Reference number(s)
481-A, 144-A

Initial Prior Authorization Methylphenidates

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.

Dexmethylphenidates

Brand Name	Generic Name	Dosage Form
Focalin	dexmethylphenidate	all products

Methylphenidates

Brand Name	Generic Name	Dosage Form
Aptensio	methylphenidate	all products
Concerta	methylphenidate	all products
Cotempla	methylphenidate	all products
Daytrana	methylphenidate	all products
Jornay	methylphenidate	all products
Metadate	methylphenidate	all products
Methylin	methylphenidate	all products
methylphenidate (all other brands)	methylphenidate	all products
QuilliChew	methylphenidate	all products
Quillivant	methylphenidate	all products
Relexxii	methylphenidate	all products

Brand Name	Generic Name	Dosage Form
Ritalin	methylphenidate	all products

Indications

FDA-approved Indications

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.

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.

Focalin, Focalin XR, QuilliChew ER, Quillivant XR

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

Jornay PM

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

Metadate CD

Metadate CD is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in pediatric patients 6 to 15 years of age.

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 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.

Narcolepsy

Methylphenidate Extended-Release, Ritalin

These products are indicated for the treatment of:

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

Methylphenidate LA, Ritalin LA

These products are indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD), in pediatric patients 6 to 12 years of age.

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.

Compendial Uses

- Narcolepsy [19-21,25]
- Cancer-related fatigue [21,26-27]

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).

- If the patient is 5 years of age or younger, the patient continues to have ADHD/ADD symptoms despite participating in evidence-based behavioral therapy (e.g., parent training in behavior management (PTBM), behavioral classroom interventions).

Cancer-Related Fatigue

Authorization may be granted when the requested drug is being prescribed for the treatment of cancer-related fatigue after other causes of fatigue have been ruled out.

Narcolepsy

Authorization may be granted when the patient has a diagnosis of narcolepsy when ALL of the following criteria are met:

- The requested drug is being prescribed by, or in consultation with, a sleep specialist.
- The diagnosis has been confirmed by a sleep study.

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 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.

Cancer-Related Fatigue

Authorization may be granted when the requested drug is being prescribed for the treatment of cancer-related fatigue after other causes of fatigue have been ruled out when ALL of the following criteria are met:

- The patient has achieved or maintained improvement in cancer-related fatigue from baseline.
- The patient's need for continued therapy has been assessed within the previous year.

Narcolepsy

Authorization may be granted when the patient has a diagnosis of narcolepsy when the following criteria is met:

- The patient has achieved or maintained improvement in daytime sleepiness with narcolepsy from baseline.

Duration of Approval (DOA):

- 481-A: DOA: 36 months
- 144-A: DOA: 12 months

References

1. Aptensio XR [package insert]. Wilson, NC: Rhodes Pharmaceuticals; October 2023.
2. Concerta [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; October 2023.
3. Cotempla XR-ODT [package insert]. Grand Prairie, TX: Neos Therapeutics Brands, LLC.; June 2021.
4. Daytrana [package insert]. Miami, FL: Noven Therapeutics, LLC; April 2024.
5. Focalin [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; October 2023.
6. Focalin XR [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; October 2023.
7. Jornay PM [package insert]. Morrisville, NC: Ironshore Pharmaceuticals Inc.; October 2023.
8. Metadate CD [package insert]. Denver, CO: Aytu BioPharma; October 2023.
9. Methylin Solution [package insert]. Florham Park, NJ: Shionogi Inc.; November 2023.
10. Methylphenidate Hydrochloride Chewable Tablets [package insert]. Lawrenceville, GA: XLCare Pharmaceuticals, Inc.; September 2023.
11. Methylphenidate Hydrochloride Extended Release Tablet [package insert]. Newton, PA: KVK-Tech, Inc.; February 2024.
12. Methylphenidate Hydrochloride (LA) [package insert]. Raleigh, NC: Mayne Pharma; November 2022.
13. Methylphenidate Osmotic Extended Release [package insert]. Alpharetta, GA: Trigen Laboratories, LLC; October 2023.
14. QuilliChew ER [package insert]. Monmouth Junction, NJ: NextWave Pharmaceuticals, Inc.; October 2023.
15. Quillivant XR [package insert]. Monmouth Junction, NJ: NextWave Pharmaceuticals, Inc.; October 2023.
16. Relexxii [package insert]. Alpharetta, GA: Vertical Pharmaceuticals, LLC; May 2024.
17. Ritalin [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; October 2023.
18. Ritalin LA [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; October 2023.
19. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. https://online.lexi.com. Accessed October 9, 2024.
20. Lexicomp Online, Lexi-Drugs Online. Waltham, MA: UpToDate, Inc.; 2024. https://online.lexi.com. Accessed October 9, 2024.
21. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 10/09/2024).

22. American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders. Fifth Edition Text Revision. Arlington, Virginia: American Psychiatric Association; 2022.
23. 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.
24. American Academy of Sleep Medicine. International Classification of Sleep Disorders, Third Edition, Text Revision. American Academy of Sleep Medicine, 2023.
25. Maski K, Trotti LM, Kotagal S, et al. Treatment of central disorders of hypersomnolence: an American Academy of Sleep Medicine clinical practice guideline. J Clin Sleep Med. 2021;17(9):1881-1893.
26. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Cancer-Related Fatigue. V.2.2024. Available at: www.nccn.org. Accessed October 28, 2024.
27. Lower EE, Fleishman S, Cooper A, et al. Efficacy of dexmethylphenidate for the treatment of fatigue after cancer chemotherapy: a randomized clinical trial. J Pain Symptom Manage. 2009;38(5):650-662.

