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ORIGINAL RESEARCH

Economic analysis of BRAF gene mutation testing in real world practice using claims data: costs of single gene versus panel tests in patients with lung cancer

Anand A. Dalal[a], Annie Guerin[b], Alex Mutebi[a] and Kenneth W. Culver[a]

[a]Novartis Pharmaceuticals Corporation, East Hanover, NJ, USA; [b]Analysis Group, Inc., Montréal, Québec, Canada

ABSTRACT

Aims: To assess the time to BRAF testing, compare the characteristics of tested vs not-tested patients, and describe the costs for sequential vs next-generation sequencing (NGS) BRAF testing.

Methods: Patients diagnosed with lung cancer after December 1, 2013 were identified from two US claims databases; their characteristics were assessed during the 12 months before diagnosis (index date). Testing modalities were analyzed from the index date to end of continuous health plan enrollment or data availability (December 2015), based on combinations of Current Procedural Terminology (CPT) procedure codes. Time to BRAF testing was assessed using Kaplan-Meier analysis. Costs were analyzed from a payer's perspective.

Results: A total of 28,011 patients newly-diagnosed with lung cancer were identified. Of them, 1,260 (4.5%) were tested for BRAF: 3.2% and 4.2% were tested at 6 and 12 months, respectively, after the index date. Compared to non-tested patients, tested patients were younger (58.3 vs 65.3 years; $p < .001$), had a lower Charlson Comorbidity Index (2.8 vs 2.9; $p = .005$), and a higher proportion had metastases (70.9% vs 43.4%; $p < .001$). In 76.0% of cases, BRAF was tested along with KRAS. BRAF was tested using NGS in 6.6% of cases. The average reimbursed amounts for the 10 most common CPT code combinations were $207–$2,074. Using the average costs of individual mutation tests, the total cost of sequential testing comprising KRAS, EGFR, ALK, ROS1, and BRAF tests was $3,763 ($464, $696, $1,070, $1,127, and $406, respectively), that of NGS was $2,860.

Limitations: Claims data did not include BRAF test results.

Conclusions: Among patients newly-diagnosed with lung cancer, 4.5% were tested for BRAF. Tested patients were younger and had a lower comorbidity burden, but more advanced disease. While reimbursed amounts varied greatly based on combinations of testing procedures, NGS testing was associated with cost savings compared to sequential testing of individual mutations.

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KEYWORDS
Non-small cell lung cancer; BRAF mutation; costs; sequential testing; next-generation sequencing; NGS

Introduction

In recent years, significant advances in the understanding of the genetic basis of non-small cell lung cancer (NSCLC) have led to the identification of mutations in various genes implicated in tumor initiation, growth, and maintenance[1–3]. The discovery of these oncogenic driver mutations has opened the door to the development of therapies directly targeting these mutations[1–3]. Several clinical studies have shown that targeted therapies can significantly improve treatment response and survival in NSCLC patients harboring the mutations they were developed to target[4–7]. In 2017, the combination of dabrafenib and trametinib became the first targeted therapy approved in the US for the treatment of metastatic NSCLC harboring the *BRAF-V600E* gene mutation, which is found in 1–2% of NSCLC patients[4,8].

The ability to detect actionable gene mutations soon after a diagnosis of lung cancer is key to identifying patients who are most likely to benefit from available targeted therapies[1,5]. Currently, several testing strategies are being employed in clinical practice to detect gene mutations in NSCLC patients[9]. The most common strategy is single-gene testing, which is often conducted in a pre-determined sequential approach, usually starting from the most common mutations, such as the *EGFR* and *ALK* gene mutations. However, sequential testing is time consuming and may require multiple biopsies or a relatively large amount of biopsied tissue, which is not always attainable in advanced NSCLC[10–12]. A more recently developed testing strategy is next-generation sequencing (NGS), in which a panel of genes is screened simultaneously using the same tissue sample[13–15].

