, consider evaluating PT/INR utilizing an alternative method. 2. Evaluate for other causes of abnormally elevated PT/INR results.

USE IN SPECIFIC POPULATIONS Pregnancy Teratogenic Effects: Pregnancy Category B. There are no adequate and well-controlled trials of CUBICIN in pregnant women. Embryofetal development studies performed in rats and rabbits at doses of up to 75 mg/kg (2 and 4 times the 6 mg/kg human dose, respectively, on a body surface area basis) revealed no evidence of harm to the fetus due to daptomycin. Because animal reproduction studies are not always predictive of human response, CUBICIN should be used during pregnancy only if the potential benefit outweighs the possible risk. **Nursing Mothers** Daptomycin is present in human milk but is poorly bioavailable orally. In a single case study, CUBICIN was administered daily for 28 days to a nursing mother at an IV dose of 6.7 mg/kg/day, and samples of the patient's breast milk were collected over a 24-hour period on day 27. The highest measured concentration of daptomycin in the breast milk was 0.045 mcg/mL. The calculated maximum daily CUBICIN dose to the infant (assuming mean milk consumption of 150 mL/kg/day) was 0.1% of the maternal dose of 6.7 mg/kg/day. Caution should be exercised when CUBICIN is administered to a nursing woman. **Pediatric Use** Safety and effectiveness of CUBICIN in patients under the age of 18 years have not been established [see *Nonclinical Toxicology* in full prescribing information]. **Geriatric Use** Of the 534 patients treated with CUBICIN in Phase 3 controlled clinical trials of complicated skin and skin structure infections (cSSSI), 27% were 65 years of age or older and 12% were 75 years of age or older. Of the 120 patients treated with CUBICIN in the Phase 3 controlled clinical trial of *S. aureus* bacteremia/endocarditis, 25% were 65 years of age or older and 16% were 75 years of age or older. In Phase 3 clinical trials of cSSSI and *S. aureus* bacteremia/endocarditis, clinical success rates were lower in patients ≥65 years of age than in patients <65 years of age. In addition, treatment-emergent adverse events were more common in patients ≥65 years of age than in patients <65 years of age. The exposure of daptomycin was higher in healthy elderly subjects than in healthy young subjects. However, no adjustment of CUBICIN dosage is warranted for elderly patients with creatinine clearance (CL_{CR}) ≥30 mL/min [see *Dosage and Administration* in full prescribing information and *Clinical Pharmacology* in full prescribing information]. **Patients with Renal Impairment** Daptomycin is eliminated primarily by the kidneys; therefore, a modification of CUBICIN dosage interval is recommended for patients with CL_{CR} <30 mL/min, including patients receiving hemodialysis or continuous ambulatory peritoneal dialysis (CAPD). In patients with renal impairment, both renal function and creatine phosphokinase (CPK) should be monitored more frequently than once weekly [see *Dosage and Administration* in full prescribing information, *Warnings and Precautions* in this summary, and *Clinical Pharmacology* in full prescribing information].

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Primary care physician shortage

Plans hope to see more care delivered by mid-level providers who will take the pressure off PCPs

Julia Brown

According to the Association of American Medical Colleges, the United States will face a shortage of 130,000 physicians by 2025, with primary care accounting for the largest share (37%).

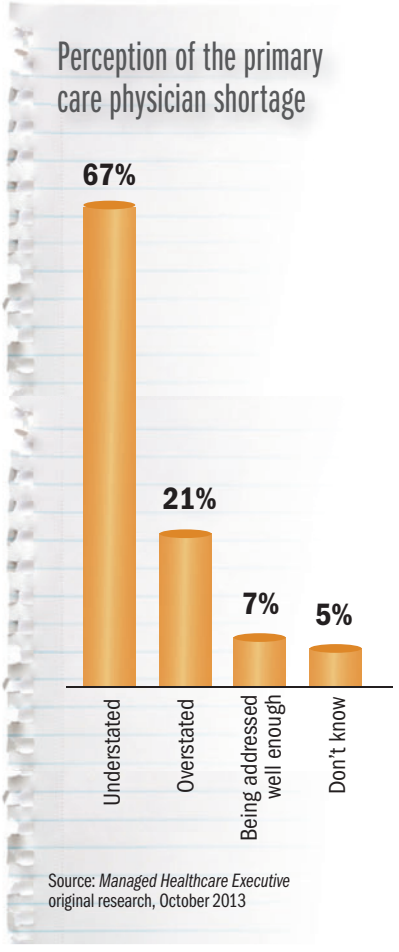
A majority of **MHE** readers say the shortage is understated (66.5%), while others say it's overstated (21.4%), being addressed well enough (6.8%) or they don't know (5.3%).

"It's a real issue," says Bob Williams, national medical leader of healthcare consulting practice Deloitte LLP. "We're suffering not only from a reduction in recruitment of primary care specialties, but also the aging out of a generation of residency-trained primary care physicians."

Although more than half of medical students indicate an interest in primary care when first starting out, only 20% stick with it by year three of medical school. Significant income gaps and reimbursement systems are often blamed. As systems began rewarding volume over value, the dynamic caused physicians to seek more patient visits in order to remain profitable.

In the last few years, Williams says, there has been an increase in recruitment but not enough to make a significant impact. The Department of Health and Human Services estimates the national physician supply with increase by only 7% in the next 10 years.

"There are fewer and fewer family practitioners out there who are really trained in primary care. I think we're going to have an imbalance for quite some time," says Bill Copeland, vice chairman, U.S. life sciences and healthcare leader and U.S. health plans leader, Deloitte LLP.



An additional 8,000 PCPs will be needed in 2025 to treat patients obtaining coverage under health reform as primary care visits are predicted to rise as high as 565 million annually, according to a study in the *Annals of Family Medicine* (November/December 2012).

"There will be an increased access issue with increased coverage, at least for awhile," Williams says. "That also impacts being able to effectively assist in the management of chronic diseases in the outpatient setting. So, it's challenging to try to move to the goals we're all trying to move toward."

Williams says health systems still have significant gaps when it comes to covering existing populations, and it's important that they engage PCPs in emerging new priorities.

"As they experiment with increased clinical integration and increased assumption of risk by providers, there's a significant need for primary care physicians to participate in that and for programs that are really going to address avoidance of readmissions to hospitals," he says.

Medicaid managed care and Medicaid fee-for-service have the most severe shortages of primary care physicians because rates are the lowest, Copeland says, making it hard for physicians to build a robust practice that has a significant Medicaid population.

For example, some exchange health plans for lower-income populations are struggling to secure enough PCPs for their networks in certain locations, he says. Although not exactly a rate issue per se—exchanges will offer commercial rates—there's a concern about building broad networks across a geography.

"Health plans are hoping this creates somewhat of a push around innovation to get mid-levels much more involved and an opportunity for broader acceptance of mid-levels in primary care," Copeland says. "This is an opportunity to seize the day and see if there can be a way to get mid-levels more involved."

It's supply and demand, he says, as well as the price that results from it. Plans might pay a premium for access into the networks they need, especially for busy practices that take care of Medicare patients and their families.

"There have been some trends focused on skills related to patient-centered medical homes and programs to try to improve the operating efficiency of smaller practices," says Williams. "Because they're small businesses, it's hard to do that—to help physicians be more efficient in the delivery of care and

to learn some of those new skills."

A near-term issue concerns the existing workforce of primary care providers, he says. Plans must figure out how to take advantage of and identify practitioners who can be part of a high-value network, and to find creative ways to engage, support and give them tools to do a better job.

"It's two separate problems," he says. "In the near-term and long-term, health plans might be able to help primary care physicians with tools—technology tools to do better care coordination—to deliver skills and help to advance skills in population health. That's something that not only will help in the near-term, but if they're successful, they will help recruit future physicians into that practice, because it will be more desirable."

Rate negotiations

More complex reimbursement contracts make it tougher on providers

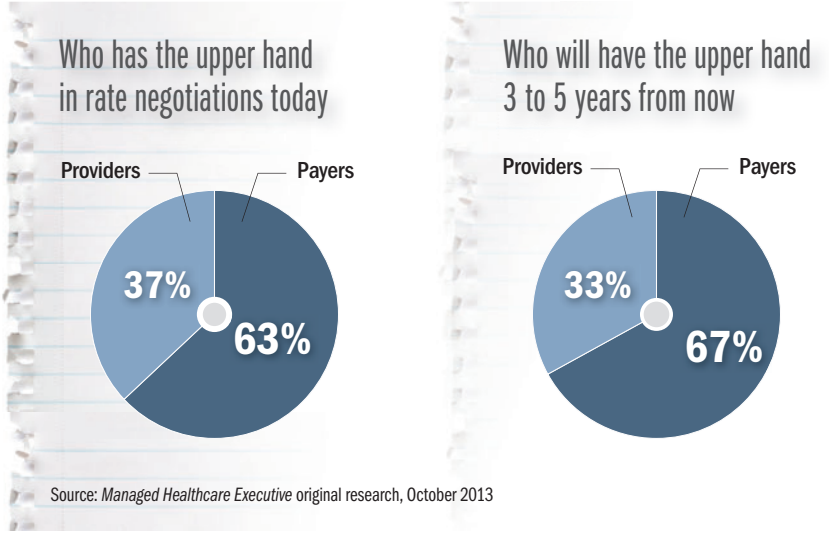
Jennifer Webb

Rate negotiations between payers and providers are, by nature, contentious and bound to become more so as payment models evolve. But in areas of the country where payers and providers have forged solid working relationships, both parties are working diligently to find equitable payment systems based on delivery and performance.

"It seems as if the areas where the relationships are more positive are ones where the clinicians have been able to come together in some sort of formal arrangement to negotiate with the local payers," says Shari M. Erickson, MPH, vice president, governmental and regulatory affairs for the American College of Physicians.

Payers want to reimburse for "value"—a combination of high or improved performance with reduced cost—instead of individual services, she says. Clinicians are exploring new delivery system models, including patient-centered medical homes and accountable care organizations.

