

# Initial Prior Authorization States Mandate PANDAS PANS Traditional

## 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	Dosage Form
Abilify	aripiprazole	oral only
Abilify Mycite	aripiprazole	all
Adderall	amphetamine- dextroamphetamine	all
Adhansia	methylphenidate	all
Adzenys	amphetamine	all
Aptensio	methylphenidate	all
aripiprazole ODT (brand unavailable)	aripiprazole	orally disintegrating tablets (ODT)
Arynta	lisdexamfetamine dimesylate	all
Azstarys	serdexmethylphenidate/ dexmethylphenidate	all
Caplyta	lumateperone	all
Cobenfy	xanomeline/trospium chloride	all
Concerta	methylphenidate	all
Cotempla	methylphenidate	all
Daytrana	methylphenidate	all
Desoxyn	methamphetamine	all

Brand Name	Generic Name	Dosage Form
Dexedrine	dextroamphetamine	all
Dyanavel	amphetamine	all
Evekeo	amphetamine	all
Fanapt	iloperidone	all
Focalin	dexmethylphenidate	all
Intuniv	guanfacine extended-release	all
Invega	paliperidone	oral only
Jornay	methylphenidate	all
Kapvay	clonidine extended-release	all
Latuda	lurasidone	all
Lybalvi	olanzapine and samidorphan	all
Methylin	methylphenidate	all
methylphenidate (all other brands)	methylphenidate	all
Mezofy	aripiprazole	all
Mydayis	amphetamine-dextroamphetamine	all
Onyda XR	clonidine extended-release	all
Opipza	aripiprazole	all
Procentra	dextroamphetamine	all
Qelbree	viloxazine extended-release	all
QuilliChew	methylphenidate	all
Quillivant	methylphenidate	all
Relexxii	methylphenidate	all
Rexulti	brexpiprazole	all
Ritalin	methylphenidate	all
Saphris	asenapine	all
Secuado	asenapine	all
Strattera	atomoxetine HCl	all
Vraylar	cariprazine	all
Vyvanse	lisdexamfetamine	all
Xelstrym	dextroamphetamine	all
Zenzedi	dextroamphetamine	all

# Indications

## FDA-approved Indications

### Abilify

Abilify (aripiprazole) Tablets are indicated for the treatment of:

- Schizophrenia
- Acute Treatment of Manic and Mixed Episodes associated with Bipolar I Disorder
- Adjunctive Treatment of Major Depressive Disorder
- Irritability Associated with Autistic Disorder
- Treatment of Tourette's Disorder

### Abilify Mycite

Abilify Mycite, a drug-device combination product comprised of aripiprazole tablets embedded with an Ingestible Event Marker (IEM) sensor intended to track drug ingestion, is indicated for the:

- Treatment of adults with schizophrenia.
- Treatment of bipolar I disorder
  - Acute treatment of adults with manic and mixed episodes as monotherapy and as adjunct to lithium or valproate.
  - Maintenance treatment of adults as monotherapy and as adjunct to lithium or valproate.
- Adjunctive treatment of adults with Major Depressive Disorder.

### Limitations of Use

- The ability of the Abilify Mycite to improve patient compliance or modify aripiprazole dosage has not been established.
- The use of Abilify Mycite to track drug ingestion in "real-time" or during an emergency is not recommended because detection may be delayed or not occur.

### Adderall

Adderall (Dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets (Mixed salts of a single entity amphetamine product)) is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) and Narcolepsy.

### Adderall XR

Adderall XR is indicated for the treatment of attention deficit hyperactivity disorder (ADHD) in adults and pediatric patients 6 years and older.

### Adhansia XR, Jornay PM

These products are indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients 6 years and older.

## Adzenys XR-ODT, Dyanavel XR

These products are indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients 6 years and older.

## Aptensio XR

Aptensio XR is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients 6 years and older.

### Limitations of Use

Pediatric patients younger than 6 years of age experienced higher plasma exposure than patients 6 years and older at the same dose and high rates of adverse reactions, most notably weight loss.

## Aripiprazole Orally Disintegrating Tablets, Oral Solution

Aripiprazole orally disintegrating tablets and oral solution are indicated for the treatment of:

- Schizophrenia
- Acute Treatment of Manic and Mixed Episodes associated with Bipolar I Disorder
- Adjunctive Treatment of Major Depressive Disorder
- Irritability Associated with Autistic Disorder
- Treatment of Tourette's Disorder

## Arynta, Vyvanse

These products are indicated for the treatment of:

- Attention Deficit Hyperactivity Disorder (ADHD) in adults and pediatric patients 6 years and older.
- Moderate to severe binge eating disorder (BED) in adults.

### Limitations of Use

- Pediatric patients with ADHD younger than 6 years of age experienced more long-term weight loss than patients 6 years and older.
- Arynta is not indicated or recommended for weight loss. Use of other sympathomimetic drugs for weight loss has been associated with serious cardiovascular adverse events. The safety and effectiveness of Arynta for the treatment of obesity have not been established.

