Texas Children's	Therapeutic Continuous Glucose Monitors (CGMs)	
Guideline # 10596	***Categories*** Administration / Non-Clinical →TCHP Utilization Management	***This Guideline Applies To:*** Texas Children's Health Plan ***Document Owner*** Andrea Canady

GUIDELINE STATEMENT: Texas Children's Health Plan (TCHP) performs authorization on Therapeutic Continuous Glucose Monitors (CGMs)

DEFINITIONS: A therapeutic continuous glucose monitor is a device used for monitoring blood glucose levels on a continual basis for persons with either type I or type II diabetes. A glucose sensor is inserted under the skin to measure glucose levels that is connected to a transmitter which displays the information on a monitoring device.

PRIOR AUTHORIZATION GUIDELINE

1. All requests for prior authorization therapeutic Continuous Glucose Monitors (CGMs) are received via online submission, fax, phone or mail by the Utilization Management Department and processed during normal business hours.

2. A therapeutic CGM device is a replacement of self-blood glucose monitoring (SBGM) 3. A therapeutic CGM (procedure code K0554) and its related supplies (procedure code K0553) are a benefit in the home setting when services are provided by home health DME and medical supplier (DME) providers.
   - 2.1. A therapeutic CGM (procedure code K0554) is a benefit once every 3 years.
   - 2.2. The supply allowance (procedure code K0553) for supplies used with the therapeutic CGM system encompasses all items necessary for the use of the device. The DME provider is responsible for delivering the appropriate items and quantities to the member to initiate and continue usage of the therapeutic CGM.

3. To request prior authorization for a therapeutic Continuous Glucose Monitoring device, clinical documentation to support the medical necessity for the selected Continuous Glucose Monitoring device must be provided.

3.1. Prior authorization is required for a therapeutic CGM device (procedure code K0554).

3.2. Prior authorization requests for the purchase of Continuous Glucose Monitoring device and its related supplies requires submission of a completed, detailed signed order by the treating physician/provider who is familiar with the member prior to supplying any medical equipment or supplies.

3.3. The initial order from a health-care provider who is managing the member's diabetes is valid for an initial 6 month period.

3.3.1. If the member demonstrates compliance with the use of the CGM and treatment plan, an additional 6 month order may be submitted.

3.3.2. After the first year, an order for replacement sensors, transmitter, and receiver (following frequency rules) may be submitted for a 12-month period.

4. Members who have Type I or Type II diabetes may be considered for therapeutic CGM. All of the following medical necessity criteria must be met.

4.1. The member has been using a SBGM and performing frequent (at least four times per day) testing.

4.2. Insulin injections are utilized three or more times per day or is on an insulin pump.

4.3. The member's insulin treatment regimen requires frequent adjustment due to SBGM or CGM testing results.

4.4. The member is able, or has a caregiver who is able, to learn to use the device, hear and view CGM alerts and respond appropriately.

4.5. A member with hypoglycemia unawareness or several episodes of hypoglycemia per day may also qualify for therapeutic CGM if the above criteria are not met.

5. The prescribing provider should also verify that the member's condition meets the manufacturers' recommendations for appropriate age range, testing and calibration requirements, and any other manufacturer recommendations prior to prescribing the CGM device.

6. CGM devices that have been purchased are expected to last a minimum of three years and may be considered for replacement when three years have passed or the equipment is no longer repairable.

6.1. The replacement of the equipment may also be considered when it has been lost or irreparably damaged.

6.1.1. A copy of the police or fire report, when appropriate, and the measures to be taken to prevent a reoccurrence must be submitted.

7. When a therapeutic CGM device (procedure code K0554) is approved, the related supplies (procedure code K0553) are also covered once per calendar month.
    7.1. Prior authorization for the initiation of therapeutic CGM monthly supplies (procedure code K0553) is required when the client already owns a device. The treating physician/provider must submit a statement with the prior authorization request, verifying the following:
        7.1.1. Member owns a therapeutic CGM device.
        7.1.2. The member's current diabetic condition meets therapeutic CGM coverage criteria.
        7.1.3. The member is compliant with CGM device usage to manage their diabetes.
8. The following services are not a benefit
    8.1. Non-therapeutic CGM devices used as an adjunct to SBGM
    8.2. Rental of therapeutic CGM devices
    8.3. Non-medical items, even if the items may be used to serve a medical purpose:
        8.3.1. Smart devices (smart phones, tablets, personal computers, etc.) used as CGM monitors
        8.3.2. Medical supplies used with non-covered equipment. An exception would be for the transmission and receiving of data, using a smart device application, from a client's personally owned smart device, who meet the medical criteria for telemonitoring services.
9. Requests that do not meet the criteria established by this guideline will be reviewed by a TCHP Medical Director/Physician Reviewer on a case by case basis and the denial policy will be followed.

