January 21, 2025

Guardant (GH) Reveal Medicare Coverage FAQ

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

Guardant Health Inc (GH)

Price:	$43.37
52-Week High:	$39.29
52-Week Low:	$15.81

Following **GH's** announcement this AM of Medicare coverage of its tissue-naïve Reveal test for minimal residual disease (MRD) *surveillance* testing, we wanted to highlight some additional salient points omitted from the company's press release. The below FAQ addresses: (1) the payment rate ($1,644), which is on the lower-end of other covered MRD tests [e.g., **NTRA's** Signatera ($3,920)], but roughly consistent with that of other tissue-naïve offerings [e.g., privately-held Naveris' NavDx ($1,800)]; (2) prospects for rate upside through CMS designation as an Advanced Diagnostic Laboratory Test (ADLT); (3) the likely testing interval to be covered; and (4) where investors can find the relevant information.

When Will the Medicare MolDx Medicare Administrative Contractors (MACs) Incorporate Reveal Surveillance Into Their Coverage Policies?

Astute investors will observe that, GH's press release notwithstanding, the billing and coding articles from the MAC with jurisdiction over the company's Redwood City, CA lab (Noridian) – as well as those of other MACs in the coordinated MolDx program (Palmetto, WPS, CGS) – does not yet reflect coverage of Reveal *surveillance* MRD testing (i.e., "PATIENTS WITHOUT CANCER"). Instead, each only establishes that the test is only covered for post-surgical use (i.e., "PATIENTS WITH CANCER"), which has been the case since early 2024.

The following tests have met the criteria for coverage under the policy:

INTENDED USE	TEST
INITIAL TEST	
Where Tumor Profiling is Utilized - From a Prior Analysis	▪ Signatera Bespoke Assay Design [by comprehensive genomic profile (CGP)] + Plasma Series Bundle for Molecular Residual Disease (Natera, Inc.)
Where Tumor Profiling is Utilized	▪ Signatera Whole Exome + Plasma Series Bundle for Molecular Residual Disease (Natera, Inc.) ▪ RaDaR Whole Exome + Plasma Series Bundle for Molecular Residual Disease (NeoGenomics Laboratories, Inc.)
Tumor Naïve Testing	▪ Guardant Reveal MRD Bundle (Guardant, Inc.)
SUBSEQUENT TEST	
May Only Be Performed if There is Clinical Evidence of a priori Change in Genetic Content	▪ Signatera Recurrence Monitoring Plasma Test Bundle (Natera, Inc.)
PATIENTS WITHOUT CANCER	
Where Tumor Profiling is Utilized - From a Prior Analysis	▪ Signatera Recurrence Monitoring Bespoke Assay Design (CGP) + Single Plasma Test (Natera, Inc.)
Where Tumor Profiling is Utilized	▪ Signatera Recurrence Monitoring Whole Exome Design + Single Plasma Test (Natera, Inc.) ▪ RaDaR Recurrence Monitoring Whole Exome Design + Single Plasma Test (NeoGenomics Laboratories, Inc.)
SUBSEQUENT TEST	
Subsequent Test	▪ Signatera Recurrence Monitoring Single Plasma Test (Natera, Inc,) ▪ RaDaR Recurrence Monitoring Single Plasma Test (NeoGenomics Laboratories, Inc.)
TUMOR NAÏVE TESTING	
Where a Baseline Tumor Profiling is Not Utilized	NavDX (Naveris, Inc.) Single Plasma Test