## Azstarys

Azstarys is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients 6 years of age and older.

## Caplyta

Caplyta is indicated for the treatment of:

- Schizophrenia in adults.
- Depressive episodes associated with bipolar I or II disorder (bipolar depression) in adults, as monotherapy and as adjunctive therapy with lithium or valproate.

## Cobenfy

Cobenfy is indicated for the treatment of schizophrenia in adults.

## Concerta

Concerta is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in children 6 years of age and older, adolescents, and adults up to the age of 65.

## Cotempla XR-ODT, Daytrana

These products are indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in pediatric patients 6 to 17 years of age.

## Desoxyn

Desoxyn is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in pediatric patients 6 years of age and older.

## Dexedrine Spansule

Dexedrine is indicated in:

- Narcolepsy
- Attention Deficit Disorder with Hyperactivity as an integral part of a total treatment program that typically includes other measures (psychological, educational, social) for patients (ages 6 years to 16 years) with this syndrome.

## Dextroamphetamine Sulfate Tablets, ProCentra, Zenzedi

These products are indicated for:

- Narcolepsy.
- Attention Deficit Disorder with Hyperactivity: As an integral part of a total treatment program which typically includes other remedial measures (psychological, educational, social) for a stabilizing effect in pediatric patients (ages 3 to 16 years) with a behavioral syndrome characterized by the following group of developmentally inappropriate symptoms: moderate to severe distractibility, short attention span, hyperactivity, emotional lability, and impulsivity. The diagnosis of this syndrome should not be made with finality when these symptoms are only of comparatively recent origin. Nonlocalizing (soft) neurological signs, learning disability, and abnormal EEG may or may not be present, and a diagnosis of central nervous system dysfunction may or may not be warranted.

## Evekeo

Evekeo (amphetamine sulfate tablets, USP) is indicated for:

- Narcolepsy
- Attention Deficit Disorder with Hyperactivity as an integral part of a total treatment program which typically includes other remedial measures (psychological, educational, social) for a stabilizing effect in children with behavioral syndrome characterized by the following group of developmentally inappropriate symptoms: moderate to severe distractibility, short attention

span, hyperactivity, emotional lability, and impulsivity. The diagnosis of the syndrome should not be made with finality when these symptoms are only of comparatively recent origin. Nonlocalizing (soft) neurological signs, learning disability, and abnormal EEG may or may not be present, and a diagnosis of central nervous system dysfunction may or not be warranted.

- Exogenous Obesity as a short term (a few weeks) adjunct in a regimen of weight reduction based on caloric restriction for patients refractory to alternative therapy, e.g., repeated diets, group programs, and other drugs. The limited usefulness of amphetamines should be weighed against possible risks inherent in use of the drug.

## Evekeo ODT

Evekeo ODT is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in pediatric patients 6 to 17 years of age.

## Fanapt

Fanapt is indicated for:

- Treatment of schizophrenia in adults.
- Acute treatment of manic or mixed episodes associated with bipolar I disorder in adults.

## Focalin, Focalin XR, QuilliChew ER, Quillivant XR

These products are indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).

## Intuniv

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

## Invega

### Schizophrenia

Invega (paliperidone) Extended-Release Tablets are indicated for the treatment of schizophrenia.

The efficacy of Invega in schizophrenia was established in three 6-week trials in adults and one 6-week trial in adolescents, as well as one maintenance trial in adults.

### Schizoaffective Disorder

Invega (paliperidone) Extended-Release Tablets are indicated for the treatment of schizoaffective disorder as monotherapy and an adjunct to mood stabilizers and/or antidepressant therapy.

The efficacy of Invega in schizoaffective disorder was established in two 6-week trials in adults.

## 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.

## Latuda

Latuda is indicated for:

- Treatment of adult and adolescent patients (13 to 17 years) with schizophrenia.
- Monotherapy treatment of adult and pediatric patients (10 to 17 years) with major depressive episode associated with bipolar I disorder (bipolar depression).
- Adjunctive treatment with lithium or valproate in adult patients with major depressive episode associated with bipolar I disorder (bipolar depression).

## Lybalvi

Lybalvi is indicated for the treatment of:

- Schizophrenia in adults
- Bipolar I disorder in adults
  - Acute treatment of manic or mixed episodes as monotherapy and as adjunct to lithium or valproate
  - Maintenance monotherapy treatment

## Methylin Oral Solution

Methylin is indicated for the treatment of:

- Attention Deficit Hyperactivity Disorder (ADHD) in adults and pediatric patients 6 years of age and older
- Narcolepsy

## Methylphenidate, Methylphenidate Extended Release, Ritalin

These products are indicated for the treatment of:

- Attention Deficit Hyperactivity Disorder (ADHD) in pediatric patients 6 years and older and adults
- Narcolepsy

## Methylphenidate CD Capsules

Methylphenidate hydrochloride extended-release capsules (CD) are indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in pediatric patients 6 to 15 years of age.