Because of the recent approval of targeted therapy for *BRAF*-mutated NSCLC, limited evidence is available on when and to whom *BRAF* gene mutation testing (BRAF testing) is administered in clinical practice. The costs associated with different BRAF testing strategies have also not been well-characterized in the literature. Therefore, this study aimed to assess the time from lung cancer diagnosis to BRAF testing, compare the characteristics of patients with lung cancer who were tested for the *BRAF* gene mutation vs those who were not tested, determine the amount reimbursed for BRAF

CONTACT Annie Guérin annie.guerin@analysisgroup.com Analysis Group, Inc., 1000 de la Gauchetière Ouest, Suite 1200, Montréal, Québec, H3B 4W5, Canada

testing, and estimate the costs of sequential/exclusionary testing vs NGS testing for the detection of the *BRAF* gene mutation in US clinical practice.

Methods

Data source

Data was obtained from two US administrative claims databases containing medical and pharmacy claims based on commercial and Medicare supplemental plans from January 1, 2006 to December 31, 2015. The data were de-identified and fully compliant with the patient confidentiality requirements of the Health Insurance Portability and Accountability Act, and no Institutional Review Board approval was required.

Sample selection

To be eligible for inclusion, patients were required to meet the following criteria: have at least two diagnoses of lung cancer (International Classification of Diseases 9/10th Revision, Clinical Modification [ICD-9 CM] codes 162.2×–162.9× and ICD-10 CM codes: C34.xx), with a second diagnosis serving as confirmation of lung cancer (given that coding errors may occur in claims data); be at least 18 years old at the index date, defined as the date of the first diagnosis of lung cancer; have continuous healthcare plan enrollment in the 12 months prior to the index date, defined as the baseline period, and in the 6 months after the index date; and have an index date falling on or after January 1, 2013, the date on which the Current Procedural Terminology (CPT) code for BRAF testing was introduced (i.e., the study period was limited to 2013–2015). Patients were excluded if they had any claims associated with a clinical trial (ICD-9 code for V70.7 or ICD-10 code for Z00.6)— as information on testing may not be included in the claims data if molecular tests were conducted as part of a clinical trial—or if, during the baseline period or any time after the index date, they had any diagnoses of colorectal cancer or skin melanoma, given that patients with these two types of cancer can also harbor the *BRAF* gene mutation and, thus, may have a claim with the CPT code for BRAF testing.

Study design

In this retrospective study, patients' characteristics were assessed during the baseline period and compared between patients who were tested and patients who were not tested for the *BRAF* gene mutation during the follow-up period, defined as the period from the index date to end of health plan continuous enrollment or end of data availability, whichever occurred first.

Different combinations of single-gene mutation tests that are commonly used to screen patients for the *BRAF* gene mutation were identified based on combinations of CPT procedure codes recorded within 7 days of each other. The 10 most common combinations and associated reimbursed amounts by commercial payers were summarized.

The total cost (i.e. the payer reimbursed amounts) to test patients for the *BRAF* gene mutation was assessed for three testing strategies: (1) *Sequential testing*: patients received single-gene tests for *EGFR*, *ALK*, *ROS1*, and *BRAF*, in sequence. The tests for the *EGFR* and *BRAF* gene mutations used real-time polymerase chain reaction (RT-PCR), those for the *ALK* gene mutation used immunohistochemistry (IHC) in 10% of the cases and fluorescence *in-situ* hybridization (FISH) in 90% of the cases, and those for the *ROS1* gene mutation used FISH; (2) *Exclusionary mutation testing*: patients were first tested for the *KRAS* gene mutation using RT-PCR and subsequently underwent the sequential testing described above; and (3) *NGS*: after being diagnosed with lung cancer, patients received a genomic sequence panel testing simultaneously for 5–50 gene mutations.

