

MTF Formulary Management for Attention Deficit/Hyperactivity Disorder (ADHD) Stimulant Agents

Defense Health Agency Pharmacy Operations Division

Bottom Line

- Ritalin LA and IR formulations were removed from the Basic Core Formulary (BCF) and designated as Uniform Formulary (UF) due to very low MTF utilization.
- Concerta and Adderall XR remain on the BCF.
- Quillivant XR oral suspension is now designated as UF.
- The new branded entrants to the market—Evekeo, Aptensio XR, and Zenzedi—were designated as UF, but are expected to have negligible clinical impact and utilization.
- Vyvanse, Focalin XR, and Daytrana remain nonformulary; they are less cost-effective than the formulary drugs.

Uniform Formulary Decision: The Director, DHA, approved the recommendations from the November 2015 DoD P&T Committee meeting on January 29, 2016.

ADHD Stimulant Uniform Formulary (UF) Agents		ADHD Stimulant Nonformulary Agents (NF)
Basic Fore Formulary (BCF) Agents, MTFs <u>must</u> have on formulary	On UF, not on BCF MTFs <u>may</u> have on formulary	MTFs <u>must not</u> have on formulary
<ul style="list-style-type: none"> • methylphenidate OROS (Concerta; generic*) • mixed amphetamine salts XR (Adderall XR, generic) 	<ul style="list-style-type: none"> • amphetamine sulfate tabs (Evekeo) • methylphenidate ER oral suspension (Quillivant XR) • methylphenidate ER (Aptensio XR) • methamphetamine HCL (Desoxyn) • dextroamphetamine (Dexedrine spansule, Dextrostat tabs, ProCentra solution, generics; Zenzedi tablets) • mixed amphetamine salts IR (Adderall IR; generic) • methylphenidate CD (Metadate CD; generic) • methylphenidate IR (Ritalin IR; generic) • methylphenidate LA (Ritalin LA; generic) • methylphenidate SR (Ritalin SR; generic) • methylphenidate ER (Metadate ER, Methylin ER; generic) • methylphenidate SR (Ritalin SR) • methylphenidate chewable tablets and solution (Methylin) • dexmethylphenidate IR (Focalin; generic) 	<ul style="list-style-type: none"> • methylphenidate patch Daytrana) • dexmethylphenidate XR (Focalin XR) • lisdexamfetamine (Vyvanse)

Note that **bolded** products are not available in generic formulations.

* At the time of the November 2015 P&T meeting, the only "AB" rated generic equivalent for Concerta OROS (osmotic controlled release oral delivery system) was by Actavis; other generic manufacturers carry a "BX" rating. Consult the Orange Book for more information.

Clinical Summary

- There were no significant updates to the previous clinical conclusions from the February 2012 Uniform Formulary class review. See previous P&T Committee meeting minutes for full clinical conclusions.
- New entrants to the class include amphetamine sulfate tablets (Evekeo), methylphenidate extended release (ER) capsules (Aptensio XR), and dextroamphetamine tablets (Zenzedi).

- Evekeo, Aptensio XR, and Zenzedi do not contain new chemical entities and were FDA-approved using data from previously approved drugs. There are no head-to-head studies between any of the new entrants and other ADHD stimulants. The active ingredients for the new drugs are available in generic formulations that are included on the UF.
- Quillivant XR is the only long-acting methylphenidate oral suspension on the market and is approved for children as young as six years of age. Immediate release methylphenidate and dextroamphetamine oral solutions are therapeutic alternatives to Quillivant XR, but must be dosed twice daily.
- Daytrana is the only transdermal patch available for ADHD, but is associated with skin reactions.
- Vyvanse remains designated as nonformulary.
 - It is approved for children and adults with ADHD. However, Military Health System utilization trends show that the vast majority of patients prescribed ADHD drugs, including Vyvanse, are in the age range of 5–14 years.
 - Vyvanse has a new FDA-approved indication for binge eating disorder, but other therapies, including, topiramate, zonisamide, and the selective serotonin reuptake inhibitors are commonly used for this condition.
- Several products are on the UF for patients with swallowing difficulties. Ritalin LA, Metadate CD, Adderall XR, and Focalin XR capsules can be opened and their contents sprinkled on food.
- The ADHD stimulants have a high degree of therapeutic interchangeability, although there are differences in the duration of action between products. The branded ADHD stimulants—Vyvanse, Daytrana Patch, Zenzedi, Evekeo, and Aptensio XR—offer no additional clinical advantages over the other stimulant agents on the UF.
 - Quillivant XR was moved from NF to UF status, recognizing that children with special needs may refuse medications sprinkled on applesauce.

References

- DoD P&T Committee minutes: <http://www.health.mil/PandT>
- Current/future drug classes under review by the DoD P&T Committee: <http://www.health.mil/About-MHS/Other-MHS-Organizations/DoD-Pharmacy-and-Therapeutics-Committee>
- TRICARE Formulary Search Tool: <http://www.health.mil/formulary>
- Prior Authorization/Medical Necessity forms: see Formulary Search Tool above.
- Formulary Management Documents (including this one) available at: <http://www.health.mil/DoDPTResources>
- Point of contact for additional information: dha.jbsa.pharmacy.list.poduf@mail.mil

Attention Deficit/Hyperactivity Disorder—Stimulants (Selected Agents) Price Comparison: Cost-Effectiveness “Rankings” Influenced by Fully Burdened Costs at all 3 Points of Service	
Drug	Cost/Month (Nov 2015)
Basic Core Formulary	
mixed amphetamine salts XR (Adderall XR, generic)	\$ Most Cost-Effective
methylphenidate OROS (Concerta; generic)	\$\$\$ Less Cost-Effective
Uniform Formulary	
methylphenidate XR suspension (Quillivant)	\$\$\$ Less Cost-Effective
dexmethylphenidate XR (Focalin XR)	\$\$\$\$ Least Cost-Effective
methylphenidate patch (Daytrana)	\$\$\$\$ Least Cost-Effective
lisdexamfetamine(Vyvanse)	\$\$\$\$ Least Cost-Effective
Legend: \$ = “Most Cost-Effective” represents Rx’s with the <u>lowest cost</u> and best clinical efficacy \$\$ = “Less Cost-Effective” represents <u>higher cost</u> Rx’s with similar clinical efficacy \$\$\$ = “Less Cost-Effective” represents <u>next higher cost</u> Rx’s with similar clinical efficacy \$\$\$\$ = “Least Cost-Effective” represents Rx’s with the <u>highest cost</u> with similar clinical efficacy	