

# ANALYSIS OF HEALTH PLAN COVERAGE POLICIES FOR MULTIGENE PANEL TESTING AND ALIGNMENT WITH NCCN GUIDELINES IN SELECT TUMORS

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## INTRODUCTION

- Biomarker testing for somatic mutations has become increasingly useful to inform cancer management decisions.<sup>1</sup>
- Multi-gene panel testing (MGPT) methods using Next Generation Sequencing (NGS) have been developed and utilized to detect multiple alterations.
- MGPT can be an efficient method to guide the use of targeted therapies.<sup>2</sup>
- Currently, there is a limited understanding of how health plans cover MGPT in accordance with NCCN Clinical Practice Guidelines In Oncology (NCCN Guidelines@).<sup>3</sup>

## OBJECTIVE

- To assess the alignment of health plan coverage policies of multigene panel tests with NCCN Guidelines@ for somatic mutation testing in select advanced/metastatic cancer tumors

## METHODS

- We reviewed NCCN guideline recommendations for MGPT in 6 cancers: prostate, non-small cell lung cancer (NSCLC), breast, melanoma, colon, and thyroid.
- The MGPT recommendations associated with each tumor and for specific biomarkers were recorded.
- We examined 14 publicly available payers' commercial coverage policies for MGPT for somatic mutations in solid tumors. Payers were chosen to provide a mix of both regional and national payers.
- Each health plan coverage policy was categorized as more restrictive, consistent, or less restrictive relative to the language in the NCCN guidelines. For example, if policy restricts on panel size yet the guidelines do not state any restrictions by panel size, we considered this "more restrictive".
- Commercial lives covered by category was estimated using the DRG Managed Market Surveyor<sup>4</sup>.

## RESULTS

- NSCLC, melanoma, prostate, and breast tumors had a recommendation for MGPT per the NCCN guidelines.
- Testing for advanced NSCLC and advanced Melanoma was recommended when feasible and testing using MGPT was implied in metastatic prostate tumors. There were no specific recommendations for MGPT in metastatic colon or thyroid tumors.
- The recommendation language for MGPT was stronger in NSCLC and Melanoma tumors and less specific in the other tumors. No recommendation on panel size was identified.

Tumor	Multi gene Panel Testing Recommendation	Biomarkers Recommended with Multigene panel Testing	Example of NCCN guideline recommendations
<b>Advanced NSCLC</b>	Yes*	EGFR, ALK, ROS1, BRAF, MET, RET, NTRK, KRAS, ERBB2, TMB	The NCCN NSCLC guidelines panel strongly advises broad molecular profiling with the goal of identifying rare driver mutations for which effective drugs may already be available or to appropriately counsel patients regarding the availability of clinical trials. Broad molecular profiling is a key component in the improvement of care of patients with NSCLC.
<b>Metastatic Colon</b>	No specific recommendation	None	No specific testing methodology is recommended.
<b>Metastatic Breast</b>	Yes	TMB-H (> or = 10 muts/mb), NTRK	TMB-H (> 10 muts/mb); detected by NGS.
<b>Metastatic Prostate</b>	Yes**	HRRm genes (i.e. BRCA1/2, ATM, PALB2, FANCA, RAD51D, CHEK2, CDK12) (rec. for metastatic), MSI/dMMR (rec. for mCRPC***)	If MSI testing is performed, testing using an NGS assay validated for prostate cancer is preferred.
<b>Advanced Melanoma</b>	Yes*	BRAF, KIT	Broader genomic profiling (e.g., larger NGS panels, BRAF non-V600 mutations) is recommended if feasible.
<b>Thyroid</b>	No specific recommendation	None	Molecular Diagnostic Testing may include multigene assays (e.g., GEC) or individual mutational analysis.