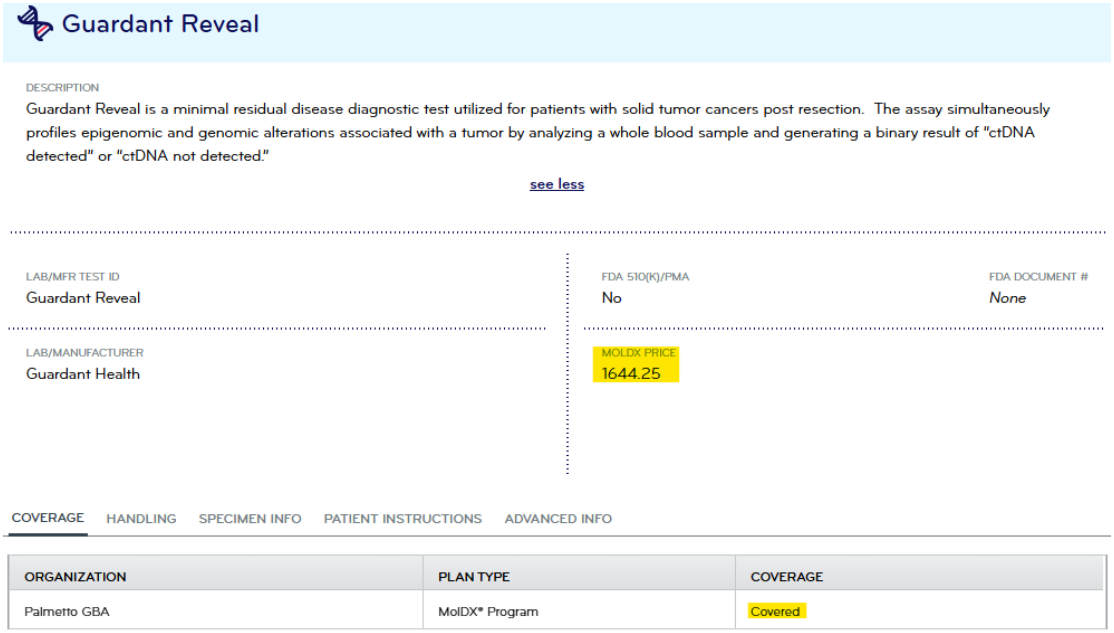
Source: Noridian Billing & Coding Article A58456 – Minimal Residual Disease Testing for Solid Tumor Cancers

We would nevertheless expect these billing articles to be updated shortly, with such publications typically posted here on Thursday mornings. Investors should therefore be looking for Guardant Reveal to be newly included under the "TUMOR NAÏVE TESTING" section within the "PATIENTS WITHOUT CANCER" grouping shown above, which is how the table currently appears (Jan. 21).

We should note, however, that it is not atypical for one or more of the MolDx MACs to update their coverage policies ahead of the others. With GH's disclosure this morning referring only to coverage from "Palmetto GBA," that may be the case here as well. That said, all of the MolDx MACs coordinate their actions, so we would expect any delay from Noridian to last no more than several weeks.

Is There a Way to Confirm Coverage in the Interim, and When Will We Know the Payment Rate?

Coverage confirmation can be found in the MolDx DEX Diagnostics Exchange Registry, which newly lists the Guardant Reveal test as "covered," along with a reimbursement rate of $1,644.25. Previously, this page had only listed coverage of the Guardant Reveal CRC Post-Surgery MRD Bundle, consistent with the coverage policy above, with a payment rate of $4,933.



Guardant Reveal

DESCRIPTION

Guardant Reveal is a minimal residual disease diagnostic test utilized for patients with solid tumor cancers post resection. The assay simultaneously profiles epigenomic and genomic alterations associated with a tumor by analyzing a whole blood sample and generating a binary result of "ctDNA detected" or "ctDNA not detected."