## Methylphenidate Chewable Tablets

### Attention Deficit Disorders

Methylphenidate hydrochloride chewable tablets are indicated as an integral part of a total treatment program which typically includes other remedial measures (psychological, educational, social) for a stabilizing effect in children with a behavioral syndrome characterized by the following group of developmentally inappropriate symptoms: moderate-to-severe distractibility, short attention span, hyperactivity, emotional lability, and impulsivity. The diagnosis of this syndrome should not be made with finality when these symptoms are only of comparatively recent origin. Nonlocalizing (soft) neurological signs, learning disability, and abnormal EEG may or may not be present, and a diagnosis of central nervous system dysfunction may or may not be warranted.

## **Narcolepsy**

### **Methylphenidate Osmotic Extended-Release, Relexxii**

These products are indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in adults (up to the age of 65 years) and pediatric patients 6 years of age and older.

### **Mezofy**

Mezofy is indicated for the treatment of schizophrenia in adult and pediatric patients 13 years and older.

### **Mydayis**

Mydayis is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients 13 years and older.

### **Limitations of Use**

Pediatric patients 12 years and younger experienced higher plasma exposure than patients 13 years and older at the same dose, and experienced higher rates of adverse reactions, mainly insomnia and decreased appetite.

### **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.

### **Opipza**

Opipza is indicated for the:

- treatment of schizophrenia in patients ages 13 years and older
- adjunctive treatment of major depressive disorder (MDD) in adults
- treatment of irritability associated with autistic disorder in pediatric patients 6 years and older
- treatment of Tourette's disorder in pediatric patients 6 years and older

### **Qelbree**

Qelbree is indicated for the treatment of Attention-Deficit Hyperactivity Disorder (ADHD) in adults and pediatric patients 6 years and older.

### **Ritalin LA**

Ritalin LA is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD), in pediatric patients 6 to 12 years of age.

### **Rexulti**

Rexulti is indicated for:

- Adjunctive treatment of major depressive disorder (MDD) in adults
- Treatment of schizophrenia in adults and pediatric patients ages 13 years and older
- Treatment of agitation associated with dementia due to Alzheimer's disease



## Limitations of Use

Rexulti is not indicated as an as needed (“prn”) treatment for agitation associated with dementia due to Alzheimer’s disease.

## Saphris

Saphris is indicated for:

- Schizophrenia in adults
- Bipolar I disorder
  - Acute monotherapy of manic or mixed episodes, in adults and pediatric patients 10 to 17 years of age
  - Adjunctive treatment to lithium or valproate in adults
  - Maintenance monotherapy treatment in adults

## Secuado

Secuado is indicated for the treatment of adults with schizophrenia.

## Strattera

Strattera is indicated for the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD).

The efficacy of Strattera was established in seven clinical trials in outpatients with ADHD: four 6 to 9-week trials in pediatric patients (ages 6 to 18), two 10-week trials in adults, and one maintenance trial in pediatrics (ages 6 to 15).

## Vraylar

Vraylar is indicated for:

- Treatment of schizophrenia in adults
- Acute treatment of manic or mixed episodes associated with bipolar I disorder in adults
- Treatment of depressive episodes associated with bipolar I disorder (bipolar depression) in adults
- Adjunctive therapy to antidepressants for the treatment of major depressive disorder (MDD) in adults

## Xelstrym

Xelstrym is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in adults and pediatric patients 6 years and older.

## Limitations of Use

Pediatric patients younger than 6 years of age experienced more long-term weight loss than patients 6 years and older.

## Compendial Uses

Adderall XR, Adhansia XR, Adzenys XR-ODT, Aptensio XR, Arynta, Concerta, Cotempla XR-ODT, Daytrana, Desoxyn, Dyanavel XR, Evekeo ODT, Focalin, Focalin XR, Jornay PM, Methylphenidate CD Capsules, Methylphenidate Osmotic Extended-Release, Mydayis, QuilliChew ER, Quillivant XR, Relexxii, Ritalin LA, Vyvanse, Xelstryl

- Narcolepsy<sup>56-59</sup>

Aptensio XR, Concerta, Cotempla XR-ODT, Daytrana, Focalin, Focalin XR, Jornay PM, Methylin Oral Solution, Methylphenidate, Methylphenidate CD Capsules, Methylphenidate Chewable Tablets, Methylphenidate Extended Release, Methylphenidate Osmotic Extended-Release, QuilliChew ER, Quillivant XR, Relexxii, Ritalin, Ritalin LA

- Cancer-related fatigue<sup>58,60-61</sup>

## Coverage Criteria

The requested drug will be covered with prior authorization when one (1) of the following criteria is met:

- The requested drug is being prescribed to treat one of the following conditions: pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections, pediatric acute onset neuropsychiatric syndrome, or autoimmune encephalitis.
- The requested drug is being used for an FDA-approved indication or an indication supported in the compendia of current literature (examples: AHFS, Micromedex, current accepted guidelines).

## Duration of Approval (DOA)

- 6847-A: DOA: 12 months

## References

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