Novel Approach Using Administrative Claims to Evaluate Trends in Oncology Multigene Panel Testing for Patients Enrolled in Medicare Advantage Health Plans

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PURPOSE To develop an approach to identify and evaluate recent use of multigene panel testing over time.

METHODS We conducted a retrospective database analysis using medical and pharmacy claims data. Medicare Advantage Prescription Drug Plan members diagnosed with select malignant solid tumors were identified. The pattern of somatic genetic testing for each patient was evaluated from January 2016 through December 2018. Tests were classified by the number of genes tested in the panel: < 50 (small or medium) and ≥ 50 (large).

RESULTS An initial feasibility study using our novel approach for identifying panel tests resulted in 2.4 and 1.2 times more large and medium panels, respectively, identified compared with using procedure codes alone. A total of 121,675 eligible patients were identified, with 131,915 unique cancer cases. Overall, 5,457 (4.5%) patients received any panel test from 2016 to 2018. We found the number of tests performed each quarter increased from 238 in Q1 of 2016 to 755 in Q4 of 2018. The highest number of cases were genitourinary cancers; however, the highest proportion of cancer-related genetic testing was among patients with respiratory cancer. Across all tumor types, the proportion of large-panel tests performed as a function of all multigene panel tests increased from 20.7% of tests in Q1 of 2016 to 46.4% of tests in Q4 of 2018. The three cancer categories with the highest count of cancer-related panel tests, respiratory cancer, GI cancer, and female reproductive cancer, had a consistently greater proportion receiving a panel test at any point postindex.

CONCLUSION Across a variety of cancers, use of somatic, large-panel cancer-related genetic testing, as a proportion of all somatic cancer-related genetic testing, increased from 2016 to 2018, although testing overall was low.

INTRODUCTION

Precision medicine has been made possible by the development and availability of genetic biomarker–driven therapies.[1] A shift in precision medicine has occurred toward designing patient treatment plans based upon a specific tumor's genetic profile, rather than the tissue type.[2] This relatively new histology-agnostic biomarker design for advanced cancers, individualized for each patient, has been facilitated by the advent of next-generation sequencing (NGS) methodologies.

First introduced in 2005, NGS refers to the development of quicker and less complicated methods for sequencing DNA and has provided platforms for sequencing DNA in a high-throughput and cost-effective manner.[3,4] Development of this method has enabled the sequencing of thousands of genes simultaneously and has allowed for targeting of specific regions of interest in the genome in parallel through the use of gene panels, which provide less expensive, rapid, multigene panel testing (MGPT) for clinical applications.[5] Although this technology is used to identify both germline (ie, hereditary) and somatic (ie, tumor) mutations, somatic testing most often is used to identify eligibility for targeted therapies in advanced and metastatic cancers, which can provide improved outcomes for patients.[6]

In addition to patients, payers also have a vested interest in the use of somatic MGPT as they seek to improve population-based outcomes. An important tool for payers is the analysis of health care claims data since clinical records for each of their members may not be available.[7,8] Identification of genetic testing in administrative claims data presents its own challenges, including clinical use of nonspecific codes limiting identification of tests and lack of ability to discern clinical intent from claims data.[7] Although these issues present challenges to researchers, health care administrative claims data can be useful for evaluating specific items such as the use of genetic panel testing over time.

CONTEXT

Key Objective

Multigene panel testing (MGPT) can be used for patients with cancer to identify mutations appropriate for targeted therapies to improve outcomes. Identifying MGPT in health care claims to assess trends in testing and population health outcomes presents challenges such as lack of coding specificity and the variability in coding and billing. We developed an approach to identify and evaluate use of MGPT over time using claims data.

Knowledge Generated

An initial feasibility study of our approach resulted in identification of more panel tests compared with use of procedure codes alone. Across a variety of cancers, use of somatic, large-panel ($\geq$ 50 genes) cancer-related genetic testing, as a proportion of all somatic cancer-related genetic testing, increased from 2016 to 2018, although testing overall (4.5%) was low.

