Closing access gaps in HER2-targeted therapy for gastroesophageal adenocarcinoma (GEA) and biliary tract cancers (BTC): Specialty pharmacy recommendations from a mixed-methods multistakeholder program

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Background

Access to HER2-targeted therapies in GEA and BTC remains inconsistent despite recent FDA approvals. Variability in biomarker testing, payer policies, and care coordination causes treatment delays. Pharmacy and oncology stakeholder engagement can inform scalable operational solutions relevant to specialty pharmacy practice.

Objective

To quantify barriers to HER2-targeted therapy and provide multistakeholder-informed recommendations, including specialty pharmacy-aligned strategies to improve biomarker testing, coverage processes, and care coordination.

Methods

A mixed-methods design began in Q1 2025 with 3 regional (North, South, West) multidisciplinary (pharmacy and oncology) roundtables (n=29 representing >121M covered US lives). Quantitative polling during the roundtables assessed barriers, priorities, and the impact of interventions, while facilitated discussions were analyzed to identify convergent and region-specific insights to be emphasized in subsequent interventions. Next, in-depth interviews (IDIs) with 6 nationally recognized experts in oncology, hematology, pharmacy, and managed care were conducted in November 2025 to further develop best practice recommendations. Finally, a national online survey was conducted from December 2025 through January 2026. The survey comprised 12 quantitative items, including single and multiple-choice questions, with open-ended options to elicit additional perspectives and contextual information to validate the roundtable and IDI-identified best practices. The survey was sent to 1,379 verified health plan pharmacy and medical professionals from a proprietary database with a goal of 50 responses.

- **3 regional multidisciplinary roundtables**
  - n=29 representing >121M covered US lives
  - **Q1 2025**
- **Survey**
  - Sent to 1,379 verified health plan pharmacy and medical professionals with a goal of 50 responses
  - **Q4 2025**
- **6 IDIs**
  - Experts in oncology, hematology, pharmacy, and managed care
  - **Q4 2025**

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Results

Roundtable participants identified opportunities for improved coordination, including benefits investigation, prior authorization (PA) support, biomarker workflow facilitation, and patient navigation. South Region stakeholders identified biomarker testing requirements, coverage variability, and PA delays as key barriers to HER2-targeted therapy access and highlighted the need to align biomarker testing practices and payer coverage policies to support timely access to precision oncology treatment. North Region discussions underscored the need for standardized guidance on HER2 testing and treatment sequencing, improved multidisciplinary care coordination, and enhanced payer education on emerging HER2-targeted therapies. West Region stakeholders emphasized operational solutions, including payer-provider communication, alignment of medical and pharmacy benefit policies, and standardized reimbursement pathways for biomarker testing to reduce disparities in access to HER2-targeted therapies.

IDIs identified multidisciplinary care and access to specialty expertise as critical determinants of outcomes, particularly for patients treated in community and rural settings. Timely biomarker testing was universally recognized as the cornerstone of treatment selection, yet administrative and coverage barriers continue to delay access to precision oncology therapies. Clinicians and managed care leaders aligned on the need to streamline coverage policies, reduce administrative burden, and strengthen patient navigation and supportive care services.

Survey results (n=50) showed strong alignment on the identified key barriers and priorities. The greatest challenge identified was the high cost of targeted therapies (80%). Barriers to HER2 testing and access included unclear coverage/high therapy costs (50%) and delays in reporting lab results (36%). Patient-level barriers included financial toxicity and PA delays (60%), delays in treatment initiation (46%), and travel burden/fragmented care (40%). Selected high-impact strategies were providing comprehensive biomarker coverage (70%), coverage of guideline-based biomarker testing (66%), and streamlining PAs (64%). Nearly all (92%) of survey respondents rated patient navigation very or extremely valuable.

