Physicians Are Frustrated With Preauthorization

BY SCOTT STEINKE

ore than two-thirds of physicians reported that they have had to wait several days for insurers to conduct prior authorization reviews for tests, procedures, and prescription drugs, and about the same proportion have had difficulty tracking which of these therapeutics are subject to review requirements, according to a national survey of physicians released by the American Medical Association.

Although physicians are frequently said to be frustrated by insurers' review requirements, this is the AMA's first national survey to measure physicians' experiences. The survey of 2,400 practitioners was conducted in May.

Nearly all physicians would like to eliminate impediments caused by preauthorization requirements, with 78% saying it is "very important" and an additional 17% saying it is "important" for insurers to eliminate preauthorization hassles.

Among the findings were the following:

- ► More than half (58%) of physicians experienced difficulty with obtaining approval from insurers on a quarter or more of preauthorization requests.
- ▶ 57% experienced a 20% rejection rate on first-time preauthorization requests.
- ▶ Just under 40% reported appealing

80% or more of insurer rejections on first-time preauthorization requests.

Physicians spend about 20 hr/wk dealing just with preauthorizations, according to the survey. Many (75%) expressed a desire for plans to implement an automated preauthorization process.

Scott Steinke is with "The Pink Sheet." This newspaper and "The Pink Sheet" are published by Elsevier.



BRIEF SUMMARY. See package insert for full Prescribing Information. For further product information and current package insert, please visit www.wyeth.com or call our medical communications

WARNING: Suicidality and Antidepressant Drugs

Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of Major Depressive Disorder (MDD) and other psychiatric disorders. Anyone considering the use of Pristiq or any other antidepressant in a child, adolescent, or young adult must balance this risk with the clinical need. Short-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24; there was a reduction in risk with antidepressants compared to placebo in adults aged 65 and older. Depression and certain other psychiatric disorders are themselves associated with increases in the risk of suicide. Patients of all ages who are started on antidepressant therapy should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. Pristiq is not approved for use in pediatric patients [see Warnings and Precautions (5.1), Use in Specific Populations (8.4), and Patient Counseling Information (17.1 in the full prescribing information)].

INDICATIONS AND USAGE: Pristiq, a selective serotonin and norepinephrine reuptake inhibitor (SNRI), is indicated for the treatment of major depressive disorder (MDD).

CONTRAINDICATIONS: Hypersensitivity-Hypersensitivity to desvenlafaxine succinate, venlafaxine hydrochloride or to any excipients in the Pristiq formulation. Monoamine Oxidase inhibitors-Pristiq must not be used concomitantly in patients taking monoamine oxidase inhibitors (MADIs) or in patients who have taken MAOIs within the preceding 14 days due to the risk of serious, sometimes fatal, drug interactions with SNRI or SSRI treatment or with other serotonergic drugs. Based on the half-life of desvenlafaxine, at least 7 days should be allowed after stopping Pristiq before starting an MAOI [see Dosage and Administration (2.5) in the full prescribing information].

days should be allowed after stopping Pristiq before starting an MAU (see Dosage and Administration (2.5) in the full prescribing information).