Relevance

Leveraging claims data to assess trends in genetic panel testing can aide in evaluating the impact of MGPT on treatment decision making and outcomes.

These data may be sourced from different payer types including commercial, Medicaid, and Medicare. Medicare beneficiaries, often $\geq$ 65 years of age, account for more than half of all new cancer cases despite representing only 14% of the US population,[8] and thus are ideal when examining oncology care trends. About one third of Medicare beneficiaries are enrolled in Medicare Advantage, which may provide additional benefits over traditional Medicare[9]; thus, this population is of particular interest in understanding the uptake of novel technologies such as MGPT.

To better understand the current use of MGPT among patients with cancer and develop a foundation to study how these trends may affect clinical outcomes, we developed an approach using health care claims data to evaluate the trends in somatic genetic testing panels over time.

METHODS

Design

This retrospective study used administrative claims data from the Humana Research Database, which includes medical and pharmacy claims, as well as enrollment data. Patients diagnosed with select malignant solid tumors were identified for this study, and the pattern of genetic testing for each patient was evaluated from January 2016 to December 2018. The full study period included dates of service from January 1, 2015 to December 31, 2018. Patient characteristics and utilization patterns of panel tests for identified patients were described.

Study Population

Patients were included in the study if they were $\geq$ 18 and < 90 years of age at index and were enrolled in a Medicare Advantage Prescription Drug (MAPD) plan (medical and pharmacy benefits) during the study time period with no more than a 30-day gap in coverage. Patients eligible for the study must have had $\geq$ 2 diagnoses of the same solid tumor cancer (genitourinary [bladder, renal, and prostate], respiratory [lung and bronchus],

dermatologic [melanoma], endocrine [thyroid], nervous system [brain and spinal cord], GI [colorectal, pancreas, stomach, small intestine, liver, gallbladder, and salivary], and female reproductive [uterus, ovarian, and breast], see the Data Supplement) on $\geq$ 2 separate claims within 7-90 days during the identification period. The index date was the date of each patient's first incident solid tumor cancer diagnosis within the identification period. The patients' incident cancer diagnosis could not have been preceded by a diagnosis for the same cancer in the identification period.

Development of Methodology to Identify Cancer-Related Panel Tests in Administrative Claims Data

In preparation for the trend analyses, methodology for identifying the most prevalent commercial somatic cancer-related panel tests in administrative claims was explored in a feasibility study. This method used a combination of current procedural terminology (CPT) codes and/or tax identification numbers (TINs) of companies performing known somatic cancer-related genetic testing.[10] The type of somatic (ie, tumor) cancer-related genetic testing patients received was classified by the number of genes tested in the panel (< 50 genes [small or medium] and $\geq$ 50 genes [large]).

Genetic tests were classified individually within each cancer type and within TINs. TINs of companies conducting known somatic NGS-specific panels included in the Centers for Medicare and Medicaid Services (CMS) national coverage determination, as well as those conducting other cancer-related large-panel tests, were identified during testing classification. Genetic tests considered germline by CPTs or companies producing only germline tests were excluded from the analysis. We defined each unique cancer genetic testing occurrence as a case, in addition to examining testing at the individual patient level for some analyses. Therefore, individual patients may be represented by more than one genetic testing case throughout the study period within select analyses.

A genetic testing case was defined as a logical grouping of all submitted claims, paid and unpaid, for a unique patient and identical, continuous or overlapping dates of service. Individual patients may have had ≥ 1 genetic testing case during the study period. A minimum of 3 days between genetic testing occurrences within a unique patient to differentiate between cases was required. The classification logic was developed to cover frequently observed code combinations used for billing genetic testing encounters, accounting for approximately > 75% of the genetic testing encounters (see the Data Supplement). Logic for the remaining genetic testing encounters consisted largely of unique code combinations observed individually at low frequency. The classification logic was guided by a certified genetic counselor.

