



Return to : FDA Approval Could Expand Cymbalta Use in Comp Cases

N/A -- FDA Approval Could Expand Cymbalta Use in Comp Cases: Top [08/30/10]

By [Greg Griggs](#), Editor

The anti-depressant drug Cymbalta, already a leading prescription in workers' compensation cases, could see expanded sales if the Food and Drug Administration follows through with an advisory panel recommendation to approve the medication's use for treating lower back pain.

A scientific advisory panel to the (FDA) voted eight to five on Aug. 19 in favor of expanding approved uses of Cymbalta, but rejected by a 9-4 vote its use for osteoarthritis.

Cymbalta (duloxetine) already had several indicated uses. The FDA approved Cymbalta for major depression and diabetic nerve pain in 2004, generalized anxiety disorder in 2007 and fibromyalgia in 2008.

If the agency follows through and grants an expanded use for back pain, Cymbalta would become the first antidepressant with such approval.

"Back injuries are the No. 1 injury we see in workers' compensation, so any new indications in this area will expand a drug's usage," said Maria Sciame, executive director of clinical services for PMSI, a Tampa, Fla.-based pharmacy benefit manager. She added that Cymbalta has seen its usage increase steadily in workers' compensation cases.

Cymbalta had a 3% annual increase in the number of workers using the drug and a 7.6% increase in the average number of days of supply, according to the 2009 edition of the PMSI annual drug trends report.

The report said that as a result of increased Cymbalta prescriptions, the use of all other antidepressants decreased. For example, Effexor (venlafaxine) had a 20% decrease and Elavil (amitriptyline) had a 9.5% decrease in the number of injured workers using those drugs.

"Cymbalta has really taken over the antidepressant component in workers' compensation," Sciame said. "It really drove utilization in that class. I think we're going to see even more of that."

Based on a PMSI review of its client data, Cymbalta represented 2% of total prescriptions last year, 2.9% of total spending, or \$5.4 million, and was used by about 4% of injured workers.

Phil Walls, senior vice president of pharmacy operations for myMatrixx, another PBM based in Tampa, said giving Cymbalta an approved use for treating back pain would allow pharmacists to collect more data on its effectiveness.

"At least we'll have a better indication of exactly what this drug is being used for," Walls said. "That's been a constant issue over the years in trying to determine the difference between approved and off-label uses."

As a non-narcotic, Cymbalta could be helpful to injured workers if it is prescribed instead of opioids, such as oxycodone, hydrocodone, or morphine, Walls believes.

"Opioids are grossly overused for treating lower back pain. Being cautious in treating that type of pain is very important and giving a physician an alternative could be a good thing for comp," Walls said. "What we don't want to see is this being additive, but if it could be a substitute, 'Let's wean them off an opioid and put them on Cymbalta,' then it could be advantageous to both the patient and the system."

John F. Aforismo, chief executive of R J Health Systems, which contracts as the clinical department of ScripNet, said Cymbalta is more appropriate for long-term use, unlike opioids, which cause patients to become reliant and require stronger doses over time.

"If Cymbalta reduces pain in two areas, something short-term -- like a narcotic analgesic -- may not be needed as much," Aforismo said. "It will not eliminate the use of narcotic analgesics, but it could reduce it or at least keep the dose at a steadier level."

Using a single drug to treat both pain and depression could lead to improved patient adherence and better clinical outcomes, he added.

Jim Andrews, senior vice president of pharmacy services at Cypress Care in Duluth, Ga., said Cymbalta has already been approved for treating chronic pain in Brazil and Mexico and will likely win full FDA approval for lower back pain.

"If that happens, and we think it will, it will mean more physicians having a lot more confidence in prescribing it," said Andrews, predicting a slow increase in usage, at least initially.

"They haven't gotten the FDA approval yet, and physicians will typically make their decisions based on the results in their patient population," he said.

Ralph Kendall, vice president of clinical services for Tampa-based Healthsystems, another PBM that specializes in workers' compensation, said he thought the advisory panel's split vote on expanding the use of Cymbalta suggested a need for caution.

"The committee that approved it was narrowly divided. They wanted more information and thought the studies could have been better represented in its statistical analysis," Kendall said. "Given that, we're very hesitant to see people use it for low back pain, which is way too general as a diagnosis. Low back pain is really a symptom, not a diagnosis."

Healthsystems clients spent about \$4.5 million for Cymbalta last year, ranking it in the top 10 in terms of drug spending, according to Kendall.

Return to : FDA Approval Could Expand Cymbalta Use in Comp Cases

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