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Precision Medicine Bulletin

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AMCP

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1 Recap & Updates on 2026 AMCP Initiatives

AMCP is launching this **quarterly bulletin** to keep our membership and the healthcare community informed on our precision medicine work — from published resources and in-progress publications to policy engagement and research — alongside other significant developments shaping precision medicine access across managed care. **Look for a new issue each quarter.**

Actions

Payers & LBMs:

- Reference AMCP resources when updating medical policies and utilization management criteria
- Share published resources with policy, pharmacy, and medical affairs teams

Pharmaceutical Manufacturers:

- Follow the progress of AMCP initiatives to understand emerging expectations
- Incorporate standardized terminology and clinical utility concepts into evidence generation and value communications
- Share AMCP educational resources in key discussions

Join an AMCP LINK Interest group or **become an AMCP sponsor to** support broader alignment around precision medicine best practices!

LBM=Laboratory benefit managers

NCCN Submission Highlights

AMCP submitted recommendations to NCCN that aim to improve guideline clarity and reduce ambiguity that can contribute to inconsistent coverage decisions, operational inefficiencies, and delays in patient access. While recommendations are under NCCN review, they highlight emerging areas where future guideline language may evolve.

Actions

Payers & LBMs:

- Review current biomarker testing policies (PA criteria, panel-size limits, workflow requirements) against the gaps AMCP flagged above
- Monitor future NCCN updates to determine whether recommendations are incorporated into upcoming guideline versions
- **Work with AMCP** and participate in future AMCP initiatives to provide payer perspectives on implementation challenge

Pharmaceutical Manufacturers:

- Monitor the status of AMCP's recommendations and future NCCN updates to understand emerging expectations
- Engage with AMCP initiatives to help support broader alignment around precision medicine best practices

AMCP-Submitted Recommendations

Strengthening recommendations for upfront CGP

Current language may allow variable interpretation of panel-based testing, leading to sequential or limited testing strategies

More explicitly endorse broad panel-based testing upfront by removing permissive language around tiered/single-gene testing, reinforcing CGP as the recommended approach when feasible, and clarifying the role of larger NGS panels in meeting biomarker testing recommendations

NCCN=National Comprehensive Cancer Network
PA=prior authorization
CGP=comprehensive genomic profiling
NGS=next generation sequencing

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AMCP-Submitted Recommendations (cont.)

Reducing treatment decisions made before molecular results are available

Existing guidance may permit immunotherapy initiation before biomarker results are returned, creating risk of suboptimal first-line treatment selection

→ **Strengthen language to reinforce completion of molecular testing prior to immunotherapy initiation whenever feasible**

Adding guidance for workflow-initiated ("reflex") biomarker testing by pathologist

Current workflows often rely on multiple handoffs before biomarker testing is initiated, contributing to delays

→ **Add guidance to support workflow-initiated (reflex) biomarker testing processes to accelerate testing and improve consistency**

Clarifying the role of complementary testing modalities

Current guidance may underemphasize RNA-based sequencing and additional protein-based biomarker testing (e.g., HER2, c-MET)

→ **More clearly position RNA-based tests as important components of comprehensive biomarker assessment and encourage concurrent use of DNA and RNA-based tests**

RNA=ribonucleic acid
DNA=deoxyribonucleic acid
HER2=human epidermal growth factor receptor 2

Upcoming Resources

Precision Medicine Publications

We are excited to have three manuscripts that will be published any day now! All publications are co-authored by **AMCP and Omnicom Health Market Access** and have been accepted for publication by AMCP.

Keep your eyes open for them in the electronic Table of Contents. We will provide full links when available!

1. **Natural Language Processing to Develop a Standardized Lexicon for Precision Medicine in Oncology**
   Using NLP to standardize precision medicine terminology and close gaps in how key concepts are defined and applied across managed care

2. **Key Considerations When Assessing Clinical Utility for Biomarker Testing: A Checklist**
   Establishing a structured framework for evaluating biomarker testing evidence to improve alignment and clarity in how clinical utility is defined and assessed

3. **Payer Coverage Principles for Precision Medicine Biomarker Testing in Oncology**
   Unveiling consensus- and evidence-driven policy considerations to support consistent coverage and access for biomarker testing

NLP=natural language processing.

Available Resources

Precision Medicine LINK Webinar

AMCP held the Precision Medicine LINK webinar on **April 30, 2026.** The webinar brought standards, advocacy, and real-world insights together to help audience create clearer, more consistent pathways to precision medicine access.

Key Topics:

- Reviewed recommended terms and definitions from the 2025 NCCN Biomarkers Resource Committee, grounding coverage and UM decisions in a shared, consistent language led by **Melissa Tjota, PhD with the University of Chicago**
- **Hilary Gee Goeckner, MSW with American Cancer Society Cancer Action Network** highlighted ongoing advocacy efforts shaping access to care across the country
- **Pam Pawloski, PharmD, Principal Research Scientist with AMCP Research Institute** shared insights from a **real-world study** exploring payer-identified gaps and opportunities in coverage for molecular testing

Missed it? Watch the recording.