Measures

Characteristics described for the patient population overall and by cancer category at index included age, sex, race, geographic location, and population density. Race was categorized on the basis of the classifications in CMS enrollment files. Patient geographic location, by region, was determined using the patient's resident state as of index. Population density was divided into four categories: rural, urban, suburban, or unknown.[11,12] The total number of cancer cases and patients and the number and proportion of patients with ≥ 1 test postindex were reported overall and across cancer categories. Furthermore, the total number of cancer-related genetic tests, the type of test (ie, small or medium and large), and the proportion of patients who received at least one test in each quarter were reported. The time to first cancer-related genetic test, the proportion of patients with > 1 cancer-related test postindex, and the proportion of patients receiving cancer-related genetic tests per quarter were reported for select cancer categories.

Analysis

Trends in testing were examined quarterly starting January 1, 2016 through December 31, 2018. Patients with cancer were identified and followed until death or disenrollment from the health plan. Use of genetic testing was examined during the follow-up period following the cancer diagnosis. Genetic testing and trends over time were examined for MAPD patients overall and by cancer category, as sample size allowed. Descriptive statistics, including counts, proportions, means, and medians with measures of variance, were reported for utilization trends, as appropriate.

Prior to study initiation, the research protocol was reviewed and approved by an independent institutional review board.

RESULTS

Feasibility Assessment of Methods to Identify Panel Tests in Administrative Claims

Our methodology was applied in a feasibility assessment among patients with select cancer types (see the Data Supplement). In comparison with identifying panel tests via CPT codes alone, our novel approach using a combination of TINs and CPTs identified 2.4 times more large-panel tests and 1.2 times more medium-panel tests in the feasibility assessment (Fig 1).

Utilization of Panel Testing

In the 121,675 patients identified for this study, there were 131,915 unique cancer cases. Characteristics of these patients are reported in Table 1. Overall, 5,457 (4.5%) patients received any panel test from 2016 to 2018 (Table 1). We found that the number of tests performed each quarter increased from 238 in Q1 of 2016 to 755 in Q4 of 2018 (Fig 2). However, the proportion of patients who indexed into the study within each quarter and received any panel test at any point in the study period was relatively stable over time (4.0%-5.2%).

Across all incident tumor types among MAPD cancer cases, the proportion of large-panel tests performed as a function of all multigene panel tests increased from 20.7% of tests in Q1 of 2016 to 46.4% of tests in Q4 of 2018 (Fig 3). The proportion of patients with > 1 test postindex was 12.8% overall and highest among patients with respiratory cancer (16.3%). The median number of days to the first cancer-related genetic test was 55 days, highest among those with genitourinary cancers (173 days) and shortest among those with respiratory cancers (36 days; Table 2).

For the three cancer categories with the highest count of cancer-related panel tests, we found that patients with respiratory cancer, on the basis of the quarter indexed into the study, had a consistently greater proportion receiving a panel test at any point postindex (12%-18%), followed by patients with GI cancer (5%-9%) and patients with female reproductive cancer (2%-3%). Among these patients, for those receiving any panel test, large-panel testing increased across the study period. The proportion of patients receiving a large-panel test was highest among those with female reproductive cancers across nearly all periods, despite the lowest number of tests across these three
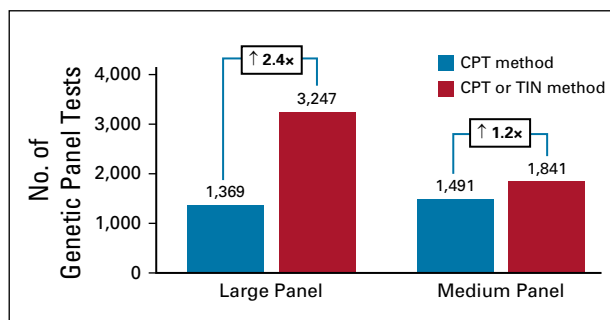

FIG 1. Comparison of genetic panel test identification methods from feasibility assessment. CPT method: large-panel CPT—81455; medium-panel CPTs—81445 and 81450. CPT, current procedural terminology; TIN, tax identification number.

