Maryland
DEPARTMENT OF HEALTH

Pharmacy
NEWS AND VIEWS

November 2019

Standards of Medical Care in Diabetes

In January 2019, the American Diabetes Association published the *Standards of Medical Care in Diabetes – 2019*. These guidelines are considered a gold standard in the approach and management of diabetes, from prevention, diagnosis and classification, non-pharmacologic and pharmacologic management, and management of complications of diabetes. These guidelines apply to all patients with diabetes, including pediatric, adult and elderly patients, and those with other comorbid conditions (cardiovascular disease, renal disease, etc.). Pharmacists play an important role in the management of diabetes and are specifically listed as a contributing member of the multi-disciplinary team. In addition to dispensing medications to treat diabetes, pharmacists are well trained to provide counseling on the importance of adherence to medications, guidance on proper administration technique for injectable medications, lifestyle recommendations regarding diet and physical activity, and advice about the prevention of complications, including foot care, tobacco treatment (cessation) and immunizations. Select information and updates for the 2019 Standards are detailed below.

Prevention and Delay of Type 2 Diabetes

Lifestyle interventions apply to both patients at risk of diabetes, and those with prediabetes and diabetes, and include an intensive behavioral intervention program designed to achieve and maintain 7% loss of initial body weight and a moderate-intensity physical activity program of at least 150 minutes per week. These recommendations were developed from the results of the original Diabetes Prevention Program study and is the foundation of the Centers for Disease Control and Prevention (CDC) National Diabetes Prevention Program. The evidence for preventing diabetes in those with prediabetes showed that incorporation of these lifestyle changes reduced the incidence of diabetes by 58%; use of metformin showed a 34% reduction.

Proper nutrition is an important tool in the prevention of type 2 diabetes. The guidelines suggest a Mediterranean style diet or low calorie, low fat diet. There is insufficient evidence to determine the effectiveness of a low-carbohydrate diet at this time.

Regarding pharmacologic intervention, metformin is recommended as preventative therapy in patients with prediabetes, especially with a BMI $\geq$ 35 kg/m^2, age < 60 years, and women with a history of gestational diabetes. Additionally, since tobacco use may increase the risk of type 2 diabetes as well as cardiovascular disease, tobacco treatment with a goal of cessation should be implemented for overall risk reduction. Many products are available over the counter (OTC) to facilitate cessation.

Diabetes Technology

The Standards acknowledge the importance of glucose monitoring in diabetes, specifically for those on an insulin-based pharmacologic regimen. Recommendations for self-monitoring of blood glucose (SMBG) using a glucose monitoring machine were updated to acknowledge the limited additional clinical benefit in those not using insulin. Additionally, since there is limited benefit, the cost effectiveness of additional medical devices and supplies (glucose meter, test strips, lancets, etc.) do not justify routine use, unless a specific clinical concern is present (e.g. hypoglycemia, impact of dietary changes on glucose levels).

Pharmacologic Approaches to Glycemic Treatment

For patients with type 1 diabetes, the gold standard continues to be insulin therapy, including multiple daily injections of prandial and basal insulin, or continuous subcutaneous insulin infusion. Rapid-acting insulin analogs are recommended to reduce the risk of hypoglycemia, and it is recommended to consider matching prandial insulin doses to planned carbohydrate intake, pre-prandial blood glucose levels and anticipated physical activity.

Metformin continues to be the preferred initial pharmacologic agent for the treatment of type 2 diabetes and is recommended to be continued unless it is not tolerated or is contraindicated. Extended-release formulations may increase tolerability in patients with gastrointestinal adverse effects. Contraindications to therapy include metabolic acidosis, hypersensitivity, and renal impairment.

In 2017, parameters to determine level of renal impairment below which metformin would be contraindicated were updated from attention to the creatinine level to consideration of an eGFR below 30 ml/1.73 m^2. Additional medications, including insulin, should be added to metformin. Escalation of therapy is recommended for those with a HbA1c $\geq$ 1.5% above glycemic target, and the choice of

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Standards of Medical Care in Diabetes *(continued)*

agents should be determined by patient characteristics and comorbid conditions:

- In patients with Atherosclerotic Cardio-vascular Disease (ASCVD), sodium-glucose cotransporter 2 (SGLT2) inhibitors or glucagon-like peptide 1 (GLP-1) receptor antagonists with demonstrated CVD benefit are recommended
- SGLT2 inhibitors showing benefit: empagliflozin (Jardiance®), canagliflozin (Invokana®)
- Of the GLP-1 receptor antagonists showing benefit, liraglutide (Victoza®) has shown the most benefit over other agents
- In patients with ASCVD at high risk of heart failure or a diagnosis of heart failure, SGLT2 inhibitors are preferred (empagliflozin, canagliflozin)
- In patients with Chronic Kidney Disease (CKD), empagliflozin, canagliflozin and liraglutide have been shown reduce the risk of Diabetic Kidney Disease (DKD) progression

If there are no significant comorbid conditions, the selected agent should be patient specific, unless there is evidence of ongoing catabolism, symptomatic hyperglycemia, or a very high HbA1c (> 10%) or blood glucose level (≥ 300 mg/dL), in which case insulin should be added. In those who do not meet the aforementioned criteria and require the greater efficacy of an injectable agent, a GLP-1 receptor antagonist is preferred ahead of insulin therapy.

