Reference number(s)
781-D

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, dexmethylphenidate) 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, dexmethylphenidate).
    - 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, dexmethylphenidate).
    - 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, dexmethylphenidate).

Reference number(s)
781-D

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.

Document History

Written by: UM Development (PL)

Date Written: 05/2012

Revised: (RP) 11/2012 (added Kapvay), 11/2013, 11/2014; (MS) 11/2015; (RP) 11/2016 (no clinical changes), 11/2017 (no clinical changes), 11/2018, 11/2019; (PM) 11/2020 (no clinical changes), 11/2021 (no clinical changes); (ASA) 11/2022 (added COT criteria, added criteria for prescriber to confirm diagnosis by appropriate tests and evaluations, and added continued symptoms despite evidence-based behavioral therapy for ADHD/ADD in patients 5 and younger to the coverage criteria), 11/2023 (no clinical changes); (MRS) 05/2024 (added Onyda XR, added age of 6 or older, removed step through behavioral therapy for patients 5 and younger, and updated title), 11/2024 (removed age of 6 or older)

Reviewed: Medical Affairs (KP) 05/2012; (LS) 11/2012; (LS) 11/2013; (DNC) 11/2014; (LS) 11/2015; (GAD) 11/2018; (CHART) 11/27/2019; (CHART) 12/3/2020, 12/2/2021, 12/01/2022, 11/30/2023, 06/13/2024, 11/21/2024

External Review: 06/2012, 02/2013, 02/2014, 02/2015, 02/2016, 02/2017, 02/2018, 02/2019, 02/2020; 02/2021, 02/2022, 02/2023, 02/2024, 09/2024 (FYI), 02/2025

CRITERIA FOR APPROVAL

1	Does the patient have a diagnosis of Attention-Deficit/Hyperactivity Disorder (ADHD) or Attention Deficit Disorder (ADD)? [If Yes, then go to 2. If No, then no further questions.]	Yes	No
2	Is this request for continuation of therapy? [If Yes, then go to 3. If No, then go to 5.]	Yes	No
3	Has the patient achieved or maintained improvement in their signs and symptoms of ADHD/ADD (Attention-Deficit/Hyperactivity Disorder or Attention Deficit Disorder) from baseline? [If Yes, then go to 4. If No, then no further questions.]	Yes	No
4	Has the patient's need for continued therapy been assessed within the previous year? [No further questions]	Yes	No
5	Has the diagnosis been appropriately documented (e.g., evaluated by a complete clinical assessment, using DSM-5, standardized rating scales, interviews/questionnaires)? [If Yes, then go to 6. If No, then no further questions.]	Yes	No
6	Has the patient experienced an inadequate treatment response to an amphetamine product (e.g., amphetamine, amphetamine-dextroamphetamine, dextroamphetamine, methamphetamine, lisdexamfetamine) OR a methylphenidate product (e.g., methylphenidate, dexmethylphenidate)? [If Yes, then no further questions. If No, then go to 7.]	Yes	No

7	Has the patient experienced an intolerance to an amphetamine product (e.g., amphetamine, amphetamine-dextroamphetamine, dextroamphetamine, methamphetamine, lisdexamfetamine) OR a methylphenidate product (e.g., methylphenidate, dexmethylphenidate)? [If Yes, then no further questions. If No, then go to 8.]	Yes	No
8	Does the patient have 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, dexmethylphenidate)? [No further questions]	Yes	No

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS**
1.	Go to 2	Deny	Your plan only covers this drug when it is used for certain health conditions. Covered uses are Attention-Deficit/Hyperactivity Disorder (ADHD) and Attention Deficit Disorder (ADD). Your plan does not cover this drug for your health condition that your doctor told us you have. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Diagnosis]
2.	Go to 3	Go to 5	
3.	Go to 4	Deny	Your plan only covers this drug if it works well for you. We have denied your request because the drug did not work well for you. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Continuation - Efficacy]

4.	Approve, 36 Months	Deny	Your plan only covers this drug when your doctor has reviewed your therapy within the last year and you still have a need for it. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Continuation - Reassessment]
5.	Go to 6	Deny	Your plan only covers this drug when you have an assessment that shows you have Attention-Deficit/Hyperactivity Disorder (ADHD) or Attention Deficit Disorder (ADD). We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Positive assessment]
6.	Approve, 36 Months	Go to 7	
7.	Approve, 36 Months	Go to 8	
8.	Approve, 36 Months	Deny	Your plan only covers this drug if you have tried other drugs and they did not work well for you. We have denied your request because: A) You have not tried an amphetamine product or a methylphenidate product, and B) You do not have a medical reason not to take them. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.

			[Short Description: Step Therapy]