Document History

Written by: UM Development (MS)

Date Written: 03/2010

Revised: 11/2010; (CY) 11/2011, 10/2012 (extended duration), 11/2012 (Quillivant XR addition); (JK) 12/2012 (shortened duration); (CS) 08/2013; (MS) 11/2013; (RP/MS) 07/2014 (extended duration; added “new to therapy” and “documented” questions); (MS) 09/2014 (operational clarification for “new to therapy” question); (RP) 11/2014 (removed new to therapy question), 05/2015 (added Aptensio XR), (NB) 10/2015 (updated denial reason #4); (RP) 11/2015 (no clinical changes), 12/2015 (Added QuilliChew ER), 11/2016 (operational change of designation from MMT to MDC-2; no clinical changes), 06/2017 (Added Cotempla XR-ODT), 11/2017 (no clinical changes; combined ref#s), 08/2018 (Added Jornay PM), 11/2018, 03/2019 (Added Adhansia XR), 11/2019 (removed MDC designation; no clinical changes), 12/2019 (Created two new Ref#s [from 481-A & 144-A] for DAW-9 Strategy for Brand Only Concerta); (PM) 11/2020 (no clinical changes); (PM/SLF) 11/2021 (removed brand Metadate ER); (MRS) 03/2022 (updated title from DAW to BOG), 03/2022 (added continued symptoms despite evidence-based behavioral therapy for ADHD/ADD in patients 5 and younger to coverage criteria; additional internal notes), 07/2022 (added new strengths of Relexxii); 09/2022 (removed BOG 3458-A and BOG 3459-A due to retirement), 11/2022 (added COT criteria for all approvable indications), 03/2023 (added prescriber restriction for narcolepsy), 11/2023 (no clinical changes); 11/2024 (removed Adhansia XR, added reactivated brand Metadate CD)

Reviewed: Medical Affairs (WF) 03/2010; (KP) 11/2010, 11/2011, 10/2012; (DC) 11/2012; (DR) 08/2013; (LB) 11/2013; (AD) 07/2014; (SS) 09/2014; (DNC) 11/2014, 05/2015; (GAD) 12/2015; (ABM) 07/2017; (GAD) 08/2018, 11/2018, 04/2019; (CHART) 11/27/2019, (EPA) 12/2019; (CHART) 12/3/2020, 12/2/2021, 03/17/2022, 08/04/2022, 12/01/2022, 03/30/2023, 11/30/2023, 11/21/2024

External Review 01/2010, 02/2011, 02/2012, 02/2013, 08/2013, 02/2014, 08/2014, 02/2015, 02/2016, 02/2017, 02/2018, 02/2019, 06/2019 (FYI), 02/2020 (FYI), 02/2020, 02/2021, 02/2022, 06/2022, 10/2022 (FYI), 02/2023, 08/2023, 02/2024, 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 go to 8.]	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	Is the patient 5 years of age or younger? [If Yes, then go to 7. If No, then no further questions.]	Yes	No
7	Does the patient continue to have ADHD/ADD (Attention Deficit Hyperactivity Disorder or Attention Deficit Disorder) symptoms despite participating in evidence-based behavioral therapy (e.g., parent training in behavior management (PTBM), behavioral classroom interventions)? [No further questions]	Yes	No
8	Does the patient have a diagnosis of narcolepsy? [If Yes, then go to 9. If No, then go to 13.]	Yes	No
9	Is this request for continuation of therapy? [If Yes, then go to 10. If No, then go to 11.]	Yes	No

10	Has the patient achieved or maintained improvement in daytime sleepiness with narcolepsy from baseline? [No further questions]	Yes	No
11	Is the requested drug being prescribed by, or in consultation with, a sleep specialist? [If Yes, then go to 12. If No, then no further questions.]	Yes	No
12	Is the diagnosis confirmed by a sleep study? [No further questions]	Yes	No
13	Is the requested drug being prescribed for the treatment of cancer-related fatigue after other causes of fatigue have been ruled out? [If Yes, then go to 14. If No, then no further questions.]	Yes	No
14	Is this request for continuation of therapy? [If Yes, then go to 15. If No, then no further questions.]	Yes	No
15	Has the patient achieved or maintained improvement in cancer-related fatigue from baseline? [If Yes, then go to 16. If No, then no further questions.]	Yes	No
16	Has the patient's need for continued therapy been assessed within the previous year? [No further questions]	Yes	No

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS**
1.	Go to 2	Go to 8	
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.	Go to 7	Approve, 36 Months	
7.	Approve, 36 Months	Deny	Your plan only covers this drug when you are 5 years of age or younger if you meet all of the following: A) You are in behavioral therapy, and B) You are still having symptoms. 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: Behavioral Therapy]

8.	Go to 9	Go to 13	
9.	Go to 10	Go to 11	
10.	Approve, 36 Months	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]
11.	Go to 12	Deny	Your plan only covers this drug if your doctor is a sleep specialist or has talked about your care plan with a sleep specialist. 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: Prescriber specialty]
12.	Approve, 36 Months	Deny	Your plan only covers this drug when you have had a sleep study that shows narcolepsy. We denied your request because your test result did not show a positive result for narcolepsy. 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: Lab/test]
13.	Go to 14	Deny	Your plan only covers this drug when it is used for certain health conditions. Covered uses are for: A) Attention-Deficit/Hyperactivity Disorder (ADHD), B) Attention Deficit Disorder (ADD), C) Narcolepsy, and D) Fatigue related to cancer. 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]
14.	Go to 15	Approve, 36 Months	
15.	Go to 16	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]
16.	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]