ADHD Narcolepsy

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Quantity Limit	
All agents	May be subject to quantity limit

Medications
Preferred Products
Atomoxetine: Strattera generic
Clonidine (extended release): Kapvay generic
Dexmethylphenidate: Focalin generic Focalin XR generic
Dextroamphetamine and Amphetamine: Adderall generic Adderall XR generic
Dextroamphetamine: Dexedrine tablet generic Dexedrine capsules generic
Methylphenidate: Metadate ER generic methylphenidate products, except: chewable tablets and ER 72mg tablets
Non-Preferred Products
Atomoxetine: Strattera Brand
Amphetamine: Dyanavel XR Adzenys ER Suspension (and generic) Adzenys XR-ODT

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Market Applicability				
Market	**GA**	**MD**	**NJ**	**NY**
Applicable	X	NA	X	X

Clonidine (extended release):
Kapvay Brand

Guanfacine (extended release):
Intuniv and generic

Dextroamphetamine and Amphetamine:
Adderall Brand
Adderall XR Brand
Mydayis ER

Dextroamphetamine:
Dexedrine spansules Brand

Dexmethylphenidate:
Focalin Brand
Focalin XR Brand

Transdermal Methylphenidate:
Daytrana

Dextroamphetamine:
ProCentra solution (and generic)
Zenzedi Brand

Methylphenidate:
Adhansia XR
Aptensio XR (and generic)
Concerta Brand
Cotempla XR - ODT
Jornay PM
Metadate CD Brand
Methylin Brand
Methylin ER Brand
Methylphenidate chewable tablets
Methylphenidate ER 72mg tablets
Relexxii ER 72mg tablets
Ritalin Brand
Ritalin LA Brand
Quillichew ER Brand
Quillivant XR Brand

Serdexmethylphenidate and Dexmethylphenidate:
Azstarys

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Market Applicability				
Market	**GA**	**MD**	**NJ**	**NY**
Applicable	X	NA	X	X

Viloxazine:
Qelbree

Attention deficit hyperactivity disorder (ADHD) may also be referred to as attention deficit disorder (ADD).

*****Individuals age 19 and over will require prior authorization for diagnosis and trial of preferred products where applicable.*****

STEP THERAPY APPROVAL CRITERIA:

Requests for a *non-preferred* ADHD agent [Azstarys, Dyanavel XR, Adenzys XR-ODT, Adzenys ER Suspension (brand and generic), Kapvay (brand), Intuniv (brand and generic), Adderall (brand), Adderall XR (brand), Mydayis ER, Dexedrine Spansules (brand), Focalin (brand), Focalin XR (brand), Daytrana, Procentra solution (and generic), Zenzedi (brand), Adhansia XR, Aptensio XR (brand and generic), Concerta (brand), Cotempla XR-ODT, Jornay PM, Metadate CD (brand), Methylin (brand), Methylin ER (brand), methylphenidate chewable tablets, methylphenidate ER 72mg tablets, Ritalin (brand), Ritalin LA (brand), Qelbree, Quillichew ER, Quillivant XR, Relexxii ER 72mg tablets (brand), Strattera (brand)] may be approved if the following step therapy criteria are met **in addition to** any prior authorization criteria listed below:

I. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to one preferred agent;

> **Preferred agents**: atomoxetine, clonidine extended-release, dexmethylphenidate (IR and XR), dextroamphetamine-amphetamine tablet (IR and ER), dextroamphetamine tablet, dextroamphetamine SR capsules, the following generic methylphenidate agents: [methylphenidate ER (not 72mg)/SR/CR tablet, methylphenidate tablet/oral solution, methylphenidate ER 24-hr tablet (AB-rated generic Concerta), methylphenidate CD/ER/LA capsule], Metadate ER.

OR

II. The preferred agents are not FDA-approved for the prescribed indication and do not have an accepted off-label use per the off-label policy for the prescribed indication and the requested non-preferred agent does; **OR**

III. The preferred agent is not acceptable due to concomitant clinical conditions, such as but not limited to the following:
   A. Individual's age: **OR**
   B. Other known disease state or medication contraindication which is not also associated with the requested non-preferred agent.

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Market Applicability				
Market	**GA**	**MD**	**NJ**	**NY**
Applicable	X	NA	X	X

PRIOR AUTHORIZATION APPROVAL CRITERIA:

I. **Dexmethylphenidate (Focalin and generic, Focalin XR and generic), Amphetamine (Dyanavel XR, Adzenys XR-ODT, Adzenys ER Suspension), Guanfacine extended release (Intuniv and generic), Clonidine extended release (Kapvay and generic), Atomoxetine (Strattera and generic), Viloxazine (Qelbree), Serdexmethylphenidate and Dexmethylphenidate (Azstarys):**

Approve Dexmethylphenidate (Focalin and generic, Focalin XR and generic), Amphetamine (Dyanavel XR, Adzenys XR-ODT, Adzenys ER Suspension), Guanfacine extended release (Intuniv and generic), Clonidine extended release (Kapvay and generic), Atomoxetine (Strattera and generic), Viloxazine (Qelbree), and Serdexmethylphenidate and Dexmethylphenidate (Azstarys) when the following FDA approved indications or medically accepted usage criteria is met, if required by benefit:

A. Individual is 6 years of age or older; **AND**
B. Individual has a diagnosis of attention deficit hyperactivity disorder (ADHD).