WARNINGS AND PRECAUTIONS: Clinical Worsening and Suicide Risk-Patients with major depressive disorder (MDD), both adult and pediatric, may experience worsening of their depression and/or the emergence of suicidal ideation and behavior (suicidality) or unusual changes in behavior, whether or not they are taking antidepressant medications, and this risk may persist until significant remission occurs. Suicide is a known risk of depression and certain other psychiatric disorders, and these disorders themselves are the strongest predictors of suicide. There has been a long-standing concern, however, that antidepressants may have a role in inducing worsening of depression and the emergence of suicidality in certain patients during the early phases of treatment. Pooled analyses of short-term placebo-controlled studies of antidepressant drugs (SSRIs and others) showed that these drugs increase the risk of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults (ages 18-24) with major depressive disorder (MDD) and other psychiatric disorders. Short-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults aged 65 and older. The pooled analyses of placebo-controlled studies in children and adolescents with MDD, obsessive-compulsive disorder (OCD), or other psychiatric disorders included a total of 24 short-term studies of 9 antidepressant drugs in over 77,000 patients. The pooled analyses of placebo-controlled studies in adults with MDD or other psychiatric disorders included a total of 24 short-term studies (endian duration of 2 months) of 11 antidepressant drugs in over 77,000 patients. The rewas a considerable variation in risk of suicidality among drugs, but a reduction with artidepressants compared to placebo in adults aged 65 and older. The pooled analyses of placebo-controlled studies in children and adolescents with MDD, obsessive-compulsive disorder (OCD), or other psychiatric disorders included a total of 24 short-term studies of 9 antidepressant drugs in over 7,400 patients. The pooled analyses of placebo-controlled studies in adults with MDD or other psychiatric disorders included a total of 295 short-term studies (median duration of 2 months) of 11 antidepressant drugs in over 7,000 patients. There was considerable variation in risk of suicidality anong drugs, but a tendency toward an increase in the younger patients for almost all drugs studied. There were differences in absolute risk of suicidality across the different indications, with the highest includence in MDD. The risk differences (ding-lacebo), however, were relatively stable within age strata and across indications. These risk differences (ding-lacebo difference in the number of cases of suicidality per 1000 patients and the proper of the proper of

3 consecutive on-therapy visits. In clinical studies, regarding the proportion of patients with sustained hypertension, the following rates were observed; placebo (0.5%), Pristig 50 mg (1.3%), Pristig 100 mg (1.0%), An ord Pristig 40 mg (2.3%), Analyses of patients in Pristig controlled studies who met criteria for sustained hypertension, hornoral Bleeding-SSRIs and SNRIs can increase the risk of bleeding events. Occombiant use of aspirin, other drugs that affect platelet function, nonsteroidal anti-inflammatory drugs, warfarin, and other anticoagulants can add to this risk. Bleeding events related to SSRIs and SNRIs have ranged from exchymosis, hematoma, epistaxis, and peterhiae to concomitant use of Pristig and NSAIDs, aspirin, or other drugs that affect coagulation or bleeding Asproximate and the concomitant use of Pristig and NSAIDs, aspirin, or other drugs that affect coagulation or bleeding. Narrow-angle Glaucoma-Hydriasis has been reported in association with Pristig therefore, patients with raised intraocular pressure or those at risk of acute narrow-angle glaucoma (angle-closure) glaucoma single-closure glau

