

# **BC PharmaCare Newsletter**

April 18, 2017 Edition 17-005

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# MANDATORY REPORTING OF DRUG SHORTAGES IN CANADA

Federal regulations on mandatory reporting for drug shortages came into effect on March 16, 2017. Drug manufacturers are now required to report product discontinuations, actual drug shortages, and expected drug shortages on a central website, <a href="www.drugshortagescanada.ca">www.drugshortagescanada.ca</a>. Previously, manufacturers voluntarily reported shortages on an industry-run website (<a href="www.drugshortages.ca">www.drugshortages.ca</a>). For more information on how and under what circumstances drug shortages or discontinuations are reported, please read the <a href="Protocol for the Notification and Communication of Drug Shortages">Protocol for the Notification and Communication of Drug Shortages</a> published by Health Canada.

Information about drug shortages affecting British Columbian pharmacies and prescribers is available on the <u>Drug Shortage Information page</u> of the PharmaCare website.



The use of PharmaNet is not intended as a substitute for professional judgment. Information on PharmaNet is not exhaustive and cannot be relied upon as complete.

The absence of a warning about a drug or drug combination is not an indication that the drug or drug combination is safe, appropriate or effective in any given patient. Health care professionals should confirm information obtained from PharmaNet, and ensure no additional relevant information exists, before making patient care decisions.



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# **BENEFITS**

# Limited Coverage Drug Program—Coverage for Attention Deficit Hyperactivity Disorder Drugs

Effective **April 18, 2017**, PharmaCare will expand its existing coverage of drugs for the treatment of pediatric patients with Attention Deficit Hyperactivity Disorder (ADHD) to include **atomoxetine**, **dextroamphetamine-amphetamine** and **lisdexamfetamine** (**Vyvanse**®) as Limited Coverage drugs through the Special Authority (SA) program.

#### **ADHD Therapeutic Review**

BC PharmaCare initiated a therapeutic review of medications for the management of ADHD.

On August 8, 2016, the Drug Benefit Council (DBC) reviewed the medications for ADHD and recommended that PharmaCare cover additional drugs for this indication for the pediatric population.

As part of the therapeutic review process, PharmaCare carefully considered feedback provided by numerous B.C. clinicians (such as general physicians, specialists and pharmacists) and advocacy groups. Additionally, it sought input from patients, caregivers, patient advocacy groups and drug manufacturers.

Based on clinical evidence, the DBC concluded there are no significant differences between the extended-release stimulants; PharmaCare therefore identified dextroamphetamine-amphetamine and lisdexamfetamine as the most cost-effective drugs among the extended-release stimulants. PharmaCare is also adding coverage for a non-stimulant option, atomoxetine, for the management of ADHD.

For more information on the therapeutic review, including links to clinical evidence documents and the DBC recommendation and reasons for recommendation, visit <a href="https://www.gov.bc.ca/pharmacare/ADHDtherapeuticreview">www.gov.bc.ca/pharmacare/ADHDtherapeuticreview</a>.

#### **PharmaCare Coverage Details**

Effective April 18, 2017, PharmaCare will cover the non-stimulant, **atomoxetine**, as a Limited Coverage drug with SA criteria for the pediatric population.

Effective April 18, 2017, PharmaCare will also cover **dextroamphetamine-amphetamine** and **lisdexamfetamine** as Limited Coverage drugs with SA criteria similar to the criteria for methylphenidate extended-release (Concerta®) for the pediatric population.

Prescribers will need to submit an SA Request for patients who are currently using atomoxetine, dextroamphetamine-amphetamine and lisdexamfetamine, but who are not currently receiving PharmaCare coverage.

For patients currently receiving PharmaCare coverage for atomoxetine, dextroamphetamine-amphetamine and lisdexamfetamine, a new SA Request does not need to be submitted.