\*When feasible. \*\*Implied but not explicit. \*\*\*Metastatic Castration- Resistant Prostate Cancer

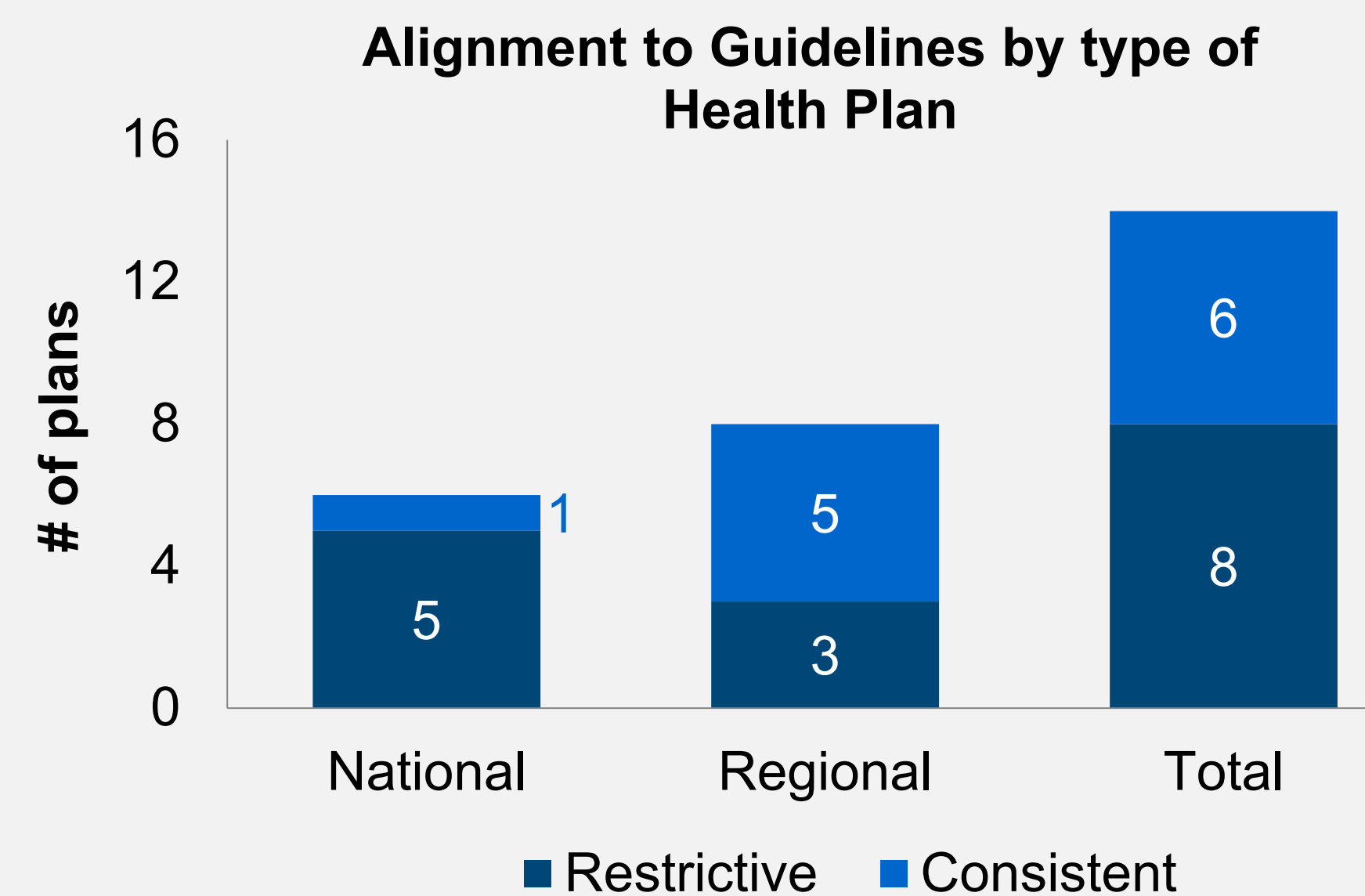
Plan	Plan Coverage Alignment to NCCN guidelines			Consistent with the following tumors				Explanation of Alignment to Guidelines
	Type of Plan	Alignment to Guidelines	NSCLC	Breast	Prostate	Melanoma		
Plan 1	National	More restrictive	×	×	✓	×	×	Policy is restricted to MGPT for TMB and immunotherapy inhibitors only whereas NCCN guidelines recommends MGPT for other biomarkers in NSCLC, Melanoma, Breast
Plan 2	National	Consistent	✓	✓	✓	✓	✓	Utilizes NCCN guidelines
Plan 3	National	More restrictive	×*	×*	×**	×**	×**	NCCN doesn't specify recommendation by panel size; Policy limits testing to NSCLC and breast cancer tumors where NCCN guidelines recommend testing in Melanoma, certain biomarkers in breast (NTRK) and prostate (MSI-H)
Plan 4	Regional	More restrictive	×*	×*	×*	×*	×*	NCCN doesn't specify recommendation by panel size
Plan 5	National	More restrictive	×*	×**	×*	×*	×*	NCCN doesn't specify recommendation by panel size; NGS is recommended in Breast Cancer for testing for (NTRK) and (TMB) and policy does not cover breast cancer testing
Plan 6	National	More restrictive	×*	×**	×**	×**	×**	NCCN doesn't specify recommendation by panel size, NGS recommended for some biomarkers in other tumors (i.e. MSI-H) or in other tumors (i.e. Melanoma)
