

Respiratory Therapy Bill Affects MD Supervision

BY DENISE NAPOLI

Newly introduced federal legislation would allow registered respiratory therapists to provide services such as smoking cessation, asthma management, and inhaler training to patients without direct on-site supervision by a physician.

A previous version of the bill was introduced in 2007, but the legislation

stalled in a House subcommittee and never came to a vote.

The Medicare Respiratory Therapy Initiative Act of 2009 (S. 343) would give patients increased access to treatment, explained two of the bill's cosponsors, Sen. Blanche Lincoln (D-Ark.) and Sen. Mike Crapo (R-Idaho). "This access will be very beneficial to the people of Idaho, many of whom live in rural areas, to get the proper health care they need with the

expenses being covered by Medicare," Sen. Crapo said in a statement.

Under current law, registered respiratory therapists (RRTs), who have a bachelor's degree but no medical school training, may provide services to patients only under the direct, on-site supervision of a physician. The new legislation would amend that to allow "general" physician supervision, such that a physician would need to be available to the

RRT and patient during care, but not necessarily physically present on-site.

It's too early to tell whether the bill will meet with success this time around, said Lynne Marcus, vice president of health affairs at the American College of Chest Physicians. However, she hopes it will at least call attention to the need for increased access. "We want to support the better utilization of nonphysician providers," she said. ■

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- SSRIs and SNRIs, including PRISTIQ, may increase the risk of bleeding events. Concomitant use of aspirin, NSAIDs, warfarin, and other anticoagulants may add to this risk.
- Mydriasis has been reported in association with PRISTIQ; therefore, patients with raised intraocular pressure or those at risk of acute narrow-angle glaucoma (angle-closure glaucoma) should be monitored.
- PRISTIQ is not approved for use in bipolar depression. Prior to initiating treatment with an antidepressant, patients should be adequately screened to determine the risk of bipolar disorder.
- As with all antidepressants, PRISTIQ should be used cautiously in patients with a history or family history of mania or hypomania, or with a history of seizure disorder.
- Caution is advised in administering PRISTIQ to patients with cardiovascular, cerebrovascular, or lipid metabolism disorders. Increases in blood pressure and small increases in heart rate were observed in clinical studies with PRISTIQ. PRISTIQ has not been evaluated systematically in patients with a recent history of myocardial infarction, unstable heart disease, uncontrolled hypertension, or cerebrovascular disease.
- Dose-related elevations in fasting serum total cholesterol, LDL (low density lipoprotein) cholesterol, and triglycerides were observed in clinical studies. Measurement of serum lipids should be considered during PRISTIQ treatment.
- On discontinuation, adverse events, some of which may be serious, have been reported with PRISTIQ and other SSRIs and SNRIs. Abrupt discontinuation of PRISTIQ has been associated with the appearance of new symptoms. Patients should be monitored for symptoms when discontinuing treatment. A gradual reduction in dose (by giving 50 mg of PRISTIQ less frequently) rather than abrupt cessation is recommended whenever possible.

- Dosage adjustment (50 mg every other day) is necessary in patients with severe renal impairment or end-stage renal disease (ESRD). The dose should not be escalated in patients with moderate or severe renal impairment or ESRD.
- Products containing desvenlafaxine and products containing venlafaxine should not be used concomitantly with PRISTIQ.
- Hyponatremia may occur as a result of treatment with SSRIs and SNRIs, including PRISTIQ. Discontinuation of PRISTIQ should be considered in patients with symptomatic hyponatremia.
- Interstitial lung disease and eosinophilic pneumonia associated with venlafaxine (the parent drug of PRISTIQ) therapy have been rarely reported.

Adverse Reactions

- The most commonly observed adverse reactions in patients taking PRISTIQ vs placebo for MDD in short-term fixed-dose premarketing studies (incidence $\geq 5\%$ and twice the rate of placebo in the 50-mg dose group) were nausea (22% vs 10%), dizziness (13% vs 5%), hyperhidrosis (10% vs 4%), constipation (9% vs 4%), and decreased appetite (5% vs 2%).

Reference: 1. Pristiq[®] (desvenlafaxine) Prescribing Information, Wyeth Pharmaceuticals Inc.

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