Cardiovascular Disease and Risk Management and Microvascular Complications

In addition to glycemic control, all patients with diabetes must be evaluated for complications of diabetes, and treatment should be initiated according to established guidelines for hyper-tension/cardiovascular disease, lipid management, antiplatelet management, chronic kidney disease, diabetic retinopathy, neuropathy and diabetic neuropathy. The 2019 Standards related to cardiovascular concerns are endorsed, for the first time, by the American College of Cardiology (ACC).

Pharmacist Involvement

Pharmacists play an important role in assisting those with diabetes. As medication experts, pharmacists can provide counseling on the various different medications and dosage forms of commonly prescribed medications, from when to administer a medication, such as short-acting versus long-acting insulin, to the appropriate administration technique of parenteral products. Additionally, pharmacists may counsel diabetics regarding appropriate lifestyle changes, especially regarding blood pressure management, smoking cessation, immunization status and general weight loss principles. This counseling may be provided in multiple settings, including during a scheduled visit at an outpatient clinic, when picking up a prescription for a medication or diabetic supply in a community pharmacy setting or during a patient consultation to recommend an over-the-counter product. These short interactions can prevent medication errors and adverse effects for all patients. The full text version of the 2019 Standards are available at https://professional.diabetes.org/content-page/practice-guidelines-resources.

References:

American Diabetes Association Clinical Diabetes 2019 Jan; 37(1): 11-34. https://doi.org/10.2337/cd18-0105

Centers for Disease Control and Prevention (CDC) National Diabetes Prevention Program. https://www.cdc.gov/diabetes/prevention/index.html

Glucophage® [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; rev May 2018.

Changes in Coverage for Antiretrovirals for the Management of HIV

Effective January 1, 2020, HIV/AIDS medications will be carved into the HealthChoice Managed Care Organization (MCO) benefit from the Maryland Medicaid Fee-for-Service program. MCOs will be responsible for processing and paying all claims for HIV/AIDS medications for their members. This change will affect all the medications that are under American Hospital Formulary Service (AHFS) Classification 8:18.08 (Antiretrovirals). Please note that from January 1, 2020 through June 30, 2020 there will be a "soothing period" during which the MCOs will continue their members' existing anti-retroviral therapy under FFS without changes. New patients placed on antiretroviral therapy during the soothing period will be subject to the MCOs' HIV/AIDS medication prescribing requirements.

For Pharmacies: When processing pharmacy claims, please utilize the appropriate BIN, PCN, Group ID, and Cardholder identification numbers based on the patient's individual MCO plan as is currently done for other covered medications.

For a full listing of all the BIN/PCN/Group ID information, please go to the online provider manual, page 9: www.mdrxprograms.com/ooep.html#CI.

Antiretrovirals Coverage on Formulary Navigator

- Electronic formulary tool with free access for prescribers, pharmacies and patients
- Multiple search options to find products by alphabet, brand and generic, and/or therapeutic class.
- More detailed information on product restrictions and prescribing requirements
- Easy access links to health plans

www.mmppi.com

FDA Approved HIV Medicines

Drug Class	Generic Name/Acronym	Brand Name
Nucleoside Reverse Transcriptase Inhibitors (NRTIs)		
	abacavir (ABC)	Ziagen
	emtricitabine (FTC)	Emtriva
	lamivudine (3TC)	Epivir
	tenofovir disoproxil fumarate (TDF)	Viread
	zidovudine (AZT, ZDF)	Retrovir
Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs)		
	doravirine (DOR)	Pifeltro
	efavirenz (EFV)	Sustiva
	etravirine (ETR)	Intelence
	nevirapine (NVP)	Viramune Viramune XR
	rilpivirine (RPV)	Edurant
Protease Inhibitors (PIs)		
	atazanavir (ATV)	Reyataz
	darunavir (DRV)	Prezista
	fosamprenavir (FPV, FOS-APV)	Lexiva
	ritonavir (RTV)	Norvir
	saquinavir (SQV)	Invirase
	tipranavir (TPV)	Aptivus
Fusion Inhibitors		
	enfuvirtide (T-20)	Fuzeon
C-C chemokine receptor type 5 (CCR5) Antagonists		
	maraviroc (MVC)	Selzentry
Integrase Inhibitors		
	dolutegravir (DTG)	Tivicay
	raltegravir (RAL)	Isentress Isentress HD
Post-attachment inhibitors		
	ibalizumab-uiyk	Trogarzo
Pharmacokinetic Enhancers (no intrinsic ARV activity)		
	cobicistat (COBI, c)	Tybost