Requests for amphetamine (Dyanavel XR, Adzenys XR-ODT, Adzenys ER suspension), Serdexmethylphenidate and Dexmethylphenidate (Azstarys), and dexmethylphenidate (Focalin and Focalin XR) agents may not be approved for the following:

A. Individual has known structural cardiac abnormalities, cardiomyopathy, serious heart rhythm abnormalities, coronary artery disease, or other serious heart problems; **OR**
B. Individual is currently using a monoamine oxidase inhibitor (MAOI) or has used an MAOI in the previous 14 days.

Requests for Strattera (atomoxetine) may not be approved for the following:

A. Individual has a diagnosis of narrow angle glaucoma; **OR**
B. Individual has a diagnosis of pheochromocytoma; **OR**
C. Individual has severe cardiac or vascular disorders whose condition would be expected to deteriorate if they experience increases in blood pressure or heart rate that could be clinically important; for example, 15 to 20 mm Hg in blood pressure or 20 beats per minute in heart rate; **OR**
D. Individual is a child or adolescent with known serious structural cardiac abnormalities, cardiomyopathy, serious heart rhythm abnormalities, or other serious cardiac problems that may place them at increased risk due to noradrenergic effects; **OR**
E. Individual is currently using a monoamine oxidase inhibitor (MAOI) or has used an MAOI in the previous 14 days**; OR**
F. Individual has active liver disease as noted by jaundice or laboratory evidence of liver injury.

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Market Applicability				
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Applicable	X	NA	X	X

Requests for Qelbree (viloxazine) may not be approved for the following:

A. Individual is currently using a monoamine oxidase inhibitor (MAOI) or has used an MAOI in the previous 14 days; **OR**
B. Individual is currently using a sensitive CYP1A2 substrate (such as, alosetron, clozapine, duloxetine, melatonin, ramelteon, tasimelteon) or a CYP1A2 substrate with a narrow therapeutic range (such as, theophylline, tizanidine) and cannot discontinue the agent.

II. **Transdermal Methylphenidate (Daytrana)**:
Approve Transdermal Methylphenidate (Daytrana) when the following FDA approved indications or medically accepted usage criteria is met, if required by benefit:

A. Individual is 6 years of age or older; **AND**
B. Individual has a diagnosis of attention deficit hyperactivity disorder; **AND**
C. Individual has had a suboptimal response to **one** maximally titrated long-acting methylphenidate product; **OR**
D. Individual has experienced **one** of the following adverse effects on previous therapy:
   1. Diminished appetite and documented weight loss from baseline over a three (3) month observation period; **OR**
   2. An elevated blood pressure over baseline demonstrated by at least three measurements over one (1) week period; **OR**
   3. Behavior or mood changes interfering with daily activities, including complaints of abdominal distress, sleep problems, or oppositional/rebellious/aggressive behavior.

Requests for transdermal methylphenidate (Daytrana) agents may not be approved for the following:

A. Individual has the following:
   1. Marked anxiety, tension or agitation; **OR**
   2. Glaucoma; **OR**
   3. Tics or a family history or diagnosis of Tourette's syndrome; **OR**
B. Individual has known structural cardiac abnormalities, cardiomyopathy, serious heart rhythm abnormalities, coronary artery disease, or other serious heart problems; **OR**
C. Individual is currently using a monoamine oxidase inhibitor (MAOI) or has used an MAOI in the previous 14 days.

III. **Dextroamphetamine (Dexedrine, Dexedrine Spansules, ProCentra solution (and generic), Zenzedi and generic products):**

A. Individual has a diagnosis of attention deficit hyperactivity disorder (ADHD); **AND**

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Market Applicability				
Market	**GA**	**MD**	**NJ**	**NY**
Applicable	X	NA	X	X

B. One of the following:
   1. Individual is 3 years of age or older and using immediate-release product; **OR**
   2. Individual is 6 years of age or older and using an extended-release product;

OR

C. Individual is 6 years of age or older; **AND**
D. Individual has a diagnosis of narcolepsy.

Requests for dextroamphetamine (Dexedrine, Dexedrine Spansules, ProCentra, Zenzedi) agents may not be approved for the following:

A. Individual has any of the following:
   1. Advanced arteriosclerosis; **OR**
   2. Symptomatic cardiovascular disease; **OR**
   3. Uncontrolled moderate to severe hypertension; **OR**
   4. Hyperthyroidism; **OR**
   5. Glaucoma; **OR**
B. Individual has an agitated state; **OR**
C. Individual has a history of drug abuse; **OR**
D. Individual is currently using a monoamine oxidase inhibitor (MAOI) or has used an MAOI in the previous 14 days.

