Optimizing The Use of Oncology Biomarker Testing Using Health Plan Best Practices and Quality Measures:

Findings from AMCP Market Insights Expert Interviews

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Diana I. Brixner, BPharm, PhD, FAMCP[#]; Noreen Matthews[*]; Terry Richardson, PharmD, BCACP[^]; Daryl Pritchard, PhD[+]; John Fox, MD, MHA[†]; Scott D. Ramsey, PhD, MD[◊]

BACKGROUND

Actionable molecular biomarkers and matched targeted therapies have significantly improved survival for cancer patients. However, many patients do not receive biomarker testing, or the results are not returned prior to initiating therapy. For health plans, precision medicine offers a promising approach to enhance quality, manage costs, utilization, and waste, and address health disparities. The realization of these benefits depends on addressing known barriers that affect appropriate biomarker testing practices.

OBJECTIVE

To identify best practices, conceptualize biomarker testing quality measures, and assess the feasibility of a national quality metric based on the AMCP's Market Insights program, which identified seven critical areas where payers can influence biomarker testing in the NSCLC precision oncology pathway.

METHODS

A targeted literature review was supplemented by eight expert interviews to verify the widespread application of precision medicine via biomarker testing across various cancers. AMCP conducted four unstructured interviews with experts in oncology, quality measurement, and biomarker testing and four structured interviews with professionals in managed care pharmacy and healthcare delivery systems. Best practices and real-world examples were extracted from these discussions.

CONCLUSIONS

Health plans and care delivery systems are well-positioned to support effective biomarker testing and are crucial in developing strategies to reduce disparities in cancer care. Establishing a national biomarker testing quality measure is complex due to the variability in cancer care and health plans in the US; thus, a simplified approach is recommended. Additionally, expert guidance has outlined numerous best practices for health plans to consider if seeking to improve the quality of cancer care through biomarker testing.

RESULTS

The interviews delineated thirteen unmet needs for professional and specialty societies, molecular diagnostic and laboratory companies, care delivery systems, and health plans to address (Table 1). Twenty-one potential best practices for health plans were identified and organized into a framework to enhance precision oncology in seven focal areas (Table 2). Additionally, four real-world examples of quality measures in biomarker testing were identified.

Table 1: 13 Unmet Needs And Recommendations For Key Stakeholders

Stakeholder	Unmet Needs and Recommendation
Professional and Specialty Societies	1. Develop Clear Biomarker Testing Guidelines: Oncology specialty societies and networks of cancer centers should establish clear and standardized guidelines for biomarker testing in oncology to guide providers, support payer policies, and ensure that patients receive the most appropriate care based on the latest evidence and best practices. 2. Develop a Lab Test Certification Program: A third-party society or accrediting agency should develop an annual certification attesting that multiplex panels meet current national guidelines for NGS testing. 3. Invest in Education and Awareness: Professional societies must educate health care providers and patients about the importance and benefits of biomarker testing in oncology, highlighting its role in personalized medicine and improved treatment outcomes.
Molecular Diagnostic and Laboratory Companies	4. Address Operational Challenges: Laboratories should invest in solutions to reduce test turnaround times. 5. Address Scientific Challenges: Molecular diagnostic and laboratory companies should engage in scientific discourse on appropriate testing methodologies and retire tests that do not include the actionable biomarkers established in guidelines relevant to their specific type of cancer.
Care Delivery Systems	6. Enhance Interdisciplinary Collaboration: Care delivery systems can foster collaboration between pharmacists, pathologists, oncologists, and other health care professionals to ensure a multidisciplinary approach to biomarker treatment decisions. 7. Biomarker Test Ordering: Care delivery systems should implement protocols to support and accelerate biomarker test ordering. This may include linking reflexive biomarker test ordering to initial diagnosis or allowing for test ordering by select health care professionals (e.g., pathologists). 8. Biopsy Referral: Measures should be implemented to deliver equitable biopsy referral for all patients, regardless of their socioeconomic status.
Health Plans	9. Improve Provider-Payer Communication: Health plans can implement strategies to improve communication between health care providers and payers regarding coverage updates and policy changes to facilitate timely and informed treatment decisions. 10. Mitigate Health Disparities: Health plans should develop strategies to ensure equitable access to biomarker testing for all patient populations, addressing barriers to insurance coverage, socioeconomic status, and other factors contributing to health disparities. 11. Leverage Prior Authorization Processes: Health plans can utilize the prior authorization to encourage biomarker testing before certain treatments, aligning treatment decisions more closely with evidence and individual patient histologic and genomic profiles. 12. Measure Biomarker Testing: Health plans should take action to pilot test quality measures or a combination of approaches to improve the appropriate use of biomarker-driven treatment selection in select cancers. 13. Utilize a Checklist for Biomarker Testing Improvement: By following this checklist, health plans can contribute to the effective, efficient, and equitable use of biomarker testing.