TABLE 1. Characteristics of the Cancer Cohort Overall and by Cancer Category

Characteristic	Overall (N = 121,675)	Genitourinary (n = 45,193)	Female Reproductive (n = 31,730)	GI (n = 18,650)	Respiratory (n = 14,680)	Dermatologic (n = 7,385)	Endocrine (n = 2,749)	Nervous (n = 1,648)
Baseline demographics								
Age, years								
Mean (SD)	71.6 (8.0)	72.3 (7.3)	70.8 (8.1)	71.6 (8.5)	72.0 (7.8)	73.1 (7.9)	68.1 (9.5)	66.1 (12.0)
Median (IQR)	71.0 (67-77)	72 (67-77)	70 (66-76)	71 (66-78)	72 (67-77)	73 (68-79)	68 (64-74)	68 (60-74)
Range	20-89	29-89	29-89	25-89	26-89	25-89	28-89	20-89
Age group, years No. (%)								
18-55	3,624 (3.0)	651 (1.4)	1,244 (3.9)	702 (3.8)	343 (2.3)	168 (2.3)	270 (9.8)	287 (17.4)
56-64	12,350 (10.1)	3,670 (8.1)	3,398 (10.7)	2,304 (12.3)	1,811 (12.3)	513 (6.9)	438 (15.9)	271 (16.4)
65-74	62,886 (51.7)	24,299 (53.8)	17,418 (54.9)	8,819 (47.3)	6,854 (46.7)	3,586 (48.6)	1,379 (50.2)	687 (41.7)
75-89	42,815 (35.2)	16,573 (36.7)	9,670 (30.5)	6,825 (36.6)	5,672 (38.6)	3,118 (42.2)	662 (24.1)	403 (24.5)
Sex, No. (%)								
Male	66,199 (54.4)	41,388 (91.6)	NA	10,652 (57.1)	7,820 (53.3)	4,791 (64.9)	812 (29.5)	865 (52.5)
Female	55,476 (45.6)	3,805 (8.4)	31,730 (100.0)	7,998 (42.9)	6,860 (46.7)	2,594 (35.1)	1,937 (70.5)	783 (47.5)
Race, No. (%)								
White	93,987 (77.2)	93,987 (77.2)	24,176 (76.2)	14,279 (76.6)	12,158 (82.8)	7,131 (96.6)	2,151 (78.2)	1,336 (81.1)
Black	20,709 (17.0)	20,709 (17.0)	5,778 (18.2)	3,179 (17.0)	1,997 (13.6)	60 (0.8)	335 (12.2)	206 (12.5)
Others	6,979 (5.7)	6,979 (5.7)	1,776 (5.6)	1,192 (6.4)	525 (3.6)	194 (2.6)	263 (9.6)	106 (6.4)
Region, No. (%)								
Northeast	3,928 (3.2)	1,544 (3.4)	993 (3.1)	544 (2.9)	523 (3.6)	187 (2.5)	98 (3.6)	54 (3.3)
Midwest	22,787 (18.7)	8,197 (18.1)	5,818 (18.3)	3,589 (19.2)	3,115 (21.2)	1,334 (18.1)	543 (19.8)	281 (17.1)
South	82,213 (67.6)	30,605 (67.7)	21,573 (68.0)	12,569 (67.4)	9,722 (66.2)	5,065 (68.6)	1,746 (63.5)	1,141 (69.2)
West	12,747 (10.5)	4,847 (10.7)	3,346 (10.5)	1,948 (10.5)	1,320 (9.0)	800 (10.8)	362 (13.2)	172 (10.4)
Population density, No. (%)								
Urban	76,320 (62.7)	28,669 (63.4)	20,633 (65.0)	11,409 (61.2)	8,619 (58.7)	4,476 (60.6)	1,734 (63.1)	988 (60.0)
Suburban	29,961 (24.6)	10,951 (24.2)	7,456 (23.5)	4,693 (25.2)	3,919 (26.7)	1,925 (26.1)	666 (24.2)	446 (27.1)
Rural	12,657 (10.4)	4,533 (10.0)	2,946 (9.3)	2,128 (11.4)	1,847 (12.6)	781 (10.6)	278 (10.1)	177 (10.7)
Missing or unknown	2,737 (2.2)	1,040 (2.3)	695 (2.2)	411 (2.2)	295 (2.0)	203 (2.7)	71 (2.5)	37 (2.2)
Postindex testing								
Proportion of patients with ≥ 1 test postindex	5,457 (4.5)	384 (0.8)	847 (2.8)	1,377 (7.4)	2,239 (15.3)	365 (4.9)	106 (3.9)	112 (6.8)

