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EXAS, GH: Next Steps on Next Gen Test Rates

John Leppard
202-935-0238
john.leppard@capitolpolicypartners.com

Key Takeaways: Following the split market reaction to **EXAS** [-29%] and **GH** [+25%] 3Q24 earnings reports last week, and investors looking to the opportunities associated with next generation colorectal cancer (CRC) screening tests Cologuard Plus and Shield, respectively, we outline our timing and outcome expectations for key upcoming policy catalysts. To quickly summarize:

- GH will likely secure endorsement of a dedicated Shield billing code at an American Medical Association (AMA) meeting ***tomorrow (Nov. 14)***, allowing for CMS designation as an Advanced Diagnostic Laboratory Test (ADLT) as early as March and payment at its $1,495 list price starting April 1. We would then expect the U.S. Preventive Services Task Force (USPSTF) to initiate a guideline review in 2H25, with completion in late 2027.
- EXAS is *unlikely* to see CMS reverse its initial denial of the company's requested 25% rate increase for Cologuard Plus ($636) relative to the legacy product ($509) in the final CY25 decisions due out in the ***next 1-2 weeks***, before pivoting to a likely successful effort at higher payments through the ADLT process in 1Q25. However, we view potential ***coverage*** delays under the existing National Coverage Determination (NCD) on CRC screening as an underappreciated sleeper issue.

EXACT Sciences Corporation (EXAS)

Price:	$50.82
52-Week High:	$79.62
52-Week Low:	$40.62

Guardant Health Inc (GH)

Price:	$31.86
52-Week High:	$37.04
52-Week Low:	$15.81

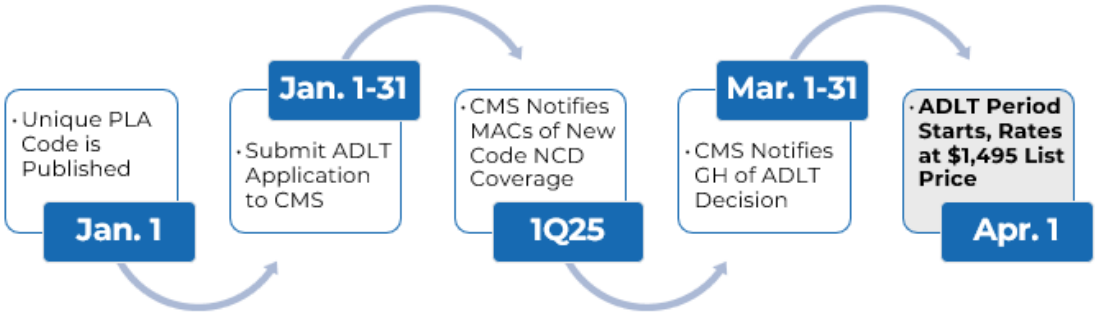
Guardant Health: Coding & Coverage

GH's disclosure last week that Medicare Administrative Contractor (MAC) Noridian has agreed to pay $920 for Shield is consistent with our previously outlined expectations of $850 to $950, though this rate will likely increase to the company's $1,495 list price by April 1 or – at latest – July 1.

The current $920 payment is associated with generic HCPCS code G0327 (colorectal cancer screening; blood-based biomarker), which CMS created in 2021 for coordination with the CRC blood-based biomarker coverage policy it had preemptively finalized in January of that year, more than three years prior to GH's Shield approval in July 2024.

To secure ADLT status and payment under the manufacturer list price (e.g., $1,495), however, each test "must be assigned a unique HCPCS code, meaning one that describes only a single test," which is granted at the discretion of the AMA. While Shield had originally been on the AMA's Proprietary Laboratory Analyses (PLA) code agenda in August, its late July approval by the FDA prompted a delay, with consideration now taking place at the Nov. 14 meeting, where we would expect endorsement.

This would likely trigger the sequence of events below, coordinated around the new code's publication date on Jan. 1 and its effective date on Apr. 1. If we are *incorrect*, we would not expect this process to be pushed out more than one calendar quarter.



Source: CMS, Capitol Policy Partners

CMS ADLT REVIEW CYCLES

QUARTER	REQUEST	REVIEW	NOTICE	EFFECTIVE
Q1	Jan. 1-31	Feb. 1-28	Mar. 1-31	Apr. 1 to Dec. 31
Q2	Apr. 1-30	May 1-30	June 1-30	July 1 to Mar. 31
Q3	July 1-31	Aug. 1-31	Sept. 1-30	Oct. 1 to Jun. 30
Q4	Oct. 1-31	Nov. 1-30	Dec. 1-31	Jan. 1 to Sept. 30

Source: CMS Guidance for Laboratories on ADLTs

While investors will be aware that the initial ADLT period technically only lasts for three calendar quarters (e.g., Apr. 1 / July 1 to Dec. 31 / Mar. 31) before reverting to the "weighted median of private payor rates," past experience shows that companies are often able to leverage CMS's calculation methodology to maintain the designation's payment advantages for far longer. We outline this dynamic below, showing all former ADLT products, their ADLT reimbursement amount versus current (4Q24) payments, and the number of years that have passed since their initial three-quarter period ended.

