KAPVAY® (clonidine hydrochloride) extended-release tablets

LENGTH OF AUTHORIZATION:

- INITIAL THERAPY – UP TO THREE MONTHS
- CONTINUATION OF THERAPY – UP TO SIX MONTHS

REVIEW CRITERIA:

- Patient must be ≥ 6 years old
- Must have a diagnosis of attention deficit hyperactivity disorder AND
- Minimum trial of one month of a methylphenidate (i.e. Daytrana, Focalin XR, Metadate) and amphetamine (i.e. Vyvanse, dextroamphetamine . . .) product. (If stimulant therapy contraindicated no methylphenidate or amphetamine trial required.) AND
- Minimum trial of one month of guanfacine, extended release tablet.

DOSING:

- Dosing 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 a day, with either an equal or higher split dosage being given at bedtime, as depicted below

- Do not substitute for other Clonidine products on a mg-per-mg basis, due to differing pharmacokinetic profiles.

- When discontinuing, taper the dose in decrements of no more than 0.1mg every 3 to 7 days.

- Not to be taken concomitantly with any other clonidine products.
Maximum Dosage Limits:

- **Adults**
  2.4 mg/day PO immediate-release tablets

- **Geriatric**
  2.4 mg/day PO immediate-release tablets

- **Adolescents**
  0.4 mg/day PO Kapvay extended-release tablets

- **Children**
  >= 6 years: 0.4 mg/day PO Kapvay extended-release tablets
  < 6 years: Safety and efficacy have not been established.