AETNA BETTER HEALTH® Coverage Policy/Guideline			
Name:	Methylphenidate Products	Page:	1 of 4
Effective Date:	12/4/2023	Last Review Date:	8/2023
Applies to:	☒Illinois ☐New Jersey ☐Pennsylvania Kids	☐Florida ☐Maryland ☐Virginia	☐Florida Kids ☐Michigan

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
Attention Deficit Hyperactivity Disorder (ADHD) 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

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:
Reference Non-Preferred drugs and Preferred with Prior Authorization drugs on the Illinois Medicaid Preferred Drug List

Policy/Guideline:

Documentation for Initial Requests for all indications:
For non-preferred medication requests, the patient is unable to take three (3) formulary alternatives for the given diagnosis due to a trial and inadequate treatment response or intolerance, or a contraindication. Documentation is required for approval.

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

- The patient has a diagnosis of Attention-Deficit/Hyperactivity Disorder (ADHD) or Attention Deficit Disorder (ADD) **AND**
    - The diagnosis has been appropriately documented (e.g., evaluated by a complete clinical assessment, using DSM-5, standardized rating scales, interviews/questionnaires) **AND**
        - The patient is 6 years of age or older
          OR
        - The patient is 5 years of age or younger
          AND
            - The patient continues 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)

    OR
    - The request is for continuation of therapy
      AND

- The patient has achieved or maintained improvement in their signs and symptoms of ADHD/ADD (Attention-Deficit/Hyperactivity Disorder or Attention Deficit Disorder) from baseline
  AND
- The patient's need for continued therapy has been assessed within the previous year

OR

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

  OR
  - The request is for continuation of therapy
    AND
  - The patient has achieved or maintained improvement in daytime sleepiness with narcolepsy from baseline

OR

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

  OR
  - The request is for continuation of therapy
    AND
  - The patient has achieved or maintained improvement in cancer-related fatigue from baseline
    AND
  - The patient's need for continued therapy has been assessed within the previous year

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]. Stamford, CT: Adlon Therapeutics L.P.; June 2021.
2. Aptensio XR [package insert]. Coventry, RI: Rhodes Pharmaceuticals L.P.; June 2021.
3. Concerta [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; April 2022.
4. Cotempla XR-ODT [package insert]. Grand Prairie, TX: Neos Therapeutics Brands, LLC.; 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]. Morrisville, NC: Ironshore Pharmaceuticals Inc.; June 2021.
9. Methylin Solution [package insert]. Florham Park, NJ: Shionogi Inc.; July 2021.
10. Methylphenidate Hydrochloride (CD) [package insert]. Parsippany, NJ: Teva Pharmaceuticals USA, Inc.; May 2022.
11. Methylphenidate Hydrochloride Chewable Tablets [package insert]. Lawrenceville, GA: XLCare Pharmaceuticals, Inc.; August 2021.
12. Methylphenidate IR Tablet [package insert]. Somerset, NJ: Solco Healthcare US, LLC; May 2022.
13. Methylphenidate ER Tablet [package insert]. Newtown, PA: KVK-Tech, Inc.; April 2021.
14. Methylphenidate Osmotic Extended Release [package insert]. Alpharetta, GA: Trigen Laboratories, LLC; June 2022.
15. QuilliChew ER [package insert]. Monmouth Junction, NJ: NextWave Pharmaceuticals, Inc.; June 2021.
16. Quillivant XR [package insert]. Monmouth Junction, NJ: NextWave Pharmaceuticals, 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, Ohio: UpToDate, Inc.; 2022; Accessed September 29, 2022.
21. Lexicomp Online, Lexi-Drugs Online, Hudson, Ohio: UpToDate, Inc.; 2022; Accessed September 29, 2022.
22. Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com. Accessed September 29, 2022.
23. American Psychiatric Association: Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition Text Revision. Arlington, Virginia: American Psychiatric Association, 2022.
24. 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.
25. American Academy of Sleep Medicine. The International Classification of Sleep Disorders, 3rd edition. Darien, IL: American Academy of Sleep Medicine, 2014.
26. Sateia MJ. International Classification of Sleep Disorders- Third Edition: Highlights and Modifications. *CHEST*. 2014;146(5):1387-1394.
27. 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.
28. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Cancer-Related Fatigue. V.2.2022. Available at: www.nccn.org. Accessed October 6, 2022.
29. 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.
30. 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.