



Division: Pharmacy Policy	Subject: State of Florida's Agency for Health Care Administration's Prior Authorization Criteria
Original Development Date:	June 4, 2015

APLENZIN[®] (bupropion hydrobromide, extended release)

CLINICAL NOTES:

Bupropion hydrobromide (Aplenzin[®]) is an oral antidepressant drug indicated for major depressive disorder and seasonal affective disorder. Aplenzin[®] is the only hydrobromide salt of bupropion on the market, all the other bupropion products are bupropion hydrochloride. The molecular weight of the HBr salt is higher than the HCl salt; therefore a larger total milligram dose of Aplenzin[®] is needed to provide the same amount of active drug.

INITIAL REVIEW CRITERIA (ALL OF THE FOLLOWING MUST BE TRUE):

- Patient must be ≥ 18 years old; AND
- Patient must have a confirmed diagnosis of Major Depressive Disorder or Seasonal Affective Disorder; AND
- Trial and failure of at least two other preferred antidepressants within the last 365 days, at least one of which was a preferred bupropion hydrochloride product and claims history. documents a minimum of at least two consecutive fills (60 day trial) of the preferred antidepressants.

CONTINUATION OF THERAPY

- Patient continues to meet all of the initial criteria.
- Claims history indicate patient is compliant with Aplenzin[®].
- Clinical notes document improvement in patient symptoms.

DOSING & ADMINISTRATION:

- Major Depressive Disorder -Initially 174 mg PO once in the morning. Based on tolerability, the dose may be increased to the target dose of 348 mg/day beginning on day 4 of treatment. If response is inadequate after several weeks, the dose may be increased to a maximum of 522 mg/day given as a single dose.
- Seasonal Affective Disorder- Initially, 174 mg PO once daily in the morning. After 7 days, the dose may be increased to the target dose of 348 mg PO once daily. Total daily doses above 348 mg/day were not evaluated in clinical trials for seasonal affective disorder. Therapy is usually initiated in the autumn, continued through the winter, then tapered and discontinued in the early spring.
- Dosage Form: Extended-release tablets: 174mg, 348 mg, 522 mg