Plan 7	Regional	More restrictive	×	×	×	×	×	Not covered for any tumor
Plan 8	Regional	Less Restrictive	✓	✓	✓	✓	✓	Medically necessary in NSCLC, prostate and Melanoma and breast, thyroid, colorectal
Plan 9	Regional	Consistent	✓	✓	✓	✓	✓	Consistent with NSCLC, melanoma, prostate, breast (assuming panel includes at least 5 NCCN recommended biomarkers)
Plan 10	Regional	Consistent	✓	✓	✓	✓	✓	Consistent with NSCLC, melanoma, prostate, breast (assuming panel includes at least 5 NCCN recommended biomarkers)
Plan 11	Regional	More restrictive	✓	×	×	×	×	Consistent with NSCLC but NGS recommended for melanoma, prostate and TMB/ NTRK (breast) and HRR/ MSI-H (prostate)
Plan 12	Regional	Consistent	✓	✓	✓	✓	✓	Consistent with NSCLC, melanoma, prostate, breast (assuming panel includes at least 5 NCCN recommended biomarkers)
Plan 13	National	More restrictive	×*	×*	✓ (multi gene panel tests)	×	×	Restricts to the smaller panels where the panel is limited to genes associated with the specific tumor type whereas NCCN makes no recommendation on panel size
Plan 14	Regional	Consistent	✓	✓	✓	✓	✓	Consistent with NSCLC, melanoma, prostate, breast (assuming panel includes at least 5 NCCN recommended biomarkers)