COMPANY	TEST	ADLT RATE	ADLT END	4Q24 RATE	%Δ ADLT RATE	YEARS POST-ADLT
Tempus AI	xT CDx	$4,500	Mar 31, 2025	$4,500	0%	-0.4
Naveris	NavDx	$1,800	Dec 31, 2024	$1,800	0%	-0.1
Castle Bios.	DecisionDx-SCC	$8,500	Mar 31, 2024	$8,500	0%	0.6
Prelude Corp	DCISion RT	$5,435	Dec 31, 2023	$5,435	0%	0.9
Castle Bios.	TissueCypher	$2,350	Dec 31, 2022	$4,950	111%	1.9
Natera	Signatera	$3,500	Mar 31, 2022	$3,590	3%	2.6
Guardant Health	Guardant360 CDx	$5,000	Dec 31, 2021	$5,000	0%	2.9
Roche	F1CDx (Liquid)	$3,500	Dec 31, 2021	$3,500	0%	2.9
Veracyte	Envisia	$5,500	Jun 30, 2021	$5,500	0%	3.4
Myriad Genetics	myChoice CDx	$4,040	Sep 30, 2020	$3,030	-25%	4.1
Castle Bios.	MyPath Melan.	$1,950	Jul 30, 2020	$1,950	0%	4.3
Biodesix	BDX-XL2	$3,520	Mar 31, 2020	$3,520	0%	4.6
Castle Bios.	DecisionDx-Melan.	$7,193	Mar 31, 2020	$7,193	0%	4.6
Roche	F1CDx	$3,500	Mar 31, 2019	$3,500	0%	5.6

Source: CMS, Capitol Policy Partners

Whether / how long GH can maintain this pricing will likely be a function of a volume versus margin tradeoff where, paradoxically, an absence of separately negotiated private payer contracts on which CMS can base its "weighted median" can help maintain the ADLT payment rate out beyond the typical three-quarter limit.

The timeline for inclusion of blood-based biomarker testing into USPSTF CRC screening recommendations – which would require commercial insurers to cover the test with $0 in patient cost-sharing – is somewhat more uncertain. However, based on the typical 4-5 years between Task Force reviews on a given subject, we would expect it to announce an updated draft research plan sometime in 2H25, leading to a ~2.5 year review that concludes in late 2027 / early 2028.

Exact Sciences: Payment Premiums & Coverage Conundrums

Following AMA endorsement of EXAS's own PLA code (0464U) for its newly approved Cologuard Plus offering, which took effect July 1, 2024, the company's pursuit of a 25% payment premium ($636) relative to the legacy version ($509) under CPT code 81528 is unlikely to succeed – in our view – when CMS releases its final CY25 decisions, typically published in late November.

TEST	CODE	DESCRIPTION
Cologuard	81528	Oncology (colorectal) screening, quantitative real-time target and signal amplification of 10 DNA markers (KRAS mutations, promoter methylation of NDRG4 and BMP3) and fecal hemoglobin, utilizing stool, algorithm reported as a positive or negative result
Cologuard Plus	0464U	Oncology (colorectal) screening, quantitative real-time target and signal amplification, methylated DNA markers, including LASS4, LRRC4 and PPP2R5C, a reference market ZDHHC1, and a protein marker (fecal hemoglobin), utilizing stool, algorithm reported as a positive or negative result

Source: American Medical Association (AMA)

In short, we count just 50 incidents of CMS reversing itself on initial decisions out of the 508 payment applications it has reviewed since 2020, equating to a 10% success rate. Moreover, so-called "fractional" rate adjustments such as this (e.g., $509 x 1.25 = $636) are themselves very rare, representing just 4% (22) of applications reviewed by the agency's Clinical Laboratory Fee Schedule (CLFS) Advisory Panel. Of these, just four were endorsed by CMS itself, *all* of which were included in the preliminary decisions released in September, rather than through a reversal in November's finalized rates.

As highlighted in last week's investor call, however, EXAS appears to be waiting for final resolution before pursuing what we suspect will be an equivalent rate premium under the ADLT pathway.

"We continue to engage with CMS on the CDLT [Clinical Diagnostic Laboratory Test] *process to seek a price increase. But if not, then we will go the ADLT path…*[which] *is slightly longer…We will start with the Medicare patients and then move into the commercial and then Medicaid patients."*

This would likely put EXAS on a similar timeline to GH above, filing an ADLT application with CMS in January, receiving notice from the agency in March, and the new payment rate taking effect on April 1.

The timing risks for a market shift to Cologuard Plus may stem less from reimbursement, however, than potential ***coverage*** limitations under the existing CRC screening NCD.