Patients currently receiving PharmaCare coverage of the brand name formulations Strattera® and Adderall XR® will need to switch to the generic formulations in order to continue receiving full coverage as only generic formulations of atomoxetine and dextroamphetamine-amphetamine will be covered by PharmaCare. This applies to a relatively small number of patients and substitution of the generic usually can be made at the pharmacy when the patient next requires a refill. Patients who have already been granted SA approval for atomoxetine and dextroamphetamine-amphetamine will not require additional SA approval to receive coverage for the generic formulations. If a patient cannot tolerate the generic formulation, prescribers may submit an SA Request for exceptional, case-by-case coverage of the brand formulation.

Guanfacine (Intuniv XR®) and methylphenidate controlled-release (Biphentin®) will remain non-benefits.

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For detailed information on the SA criteria for **atomoxetine**, **dextroamphetamine** and **lisdexamfetamine** and for the appropriate SA Request forms, visit <a href="www.gov.bc.ca/pharmacarespecialauthority">www.gov.bc.ca/pharmacarespecialauthority</a> and select the drug name from the list of drugs.

#### Changes to the maximum reimbursement of methylphenidate extended-release formulations

Effective April 18, 2017, all new SA Requests for methylphenidate extended-release will be eligible for reimbursement up to the price of generic methylphenidate extended-release. PharmaCare will continue fully covering brand name methylphenidate extended-release (Concerta®) for patients granted SA approval for that drug prior to April 18, 2017. Changes have been made to the SA criteria for methylphenidate extended-release to allow for easier qualification for this drug.

### Change to the Collaborative Prescribing Agreement (CPA) for extended-release methylphenidate

With the addition of several ADHD drugs to the PharmaCare formulary, the methylphenidate extended-release CPA is being discontinued.

Please note that PharmaCare will continue covering patients who were prescribed extended-release methylphenidate under the CPA before April 18, 2017. From that date forward, prescribers can submit one SA Request for their patients beginning therapy with dextroamphetamine-amphetamine, lisdexamfetamine, and extended-release methylphenidate.

Coverage is, as usual, subject to the rules of a patient's PharmaCare plan, including any annual deductible requirements. Note that PharmaCare cannot provide any retroactive coverage. To secure coverage, active SA approval must be in place before the drug is dispensed.

# **Limited Coverage Drugs**

The following drugs have been added as Limited Coverage Drugs under Fair PharmaCare, and PharmaCare Plans C, F and, where indicated, Plan G.

COVERAGE EFFECTIVE	April 18, 2017		
DRUG NAME	atomoxetine		
INDICATION	Attention Deficit Hyperactivity Disorder (ADHD)		
DIN	2318024	APO-ATOMOXETINE 10 mg capsule	
DIN	2445883	ATOMOXETINE 10 mg capsule	
DIN	2386410	SANDOZ ATOMOXETINE 10 mg capsule	
DIN	2314541	TEVA-ATOMOXETINE 10 mg capsule	
DIN	2318032	APO-ATOMOXETINE 18 mg capsule	
DIN	2445905	ATOMOXETINE 18 mg capsule	
DIN	2386429	SANDOZ ATOMOXETINE 18 mg capsule	
DIN	2314568	TEVA-ATOMOXETINE 18 mg capsule	
DIN	2318040	APO-ATOMOXETINE 25 mg capsule	
DIN	2445913	ATOMOXETINE 25 mg capsule	
DIN	2386437	SANDOZ ATOMOXETINE 25 mg capsule	
DIN	2314576	TEVA-ATOMOXETINE 25 mg capsule	

