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June 9, 2024

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Via ECF

Jarrett B. Perlow, Clerk of the Court
Office of the Clerk, U.S. Court of Appeals for the Federal Circuit
717 Madison Place, NW
Washington, DC 20439

Re: *Natera, Inc. v. NeoGenomics Laboratories, Inc.*, Nos. 24-1324, -1409
(oral argument held March 29, 2024; Moore, C.J., Taranto, Chen, JJ.)
Rule 28(j) Letter: New Medicare approval

Dear Mr. Perlow:

On June 6, 2024, NeoGenomics's RaDaR received approval for Medicare reimbursement in a new indication: HPV-negative head and neck squamous cell cancer. Ex.1. The approval is based on RaDaR's having met coverage requirements for the additional indication from the Centers for Medicare & Medicaid Services' Molecular Diagnostics Service Program (MolDX) and is effective for RaDaR testing since March 20, 2024. *Id.*

This approval further confirms the grave public harm caused by the preliminary injunction. At oral argument, the Court asked whether patients are being deprived of using a test for which Signatera is not a substitute. Arg.Audio(40:20-41:10). As NeoGenomics's opening brief explained, and Natera never contested, RaDaR was and is being considered for Medicare coverage for cancers beyond those for which Signatera is currently covered. Neo.Br.51. MolDX's approval makes RaDaR the first and only Medicare-approved tumor-informed MRD assay for the identified cancer. Neo.Br.51; Ex.1; Appx911 (Natera explaining no other tumor-informed test has Medicare approval). The approval thus adds to the direct patient harm threatened and actually being caused by the injunction: patients with the specified head-and-neck cancer cannot obtain Medicare reimbursement for any tumor-informed

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MRD assay, even though testing after March 20, 2024 could now be reimbursed, absent the injunction. According to Natera itself, that effectively takes such testing off the table for many patients: “reimbursement through Medicare is crucial because otherwise these tests would be quite substantial” and “the demographic that is susceptible to cancer skews older.” Appx20367. Nor is this likely to be the only cancer for which RaDaR is the only Medicare-approved tumor-informed test—NeoGenomics also identified lung cancer as another for which RaDaR is being considered for Medicare approval and Signatera is not (at least as of briefing). Neo.Br.51.

As NeoGenomics previously explained, these harms flow from the differentiated nature of these tests. Neo.Reply.33. Regardless of Natera’s infringement allegations, it is undisputed that RaDaR and Signatera work differently, including because RaDaR targets up to 48 tumor-specific variants and Signatera identifies merely 16. Neo.Reply.25. Patients should not be deprived medical access to such differentiated treatment without a far more compelling showing than the one Natera made here.

Respectfully submitted,

/s/ Deanne E. Maynard
Deanne E. Maynard

Nos. 24-1324, -1409

**UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT**

NATERA, INC.,

Plaintiff-Appellee,

v.

NEOGENOMICS LABORATORIES, INC.,

Defendant-Appellant.

Appeals from the United States District Court for the Middle District of North
Carolina, No. 1:23-cv-00629; Hon. Catherine C. Eagles

**DECLARATION OF DEANNE E. MAYNARD IN SUPPORT OF
NEOGENOMICS LABORATORIES, INC.'S 28(j) LETTER**

I, Deanne E. Maynard, declare under penalty of perjury under 28 U.S.C.

§ 1746:

1. I am an attorney duly licensed to practice law in the District of Columbia and the state of Virginia, and I am admitted to practice before this Court. I am a partner with the law firm of Morrison & Foerster LLP, and counsel of record for appellant NeoGenomics Laboratories, Inc. in this appeal. I make this declaration in support of NeoGenomics's 28(j) letter.

2. Attached as Exhibit 1 is a true and correct copy of the coverage approval NeoGenomics received from administrative contractor Palmetto GBA, which the record explains oversees the Centers for Medicare & Medicaid Services'

Molecular Diagnostic Services Program (MolDX). *See* Appx883 (describing Palmetto); Appx2438-2439 (explaining that contractors grant approvals).

Executed on this 9th day of June, 2024.

/s/ Deanne E. Maynard

Deanne E. Maynard

EXHIBIT 1

June 6, 2024

The Technical Assessment (TA) documentation for the test listed below has been reviewed by MolDX®. Please see table below for details.

DEX Z-Code®	For patients with cancer: Z03LM: RaDaR HNSCC: Molecular Residual Disease Detection Assay-Whole Exome Design and Personalized MRD Plasma Test Bundle For patients with a personal history of cancer: Z03LN: RaDaR HNSCC: Molecular Residual Disease Detection Assay – Whole Exome Design and Personalized MRD Plasma Test Z03LK: RaDaR HNSCC: Molecular Residual Disease Detection Assay – Personalized MRD Plasma Test
Test Name	RaDaR for HPV-negative head and neck squamous cell cancer (HNSCC)
Recommended CPT® Code	81479
Technical Assessment Result	Successful
MolDX Price	For patients with cancer: Z03LM: RaDaR HNSCC: Molecular Residual Disease Detection Assay-Whole Exome Design and Personalized MRD Plasma Test Bundle (2 time points): \$4672.45 For patients with a personal history of cancer: Z03LN: RaDaR HNSCC: Molecular Residual Disease Detection Assay – Whole Exome Design and Personalized MRD Plasma Test: \$3878.45 Z03LK: RaDaR HNSCC: Molecular Residual Disease Detection Assay – Personalized MRD Plasma Test: \$794.00.
Effective Date	3/20/2024
Review Notes	In order for a service to be covered by Medicare, the test must demonstrate Analytical Validity (AV), Clinical Validity (CV) and Clinical Utility (CU) in accordance with the policy under which the laboratory is seeking coverage. For Z-Codes listed above,

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	the reviewer has found that this test has met the criteria for coverage under L38779. This test has met criteria for the following intended use(s): 1. Patients with advanced stage II-IV HPV-negative head and neck squamous cell cancer (HNSCC) in the adjuvant setting. Note that the number of informative timepoints in the adjuvant setting is 2. <i>Relevant Z-code:</i> Z03LM Whole Exome Design + 2 plasma timepoints in a personalized MRD plasma test bundle. 2. For the surveillance of recurrence in patients with a personal history of advanced stage II-IV HPV-negative HNSCC, according to the following: • Not more often than every three months for the first 24 months, • Not more often than every six months between months 25 and 60, • Not more often than annually thereafter. Until if and when a positive test result is detected. <i>Relevant Z-codes:</i> Z03LN: RaDaR HNSCC: Molecular Residual Disease Detection Assay – Whole Exome Design and Personalized MRD Plasma Test Z03LK: RaDaR HNSCC: Molecular Residual Disease Detection Assay – Personalized MRD Plasma Test
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Your test will be updated in the DEX® Diagnostics Exchange Registry and an automated email notification will be sent at that time. Please contact us with any questions.

Best regards,

MoIDX®

MoIDX@PalmettoGBA.com



Ver. 2, Rev. 7/31/2023

CERTIFICATE OF COMPLIANCE

This letter complies with the type-volume limitation of Federal Rule of Appellate Procedure 28(j) because the body of the letter contains 350 words.

Dated: June 9, 2024

/s/ Deanne E. Maynard
Deanne E. Maynard

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