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AdvaMed
Advanced Medical Technology Association

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National Clinical Care Commission
https://health.gov/hcq/national-clinical-care-commission.asp

Dear NCCC Members,

The Advanced Medical Technology Association (AdvaMed) appreciates the opportunity to submit comments to the Commission on diabetes treatment programs. AdvaMed member companies produce the broad range of medical devices and technologies that play a crucial role in allowing Americans and many others throughout the world lead healthy, productive, and independent lives.

AdvaMed member companies have been at the forefront of the development of transformative technologies that will allow persons with diabetes to better manage and improve glycemic control, assess needed therapy on a timely basis, and adhere to their treatment regimens more effectively. More effective day-to-day management of diabetes is also expected to reduce utilization of other health care services related to complications that accompany ineffective diabetes management.

While many private payers are moving forward with coverage and payment policies that will provide their enrollees access to these new technologies, existing Medicare regulatory and statutory authorities have not provided a clear pathway to coverage and payment for many of these new technologies, including those with digital components, and have also created barriers to coverage. A recent example of barriers created by Medicare's regulations was the agency's coverage decision on continuous glucose monitoring (CGM) and subsequent clarification regarding the use of a smart device in conjunction with CGM. Initially CMS prohibited coverage of all supplies used with CGM when one of the supplies included a smart device because the smart device was considered a non-medical supply. Subsequently CMS decided to allow use of a smart device for reviewing glucose data "on some days", so long as beneficiaries also have and pay for a "durable" CGM receiver that qualifies for coverage under longstanding program regulations. In addition, while the FDA has been a leader in reviewing and approving interoperable closed-loop/artificial pancreas technologies, CMS has yet to provide guidance clarifying how these systems will be able to covered by Medicare, especially the algorithm component FDA has defined as an essential element of an AP system..

AdvaMed believes that CMS can take immediate steps, without new legislation from Congress authoring the agency to do so, to revise existing regulations and coverage policies that create barriers to coverage for new diabetes technologies. This should be the first step in a continuous commitment by CMS to revisit, on a regular basis and with consultation from patient, provider

and manufacturer stakeholders, existing regulations and policies to determine if they create unreasonable barriers to coverage of innovative diabetes technologies as they are approved by FDA, and to make recommendations on how policies should be changed to provide Medicare beneficiaries access to the health benefits these technologies offer. Furthermore, Medicare's commitment to a proactive and ongoing process for evaluating polices as they affect new diabetes technologies would affect non-Medicare patient access to innovative diabetes technologies, since private plans often look to Medicare policies as they consider their own positions on coverage and payment.

Specific areas where regulations could be revised and clarified at the present time are listed below.

- **Remove the CGM coverage restriction that patients self-test with BGM at least 4 times per day prior to using CGM.**
    - For insulin patients on multiple daily injections, CGM coverage is restricted to patients with a documented history of self-testing with BGM at least 4 times per day. There is no clinical support for this restriction and removing the requirement will facilitate CGM coverage for persons who are aging into Medicare and who have been on CGM prior to Medicare eligibility. Physicians could be authorized to attest that beneficiaries meet the coverage criteria.

- **Update and Align CGM and Insulin Pump Coverage Criteria (in LCD L 33822 for CGMs and LCD L33794 and NCD CMS Pub. 100-03 for insulin pumps).**
    - In general, align coverage criteria for CGMs and insulin pumps with each other and update for current clinical standards:
    - CGM criteria require in-person visit with treating practitioner **every 6 months** and external infusion pumps require in-person visit **every 3 months**.
    - Allow use of a patch pump or inhaled insulin to prove multiple daily injections of insulin for CGM coverage.
    - Revise C-peptide testing standards for insulin coverage criteria to reflect current standards of care.
    - For beneficiaries using both CGM and sensor-connected insulin pumps performing functions of a CGM receiver, allow CGM sensors and supplies to be covered as accessories to the pump, without the need for an additional CGM receiver, under the same benefit category that the pump itself is reimbursed.

- **Allow use of remote monitoring technologies and existing PFS codes for in-person visit requirements.**

- **Ensure coverage for new and emerging closed-loop and artificial pancreas technologies**
    - New policies are needed to clarify how Medicare will cover and reimburse FDA-approved hybrid integrated closed-loop insulin delivery systems and artificial

pancreas technologies, including interoperable components of these systems. Specific coverage/reimbursement issues include:

- Coverage and payment for advanced algorithm software used with these systems
- Use of a personally-owned smart device with software applications to integrate the components.

We thank you for consideration of these recommendations. If you have any questions, please contact Richard Price at rprice@advamed.org.

Sincerely,

Donald May
Executive Vice President
Payment and Health Care Delivery