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2318059	APO-ATOMOXETINE 40 mg capsule	
2445948	ATOMOXETINE 40 mg capsule	
2386445	SANDOZ ATOMOXETINE 40 mg capsule	
2314584	TEVA-ATOMOXETINE 40 mg capsule	
2318067	APO-ATOMOXETINE 60 mg capsule	
2445956	ATOMOXETINE 60 mg capsule	
2386453	SANDOZ ATOMOXETINE 60 mg capsule	
2314592	TEVA-ATOMOXETINE 60 mg capsule	
2362511	TEVA-ATOMOXETINE 80 mg capsule	
2386461	SANDOZ ATOMOXETINE 80 mg capsule	
2318075	APO-ATOMOXETINE 80 mg capsule	
2362538	TEVA-ATOMOXETINE 100 mg capsule	
2386488	SANDOZ ATOMOXETINE 100 mg capsule	
2318083	APO-ATOMOXETINE 100 mg capsule	
Yes (Limited Coverage)		
No		
	2445948 2386445 2314584 2318067 2445956 2386453 2314592 2362511 2386461 2318075 2362538 2386488 2318083 Yes (Limited Cov	

COVERAGE EFFECTIVE	April 18, 2017		
DRUG NAME	dextroamphetamine-amphetamine		
INDICATION	Attention Deficit Hyperactivity Disorder (ADHD)		
DIN	2440369	PMS-AMPHETAMINES XR 5 mg ER capsule	
DIN	2457288	SANDOZ AMPHETAMINE XR 5 mg ER capsule	
DIN	2439239	ACT AMPHETAMINE XR 5 mg ER capsule	
DIN	2440377	PMS-AMPHETAMINES XR 10 mg ER capsule	
DIN	2457296	SANDOZ AMPHETAMINE XR 10 mg ER capsule	
DIN	2439247	ACT AMPHETAMINE XR 10 mg ER capsule	
DIN	2440385	PMS-AMPHETAMINES XR 15 mg ER capsule	
DIN	2457318	SANDOZ AMPHETAMINE XR 15 mg ER capsule	
DIN	2439255	ACT AMPHETAMINE XR 15 mg ER capsule	
DIN	2440393	PMS-AMPHETAMINES XR 20 mg ER capsule	
DIN	2457326	SANDOZ AMPHETAMINE XR 20 mg ER capsule	
DIN	2439263	ACT AMPHETAMINE XR 20 mg ER capsule	
DIN	2457334	SANDOZ AMPHETAMINE XR 25 mg ER capsule	
DIN	2440407	PMS-AMPHETAMINES XR 25 mg ER capsule	
DIN	2439271	ACT AMPHETAMINE XR 25 mg ER capsule	
DIN	2457342	SANDOZ AMPHETAMINE XR 30 mg ER capsule	
DIN	2440415	PMS-AMPHETAMINES XR 30 mg capsule	
DIN	2439298	ACT AMPHETAMINE XR 30 mg ER capsule	
PLAN G BENEFIT?	Yes (Limited Coverage)		
PLAN P BENEFIT?	No		

COVERAGE EFFECTIVE	April 18, 2017		
DRUG NAME	lisdexamfetamine (Vyvanse®)		
INDICATION	Attention Deficit Hyperactivity Disorder (ADHD)		
DIN	02439603	10 mg capsule	
DIN	02347156	20 mg capsule	
DIN	02322951	30 mg capsule	
DIN	02347164	40 mg capsule	
DIN	02322978	50 mg capsule	
DIN	02347172	60 mg capsule	
DIN	02458071	70 mg capsule	
PLAN G BENEFIT?	Yes (Limited Coverage)		
PLAN P BENEFIT?	No		

COVERAGE EFFECTIVE	April 18, 2017		
DRUG NAME	methylphenidate (extended-release)		
INDICATION	Attention Deficit Hyperactivity Disorder (ADHD)		
DIN	2315068	TEVA-METHYLPHENIDATE ER-C 18 mg ER tablet	
DIN	2315076	TEVA-METHYLPHENIDATE ER-C 27 mg ER tablet	
DIN	2315084	TEVA-METHYLPHENIDATE ER-C 36 mg ER tablet	
DIN	2315092	TEVA-METHYLPHENIDATE ER-C 54 mg ER tablet	
PLAN G BENEFIT?	Yes (Limited Coverage)		
PLAN P BENEFIT?	No		