

STEP THERAPY CRITERIA

**BRAND NAME
(generic)**

INTUNIV
(guanfacine extended-release)

KAPVAY
(clonidine extended-release)

Status: CVS Caremark Criteria

Type: Initial Step Therapy; Post Step Therapy Prior Authorization

POLICY

FDA-APPROVED INDICATIONS

Intuniv

Intuniv is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) as monotherapy and as adjunctive therapy to stimulant medications.

Kapvay

Kapvay (clonidine hydrochloride) extended-release is indicated for the treatment of attention deficit hyperactivity disorder (ADHD) as monotherapy and as adjunctive therapy to stimulant medications.

INITIAL STEP THERAPY

If the patient has filled a prescription for a 30 day supply of amphetamine-dextroamphetamine, dextroamphetamine, methamphetamine, lisdexamfetamine, methylphenidate or dexamethylphenidate product within the past 180 days under a prescription benefit administered by CVS Caremark, then the requested drug will be paid under that prescription benefit. If the patient does not meet the initial step therapy criteria, then the claim will reject with a message indicating that a prior authorization (PA) is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- The patient has the diagnosis of Attention-Deficit Hyperactivity Disorder (ADHD) or Attention Deficit Disorder (ADD)

AND

- The patient has experienced an inadequate treatment response, intolerance or contraindication to an amphetamine product (i.e., amphetamine-dextroamphetamine, dextroamphetamine, methamphetamine, lisdexamfetamine) or a methylphenidate product (i.e., methylphenidate or dexamethylphenidate product)

REFERENCES

1. Intuniv [package insert]. Lexington, MA: Shire US Inc; July 2016.
2. Kapvay [package insert]. St. Michael, Barbados: Concordia Pharmaceuticals, Inc.; August 2016
3. AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexis-Comp, Inc.; http://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. Accessed November 2017.
4. Micromedex Solutions [database online]. Greenwood Village, CO: Truven Health Analytics Inc. Updated periodically. www.micromedexsolutions.com [available with subscription]. Accessed November 2017.
5. American Academy of Pediatrics. ADHD: Clinical Practice Guideline for the Diagnosis, Evaluation, and Treatment of Attention-Deficit/Hyperactivity Disorder in Children and Adolescents. *Pediatrics*. 2011; 128(5):1007-1022. <http://pediatrics.aappublications.org/content/early/2011/10/14/peds.2011-2654>.