Collaborative Guidelines for Dexcom G5 Non-Adjunctive Dosing in the School Setting January 2017

On December 20th, 2016 the FDA approved non-adjunctive use of the Dexcom G5 CGM, meaning that with proper twice daily finger-stick calibration the CGM 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 this change in labeling. Several clinical trials are in the process of investigating how to best utilize CGM in a non-adjunctive capacity for pediatric patients. Dexcom has begun to provide some clinical guidance on non-adjunctive use which are available at Dexcom.com/guides.

At this time, however, there is very limited clinical evidence guiding safe and appropriate use of non-adjunctive CGM data especially as it pertains to the school setting. While many skilled parents will be able to develop and implement complex blood sugar management decisions based on the CGM value and trend arrows, it may be unsafe to expect school health aids to do so at this time. As such we are recommending the following guidelines be used in schools for non-adjunctive CGM dosing pending further ADA/JDRF guidelines and additional clinical research. These guidelines will be reviewed and updated as needed by the *Collaborative Review Committee* in Summer 2017.

General

- 1. The CGM should be calibrated twice a day generally when the blood sugar is stable and not when the child is about to eat. This is usually done at home, but can be verified in the CGM calibration history.
- 2. Acetaminophen (Tylenol) can falsely elevated 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.
- 3. Remember that if a child is sent to the school nurse's office, another person must always accompany the child, especially if the child is hypoglycemic.

Meals:

4. For meal based correction boluses, 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 physician's school order form.

Lows

- 5. 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 above.
- 6. 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 physician's school order form.

Highs

- 7. 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 physician's school order form.
- 8. If the finger-stick BG is >300 mg/dL, check for serum or urine ketones and treat as per the physician's school order form.