"Both of these factors are changing the conversation significantly," Erickson says. "How do you effectively pay for value and provide true and meaningful incentives for clinicians? There are many differing viewpoints on this question."



Source: *Managed Healthcare Executive* original research, October 2013

While payers are widely viewed as having the upper hand in negotiations in our survey, the ground might be leveling for providers who have joined larger organizations, such as hospital outpatient departments and independent practice associations (IPAs) that negotiate on behalf of members.

In fact, at least 550,000 physicians have joined physician organizations, according to Robert Jenkins, CEO of the Managed Care Information Center, Wall Township, N.J. The center publishes the National Directory of Physician Organizations, which documents 505 IPAs and 568 physician hospital organizations, plus multispeciality medical groups and primary care networks, Jenkins says.

However, Erickson notes, many of the country's patients still receive their care from clinicians in small- to medium-sized practices that find it "very challenging to effectively negotiate with payers, which leads to the view that payers have the upper hand."

In the future, more complex reimbursement arrangements and risk shifting to providers will make the negotiation process itself more involved on both sides of the boardroom table.

"They're getting beat up," Jenkins says of independent providers. "I think they need all the help they can get."

In the **MHE** survey, both payers and providers were in general agreement that the negotiations now and in the future will favor the payer community. Although, not surprisingly, 75% of the providers we polled said "payers have the upper hand today," while 54% of the payers themselves said so, too.

Health status

Young invincibles who are used to their parents' plans will no doubt want to continue coverage

Marie Rosenthal

The newly insured will arrive in the market with unknown histories and uncertain futures. Plans must predict their health status and health needs to determine their relative risk.

"Like anything, it is never simple," says Don Hall, principal of consulting firm DeltaSigma LLC, and an **MHE** editorial advisor. He sees three populations of uninsured:

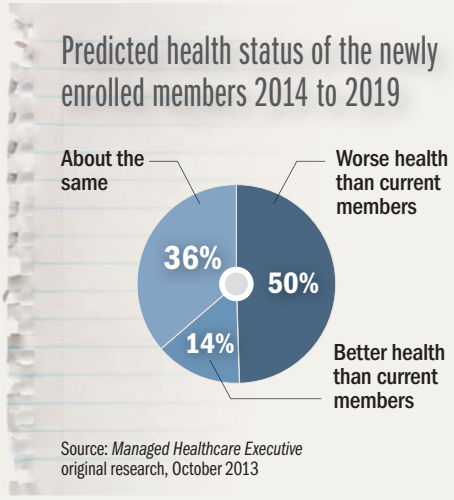
- Unemployed, childless adults—many of whom are homeless and qualify for Medicaid. "They will have a high likelihood of needing care, but predominantly in behavioral health," Hall says.
- The working poor who will qualify for Medicaid because income-qualifications levels are rising. Because they can work, they should be relatively healthy.
- The exchange population, which is a mixed range from those in the high-risk pool to young, healthy adults.

"Many of those will be young, healthy adults. We will find pockets within these populations that will have a high need, but there won't be a lot of need in general," says Hall.

He doesn't believe the country will see the pent-up demand that some have predicted.

"States that have expansions have not seen that happen," he says. "People without a lot of money have been accessing care through federal and rural health centers. Getting insurance only means that they will be using more private providers instead of federally-funded health centers."

Utilization could run steady, except in one subpopulation of covered Americans in the Medicaid expansion—the childless adults who are not working and need treatment for behavioral health conditions. And that is a group for which



Age-rate bands

Payers wanted more time to phase in premium adjustments for age

Julie Miller

Prevailing state regulations allow insurers to vary premium costs over a range of age groups, for example, at a ratio of 5-to-1 between older and younger people because older people typically use more healthcare. However, in the exchanges, PPACA limits the range to just 3-to-1, beginning with 2014 coverage plans.

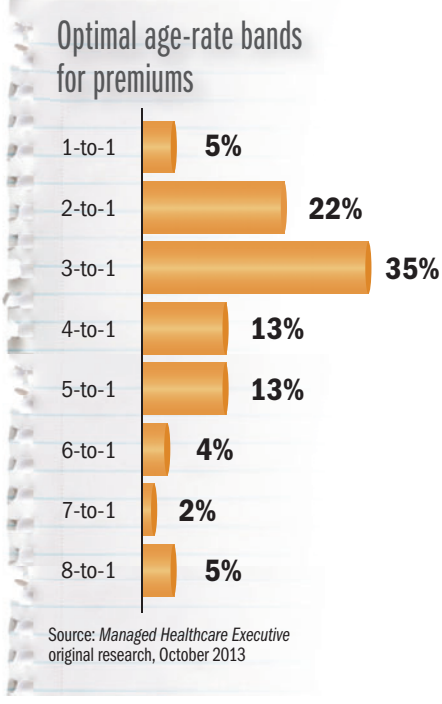
For example, if a 21-year-old's 2013 annual premium is $1,200, a 60-year-old's annual 2013 premium might be $6,000 in a typical state. In 2014, under the 3-to-1 rate band, the younger individual would pay $1,800 or 50% more, and the older individual would pay $5,400, or 10% less.

Forty-two states currently have bands of 5-to-1 or greater, according to America's Health Insurance Plans (AHIP).

"The premiums and benefits that people will be shopping for in the exchanges in October reflect this new change in age rates," says Robert Zirkelbach, AHIP press secretary. "So that's already been implemented into the policies."

Zirkelbach says age-rate restrictions are one of the factors causing 2014 exchange premiums to be higher in comparison to 2013 rates. Many PPACA critics have warned of premium "rate shock" for next year.

Taxes on insurers, covering adult children up to age 26, richer benefit plans and other reform policies will also contribute to higher prices for coverage, Zirkelbach says. It's not just the age-rate limitation. AHIP has advocated for a longer time frame to phase in the new ranges, rather than jumping to 3-to-1



no one is prepared for because of the "drastic shortage of behavioral health resources in this country," he says.

What will be crucial to the future of the exchanges is attracting the young invincibles who have above average health status as a population. In contrast, there won't be a lot of marketing directed toward those with chronic conditions or older people who might be expected to seek out insurance, regardless of marketing messages.

"I think it was a brilliant stroke by the Obama administration to cover everyone up to 26 years old on their parents' health plans," says Hall. "They have been getting health insurance as adults where before they might have been uninsured, so that when they age out of the plan, the expectation is that they need health insurance. It created the demand that will feed the exchanges going forward."

overnight, but lawmakers weren't open to changing the rule.

"We'll talk about it to the extent that it helps explain what's happening to premiums and help explain some of the changes that people are experiencing," he says.

The policy increases the likelihood that younger, healthier people will wait to purchase health insurance until after they get sick or injured, thus driving up costs overall, as the risk pool skews toward those with greater healthcare needs.

New limits will increase premiums 30% for those ages 21 to 29, according to Oliver Wyman Consulting.

Younger individuals will have three choices:

- Purchase coverage at a higher rate;
- Purchase catastrophic coverage; or
- Pay a penalty for no coverage.

Bronze plans

Bronze plans will serve the hold-outs who have not purchased insurance in the past

Jamie J. Gooch

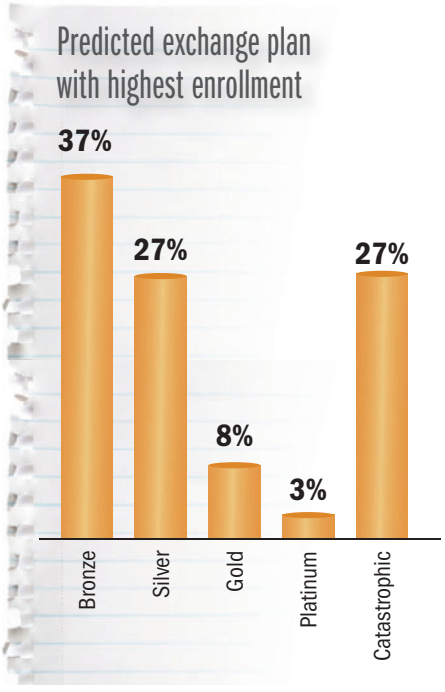
Of the new Patient Protection and Affordable Care Act qualified health plans, known as the "metal" plans, 37% of the **MHE** survey respondents believe the Bronze plan will have the highest enrollment.

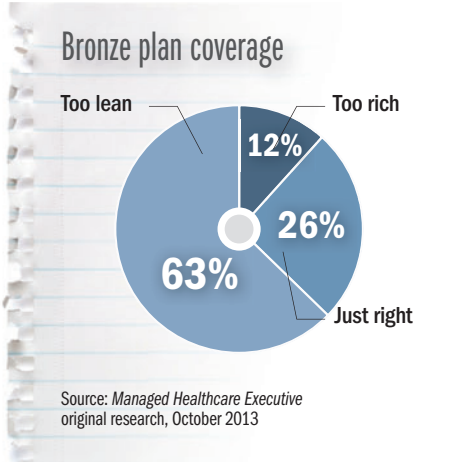
The Bronze plan, which will have the highest out-of-pocket costs for members with its 60% actuarial value, will also have the lowest premiums. The plan's presumed popularity is to be expected, largely because of the demographic that the exchanges are expected to serve.

"The lower-priced exchange plans will be the most popular because they will be serving the insurance market's hold-outs and left-outs, and the employer market's reluctant dropouts," says J.D. Kleinke, medical economist, author and **MHE** editorial advisor. "A large share of these people have traditionally not purchased coverage, and we can only presume that is because it has been too expensive—relative to their means and other choices—or because they did not find the old plans of sufficient value, or because they are part of groups dropped by employers happy to push their coverage over to the exchange plans."

Because many have not purchased coverage before, it is safe to assume that they will equate lower premiums and the promise of essential health benefits as delivering a higher value. Survey respondents didn't seem to have the same opinion, with 63% of respondents saying the Bronze plan's coverage is too lean, compared to 12% who said it was too rich.

