June 13, 2019

To whom it may concern:

Continuous Glucose Monitors (CGM’s) are another tool in the management of Diabetes Mellitus. These devices are an aide to the management of diabetes. A CGM can provide more frequent information about glucose levels as well as the direction and speed of change, which may help to decrease the incidence and severity of hypoglycemia and hyperglycemia. All students using a CGM at school must have the ability to check a finger stick blood glucose with a meter in the event of CGM failure or apparent discrepancy.

As each CGM has differing FDA approvals, please refer to the information below.

1) **Dexcom G4** is not FDA approved for making treatment decisions. When the CGM alarms, treatment should be determined based on a finger stick blood glucose.

2) **Dexcom G5** is FDA approved for making treatment decisions. Correction doses of insulin for hyperglycemia, or the intake of carbohydrates for treating hypoglycemia can be determined at school based on the CGM if the sensor glucose value is between 80mg/dL and 350mg/dL and there is a directional arrow; unless otherwise directed by the provider. Insulin doses may be adjusted based on trend arrows following the “Primary Children’s Diabetes Clinic: Adjusting insulin doses based on CGM trend arrows” guidelines. If the symptoms of the student don’t match the CGM reading, check a finger stick blood glucose with a meter. In addition, the parent/guardian must sign the CGM section of the DMMO verifying they are responsible for calibrating the CGM at home two times daily and approve the school personnel or school nurse to treat hypoglycemia or give insulin doses based on the CGM.

3) **Dexcom G6** is FDA approved for making treatment decisions. Correction doses of insulin for hyperglycemia, or the intake of carbohydrates for treating or preventing hypoglycemia can be determined at school based on the if the sensor glucose value is between 80mg/dL and 350mg/dL and there is a directional arrow; unless otherwise directed by the provider. Insulin doses may be adjusted based on trend arrows following the “Primary Children’s Diabetes Clinic: Adjusting insulin doses based on CGM trend arrows” guidelines. The “Urgent Low Soon Alert” signifies that a glucose of 55mg/dL will be reached within 20 minutes. This should be treated based on the student’s hypoglycemia treatment plan. If the symptoms of the student don’t match the CGM reading, check a finger stick blood glucose with a meter. In addition, the parent/guardian must sign the CGM section of the DMMO verifying they approve the school personnel or school nurse to treat hypoglycemia or give insulin doses based on the CGM.

4) **Medtronic** 530G and 630G with Enlite Sensor, and 670G with Guardian sensor are not FDA approved for making treatment decisions. When the CGM alarms, treatment should be determined based on a finger stick blood glucose. If the pump requests a calibration, the student can calibrate this on their own. The school nurse and the parent must put a plan in place for calibrating the CGM at school if the pump requests a calibration and the student is unable to calibrate the CGM independently. The reading used to calibrate the CGM must come from a finger stick blood glucose using a meter. In addition, the parent/guardian must sign the CGM section of the DMMO verifying they approve the school personnel or school nurse to assist with calibrations.

5) **Freestyle Libre** is not FDA approved for making treatment decisions in individuals under the age of 18 and does not have any alarms. In those over 18 years of age it is FDA approved for making treatment decisions. Correction doses of insulin for hyperglycemia, or the intake of carbohydrates for treating hypoglycemia can be determined in adults based on the CGM if the sensor glucose value is between 80mg/dL and 350mg/dL and there is a directional arrow; unless otherwise directed by the provider. Insulin doses may be adjusted based on trend arrows following the “Primary Children’s Diabetes Clinic: Adjusting insulin doses based on CGM trend arrows” guidelines. If the symptoms of the student don’t match the CGM reading, a finger stick blood glucose should be checked with a meter. In addition, the parent/guardian must sign the CGM section of the DMMO verifying they approve the school personnel or school nurse to treat hypoglycemia or give insulin doses based on the CGM and that they know it’s not FDA approved for those under 18 years of age.

**Based on FDA guidelines and standards of practice, we recommend the following approach to the use of CGM’s in schools:**

* Dexcom G5 and G6 are the only CGM’s FDA approved for making treatment decisions in those under 18 years old. Correction doses of insulin for hyperglycemia, or the intake of carbohydrates for treating hypoglycemia can be determined at school based on the CGM if the sensor glucose value is between 80mg/dL and 350mg/dL and there is a directional arrow. In addition, the parent/guardian must sign the CGM section on the DMMO verifying they are responsible for maintaining the CGM at home and approve of the school to make treatment decisions based on the CGM readings and arrow.
* With any CGM there may be a lag time between real time glucose values and the CGM reading. Due to this, it may appear that the student is not responding to the treatment for hypoglycemia. We recommend that treatment be given for hypoglycemia with the initial reading from the CGM. Before treating hypoglycemia for a second time, a finger stick glucose should be checked, and treatment decisions should be made based upon the finger stick. This should be repeated with all subsequent hypoglycemia within a 1-hour time frame of the initial hypoglycemia.
* As there are no clear guidelines regarding adjusting insulin doses at school based on CGM arrows, each school district needs to determine if this responsibility can be delegated to the non-medical school personnel who are administering the insulin.
* If CGM alarms are an option, they should be set so they do not alarm unnecessarily and disrupt the class frequently; but set to warn of possible low blood glucose or high blood glucose readings. Parents should speak with their provider to determine where the child’s alarms should be set.
* School personnel are not responsible to review CGM data outside of meal times. The CGM should be reviewed if the CGM alarms or any time the student is symptomatic.
* School personnel should not be required to have the CGM data transmitted to school or personal devices. The parent is to provide the receiver for the CGM and the student should have this on them at all times.
* Schools cannot calibrate the CGM, even if the reading from the CGM and the meter differ; unless the student wears a Medtronic pump and all criteria are met.
* If anything more needs to be done with the CGM, a parent must come to the school and manage it independently. This may include CGM malfunctions or error messages.
* These recommendations are based on FDA guidelines and standards of practice.

--Mary Murray, MD, Medical Director, Primary Children’s Diabetes Program