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Supplemental online content for:

Private Payer and Medicare Coverage Policies for Use of Circulating Tumor DNA Tests in Cancer Diagnostics and Treatment

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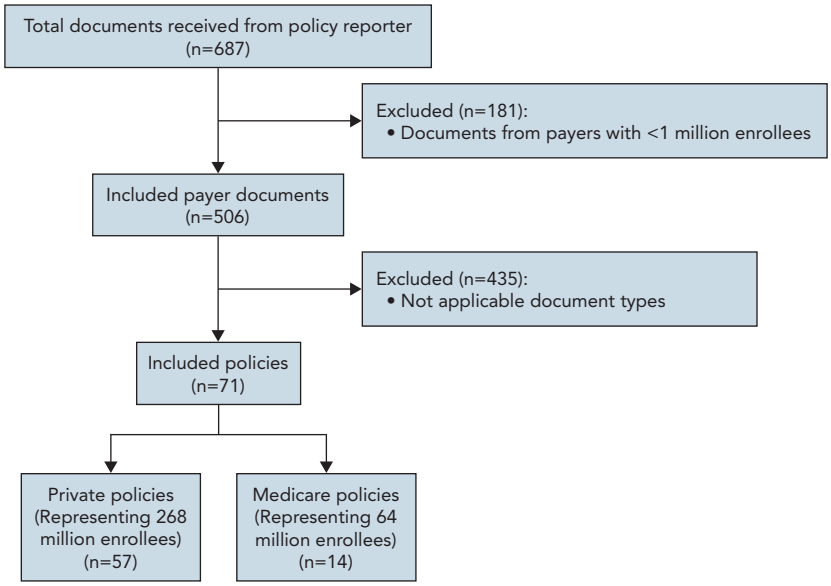

eFigure 1. PRISMA diagram.

eTable 1. Variables Coded for Private and Medicare Policies

Variable Name	Variable Definition	Variable Details/Coding[a]
Policy unique ID	Automatic unique number	Fill down sequentially
Payer name	Payer full name	(eg, Aetna)
Payer type	Private or public	Private or public
Policy title	Official name of policy	(copy from Policy Source Information table)
Policy from third party?	Was this policy adapted by the payer from a third party (eg, eviCore)?	Yes (note third party)/No
Policy date (effective date)	Date of policy	(MM/DD/YYYY)
Policy exists (screening variable, additional variables are not coded if no policy exists; lack of policy does not equate to a negative policy)	Yes/No	Yes/No
Coverage	Yes/No	Yes/No
Noncoverage	Reason stated for noncoverage, if provided/applicable	Copy/Paste from policy
Covered clinical scenario	For which clinical indications is ctDNA considered medically necessary (eg, for all solid tumors, for advanced lung cancer)?	Copy/Paste from policy
Prior authorization	Yes/No	Yes/No
Prior authorization details	Specific details of prior authorization requirements	Copy/Paste from policy
Evidence cited and study type	Evidence cited that support or refute the coverage or lack of coverage, and the study type	Copy/Paste from policy
Cancers included	Covered cancers (eg, lung cancer, pan-cancer, solid tumors)	Copy/Paste from policy
How ctDNA testing is covered	Policy covers any liquid biopsy testing or specific named tests	Copy/Paste from policy
How monitoring is covered	Policy covers any liquid biopsy testing for monitoring	Copy/Paste from policy
How MRD testing is covered	Policy covers any liquid biopsy testing for MRD	Copy/Paste from policy

Abbreviations: ctDNA, circulating tumor DNA; MRD, minimal residual disease.
[a]For variables that were copy/paste, we subsequently coded these into discrete categories for counting purposes.

eAppendix 1. Definitions

Initial treatment selection: Sequencing of circulating tumor DNA (ctDNA) to inform and select targeted therapy.

Progression: Identify mechanisms of therapeutic resistance in nonresponders or at time of progression.

Minimal residual disease (MRD): Measure presence of ctDNA as an indicator for tumors that may not be detected using conventional methods (eg, imaging) after completion of treatment (eg, surgery). This may also be called molecular residual disease.