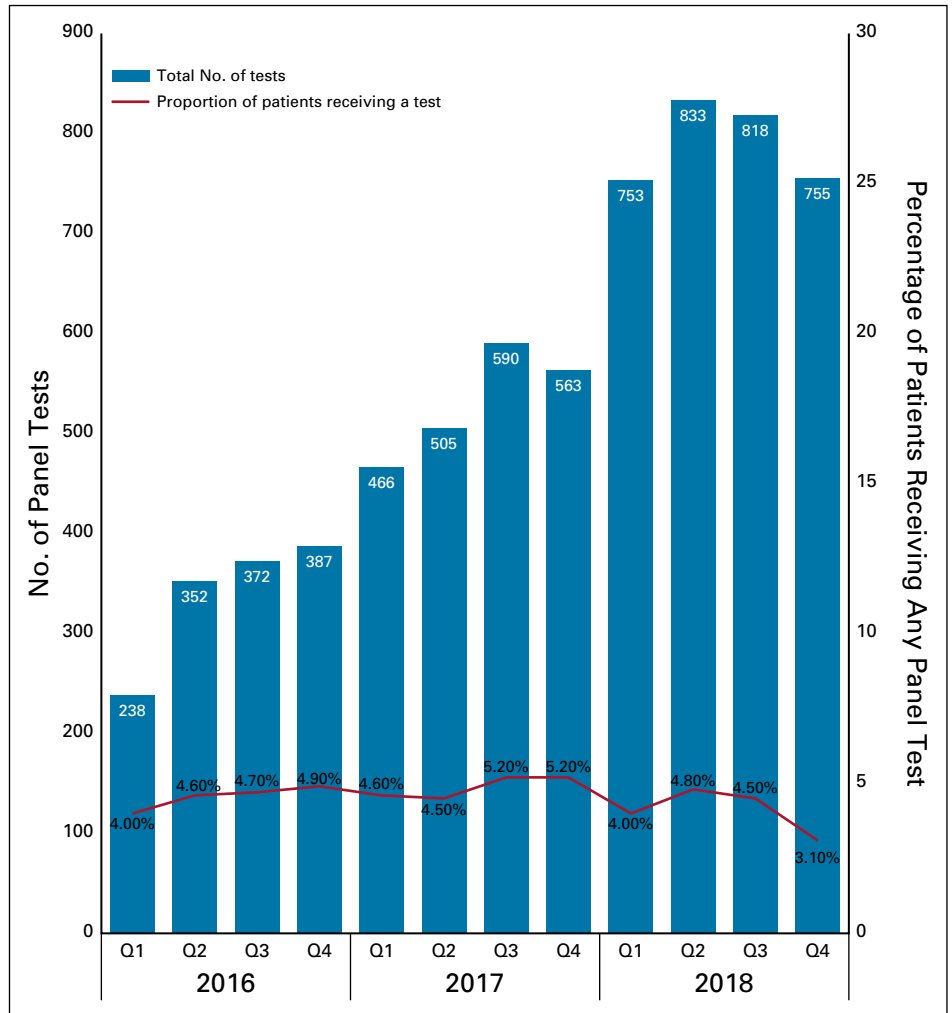Abbreviations: IQR, interquartile range; NA, not available; SD, standard deviation.

FIG 2. Total number of panel tests performed per quarter.

cancer categories. Large-panel testing was near or more than 50% for all three of these categories by Q4 of 2018. Specifically, large-panel testing across GI cancers increased the most from Q1 of 2016 (17.2%) to Q4 of 2018 (50.3%; Fig 4).

