

Wyoming Drug Utilization Review

FreeStyle Libre: New Technology in Continuous Glucose Monitoring

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Diabetes is a complex, chronic illness requiring continuous medical care. Diabetes, caused by various genetic and environmental factors, can result in the progressive loss of β -cell mass and/or function and peripheral resistance that manifests clinically as

hyperglycemia.¹ Once hyperglycemia occurs, patients with all forms of diabetes are at risk for developing micro- and macrovascular complications.² Microvascular atherosclerotic cardiovascular disease, such as coronary heart disease, cerebrovascular disease, or peripheral arterial disease, is the leading cause of morbidity and mortality for individuals with diabetes.¹ Other complications include hypertension, dyslipidemia, diabetic or chronic kidney disease, diabetic retinopathy, and neuropathy.¹ Hypoglycemia is also a consequence of poor diabetic control that results in increased risk of neurological damage.³

Most patients using intensive insulin regimens (multiple-dose insulin or insulin pump therapy)

should perform self-monitoring blood glucose (SMBG) prior to meals and snacks, at bedtime, occasionally post-prandially, prior to exercise, when they suspect low blood glucose, after treating low blood glucose until they are normoglycemic, and prior to critical tasks such as driving.¹ Under this recommendation from the American Diabetes Association, 6-10 times daily SMBG is required. Similarly, the National Institute for Health and Care Excellence (NICE; NG17) guideline recommends SMBG 4-10 times daily.⁴ Goals for pre-prandial capillary plasma glucose range from 80-130 mg/dL and peak post-prandial capillary plasma glucose <180 mg/dL.¹ Hemoglobin A1C levels reflect the average glycemic control over approximately 3 months and has strong predictive value for diabetes complications. It is recommended to perform hemoglobin A1C tests quarterly in patients with diabetes.¹ Hemoglobin A1C goals range from <6.5% to <8% based on various comorbidities and risk factors.¹

Current methods to measure plasma glucose include self-monitoring capillary blood glucose, continuous glucose monitoring (CGM), and intermittent “flash” continuous glucose monitoring. SMBG only gives snapshots of blood glucose concentrations without a glycemic profile between sampling moments. It is also a burden for patients, especially children with diabetes that require intensive insulin regimens causing pain, discomfort and accumulated injury to the fingers.² There are multiple CGM devices; they all require at least twice daily finger-stick glucose level measurements to calibrate the device, and last 7 days.^{5,6} Real-time CGM will trigger an alarm to alert users to the potential risk of hypoglycemia or hyperglycemia.² FreeStyle Libre is the only intermittent “flash” continuous glucose monitoring system on the market, approved in September 2017

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in the United States for people 18 years and older. The sensor is put in place by a single-use applicator, and automatically measures glucose every minute for up to 14 days. Scanning of the sensor by a separate reader collects the glucose measurements and trend at the moment of scanning plus up to 8 hours of prior readings every 15 minutes.³ FreeStyle Libre is factory calibrated and does not require finger-stick glucose level measurements.² The sensor data is read by a special hand-held scanner held over the sensor. There is no alarm to alert users of potential risk of hypoglycemia or hyperglycemia.⁵

On average, FreeStyle Libre users scan the device 15 times per day, and the reader is reported to be user friendly.^{2,3} 60% of children who used FreeStyle Libre gave a pain score of 0 using Visual Analog Scale.⁵ It was found to be “life-changing” for parents to check children’s plasma glucose, especially at night.⁵ In the adult population, 98.6% of the insertions had a pain rating of ≤ 2 .⁷ Moderate to severe itching was found 0.5% of the time, moderate erythema 4.0% of the time, and 98.6% of the insertions had a pain rating of ≤ 2 .⁷ Incidence of mild adverse reactions was $<9\%$ for any individual category of skin issues including edema, rash, induration, bruising, bleeding, and others.⁷

Studies reported mean absolute relative difference (MARD) as well as error grid analyses. MARD is expressed in percentages; lower MARD value indicates lower percent error between methods.⁸ The error grid method describes the clinical accuracy of a test method compared with a reference method based on paired glucose samples and the clinical significance of the differences between them. Zones A ($<20\%$ paired error) and B ($>20\%$ paired error) are considered acceptable with little or no effect on clinical outcomes.⁸

FreeStyle Libre had 99.7% paired results with finger-prick capillary sampling for zones A and B for adults with type 1 and type 2 diabetes.⁷ Patients with type 2 diabetes found 43% reductions in time in hypoglycemia ($P < 0.01$) when using FreeStyle Libre

for 6 months.² Both FreeStyle Libre and Dexcom G5 mobile CGM sensors perform safely and efficiently.⁶ Dexcom G5 has greater accuracy compared to FreeStyle Libre; overall absolute relative difference was 12.3% for FreeStyle Libre compared to Dexcom G5 9.8% ($p < 0.001$).⁶

In children and adolescent populations, FreeStyle Libre readings were highly correlated with blood glucose paired readings ($p < 0.001$), 98.7% were in zones A and B.⁵ MARD was 16%.⁵ When studied for congenital hyperinsulinism, FreeStyle Libre only identified 52% of 42 hypoglycemic episodes (<63 mg/dL) in the study.³ It was found in a 10 week trial Hemoglobin A1C improved vs baseline $-0.4\% \pm 0.6\%$ ($p < 0.1$) in children ages 4 to 17 years with type 1 diabetes.²

FreeStyle Libre is a safe offering to monitor plasma glucose. Its continuous monitoring system gives unique insight over isolated finger-stick glucose levels.² It is recognized that healthcare professionals and users need appropriate education on this system to harness full benefits.

References

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P&T Committee Meeting Update

The P&T Committee met for its quarterly business meeting on May 3, 2018.

Highlights of this meeting include:

Spiriva Respimat will remain non-preferred, but will be allowed for patients aged 6 and older, without COPD, as an add-on to an inhaled corticosteroid and a long-acting bronchodilator.

Lonhala will be allowed for patients who are unable to appropriately use an inhaler.

Continuous glucose monitoring devices including Dexcom, FreeStyle and MiniMed brands, will be allowed for patients who require three or more insulin injections per day. The devices will be further limited to labeled age requirements.

The Committee is considering a policy limiting opiate first-fills to a 7 day supply. This will be put out for public comment and brought back for further discussion in August.

The proposed prior authorization criteria will be posted for public comment at www.uwyo.edu/DUR. Comments may be sent by email to alewis13@uwyo.edu or by mail to: Wyoming Drug Utilization Review Board, Dept. 3375, 1000 E. University Avenue, Laramie, WY 82071. Comments should be received prior to July 1, 2018.

The next P&T Committee meeting will be held August 9, 2018 in Cheyenne. An agenda will be posted approximately two weeks prior to the meeting.

Wyoming Online Prescription Database

The prescription drug monitoring program, Wyoming Online Prescription Database (*WORx*), is available online. This tool gives a narcotic profile, regardless of payer, through the Board of Pharmacy. Features of *WORx* include:

- Monitoring program reports available 24/7: no waiting, no faxing
- Enhancement to the faxed request (which is still available)
- Controlled substances dispensed in Schedules II, III, IV
- User friendly registration
- New report format that eliminates duplicates
- Weekly updates
- More information on reports such as “days supply”
- A tool for use by practitioners and pharmacists

Register at WORXPDMP.com. For more information contact the Wyoming State Board of Pharmacy: David N. Wills, MBA, *WORx* Coordinator (david.wills@wyo.gov) or Mary Walker, R.Ph., Executive Director (mary.walker@wyo.gov).

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