

Progressive Medication Program for Serotonin-Norepinephrine Reuptake Inhibitors (Cymbalta, Pristiq)

Origination: 12/29/11	Revised:	Annual Review:
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Purpose:

To provide guidelines and criteria for the review and decision determination of requests for medications that requires prior authorization.

Background Information:

Medication Summary

- Serotonin (5-HT) and norepinephrine (NE) reuptake inhibitors work by blocking the central presynaptic reuptake of 5-HT and NE, resulting in an increased sustained level of these neurotransmitters. Serotonin is a neurotransmitter which regulates an extensive modulatory behavioral system in the brain. The serotonergic system is known to modulate mood, emotion, sleep, and appetite and thus is implicated in the control of numerous behavioral and physiological functions. Norepinephrine is an adrenergic neurotransmitter which appears to be involved in a range of psychological processes, including mood stabilization, sleep regulation, overall alertness and arousal, and in regulating response to stressors which might initiate or exacerbate depressive symptomatology.
- There are currently three (3) serotonin-norepinephrine reuptake inhibitors on the market: venlafaxine (Effexor), desvenlafaxine (Pristiq), and duloxetine (Cymbalta). Venlafaxine is indicated for depression, generalized anxiety disorder (GAD), social anxiety disorder (SAD) and panic disorder. Desvenlafaxine is indicated for depression. Duloxetine is indicated for depression and generalized anxiety disorder (GAD).
- Duloxetine is also indicated for diabetic neuropathy, fibromyalgia, chronic musculoskeletal pain (chronic low back pain and osteoarthritis).
- There is no clinical advantage to doses of duloxetine above 60mg.

Reference Statement

- Guidelines are compiled from available US Food and Drug Administration (FDA) approved indications, general practice guidelines, and/or evidence-based uses established through phase III clinical studies without published conflicting data. Only clinical studies published in their entirety in reputable peer-reviewed journals will be evaluated.

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Background Information, continued:

Eligibility Criteria

- Member must be eligible and have applicable benefit coverage.
- Prior authorization requests that do not meet clinical criteria in this Procedure will be forwarded to a Clinical Pharmacist for review.

Exclusion Criteria

- Concurrent use of monoamine oxidase inhibitors (MAOI).
- For desvenlafaxine, any hypersensitivity to venlafaxine or desvenlafaxine.
- For duloxetine, members with *uncontrolled* closed-angle glaucoma.
- Members under eighteen (18) years of age, as safety and efficacy have not been established.

Procedure:

- 1.0 Request for *initial therapy* with desvenlafaxine (Pristiq) requires documentation from the Member's medical records maintained by the requesting independent practitioner's office verifying the following:
 - 1.1 Member is new Member to AvMed (eligibility within the past 120 days) and has been on targeted medication prior to joining AvMed (evidenced by progress notes from prescriber indicating use or documented previous fill history with pharmacy);
- OR**
- 1.1 Member has tried and failed at least one (1) of the following selective serotonin reuptake inhibitors (SSRI): citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline AND the serotonin-norepinephrine reuptake inhibitor venlafaxine;
- 1.2 If all criteria are met, request may be approved for one (1) month with a quantity limit of 400mg daily for 30 days. Refills should continue to process every month thereafter.

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Procedure, continued:

- 2.0 Request for *initial therapy* with duloxetine (Cymbalta) **for depression or GAD** requires documentation from the Member's medical records maintained by the requesting independent practitioner's office verifying the following:
- 2.1 Member is new Member to AvMed (eligibility within the past 120 days) and has been on targeted medication prior to joining AvMed (evidenced by progress notes from prescriber indicating use or documented previous fill history with pharmacy);
- OR**
- 2.1 Member has tried and failed at least one (1) of the following selective serotonin reuptake inhibitors (SSRI): citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline AND the serotonin-norepinephrine reuptake inhibitor venlafaxine;
- 2.2 If all criteria are met, request may be approved for one (1) month with a quantity limit of 30 tablets for 30 days. Refills should continue to process every month thereafter.
- 3.0 Request for *initial therapy* with duloxetine (Cymbalta) **for diabetic neuropathy, fibromyalgia, musculoskeletal pain or osteoarthritis** requires documentation from the Member's medical records maintained by the requesting independent practitioner's office verifying the following:
- 3.1 Member is new Member to AvMed (eligibility within the past 120 days) and has been on targeted medication prior to joining AvMed (evidenced by progress notes from prescriber indicating use or documented previous fill history with pharmacy);
- OR**
- 3.1 Medication is prescribed by a specialist, either a pain specialist or neurologist;
- 3.2 If all criteria are met, request may be approved for one (1) month with a quantity limit of 30 tablets for 30 days. Refills should continue to process every month thereafter.

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References:

1. DRUGDEX[®] System (electronic version). Thomson MICROMEDEX, Greenwood Village, Colorado, USA. Available at: <http://csi.micromedex.com>.
2. Lexi-Comp Online (electronic version) Lexi-Comp Inc. 1978-2010, Hudson, Ohio, USA. Available at: <http://online.lexi.com/crlsql/servlet/crlonline>.
3. Comparative Effectiveness of Second-Generation Antidepressants in the Pharmacologic Treatment of Adult Depression: Exec. Summary. No. 7. (AHRQ Pub. No. 07- EHC007-1).
4. Second-Generation Antidepressants in the Pharmacologic Treatment of Adult Depression: An Update of the 2007 Comparative Effectiveness Review: Comparative Effectiveness Review Executive Summary No. 46 (AHRQ Pub. No. 12-EHC012-1).
5. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2011. URL: <http://www.clinicalpharmacology.com>. Accessed December 23, 2011.

Disclaimer Information:

Coverage Issues Guidelines and Medical Technology Assessment Recommendations are developed to determine coverage for AvMed Health Plans' benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. AvMed Health Plans makes coverage decisions using these guidelines, along with the Member's benefit document. The use of this guideline is neither a guarantee of payment nor a final prediction of how specific claim(s) will be adjudicated.

Coverage Issues Guidelines and Medical Technology Assessment Recommendations are developed for selected therapeutic or diagnostic services found to be safe, but proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the AvMed Health Plans service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations.

Treating providers are solely responsible for the medical advice and treatment of Members. This guideline may be updated and therefore is subject to change.