



Prior Authorization Approval Criteria

Kapvay (clonidine extended release)

Generic name:	clonidine extended release
Brand name:	Kapvay
Medication class:	Antiadrenergic Agents – Centrally Acting
FDA-approved uses:	treatment of attention deficit hyperactivity disorder (ADHD) as monotherapy or as adjunctive therapy to stimulant medications.
Available dosage forms:	0.1mg tablets
Usual dose:	Therapy should be initiated with one 0.1 mg tablet at bedtime, and the daily dosage should be adjusted in increments of 0.1 mg/day at weekly intervals until the desired response is achieved. Doses should be taken twice daily, divided equally or split with the higher dose given at bedtime. Dosages higher than 0.4 mg/day (0.2 mg twice daily) were not evaluated in clinical trials for ADHD and are not recommended. When discontinuing therapy, the dosage should be tapered in decrements of no more than 0.1 mg every 3 to 7 days.
Approximate monthly cost: (based on AWP 2011)	\$150-\$300/month for 0.2mg-0.4mg/day
Duration of therapy:	indefinite

Criteria for use *(bullet points below are all inclusive unless otherwise noted):*

- The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patient's medical records.
- Must be clinically diagnosed with ADHD.
- Must be 6 years of age or older.
- Must have tried the following stimulants:
 - Must have tried and failed or intolerant to a long acting methylphenidate.
 - Must have tried and failed or intolerant to a long acting mixed amphetamine salt.
- Or
 - Patient has any contraindications to the use of stimulants such as tics, sleep problems, history of substance abuse and/or aggression.
- Must have tried and failed immediate release clonidine.

Monitoring:

- Heart rate and blood pressure should be determined prior to initiation of therapy, following dosage increases, and periodically during therapy

Contraindication:

- patients with known hypersensitivity to clonidine

Not approved if:

- Patient does not meet the above stated criteria
- Patient has any contraindications to the use of clonidine.

FCHP Pharmacy and Therapeutics Committee approval: _____

Date: _____

Adopted: 06/08/11