Precision Medicine Podcast

In this episode of Unscripted, guest host **Steve Kheloussi**, Principal Consultant with Kheloussi Consulting, sits down with **Dr. John Fox**, Senior Medical Director for the Americas at Illumina, to untangle the complexities of clinical utility.

Key Topics:

- Discussed why defining clinical utility remains a challenge across healthcare stakeholders and why greater alignment is needed
- Explored the role of biomarker testing in improving diagnosis, treatment selection, and patient outcomes—from pediatric rare diseases to oncology
- Highlighted how demonstrating the clinical value of biomarker testing can support broader adoption, coverage, and implementation of precision medicine

Tune in: Listen to the episode.

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Available Resources

Precision Medicine Resource Page

Looking for a one-stop hub? AMCP's Precision Medicine Resource page brings together the initiative's publications, webinars, podcasts, and ongoing research in one place — a quick way to catch up or point colleagues to the latest work.

Explore it here: Precision Medicine Initiative | AMCP.org.

Research Activity

An Assessment of Biomarker testing in NSCLC

Through this retrospective analysis of administrative data led by Pam Pawloski, PharmD, BCOP, AMCP Research Institute's objective is to assess the biomarker testing landscape in non-small cell lung cancer (NSCLC), relative to the rate of receipt of biomarker testing by demographics, payer type, year, and time to testing and treatment initiation. Preliminary results demonstrate suboptimal testing rates and variations in testing based on patient demographics (age) and payer type. Patients with and without biomarker testing receive targeted therapy.

Broad Molecular Testing in NSCLC Initiative

This mixed methods research initiative funded by LUNGevity and the American Cancer Society (ACS) Cancer Action Network (CAN) and led by Pam Pawloski, PharmD, BCOP at ARI is designed to better understand and address gaps in coverage for broad molecular testing in non-small cell lung cancer (NSCLC) among regional and mid-size payers. Leaders in decision-making roles related to biomarker testing will be asked to participate in surveys and interviews in the coming months.

NSCLC=non-small cell lung cancer

2 Guideline Review
NCCN Practice Guidelines in Oncology: NSCLC

Version 5. 2026, Published March 13, 2026

Changes to NCCN guideline language frequently influence payer medical policies, PA requirements, and clinical practice. Staying informed allows organizations to proactively evaluate whether coverage remains aligned with current evidence and guidelines

Actions

Payers & LBMs:

- Share these guideline updates with medical policy committees, oncology pharmacists, laboratory benefit management teams, and UM reviewers
- Evaluate whether current coverage criteria reflect the latest NCCN recommendations.
- Identify opportunities to reduce unnecessary barriers to guideline-concordant biomarker testing

Pharmaceutical Manufacturers:

- Review how guideline updates may affect market access strategies
- Anticipate potential changes in payer coverage and provider adoption
- Update field medical and market access teams on changes that may influence stakeholder discussions

General Recommendations

Topic	Summary
Lab accreditation	Testing labs must be, at minimum, CLIA-accredited.
Core biomarker panel	Complete testing covers EGFR, ALK, ROS1, BRAF, NRG1 fusions, KRAS, MET, RET, ERBB2/HER2, and NTRK1/2/3 — **via a single assay or limited combination.**

CLIA= Clinical Laboratory Improvement Amendments

Broad-Panel NGS Testing Recommendations

Topic	Summary
Sequential single-gene testing	**Not preferred**; tiered approaches **are acceptable** when co-occurring biomarkers are low-prevalence.
Large panel NGS (>50 genes)	**Maybe practical**, Either **a single assay or limited combination may be appropriate**
RNA-based NGS	**Recommended** when DNA-based NGS does not identify a driver oncogene.
Concurrent RNA + DNA NGS	Permissible; **may** increase detection of novel fusions and **can be performed concurrently or sequentially**

Tissue and ctDNA-based Testing Recommendations

Topic	Summary
Tissue testing	**Recommended** in both early-stage and advanced/metastatic disease.
Liquid (ctDNA) testing	**Recommended** only in advanced/metastatic disease; should not be a substitute for histologic tissue diagnosis.
Concurrent tissue + ctDNA	Permissible and **can be** performed to achieve complete genotyping; evidence supports complementarity, but no formal recommendation is made.
Repeat testing at disease progression	Permissible. concurrent tissue + ctDNA testing **may** help identify resistance mechanisms. Repeat testing for EGFR p.T790M **is recommended**; testing for other resistance mechanisms is permissible and **may be used**

ctDNA=circulating tumor DNA
EGFR=epidermal growth factor receptor

Questions?

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