IV. **Dextroamphetamine and Amphetamine (Adderall, Adderall XR and generic products):**

A. Individual has a diagnosis of attention deficit hyperactivity disorder (ADHD); **AND**
B. One of the following:
   1. Individual is 3 years of age or older and using an immediate-release product; **OR**
   2. Individual is 6 years of age or older and using an extended-release product;

OR

C. Individual is 6 years of age or older; **AND**
D. Individual is using an immediate-release product for the treatment of narcolepsy.

Requests for amphetamine/dextroamphetamine salt combination (Adderall, Adderall XR) agents may not be approved for the following:

A. Individual has any of the following:
   1. Advanced arteriosclerosis; **OR**
   2. Symptomatic cardiovascular disease; **OR**
   3. Uncontrolled moderate to severe hypertension; **OR**
   4. Hyperthyroidism; **OR**

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Market Applicability				
Market	**GA**	**MD**	**NJ**	**NY**
Applicable	X	NA	X	X

5. Glaucoma; **OR**

B. Individual has an agitated state; **OR**
C. Individual has a history of drug abuse; **OR**
D. Individual is currently using a monoamine oxidase inhibitor (MAOI) or has used an MAOI in the previous 14 days.

V. **Dextroamphetamine and Amphetamine (Mydayis ER products):**

A. Individual has a diagnosis of attention deficit hyperactivity disorder (ADHD); **AND**
B. Individual is 13 years of age or older.

Requests for amphetamine/dextroamphetamine salt combination (Mydayis) agents may not be approved for the following:

A. Individual has known structural cardiac abnormalities, cardiomyopathy, serious heart arrhythmia, coronary artery disease, or other serious heart problems; **OR**
B. Individual is currently using a monoamine oxidase inhibitor (MAOI) or has used an MAOI in the previous 14 days.

VI. **Methylphenidate (Methylin, Methylin ER, Ritalin, and generic products (not methylphenidate ER 72mg tablets):**

A. Individual is 6 years of age or older; **AND**
B. One of the following:
1. Individual has a diagnosis of attention deficit hyperactivity disorder (ADHD); **OR**
2. Individual has a diagnosis of narcolepsy.

OR

C. Individual is 4 or 5 years of age; **AND**
D. Individual has a diagnosis of attention deficit hyperactivity disorder (ADHD); **AND**
E. Individual and caregivers have participated in behavioral interventions; **AND**
F. Individual continues with moderate-to-severe disturbance in function. (AAP 2019).

VII. **Methylphenidate (Adhansia XR, Aptensio XR, Cotempla XR-ODT, Concerta, Jornay PM, Metadate CD, Metadate ER, methylphenidate ER 72mg tablets, Relexxii ER 72mg tablets, Quillichew ER, Quillivant XR, Ritalin LA and generic products):**

A. Individual is 6 years of age or older; **AND**
B. Individual has a diagnosis of attention deficit hyperactivity disorder (ADHD);

OR

C. Individual is 4 or 5 years of age (excluding Aptensio XR); **AND**

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Applicable	X	NA	X	X

D. Individual has a diagnosis of attention deficit hyperactivity disorder (ADHD); **AND**
E. Individual and caregivers have participated in behavioral interventions; **AND**
F. Individual continues with moderate-to-severe disturbance in function. (AAP 2019)

Requests for oral methylphenidate agents may not be approved for the following:

A. Individual has known structural cardiac abnormalities, cardiomyopathy, serious heart arrhythmia, coronary artery disease, or other serious heart problems; **OR**
B. Individual is currently using a monoamine oxidase inhibitor (MAOI) or has used an MAOI in the previous 14 days.

Notes:
Stimulant agents (methylphenidate, amphetamines, Vyvanse, methamphetamines, dexmethylphenidate, dextroamphetamine) have a black box warning for the potential for abuse and dependence. CNS stimulants have a high potential for abuse and dependence. Assess the risk of abuse prior to prescribing and monitor for signs of abuse and dependence while on therapy.

Strattera (atomoxetine) has a black box warning for suicidal ideation in children and adolescents. Strattera was noted to increase the risk of suicidal ideation in short-term studies in children or adolescents with ADHD. The risk of use with the clinical need should be considered. Comorbidities occurring with ADHD may be associated with an increase in the risk of suicidal ideation and/or behavior. Individuals who are started on therapy should be monitored closely for suicidality (suicidal thinking and behavior), clinical worsening, or unusual changes in behavior. Strattera is approved for ADHD in pediatric and adult individuals and not approved for major depressive disorder.

Qelbree (viloxazine) has a black box warning for suicidal thoughts and behaviors. In clinical studies, higher rates of suicidal thoughts and behavior were reported in pediatric patients with ADHD treated with Qelbree than in patients treated with placebo. Closely monitor all Qelbree-treated patients for clinical worsening, and for emergence of suicidal thoughts and behaviors.

Key References:

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Market Applicability				
Market	**GA**	**MD**	**NJ**	**NY**
Applicable	X	NA	X	X

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