

# Initial Step Therapy; Post Step Therapy Prior Authorization Intuniv, Kapvay, Onyda XR

## Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Intuniv	guanfacine extended-release
Kapvay	clonidine extended-release
Onyda XR	clonidine extended-release

## Indications

### 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.

#### Onyda XR

Onyda XR is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) as monotherapy and as adjunctive therapy to central nervous system (CNS) stimulant medications in pediatric patients 6 years of age and older.

# Initial Step Therapy

Include Rx and OTC products unless otherwise stated.

If the patient has filled a prescription for at least a 30-day supply of an amphetamine product (e.g., amphetamine, amphetamine-dextroamphetamine, dextroamphetamine, methamphetamine, lisdexamfetamine) OR a methylphenidate product (e.g., methylphenidate, dexamethylphenidate) 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

### Attention-Deficit/Hyperactivity Disorder (ADHD) or Attention Deficit Disorder (ADD)

Authorization may be granted when the patient has a diagnosis of Attention-Deficit/Hyperactivity Disorder (ADHD) or Attention Deficit Disorder (ADD) when ALL of the following criteria are met:

- The diagnosis has been appropriately documented (e.g., evaluated by a complete clinical assessment, using DSM-5, standardized rating scales, interviews/questionnaires).
- The patient meets ONE of the following:
  - The patient has experienced an inadequate treatment response to an amphetamine product (e.g., amphetamine, amphetamine-dextroamphetamine, dextroamphetamine, methamphetamine, lisdexamfetamine) OR a methylphenidate product (e.g., methylphenidate, dexamethylphenidate).
  - The patient has experienced an intolerance to an amphetamine product (e.g., amphetamine, amphetamine-dextroamphetamine, dextroamphetamine, methamphetamine, lisdexamfetamine) OR a methylphenidate product (e.g., methylphenidate, dexamethylphenidate).
  - The patient has a contraindication that would prohibit a trial of an amphetamine product (e.g., amphetamine, amphetamine-dextroamphetamine, dextroamphetamine, methamphetamine, lisdexamfetamine) AND a methylphenidate product (e.g., methylphenidate, dexamethylphenidate).

# Continuation of Therapy

## Attention-Deficit/Hyperactivity Disorder (ADHD) or Attention Deficit Disorder (ADD)

Authorization may be granted when the patient has a diagnosis of Attention-Deficit/Hyperactivity Disorder (ADHD) or Attention Deficit Disorder (ADD) when ALL of the following criteria are met:

- The patient has achieved or maintained improvement in their signs and symptoms of ADHD/ADD from baseline.
- The patient's need for continued therapy has been assessed within the previous year.

## Duration of Approval (DOA)

- 781-D: DOA: 36 months

## References

1. Intuniv [package insert]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; August 2020.
2. Kapvay [package insert]. Dublin 9, Ireland: Concordia Pharmaceuticals; February 2020.
3. Onyda XR [package insert]. Monmouth Junction, NJ: Tris Pharma, Inc.; September 2024.
4. Lexicomp Online, Pediatric and Neonatal Lexi-Drugs Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed November 6, 2024.
5. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 11/6/2024).
6. American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition Text Revision. Arlington, Virginia: American Psychiatric Association; 2022.
7. Wolraich ML, Hagan JF, Allan C, et al. AAP Subcommittee On Children And Adolescents With Attention-Deficit/Hyperactive Disorder. Clinical Practice Guideline for the Diagnosis, Evaluation, and Treatment of Attention-Deficit/Hyperactivity Disorder in Children and Adolescents. Pediatrics. 2019;144(4):e20192528.