



# Pharmacy News & Views

October 2014

Maryland Department of Health & Mental Hygiene / Office of Systems, Operations and Pharmacy

## Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors for the Treatment of Diabetes

Sodium-glucose co-transporter 2 (SGLT2) inhibitors are the newest class of oral agents approved by the Food and Drug Administration (FDA) for the treatment of diabetes. These drugs control plasma glucose levels by affecting various processes in the kidneys. Plasma glucose is reabsorbed in the proximal tubules, facilitated by the SGLT2 transporter system.<sup>1</sup>

When confronted with high glucose plasma levels seen in patients with uncontrolled diabetes, the glucose transporter system is unable to function properly. Excess glucose that is not reabsorbed is excreted into the urine. This results in

patients with uncontrolled diabetes displaying the symptom of glucosuria, which has always been thought of as an indicator that a patient's plasma glucose level was poorly controlled. SGLT2 inhibitors intentionally block the glucose transport system from reabsorbing glucose.

Since the mechanism of action of these drugs results in excess glucose being excreted in the urine, the possibility of increasing the risk of the following adverse effects must be considered<sup>2</sup>:

- Urinary tract infections
- Vaginal fungal infections
- Fluid imbalance resulting from increased diuresis
- Hypotension as a result fluid imbalance and diuresis

These drugs were approved by the FDA after the publication of the diabetes treatment guidelines in January 2014.<sup>3</sup> Hence, at present these medications, like many other agents used to treat diabetes, may be considered second line treatment options since metformin remains the standard first line drug therapy for the treatment of type 2 diabetes.

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The SGLT-2 drug class has been added to the Maryland Medicaid Preferred Drug List (PDL). The drugs are listed in the following table with their FDA approved indications. The complete PDL is posted on the MMPP website at: <https://mmcp.dhmv.maryland.gov/pap/SitePages/druglist.aspx>

DRUG	FDA INDICATION
canagliflozin (Invokana <sup>®</sup> )	Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. <sup>4</sup>
canagliflozin/ metformin (Invokamet <sup>®</sup> )	Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus who are not adequately controlled on a regimen containing metformin or canagliflozin or in patients already being treated with both canagliflozin and metformin. <sup>5</sup>
dapagliflozin (Farxiga <sup>®</sup> )	Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. <sup>6</sup>
empagliflozin (Jardiance <sup>®</sup> )	Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. <sup>7</sup>

## Clinical Criteria

The Department updated its clinical criteria link to include the SGLT2 inhibitors' class. Clinical criteria are based on FDA approved indications and exist to ensure appropriate utilization of medications. A listing of specific drugs is posted on the MMPP website at the link below:

<https://mmcp.dhmdh.maryland.gov/pap/SitePages/Clinical20Criteria.aspx>

Many of the clinical criteria are automated in the claims processing system and in many cases no intervention by the prescriber will be necessary in order to obtain the non-preferred drug. For example, with the SGLT-2 inhibitors,

while Invokana® (canagliflozin) is the preferred agent, a trial of metformin therapy is required prior to approval. The claims processing system will evaluate the patient's claims data, and if a previous claim for metformin is found, the system will automatically adjudicate the claim for Invokana® without the need for further approval. If a patient is newly enrolled in Medicaid with no prior claims history available, but was previously prescribed metformin, the prescriber would need to contact the help desk at **800-932-3918** and provide that information in order to obtain approval.

## Emergency Supply of Medications and Prior Authorizations

All Maryland Medical Assistance recipients are entitled to receive a 72-hour supply of medicine (30-day supply for atypical antipsychotics not on the preferred drug list) while awaiting prior authorization or approval to dispense a non-formulary, non-preferred, or Tier 2 medication. If the prescriber is unavailable, all Maryland Medicaid HealthChoice managed care organizations (MCOs) and the Maryland Medicaid fee-for-service Pharmacy Program will cover a minimum 72-hour supply of drugs.

In the event an emergency supply is needed, the pharmacist needs to call **800-932-3918** to request authorization to dispense an emergency supply of a prescription. In the case of sprays, inhalers, eye or ear drops, creams, ointments, antibiotics etc., it may be necessary to dispense the entire prescription as an emergency supply due to the way the drug is packaged or administered.

During the 72-hour window, the pharmacist is to contact the prescriber who must obtain prior authorization before the remainder of the prescription can be dispensed. After prior authorization has been established, the pharmacist can dispense the remainder of the prescription.

## References

- <sup>1</sup> Abdul-Ghani MA, Norton L, Defronzo RA. Role of sodium-glucose cotransporter 2 (SGLT 2) inhibitors in the treatment of type 2 diabetes. *Endocr Rev.* 2011Aug;32(4):515-31.
- <sup>2</sup> Standards of Medical Care in Diabetes — 2014. American Diabetes Association. *Diabetes Care* 2014;37, Supp. 1.
- <sup>3</sup> Beyond Metformin: Safety Considerations in the Decision-Making Process for Selecting a Second Medication for Type 2 Diabetes Management Reflections From a Diabetes Care Editors' Expert Forum. *Diabetes Care* 2014;37:2647–2659.
- <sup>4</sup> Invokana® [package insert]. Titusville (NJ): Janssen Pharmaceuticals, Inc.; 2013 March.
- <sup>5</sup> Invokamet™ [package insert]. Titusville (NJ): Janssen Pharmaceuticals, Inc.; 2013 August.
- <sup>6</sup> Farxiga® [package insert]. Princeton (NJ): Bristol Myers-Squibb Company; 2014 January.
- <sup>7</sup> Jardiance® [package insert]. Ridgefield (CT): Boehringer Ingelheim Pharmaceuticals, Inc.; 2014 August.