Measures and outcomes

Study measures included the time from lung cancer diagnosis to BRAF testing, the cost to payers (i.e. reimbursed amount) for BRAF testing based on different combinations of gene mutation tests (e.g. KRAS + BRAF) and sample preparation techniques (e.g. KRAS + BRAF + microdissection), and the cost of sequential, exclusionary mutation, and NGS testing from the perspective of both a commercial payer and Medicare. To estimate the total cost of sequential and exclusionary mutation testing, the cost of each component of the testing sequence (i.e. EGFR, ALK, ROS1, BRAF, and KRAS) was estimated separately and then summed.

Claims data were used to estimate the costs from the perspective of a commercial payer, excluding from the analysis the claims for which no amount had been reimbursed by payers. Costs were adjusted for inflation using the US Consumer Price Index (CPI), Medical Care Component in 2015 US dollars.

The Centers for Medicare & Medicaid Services (CMS) reimbursement rates were used to estimate costs from the perspective of Medicare.

Statistical analysis

Continuous variables (patient characteristics and costs) were summarized using means, medians, and standard deviations; categorical variables were summarized using counts and percentages. Statistical comparisons of patient characteristics were conducted between the BRAF tested and not-tested patients using Wilcoxon rank-sum tests for continuous variables and Chi-square tests for categorical variables. The time from lung cancer diagnosis to the first *BRAF* gene mutation test was assessed using Kaplan-Meier analysis, to account for censoring in the data.

Results

A total of 28,011 patients with newly-diagnosed lung cancer were included in the analysis (Figure 1). Of them, 1,260 (4.5%) were tested for the *BRAF* gene mutation (Table 1), ranging from 3.5% in 2013 to 6.2% in 2015. Compared to