"Many of these folks will be exposed to premium prices for the first time," Kleinke says of the potential Bronze plan members, "and many will be too young to remember the 1990s era, when low premiums translated into less coverage and restricted choices in providers—when it came time to find one—long after the enrollment decisions had been made."





Source: *Managed Healthcare Executive* original research, October 2013

Narrow and tiered networks

Exclusive networks have big market potential, but members need a better understanding

Julie Miller

Since their peak in the 1990s, HMO product designs have steadily declined in enrollment. While the emerging narrow- and tiered-network products seem quite similar on the surface, they have distinct advantages over the HMOs of the past.

For example, advanced technology that wasn't available in the 1990s will allow payers and network providers to share information. Better information allows for improved care and enhanced measurement of quality, which allows payers to be more selective in their provider choices.

"It's absolutely a result of the industry focus on improving quality and cost effectiveness of care," says Wendy Sherry, vice president of product development for Cigna.

Narrow networks can direct members to high performers while also rewarding high performers for better care and reduced costs.

"Not all doctors are created equal," she says. "What narrow and tiered networks allow us to do is recognize and reward those doctors who best manage quality and cost efficiency of care."

Sherry says Cigna measures providers with accepted industry benchmarks such as readmission rates, choice of laboratory services and use of beta blockers. They're compared to their peers, and the top performers are considered for best network placement.

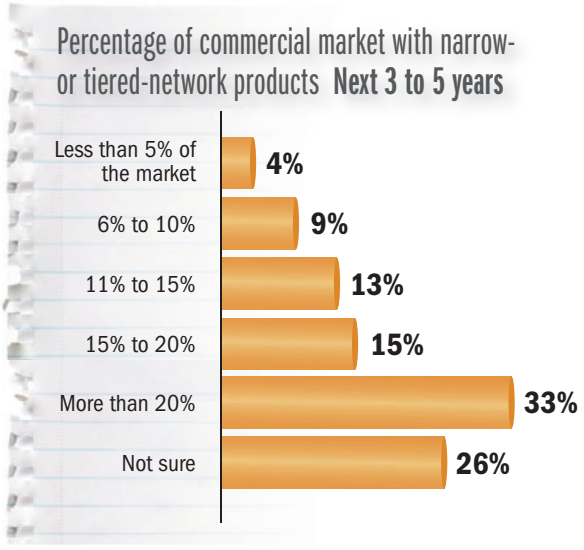
Accountable care organizations (ACOs) are ideally suited to become exclusive plan-design networks because most already have robust care service capabilities and, by nature of being an ACO, are already working toward high quality.

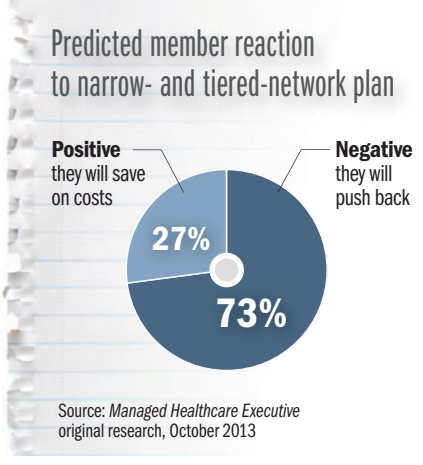
"The accountable care movement is about sharing information around quality and cost," she says. "We're in an era now where there is greater opportunity to share information."

However, members tend to have a negative outlook on any design that limits choice. Payers might have to sell them on the advantages of narrow networks.

"Where it becomes negative is for those customers whose doctors, for lack of a better way of saying it, haven't made the cut," Sherry says.

For example, it's especially difficult for members who have seen the same physician for 20 years and have to change because their physician—however pleasant at the bedside—just doesn't deliver the best quality. Sherry says plans must encourage members to understand the cost and quality proposition.





ACO participation

Shared Savings model will have to mature and refine to adapt to industry changes

Mari Edlin

The number of accountable care organizations (ACOs) has doubled during the past year with Medicare ACOs taking the lead over commercial entries into the healthcare space, according to Leavitt Partners.

After the inauguration of the Medicare Pioneer ACO Program in January 2012 with 32 participating ACOs, the program grew to 106 total ACO players by January 2013 providing care for about 1.6 million beneficiaries, according to the Medicare Payment Advisory Commission (MedPAC).

Despite the growth of Medicare ACOs, Stephen Thome, senior manager, healthcare practice for Ernst & Young in Cleveland, says commercial ACOs are growing at an organic pace and are not

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affected by the same regulations as their Medicare counterparts such as federal governance, management and leadership requirements.

"Commercial payers have come up with accommodations to share start-up costs, and the process for attributing patients to the ACO can be more transparent and timely," he says.

He also says ACOs will need to develop a more sustainable payment model to survive long term. The initial Shared Savings model will need to mature to provide more predictable payment streams and to align incentives for payers and providers.

"They will also need to deliver on medical management, and provide better care for less," Thome says. "Otherwise, they will become irrelevant and add another layer of costs."

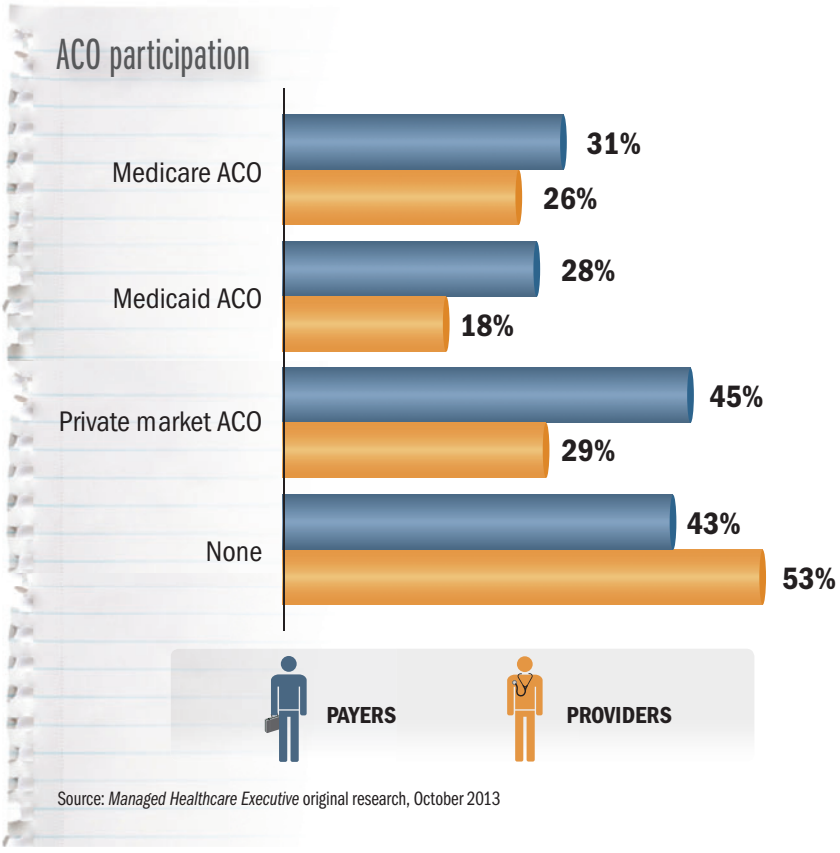
But as the competition among ACOs increases, he believes that the healthcare marketplace will see a bend in the cost curve and improved quality of care.

"Five years ago, the partnerships between plans and providers in an ACO would have been unthinkable," he says.

Any ACO partnership would require an information technology infrastructure, says Gene Muise, director of pharmacy for Mount Auburn Cambridge Independent Practice Assn. (MACIPA), a 500-multispecialty physician group in Cambridge, Mass., and an original Pioneer ACO.

"If ACOs can meet performance measures, improve quality, save money and boost buy-in and communications with health plans, the model holds promise for the future," Muise says.

MACIPA has experience with models similar to an ACO as far back as 1985, when it secured risk-based contracts covering individuals in HMOs offered by Tufts Health Plan, followed by Blue Cross Blue Shield of Massachusetts and Harvard Pilgrim Health Care in the mid-1990s.



Source: *Managed Healthcare Executive* original research, October 2013

ACO models

Physician-led models seem to have several advantages

Mari Edlin

The first year experiences for Medicare's Pioneer ACOs showed mixed results. Only one-third of the 32 participants in the pilot reduced costs. However, all of the participants met the quality performance metrics.

"When the Medicare ACOs are redesigned properly, they can save money," says Don Crane, president and CEO of the California Association of Physician Groups, based in Los Angeles. "The Shared Savings Program with its fee-for-service model has an inherent flaw—it provides an incentive for providers to churn."

He suggests switching to a global capitated model to solve the problem.

Doug Chaet, senior vice president, contracting and provider networks, Independence Blue Cross based in Philadelphia, and **MHE** editorial advisor, agrees with Crane that ACOs have the potential to rein in healthcare spending growth.

"Some ACOs will save money because the new organizations are structured to enhance quality, lower costs and develop high-level coordinated care, which is often missing among providers," he says.

Chaet emphasizes the need to develop an ACO structure that provides engagement, support and tools. He recommends a combination of price, quality data and information technology to engage providers; incentives for providers to promote care coordination, and for members to select more experienced providers offering the same or better quality services at a lower cost; and

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an investment in infrastructure.

To be successful, ACOs need to use a population-based, prospective system with incentives, Crane says. Also, the initial ACO pilot might have had more success if it had more patient engagement.