Drug Class	Generic Name/Acronym	Brand Name
Combination Medications		
	abacavir/lamivudine	Epzicom
	abacavir/dolutegravir/lamivudine	Triumeq
	abacavir/lamivudine/zidovudine	Trizivir
	atazanavir/cobicistat	Evotaz
	bictegravir/emtricitabine/tenofovir ala-fenamide	Biktarvy
	darunavir/cobicistat	Prezcobix
	darunavir/cobicistat/emtricitabine/ tenofovir alafenamide	Symtuza
	dolutegravir/lamivudine	Dovato
	dolutegravir/rilpivirine	Juluca
	doravirine/lamivudine/tenofovir disoproxil fumarate	Delstrigo
	efavirenz/emtricitabine/tenofovir disoproxil fumarate	Atripla
	efavirenz/lamivudine/tenofovir disoproxil fumarate	Symfi Symfi Lo
	elvitegravir/cobicistat/mtricitabine/ tenofovir alafenamide	Genvoya
	elvitegravir/cobicistat/emtricitabine/ tenofovir disoproxil fumarate	Stribild
	emtricitabine/rilpivirine/tenofovir alafenamide	Odefsey
	emtricitabine/rilpivirine/tenofovir disoproxil fumarate	Complera
	emtricitabine/tenofovir alafenamide	Descovy
	emtricitabine/tenofovir disoproxil fumarate	Truvada
	lamivudine/tenofovir disoproxil fumarate	Cimduo, Temixys
	lamivudine/zidovudine	Combivir
	lopinavir/ritonavir	Kaletra

References: US Department of Health and Human Services. AIDS info. https://aidsinfo.nih.gov/

Pharmacists are required to contact the participant's respective MCO PBM for any billing issues, including rejected claims or prior authorization.

Coming Soon!

The Office of Pharmacy Services will be implementing quantity limits on stimulants. Stay tuned for details!

Maryland
DEPARTMENT OF HEALTH

Larry Hogan, Governor
Boyd K. Rutherford, Lt. Governor
Robert R. Neall, Secretary

Office of Pharmacy Services

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CONTINUING EDUCATION SEMINAR
December 7, 2019

Treatment of Hepatitis C and Comorbid Conditions

Register at www.mmppi.com

SUPPORT Act Mandates

The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (SUPPPORT Act) established updated requirements for both Fee-for-Service (FFS) and Managed Care Organizations (MCOs) programs that participate in the Medicaid program regarding drug utilization review (DUR). Effective October 1, 2019, both programs, FFS and MCOs, implemented:

- Opioid prescription claims review at Point-of-Sale (POS)
- Retrospective reviews of opioid claims
- Management and monitoring of antipsychotic medications in children
- Morphine Milligram Equivalents (MME) safety edits
- Process to identify fraud and abuse
- Mandatory DUR reporting

For the claims review process, pharmacists will continue to receive safety edits to identify therapeutic duplications, early refills and quantity limits (including maximum daily morphine milligram equivalents) of prescription opioids. Additionally, new edits include identification of concurrent utilizers of opioids and benzodiazepines, and opioids and antipsychotics. The alert is the NCPDP exception 88 "DRUG TO DRUG INTERACTION PRO-DUR ALERT". While no ProDUR intervention and outcome codes are required for this alert, pharmacists should continue to counsel patients on the identified drug-drug interaction and potential adverse effects of concurrent use. These adverse effects include increased risk of respiratory depression, hypotension, profound sedation, coma, and death.

Each program must also have a retrospective review process to identify these claims. Monitoring and management of antipsychotics in children must occur and be reported annually. A process must be in place to identify fraud and abuse of opioids by providers, pharmacies and participants. Each organization that participates in the Medicaid program must have a DUR Board and report the above activities annually. The full regulation can be found at: Opioid Legislation www.congress.gov/115/bills/hr6/BILLS-115hr6enr.pdf

TELEPHONE NUMBERS

- **Conduent Technical Assistance**
  800-932-3918
  24 hours a day, 7 days a week
- **Maryland Medicaid Pharmacy Access Hotline**
  800-492-5231 (option three)
  Monday-Friday, 8:00 am - 5:00 pm
- **Kidney Disease Program**
  410-767-5000 or 5002
  Monday-Friday, 8:00 am - 5:00 pm
- **Breast and Cervical Cancer Diagnosis and Treatment**
  410-767-6787
  Monday-Friday, 8:00 am - 4:30 pm
- **Maryland AIDS Drug Assistance Program**
  410-767-6535
  Monday-Friday, 8:30 am - 4:30 pm
- **Peer Review Program**
  855-283-0876
  Monday-Friday, 8:00 am - 6:00 pm