Program: Cymbalta (duloxetine)

DESCRIPTION

The purpose of this document is to provide approval criteria and guidelines for prior authorization of benefits (PAB) of Cymbalta (duloxetine HCI). Claims submitted without obtaining prior authorization of benefits will reject on the pharmacy claim system.

Applicable lines of business

RIteCare and Managed Pharmacy

Impacted Formulary Medications

Cymbalta (duloxetine HCI) 20mg, 30mg, 60mg capsules May be subject to Quantity Limits or Dose Optimization

APPROVAL DURATION AND QUANTITY LIMITS

Approval Duration: 1 year

APPROVAL CRITERIA:

I. Request for Cymbalta duloxetine HCI) 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 requested Non-Preferred brand name SNRI agent 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 or any other agent that is FDA approved or medically accepted for neuropathic pain associated with diabetic peripheral neuropathy within the previous 180 days:

- A. Carbamazepine
- B. Tricyclic antidepressants
- C. Gabapentin
- D. Trazadone
- E. Lyrica

OR

III. Patient has a diagnosis of Generalized Anxiety Disorder **AND** patient had a trial of one of the following medications or any other agent that is FDA approved or medically accepted for Generalized Anxiety Disorder within the previous 180 days:

- A. Benzodiazepines
- B. Venlafaxine (immediate or extended release products

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. Low Cervical
- 3. Trapezius
- 4. Supraspinatus
- 5. Second rib
- 6. Lateral epicondyle
- 7. Gluteal
- 8. Greater trochanter
- 9. Knee;

AND

C. Trial of one of the following medications that is FDA approved or medically accepted for the treatment of fibromyalgia within the previous 180 days:

- 1. Cyclobenzaprine; **OR**
- 2. Tricyclic antidepressants; OR
- 3. Fluoxetine; **OR**
- 4. Lyrica OR
- 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.

Look Back Criteria in Claims System

Not applicable