Medicare policies are consistently recorded and available to the public on the Centers for Medicare & Medicaid Services (CMS) website. The website has both draft and final versions, along with public comments.

Medicare National Coverage Determinations (NCDs) are developed and issued by CMS and coverage decisions apply to all 50 states and Puerto Rico. When it comes to molecular testing, Medicare will commonly not issue a NCD but defer to the individual Local Coverage Determinations (LCDs).

Medicare LCDs are developed and issued by ≥1 of 7 Medicare Administrative Contractors (MACs). These LCDs apply only to the states in which the test or service was performed. Of the 7 MACs, 4 routinely issue LCDs for molecular tests. These LCDs have previously been written to address individual tests (eg, Guardant360) but also need to be written to address a category of testing (eg, minimal residual disease).

MAC jurisdictions—represented with policies in this study (28 states)

Noridian covers California, Nevada, Hawaii, Washington, Oregon, Idaho, Montana, Wyoming, North Dakota, South Dakota, Utah, Arizona, Alaska.

Palmetto covers Georgia, Alabama, Tennessee, South Carolina, North Carolina, Virginia, West Virginia.

WPS covers Michigan, Indiana, Nebraska, Iowa, Missouri, Kansas.

CGS covers Ohio, Kentucky.

MAC jurisdictions—not represented with policies in this study (22 states and Puerto Rico)

Novitas covers Pennsylvania, New Jersey, Maryland, Delaware, Colorado, New Mexico, Texas, Oklahoma, Arkansas, Louisiana, Mississippi.

NGS covers New York, Vermont, New Hampshire, Massachusetts, Connecticut, Rhode Island, Maine, Wisconsin, Minnesota, Illinois.

FCSO covers Florida, Puerto Rico.

Cell-free DNA (cfDNA) are degraded DNA fragments released to the blood plasma. cfDNA can be used to describe various forms of DNA freely circulating the bloodstream, including circulating tumor DNA (ctDNA) and cell-free fetal DNA (cffDNA). Elevated levels of cfDNA are observed in cancer, especially in advanced disease.

Circulating tumor DNA (ctDNA) is tumor-derived fragmented DNA in the bloodstream that is not associated with cells. ctDNA should not be confused with cell-free DNA (cfDNA), a broader term that describes DNA that is freely circulating in the bloodstream but is not necessarily of tumor origin. ctDNA originates directly from the tumor or from circulating tumor cells (CTCs). Because ctDNA may reflect the entire tumor genome, it has gained traction for its potential clinical utility; "liquid biopsies" in the form of blood draws may be taken at various time points to monitor tumor progression throughout the treatment regimen.

Circulating tumor cells (CTCs) are whole tumor cells shed into the vasculature from a primary tumor and are carried around the body in the blood. CTCs may constitute seeds for subsequent growth of additional tumors (metastasis) in distant organs, a mechanism that is responsible for most cancer-related deaths. We do not examine coverage policies for CTC testing in this study.

eAppendix 2. Policy Reporter

Policy Reporter, a TrialCard company, provides innovative healthcare software solutions to track payer policies in near real time and enhances market access for the therapies patients need most. The company's patented software-driven solutions include a suite of billing and reimbursement tools for providers and laboratories, market intelligence tools for payers, and a suite of market access solutions for life science companies.

Policy Reporter includes policies from 1,066 payers offering government, commercial, public, public employees, international, and undefined types of products. Some payers offer multiple types of products (eg, government [Managed Medicare, Medicaid], and commercial).

Policy Reporter Covered Lives data are calculated using a proprietary methodology utilizing multiple sources of information from a plan's self-reported data. This includes annual/quarterly reports, press releases, US Securities and Exchange Commission (SEC) filings, National Association of Insurance Commissioners (NAIC) reported data, and Centers for Medicare & Medicaid Services (CMS) data with permissions/licenses. Figures have been validated using multiple sources when available. Any conclusions or analyses are not endorsed by entities of original or commingled data sources. Specifically, but not exclusively, CMS, the NAIC, the SEC, or any other third party is not liable whatsoever for the data contained within this file or your use of the data. The third parties have not endorsed the data and they are not responsible for its contents in any way.