



Prior Authorization Protocol

**ADZENYS XR-ODT, DYANAVEL XR (amphetamine extended-release),
QUILLICHEW ER, QUILLIVANT XR (methylphenidate extended-release)**

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Coverage of drugs is first determined by the member's pharmacy benefit. Please consult with or refer to the Evidence of Coverage document.

I. FDA Approved Indications:

- Dyanavel XR, Quillichew ER, Quillivant XR: For the treatment of Attention Deficit/Hyperactivity Disorder (ADHD)
- Adzenys XR-ODT: For the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients 6 years and older.

II. Health Net Approved Indications and Usage Guidelines:

- Diagnosis of attention deficit hyperactivity disorder
AND
- Medical justification why other dosage forms cannot be used (e.g., inability to swallow tablets or capsules)

III. Coverage is Not Authorized For:

- Non-FDA approved indications, which are not listed in the Health Net Approved Indications and Usage Guidelines section, unless there is sufficient documentation of efficacy and safety in the published literature.

IV. General Information:

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V. Therapeutic Alternatives:

Drug	Dosing Regimen	Dose Limit/ Maximum Dose
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* Requires Prior Authorization

VI. Recommended Dosing Regimen and Authorization Limit:

Drug	Dosing Regimen	Dose Limit/ Maximum Dose
Dyanavel XR	<u>Patients 6 years and above:</u> 2.5 - 5 mg PO QD Dose may be increased every 4 to 7 days in increments of 2.5 to 10 mg per day to a maximum of 20 mg/day.	Length of Benefit
Adzenys XR-ODT	Patients 6 to 17 years:	Length of Benefit

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	<u>6.3 mg PO QD</u> <u>Increase dose in increments of 3.1 mg or 6.3 mg at weekly intervals. The maximum recommended dose is 18.8 mg/day for patients 6 to 12 years, and 12.5 mg for patients 13 to 17 years.</u> Patients 18 years and above: 12.5 mg PO QD	
Quillichew ER	Patients 6 years and above: 20 mg PO QD Dose may be titrated weekly in increments of 10 mg, 15 mg, or 20 mg per day. Daily dosage above 60 mg is not recommended	Length of Benefit
Quillivant XR	Patients 6 years and above: 20 mg PO QD Dose may be titrated weekly in increments of 10 mg to 20 mg. Daily dosage above 60 mg is not recommended	Length of Benefit

VII. Product Availability:

Adzenys XR-ODT: Extended-release orally disintegrating tablets: 3.1 mg, 6.3 mg, 9.4 mg, 12.5 mg, 15.7 mg, 18.8 mg
 Dyanavel XR: Extended-release oral suspension: 2.5 mg/ml
 Quillichew ER: extended-release chewable tablets: 20 mg, 30 mg, 40 mg
 Quillivant XR: extended-release oral suspension: 25 mg (5mg/ml)

VIII. References:

1. Dyanavel XR [package insert]. Monmouth Junction, NJ: Tris Pharma: November 2015.
2. Micromedex® DrugDEX, (online database). Truven Health Analytics, Greenwood Village, Colorado, USA. Accessed: June 2016.
3. Adzenys XR-ODT [package insert]. Grand Prairie, TX: Neos Therapeutics. January 2016.
4. Quillichew ER [package insert]. Monmouth Junction, NJ: Tris Pharma. December 2015.
5. Quillivant XR [package insert]. Monmouth Junction, NJ: Tris Pharma. May 2016.



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The materials provided to you are guidelines used by this health plan to authorize, modify, or determine coverage for persons with similar illnesses or conditions. Specific care and treatment may vary depending on individual needs and the benefits covered under your contract.