Clinical Policy: Clonidine ER (Kapvay)

Reference Number: ERX.NPA.86
Effective Date: 09.01.18
Last Review Date: 08.21
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Clonidine ER (Kapvay®) is a centrally acting alpha$_2$-adrenergic agonist.

FDA Approved Indication(s)
Kapvay is indicated for the treatment of attention deficit hyperactivity disorder (ADHD) as monotherapy and as adjunctive therapy to stimulant medications.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Kapvay is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Attention Deficit Hyperactivity Disorder (must meet all)**:**

1. Diagnosis of ADHD;
2. Age ≥ 6 years;
3. Failure of a 4 week trial of immediate-release clonidine tablets or clonidine transdermal patch, unless clinically significant adverse effects are experienced;
4. Member meets one of the following (a or b):
   a. Member or parent/guardian of member has a history of substance abuse;
   b. Failure of two formulary, extended-release, central nervous system stimulants (i.e., amphetamine or methylphenidate) from the same therapeutic class, each tried at maximally indicated doses, unless clinically significant adverse effects are experienced or all are contraindicated;
5. Dose does not exceed 0.4 mg (4 tablets) per day.

Approval duration: 12 months

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Attention Deficit Hyperactivity Disorder (must meet all)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 0.4 mg (4 tablets) per day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
ADHD: attention deficit hyperactivity disorder
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
clonidine immediate-release tablets (Catapres®) or transdermal patch (Catapres-TTS)	0.1 to 0.4 mg/day	0.4 mg/day
Long-Acting Amphetamines		
Adzenys XR ODT™ (amphetamine ER)	Refer to prescribing information	12.5 mg/day
Dyanavel® XR (amphetamine ER)		20 mg/day
amphetamine/ dextroamphetamine salts ER (Adderall® XR)		20 mg/day (20-30 mg/day if ≥ 6 years)
dextroamphetamine ER (Dexedrine Spansule®)		40 mg/day
Long-Acting Methylphenidates		
dexmethylphenidate ER (Focalin XR®)	Refer to prescribing information	40 mg/day (30 mg/day if 6-17 years)
methylphenidate ER (Aptensio XR™, Metadate CD®, QuilliChew ER®, Quillivant XR®, Ritalin LA®)		60 mg/day
methylphenidate ER (Concerta®)		72 mg/day
Daytrana® (methylphenidate transdermal)		One 30 mg/9-hour patch/day
Cotempla XR-ODT® (methylphenidate ER)		51.8 mg/day
Adhansia XR (methylphenidate)		6 to 17 years: 70 mg Adults: 85 mg

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings
- Contraindication(s): history of a hypersensitivity reaction to clonidine
- Boxed warning(s): none reported

Appendix D: General Information
- The use of two alpha$_2$ adrenergic receptor agonists (e.g., guanfacine and clonidine) concurrently is not recommended as this is considered duplicate therapy.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
ADHD	Children ≥ 6 years and adolescents: Initially 0.1 mg/day PO at bedtime. Increase the dose in 0.1 mg/day increments weekly up to 0.4 mg/day PO as needed to attain the desired response. Doses > 0.1 mg/day PO should be divided into 2 doses taken in the morning and at bedtime.	0.4 mg/day

VI. Product Availability
Extended-release tablet: 0.1 mg

VII. References
1. Kapvay Prescribing Information. St. Michael, Barbados: Concordia Pharmaceuticals Inc.; November 2020. Available at: https://dailymed.nlm.nih.gov/dailymed/. Accessed April 30, 2021.
2. American Academy of Child and Adolescent Psychiatry. Practice parameter for the assessment and treatment of children and adolescents with Attention-Deficit/Hyperactivity Disorder. J Am Acad Child Adolesc Psychiatry. 2007;46(7):894-921.
3. American Academy of Pediatrics subcommittee on attention-deficit/hyperactivity disorder, steering committee on quality improvement and management. Clinical Practice Guideline for the Diagnosis, Evaluation, and Treatment of Attention-Deficit/Hyperactivity Disorder in Children and Adolescents. Pediatrics Oct 2019, 144 (4) e20192528; DOI: 10.1542/peds.2019-2528.
4. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2017. Available at: http://www.clinicalpharmacology-ip.com/. Accessed April 30, 2021.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created: adapted from ERX.ST.06; removed time frame for history of substance abuse; removed 2 week length of trial for amphetamine and methylphenidate; removed requirement that member is not currently on guanfacine ER therapy; references reviewed and updated.	06.05.18	08.18
3Q 2019 annual review: no significant changes; removed 0.2 mg dosage form; references reviewed and updated.	05.05.19	08.19
3Q 2020 annual review: added requirement for a prior trial of immediate-release clonidine tablets or clonidine transdermal patch; references reviewed and updated.	05.04.20	08.20
3Q 2021 annual review: revised redirection from failure of 1 methylphenidate and 1 amphetamine product to failure of 2 extended-release formulations from one therapeutic class; references reviewed and updated.	04.30.21	08.21

Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional

medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.