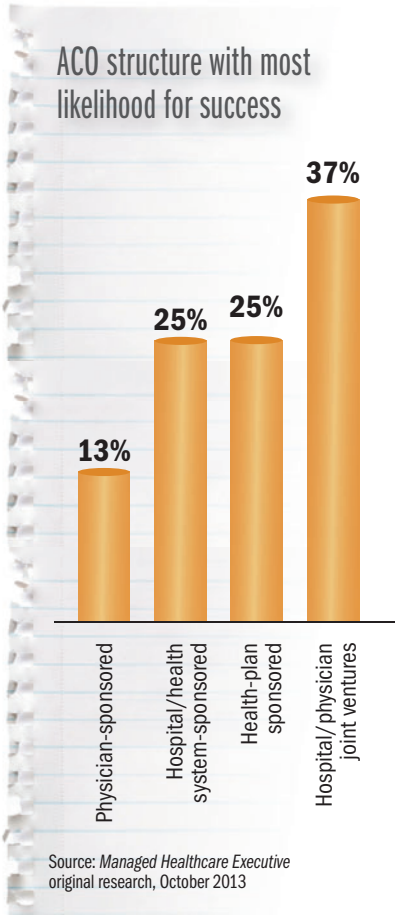
"Many patients don't even know they are in an ACO. It should be a voluntary, opt-in program with incentives or mandates for members to stay in the ACO network," he says. "If they migrate outside, it is difficult to manage costs and quality, and coordinate other services."

On the other hand, Crane says the results for the commercial ACOs in California, with which he is familiar, have had success. He attributes their performance to an HMO foundation, which by design, encourages members to use services and providers within closed networks.

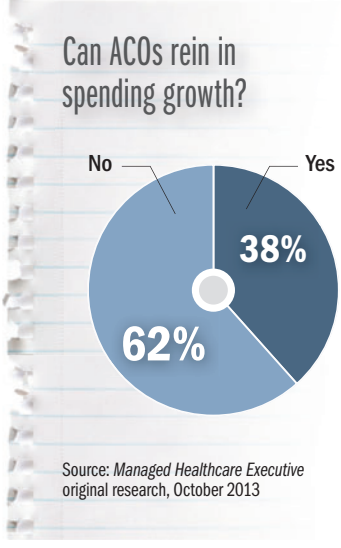
Crane says unequivocally that physician group-sponsored ACOs are on the surest road to success with their capitated, centrally managed structure. While he acknowledges that plan-sponsored ACOs and physician/hospital partnerships can also work well, he is more reticent about putting his money on hospital-led ACOs. He believes health systems have little incentive to reduce the use of expensive services.

"Historically, physician-driven structures have had the most success in reducing unnecessary medical costs," Chaet says. "The reason may be that most of the savings comes from a reduction in facility expense. For physicians in a successful performance-based contract, this means increased reimbursement because they now become eligible for a share of dollars that previously flowed to the hospital. For hospital-sponsored entities, successful performance may mean a net reduction in revenue for the facility."

According to the Centers for Medicare and Medicaid Services (CMS), about 50% of Medicare ACOs are physician-led organizations that serve fewer than 10,000 Medicare beneficiaries.



Source: *Managed Healthcare Executive* original research, October 2013



Source: *Managed Healthcare Executive* original research, October 2013

ACO formulary

Anticipate larger ACOs eventually opting for formularies

Mari Edlin

Although ACOs are growing, their member populations still remain small—too small for most to consider developing their own formularies, says Brian Solow, MD, chief medical officer for OptumRx, a pharmacy benefits manager.

"Instead, it makes more sense for them to look to PBMs to create drug lists appropriate for both ACO management and members," he says.

Only a limited number of pharmacy directors contracting with an ACO say their organizations have

Specialty pharmacy

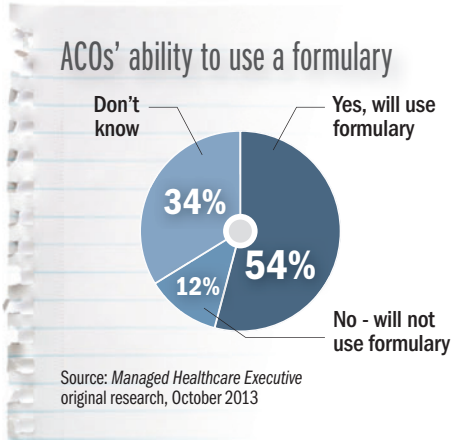
New cost control ideas will be needed in the future

Mari Edlin

As many as 907 biologics targeting more than 100 conditions are currently in the pipeline, according to the Pharmaceutical Research and Manufacturers of America (PhRMA). More than one-third are cancer therapeutics, 176 candidates tackle infectious diseases and 58 drugs treat cardiovascular disease.

The annual growth in specialty drug cost is expected to increase 22 % in 2014 and by 67% for specialty drug spending by the end of 2015, according to Express Scripts.

Ruth Opdycke, president, TPG Healthcare Consulting, a pharmacy benefit consulting group, provides her



their own formularies, but 72% of the 40 in a survey conducted by Decision Resources Group's Physician & Payer Forum expect that to change—developing a formulary distinct from that of a managed care organization—in the next three years. The survey respondents also anticipate that already existing ACO-driven formularies will become more restrictive or adopt similar restrictions already imposed on MCO formularies.

Only 13% of the pulmonologists in that survey, who currently participate in an ACO, report having a distinct formulary, limited by the shortage of lives they cover. These physicians, serving an average of 10,000 patients in their ACOs, estimate they would need 30,000 members to justify their own formulary.

Dr. Solow says that the objectives of PBMs in creating a formulary are the same as those of ACOs—achieving quality, good outcomes and cost savings—and that PBMs and their pharmaceutical and therapeutic committees have more experience in looking at drugs clinically, and selecting the right medications to achieve the right outcomes.

He also says that PBMs have experience in applying utilization management techniques, especially to high-cost specialty drugs prescribed on and off label.

"In the past, physicians have not had much responsibility for developing formularies, but as part of an ACO, they need to assume more responsibility," Dr. Solow says.

He doesn't anticipate that formularies developed by ACOs would differ much from those created by a PBM, and that plans would likely adopt formularies similar to those used outside of an ACO.

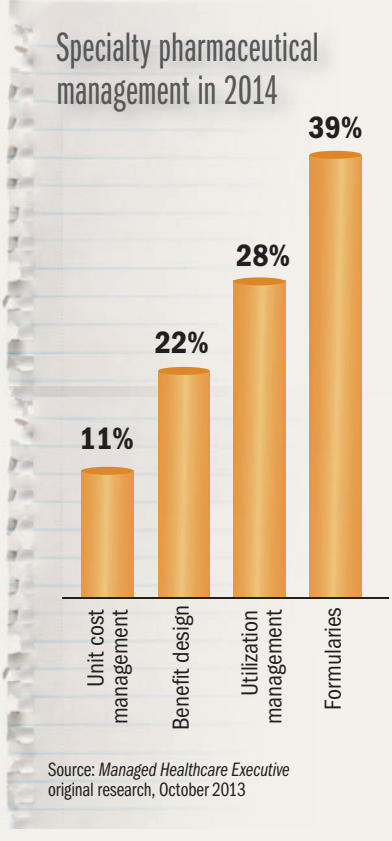
On the other hand, Dr. Solow says that if ACOs prepare their own drug lists, they can target their specific populations, identify gaps in care and provide the right incentives.

take on how to manage costs for the onslaught of specialty drugs in the U.S. marketplace. She says the management tactics are multi-pronged and include:

- **Distribution channel management and provider reimbursement models.** Effectively negotiate for product level discounts in both the pharmacy and medical benefits.
- **Site of care management.** Identify and utilize the lowest site of care for product administration, such as hospitals, providers' offices and home infusion services, especially for specialty products adjudicated under the medical benefit.
- **Benefit design.** Build appropriate designs to the extent possible given the 2014 and beyond changes to maximum out-of-pocket limits.
- **Formulary control.** Use preferred products and/or an overlay of the benefit design by excluding certain non-preferred specialty products altogether.
- **Utilization management controls.** Put in place clinical pathways, prior authorization, step therapy and quantity and duration limits.
- **Outcomes oversight/management.** Use clinical services to monitor patient response/outcomes to determine if the expected therapeutic outcomes are being achieved.
- **Medical benefit adjudication.** Assure that the medical benefit adjudicator has the appropriate claims benefit edits in place to manage specialty products administered under the medical benefit at the specific drug level.

Randy Vogenberg, principal, Institute for Integrated Healthcare in Greenville, S.C., is not as optimistic. He says payers really can't effectively manage drug costs aside from cost shifting, which he believes does not dovetail with an emphasis on the total cost of care, effective patient management and outcomes.

Opdycke anticipates that therapeutic areas, such as breast and lung cancer, lymphomas, hepatitis C, multiple sclerosis and rheumatoid arthritis, will continue to fill the specialty pipeline.



Small employers

Defined-contribution products and private exchanges are trending among small employers

Jamie J. Gooch

Some estimates place the ratio of small businesses—those with 50 or fewer full-time employees—to be as high as 75% of all U.S. companies. Many of them don't offer health insurance to their workers now, and most (68%) survey respondents expect the ones that do to stop providing insurance and send employees to individual exchanges.

Not so fast, says Dan Hilferty, president and CEO of Independence Blue Cross and **MHE** editorial advisor.

"We believe that employer-sponsored business will continue to be a very important segment in the marketplace, and we think that for most small employers, 2014 will be a wait-and-see year, watching how the federal exchanges evolve," he says. "We also think the small-group marketplace will stay viable because health insurance is an important employee benefit. The emphasis will be more on how the employer will offer coverage, and we will need to provide both the popular standard options and new alternatives like defined contribution, private exchanges or individual products."

Those options will help dictate whether small employers choose to offer more robust health insurance plans as a competitive advantage, take a bare bones approach or just pay the Patient Protection and Affordable Care Act's penalty for not providing adequate coverage.

"Employers will have many decisions to make in light of reform, including the continuing question about affordability," says Hilferty. He says insurers need "to do everything we can to help employers keep costs down and provide a full array of options for products and services that meet the required essential health benefits and exceed our customers' expectations."

Only 13% of the survey respondents expect small employers to purchase off-exchange products directly from carriers.

Job impact

Employers are threatening to cut hours to avoid PPACA requirements

Julia Brown

The Republican National Committee argues that 8.2 million Americans working part-time cannot find full-time work because of PPACA. However, the Bureau of Labor Statistics says that not only are there fewer part-time workers today than in 2010 when the law was passed, but the number has been trending downward.