*(Emergency Supply continued)*

The recipient may present mobility or access issues that make returning to the pharmacy very difficult or expensive. The pharmacist should take this factor into consideration when deciding whether or not to dispense an emergency supply.

If a patient is currently prescribed a non-preferred agent, the pharmacy will need the prescriber to write or call in a new prescription to switch the patient to the preferred drug. Alternatively, the prescriber may obtain a PA for the non-preferred agent by calling 800-932-3918 or submitting a completed PA form via fax to 866-440-9345.

*It would be beneficial if the pharmacist can advise the prescriber of the alternative drugs that are preferred and do not require preauthorization* (refer to PDL).

### Maryland Medicaid Peer Review Program for Atypical Antipsychotics

Maryland Medicaid has put in place a pre-authorization program for the use of antipsychotics in children. This program covers all children under age 18. Please refer to this link:

<https://mmcp.dhmdh.maryland.gov/pap/SitePages/Peer%20Review%20Program.aspx>

### Maryland Medicaid PDL Posted on Epocrates


Another useful formulary tool is available online through the Epocrates website. Epocrates provides information on the formulary status of medications across various health plans. The system can be accessed from hand held devices such as tablets or smart phones or from a desktop or laptop computer. The formularies for the eight Managed Care Organizations (MCOs) are also listed on Epocrates. The service is provided at no charge to all providers.

*Go to the link below to log into an existing*

*Epocrates account or create a new account:*

<https://www.epocrates.com/account.do?mode=summary>

Once an account has been created, the user will need to add the Maryland Medicaid Pharmacy Program (MMPP) PDL as the formulary that they would like to view. To do this, log on to Epocrates and select "Edit Formularies" under the "My Account" tab on the main menu. The user is then prompted to "Select State" (choose Maryland) and under the "Select Category" tab, pick "Health Plans."

A listing of available formularies for Maryland is displayed. The formulary named "MD Medicaid (fee for service)" contains the MMPP PDL. Add the "MD Medicaid (fee for service)" to the "Formularies On My Device" section to save as a preferred formulary. Once the formulary is selected, specific drugs can be searched by the user by clicking on the  tab at the top of the page. Then, a new page opens. The first tab is the "DRUGS" tab. The user is now ready to search for drugs by typing the drug name in the DRUG LOOKUP box.

Maryland Medicaid Preferred drugs are noted in the Epocrates system and are coded as "P"; while non-preferred drugs are coded as "N". Other drugs that are not included on the PDL, but are covered by MMPP, are coded as "Y" to represent that it is a covered drug. Drugs not covered by MMPP are coded as "NC". Drugs which have clinical criteria are noted with the code "PA". Additional comments are also included to provide further details.



Maryland Department of  
Health and Mental Hygiene  
Office of Systems, Operations  
and Pharmacy



## Pharmacy News & Views

### Maryland Medicaid Pharmacy Program

201 West Preston Street, 4th Floor  
Baltimore, Maryland 21201  
1-800-492-5231 (select option 3)  
<http://mmcp.dhmh.maryland.gov/pap>

Martin O'Malley, Governor  
Anthony G. Brown, Lt. Governor  
Joshua M. Sharfstein, MD, Secretary



Email  
Newsletter

Sign up to receive electronic copies of  
MMPP Newsletters and Advisories at: [www.  
marylandmedicaidpharmacyinformation.com](http://www.marylandmedicaidpharmacyinformation.com)

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### 30-day Emergency Supply of Atypical Antipsychotic Agents

When the prescriber is not available to obtain prior authorization for an antipsychotic medication that is non-preferred or second tier, the pharmacist can obtain a one-time only authorization to dispense up to a 30-day emergency supply.

*Do not let patients leave the pharmacy without medication if there is concern that the patient will be unwilling or unable to return at a later time that day after prior authorization is approved.*

To obtain authorization for an emergency supply of an antipsychotic, call Xerox Technical Assistance at **800-932-3918**. During the 30-day window, the pharmacist must notify the prescriber of the need to obtain a PA before the prescription can be filled a second time and make a note for his or her records of the date, time and person contacted at the prescriber's office.

### Tier 2 and Non-Preferred Antipsychotic Review Process

All claims for Tier 2 or non-preferred antipsychotics for patients age 18 or older require authorization. The claim will deny at point of service and will not process. An electronic message will display on your system with instructions as to how to proceed. The Tier 2 and Non-Preferred Prior Authorization Form can be found at:

[https://mmcp.dhmh.maryland.gov/pap/docs/Tier2%20and%20NPD%  
20Antipsychotic%20PA.pdf](https://mmcp.dhmh.maryland.gov/pap/docs/Tier2%20and%20NPD%20Antipsychotic%20PA.pdf)

### TELEPHONE NUMBERS

**Xerox Technical Assistance**  
1-800-932-3918  
24 hours a day, 7 days a week

**Maryland Medicaid  
Pharmacy Access Hotline**  
1-800-492-5231 (option three)  
Monday-Friday, 8:00 am - 5:00 pm

**Kidney Disease Program**  
1-410-767-5000 or 5002  
Monday-Friday, 8:00 am - 5:00 pm

**Breast & Cervical Cancer  
Diagnosis and Treatment**  
1-410-767-6787  
Monday-Friday, 8:00 am - 4:30 pm

**Maryland AIDS Drug  
Assistance Program**  
1-410-767-6535  
Monday-Friday, 8:30 am - 4:30 pm