Pharmacy Policy Bulletin

Category:	Managed Rx Coverage
Number:	J-305
Subject:	Cymbalta® (duloxetine)
Effective Date Begin:	December 3, 2008
Effective Date End:	
Original Date:	September 3, 2008
Review Date(s):	December 2, 2009 December 3, 2008 September 3, 2008

Policy Applies to: *Commercial* and *Medicare* plans

NOTE: For Medicare Part D members, this policy applies to only "new starts", or those members who have not yet been treated with duloxetine.

Background: Duloxetine (Cymbalta®) is indicated for the treatment of major depressive disorder, generalized anxiety disorder, fibromyalgia, and the management of neuropathic pain associated with diabetic peripheral neuropathy (DPN). Duloxetine acts as an inhibitor of neuronal serotonin and norepinephrine reuptake. It is presumed that increasing both serotonin and norepinephrine are primarily responsible for duloxetine's antidepressive and central pain inhibitory effects, although the exact mechanism is unknown.

Approval Criteria: When a benefit, coverage for duloxetine will be approved if members not currently receiving treatment with duloxetine meet one of the following criteria:

1. The member has at least one claim for two (2) different antidepressant or anti-anxiety agents within the past 24 months **OR**
2. The member has a previous paid claim for duloxetine (Cymbalta®) within the previous 120 days.

Members who meet the criteria as outlined above will receive automatic authorization at the point of service without documentation of additional information. Claims will automatically adjudicate on-line, with no prior authorization required.

Members who do not meet any of the above criteria will require prior authorization. One of the following criteria would then need to be documented:

1. The member must have a documented diagnosis of DPN, **OR**
2. The member must have a documented diagnosis of a neuropathic pain condition other than DPN and have tried and failed one therapeutic alternative (e.g. tricyclic antidepressant (TCA), antiepileptic (AED), **OR**
3. The member must have a documented diagnosis of depression and have tried and failed at least two (2) antidepressant agents (e.g. SSRI, SNRI, TCA, MAO inhibitor) **OR**
4. The member must have a documented diagnosis of generalized anxiety disorder and have tried and failed two (2) anti-anxiety agents (e.g. SSRI, benzodiazepine) **OR**
5. The member has a documented diagnosis of fibromyalgia as determined by clinical notes including, but not limited to,

confirmation of widespread bilateral pain both above and below the waist for > 3 months duration AND the presence of at least 11 of 18 specific tender points AND documented fibromyalgia-related symptoms (e.g. fatigue, sleep disturbance, neurologic symptoms, and/or exercise intolerance). **AND**

6. The member has a documented trial and failure of at least one additional agent used to treat fibromyalgia (e.g. TCA, cyclobenzaprine, SSRI, tramadol).

Duration of Authorization:

If approved, up to a lifetime authorization may be granted.

References:

1. Dworkin RH, O'Connor AB, Backonja M, et al. Pharmacologic management of neuropathic pain: evidence-based recommendations. Pain. Dec 2007;132(3):237-51.
2. Institute for Clinical Systems Improvement (ICSI). Assessment and management of acute pain. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2008 Mar.
3. Russell IJ, Mease PJ, Smith TR, et al. Efficacy and safety of duloxetine for treatment of fibromyalgia in patients with or without major depressive disorder: Results from a 6-month, randomized, double-blind, placebo-controlled, fixed-dose trial. Pain. 2008; 136:432-444.
4. Arnold LM, Lu Y, Crofford LJ, et al. for the Duloxetine Fibromyalgia Trial Group. A double-blind, multicenter trial comparing duloxetine with placebo in the treatment of fibromyalgia patients with or without major depressive disorder. Arthritis & Rheumatism. Sept 2004;50(9):2974-2984.
5. Arnold LM, Rosen A, Lu Pritchett Y, et al. A randomized, double-blind, placebo-controlled trial of duloxetine in the treatment of women with fibromyalgia with or without major depressive disorder. Pain. 2005;119:5-15.
6. Wolfe F, Smythe HA, Yunus MB, et al. The American College of Rheumatology 1990 criteria for the classification of fibromyalgia: Report of the multicenter criteria committee. Arthritis & Rheumatism. Feb 1990;33(2):160-172.
7. Gartlehner G, Hansen RA, Thieda P, et al. Comparative Effectiveness of Second-Generation Antidepressants in the Pharmacologic Treatment of Adult Depression. Comparative Effectiveness Review No. 7. (Prepared by RTI International-University of North Carolina Evidence-based Practice Center under Contract No. 290-02-0016.) Rockville, MD: Agency for Healthcare Research and Quality. January 2007. Available at: www.effectivehealthcare.ahrq.gov/reports/final.cfm
8. American Psychiatric Association practice guideline for the treatment of patients with major depressive disorder. Am J Psychiatry 2000 Apr;157(4 Suppl):1-45.
9. Carville SF, Arendt-Nielsen S, Bliddal H, et al. EULAR evidence based recommendations for the management of fibromyalgia syndrome. Ann Rheum Dis. October 2007. Available at: http://ard.bmj.com/cgi/content/abstract/ard.2007.071522v3
10. Goldenberg DL, Burckhardt C, Crofford L. Management of Fibromyalgia Syndrome. JAMA. Nov 2004;292(19):2388-2395.
11. Kapczinski F, Lima MS, Souza JS, Schmitt R. Antidepressants for generalized anxiety disorder. Cochrane Database of Systematic Reviews. (2):CD003592, 2003.
12. Hansen RA, Gaynes BN, Gartlehner G, Moore CG, Tiwari R, Lohr KN. Efficacy and tolerability of second-generation antidepressants in social anxiety disorder. International Clinical Psychopharmacology. May 2008;23(3):170-179.
13. Goldstein DJ, Lu Y, Detke MJ, Wiltse C, Mallinckrodt C, Demitrack MA. Duloxetine in the treatment of depression: A double-blind placebo-controlled comparison with paroxetine. Journal of Clinical Psychopharmacology. Aug 2004;24(4):389-399.
14. Detke MJ, Lu Y, Goldstein DJ, McNamara RK, Demitrack MA. Duloxetine 60mg once daily dosing versus placebo in the acute treatment of major depression. Journal of Psychiatric Research. Nov-Dec 2002;36(6):383-390.
15. Goldstein DJ, Mallinckrodt C, Lu Y, Demitrack MA. Duloxetine in the treatment of major depressive disorder: A double-blind clinical trial. J Clin Psychiatry. Mar 2002;63(3):225-231.
16. Rynn M, Russell J, Erickson J, et al. Efficacy and safety of duloxetine in the treatment of generalized anxiety disorder: a flexible-dose, progressive-titration, placebo-controlled trial. Depress Anxiety. 2008;25(3):182-9.
17. Detke MJ, Wiltse CG, Mallinckrodt CH, McNamara RK, Demitrack MA, Bitter I. Duloxetine in the acute and long-term treatment of major depressive disorder: a placebo- and paroxetine-controlled trial. Eur Neuropsychopharmacol. Dec 2004;14

treatment of major depressive disorder: a placebo- and paroxetine-controlled trial. Eur Neuropsychopharmacol. Dec 2004;14 (6):457-70.
18. Perahia DG, Wang F, Mallinckrodt CH, Walker DJ, Detke MJ. Duloxetine in the treatment of major depressive disorder: a placebo- and paroxetine-controlled trial. Eur Psychiatry. Sept 2006;21(6):367-78.

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