Similarly, observers say the reform law is killing jobs. A Congressional Budget Office (CBO) report shows that the law would reduce labor in the economy by one-half of 1%.

Sheila Burke, senior public policy advisor for law firm Baker Donelson, says the exact effect the law will have on jobs is difficult to predict.

"Everyone from CBO to the Urban Institute has looked at this question, and what has complicated it, of course, is the delay in the employer mandate," she says.

In July, the Obama administration allowed businesses an extra year to comply with a requirement that they provide their employees with insurance. Under the provision, companies with 50 or more workers will have to pay a penalty up to $3,000 per employee for not offering coverage, beginning in 2015.

"The question will be the extent to which employers find it in their interest to either continue coverage or to offer coverage in the absence of the penalty occurring this year," Burke says. "It will be a calculation for each of them as to what the financial implications will be."

However, the penalty on employers is relatively light compared to the cost of health insurance. Currently, the average annual premiums for employer-sponsored health insurance are $5,884 for single coverage and $16,351 for family coverage, according to the 2013 benefit survey conducted by Kaiser Family Foundation and Health Research & Educational Trust.

"I don't anticipate seeing any big changes in the very large firms and what they currently offer, although there is certainly the possibility of changing

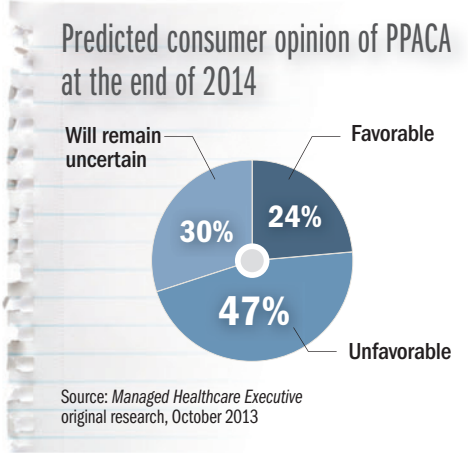
Consumers

Consumers need in-person assistance to understand the health law and what it means to them

Jennifer Webb

Many provisions of the Patient Protection and Affordable Care Act take effect in 2014, yet consumers have a generally negative opinion of the law. Far fewer understand how it will impact their healthcare coverage because consumers are confused by the continued debate among lawmakers and advocacy groups about its merits, says Kathleen Stoll, deputy executive director and director of health care policy for Families USA, a national nonprofit, nonpartisan organization.

The organization applauds PPACA as "affordable, accessible and comprehensive" by providing fairer treatment for people with pre-existing health conditions, helping low- and middle-income people buy coverage, providing fairer and more affordable coverage for women and older Americans, and by helping young adults buy health coverage.



"Unfortunately, the public has received a lot of blatantly false information about the law and what it does from opponents who want to continue the political debate after more than three years," she says.

As consumers learn more about the law and receive help with purchasing the insurance coverage they want, they will support it, Stoll says.

The key will be to deliver easy-to-understand, factual information that consumers can use to compare plans and make decisions.

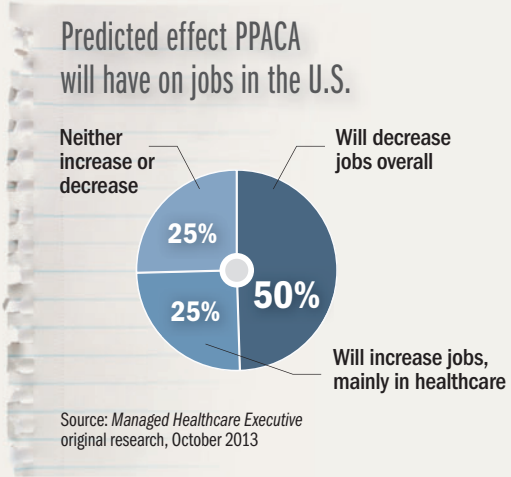
"People want the facts from trusted messengers in their community, and they want to know what the law will do to help them and their families. People want easy-to-understand marketplace websites where they can find out what help they can receive and easily compare health insurance plans," Stoll says.

For individuals who are not familiar with using web-based applications, or who may be unfamiliar with health insurance terms such as "deductibles," "copays" and "cost-sharing limits," in-person help will be critical. The federal government has provided funding to in-person helpers and navigators as part of the reform law.

their requirements with respect to premiums," she says. "On the small-employer side, it is much more of an open issue."

Large firms will most likely be looking at cost-sharing and the structure of their plans, and where they might reduce their exposure, Burke says, but employers with relatively low-wage workers will have to take into consideration whether their workforce is likely to be worse off or better off if they provide coverage. If they do offer acceptable coverage to workers, the individuals cannot get a subsidy.

"The subsidies that the federal government is providing in terms of the tax credits to small employers—very small employers—of course goes away after two years," she says. "A query is whether or not an employer is prepared to commit without knowing what the long-term implications will be."



Competitiveness in the industry—or whether or not an employer needs to provide coverage to attract or retain workers—will also factor into employers' decisions.

A report from the Brookings Institution shows that jobs in the healthcare industry have grown faster than in any other. Some 2.6 million jobs have been added to the sector over the last decade, accounting for a 22.7% employment growth over 10 years—compared with a 2.1% employment growth rate in other industries.

"There will be a large number of individuals coming into the system and a desire on the part of large healthcare providers to expand their workforce," Burke says. **MHE**

PAYERS warm up to RETAIL CLINICS

Stakeholders weigh the pros and cons of care in scaled-down settings

By Morgan Lewis, Jr.

Retail health clinics, typically located in pharmacy chain stores, offer convenience for members and lower costs for payers. As an alternative to physicians' offices and emergency departments, retail clinics' impact on care coordination and overall quality is still in dispute.

Operators contend that all their respective clinics are connected with electronic health record (EHR) systems, which offer them an opportunity to coordinate care. They also provide care summaries to patients' primary care physicians, and encourage patients to establish a relationship with a physician if they do not have a medical home or regular source of care—even going to the extent of helping them find available practices.

Family physicians, however, are still wary that these clinics are an intrusion in the physician-patient relationship, and that the nurse practitioners (NPs) who often staff these facilities are not qualified to manage chronic conditions as well as a physician-led team, according to the American Academy of Family Physicians (AAFP).

Regardless, major retail/convenient care clinics are in growth mode again, buoyed by patient preference as well as the healthcare reform law that will unleash millions of newly insured members into the market. To capture more of these consumers, retail clinics are expanding services to include preventive care, physicals and weight management.

"Nationally, payers warmed up to retail clinics," says Thomas Charland, CEO of Merchant Medicine LLC, a research and consulting firm that covers retail and urgent care clinics. "Even to the point where a number of the health plans not only embraced it, but offered lower copays to members to create steerage toward these clinics and away from the emergency room."

CLINIC BUSINESS

As of September 1, there were 1,475 retail health clinics in the United States, according to Merchant Medicine, up from 901 clinics at the end of 2007. After rapid growth from 2003 through 2008, retail health clinic expansion was flat in 2009 and 2010.

The business cycle was due to the economic recession, but also the ebb and flow of consumer demand for services. For example, upper respiratory infections drove much of their business but were seasonal, which required the clinics to alter their business models.

"For the off-season, there was a lot of cash burn," says Charland. "They wanted these clinics to be open and convenient so they staffed them year-round, and the providers were literally just reading books. There were no patients."

When the clinics were losing money, their in-demand NPs would find new jobs, Charland says.

Fall and winter were the busiest times for acute visits, so retail clinics added services to increase demand in slow months: summer camp physicals for the spring and school sports physicals for the late summer, primarily to attract time-starved parents eager for any licensed healthcare practitioner to sign the required forms. Other non-traditional non-acute services such as weight management and smoking cessation have been added, as well as biometric screenings, tuberculosis testing and blood glucose testing and monitoring.

"I don't think they are taking it to the extent where they are practicing as a medical home," says Charland. "But they're moving in that direction."

CARE CONTINUITY

Driving consumer and payer acceptance is the fact that 50% to 60% of patients visiting retail health clinics lack a regular primary care physician to begin with, according to the Convenient Care Assn., the trade group representing retail health clinics. As a consequence, these patients have no continuity in their care to disrupt, says CCA Executive Director Tine Hansen-Turton, JD.

"If anything, the clinics are important as an entry point into care for these patients," Hansen-Turton says. "For patients who do not have a PCP, the clinics emphasize the importance of having a healthcare home and make attempts to ensure the patient will find a regular source of care."

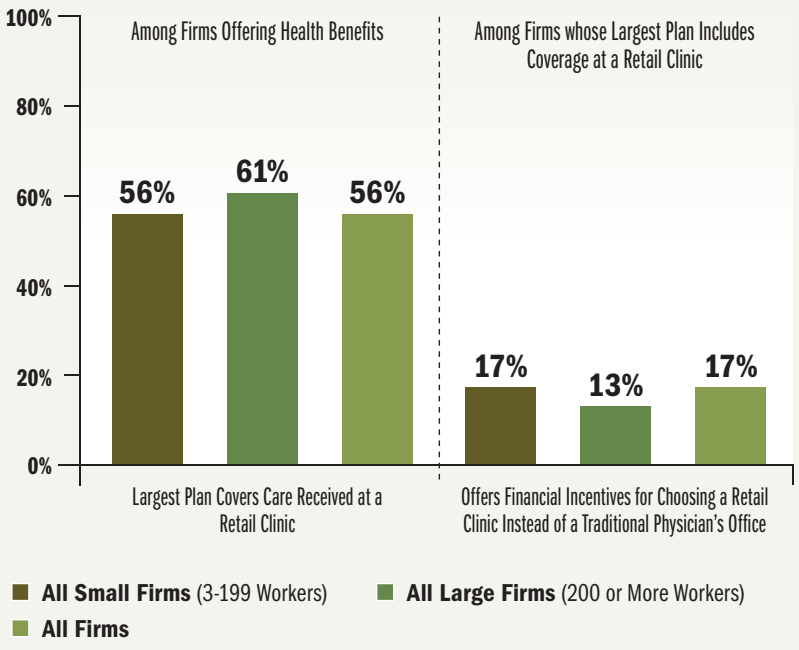
Over the years, health systems and physician groups recognized this opportunity and partnered with retail health clinics to secure PCP and specialist referrals and monitor the quality of care delivered by the NPs. Cleveland Clinic, for example, has as a clinical affiliation with CVS's MinuteClinic in Ohio and Florida, and Ochsner Health System in New Orleans partnered with Walgreens' Healthcare Clinic (formerly Take Care Clinic).

