

October 9, 2024

## Exact Sciences (EXAS): Rate Reversal Prospects

**Key Takeaways:** With FDA's early [approval](#) of **Exact Sciences' (EXAS)** Cologuard Plus last week coming on the heels of CMS's preliminary [rejection](#) of EXAS's requested 25% rate increase (\$636) relative to the legacy product (\$509), we see low odds of reversal in the final rate decision due mid-November. Commercial payers may therefore also balk at this valuation. However, FDA approval likely entitles EXAS to Advanced Diagnostic Laboratory Test (ADLT) status, with Medicare reimbursement at the company's list price for an initial three quarters starting as early as 1Q25, before being reset at the commercial median.

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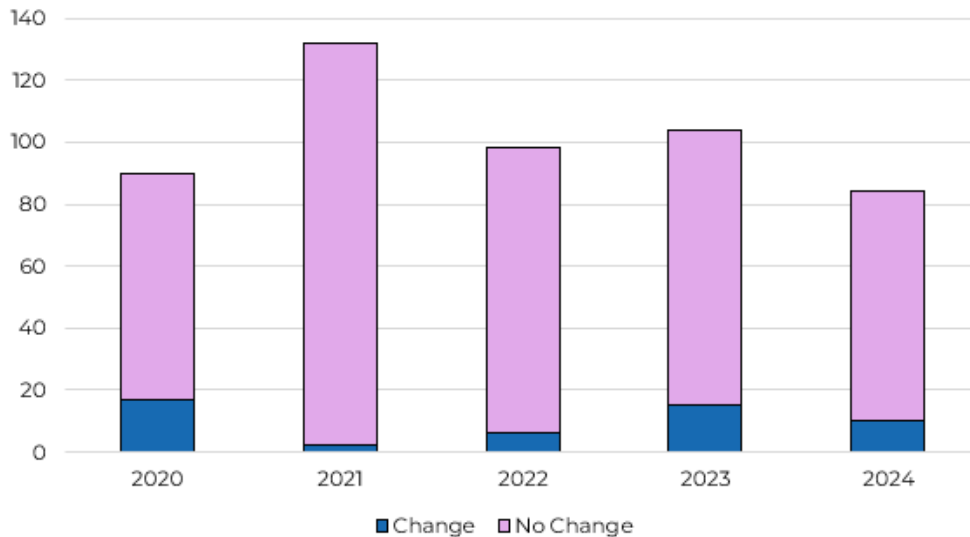
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### EXACT Sciences Corporation (EXAS)

<b>Price:</b>	\$69.25
<b>52-Week High:</b>	\$79.62
<b>52-Week Low:</b>	\$40.62

### CMS Changing Its Mind: Proposed vs Final



Source: Capitol Policy Partners

- A review of CMS rate determinations over the last five years (2020-2024) shows that – in aggregate – the agency has reversed just 10% of preliminary decisions.
- So-called “fractional” rate recommendations such as these [e.g., legacy Cologuard (\$509) x 1.25 x \$636] are themselves very rare, representing just 4% [N = 22] of the 508 total payment applications CMS has reviewed since 2020.
- Of those 22 fractional payments endorsed by the [Clinical Laboratory Fee Schedule \(CLFS\) Advisory Panel](#), CMS has agreed to just four (18%), all of which were included in the preliminary decisions, with *none* involving a change for the final rate release.
- In this particular case, we also note that the Advisory Panel did *not* actually recommend a 25% premium, which was rather the opinion of a minority (4/9) of panel members, with the majority (5/9) having endorsed a straight 1.0 crosswalk to the legacy test valuation (i.e., \$509). It was this majority opinion with which the agency's preliminary decision agreed.

- Recall also that reimbursement decisions are ultimately driven by an assessment of the marginal resource costs associated with performing any given test, and with EXAS having publicly acknowledged in June that “the unit cost of Cologuard Plus is **lower** than existing Cologuard by about 5%,” the prospects for an atypical reversal in November, arriving at a still more atypical fractional conclusion, would appear slim.