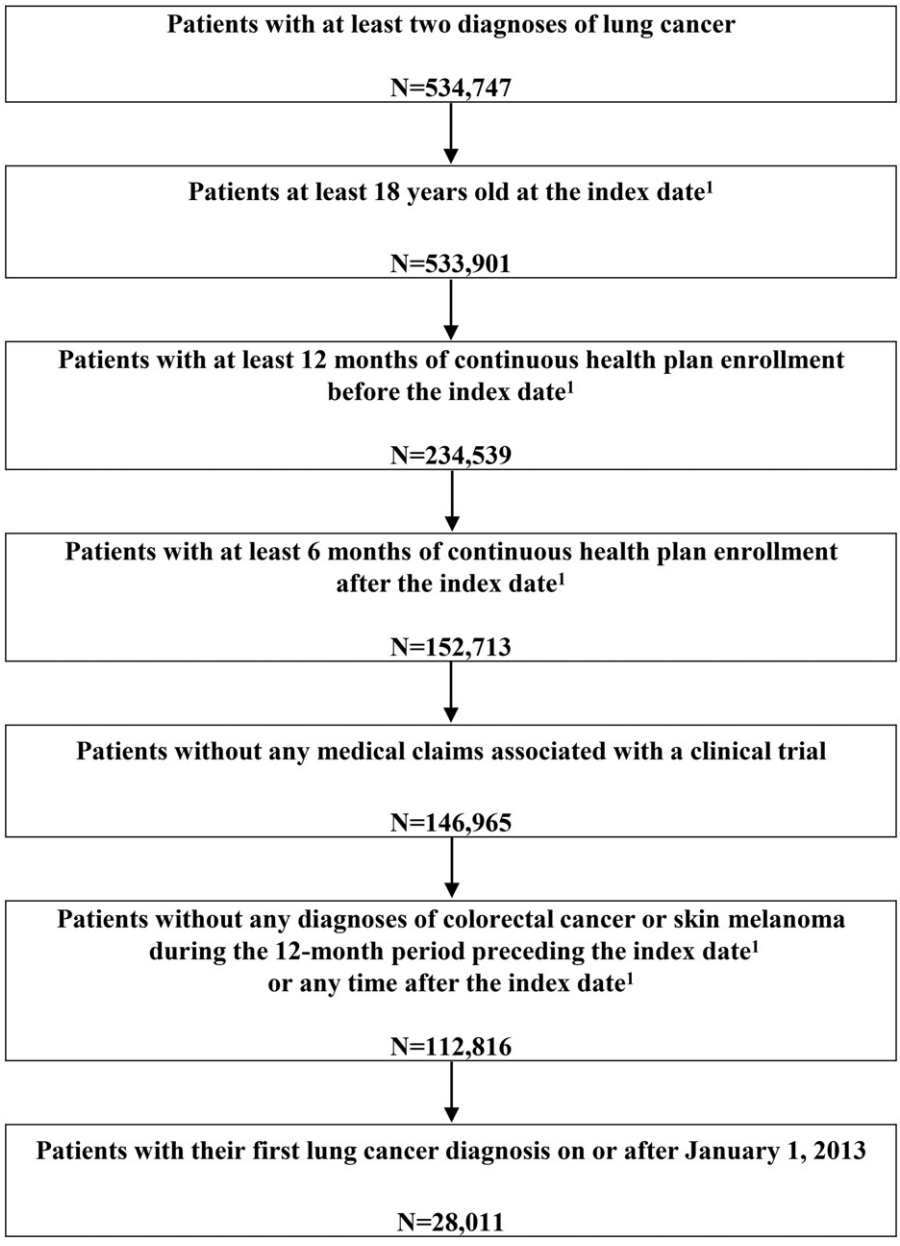

Figure 1. Sample selection of patients newly-diagnosed with lung cancer[1]. Index date was defined as the date of the first lung cancer diagnosis.

patients not tested for the *BRAF* gene mutation, those who were tested were younger (65.3 vs 58.3 years; $p < .001$), had a lower Charlson Comorbidity Index (2.9 vs 2.8; $p = .005$), and a higher proportion of them had metastases (43.4% vs 70.9%; $p < .001$).

Of the 1,260 (4.5%) patients tested for the *BRAF* gene mutation, 3.2% and 4.2% were tested by 6 and 12 months following the index date (i.e. first lung cancer diagnosis), respectively (Figure 2). Among all the patients tested for the *BRAF* gene mutation, 76.0% were also tested for *KRAS*, and NGS was used in 6.6% of tested patients (Table 2). Microdissection and molecular pathology procedures (level 5) were commonly used to prepare the sample for testing (Table 2). The reimbursed amounts varied across testing combinations, ranging from $207 (when only the CPT code for BRAF testing was used) to $2,074 (when the CPT codes for BRAF testing, KRAS testing, microdissection, and molecular pathology procedure, level 5, were used) (Table 2).

From the perspective of a commercial payer, the average cost of sequential testing was estimated at 3,299 ($406 for BRAF, $1,127 for ROS1, $1,070 for ALK, and $696 for EGFR), that of exclusionary mutation testing was estimated at $3,763 ($406 for BRAF, $1,127 for ROS1, $1,070 for ALK, $696 for EGFR, and $464 for KRAS), and that of NGS was estimated at $2,860 (Figure 3).

From the perspective of Medicare, based on CMS reimbursement rates, the average cost of sequential testing was estimated at $1,400 ($179 for BRAF, $463 for ROS1, $428 for ALK, and $330 for EGFR), that of exclusionary mutation testing was estimated at $1,794 ($179 for BRAF, $463 for ROS1, $428 for ALK, $330 for EGFR, and $394 for KRAS), and that of NGS was estimated at $623 (Figure 3).

Table 1. Comparison of patient characteristics between patients tested for BRAF gene mutation and those not tested for BRAF gene mutation.

