SmartPA Criteria Proposal

Drug/Drug Class:	ADHD: Methylphenidate, Long Acting PDL Edit
First Implementation Date:	January 10, 2019
Proposed Date:	September 17, 2020
Prepared For:	MO HealthNet
Prepared By:	MO HealthNet/Conduent
Criteria Status:	☐Existing Criteria ☒Revision of Existing Criteria ☐New Criteria

Executive Summary

Purpose: The MO HealthNet Pharmacy Program will implement a state-specific preferred drug list.

Why Issue Selected: The CNS stimulant therapeutic class has been edited within the MO HealthNet Pharmacy Program, since 1992. In August of 2003, the restriction on these medications was significantly lessened with the implementation of a stimulant clinical edit, eventually leading to an ADHD therapy edit which now includes Non-Stimulant ADHD medications. With the increased recognition of impairment due to adult attention deficit disorder, there is a need to re-evaluate the products used to treat ADHD.

Participants that are currently on a drug that is listed as non-preferred are not required to switch to a preferred agent as long as they have been compliant with their current therapy.

Total program savings for the PDL classes will be regularly reviewed.

Program-Specific Information:

Preferred Agents	Non-Preferred Agents
• Concerta®	• Adhansia XR™
• Daytrana®	• **Aptensio XR™**
• Focalin XR®	• Cotempla XR ODT™
• Metadate® ER	• Dexmethylphenidate XR
• Methylphenidate CD	• Jornay PM™
• Methylphenidate LA	• Metadate CD®
• Methylphenidate SR	• **Methylphenidate ER Caps (gen Aptensio XR™)**
• Quillichew ER™	• Methylphenidate ER (gen Concerta®)
• Quillivant XR®	• Methylphenidate ER 72mg Tabs (gen Relexxii™ ER)
	• Relexxii™ ER
	• Ritalin LA®

Type of Criteria:	☐ **Increased risk of ADE**	☒ **Preferred Drug List**
	☒ **Appropriate Indications**	☐ **Clinical Edit**
Data Sources:	☐ **Only Administrative Databases**	☒ **Databases + Prescriber-Supplied**

Setting & Population

- Drug class for review: ADHD: Methylphenidate, Long Acting
- Age range: All appropriate MO HealthNet participants aged 6 years and older

Approval Criteria

- Dosage within approved dosage limitations **AND**
- Participant demonstrates compliance to prescribed therapy **OR**
- Failure to achieve desired therapeutic outcomes with trial on 3 or more preferred agents
    - Documented trial period for preferred agents (90 out of 120 days) **OR**
    - Documented ADE/ADR to preferred agents
- Therapy may be approved for indications below (clinical consultant review may be required):
    - Attention Deficit Hyperactivity Disorder
    - Opioid-Induced Sedation or Depression in the treatment of Cancer
    - Idiopathic hypersomnia
    - **Narcolepsy**
- Participant aged ≥ 6 years and < 18 years: appropriate diagnosis (see above)
- Participant aged ≥ 18 years and < 23 years:
    - Appropriate diagnosis (see above)
    - For ADHD therapy: Goals of therapy clearly defined by prescriber (may include academic/work enrollment)
- Participant aged > 23 years:
    - Diagnosis of Opioid-Induced Sedation or Depression in the treatment of Cancer or Idiopathic hypersomnia **OR**
    - Diagnosis of ADHD:
        - Positive diagnosis – Diagnostic criteria including:
            - At least 5 of the 9 symptoms of inattention and/or at least 5 of the 9 symptoms of hyperactivity and impulsivity from the DSM-5
            - Symptoms are present in 2 or more settings
            - Clear evidence that the symptoms interfere with social, academic or occupational functioning.
                - DSM-5 Diagnostic Criteria - Attention-Deficit/Hyperactivity Disorder (ADHD)
        - Claim may be flagged for clinical consultant review secondary to comorbid substance use disorder diagnosis (see Appendix I for specific ICD-10 Diagnoses Codes inclusion/exclusion criteria)
        - Claim flagged for clinical consultant review secondary to concomitant psychiatric medication use of 3 or more agents (including requested ADHD therapy)
        - Claim flagged if concomitant use of benzodiazepines present
        - Psychiatric Specialist Consult (within most recent 6 months) required for diagnosis and treatment initiation (participant may receive regular follow-up by primary care physician)
        - Adequate trial required for monotherapy
        - Goals of therapy clearly defined by prescriber
- **For methylphenidate ER 72mg tabs (gen Relexii™ ER): Clinical Consultant Review**

Denial Criteria

- Lack of adequate trial on required preferred agents
- Therapy will be denied if all approval criteria are not met
- Participant aged < 6 years: Clinical Consultant Review
- Claim exceeds maximum dosing limitation for the following:

DAYTRANA 10 MG/9 H PATCH	METHYLPHENIDATE	1 patch per day
DAYTRANA 15 MG/9 H PATCH	METHYLPHENIDATE	
DAYTRANA 20 MG/9 H PATCH	METHYLPHENIDATE	
DAYTRANA 30 MG/9 H PATCH	METHYLPHENIDATE	

Required Documentation

Laboratory Results:		Progress Notes:	X
MedWatch Form:		Other:	X

Disposition of Edit

Denial: Exception Code “0160” (Preferred Drug List)
Rule Type: PDL

Default Approval Period

3 months

References

1. Evidence-Based Medicine and Fiscal Analysis: “Attention Deficit Hyperactivity Disorder (ADHD) Agents – Therapeutic Class Review”-, Conduent Business Services, L.L.C., Richmond, VA; July 2020.
2. Psychology Prior Authorization Advisory Committee Meeting. "Evidence-Based Practice Discussion – ADHD and Stimulant Therapy". MO HealthNet Division. November 2007.
3. Drug Prior Authorization Sub-Committee Meeting. “ADHD Adult Therapy.” Department of Mental Health/Division of Medical Services. March/April/June 2005.American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders (5th ed.), Washington, DC; 2013.Lippincott, Williams, Wilkins.
4. Drug Effectiveness Review Project – Drug Class Review: Pharmacologic Treatments for Attention Deficit Hyperactivity Disorder. Center for Evidence-Based Policy, Oregon Health & Science University; September 2005/Updated July 2015; Preliminary Scan Report June 2016.
5. Evidence-Based Medicine Analysis: “Attention Deficit Hyperactivity Disorder (ADHD)”, UMKC-DIC; July 2020.
6. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2020.
7. USPDI, Micromedex; 2020.
8. Facts and Comparisons eAnswers (online); 2020 Clinical Drug Information, LLC.