10. Preauthorization is based on medical necessity and not a guarantee of benefits or eligibility. Even if preauthorization is approved for treatment or a particular service, that authorization applies only to the medical necessity of treatment or service. All services are subject to benefit limitations and exclusions. Providers are subject to State and Federal Regulatory compliance and failure to comply may result in retrospective audit and potential financial recoupment.

RELATED DOCUMENTS:

REFERENCES:

Government Agency, Medical Society, and Other Publications:

Texas Medicaid Provider Procedure Manual – Accessed May 10, 2020

http://www.tmhp.com/manuals_pdf/tmppm/tmppm_living_manual_current/2_DME_and_Supplies.pdf

PEER REVIEWED PUBLICATIONS:

Langendam, M., Luijf, Y. M., Hooft, L., Devries, J. H., Mudde, A. H., & Scholten, R. J. (2012). Continuous glucose monitoring systems for type 1 diabetes mellitus. Cochrane Database Syst Rev, 1, CD008101.

Lal R, Maahs D Clinical Use of Continuous Glucose Monitoring in Pediatrics. Diabetes Technol Ther. 2017 May;19(S2):S37-S43

Lagarde WH, Barrows FP, Davenport ML, et al. : Continuous subcutaneous glucose monitoring in children with type 1 diabetes mellitus: a single-blind, randomized, controlled trial. Pediatr Diabetes 2006;7:159–164

Rodbard, D. Continuous Glucose Monitoring: A Review of Successes, Challenges, and Opportunities Diabetes Technol Ther. 2016 Feb 1; 18(Suppl 2): S2-3–S2-13.

Poolsup, N., Suksomboon, N., & Kyaw, A. M. (2013). Systematic review and metaanalysis of the effectiveness of continuous glucose monitoring (CGM) on glucose control in diabetes. Diabetol Metab Syndr, 5, 39.

Yeh, H. C., Brown, T. T., Maruthur, N., Ranasinghe, P., Berger, Z., Suh, Y. D., et al. (2012). Comparative effectiveness and safety of methods of insulin delivery and glucose monitoring for diabetes mellitus: a systematic review and meta-analysis. Ann Intern Med, 157(5), 336-347.

Slover, R. H., Welsh, J. B., Criego, A., Weinzimer, S. A., Willi, S. M., Wood, M. A., & Tamborlane, W. V. (2012). Effectiveness of sensor-augmented pump therapy in children and adolescents with type 1 diabetes in the STAR 3 study. Pediatr Diabetes, 13(1), 6-11.

Bergenstal, R. M., Tamborlane, W. V., Ahmann, A., Buse, J. B., Dailey, G., Davis, S. N., et.al. (2011). Sensor-augmented pump therapy for A1C reduction (STAR 3) study: results from the 6-month continuation phase. Diabetes Care, 34(11), 2403-2405.

Chase, H. P., Beck, R. W., Xing, D., Tamborlane, W. V., Coffey, J., Fox, L. A., Ruedy, K. J. (2010). Continuous glucose monitoring in youth with type 1 diabetes: 12-month follow-up of the Juvenile Diabetes Research Foundation continuous glucose monitoring randomized trial. Diabetes Technol Ther, 12(7), 507-515.

Foster, N. C., Miller, K. M., Tamborlane, W. V., Bergenstal, R. M., & Beck, R. W. (2016). Continuous Glucose Monitoring in Patients With Type 1 Diabetes Using Insulin Injections. Diabetes Care, 39(6), e81-82.

Juvenile Diabetes Research Foundation CGM, J.-C. (2010). Effectiveness of continuous glucose monitoring in a clinical care environment: evidence from the Juvenile Diabetes Research Foundation continuous glucose monitoring (JDRF-CGM) trial. Diabetes Care, 33(1), 17-22. November 2016 © Evidence-Based Outcomes Center Quality and Outcomes Center, Texas Children's Hospital 4

Glowinska-Olszewska, B., Tobiaszewska, M., Luczynski, W., & Bossowski, A. (2013). Monthly use of a real-time continuous glucose monitoring system as an educational and motivational tool for poorly controlled type 1 diabetes adolescents. Adv Med Sci, 58(2), 344-352.

Rachmiel, M., Landau, Z., Boaz, M., Mazor Aronovitch, K., Loewenthal, N., Ben-Ami, M., et.al. (2015). The use of continuous glucose monitoring systems in a pediatric population with type 1 diabetes mellitus in real-life settings: the AWeSoMe Study Group experience. Acta Diabetol, 52(2), 323-329.

Huang, E. S., O'Grady, M., Basu, A., Winn, A., John, P., Lee, J., et.al. (2010). The cost effectiveness of continuous glucose monitoring in type 1 diabetes. Diabetes Care, 33(6), 1269-1274.

Klonoff,D, Buckingham, B, Christiansen J., Montori V. (2011)Continuous Glucose Monitoring: An Endocrine Society Clinical Practice Guideline The Journal of Clinical Endocrinology & Metabolism, Volume 96, Issue 10, 1 October 2011, 2968–2979

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