	Tested cohort ($n = 1,260$)	Non-tested cohort ($n = 26,751$)	*p*-value
Demographic characteristics			
Age in years, mean (SD)[a]	58.3 (9.8)	65.3 (11.7)	<.001
Female, *n* (%)	67.2 (53.3)	13,579 (50.8)	.074
Region of residence, *n* (%)			
South	532 (42.2)	9,370 (35.0)	<.001
North central	299 (23.7)	6,531 (24.4)	.581
Midwest	164 (13.0)	3,307 (12.4)	.491
West	146 (11.6)	2,581 (9.6)	.023
Northeast	118 (9.4)	4,847 (18.1)	<.001
Unknown	1 (0.1)	115 (0.4)	.058
Type of healthcare plan,[a] *n* (%)			
PPO	881 (69.9)	15,741 (58.8)	<.001
HMO and POS with capitation	133 (10.6)	3,075 (11.5)	.306
CDHP and HDHP	77 (6.1)	1,383 (5.2)	.142
Comprehensive	53 (4.2)	4,592 (17.2)	<.001
Indemnity	28 (2.2)	719 (2.7)	.316
Unknown	20 (1.6)	354 (1.3)	.425
Type of coverage,[a] *n* (%)			
Commercial	1,109 (88.0)	16,260 (60.8)	<.001
Medicare supplemental	151 (12.0)	10,491 (39.2)	<.001
Observation period duration in months, mean (SD) [median]	14.6 (7.1)[13]	14.7 (7.3)[12]	.776
Year of first lung cancer diagnosis, *n* (%)			
2013	445 (35.3)	12,442 (46.5)	<.001
2014	575 (45.6)	10,707 (40.0)	<.001
2015	240 (19.0)	3,602 (13.5)	<.001
Year of first *BRAF* test, *n* (%)			
2013	235 (18.7)	—	—
2014	532 (42.2)	—	—
2015	493 (39.1)	—	—
Charlson comorbidity index, mean (SD) [median]	2.8 (2.9)[2]	2.9 (2.8)[2]	.005
Patients with metastatic disease, *n* (%)	893 (70.9)	11,611 (43.4)	<.001
Location of metastases, *n* (%)			
Respiratory system	760 (60.3)	8,294 (31.0)	<.001
Lymph nodes	659 (52.3)	7,654 (28.6)	<.001
Bone/bone marrow	537 (42.6)	6,169 (23.1)	<.001
Brain	453 (36.0)	5,089 (19.0)	<.001
Liver	334 (26.5)	3,839 (14.4)	<.001
Digestive system	136 (10.8)	1,271 (4.8)	<.001
Adrenal gland	120 (9.5)	990 (3.7)	<.001
Other digestive organs and spleen	66 (5.2)	55 (2.2)	<.001
Breast	54 (4.3)	400 (1.5)	<.001
Skin	52 (4.1)	529 (2.0)	<.001
Genital organs	26 (2.1)	314 (1.2)	.005
Ovary	25 (2.0)	199 (0.7)	<.001
Kidney and urinary organs	9 (0.7)	91 (0.3)	.030
Other	334 (26.5)	3,040 (11.4)	<.001

[a]As of the index date, which was defined as the date of the first lung cancer diagnosis.

Discussion

The optimal use of available and effective targeted therapies for *BRAF*-mutated NSCLC is contingent on the ability to promptly detect the *BRAF* gene mutation after a lung cancer diagnosis. However, there exists limited information on the timing and costs of BRAF testing and to whom it is administered in the US. Accordingly, this retrospective claims data study assessed the time from lung cancer diagnosis to BRAF testing, the characteristics of patients diagnosed with lung cancer who were tested or not tested for the *BRAF* gene mutation, the amounts reimbursed for BRAF testing using different testing combinations, and the cost of sequential/exclusionary vs NGS testing in US clinical practice from the perspective of a commercial payer and Medicare.

The results of this study showed that, out of a study sample of 28,011 patients diagnosed with any stage and any histological sub-type of lung cancer between January 2013 and December 2015, 4.5% were tested for the *BRAF* gene mutation, with 3.2% of them tested within 6 months of a lung cancer diagnosis. Notably, compared to patients who were not tested for the *BRAF* gene mutation, those who were tested tended to be younger and have a lower comorbidity burden, but were also more likely to have metastatic disease. This finding suggests that there may be a negative bias towards older patients, in line with previous studies in which older people were found to receive sub-optimal or inadequate treatment and less rigorous disease staging compared to younger patients, including cancer patients[16–18]. One reason for this treatment disparity has been attributed to the increased comorbidity burden that older patients tend to exhibit[18].

