November 19, 2022

DME MAC Medical Directors
26 Century Blvd., Ste ST610
Nashville, TN 37214-3685

Subject: Proposed Local Coverage Determination Modifying Coverage Criteria for Continuous Glucose Monitors (CGMs)
Dear DME MAC Medical Directors,

We thank you for the opportunity to submit comments for the Proposed Local Coverage Determination Modifying Coverage Criteria for Continuous Glucose Monitors (CGMs). The National Community Pharmacists Association (NCPA) represents over 19,400 independent pharmacies across the country. Together, our members represent a $78.5 billion healthcare marketplace, employ 240,000 individuals, and provide an expanding set of healthcare services to millions of patients every day. Independent pharmacies provide services beyond dispensing, such as point-of-care testing, lifestyle and weight management, chronic disease management, diabetes prevention and education, and contraceptive prescribing. As medication experts, pharmacists are highly qualified to analyze and optimize medication regimens to lower costs and improve health.

The expanded coverage for CGMs under the proposed LCD to include the indication of problematic hypoglycemia is a positive step forward in providing care to patients with diabetes. These modifications reflect a thorough review of the evidence, and we commend the DME MACs for their work on this proposal. Independent pharmacies supply CGM and related supplies covered under DME or Medicare Part B on a regular basis and have received excellent feedback regarding use of these devices.

NCPA submits the following comments in response to the Proposed Local Coverage Determination Modifying Coverage Criteria for Continuous Glucose Monitors (CGMs).

1. **We suggest that the language regarding beneficiary eligibility be adjusted from "daily administration of insulin" to "the beneficiary is treated with any insulin**." In the proposed LCD, *"The beneficiary for whom a CGM is being prescribed, to improve glycemic control, meets at least one of the criteria below: A. The beneficiary is insulin-treated with at least one daily administration of insulin; or,…"*[1] Under the previous LCD, daily administration clarifies insulin usage in its requirements as "*The beneficiary is insulin-treated with multiple (three or more) daily administrations of insulin or a continuous subcutaneous insulin infusion (CSII) pump; and,…*".[2] This reference in the existing policy makes it clear that usage of an insulin

1. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=39473&ver=16&bc=0
2. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33822

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pump will meet beneficiary requirements for CGM. This is also unclear for usage of daily administration, including via, inhalation and pump of insulin. To ensure that users of pumps and once-weekly insulin, as well as those administering injected or inhaled insulin can all qualify for a CGM, we would suggest that the new eligibility criterion that now references once daily administration of insulin be revised to require that "the beneficiary is treated with any insulin."

2. Under the proposed LCD, the supply allowance (code K0553 or A4238) is billed as one (1) unit of service (UOS) per thirty (30) days.[1] However, there is no explicit provision of regulation or law requiring that CGMs *must* be billed per thirty days. All other supplies for patients with diabetes are allowed to be billed per ninety (90) days. This inconsistency increases administrative burden on dispensing pharmacists and adds to patient confusion. For example, a patient may pick up a CGM device and supplies for ninety days, but the pharmacy calls the patient every thirty days to bill for the service. **We encourage CMS to consider allowing CGM devices to be billed per ninety-day supply to harmonize days supply with dispensing of insulin pump supplies.** This will decrease confusion for pharmacies, patients, providers, and DME MACs.

3. Pharmacies currently bill for CGM devices as DME. The LCD proposal includes a requirement for an in-person treating practitioner visit or telehealth visit every 6 months to assess adherence. Pharmacists are not currently allowed to bill directly as treating practitioners, although they dispense all devices, and see patients more frequently than primary care physicians. Pharmacist-led continuous glucose monitoring programs have shown to be successful and more convenient for patients.[2,3] Patients saw significantly greater A1c reductions in two pharmacist-driven encounters vs single physician-driven encounters.[3] Pharmacists are able to provide in-person visits within the pharmacy for patients who may not respond to telehealth appointments. Several pharmacies have secure video channels to complete virtual visits as well. Direct pharmacist billing may be accomplished through an 'other licensed practitioner' (OLP) designation. Pharmacists would then be able to dispense all diabetic supplies as well as provide the six-month adherence assessments with more convenience than physicians from direct access to dispensing records. **We urge CMSto consider the benefit of pharmacist-driven CGM programs through eligibility to provide adherence appointments direct billing for services.**

NCPA thanks DME MAC Medical Directors for the opportunity to share comments on the Proposed Local Coverage Determination Modifying Coverage Criteria for Continuous Glucose Monitors (CGMs) and welcomes the opportunity to work with the DME MAC Medical Directors to offer possible solutions and ideas. Please feel free to contact me at Jessica.satterfield@ncpa.org or (703)-838-2669 with any questions.

Sincerely,

Jessica Satterfield, PharmD, MBA
Associate Director, Policy and Pharmacy Affairs

3. Siemens R. Remote Pharmacist-Assisted Flash Continuous Glucose Monitoring Improves Glycemic Outcomes in Patients With Poorly Controlled Diabetes: A Retrospective Case Series. Clin Diabetes. 2022 Spring;40(2):211-221. doi: 10.2337/cd21-0088. Epub 2022 Apr 15. PMID: 35669305; PMCID: PMC9160561.
4. Sherrill CH, Houpt CT, Dixon EM, Richter SJ. Effect of Pharmacist-Driven Professional Continuous Glucose Monitoring in Adults with Uncontrolled Diabetes. J Manag Care Spec Pharm. 2020 May;26(5):600-609. doi: 10.18553/jmcp.2020.26.5.600. PMID: 32347180.Anderson L, et.al. Pharmacist Provision of Hormonal Contraception in the Oregon Medicaid Population. Obstet Gynecol. 2019;133(6):1231-1237. doi: 10.1097/AOG.0000000000003286.