> **2. The Cologuard™ – Multi-target Stool DNA (sDNA) Test (effective October 9, 2014)**
>
> Screening stool or fecal DNA (deoxyribonucleic acid, sDNA) testing detects molecular markers of altered DNA that are contained in the cells shed by colorectal cancer and pre-malignant colorectal epithelial neoplasia into the lumen of the large bowel. Through the use of selective enrichment and amplification techniques, sDNA tests are designed to detect very small amounts of DNA markers to identify colorectal cancer or pre-malignant colorectal neoplasia. The Cologuard™ – multi-target sDNA test is a proprietary in vitro diagnostic device that incorporates both sDNA and fecal immunochemical test techniques and is designed to analyze patients' stool samples for markers associated with the presence of colorectal cancer and pre-malignant colorectal neoplasia.
>
> Effective for dates of service on or after October 9, 2014, The Cologuard™ test is covered once every three years for Medicare beneficiaries that meet all of the following criteria:

In contrast to most policies, the current NCD refers *explicitly* to "Cologuard™" rather than a more generic *classification* of tests, as is the case with its description of blood-based biomarker products:

3. Blood-based Biomarker Tests (effective January 19, 2021)

Blood-based DNA testing detects molecular markers of altered DNA that are contained in the cells shed into the blood by colorectal cancer and pre-malignant colorectal epithelial neoplasia.

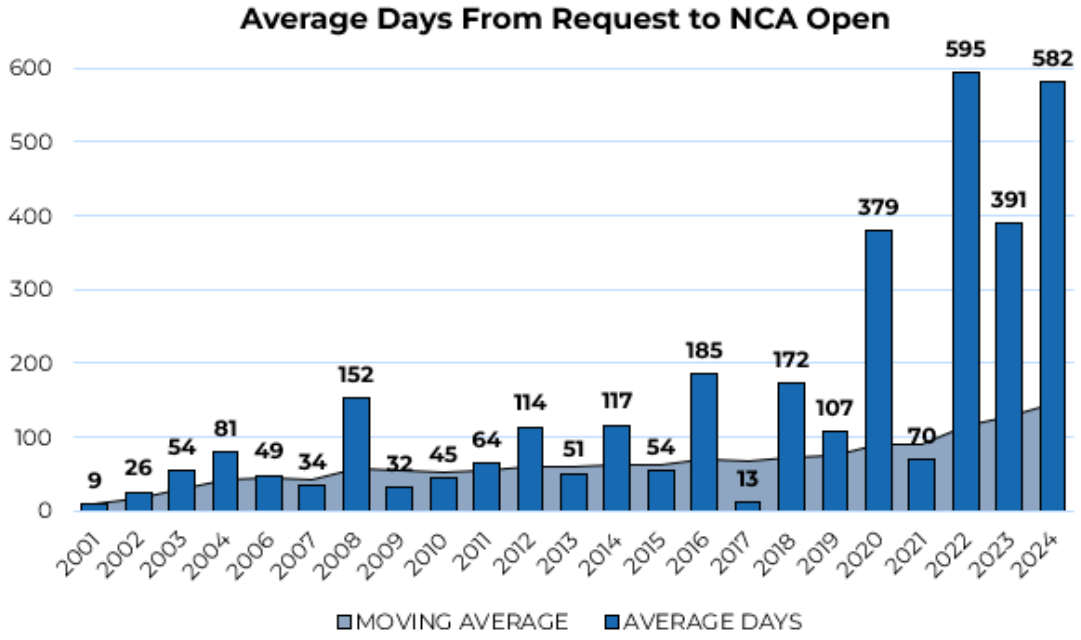
Effective for dates of service on or after January 19, 2021, a blood-based biomarker test is covered as an appropriate colorectal cancer screening test once every 3 years for Medicare beneficiaries when performed in a Clinical Laboratory Improvement Act (CLIA)-certified laboratory, when ordered by a treating physician and when all of the following requirements are met:

A strict reading of this policy would therefore imply that alternative multi-target stool DNA (sDNA) tests – such as Cologuard Plus™ – are ***not*** covered. Indeed, the fact that the AMA has created two distinct billing codes for these products [Cologuard (Legacy): 81528, Cologuard Plus: 0464U] effectively implies that the two should not be viewed / described as interchangeable. That sentiment would also appear to be reflected in the current list of NCD-covered billing codes, which includes both the legacy code (81528) and generic blood-based biomarker code (G0327), but ***not*** the Cologuard Plus code (0464U).

In our view it is a question of when – not if – CMS will eventually cover Cologuard Plus, but we have been unable to identify any notification from the agency to its MACs that specifically directs such actions, and suspect that the overly specific NCD language will likely need to be changed to provide greater clarity.

To that point, CMS has already accepted a formal NCD reconsideration request from **Geneoscopy (private)** following FDA approval of its own *RNA*-based ColoSense test, though a formal initiation of the review – starting a 9-10 month process – has been delayed due to insufficient staff capacity, and it remains on the NCD Wait List.

It is therefore unclear when the agency might be able to address the matter, but we would note that the average time between an NCD request being submitted and the initiation of a review has been steadily increasing in recent years, with the five-year average now at nearly 15 months.



Source: CMS, Capitol Policy Partners

With CMS indicating in its recent CY25 Physician Fee Schedule that the CRC screening reconsideration request was accepted "in June 2024," this would imply a formal *opening* of the analysis in 2H25, with the review itself likely lasting until ~mid-2026.

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