The proportion and characteristics of patients tested for the BRAF gene mutation should be interpreted in the context of the period 2013–2015 covered by the data. At that time, the BRAF mutation was not an actionable mutation for NSCLC, and BRAF testing was not recommended in NSCLC treatment guidelines. It was only in 2017, following the Food and Drug Administration's approval of the dabrafenib and trametinib combination for the treatment of metastatic NSCLC with the BRAF V600E mutation[19], that the National Comprehensive Cancer Network guidelines were updated to recommend testing for the BRAF gene mutation[20]. Nevertheless, it should be noted that the present study was not designed to either estimate the prevalence of BRAF testing or investigate the reasons why patients with certain characteristics are more or less likely to be tested for the BRAF gene mutation in a more contemporary context. Further studies are needed to better understand whether and why certain patient sub-populations may not to be tested for BRAF. This is particularly important given the recent approval of the first targeted therapy for the treatment of BRAF-mutated NSCLC.

Not surprisingly, the majority of patients (76%) who were tested for BRAF with a single-gene sequential approach were also tested for KRAS, one of the most common gene mutations in NSCLC[21]. Depending of the combination of single-gene tests used to ultimately test patients for BRAF, the reimbursed amounts were found to vary. Nevertheless, costs were consistently higher for sequential/exclusionary testing than for NGS, both from the perspective of a commercial payer ($3,299/$3,763 for sequential/exclusionary vs $2,860 for NGS) and Medicare ($1,400/$1,794 for sequential/exclusionary vs $623 for NGS). This suggests that, for patients harboring the *BRAF* gene mutation, NGS is associated with cost savings, given that, when testing is done in sequence, BRAF is typically tested after other more common gene mutations. However, as the number of actionable mutations increases, more targeted therapies become available, and the cost of NGS testing decreases, NGS is likely to become more widely used in clinical practice, considering its ability to simultaneously screen for multiple mutations without the need for re-biopsy. For patients with less common mutations, including

	All Patients (N=28,011)
Number of patients with BRAF testing, N (%)	1,260 (4.50%)

	1-Month Rate	2-Month Rate	3-Month Rate	6-Month Rate	12-Month Rate
Number of patients at risk, N	27,571	27,372	27,281	27,052	13,831
% Tested (95% confidence interval)	1.6 (1.4 ; 1.7)	2.3 (2.1 ; 2.5)	2.6 (2.4 ; 2.8)	3.2 (3.0 ; 3.4)	4.2 (3.9 ; 4.4)

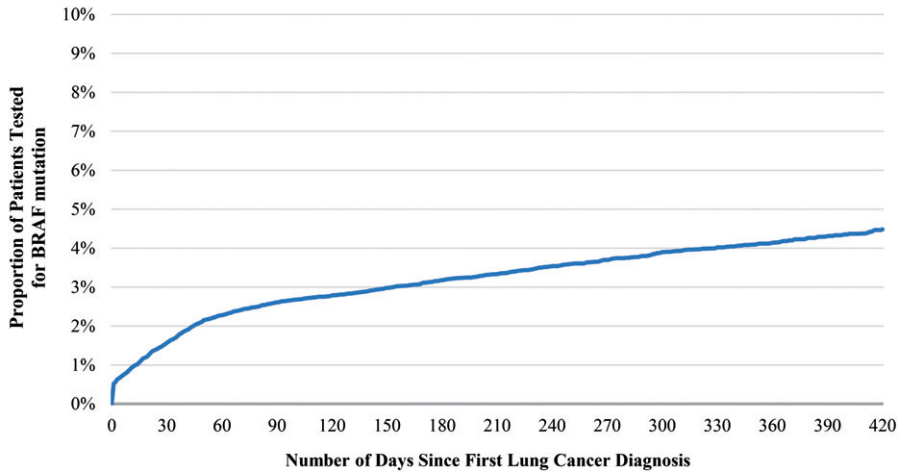

Figure 2. Time from first lung cancer diagnosis to *BRAF* gene mutation testing.