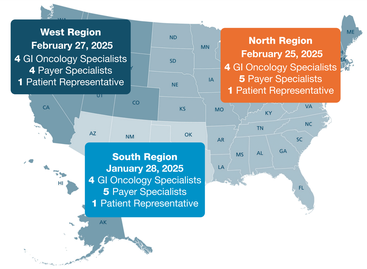
Conclusion

Mixed-methods findings demonstrate consistent barriers to HER2-targeted therapy across regional multidisciplinary roundtables, expert interviews, and a national managed care survey. Solutions emphasized improved coordination, policy alignment, and patient support, with specialty–aligned services enabling streamlined access and reducing delays in biomarker-driven oncology care.

Implications for Specialty Pharmacy Practice

Integrating benefits navigation, clear biomarker testing guidelines, and patient support services that accelerate time to treatment may reduce disparities in care for patients with HER2-positive gastrointestinal cancers.

Top Insights from the Roundtable Polling by Region



Greatest opportunity for collaboration between oncology and payers to optimize care for patients with GEA or BTC (choose one)

Greatest impact on improving outcomes for patients with GEA or BTC (choose one)

Primary gap or challenge for HER2-targeted therapies in GEA and BTC (choose all that apply)

Most effective educational strategy to address known barriers to HER2-targeted therapy (choose one)

6 IDIs: 3 oncologists, 3 managed care/health plan decision makers

Timely, Multidisciplinary Care is Critical

Delays in diagnosis, testing, and treatment—especially in community settings—are major barriers. Health plans should prioritize access to subspecialists and coordinated care.

Biomarker Testing Drives Modern Therapy

HER2 and other molecular markers are essential for guiding treatment. Coverage policies must keep pace with evolving standards and ensure access to testing.

Administrative Burden and Financial Toxicity Remain High

Prior authorization, site-of-care restrictions, and high out-of-pocket costs impede care. Streamlining processes and supporting navigation can mitigate these barriers.

OBMs Can Help—but Must Be Patient-Centered and Flexible

Oncology Benefit Managers (OBMs) are valuable for aligning coverage with best practices but must avoid adding unnecessary bureaucracy and should engage clinicians early.

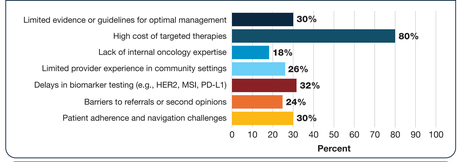
Holistic, Patient-Centered Support is Needed

Beyond drugs and procedures, patients need nutrition, mental health, and social support, as well as clear, empathetic communication from both providers and payers.

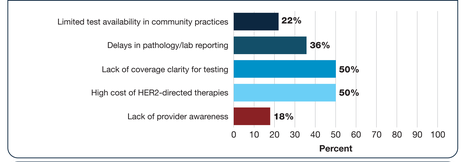
Survey Results

Professional affiliation of survey respondents

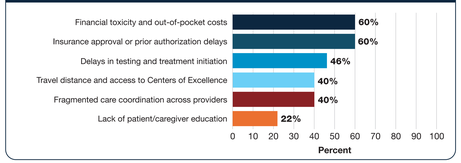
What are the most significant challenges in managing patients with GEA and BTC? (Select up to 3)



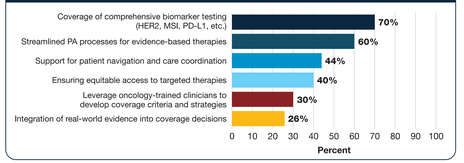
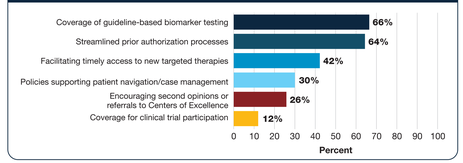
What are the most common barriers to ensuring timely HER2 testing and access to HER2-directed therapies? (Select up to 2)



What are the most common barriers patients face across the GEA and BTC treatment journey? (Select up to 3)



Which elements are most important to include as best practices for payer management of GEA and BTC? (Select up to 3)



Which payer strategies have been most effective in improving outcomes for GEA and BTC patients? (Select up to 3)