Affiliated practices and health systems even educate patients on Healthcare Clinic's services and coordinate care for additional services as appropriate, according to Heather Helle, divisional vice president, Walgreens Consumer Solutions.

"We can serve as an extension of their practices," she says in an email to MHE, "…while health systems serve as a resource for specialty care, second opinions and rapid access to service outside of the scope of our clinics such as X-rays and EKGs."

These types of affiliations will become the norm as formerly uninsured patients gain coverage and face a shortage of primary care physicians, according to consulting firm Accenture in its report "Retail medical clinics: From Foe to Friend?" According to the report, relationships are key to "a secure niche in the marketplace."

RETAIL CLINICS:
Percentage of firms that offer a financial Incentive to use, by firm size, 2013



Source: Kaiser/HRET Survey of Employer-Sponsored Health Benefits, 2013.

STAYING CONNECTED

In the eyes of payers and employers, reducing the silos of care is a major concern. The prevalence of EHR systems used by the clinic providers offers reassurance. All Convenient Care Assn. members, including MinuteClinic and Healthcare Clinic, operate with EHR systems, as oppose to about 72% of office-based physicians, according to the U.S. Department of Health and Human Services' Office of the National Coordinator for Health Information Technology.

Patients seen at the retail clinics receive a copy of their medical record after the visit, which they can share and discuss with their other providers. If the patient has a regular primary care physician, the record is faxed to the practice or transferred electronically.

Walgreens' Helle says that currently patient information collected at HealthCare Clinics is exchanged either by direct call or fax.

"We are in the process of making available electronic transfer of patient visit information for those PCP/specialists who are interested in receiving it in electronic format," she says.

Although retail clinics are forming alliances with large physician groups and health systems, independent family physicians and pediatricians have not warmed to the operators.

In 2010, the AAFP revised its first official policy (dating from 2005) regarding the clinics in light of their expansion into preventive care services.

New evidence has emerged that supports the AAFP's concerns about fragmentation. An analysis of 127,358 patients who visited retail health clinics for one of 11 common ailments showed that they were less likely over the next 12 months to visit a primary care physician for a similar complaint, according to the *Journal of General Internal Medicine* study by the RAND Corp., first published online in October 2012. Patients who visited retail clinics were also less likely to see the same physician for their medical needs, according to the results.

Conversely, however, researchers found no evidence that the clinics "disrupted preventive medical care or management of diabetes," according to the study.

"It may look to payers as if they can get an individual piece in a cheaper format, but that may be penny wise, pound foolish," says Jeffery J. Cain, MD, FAAFP, president of the AAFP. "If you get a little cheaper part with a lower price for a less effective visit, you end up with higher utilization overall because of increased referrals, increased, unnecessary ER visits and hospitalizations. You've saved money on the office visit, but lost money on the global care of the patient."

Even so, the market is still demanding the convenient service hours of the clinics.

Dr. Cain points out that AAFP members are responding to market demands by expanding hours and structuring their practices for walk-in visits. A 2012 survey of members showed 71% of family physicians offer same-day appointments, 45% have evening hours and 31% offer weekend appointments.

"Often times those minor visits are used by family doctors to talk with patients about other aspects of their care," Dr. Cain says. "The visit may start with looking at a sinus infection, but we end up talking about their cholesterol or the last time they had their diabetes checked."

FUTURE GROWTH

Accenture predicts that by 2015 there will be 2,868 retail health clinics with the capacity for 10.8 million patient visits, up from 5.1 million in 2011. Patient volume should sustain those new locations because they will likely be included in most plan networks, and a HarrisInteractive/HealthDay poll shows that adults who have visited retail clinics grew to 27% in 2012 from 7% in 2008.

Employers, too, seem to be supportive. Fifty-six percent of employers offering health benefits cover retail health clinics, according to the Kaiser Family Foundation and the Health Research & Educational Trust's 2013 Employer Health Benefits survey. Of those employers, 17% provide a financial incentive to receive services in a retail clinic instead of physician's office.

"From the insurer's perspective, they want the patient to go to the lowest-cost access point that is still appropriate to care for their needs," says the CCA's Hansen-Turton. "This makes sense from a financial perspective, and also from the standpoint of reducing the burden on emergency services."

Whether or not they impact overall quality of care in the long term is yet to be seen.

"Retail clinics are still in their infancy," said RAND study co-author Rachel O. Reid of the University of Pittsburgh School of Medicine in a prepared statement.

Observers believe the systemwide effect of retail clinics on preventive care or continuity of medical care must be studied further.

Morgan Lewis Jr. is a Pennsylvania-based freelance writer.

FACT FILE... Convenient Care Clinics

- There are approximately 1,475 retail clinics in the U.S.
- By 2015, there will be as many as 2,800 or more.
- Retail clinics recorded 5.1 million visits in 2011.
- Most are located in retail drug stores and grocery stores.
- More than one in three consumers are receptive to the retail clinic model, and baby boomers are especially interested.
- Millennials are the least likely to use a retail clinic.
- Nurse practitioners or physician assistants usually staff the clinics with varying oversight by physicians, depending on state law.
- Top brands include: MinuteClinic by CVS; Healthcare Clinic by Walgreens; Target Clinic by Target; as well as several hospital-system and independent brands.
- Most clinics are open seven days a week and have contracts with insurance carriers.

Sources: Wikipedia, Deloitte, Accenture

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Senior population requires high-touch hypertension care

Remote monitoring helps keep tabs on progress

JILL SEDERSTROM

HYPERTENSION has high prevalence rates in the elderly and is linked to significant healthcare spending, driving some plans to increase their efforts to effectively prevent and manage high blood pressure in their older patient population.

One study using data from the National Health and Nutrition Examination Survey found that between 1999 and 2004, 67% of all U.S. adults over the age of 60 had high blood pressure.

Hypertension is not only prevalent in elderly adults, it can also contribute to serious and costly adverse events. According to a 2011 expert consensus document from the American College of Cardiology Foundation and the American Heart Assn., hypertension is the most important risk factor for cardiovascular disease in older Americans.

The consensus committee—which was co-chaired by Wilbert S. Aronow, MD, FACC, FAHA—also noted that approximately 69% of patients who have their first myocardial infarction had hypertension before the event, while that's also the case for 77% of those who have their first stroke and 74% of those who experience incident heart failure.

"Seniors have a higher prevalence of hypertension, especially elderly women, and they are undertreated more than younger people," says Dr. Aronow, professor of medicine at West Chester Medical Center/New York Medical College. "They have more comorbidities, and since hypertension is the number one contributing factor to cardiovascular disease, hypertension is a very major contributor to cardiovascular disease in the elderly."

The Centers for Disease Control and Prevention estimates that high blood pressure costs the United States approximately $47.5 billion a year in direct medical expenses.

Jill Sederstrom is a freelance writer based in Kansas City

MANAGING SENIORS

While many of the same recommendations to treat hypertension in younger patients—such as diet, exercise, medication and weight loss—ring true for the elderly as well, healthcare experts say there are certain factors that make this group unique and more difficult to treat. For instance, some seniors are no longer able to cook for themselves. Instead, they rely on packaged food or dining out, options that may make it more difficult to avoid sodium or maintain healthy eating habits.

"A low sodium diet is more important in the elderly than in younger people because they are more sodium-sensitive," Dr. Aronow says.

CareMore, a WellPoint subsidiary that serves approximately 70,000 seniors in its Medicare health plans, has a chronic disease management program that works to specifically address care obstacles for seniors. Upon entering a CareMore plan, beneficiaries are given a healthy start exam that identifies any physical, social or mental health issues a patient may have.

Those patients who are identified for hypertension management services typically make up 15% to 20% of the plan's sickest patients who have uncontrolled blood pressure.

Peggy Salazar, MSN, FNP, director of clinical programs, says education is an essential aspect of their "high touch" hypertension program, whether it's teaching patients what signs and symptoms of high blood pressure to look for, how to take their medication or what kinds of foods will increase their blood pressure.

Experts agree that frequent and regular measurement of blood pressure—especially in the home—is also essential to effective management.

"Data from ambulatory blood pressure monitoring or data from home blood pressures more accurately correlates with cardiovascular events than

blood pressure [readings] in the physician's office," Dr. Aronow says, adding that seniors blood pressure measurements should be taken both sitting and standing to get accurate results.

He says tracking methods don't have to be sophisticated—a piece of paper and pencil may be all that's necessary—but CareMore has turned to a real-time technique to monitor its patients at home.

Through their plan, patients are given a blood pressure device and trained how to take the measurements themselves at home. Data is transmitted back to CareMore where nurse practitioners are able to monitor the data on a daily basis. This data transmission is done automatically, making the technology easy to use.

"We set parameters for patients for alerts if the blood pressure goes over a certain number, and [the nurse practitioners] will call the patient," Salazar says. "They will verify symptoms, verify blood pressure, have them re-check, check on whether they took their medications and treat."

If a patient doesn't measure their blood pressure for a day, a team will contact the patient directly.

"The challenges we get with some of our seniors is they are forgetful sometimes," Salazar says. "They forget to take their medication, and sometimes they don't have the support. They have limitations in their functional state."

CareMore created a plan that centers around accessibility for its members.

"We have what we call care centers where we have our disease management programs, and they are located in the communities we serve," says David Ramirez, MD, director of quality management for CareMore. "We also provide transportation to our members to get them to their medical services."