Table 2. *BRAF* gene mutation test-related reimbursed amounts across the 10 most common sequential testing combinations.Combinations of CPT procedure codes

	n	Reimbursed amounts, Mean (SD) [median]
81210 + 81275	399	442 (623) [368]
81210 + 88381 + 81275	266	1,150 (1,195) [683]
81210 + 88381 + 81275 + 81404	194	2,074 (2,786) [828]
81210 + 81275 + 81404	81	2,019 (2,079) [1,155]
81210	74	207 (241) [118]
81210 + 81406 + 81275 + 81404	61	1,054 (838) [837]
81210 + 88381	56	566 (483) [338]
81406 + 88381 + 81404	36	1,554 (789) [1,639]
81445 + 88381	32	1,874 (2,218) [783]
81406	23	1,724 (2,502) [154]

CPT codes	Definitions
81210	*BRAF* (B-Raf proto-oncogene, serine/threonine kinase), gene analysis, V600 variant(s)
81275	*KRAS* (Kirsten rat sarcoma viral oncogene homolog) gene analysis; variants in exon 2 (e.g. codons 12 and 13)
88381	Microdissection (i.e. sample preparation of microscopically identified target); manual
81404	Molecular pathology procedure, Level 5
81406	Molecular pathology procedure, Level 7 (e.g. analysis of 11–25 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of 26–50 exons, cytogenomic array analysis for neoplasia)
81445	Targeted genomic sequence analysis panel, solid organ neoplasm, DNA analysis, and RNA analysis when performed, 5–50 genes (e.g. *ALK*, *BRAF*, *CDKN2A*, *EGFR*, *ERBB2*, *KIT*, *KRAS*, *NRAS*, *MET*, *PDGFRA*, *PDGFRB*, *PGR*, *PIK3CA*, *PTEN*, *RET*); interrogation for sequence variants and copy number variants or rearrangements, if performed
81455	Targeted genomic sequence analysis panel, solid organ or hematolymphoid neoplasm, DNA analysis, and RNA analysis when performed, 51 or greater genes (e.g. *ALK*, *BRAF*, *CDKN2A*, *CEBPA*, *DNMT3A*, *EGFR*, *ERBB2*, *EZH2*, *FLT3*, *IDH1*, *IDH2*, *JAK2*, *KIT*, *KRAS*, *MLL*, *NPM1*, *NRAS*, *MET*, *NOTCH1*, *PDGFRA*, *PDGFRB*, *PGR*, *PIK3CA*, *PTEN*, *RET*), interrogation for sequence variants and copy number variants or rearrangements, if performed

Abbreviations. CPT, Current Procedural Terminology; SD, standard deviation.

BRAF and other mutations such as MET, RET, and HER2 for which targeted therapies are in development[22–24], the use of NGS is likely to result in considerable cost savings for both payers and patients.

Some limitations should be considered. First, this study is subject to intrinsic limitations of claims data, including inaccuracies in coding diagnoses, procedures, or pharmacy claims. Second, since this study focused only on the *BRAF*

