

Collaborative Guidelines for CGM/iCGM Therapeutic Dosing in the School and Child Care Setting –Colorado

Introduction

The FDA has approved three continuous glucose monitoring (CGM) systems for therapeutic dosing for the pediatric population. These include the Dexcom G5 and G6 CGM and the Abbott Freestyle Libre 2 Integrated Continuous Glucose monitoring (iCGM) system for therapeutic use^{1-3,7}, meaning that with proper technique, these CGM/iCGMs can be used directly to make treatment decisions without needing to test finger-stick blood glucose (BG) values. The *Colorado Kids with Diabetes Care and Prevention Collaborative* is supportive of these changes in labeling. These CGM/iCGMs have different operating procedures, which will be addressed in these guidelines.

The REPLACE-BG study⁴ demonstrated the safety of direct dosing from CGM values without confirmatory finger-sticks. The Endocrine Society⁵ has also come out with expert guidelines for pediatric dosing from CGM values. In addition, Dexcom provides some clinical guidance on non-adjunctive use that are available at Dexcom.com/guides. After over three years of clinical experience with therapeutic dosing, we are recommending the following guidelines be used in schools for therapeutic CGM dosing.

Guidelines for Safe Use of the *Dexcom G5 CGM* for Therapeutic Dosing

General

1. The CGM should be calibrated twice a day generally when the blood sugar is stable (such as before a meal).. This is usually done at home, but can be verified in the CGM calibration history. Calibration should be provided if needed during an off-site school-sponsored activity. *Note: Calibrating more than twice a day may cause the CGM to give inaccurate glucose readings.*
2. **If there are no trend arrows displayed with the sensor** glucose reading, then the CGM may not be measuring correctly and should not be used for dosing (use a finger-stick blood glucose to dose in this case).
3. Acetaminophen (Tylenol) can falsely elevate CGM values, and the CGM readings should not be used for dosing within 4-8 hours of acetaminophen administration. Be cautious as many combination “cold and flu” medications contain acetaminophen without having “Tylenol” in the name.
4. Child should be treated *immediately (i.e. classroom, playground)* if symptomatic or if blood glucose is below *Target Range*. Remember that if a child is sent to the school health office, another responsible person must always accompany the child.

Meals

5. For correction boluses at mealtime, the CGM value may be used in place of finger-stick testing provided the value is in the range of 80 to 250 mg/dL. If the CGM value is less than 80 mg/dL or greater than 250 mg/dL, then a finger-stick BG value should be obtained and correction dosing should occur based on the finger-stick value, as per the health care provider orders/Diabetes Medical Management Plan (DMMP).
6. Trend Arrows: The health care provider may indicate on the DMMP the use of trend arrows at mealtime in determining insulin dosing/treatment.

Lows

7. If a child feels that his/her blood sugar is low or if the CGM is reading < 80 mg/dL, then check a finger-stick BG and provide carbohydrates based on the finger-stick BG reading and symptoms and recheck finger-stick BG in 15 min. If still low, repeat the treatment.
8. If the CGM is reading low, but the child is not symptomatic, confirm glucose with a finger-stick prior to treating. Treat according to the finger-stick value, as per the health care provider’s school orders/DMMP.

9. For the DEXCOM G5 CGM: these trend arrows may be used in treatment decisions (as agreed upon by the school nurse and parent or per DMMP):

CGM 70-80 with 1 arrow facing down give 7.5gm of fast-acting carbohydrate*

CGM 70-80 with 2 arrows facing down give 15gms of fast-acting carbohydrate*

CGM 70-80 with level arrow consider giving complex carb snack* (10-15gms of carbs) without insulin bolus per parent and school nurse as indicated on the IHP.

*No insulin should be given for the treatment of lows or pending lows as described above. Fast-acting carbohydrates include but are not limited to: juice, glucose tablets, Skittles, honey, regular soda, etc.

