

CAPITOL STREET

December 11, 2024

Inspire V & Cologuard Plus Pay Outlook

Medicare Coverage Likely; Reimbursement Rate for *Inspire V* Less Certain

Relevant Companies



»» Our Take & Next Up

Exact Sciences' Cologuard Plus and Inspire Medical's Inspire V should have no problem securing Medicare coverage, in our view, but the payment rate for Inspire V remains cloudy. Our base case for Inspire V (60% odds) is that in the short-term, it will be assigned the same reimbursement code as its prior product for physician insertion of the device (CPT 64582: \$816), with potential upside from a lame duck deal to boost physician rates for CY25. However, we believe there is some risk of downward revision of the physician rate to account for reduced procedure times associated with the new technology.

»» Key Points

Inspire Medical Systems

Inspire Medical's newest implantable device, *Inspire V*, for the treatment of obstructive sleep apnea (OSA) should have no problem securing Medicare coverage, in our view. The product cleared the first hurdle for coverage by garnering FDA approval via a premarket approval (PMA) supplement on Aug. 2, 2024 ([link](#)). Additionally, the company's legacy products are covered by Medicare Administrative Contractors (MACs) in all 50 states, suggesting that medical directors have viewed the base technology as reasonable and necessary for the Medicare population.

However, it's less certain whether *Inspire V* will gain a premium reimbursement rate in line with its predecessor products.

- The company is working on building inventory and plans full launch in 2025. We do not anticipate the company needing a new CPT code for *Inspire V* (co management has voiced the same opinion). The newer product is similar, but with a next generation neurostimulator and Bluetooth patient remote and physician programmer.
- Our base case (60% odds) is that in the short-term, the product will be assigned the same code and rate as its prior product for physician insertion of the device (CPT 64582: \$816). The alternative is that CMS will use a temporary code that will be priced by each individual Medicare Administrative Contractor. However, this is a lengthier process and could result in a lower paying rate.

In the longer-term (2-3 years), however, we believe there is some risk of downward revision of the physician payment rate should the American Medical Association (AMA) Relative Value Update Committee (RUC) take into account reduced procedure times associated with the new technology. A similar situation has occurred for certain radiation therapy and other implant codes in the past. We note that HHS Secretary nominee

RFK Jr. wants to revamp the RUC/CMS process altogether, but we note this could take some time ([here](#)). The RUC is criticized as having too much outside influence on CMS payment rates.

Overall PFS rates may see some upward revision for CY25 if included in a post-election lame duck deal, similar to past years. Competitors include **LivaNova (LIVN)** and **Nyxoah (NYXH)**.

TABLE 1:
Historic Rates for CPT 64582
Open implantation of hypoglossal nerve neurostimulator array, pulse generator, and distal respiratory sensor electrode or electrode array

	Final CY2024	Final CY2025	% Change
Outpatient Prospective Payment System	\$30,198	\$30,474	1%
Ambulatory Surgery Centers	\$25,620	\$25,832	1%
Physician Fee Schedule	\$837	\$816	(2.5%)

Source: CMS and Capitol Street, 2024

Exact Sciences Cologuard Plus

We believe EXAS' Cologuard Plus is also likely to be covered by Medicare under an updated National Coverage Determination (NCD) for Colorectal Cancer Screening Tests. The existing NCD ([here](#)) only includes the legacy *Cologuard* test and will therefore likely need to undergo a reconsideration to add the new test. Recall that Medicare added colorectal cancer screening to its NCD waitlist on August 15 (see our analysis ([here](#))), making an NCD reconsideration on this topic very likely.

In our view, CMS will likely open an NCD reconsideration late this year or 1Q25 and we expect the new NCD to be finalized in nine months (or less). Nine months is the typical timeframe for the NCD process if a coverage advisory meeting isn't needed, which we don't anticipate will be required. As a reminder, *Cologuard Plus* was approved by the FDA on Oct. 4 ([here](#)) and has greater sensitivity than the legacy *Cologuard* test, while reducing false positives by more than 30 percent.

Exact may be able to set an even higher rate (than \$592) for the test under an Advanced Diagnostic Lab Test (ADLT) application (\$600+), though it's unclear whether the company will pursue that route. ADLT status allows a test to be paid at the actual list charge for the first three calendar quarters (ADLT FAQ [here](#)).

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