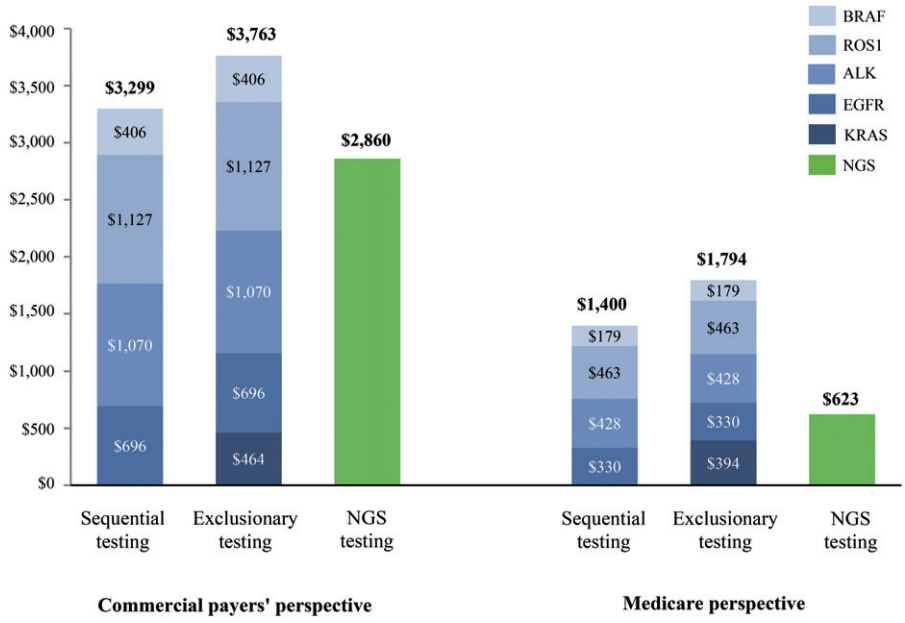

Figure 3. Reimbursed amounts for sequential testing vs NGS based on claims data and CMS reimbursement rates. Abbreviations. NGS, next-generation sequencing; CMS, Centers for Medicare & Medicaid Services.

gene mutation, the results may not be generalizable to other mutations. In addition, for patients harboring different types of mutations, using an exclusionary testing approach could result in one type of mutation not being detected, and thus being not included in the study, if another type of mutation is detected first.

Third, to identify BRAF tests and associated reimbursed amounts, an algorithm based on a selected list of CPT codes recorded within 7 days of each other was developed; since multiple combinations of CPT codes are used when a BRAF test is performed, estimating the total cost of BRAF testing can be challenging. Furthermore, prior to 2013, BRAF testing was coded using a combination of CPT codes that was not unique to the *BRAF* gene mutation; therefore, it is possible that some physicians continued to use that combination after 2013. Moreover, as some payers may reject NGS payments, it is possible that some laboratories choose to use combinations of CPT codes rather than NGS codes, even when performing NGS[7]; as a result, the frequency of NGS testing observed in the current study may have been under-estimated. In addition, BRAF tests that were not reimbursed by commercial payers were not included in the analysis. Lastly, patients included in this study were diagnosed with lung cancer, but not specifically NSCLC, which is the type of lung cancer harboring the *BRAF* gene mutation, as there is currently no ICD-9/10 code for NSCLC. Additionally, this study included patients with any stage of lung cancer. However, since NSCLC represents ~85% of all lung cancer cases[25] and is generally diagnosed at an advanced stage, we expect the results of this study, particularly those related to the cost of testing, to have considerable relevance to NSCLC patients.

Conclusions

Among patients newly diagnosed with lung cancer, 4.5% were tested for the *BRAF* gene mutation. Tested patients were younger and had a lower comorbidity burden, but more advanced disease. The amounts reimbursed for BRAF testing varied greatly based on the modality used (i.e. the combination of procedures that was used for testing); however, the findings of this study suggest that, based on administrative claims, NGS testing is associated with cost savings compared to sequential testing of individual mutations.

Transparency

Declaration of funding

Funding for this research was provided by Novartis Pharmaceuticals Corporation.

Declaration of financial/other relationships

AAD, AM, and KWC are employees of Novartis Pharmaceuticals Corporation and may own stock or stock options. AG is an employee of Analysis Group, Inc., which has received consultancy fees from Novartis Pharmaceuticals Corporation for this study. JME peer reviewers for this manuscript have no relevant financial or other relationships to disclose.

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Previous presentations

A synopsis of the current research was presented in poster format at the Academy of Managed Care Pharmacy (AMCP) 2017 Nexus Meeting, which took place in Dallas, TX, in October 2017, and the National Association of Specialty Pharmacy (NASP) annual meeting, which took place in Las Vegas, NV, in November 2017.

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