Highs

10. If the CGM is reading >250 mg/dL then check BG with a finger-stick and correct based on the finger-stick value, as per the health provider's school orders/DMMP.
11. If the finger-stick BG is >300 mg/dL and it has been 2 hours or more since the child has received insulin by injection or BG > 300 once for a child on a pump, check for serum or urine ketones (if possible) and treat as per the child's health care provider orders/DMMP. Follow the **Standards of Care for Diabetes Management in the School Setting & Licensed Child Care Facilities – Colorado 2020**.
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Guidelines for Safe Use of the Dexcom G6 CGM for Therapeutic Dosing

General

1. The G6 has also been approved to be factory calibrated, meaning that no routine finger-stick calibrations are necessary as part of its use. Therefore, no calibrations are needed as long as the sensor code was entered when the sensor was started. A sensor code is entered each time a new sensor session is started, which permits no calibrations. If the family does not enter the sensor code when starting the sensor, then the G6 will require a fingerstick calibration every 12 hours (this is rare).
2. Check the blood glucose via finger-stick if the child's symptoms do not match the sensor readings (e.g. the child feels low but the sensor is not reporting a low value).
3. If the CGM is reading "LO" or "HI" then check blood glucose with a finger-stick.
4. If there are no trend arrows displayed with the sensor glucose reading, the CGM may not be measuring correctly and should not be used for dosing (use a finger-stick blood glucose to dose in this case).
5. Acetaminophen does not affect the G6 CGM.
6. Child should be treated *immediately* (i.e. classroom, playground) if symptomatic or if blood glucose is below *Target Range*. Remember that if a child is sent to the school health office, another responsible person must always accompany the child.

Meals

7. For correction boluses at mealtime, the G6 sensor value may be used in place of finger-stick testing and correction dosing should occur as per the health care provider's school orders/DMMP.
8. Trend Arrows: The health care provider may indicate on the DMMP the use of trend arrows at mealtime in determining insulin dosing/treatment.

Lows

9. If a child feels that his/her blood sugar is low then the CGM sensor reading may be used to determine treatment. Provide carbohydrates based on the sensor reading and symptoms and recheck sensor reading BG in 15 min. If still low, repeat the treatment.
10. The Dexcom G6 has an optional "Urgent Low Soon Alert" which notifies you when the reading is predicted to reach 55 mg/dL within 20 minutes. It is OK to treat with carbohydrates for an urgent low soon alert even if the current CGM value is not low. The "Urgent Low Alert" (not optional) will alarm at 55mg/dl.
11. If the CGM is reading low, but the child is not symptomatic, confirm glucose with a finger-stick prior to treating. Treat according to the finger-stick value, as per the health care provider's school orders/DMMP.

12. For the DEXCOM G6 CGM: these trend arrows may be used in treatment decision (as agreed upon by the school nurse and parent or per DMMP):

CGM 70-80 with 1 arrow facing down give 7.5gm of fast-acting carbohydrate*

CGM 70-80 with 2 arrows facing down give 15gms of fast-acting carbohydrate*

CGM 70-80 with level arrow consider giving complex carb snack* (10-15gms of carbs) without insulin bolus per parent and school nurse as indicated on the IHP.

*No insulin should be given for the treatment of lows or pending lows as described above. Fast-acting carbohydrates include but are not limited to: juice, glucose tablets, Skittles, honey, regular soda, etc.

Highs

13. The CGM sensor reading may be used for correction and dosing per the health care provider order/DMMP.

14. If the sensor glucose reading is >300 mg/dL over a 2 hour period or longer for the child getting insulin by injection or BG > 300 once for a child on a pump, check for serum or urine ketones (if possible) and treat per the health care provider's school orders/DMMP. Follow the **Standards of Care for Diabetes Management in the School Setting & Licensed Child Care Facilities – Colorado 2020**.

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Guidelines for Safe Use of the *Abbott Freestyle Libre 2* for Therapeutic Dosing

General

1. Approved for children 4 y.o. and older.

2. Approved to be factory calibrated.

3. Scan the sensor with handheld reader to see glucose reading, trend arrow and eight-hour history

4. Sensor will alert automatically without scanning when glucose levels are high or low.

5. Check the blood glucose via finger-stick if the child's symptoms do not match the sensor readings (e.g. the child feels low but the sensor is not reporting a low value).

6. Vitamin C supplements (more than 500mg/day) may falsely raise the sensor glucose readings.

7. Acetaminophen does not affect the Abbott Freestyle Libre 2.

8. Child should be treated *immediately* (i.e. classroom, playground) if symptomatic or if blood glucose is below *Target Range*. Remember that if a child is sent to the school health office, another responsible person must always accompany the child.