see less

LAB/MFR TEST ID
Guardant Reveal

FDA 510(K)/PMA
No

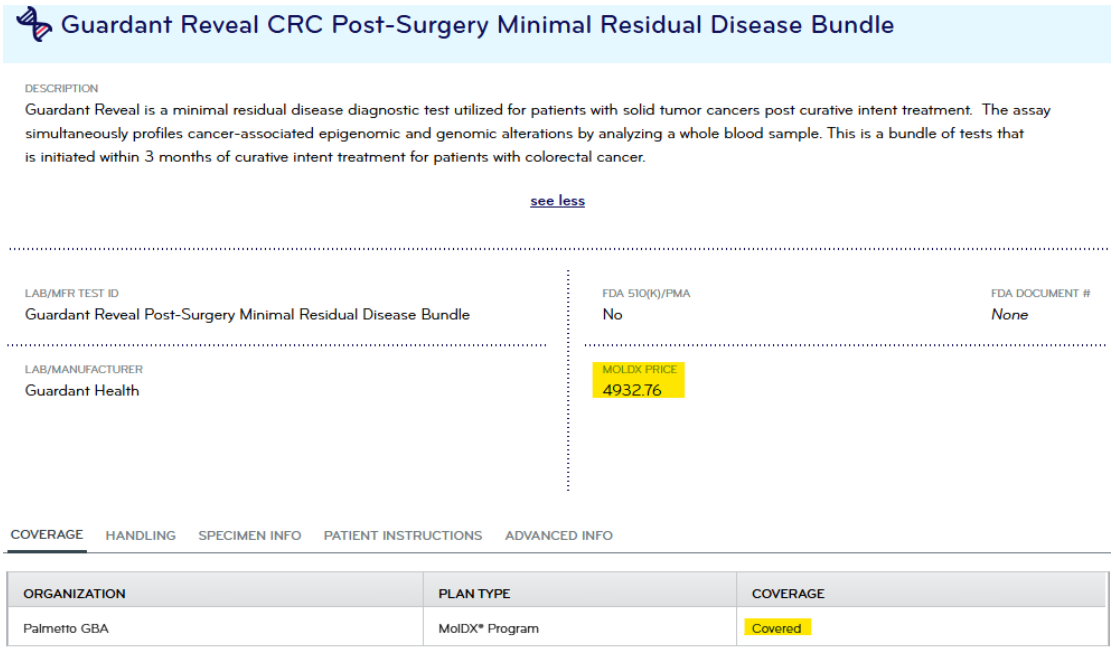
FDA DOCUMENT #
None

LAB/MANUFACTURER
Guardant Health

MOLDX PRICE
1644.25

COVERAGE | HANDLING | SPECIMEN INFO | PATIENT INSTRUCTIONS | ADVANCED INFO

ORGANIZATION	PLAN TYPE	COVERAGE
Palmetto GBA	MolDX® Program	Covered



Guardant Reveal CRC Post-Surgery Minimal Residual Disease Bundle

DESCRIPTION

Guardant Reveal is a minimal residual disease diagnostic test utilized for patients with solid tumor cancers post curative intent treatment. The assay simultaneously profiles cancer-associated epigenomic and genomic alterations by analyzing a whole blood sample. This is a bundle of tests that is initiated within 3 months of curative intent treatment for patients with colorectal cancer.

see less

LAB/MFR TEST ID
Guardant Reveal Post-Surgery Minimal Residual Disease Bundle

FDA 510(K)/PMA
No

FDA DOCUMENT #
None

LAB/MANUFACTURER
Guardant Health

MOLDX PRICE
4932.76

COVERAGE | HANDLING | SPECIMEN INFO | PATIENT INSTRUCTIONS | ADVANCED INFO

ORGANIZATION	PLAN TYPE	COVERAGE
Palmetto GBA	MolDX® Program	Covered

While $1,644 is on the lower end of the listed payment rates for covered MRD tests – which range from $1,589 (Signatera Breast – Plasma Series Bundle) to $7,489 (Signatera IO Monitoring – Tumor / Normal Sequencing), it is also roughly equivalent to the only other tissue-naïve offering that MolDx covers, with a rate of $1,800 for Naveris' NavDx. We should note, however, that NavDx is only indicated for HPV-driven oropharyngeal cancers, rather than CRC.

