	TTER HEALTH®		*a e	etna [®]
Coverage I	Policy/Guideline			
Name:	ne: Methylphenidate Products		Page:	1 of 4
Effective D	ate: 12/16/2022		Last Review Date:	3/2022
A !	□Illinois	□Florida	⊠Florida Kids	
Applies to:	⊠New Jersey	□Maryland	□Michigan	
	⊠Pennsylvania Kids	□Virginia		

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for methylphenidate products under the patient's prescription drug benefit.

Description:

Adhansia XR, Aptensio XR, Jornay PM

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

Concerta, Methylphenidate Osmotic ER

These products are 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

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

Daytrana, Focalin, Focalin XR, Methylphenidate CD, QuilliChew ER, Quillivant XR

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

Methylphenidate Chewable Tablets

Attention Deficit Disorders

Narcolepsy

Methylphenidate, Methylphenidate Extended Release, Methylin Oral Solution, Ritalin, Ritalin SR

<u>Attention Deficit Hyperactivity Disorder (ADHD)</u> in adults and pediatric patients 6 years of age and older.

Narcolepsy

Relexxii

Relexxii is 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.

Ritalin LA

			* ac	etna **
AETNA BE	TTER HEALTH®			
Coverage	Policy/Guideline			
Name:	Name: Methylphenidate Products		Page:	2 of 4
Effective [Date: 12/16/2022		Last Review Date:	3/2022
Applies to:	□Illinois	□Florida	⊠Florida Kids	
	⊠New Jersey	□Maryland	□Michigan	
	⊠Pennsylvania Kids	□Virginia		

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

Compendial Uses

Narcolepsy

Cancer-related fatigue

Applicable Drug List:

Dexmethylphenidate
Methylphenidate capsule CD
Methylphenidate chew
Methylphenidate solution
Methylphenidate IR tablet
Methylphenidate tablet ER

Policy/Guideline:

The requested drug will be covered with prior authorization when the following criteria are met:

 Patient has a diagnosis of Attention-Deficit Hyperactivity Disorder (ADHD) or Attention-Deficit Disorder (ADD)

AND

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

AND

• The diagnosis has been appropriately documented (e.g., evaluated by a complete clinical assessment, using DSM-5, standardized rating scales, interviews/questionnaires)

OR

Patient has the diagnosis of narcolepsy

AND

The diagnosis has been confirmed by a sleep study

OR

 The requested drug is being prescribed for the treatment of cancer-related fatigue after other causes of fatigue have been ruled out

			♦ a	etna
AETNA BE	TTER HEALTH®			
Coverage	Policy/Guideline			
Name:	Methylphenidate Products		Page:	3 of 4
Effective D	Date: 12/16/2022		Last Review Date	e: 3/2022
Applies to:	□Illinois	□Florida	⊠Florida Kids	
	⊠New Jersey	□Maryland	□Michigan	
	⊠Pennsylvania Kids	□Virginia		

Approval Duration and Quantity Restrictions:

Approval:

Attention-Deficit Hyperactivity Disorder (ADHD) or Attention-Deficit Disorder (ADD): Approve 12 months

Narcolepsy: Approve 12 months

Cancer-related fatigue: Approve 12 months

Quantity Level Limit: Reference formulary for drug specific quantity level limits

References:

- 1. Adhansia XR [package insert]. Wilson, NC: Purdue Pharma L.P.; June 2021.
- 2. Aptensio XR [package insert]. Greenville, NC: Patheon Manufacturing Services LLC; June 2021.
- 3. Concerta [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; June 2021.
- 4. Cotempla XR-ODT [package insert]. Grand Prairie, TX: Neos Therapeutics, Inc.; June 2021.
- 5. Daytrana [package insert]. Miami, FL: Noven Therapeutics, LLC; June 2021.
- 6. Focalin [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; June 2021.
- 7. Focalin XR [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; June 2021.
- 8. Jornay PM [package insert]. Cherry Hill, NJ: Ironshore Pharmaceuticals, Inc.; June 2021.
- 9. Methylin Solution [package insert]. Florham Park, NJ: Shionogi Inc.; July 2021.
- 10. Methylphenidate CD capsules [package insert]. Brookhaven, NY: Amneal Pharmaceuticals of New York, LLC; June 2021.
- 11. Methylphenidate Chewable Tablets [package insert]. Central Islap, NY: Ascent Pharmaceuticals, Inc.; August 2021.
- 12. Methylphenidate Tablets [package insert]. Central Islip, NY: Ascent Pharmaceuticals, Inc.; August 2021.
- 13. Methylphenidate ER Tablets [package insert]. Newtown, PA: KVK-Tech.; April 2021.
- 14. Methylphenidate Osmotic Extended Release [package insert]. Central Islip, NY: Ascent Pharmaceuticals Inc.; August 2021.
- 15. QuilliChew ER [package insert]. Monmouth Junction, NJ: Tris Pharma, Inc.; June 2021.
- 16. Quillivant XR [package insert]. Monmouth Junction, NJ: Tris Pharma, Inc.; June 2021.
- 17. Relexxii [package insert]. Alpharetta, GA: Vertical Pharmaceuticals, LLC; June 2022.
- 18. Ritalin/Ritalin SR [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; June 2021.
- 19. Ritalin LA [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; June 2021.
- 20. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: UpToDate, Inc.; 2021; Accessed November 1, 2021.
- 21. Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com. Accessed November 1, 2021.

			♥ a	etna
AETNA BE	TTER HEALTH®			
Coverage	Policy/Guideline			
Name: Methylphenidate Pr		roducts	Page:	4 of 4
Effective D	Date: 12/16/2022		Last Review Da	te: 3/2022
Analiaa	□Illinois	□Florida	⊠Florida Kids	
Applies to:	⊠New Jersey	□Maryland	□Michigan	
	⊠Pennsylvania Kids	□Virginia		

- 22. Morgenthaler TI, Vishesh KK, Brown T, et al. Practice Parameters for the Treatment of Narcolepsy and other Hypersomnias of Central Origin. *Sleep* 2007;30(12):1705-11.
- 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 Psychiatric Association: Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition. Arlington, VA, American Psychiatric Association, 2013. https://dsm.psychiatryonline.org
- 25. FDA Drug Safety Communication. Safety Review Update of Medications used to treat Attention-Deficit/Hyperactivity Disorder (ADHD) in children and young adults. http://www.fda.gov/DrugS/DrugSafety/ucm277770.htm.
- 26. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology. Cancer-related fatigue V.1.2021. Available at: www.nccn.org. Accessed November 2021.
- 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 Nov;38(5):650-62
- 28. Bower JE, Bak K, Berger A, et al: Screening, Assessment, and Management of Fatigue in Adult Survivors of Cancer: An American Society of Clinical Oncology Clinical Practice Guideline Adaptation. *J Clin Oncol* 2014; 32(17):1840-1850.
- 29. Krahn LE, Hershner S, Loeding LD, et al. Quality Measures for the Care of Patients with Narcolepsy. *J Clin Sleep Med* 2015; 11(3): 335-355.