Another challenge with seniors is that they are often on multiple medications, and Dr. Aronow says the best drug to use to combat hypertension often depends on the individual.

"You have to avoid drugs that raise blood pressure and interfere with the action of blood pressure," he says. "For example, non-steriodal anti-inflammatory drugs, over the counter medications, increase blood pressure and they interfere with the efficacy of blood pressure lowering medications."

Dr. Ramirez says CareMore looks at the whole patient before making medication decisions to try to avoid any drug interactions or safety concerns.

"Our clinicians are very experienced in dealing with patients who have 10 to 15 different medications," Dr. Ramirez says. "The side effects and the dosing is a little bit different for the elderly, and that comes with the experience of taking care of a senior population."

CURBING COSTS

Healthcare experts agree that prevention and management is more cost effective than paying for later adverse events related to high blood pressure.

"Health plans could give out free medication and they would save money in the long run," Dr. Aronow says.

One health plan has essentially done just that for its highest risk Medicare members. In 2013, Humana partnered with Walmart to offer a plan for their Medicare Part D members that offers 10 hypertension medications for a penny if the prescriptions are filled at a Walmart or Sam's Club pharmacy.

Betsy Warren, PharmD, director of Medicare Pharmacy for Humana Pharmacy Solutions, says beneficiaries in the plan were able to purchase medication for that price regardless of whether they had met their deductible or if they were in the coverage gap.

The company chose hypertension medications for the partnership due to its high prevalence in Medicare members.

"We picked a category that had a wide variety of generic drugs available, and because of the prevalence of hypertension, we just thought it was a nice match," Dr. Warren says.

Research has shown that reducing the patient's financial obligation has significant impacts on adherence.

A previous 2004 study done by Dr. Aronow and his colleagues found that systemic hypertension was adequately controlled in 70% of patients who received their medications at minimal or no cost, while it was controlled in only 38% of those who had to pay for their medications.

Dr. Warren says Humana hasn't specifically tracked whether offering the hypertension medications for a penny has effected patient adherence rates, but says the company has employed other policies as well to keep medication costs down for the patient. In addition to offering a plan with medications for a penny, Warren says all of Humana's Part D Prescription Drug Plans and most of the Medicare Advantage Prescription Drug plans offer a zero dollar co-payment for generic drugs once a patient reaches their deductible and they use a mail order pharmacy.

Humana also has a program where they can identify members who are late in refilling their hypertension medications and can call them to try to help coordinate re-filling the drug.

Dr. Ramirez says CareMore hasn't done a rigorous analysis to determine whether there are cost savings from its program to the health plan itself, but says he believes having more patients with controlled blood pressure likely has a significant impact.

"We really strongly believe our utilization at the hospital and the emergency room is really low, particularly given how sick a lot of our patients are, and we attribute that to controlling chronic diseases like blood pressure and diabetes," he says. **MHE**

Exchange formularies need additional flexibility

Pharmacy leaders say PPACA is too prescriptive

BY MARI EDLIN

THE ESSENTIAL HEALTH BENEFITS (EHB) for pharmaceutical drugs mandated by the Patient Protection and Affordable Care Act (PPACA) for health exchanges should create consistency. However, some organizations believe the rules actually sacrifice flexibility.

Edith Rosato, CEO of the Academy of Managed Care Pharmacy (AMCP), a national professional organization, says PPACA is too prescriptive.

"Instead, plans should be able to look at their populations and find the most appropriate, affordable and accessible drugs based on clinical evidence to improve quality of life and produce the best outcomes. A mandate is unnecessary," she says.

A benchmark plan—that is, a "typical" plan in the state that must be used as a benchmark for defining specific benefits—is chosen by each state according to PPACA guidance. Rosato objects to regulators and benchmark plans dictating what should be included on a formulary. That should be the role of pharmaceutical and therapeutic (P&T) committees, she says.

Rich Cunningham, segment vice president, Humana Pharmacy Solutions, agrees. He says that under the exchange, plans have less ability to develop tiering and cost-share structures. Humana's P&T committee has studied each drug category and chosen drugs from the benchmark plan to best serve its members.

Humana and its PBM, Humana Pharmacy Solutions, will offer benefits under the exchanges.

FOLLOW THE RULES

Insurers selling non-grandfathered individual and small-group policies must include 10 categories of essential health benefits, including prescription drugs, beginning Jan. 1, 2014. Qualified health plans in the exchanges, however, may choose to provide benefits beyond those mandated, and that means drugs on formulary. While plans are permitted to substitute within benefit categories, they are not allowed to substitute across categories.

A recent study by the Urban Institute of 10 states as they implement healthcare reform indicates that insurers are engaging in minimal substitution of covered benefits in the first year of the exchange, generally keeping pace with the benchmark plans. If there are no drugs in a category or class on the benchmark plan, health plans must cover one agent. Most of the differences have been found in cost sharing and plan design.

Under the EHB for prescription drugs, insurers must cover at least one drug in every category and class in the United States Pharmacopeia (USP) classification system or the same number of prescription drugs in each category and class as the benchmark plan in their state. Two different dosages or strengths of the same drug do not count as two separate entities on a formulary.

Key plans analyzed in a formulary study by Avalere Health in January 2012 covered more than one drug per class—which is the Department of Health and Human Services (HHS) minimum rule. They also covered at least 50% of both brand name and generic drugs in most classes.

The Centers for Medicare and Medicaid Services (CMS) has not yet released guidance on formulary tiers.

PPACA, however, enables insurers to deviate from a benchmark plan if they provide benefits that are "substantially equal" to the benchmark in covered benefits and limits. The EHB offerings should be equal in scope to a typical employer health plan.

Insurers must also submit their drug lists to the federal or state exchanges or both, and if a drug is not on formulary, provide enrollees an opportunity to request a clinically appropriate drug.

Mari Edlin is a freelance writer based in Sonoma, Calif.

AMCP, PCMA

AMCP does not support the idea that a formulary should be based on USP classification—Medicare Part D, for example, uses the American Hospital Formulary Service as an alternative to USP—or on benchmark requirements. Rosato would prefer that insurers have more flexibility in developing evidence-based formularies to specifically meet the needs of their populations.

Part D regulations call for coverage of "substantially all" medications in six protected classes—anti-cancer, anti-psychotic, anti-convulsant, anti-depressants, immunosuppressant and HIV and AIDS drugs. Charles Cote, vice president, strategic communications for The Pharmaceutical Care Management Assn. (PCMA), the trade group representing PBMs, says a similar mandate for exchanges would have driven up costs.

"We were pleased that regulators rejected the 'protected class' approach that shields competing drug companies from offering competitive pricing to be included on formularies," says Cote. "Unfortunately, protected classes are used in Medicare and increase costs by $4.2 billion, according to CMS. There is no evidence that protected classes improve quality or access, and they should not be imposed on plans in the exchanges."

PCMA believes that plans can negotiate greater price concessions from competing drug makers—and reduce overall prescription drug benefit costs—when they have more flexibility to design clinically-based formularies.

Although AMCP has its reservations about EHB, Rosato says the organization supports access to drugs—one of the key initiatives of the health reform law—and medication management. She is optimistic that HHS will eventually reconsider the essential health benefits and make changes based on other parameters to control costs.

Lisa Zamosky, WebMD health reform expert, says that formularies may not necessarily be more restrictive under the exchange, but that it will depend on the state and specific insurance plans.

"In some cases, consumers may have richer benefits than they do now. Or health plans may already be offering more drugs on their formulary than the law requires," she says. "Plans will have the option of reducing their offerings to match the benchmark plan in the states where they sell insurance."

Zamosky says that when it comes to getting coverage for more expensive brand drugs, consumers may be subject to various cost-control designs, such as the tiering, prior authorization, step therapy and the use of mail order to obtain prescriptions.

"These are not new practices, but consumers should expect to see more of this going forward," she says.

Jenna Stento, senior manager of Avalere Health, an advisory health services company based in Washington, D.C., says that the newly insured will be more price-sensitive and choose plans with the lowest premium. For that reason, she anticipates that insurers will more tightly manage their benefits.

"They are well-positioned to meet these needs," Stento adds, "by requiring coinsurance rather than a set copayment to keep premiums down as product costs rise. Insurers will appeal to those most price-sensitive through their formularies."

She expects that with time, there will be more restrictions. She anticipates that insurers will utilize more prior authorization, step therapy and narrower pharmacy networks, as well as more incentives to use generics.

CONSUMER PREFERENCES

Julie Huppert, vice president, healthcare reform for Express Scripts, a PBM based in St. Louis, says insurers are well positioned to deliver prescription drug costs while meeting federal requirements.

"We already work with clients to evaluate the marketplace, the effect of healthcare reform and how to best position health plans by applying utilization management, creating specific networks and offering home delivery, which will be allowed under the exchanges," she says.

She is concerned, however, that essential health benefits will require more expansive formularies, adding drugs that may not be medically necessary.

"The requirements take away insurers' ability to construct their own formularies because they must use a uniform drug list. This could negatively impact affordability," she says.

In November 2012, Express Scripts commissioned an independent consumer market research study of the new public exchange consumer and how pharmacy benefits can influence plan selection in the public exchange marketplace. The study focuses on the uninsured, those who currently purchase insurance on their own and those insured through their employers.

Express Scripts concluded that the "long-term" uninsured are likely to be focused on cost and be more receptive to a benefit at a lower cost, while those who recently lost coverage will be seeking options similar to what they had under employer-based coverage. They are willing to pay more for access to broader drug and network coverage, she says.

In addition, the study reveals that the higher the subsidies, the more premium and cost sharing are neutralized as a choice factor. This also increases the influence of pharmacy network, copayments and formulary in regard to plan selection.

For the uninsured, she recommends a narrow, high-performance, managed network, a $100 deductible, higher drug copayment tier structure and home delivery. **MHE**

Technology helps community clinics take enrollment to the street

Centers reach out to low-income populations

BY ANKENY MINOUX AND STEVEN ABRAMSON

UNDER THE Patient Protection and Affordable Care Act (PPACA), the nation's community clinics are being fueled to better provide healthcare to uninsured and low-income populations with a much needed injection of $11 billion in funds. These health centers represent a critical population to target in the nation's quest to expand healthcare coverage. As such, they will become an important source of members for the nation's health plans.

