February 19, 2015

Dear Medical Director:

The American Academy of Pediatrics (AAP), representing over 62,000 pediatricians, pediatric medical subspecialists and pediatric surgical specialists and dedicated to the health, safety, and well-being of infants, children, adolescents and young adults, is writing to provide clarification and advocate for appropriate benefits coverage for pediatric diabetic supplies, including blood sugar testing strips. The American Academy of Pediatrics (AAP) and AAP Section on Endocrinology are concerned that the ability to safely monitor the blood sugars of children with Type 1 Diabetes is often impacted by limitations in the quantity of blood sugar testing strips allotted monthly. The welcomed advances in insulin pump therapy and basal bolus insulin therapy provide improved diabetes outcomes yet carry the burden of increased blood sugar testing. Children and adolescents with diabetes are at increased risk for erratic fluctuations in blood sugars due to pubertal and growth hormone fluctuations, exercise, growth and variable schedules at school, after school programs and home. **We are advocating that your health plan coverage policy for blood glucose monitoring be expanded to cover up to 12 glucose test strips per day in children with type 1 diabetes.**

The safe management of pediatric patients with diabetes depends critically on the ability to do accurate and adequate blood glucose monitoring prior to all meals and bedtime and to verify suspected and potentially dangerous hypoglycemia or hyperglycemia triggered by illness, exercise, insulin pump malfunctions or infusion set issues, concomitant medications, hormonal fluctuations and/or noncompliance with dietary recommendations. In children, the need for frequent blood glucose testing and to monitor insulin administration safely is well documented and the practice of multiple daily testing for mealtime insulin dosing and activity/illness as well as suspected hypo or hyperglycemia testing is widely considered to be the standard of care. A patient’s ability to do adequate blood sugar testing reduces the risk for hypoglycemic seizures, adverse effects on cognitive function or hospitalization for diabetic ketoacidosis.

We often experience the burden of having to appeal insurance restrictions limiting children to using 4-6 blood glucose strips per day to be able to provide for their safe care. The basis for limiting blood testing to supplies to 4 tests per day is based predominantly on adult-oriented Title 19 Durable Medical Equipment (DME) guidelines for adults with type 2 diabetes. These guidelines should not be applied to Pediatric (or adult) Type 1 Diabetes patients. Access to adequate testing supplies allows children with Type 1 diabetes to maintain safe and improved glycemic control and can thereby result in potential cost-savings from the reduction of both short- and long-term unsafe complication. As detailed in the attached Background Information, according to established outcomes of longitudinal studies and peer reviewed research, there is documented
evidence that underscores the clinical recommendations for frequent monitoring of blood sugars in children (and adults) with Type 1 diabetes. (References are attached for your convenience).

We would welcome the opportunity to partner with your organization to create policy for removing unnecessary barriers to allow for adequate blood sugar testing in children with diabetes. We have a shared goal of providing quality care and preventing disability and diabetes complications. We hope that your organization will value the insights and experience of the pediatric endocrinology community. We would welcome the opportunity to discuss this further with you or your staff via conference call. For additional information or to arrange a call, please contact Laura Laskosz, AAP Staff Manager, at 847.434.4928 or at llaskosz@aap.org.

Sincerely,

/S/

Sandra G. Hassink, MD, FAAP
President

SGH/l
**Background Information**

Diabetes is one of the most common chronic childhood diseases and its incidence continues to rise. Children with diabetes and their caregivers are counselled to have the child or adolescent maintain blood glucose levels in the near-normal range with usual childhood activities encouraged. Yet it is extremely challenging to avoid recurrent episodes of hypoglycemia or hyperglycemia. Data from the T1D Exchange Clinic Network has been recently published that demonstrates the practice of more frequent self-monitoring of blood glucose (SMBG) and the practice of performing SMBG before giving an insulin bolus is associated with improvement in glycemic control. Careful blood sugar monitoring and improved diabetes control is associated with decreased rates of diabetic ketoacidosis or cerebral edema events (1). The limitation of testing supplies can endanger children and adolescents with diabetes as well as impede efforts to achieve recommended glycemic targets. The goals of intensive management of diabetes were established in 1993 by the Diabetes Control and Complications Trial. This study provided clear evidence linking aggressive management of diabetes with the resultant lowering of average blood glucose levels and decreased diabetes complications. This landmark study found it most difficult to achieve improved glycemic control in the adolescent population subset who had fluctuating pubertal and growth related hormones and variable daily activities. The standards of diabetes care recommending frequent SMBG to prevent sustained hyperglycemia are based on the need to minimize long-term microvascular and macrovascular complications as well as acute dangerous complications of basal bolus insulin administration (2,3).

Medical advancements have improved the technology to support intensive diabetes management with the introduction of new insulin analogs, improved insulin infusion pumps, and continuous glucose monitoring systems. The advances in pediatric insulin pump therapy have been most successful and safe in those patients with more frequent SMBG (4). These approaches, which provide more physiologic evidence-based diabetes care to patients, have led to increasingly younger ages for pump initiation and stricter goals for glycemic control. The successful management of diabetes in children and adolescents continues to rely on frequent SMBG if it is to be delivered safely. Hypoglycemia-induced seizures or loss of consciousness can occur if insulin dosing is not carefully monitored with frequent SMBG.

An association between SMBG frequency and diabetes control (HbA1c) has been shown consistently in several longitudinal peer reviewed studies (5-9). Many parents monitor children’s blood sugars at an average rate of 6-10 times per day and more frequently if the children are younger or unreliable in recognizing or communicating symptoms of hypoglycemia. Additional blood glucose testing is necessary and essential for children and adolescents with diabetes who are at risk for wide fluctuations in blood sugar as a result of growth, menses, and illness or pump malfunction.

Currently no federal laws or regulations specifically define adequate coverage of blood glucose testing supplies for children. However, chronic disease management is required of all private plans as an essential health benefit under the Affordable Care Act. There are safety issues unique to children in using insulin therapy for diabetes. Limiting the ability to monitor glucose fluctuation is a major safety issue may restrict the physician and family from making appropriate clinical decisions.
References: