

December 5, 2024

Chiquita Brooks-LaSure Administrator Centers for Medicare & Medicaid Services Department of Health and Human Services 7500 Security Boulevard Baltimore, MD 21244

Re: CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies (CMS-1807-F); *Insertion, and Removal and Insertion of New 365-Day Implantable Interstitial Glucose Sensor System (HCPCS Codes G0564 and G0565)* 

Dear Administrator Brooks-LaSure,

The Endocrine Society thanks you for finalizing policies that will positively affect our members in the Calendar Year (CY) 2025 Medicare Physician Fee Schedule (MPFS) final rule. We submitted comments in support of many of the policies that were finalized. We recognize that the agency finalized policy that was not included in the proposed rule, related to implantable glucose monitors, which are covered using Category III CPT codes 0446T and 0448T. As such, we wish to provide the following comments.

Founded in 1916, the Endocrine Society represents approximately 18,000 physicians and scientists engaged in the treatment and research of endocrine disorders, such as diabetes, hypertension, obesity, osteoporosis, endocrine cancers (i.e., thyroid, adrenal, ovarian, pituitary) and thyroid disease.

In response to a comment submitted by an interested party on the CY 2025 MPFS proposed rule, CMS created and finalized two new HCPCS codes to report services associated with the FDA recently approved implantable 365-day continuous glucose monitoring (CGM) system. The new codes, G codes G0564 (*Creation of subcutaneous pocket with insertion of 365-day implantable interstitial glucose sensor, including system activation and patient training*) and G0565 (*removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new 365-day implantable sensor, including system activation*) describe the services associated with the use of 365-day CGM system. The new codes will be contractor priced as of January 1, 2025.

Currently, there are two Category III CPT codes 0446T and 0448T used to report services for the use of 180-day CGM systems. However, given the recent approval of the 365-day CGM system, the manufacturer has removed the 180-day CGM system from the market completely, and instead will only manufacture the 365-day CGM system.

2055 L Street NW Suite 600 Washington, DC 20036 T. 202.971.3636 F. 202.736.9705 endocrine.org



Given the recent advancement in technology, and the subsequent removal of the 180-day CGM system from the market, we suggest an alternative proposal to using the new HCPCS G codes for the 365-day CGM system. The Endocrine Society believes that the current Category III CPT codes are appropriate for use with the 365-day CGM system if the agency were to update the practice expense (PE) inputs to reflect the new CGM system. The descriptors for the CPT Category III codes, 0446T (Creation of subcutaneous pocket with insertion of implantable interstitial glucose sensor, including system activation and patient training) and 0448T (removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new implantable sensor, including system activation) are agnostic to the length of time the CGM system is used in the body and had been used with the original 90-day sensor. Therefore, the current Category III CPT codes are appropriate to use for reporting the services associated with the 365-day CGM system. The physician work is the same and only the PE inputs require adjustment to reflect accurate pricing of the 365-day CGM system. The agency has the authority to make PE adjustments as needed, and we recommend CMS use that authority to update the PE for Category III CPT codes 0466T, and 0448T in the next quarterly update. The Endocrine Society will provide invoices supporting the price change if they are attainable. Since the 365day CGM device was approved in September of 2024, it may take time for our members to use the new technology and have invoices readily available. We know that Senseonics, the device manufacturer, is also ready to assist the agency to appropriately price the new sensor.

Should the agency implement our proposal, we then respectfully request that CMS issue a correction notice, or sub-regulatory guidance that provides information to providers and other stakeholders clarifying that the newly created G codes for the 365-day CGM system should not be used, and that Category III CPT codes (0446T and 0448T) are appropriate to report services for the 365-day CGM system.

Thank you for the opportunity to provide these comments. If you need additional information or would like to set up a meeting to discuss this issue, please contact Endocrine Society Director of Advocacy & Policy Rob Goldsmith at <u>rgoldsmith@endocrine.org</u>.

Sincerely,

Robert W. Lash, MD

cc: Jonathan Blum, Principal Deputy Administrator and Chief Operating Officer



Dr. Meena Seshamani, Deputy Administrator and Director of the Center for Medicare

Ryan Howe, Director, Hospital & Ambulatory Policy Group

Gift Tee, Deputy Director, Hospital & Ambulatory Policy Group Lindsey Baldwin, Director, Division of Physician Practitioner Services, HAPG