DISCUSSION

The primary goal of this study was to develop an approach to measure genetic panel test utilization using health care administrative claims and understand cancer-related genetic testing trends over time in an older population with
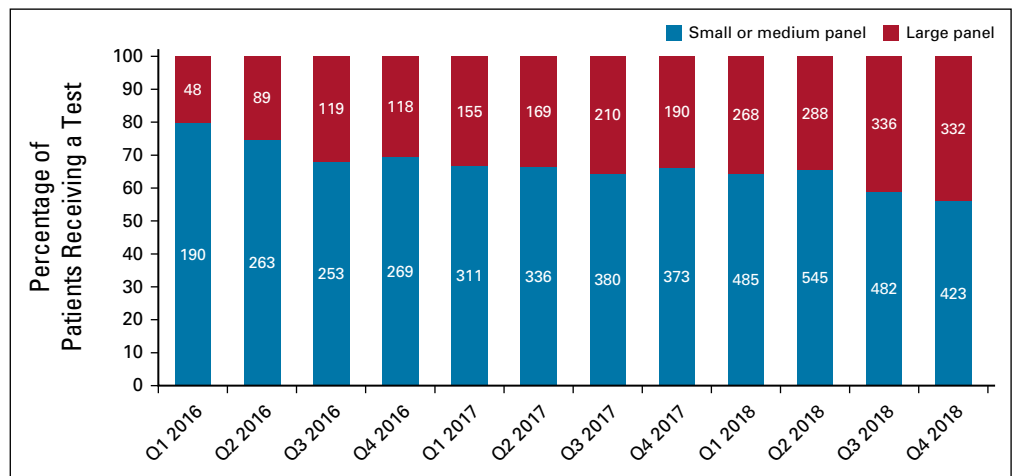
FIG 3. Proportion of patients receiving a large-panel test versus medium- or small-panel test each quarter.

TABLE 2. Time to First Cancer-Related Genetic Test and Patients With > 1 Cancer-Related Genetic Test

Variable	Overall (N = 5,457)	Genitourinary (n = 384)	Respiratory (n = 2,239)	Dermatologic (n = 365)	Endocrine (n = 106)	Nervous (n = 112)	GI (n = 1,377)	Female Reproductive (n = 874)
Time from index to first cancer-related genetic test, days								
Mean (SD)	145.4 (200.3)	271.4 (268.6)	99.7 (162.1)	150.7 (213.4)	182.1 (237.3)	110.2 (155.6)	157.8 (200.7)	203.4 (222.1)
Median (IQR)	55 (21-193)	173 (54-437)	36 (14-96)	55 (21-183)	77 (18-233)	48 (10-122)	67 (27-240)	92 (46-292)
Range	0-1,054	0-1,050	0-1,000	0-1,035	0-911	0-688	0-1,054	0-1,054
Proportion of patients with > 1 cancer-related genetic test, postindex, n (%)	700 (12.8)	46 (12.0)	365 (16.3)	48 (13.2)	< 10	< 10	156 (11.3)	79 (9.0)

NOTE. Cancers were grouped by system and included the following cancer types: genitourinary (bladder, kidney, renal pelvis, and prostate), respiratory (bronchus and lung), dermatologic (melanoma), endocrine (thyroid), CNS (brain and spinal cord), GI (colorectal, pancreas, stomach, small intestine, liver, gallbladder, and salivary), and female reproductive (uterus, ovarian, and breast).

Abbreviations: IQR, interquartile range; SD, standard deviation.