Meals

9. For correction boluses at mealtime, the Abbott Freestyle Libre 2 sensor value may be used in place of finger-stick testing and correction dosing should occur as per the provider's school orders/DMMP.

10. Trend Arrows: The health care provider may indicate on the DMMP the use of trend arrows at mealtime in determining insulin dosing/treatment.

Lows

11. If a child feels that his/her blood sugar is low then the iCGM sensor reading may be used to determine treatment. Provide carbohydrates based on the sensor reading and symptoms and recheck sensor reading BG in 15 min. If still low, repeat the treatment.

12. If the iCGM is reading low, but the child is not symptomatic, confirm glucose with a finger-stick prior to treating. Treat according to the finger-stick value, as per the health care provider's school orders/DMMP.

13. Following a low sensor glucose reading, scan every 15 minutes until a steady target glucose level is reached. For the Abbott Freestyle Libre 2 these trend arrows may be used in treatment decision (as agreed upon by the school nurse and parent or per DMMP):

iCGM 70-80 with arrow angled down give 7.5gm of fast-acting carbohydrate*

iCGM 70-80 with arrow facing straight down give 15gms of fast-acting carbohydrate*

iCGM 70-80 with level arrow consider giving complex carb snack *(10-15gms of carbs) without insulin bolus per parent and school nurse as indicated on the IHP.

*No insulin should be given for the treatment of lows or pending lows as described above. *Fast-acting carbohydrates* include but not limited to: juice, glucose tablets, Skittles, honey, regular soda, etc.

Highs

14. The iCGM sensor reading may be used for correction and dosing per the physician's school order form.
15. If the sensor glucose reading is >300 mg/dL x 2 over a 2 hour period or longer for the child getting insulin by injection or BG > 300 once for a child on a pump, check for serum or urine ketones (if possible) and treat per the health care provider's school orders/DMMP. Follow the **Standards of Care for Diabetes Management in the School Setting & Licensed Child Care Facilities – Colorado 2020**.
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References:

1. Forlenza GP, Argento NB, Laffel LM. Practical Considerations on the Use of Continuous Glucose Monitoring in Pediatrics and Older Adults and Nonadjunctive Use. *Diabetes Technol Ther.* 2017;19(S3):S13-s20.
2. Shah VN, Laffel LM, Wadwa RP, Garg SK. Performance of a Factory-Calibrated Real-Time Continuous Glucose Monitoring System Utilizing an Automated Sensor Applicator. *Diabetes Technol Ther.* 2018;20(6):428-33.
3. Wadwa RP, Laffel LM, Shah VN, Garg SK. Accuracy of a Factory-Calibrated, Real-Time Continuous Glucose Monitoring System During 10 Days of Use in Youth and Adults with Diabetes. *Diabetes Technol Ther.* 2018;20(6):395-402.
4. Aleppo G, Ruedy KJ, Riddlesworth TD, Kruger DF, Peters AL, Hirsch I, et al. REPLACE-BG: A Randomized Trial Comparing Continuous Glucose Monitoring With and Without Routine Blood Glucose Monitoring in Adults With Well-Controlled Type 1 Diabetes. *Diabetes care.* 2017;40(4):538-45.
5. Laffel LM, Aleppo G, Buckingham BA, Forlenza GP, Rasbach LE, Tsalikian E, et al. A Practical Approach to Using Trend Arrows on the Dexcom G5 CGM System to Manage Students and Adolescents With Diabetes. *Journal of the Endocrine Society.* 2017;1(12):1461-76.
6. Sherr, J., Tauschmann, M., Battelino, T., de Bock, M., Forlenza, G., Roman, R., Hood, K., Maahs, D. (2018, Oct). ISPAD clinical practice consensus guidelines 2018: diabetes technologies. *Pediatric Diabetes* October 2018; 19 (Suppl. 27): 302–325.
7. Abbott. (2020, June 15). Press Release Abbott's Freestyle Libre 2 ICGM cleared in U. S. for Adults and children with diabetes, achieving highest level of accuracy and performance standards. <https://abbott.mediaroom.com/press-releases>

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