Texas Medicaid posted a draft policy to add Therapeutic Continuous Glucose Monitoring (CGM) as a Durable Medical Equipment (DME) benefit for the current “Diabetic Equipment and Supplies – Home Health policy.” The draft policy was posted for public comment between October 17, 2019 and November 1, 2019. Texas Medicaid received a total of 152 comments from 90 state stakeholders. A summary of comments relating to the proposed policy and HHSC’s responses follow.

1. All comments received supported Texas Medicaid adding therapeutic CGM to improve diabetic management.
   
   Response: HHSC appreciates the support for this important new benefit.

2. More than half of the total comments requested HHSC to expand the benefit to all FDA approved devices including adjunct (non-therapeutic) CGM devices for clients with Type 1 diabetes. Among these comments, the majority mentioned the CGM integrated insulin pump system – closed loop system, marketed as Medtronic’s 670G.

   Response: HHSC will be moving forward with implementing the therapeutic CGM benefit to avoid any delays in accessing that benefit. However, HHSC will take into consideration the possibility of adding adjunctive CGM devices (as well as the pump systems) as a Medicaid benefit for Type 1 diabetics.

3. The majority of the comments received were in support of the outlined benefit criteria for the proposed benefit. A number of commenters suggested also including diabetic clients who have severe hypoglycemia or hypoglycemia unawareness.

   Response: HHSC agrees that clients with severe hypoglycemia or hypoglycemia unawareness will benefit from therapeutic CGM. The proposed criteria should capture all clients under level 3 hypoglycemia and most clients with hypoglycemia unawareness.

   HHSC made the following changes to the policy as a result of some of the comments, including an additional criterion for eligibility:
41.5. A client with hypoglycemia unawareness or several episodes of hypoglycemia a day also qualifies for the therapeutic CGM benefit if the client does not meet criteria outlined above in lines 41.1-41.4.

4. Several commenters suggested reducing the frequency threshold of Self Blood Glucose Monitoring (SBGM) from at least four times per day to at least two times per day

   Response: HHSC declines to revise the policy in response to this comment. At least four times per day is the medical criteria for therapeutic CGM recommended by most professional guidelines.

5. Several commenters suggested an additional supplies benefit for therapeutic CGM such as standard glucometer, strips, alcohol wipes.

   Response: HHSC’s intent within the policy language is that therapeutic CGM supplies (K0553) should encompass all the items necessary for the use of the therapeutic CGM device. The DME provider is responsible for delivering the appropriate items and quantities for the client to initiate and continue use of the therapeutic CGM; this includes any “back-up supplies” for the therapeutic CGM. See policy line 70 for further detail.

6. A few commenters suggested keeping glucometers as a benefit in addition to CGM.

   Response: Currently, Texas Medicaid does not cover standard home glucose monitors. Addition of coverage would require legislative action and is therefore outside the scope of this policy update. The clinical use of glucometers is currently covered by Texas Medicaid under a short-term clinical CGM benefit. Please refer to the Medical and Nursing Specialists, Physicians and Physician Assistants Handbook, Section 9.2.24 Continuous Glucose Monitoring (CGM) (http://www.tmhp.com/Manuals_HTML1/TMPPM/Current/index.html#t=TMPPM%2F2_Med_Specs_and_Phys_Srvs%2F2_Med_Specs_and_Phys_Srvs.htm&rhsearch=cgm&rhlterm=cgm&rhsyns=%20) for further information.

7. Two commenters questioned the prior authorization process for clients who already own a therapeutic CGM device and only require therapeutic CGM supplies.

   Response: HHSC has made the following changes to the policy in response to this comment:
44. “A one-time prior authorization is required at the initiation of a therapeutic CGM monthly supplies allowance (procedure code K0553) for a client-owned device. The physician must submit a statement that the client owns a therapeutic CGM device (as defined by CMS) and the client’s current condition meets the criteria outlined in this policy for the therapeutic CGM benefit, or the client is compliant with using the CGM device to manage his or her diabetes.”

8. One commenter suggested expanding the therapeutic CGM benefit to clients with diabetes caused by other conditions.

Response: HHSC declines to amend the policy in response to this comment. This policy will cover all clients with diabetes who meet the medical necessity criteria for therapeutic CGM with any diagnosis listed in Table B - Diagnosis Codes for Diabetic Supplies, regardless of etiology. Please see line 81 for further details.

9. A couple of commenters questioned the prior authorization request timeline and suggested increasing from within three to five business days after the start of service (Line 32).

Response: HHSC declines to amend the policy in response to this comment. This section of the Diabetic Equipment and Supplies – Home Health policy was not within the scope of the current review to add the therapeutic CGM benefit.

10. One commenter requested verification of the benefit for tubeless external insulin infusion pumps.

Response: The section of the policy pertaining to external infusion pumps was not within the scope of the current review; this policy review was focused on coverage of therapeutic CGM. Please refer to the Durable Medical Equipment, Medical Supplies, and Nutritional Products Handbook, Section 2.2.11.6 Tubeless External Insulin Infusion Pumps (http://www.tmhp.com/Manuals_HTML1/TMPPM/Current/index.html#t=TMPPM%2F2_DME_and_Supplies%2F2_DME_and_Supplies.htm&rhsearch=Tubeless%20External%20Insulin%20&rhhlterm=Tubeless%20External%20Insulin%20&rhyns=%20) for further details.