FIG 4. Proportion of patients receiving large-panel testing among those receiving any panel test each quarter for three cancer categories.
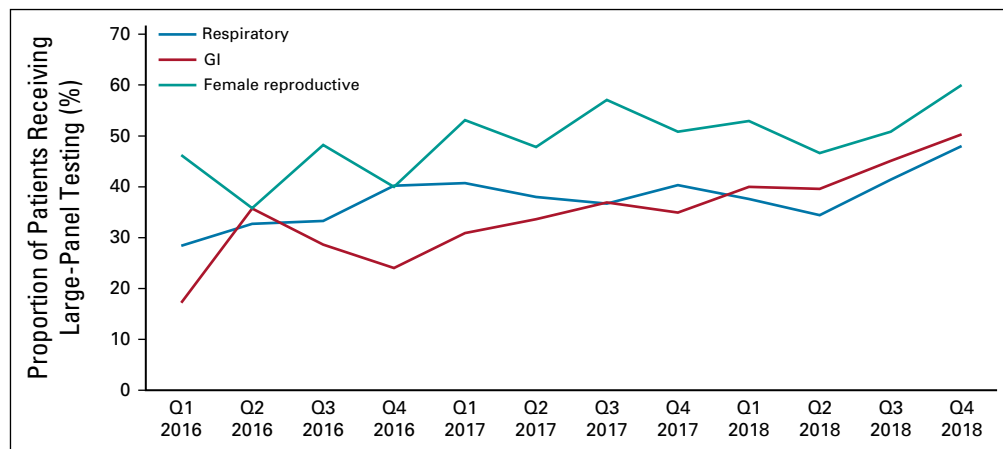
cancer. More than half of all new cancer cases occur in patients older than 65 years,[13] who comprise the majority of the Medicare Advantage population, thus making this study perspective unique and relevant. To our knowledge, this is the first examination of MGPT trends over time for patients with a broad range of solid tumor cancers enrolled in Medicare Advantage.

In our feasibility study, we found use of CPT codes alone may underestimate the number of genetic panel tests measured in administrative claims data. Although our approach provides an opportunity to better identify particular mutational analyses performed for patients with cancer, thus allowing for better understanding of clinical outcomes associated with particular testing, TIN information is not always available and variable billing and coding presents challenges for consistent identification. Thus, development and validation of novel approaches to identify genetic tests in administrative claims data, in addition to greater consistency in billing rules, is warranted to facilitate future research.

In our study, we found the proportion of patients receiving ≥ 1 cancer-related genetic test remained relatively stable over the study time period; however, the proportion of large-panel tests compared with small- or medium-panel tests completed increased substantially over the 3-year study period. As expected, the respiratory cancer cohort had the highest number and proportion of tests. Patients with lung cancers often receive genetic testing as part of a clinical decision making for systemic therapy given the number of treatments effective in those with specific tumor gene mutations (eg, *EGFR, ALK, ROS1*, and *BRAF*).[14] In fact, more than 80% of lung cancers in the United States are non–small-cell lung cancers (NSCLC), which would benefit from treatment designed with the tumor genetics taken into account.[14] A 2017 study identified that the highest proportion of gene-specific somatic cancer biomarker tests (*EGFR, BRAF*, and *KRAS*) among Medicare Advantage patients were those with lung cancer, followed by colon cancer.[15] Although that study did not specifically

include or examine panel tests, the cancer populations that had the highest gene-specific somatic testing are similar to that of our study.

Although we observed an increase in the number of genetic panel tests over time, the proportion of tests as a function of the number of cancer cases remained stable over the study time period; however, the proportion of large-panel tests, as a function of all panel testing completed, more than doubled from the beginning of 2016 through 2018, indicating a shift in the type of panel testing chosen by providers in the data we examined. Specifically, for patients with NSCLC, increased trends in testing have been reported. In an advanced NSCLC cohort, Gutierrez et al noted an increase in NGS testing from 2% in 2013 to 16% in 2015.[16] Another study reported an increase in NGS panel testing from 13% in 2017 to 26% in 2019 among patients with advanced NSCLC, also noting the shift from single- and small-panel testing to NGS panel testing in more recent years, as we reported in our study.[17] Evaluating *ROS1* testing in patients with advanced NSCLC from 2016 to 2018, NGS testing was noted to increase over time becoming as commonly used as other types of biomarker testing for *ROS1*.[18] Similarly, the testing method for *ALK* in patients with advanced NSCLC shifted, where NGS increased in use from 4.5% in 2011 to 21.2% in 2017.[19]