COVERED TESTS	COMPANY	MOLDX PRICE
Signatera - Single Plasma Test	Natera	$3,920
Signatera Breast - Bespoke Assay Design from CGP Sequencing & Initial Plasma Test	Natera	$2,098
Signatera Breast - Bespoke Assay Design from CGP Sequencing & Plasma Series Bundle	Natera	$2,893
Signatera Breast - Plasma Series Bundle	Natera	$1,589
Signatera Breast - Tumor/Normal Sequencing, Bespoke Assay Design, & Initial Plasma Test	Natera	$3,878
Signatera Breast - Tumor/Normal Sequencing, Bespoke Assay Design, & Plasma Series Bundle	Natera	$4,673
Signatera CRC/MIBC - Bespoke Assay Design from CGP Sequencing & Initial Plasma Test	Natera	$2,098
Signatera CRC/MIBC - Bespoke Assay Design from CGP Sequencing & Plasma Series Bundle	Natera	$4,118
Signatera CRC/MIBC - Plasma Series Bundle	Natera	$3,178
Signatera CRC/MIBC - Tumor/Normal Sequencing, Bespoke Assay Design, & Initial Plasma Test	Natera	$3,878
Signatera CRC/MIBC - Tumor/Normal Sequencing, Bespoke Assay Design, & Plasma Series Bundle	Natera	$5,898
Signatera IO Monitoring - Bespoke Assay Design from CGP Sequencing & Plasma Series Bundle	Natera	$5,709
Signatera IO Monitoring - Plasma Series Bundle	Natera	$4,769
Signatera IO Monitoring - Tumor/Normal Sequencing, Bespoke Assay Design, & Plasma Bundle	Natera	$7,489
Signatera Ovarian - Bespoke Assay Design from CGP Sequencing & Initial Plasma Test	Natera	$2,098
Signatera Ovarian - Bespoke Assay Design from CGP Sequencing & Plasma Series Bundle	Natera	$2,893
Signatera Ovarian - Plasma Series Bundle	Natera	$1,589
NavDx (Oropharyngeal) - MA	Naveris	$1,800

Source: MolDx DEX Registry

Is There Room for Upside in This Payment Rate?

Potentially, though we lean against it.

GH has previously discussed the possibility of CMS granting Reveal ADLT status, which would entitle it to three quarters of reimbursement at the company-set list price. While it is unclear to us exactly what that is, we would highlight a boilerplate Advance Beneficiary Notice of Non-Coverage (ABN) provided by GH [*see here*] – which patients are asked to sign when the test they are receiving may not be covered, acknowledging that they may need to pay out-of-pocket – that cites potential beneficiary costs of "no more than $5,000" for Reveal. It is certainly possible that this is referring only to the post-CRC surgery bundle, but this and the other MRD testing rates listed above suggest there is likely room for upside through any ADLT designation.

The reason we have remained cautious on that possibility, however, is largely as follows:

- CMS guidance on the issue states that any ADLT must "provide **new clinical diagnostic information** that cannot be obtained from any other test **or combination of tests**."
- The agency could therefore conclude that the **"clinical diagnostic information"** from Reveal could already be gleaned from NTRA's Signatera, even if the Reveal *methodology* is distinct by virtue of its being tissue-naïve."
- By way of example, Signatera itself was granted ADLT status in July 2021, but following MolDx coverage of post-CRC surgery coverage for Reveal in January 2024, it has not yet received the same distinction, despite the fact that CMS reviews ADLT applications on a quarterly basis.
- If we are incorrect, however, the argument from GH would likely need to be that Reveal surveillance testing via a single plasma test provides new clinical diagnostic information beyond what Signatera can offer, or perhaps that tissue sampling may not be viable for all patients, and Reveal therefore addresses an alternative patient population.
- While it's certainly true that a tissue-naïve approach represents a more convenient methodology for patients, and is therefore a *competitive* advantage, it does not *necessarily* follow that it provides *new* information that cannot otherwise be had from "any other test or combination of tests."
- Should CMS reach that conclusion, however, the earliest we would likely hear would be ~mid-March or ~mid-June, consistent with CMS's ADLT review schedule.

ADLT APPLICATION TIMELINE

QUARTER	REQUEST	CMS REVIEW	NOTIFICATION	ADLT PERIOD
Q1	Jan. 1 to Jan. 31	Feb. 1 to Feb. 28	Mar. 1 to Mar. 31	Apr. 1 to Dec. 31
Q2	Apr. 1 to Apr. 30	May 1 to May 30	June 1 to June 30	July 1 to Mar. 31
Q3	July 1 to July 31	Aug. 1 to Aug. 31	Sept. 1 to Sept. 30	Oct. 1 to June 30
Q4	Oct. 1 to Oct. 31	Nov. 1 to Nov. 30	Dec. 1 to Dec. 31	Jan. 1 to Sept. 30

CMS Guidance for Laboratories on ADLTs

Do We Know the Likely Cadence / Interval of Covered Surveillance Testing?

The Medicare coverage policy itself merely references coverage "according to testing scheduled outlined in national (i.e., NCCN) or society guidelines." However, per disclosures from both GH and NTRA, this has equated to once every six months beginning 24 months after curative-intent treatment.

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