CAPITOL STREET

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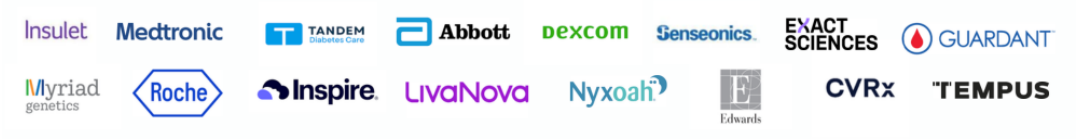
FAQs: MedTech, Diagnostics & Life Sciences

Relevant Companies



Our Take & Next Up

From time to time we publish a list of the inbound questions we are receiving. See below for our take on Medicare coverage of insulin pumps and continuous glucose monitors (CGMs) and next generation sequencing (NGS) tests, CMS coding for Hypoglossal Nerve Neurostimulators (HGNS) and AI, and the outlook for Medicare's accelerated coverage pathway for breakthrough devices (MCIT 2.0) and Sec. 232 tariffs on MedTech.

Key Points

Q. Will CMS update its coverage policies on insulin pumps (PODD, MDT, TNDM) and CGMs (ABT, DXCM, MDT, SENS)?

A. Yes, we believe that they will: The hodgepodge of LCDs (here) and NCDs (here) in the space are ripe for updates.

- It's a complicated history, but we think CMS will update its coverage policies on insulin pumps and continuous glucose monitors (CGMs) over time. A recently introduced bipartisan bill in the Senate (DIABETES Act) would require CMS to issue a proposed National Coverage Determination (NCD) for insulin infusion pumps within 180 days of enactment, which could push the agency to act (without bill passage having to take place).
- Additionally, we believe an updated Local Coverage Determination (LCD) providing incremental Medicare coverage of CGMs for Type 2 non-insulin users is likely in 2026/2027 (our take here). Two Durable Medical Equipment (DME) Medicare Administrative Contractors (MACs) - Noridian and CGS - typically work in unison and manage the four Medicare jurisdictions, effectively making it a national coverage policy (here).

Q. Could Medicare broaden coverage of next-generation sequencing (NGS) tests (EXAS/ABT, GH, MYGN, RHHBY)?

A. We think so; stakeholders are asking CMS for the NGS NCD to be reopened to account for updated FDA indications etc, which we view as reasonable, though the process would take time. We believe CMS

will likely take a step-wise approach to expanding coverage for FDA-authorized NGS tests, with discretion over lab-developed tests (LDTs) left to MACs. CMS hasn't made a major revision to its NGS NCD (here) in over five years, meaning it's likely ripe for an update. Stakeholder groups say newer evidence supports removing the requirement that patients have advanced cancer to receive somatic testing, allowing repeat testing when supported by FDA labeling, expanding germline testing beyond breast and ovarian cancers to other hereditary cancers, and permitting MACs to cover additional tests when supported by clinical evidence.

Q. What's the latest on CMS coding for Hypoglossal Nerve Neurostimulator (HGNS) codes (INSP, LIVN, NYXH)?

A. CMS made a short-term fix, but we believe that a sensible permanent fix will take longer to play out. On Feb. 26, CMS announced the creation of six new HCPCS codes to the April 2026 Integrated Outpatient Code Editor (effective Jan. 1, 2026). CMS noted recent confusion regarding coding for HGNS for the treatment of obstructive sleep apnea (OSA) following a prior coding change on Jan. 22 (here). We had said the update was likely an improvement from the status quo (here) and it now looks like OPPS payment for C-code 8011 will be priced similarly to prior CPT code 64582 at $31,526, according to recent comments from NYXH (here). In the longer term, movement on HGNS codes is expected at the next American Medical Association (AMA) Current Procedural Terminology (CPT) Editorial Panel meeting on April 30-May 2 (here). This is also a likely positive, though the coding changes wouldn't go into effect until Jan. 1, 2028. We look to the draft CY 2027 PFS and OPPS payment rules in July for guidance and future MLN/CMS transmittals in the interim.

Q. What's the latest on Medicare's accelerated coverage pathway (MCIT 2.0) for breakthrough devices (ABT, EW, MDT)?

A. CMS is asking for feedback on a new MCIT-like pathway, we are calling MCIT 2.0, which we think could be unveiled in a reasonably favorable way, later this year. Medicare Coverage of Innovative Technologies (MCIT) 1.0 (here) would have provided automatic coverage for 4 years for FDA approval of a breakthrough device, but was rescinded by the Biden Administration. There is a Transitional Coverage for Emerging Technologies (TCET), enacted under the Biden Administration (here), which has included only a handful of devices, with the pilot including EW, ABT, Impulse Dynamics and possibly CVRx. We note the MCIT pathway is favored by the MedTech industry as v1 provided no limit on the number of devices eligible and no restriction on diagnostic devices. We could see a new-ish program being announced in mid-late 2026.

Q. What's the status of the Commerce Dept.'s Sec. 232 investigation on MedTech?

A. A 232 report on MedTech is due May 30, 2026 – high-volume & commoditized products (PPE & medical consumables) are most at risk. The Supreme Court's February ruling blocking the use of IEEPA tariffs (here) left Pharma and MedTech in the same position with Sec. 232 tariffs still at the administration's disposal (our take here and here). The White House quickly implemented new Sec. 122 tariffs of 10% (soon to be 15%) to fill the void, but we have said they may be more aggressive in advancing Sec. 232 tariffs as a result of the SCOTUS decision (our take here). It remains unclear how a MedTech tariff would be implemented or if there's a possibility for appeals/delays or carve-outs; however, we believe high-volume & commoditized products (PPE & medical consumables) are likely most at risk. Also potentially at risk are products that rely on foreign-made components such as MRI machines and other imaging equipment. Durable medical equipment intended for handicapped or disabled persons (wheelchairs, hearing aids, etc.) are typically afforded duty-free

treatment under an international trade agreement known as the “Nairobi Protocol” (our take here). It appears that the Nairobi protocol would supersede Sec. 232 tariffs (here).

Q. What’s the latest on CMS coding for Artificial Intelligence (TEM & others)?

A. Reimbursement codes for Artificial Intelligence (AI) “algorithm-only” tests were considered by the AMA CPT Editorial Panel in early February and will be discussed again in April/May. Several new reimbursement codes for AI “algorithm-only” tests were on the agenda for the American Medical Association’s (AMA) Current Procedural Terminology (CPT) Editorial Panel meeting in Palm Springs on Feb. 5-7, 2026 (summary of panel actions here).

- A few AI codes were approved, but most of them were withdrawn (likely not ready for primetime).
- Another set of AI codes will be discussed at the panel’s next meeting April 30-May 2, 2026 (here), including a prognostic assessment of HER2-/HR+ breast cancer using AI-enabled digital pathology. Most other AI codes involve imaging, such as a Cat. I code for intra procedural coronary FFR using AI-enhanced 3D mapping.
- The CPT panel will also discuss refinements to its conceptual foundation for AI-related coding, also known as Appendix S (here).

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