New Agent Approved for Two Neuropathic Pain Conditions

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Pregabalin, a drug that binds to calcium channels in the central nervous system, has received Food and Drug Administration approval for the management of pain associated with postherpetic neuralgia and diabetic peripheral neuropathy, making it the first drug indicated for both neuropathic pain conditions.

Pregabalin is the second drug approved specifically for treating pain associated with diabetic peripheral neuropathy (DPN); duloxetine (Cymbalta), was approved in September for this use. Other drugs approved for postherpetic neuralgia (PHN) pain are gabapentin (Neurontin) and the 5% lidocaine patch.

Pregabalin will not be available until the Drug Enforcement Administration decides on its controlled substance category. A company spokesperson would not speculate about when pregabalin would become available in pharmacies and declined to provide details on why it is under review as a controlled substance.

The two approvals were based on six placebo-controlled, double-blind studies involving more than 1,000 patients—three studies in patients with PHN and three in patients with DPN. Findings showed the drug provided quick and clinically meaningful pain reduction in a significant proportion of patients, according to Pfizer, which will market pregabalin under the trade name Lyrica.

In DPN trials, about half the patients had at least a 50% response rate and in PHN trials, the response rates were a little lower, but “still considered impressive,” said Brett R. Stacey, M.D., one of the trial investigators.

Pregabalin will act more quickly to lessen pain than tricyclic antidepressants, which need to be started at a low dose, said Dr. Stacey, medical director of the comprehensive pain center at Oregon Health and Science University, Portland.

The time to onset of pain relief can begin the day after the start of treatment, he added. Pregabalin also has a narrow dose range, which will make it easier to prescribe than gabapentin, which has a “huge” dose range because of variable absorption across the GI tract, he said.

Dr. Stacey has also paid research for Pfizer and has been a consultant to the company for gabapentin and pregabalin.

The recommended dosage for pain after shingles is 150-300 mg per day, given in two or three doses; the dosage can be increased up to 600 mg per day, based on tolerability, if patients do not experience sufficient reductions in pain, according to the Pfizer spokesperson. The diabetic nerve pain recommended dosage is 100 mg per day, given in three doses.

Where this fits in with other available treatments depends on various factors, including price. If it is reasonably priced, he said he would be more likely to start patients on the drug. It will be helpful in patients with contraindications to tricyclics and a good try in patients who have been treated with gabapentin and continue to have pain, he added. (Price was not available at press time.)

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