11. Two commenters expressed concern with line 41.4 of the draft policy that requires a client or caregiver to “hear and view therapeutic CGM alerts” as individuals with sensory disabilities may not be able to do so and some products do not have an audible alarm.
Response: HHSC agrees to amend the policy language from “hear and view” to “hear, view or both”.

12. One commenter asked for clarification as to whether the new benefit is limited strictly to homebound members.

Response: The proposed therapeutic CGM benefit is a DME benefit for any client with diabetes client who meets the medical necessity criteria outlined in the policy.

13. One commenter suggested changing the Roman numerals to Arabic numerals as per current terminology for diabetic types.

Response: HHSC has made changes to the policy as a result of this comment to replace “type I” and “type II” with “type 1” and “type 2” throughout the policy.

14. One commenter suggested adding a citation to differentiate between the proposed therapeutic CGM policy and the current clinical short-term CGM benefit.

Response: HHSC has made changes to the policy as a result of this comment to differentiate between therapeutic CGM and clinical short-term CGM. Additional changes will be made to the Medical and Nursing Specialist, Physician, and Physician Assistants Handbook, Section 9.2.24 Continuous Glucose Monitoring (http://www.tmhp.com/Manuals_HTML1/TMPPM/Current/index.html#t=TMPPM%2F2_Med_Specs_and_Phys_Srvs%2F2_Med_Specs_and_Phys_Srvs.htm&rhsearch=cgm&rhhltterm=cgm&rhsyns=%20) to provide greater clarification.

15. One commenter asked for clarification of how extra supplies are defined when billing for K0553.

Response: HHSC’s intent within the policy language is that procedure code K0553 is a bundled procedure code billed per unit for one month’s worth of supplies. This includes all the necessary supplies and accessories a client may need to utilize their therapeutic CGM device appropriately. The amount of supplies received will be tailored to the individual client’s device and associated supply needs.

HHSC has made the following changes to line 43 of the policy as a result of this comment to avoid any confusion:

43. “When a therapeutic CGM device (procedure code K0554) is covered, the related supply allowance (procedure code K0553) is also covered with no need for separate prior authorization. Prior
authorization is required for any extra amount of supplies that exceed the allowance.”

16. One commenter asked for clarification around documentation requirements as well as requested a change to the length of time that clients must demonstrate treatment compliance before receiving 12 months of supplies at a time.

Response: HHSC declines to revise the policy in response to this comment because prior authorization is not required for therapeutic CGM supplies. Line 66 in the policy refers to the length of time for the physician’s order, not prior authorization. Documentation must be maintained in the client record, not submitted to HHSC.

17. One commenter requested HHSC provide claims information to the DME supplier to ensure no other home glucose monitors have been provided in the past three years.

Response: HHSC declines to revise the policy language in response to this comment. Ordering providers are expected to coordinate with the client and DME providers to avoid duplicating this equipment.

18. One commenter suggested adding medical necessity criteria for therapeutic CGM to the section of the policy pertaining to verbal and written orders.

Response: HHSC declines to revise the policy language in response to this comment. Medical criteria specifically pertaining to therapeutic CGM is not appropriate in the policy scope section that applies to all diabetic management benefits.

19. One commenter expressed concern over the challenge for the ordering provider to prescribe the appropriate therapeutic CGM device based on manufacturers’ recommendations, as well as the burden this may cause to health plans overseeing the benefit. Another commenter supported the ordering provider being responsible for this verification and did not want to see health plans denying coverage based on preferred therapeutic CGM systems.

Response: HHSC appreciates the concern about the burden on ordering providers, however providers are expected to be knowledgeable about the devices they are prescribing, and health plans are expected to monitor administration of Medicaid benefits appropriately. Coverage should be provided for whichever FDA-
approved device is ordered as long as it follows manufacturer recommendations and is medically necessary as defined in this policy.

20. One commenter requested clarification of Clinical Nurse Specialists as an allowable ordering provider and whether that was added to include certified diabetes educators.

Response: HHSC notes that this section is part of existing policy language and was not updated as part of this review. Ordering providers are not required to hold additional certification as Certified Diabetes Educators.

21. One commenter requested clarification as to whether therapeutic CGM would become a benefit for CHIP members as well.

Response: HHSC notes that the therapeutic CGM benefit is specific to the Texas Medicaid population only at this time and does not include CHIP.

22. One commenter questioned the three-year prohibition against coverage for glucometers billed using procedure codes E2100 and E2101 for clients who are utilizing therapeutic CGM devices and requested exceptions be allowed.

Response: HHSC declines to revise the policy in response to this comment. Providers may always request coverage for exceptional circumstances; however, this policy statement is meant to prevent Texas Medicaid from covering more than one kind of device within any three-year period. Therapeutic CGMs are meant to replace traditional home glucose monitors.

23. One commenter expressed concern regarding Texas Medicaid’s absolute exclusion of any item of DME from the home health policy as such exclusions violate federal Medicaid requirements explained in 42 C.F.R. §440.70(b)(3)(v).

Response: HHSC acknowledges the provisions of 42 C.F.R. §440.70(b)(3)(v) and has a process in place to request items of DME not currently listed as a covered benefit. HHSC provides an Exceptional Circumstances provision for medically necessary DME and supplies that are not otherwise covered as a benefit under Texas Medicaid for clients 21 years of age and older. Please note, staff are in the process of making current Exceptional Circumstances processes
and managed care requirements more transparent and readily available. HHSC has made the following changes to the policy language in line 2.5 as a result of this comment to comply with federal requirements:

2.5. “The requested equipment or supplies must be safe for use in the home or any other setting in which normal life activities take place.”