For women with breast cancer enrolled in commercial US plans, there was an increasing trend in gene expression profiling panels from 2.2% in 2006 to 18.8% in 2012.[20] Although not specifically NGS testing, gene expression profiling provides an analogy to adoption rates of NGS panels. This increase in use may have been because of the fact that large-panel tests can be used to identify patients who may be candidates for clinical trials, specifically for those who have progressed on a given therapy. Additionally, the release of the national coverage determination parameters regarding genetic panel testing in early 2018, when Medicare first started covering next-generation tumor sequencing for patients with advanced cancer, may have contributed to the increasing use of these tests later in our

study period.[21] In fact, there was a significant surge in private payer policy coverage of genetic testing after the release of these guidelines.[22] Although some initial work, most commonly in the NSCLC space, has been conducted evaluating the impact of large-panel testing on treatment selection and outcomes, further research and the influence on outcomes is warranted.[16,23,24]

Additionally, we found that 16.3% of patients in the lung cancer cohort received more than one panel test in the postindex time period; these tests may have been multiple small- or medium-panel tests conducted to look for different mutations. Patients may get a small or more selective test early to identify currently actionable mutations, but if they progress on treatment, then they may have a large-panel test conducted for other possible effective treatments and/or for clinical trial participation. Specifically, for patients with advanced NSCLC, studies have reported routine testing for *EGFR* and/or *ALK* may still most commonly involve a series of tests.[16,24,25] For patients with lung cancer, the time to their first genetic test may be shorter relative to patients with other types of cancer given the number of targeted therapies available for this cancer type. From 2006 to 2018, there were 31 genome-targeted or genome-informed drugs approved by the US Food and Drug Administration, with 10 of those targeting NSCLC.[26] Additionally, many patients with lung cancer are diagnosed at an advanced stage of the disease necessitating rapid identification of possible therapies to slow the spread of the cancer. It is also possible the differences in time to testing may be reflective of the line of therapy when the test is conducted, which varies across cancer types.

Limitations common to studies using administrative claims data apply to this study. Claims data do not provide information on stage of illness or enrollment in a clinical trial, which may influence therapy selection. Additionally, site of service in establishing testing patterns (eg, academic *v* community) was not assessed. Furthermore, the algorithms developed for identifying genetic testing panels related to specific cancers and the size of panel (eg, small, medium, and large) via claims data have not been validated; thus,

misclassification or misidentification of the genetic testing types is possible and generalizability to other data sets or outside Medicare Advantage populations may be limited. However, development of these algorithms was guided by an expert panel (physician, pharmacists, and genetic counselor). This study focused on somatic genetic testing as these tests most often help guide treatment decisions. Thus, genetic testing overall may be underreported for those cancer types where germline testing is conducted. Additionally, variations in coding practices for NGS testing have been reported, supporting the current need for algorithms, such as those used in this study, to identify this type of testing in claims.[27] The broader systematic approach used in administrative claims may have identified tests that would not have been identified if only a narrow range of CPT codes had been used.[10]

Additionally, some patients may have had cancer diagnoses prior to the identification period; therefore, we could not ascertain where patients were in the life cycle of their cancer diagnosis and treatment. Because of the makeup of the study population, this study is not necessarily generalizable to younger and commercial patient groups. In light of the heterogeneity in age-related cancer incidence and outcomes, as well as benefit design, between patients enrolled in Medicare Advantage and commercial plans, it was not deemed appropriate to include commercial patients and combine them in the analysis. Last, this study was descriptive and there were no adjustments made for any confounding factors, as such the study design does not lend itself to causal inference.

In conclusion, across a variety of cancers, use of large-panel cancer-related genetic testing increased, as a proportion of all somatic cancer-related genetic testing, from 2016 to 2018, although testing overall was low. As more treatment options in oncology become available for which panel testing may be used, further research is needed to understand the impacts of panel testing on treatment decision making, subsequent patient outcomes, and the impacts policy changes may have on use of this testing.

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DISCLAIMER

K.B. and R.H. were employees of Humana Inc at the time this research was conducted.

AUTHOR CONTRIBUTIONS

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Collection and assembly of data: Eleanor O. Caplan, Erin Ferries
Data analysis and interpretation: All authors
Manuscript writing: All authors

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