Custom Criteria for
BlueCross Blue Shield of Rhode Island Commercial

CYMBALTA® (duloxetine HCl)

GPI CODING:

58180025106720 Cymbalta 20mg
58180025106750 Cymbalta 60mg

DESCRIPTION:

CYMBALTA (duloxetine HCl) is a serotonin and norepinephrine reuptake inhibitor (SNRI). Cymbalta (duloxetine HCl) is indicated for: Major Depressive Disorder (MDD), Generalized Anxiety Disorder (GAD), Diabetic Peripheral Neuropathic Pain (DPNP), Fibromyalgia (FM), and Chronic Musculoskeletal Pain. The purpose of the criteria is to provide approval guidelines for prior authorization of benefits (PAB) of Cymbalta (duloxetine HCl). Claims submitted without obtaining prior authorization of benefits will reject on the pharmacy claim system. Cymbalta (duloxetine) 20mg, 30mg, and 60mg capsules may be subject to Quantity Limits or Dose Optimization.

APPROVAL DURATION:

Approval duration: until 12/31/14

CRITERIA FOR CYMBALTA

I. Request for Cymbalta(duloxetine HCl) may be approved if patient has a diagnosis of Major Depressive Disorder (MDD), Depressive disorder or Dysthymia **AND**
   A. Patient has tried, failed or is intolerant to **two** generic antidepressants, one of which is an SSRI; **OR**
   B. Patient is currently being treated with the Cymbalta in the last 60 days.
   OR

II. Patient has a diagnosis of neuropathic pain associated with diabetic peripheral neuropathy **AND** patient had a trial of one of the following medications:
   A. Carbamazepine
   B. Tricyclic antidepressants
   C. Gabapentin
   D. Trazodone
   E. Lyrica
   OR

III. Patient has a diagnosis of Generalized Anxiety Disorder **AND** patient had a trial of one of the following medications:
   A. Benzodiazepines
   B. Venlafaxine (immediate or extended release products)
   C. Escitalopram, paroxetine, or sertraline
   OR

IV. Patient has a diagnosis of Fibromyalgia and meets ALL of the following criteria:

A. Patient has widespread pain (on the left and right side of the body and above and below the waist) AND axial skeletal pain (cervical spine or anterior chest or thoracic spine or low back) present for at least 3 months

AND

B. Pain in at least 11 of 18 specific tender point sites after digital palpitation with an approximate force of 4kg. Tender point sites are bilateral and include the following:
   1. Occiput
   2. Trapezius
   3. Supraspinatus
   4. Second rib
   5. Lateral epicondyle
   6. Gluteal
   7. Greater trochanter
   8. Knee

AND

C. Trial of one of the following medications that is FDA approved or medically accepted for the treatment of fibromyalgia:
   1. Cyclobenzaprine
   2. Tricyclic antidepressants
   3. Fluoxetine
   4. Lyrica
   5. Savella

Note: For a tender point to be considered "positive" the patient must state that the palpitation was painful. "Tender" is not considered painful.

V. Patient has a diagnosis of chronic musculoskeletal pain and meets ALL of the following criteria:

A. Patient is participating in a physical activity program or graded exercise program to improve function (e.g., exercise, occupational, physical therapy) **AND**

B. Patient has tried and had an inadequate response to at least TWO drugs from the following options (at least a 30 day trial):
   1. Tramadol
   2. NSAIDs (e.g., diclofenac, etodolac, ibuprofen, meloxicam, nabumetone, salsalate)
   3. Opioids (e.g., codeine, hydrocodone, morphine, oxycodone)