But a critical problem remains: how to get eligible Americans to enroll in government-sponsored programs and connect with the system quickly and efficiently? And how can health centers overcome the many outreach obstacles presented when assisting this population?

Many health centers are just now beginning to explore enrollment barriers and the reality of the task ahead. Until recently, many politicians and some healthcare leaders erroneously believed that once the individual mandate kicks in, the enrollment dilemma for health plans will be solved. It could take years for enrollment efforts to catch up with the hodgepodge of outreach efforts, specifically those targeting Medicaid populations.

The good news is that enrollment programs are up and running. The bad news is that there is considerable information to communicate to millions of people in a short period of time.

According to the *New York Times*, while 30 million people will soon be eligible for coverage, as many as three-fourths are unaware of their options. Even in California, a state farther ahead than many others in its effort to educate uninsured populations, more than 78% of the population is unaware of their coverage options and what they need to do next. Newly-eligible individuals will continue to seek care within health centers and, more than ever, will need to be screened to identify which programs they qualify for, and to determine the most effective methods for enrolling.

It is expected, however, that millions of American may not in enroll in health plans, at least attributed in part to confusion and lack of direction and guidance.

These problems and possibilities leave health plans and health centers with a great responsibility to become active leaders in the effort to reach out and expand enrollment. First they must help patients that need quality healthcare and, for pragmatic reasons, help reduce the burden of bad debt. Also they can help health plans to build membership within targeted Medicaid and charity care populations.

However, enrollment itself will be challenging. There are many reasons why, including:

The information isn't getting through to targeted populations. Many of the populations who are newly eligible for low-cost or subsidized health coverage programs are transient and difficult to reach through traditional advertising methods, such as radio, television and billboards.

It's a highly diverse population. Americans who are eligible for Medicaid today range from young working adults, to working families, to the homeless. Clinics in some communities may also need to assist legal immigrants who are unsure if they qualify to enroll. Additionally, health plans must ensure they are communicating in the languages understood by this targeted, diverse population. In states like California and Texas, translation of materials needs to go well beyond Spanish and Vietnamese to other languages, such as Filipino, Punjabi, Cantonese and Arabic.

The message is complicated and misunderstood. How healthcare reform works is still very misunderstood by most Americans. Many consumers

Ankeny Minoux is COO of PointCare, developer of cloud-based, health coverage screening software. Steven Abramson is Marketing Manager for ChapCare, a community health center in Pasadena, Calif.

do not realize that their income levels will qualify them for free or low-cost healthcare, and many will be eligible for subsidies.

People are people. Many people aren't going to enroll until they have to—waiting until they are sick. Buying food, clothing and other necessities often takes precedence over healthcare coverage premiums.

SCREENING A CRITICAL STEP

The real challenge for health clinics to tackle is that all patients must first be screened to ensure eligibility. Screening patients means identifying and helping them understand which coverage they may qualify to receive. For many community clinics it could be Medicaid, but it could also be a county program to help single pregnant women, a displaced worker or an immigrant awaiting legal status. The next step is to enroll these patients. Unfortunately, signing up for a plan or program is often complicated and time-consuming, as it may involve providing verification of income, proof of residency and proof of identity, such as a driver's license or birth certificate.

To overcome current barriers, enrollment efforts will need to change. Simply reaching out and connecting with potential eligibles via traditional marketing methods is only part of the equation. Many people will need to be reached on a one-on-one basis—on the streets where they live.

For example, the Community Health Alliance of Pasadena (ChapCare) CEO, Margaret B. Martinez, MPH, challenged her staff to find solutions that would enable their team already going out into the community to provide ready access and to track their outreach efforts. ChapCare provides more than 55,000 medical, dental and behavioral health visits annually.

The staff identified two options for reaching potential patients: as they came into the clinic; and directly on the street where they live and work.

Technology helped address the challenges. In the clinic, office staff has access to cloud-based software featuring a quick questionnaire and database of every state, county and federal health coverage program in California. When an uninsured patient comes into the facility, clinic workers walk them through five screening steps that cover basic information, such as employment status, demographic information, income and health conditions.

To make it easier for patients, clinic workers also go out into the streets daily with laptops and tablets that can access the software and screen people before they come into the clinic. ChapCare's leaders believe that the more screenings are done in the field, the more efficient it will be once those patients walks into the clinic—giving the staff more time for care.

Clinic leaders also note that one value of a proactive approach to enrollment is that patients are much more willing to come to the clinic before a problem becomes acute when they know they have coverage. Having the ability to identify health coverage options quickly at the point-of-care, and enroll patients onsite, gives community health centers more time to focus on patients' healthcare needs.

ChapCare is also using software to provide a back-end tracking system that will help them track and follow-up on enrollment. The clinic is now enrolling about 100 to 200 people per month.

NEXT STEPS/SOLUTIONS

Industry leaders can ensure better communication with at-risk populations. Strategies that should be considered include:

- Develop partnerships and collaborate closely with local community health clinics and providers. They are closest to the uninsured population and can help with education and outreach.
- Expand community-based and highly localized enrollment events, health fairs, etc. Partner with community groups. Use available tools to communicate information, track and follow up.
- Use technology to provide tools to people in the field. Speak and provide screening and enrollment materials in multiple languages.
- Create efficient and simple screening programs to quickly identify appropriate programs.
- Adapt on-site technology. Health plans may want to consider helping community clinics add self-service kiosks to assist with enrollment.
- Ensure patients are tracked to determine when they enroll and follow up if they don't. Always keep in mind that outreach and enrollment are separate activities.
- Track efforts and results so if patients don't enroll, the clinic staff can go back out and provide further assistance.
- Utilize technology that can provide reports and record outreach efforts. This is helpful for tracking, but also necessary for clinics that need to report on activities as part of the effort to secure/retain grant monies.

It's not just clinics and community health centers that need to get involved in enrollment. All providers, hospitals and health plans will need to find ways to integrate efforts into their programs.

The next several months present many challenges, and much will be learned as we all work together in a new system. Programs utilizing effective marketing, outreach and technology to provide information, foster education and create efficiencies will be an important part of the process.

If providers can have greater access to technology, they can ensure efficient enrollment. **MHE**

MHE Resource

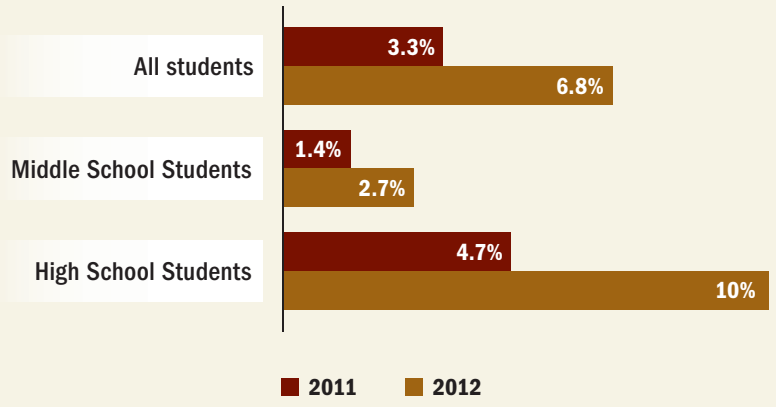
CDC seeks answers on e-cigarettes

ABOUT HALF of the 45 million Americans who smoke cigarettes try to quit each year, according to the Centers for Disease Control and Prevention (CDC). One of the ways to attempt quitting is to use a substitute such as nicotine gum or the electronic cigarette, which is rising in popularity.

Electronic cigarettes, or e-cigarettes, are battery-powered devices that look very much like a typical cigarette and provide doses of nicotine in an aerosol. Cartridges typically contain nicotine, a component to produce the aerosol and flavorings, such as mint.

CDC is concerned because young adults and children are beginning to use e-cigarettes, and the products' safety is uncertain. Issues include the potential negative impact of nicotine on adolescent brain development, as well as the risk for nicotine addiction and initiation of the use of conventional cigarettes or other tobacco products.

E-CIGARETTE USE AMONG STUDENTS 2011-2012



Source: CDC, National Youth Tobacco Survey

NO REGULATION

The Food and Drug Administration does not regulate the products, and few states have restrictions on selling e-cigarettes to minors.

According to the CDC's National Youth Tobacco Survey, the percentage of high school students who reported using an e-cigarette even one time rose from 4.7% in 2011 to 10.0% in 2012. Students using e-cigarettes within the past 30 days also rose from 1.5% to 2.8%.

For younger middle school students, use also doubled. During 2011 and 2012, among all students in grades 6 to 12, the prevalence of trying e-cigarettes even once increased from 3.3% to 6.8%—more than double. Altogether, in 2012 more than 1.78 million middle and high school students nationwide reported that they had tried e-cigarettes.

CDC Director Tom Frieden, MD, MPH, said in a statement that "Nicotine is a highly addictive drug. Many teens who start with e-cigarettes may be condemned to struggling with a lifelong addiction to nicotine and conventional cigarettes."

According to Tim McAfee, MD, MPH, director of the CDC Office on Smoking and Health, 90% of smokers begin the habit as teenagers.

Some students in the survey reported current use of both e-cigarettes and conventional cigarettes, an increase of 0.8% to 1.6%.

Experts believe the market for e-cigarettes will grow as they become a replacement for, or complement to, traditional cigarettes. The products have been on the market in the United States for about four years.

In March, former U.S. Surgeon General Richard Carmona, MD, who was an advocate for banning all tobacco products, joined the board of directors for the country's largest e-cigarette marketer.

CDC recommends developing strategies to prevent marketing, sales and use of e-cigarettes among minors.

For health plans, the concern is not only offering cessation to those who smoke, but also the fact that young adult nicotine use could create higher premiums as well. **MHE**

—Julie Miller

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