ADVERSE REACTIONS: Clinical Studies Experience: The most commonly observed adverse reactions in Pristiq-treated MDD patients in short-term fixed-dose studies (incidence ≥5% and at least twice the rate of placebo in the 50- or 100-mg dose groups) were nausea, dizziness, insomnia, hyperhidrosis, constipation, somnolence, decreased appetite, anxiety, and specific male sexual function disorders. Adverse reactions reported as reasons for discontinuation of treatment- The most common adverse reactions leading to discontinuation in at least 2% of the Pristiq-treated patients in the short-term studies, of placebo in the 50- or 100-mg dose groups) were nausea, dizziness, insomnia, hyperhidrosis, constipation, somnolence, decreased appetite, anxiety, and specific male sexual function disorders. Adverse reactions reported as reasons for discontinuation of treatment- The most common adverses reactions dealing to discontinuation in at least 2% of the Pristid-reated patients in the short-term study, up to 9 months, the most common was vomiting (2%). Common adverse reactions in placebo-controlled MDD studies- Table 3 in full PI shows the incidence of common adverse reactions in that occurred in 22% of Pristiq-treated MDD patients at any dose in the 8-week, placebo-controlled, fixed-dose, premarketing clinical studies. In general, the adverse reactions were most frequent in the first week of treatment. Cardiac disorders: Palpitations, Tachycardia, Blood pressure increased; Gastrointestinal disorders: Nausea, Dry mouth, Diarrhea, Constitation, Voniting; General disorders and administration site conditions, Fatigue, Chilis, Feeling jittery, Asthenia; Metabolism and nutrition disorders: Decreased appetite, weight decreased; Nervous system disorders: Dizziness, Somnolence, Headache, Tremor, Paraesthesia, Disturbance in attention; Psychiatric Disorders: Insomnia, Anxiety, Nervousness, Irritability, Abnormal dreams; Renal and urinary disorders: Wirnary hestation; Respiratory, thoracic, and mediasthal disorders: Whydriasis, Tinnitus, Dysgeusia; Vascular Disorders: Hoperindrosis, Rash; Decaid Senses: Vision blurred; Mydriasis, Tinnitus, Dysgeusia; Vascular Disorders: Hoperindrosis, Rash; Decaid Senses: Vision blurred; Mydriasis, Tinnitus, Dysgeusia; Vascular Disorders: Hoperindrosis, Rash; Decaid Senses: Vision blurred; Mydriasis, Tinnitus, Dysgeusia; Vascular Disorders: Hoperindrosis, Rash; Decaid Senses: Vision blurred; Mydriasis, Tinnitus, Dysgeusia; Vascular Disorders: Hoperindrosis, Rash; Decaid Senses: Vision blurred; Mydriasis, Tinnitus, dose group (8-week, placebo-controlled, fixed and flexible-dose, premarketing dyn

controlled clinical studies with doses of 50-400 mg, systelic orthostatic hypotension (docrasse ≥30 mm Hg from supine to standing position) occurred more frequently in patients ≥65 years of age receiving Pristiq (19%, 18/6) versup alcoholo (2.5%). All (1) compared to patients >655 years of age receiving Pristiq (19%, 18/6) versup alcoholo (2.5%). All (1) compared to patients >655 years of age receiving Pristiq (19%, 18/6) versup alcoholo (2.5%). All (1) compared to patients >655 years of age receiving Pristiq (19%, 18/6) versup alcoholo (2.5%). All (1) compared to patients >655 years of age receiving Pristiq (19%, 18/6) versup alcoholo (1

ventafaxine overdosage may be associated with an increased risk of fatlal outcomes compared to that observed with SSRI antidepressant products, but lower than that for tricyclic antidepressants. Epidemiological studies have shown that ventafaxine-treated patients have a higher pre-existing burden of suicide risk factors than SSRI-treated patients. The extent to which the finding of an increased risk of fatal outcomes can be attributed SSRI-treated patients. The extent to which the finding of an increased risk of fatal outcomes can be attributed to the toxicity of venidafaxine in overdosage, as opposed to some characteristic(s) of venidafaxine-treated patients, is not clear. Prescriptions for Pristig should be written for the smallest quantity of tablets consistent with good patient management, in order to reduce the risk of overdose. Management of Overdosage-Treatment should consist of those general measures employed in the management of overdosage with any SSRI/SNRI. Ensure an adequate ainvay oxygenation, and ventilation. Monitor cardiac rhythm and vital signs. General supportive and symptomatic measures are also recommended. Gastric lavage with a large-bore orgastric tube with appropriate ainvay protection, if needed, may be indicated if performed soon after ingestion or in symptomatic patients. Activated charcoal should be administered. Induction of emesis is not recommended. Because of the moderate volume of distribution of this drug, forced diversis, dialysis, hemoperfusion, and exchange transfusion are unlikely to be of benefit. No specific antidotes for desveniafaxine are known. In managing an overdose, consider the possibility of multiple drug involvement. The physicians bould consider contacting a poison control center for additional information on the treatment of any overdose. Telephone numbers for certified poison control centers are listed in the Physicians besk Reference (PDRⁿ). This brief summary is based on Pristig Prescribing Information W10529C009, revised September 2009