### ADLT Timing & Reimbursement

Notwithstanding this lack of formal CMS endorsement, FDA approval of Cologuard Plus should make the test eligible for ADLT status, and therefore payment at whichever list price EXAS selects for at least three quarters following that designation. This earlier- than-anticipated approval should allow the company to submit its ADLT request during the current application window, implying a decision in mid-December and the payment rate taking effect Jan. 1. A worst-case scenario would likely be a delay to April 1.

#### ADLT REVIEW CYCLES

REQUEST	DECISION	ADLT PERIOD
Oct 1 to Oct 31	Dec 1 to Dec 31	Jan 1 to Sept 30
Jan 1 to Jan 31	Mar 1 to Mar 31	Apr 1 to Dec 31
Apr 1 to Apr 30	June 1 to June 30	July 1 to Mar 31
July 1 to July 31	Sep 1 to Sep 30	Oct 1 to June 30

Source: CMS

Recall that agency [guidance](#) specifies that reimbursement for such tests is to be set at the “actual list charge” / “publicly available rate,” defined below:

- Actual List Charge:** The **publicly available rate** on the first day a new ADLT is obtainable by a patient who is covered by private insurance, or marketed to the public as a test a patient can receive, even if the test has not yet been performed.
- Publicly Available Rate:** The lowest amount charged for the ADLT that is readily accessible in such forums as a **company website, test registry, or price listing**, to anyone seeking to know how much a patient who does not have the benefit of a negotiated rate would pay for the test.

This means that, should EXAS establish a cash price of \$636 (i.e., \$509 x 1.25) at launch, that will serve as the Medicare payment rate as well before resetting at the end of three quarters – and annually thereafter – “based on the weighted median of private payer rates.” The durability of this ADLT rate will therefore depend on the extent to which private insurers push back against any Cologuard Plus premium, but we note that most [prior ADLTs](#) have seen Medicare rate stability long after those initial three quarters expire, as shown in the table below.

COMPANY	TEST	START	END	ADLT RATE	YEARS POST-ADLT	3Q24 RATE	%Δ ADLT RATE
Castle Bios.	DecisionDx-SCC	Jul 1, 2023	Mar 31, 2024	\$8,500	0.5	\$8,500	0%
Prelude Corp	DCISion RT	Apr 1, 2023	Dec 31, 2023	\$5,435	0.8	\$5,435	0%
Castle Bios.	TissueCypher	Apr 1, 2022	Dec 31, 2022	\$2,350	1.8	\$4,950	111%
Natera	Signatera	Jul 1, 2021	Mar 31, 2022	\$3,500	2.5	\$3,590	3%
Guardant Health	Guardant360 CDx	Apr 1, 2021	Dec 31, 2021	\$5,000	2.8	\$5,000	0%
Roche	FICDx (Liquid)	Apr 1, 2021	Dec 31, 2021	\$3,500	2.8	\$3,500	0%
Veracyte	Envisia	Oct 1, 2020	Jun 30, 2021	\$5,500	3.3	\$5,500	0%
Myriad Genetics	myChoice CDx	Jan 1, 2020	Sep 30, 2020	\$4,040	4.0	\$3,030	-25%
Castle Bios.	MyPath Melan.	Oct 1, 2019	Jul 30, 2020	\$1,950	4.2	\$1,950	0%
Biodesix	BDX-XL2	Jul 1, 2019	Mar 31, 2020	\$3,520	4.5	\$3,520	0%
Castle Bios.	DecisionDx-Melan.	Jul 1, 2019	Mar 31, 2020	\$7,193	4.5	\$7,193	0%
Roche	FICDx	Jul 1, 2018	Mar 31, 2019	\$3,500	5.5	\$3,500	0%

Source: Capitol Policy Partners

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