Table 2: Framework For Potential Health Plan Best Practices in Oncology Biomarker Testing

BIOMARKER TESTING ORDERING	TESTING PERFORMANCE	RESULT REPORTING	TREATMENT DECISION	QUALITY IMPROVEMENT	COST EFFECTIVENESS	HEALTH DISPARITIES
• Provide coverage of biomarker testing based on guidelines • Provide coverage for FDA-approved biomarkers • Provide coverage for next-generation sequencing (NGS) • Allow for reflex test ordering • Provide coverage for liquid biopsy	• Enhance care through interdisciplinary collaboration by leveraging the expertise of various specialists	• Set benchmarks for the duration of time from test ordering to result reporting • Foster clear and prompt communication of test results	• Prioritize biomarker testing before treatment initiation • Develop systems or protocols to align biomarker test results with recommended treatments • Consider the use of a multi-expertise molecular tumor board to guide treatment decisions	• Assess if biomarker testing is sufficiently comprehensive to provide a complete picture of relevant prognostic and predictive biomarkers • Ensure that testing is aligned with current guidelines and best practices • Establish benchmarks for the time from test ordering to result reporting • Measure the percentage of patients who undergo biomarker testing and have their cases reviewed by a molecular tumor board • Measure the percentage of patients who do not begin therapy until after biomarker test results have returned	• Collaborate with molecular testing laboratories for more affordable testing options • Assess policies to promote cost-effective care, considering the implications of treatment choices on overall health care costs and the potential savings from accurate early treatment selection • Develop objective criteria and guidelines on testing frequency	• Emphasize the importance of broad genetic testing to capture a wider array of actionable mutations to reduce racial and ethnic disparities that stem from limited diversity in clinical trials • Work to mitigate access barriers to testing and treatment for underserved populations

Real-World Examples of Quality Improvement Efforts in Oncology Biomarker Testing

Quality Measurement in Washington State[1]

BIOMARKER TESTING FOR METASTATIC LUNG CANCER

Biomarker testing for metastatic lung cancer
• Receipt of NGS, EGFR, ALK or ROS1 test

Population: Patients with non-small cell lung cancer with metastatic disease

Reporting Years: 2018-2020

Time Period: The testing period begins two months prior to diagnosis and continues through four months following diagnosis.

Molecular Profiling Through Use of PA and Peer Review[2]

PROTOCOL FOR TESTING REQUIREMENT

Prior Authorization Algorithms → Documentation required for molecular profiling of EGFR, ALK, ROS1, BRAF genes prior to approval for ICI therapy.

Proactive Peer Consultation → If documentation is not provided, peer consultation is initiated to assure completion of genomic testing prior to therapy.

Molecular Tumor Board Review[3]

MOLECULAR TUMOR BOARD FLOW DIAGRAM

Tumor genetic testing ordered and results returned → **Personalized Medicine Clinical Service** discussion and review → Expedited consult communicated to ordering clinician / Referral to **Clinical Genomics Action Committee** → Consult report generated and documented in EHR → Discussion with oncologist and patient → Assistance with acquisition of off-label therapy if needed

PIMSH13 – Oncology: Mutation Testing for Stage IV Lung Cancer Completed Prior to the Start of Targeted Therapy[4,5]

Measure Description Proportion of stage IV nsNSCLC patients tested for actionable biomarkers and received targeted therapy or chemotherapy based on biomarker results

Numerator: Patients who received mutation testing for all actionable biomarkers at Stage IV diagnosis of nsNSCLC (including NTRK1/2/3, RET, MET, ROS1, EGFR, EGFR T790M, BRAF mutation, ALK rearrangement, CD274(PD-L1), KRAS, ERBB2 mutation) AND lung cancer treated with appropriate mutation-directed therapy or standard chemotherapy if biomarker results are negative

Denominator: Patients with stage IV nsNSCLC receiving initial treatment during the measurement period AND patient encounter during the performance period

Measure Type: Process

Endorsed by The US Oncology Network Steering Committee

Author Affiliations: [#]University of Utah, [*]AMCP, [^]Impact Education, LLC, [+]Personalized Medicine Coalition, [†]Illumina, Inc., [◊]Hutchinson Institute for Cancer Outcomes Research

NSCLC: non-small cell lung cancer

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1. Hutchinson Institute for Cancer Outcomes Research. Community Cancer Care in Washington State: Quality and Cost Report 2024. © 2024 Fred Hutchinson Cancer Center, Seattle, WA. Accessed July 2024. https://www.fredhutch.org/content/dam/www/research/institute-networks-ircs/hicor/CCCReport/HICOR-Community-Cancer-Care-Report-2024-Quality-and-Care.pdf
2. Hamilton S, Sagar B, Christensen K, Dollear T, Bowers A. Increased Adherence to Molecular Profiling Recommendations in Non-Small Cell Lung Cancer (NSCLC) Through Use of Prior Authorization and Peer Review. Abstract 9129. Presented at ASCO 2022. Evicore website. Accessed April 2023. https://www.evicore.com/insights/new-molecular-profiling-and-prior-auth-for-nsclc
3. Leaving No Stone Unturned for Cancer Treatment Options. Bon Secours website. Published December 30, 2021. Accessed April 3, 2024. https://blog.bonsecours.com/news/precision-oncology-cancer-treatment-collaboration-richmond/
4. McKesson's Practice Insights Designated as a 2024 Qualified Clinical Data Registry by Centers for Medicare & Medicaid Services. The US Oncology Network in The News website. Published February 8, 2024. Accessed April 22, 2024. https://usoncology.com/news/mckessons-practice-insights-designated-as-a-2024-qualified-clinical-data-registry-by-centers-for-medicare-medicaid-services/
5. PIMSH13 – Oncology: Mutation Testing for Stage IV Lung Cancer Completed Prior to the Start of Targeted Therapy. Healthmonix website. Accessed April 22, 2024. https://healthmonix.com/mips_quality_measure/pimsh-13/

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