\*No due to panel size restriction

\*\*No due to panel size restriction and tumor restriction

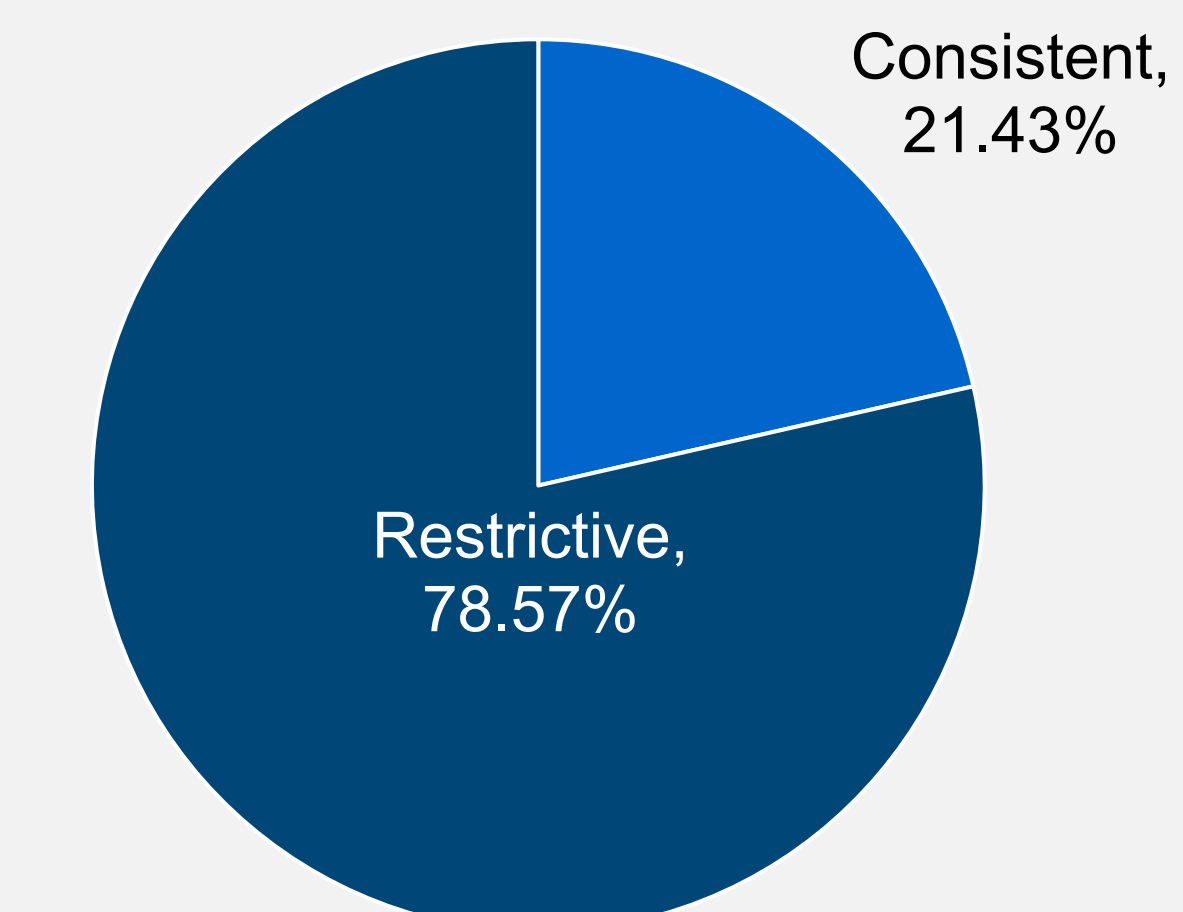
✓ Yes × No

- Eight of the health plans were regional and 6 were national plans, comprising a total of 105 million commercially covered lives.
- Eight (57%) health plans were considered to be more restrictive than the NCCN guidelines while 6 (43%) were consistent or less restrictive with NCCN guidelines.
- Of the plans considered to be more restrictive than the guidelines, 62.5% (5/8) had panel size restrictions and 62.5% (5/8) restricted testing coverage to select or all tumors.
- Plans that restricted coverage to select tumors had the greatest coverage for NSCLC with variable coverage of other tumors.



- An estimated, 21.4% of commercially covered lives were under a consistent/less restrictive plan and 78.6% were under a more restrictive plan.

## By commercial lives covered



## DISCUSSION

- The results of this study indicate variability in the alignment of MGPT coverage policies to the NCCN guidelines of select solid tumors.
- Limitations on coverage due to panel size or tumor was common and may be due to ambiguity in the recommendation language and/or the lack of panel size recommendations in the NCCN guidelines.
- Limitations of our study include the choice of payers in our analysis as these payers represent only a portion of U.S. payers and member benefits may vary within a health plan. Our interpretation of coverage restrictions for MGPT may also have impacted the results.
- Further specificity in guideline recommendations could help guide and direct health plan coverage policies in the future.
- Additional alignment of policies to clinical guidelines can ensure clinically appropriate access to MGPT.

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