



The Role of Real-World Evidence in Oncology Management



Panel

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Background

The evolving use of real-world evidence (RWE) in oncology management is impacting oncology access stakeholders and their management decisions. In this 4-episode video series, our panel reviews the opportunities and challenges in implementing real-world evidence in oncology management.

Key Highlights

- 1 Episode 1:** Real-world evidence is increasingly informing management decisions for oncology populations, serving as a bridge between clinical and safety data with real-world outcomes. Our panelists discuss opportunities for and challenges to incorporating RWE in oncology management.
- 2 Episode 2:** Clinical pathways play an important role in oncology management, with a direct impact on how providers select treatments. RWE serves as one resource to support pathway optimization.
- 3 Episode 3:** Decision-makers are looking for impactful RWE from high-quality, reputable sources. Our panelists weigh in on the types of RWE they incorporate in their decision-making.
- 4 Episode 4:** Our panelists share examples of how real-world evidence has made real-world impacts, from changes in operationalization to changes in coverage.

“The challenge is while we may want to use real-world evidence to make the most informed decision for our patients and our organization, at the end of the day you can run into significant roadblocks. Improved transparency and **collaboration between practices, payers, and our life science partners can really help navigate some of the challenges** we see.”

— Dr Kirollos Hanna

Real-World Evidence Standards

To support payer decision-making based on RWE, the Academy of Managed Care Pharmacy (AMCP) Research Institute has developed RWE standards. Designed in partnership with IQVIA, payers, pharmaceutical companies, and others, the AMCP RWE standards provide a framework to facilitate payer-specific assessments of RWE and guidance for designing RWE studies and communicating results that will be most impactful for payer formulary and coverage decisions. These standards include a framework that outlines which RWE study types and endpoints might be available to support coverage and reimbursement decisions.

AMCP Real-World Evidence Framework Across Stages of the Drug Life Cycle¹

	Preapproved Product Dossier (1+ Years Before Launch)	Approved Product Dossier (at Product Launch)	Updated Approved Product Dossier (2+ Years After Launch)	Indication Expansion Dossier (1+ Years After Launch)
Study type (examples)	- Epidemiology and natural history of disease (eg, real-world diagnosis and treatment patterns) - Description of clinical outcomes associated with standard of care (SOC) - Subgroup analyses - Real-world patient experience - Total cost of care analyses - Economic models	- Pragmatic clinical trial - Adaptive trials - External control arm - Indirect treatment comparison - Analyses of outcomes of patients treated under compassionate use programs - Subgroup analyses - Biomarker validation studies - Real-world patient experience - Economic models	- Real-world safety and effectiveness studies (single arm or comparative) - Rollover studies/long-term extension - Subgroup analyses - Real-world endpoint validation studies - Real-world patient experience - Meta-analyses of real-world evidence or clinical trials - Economic models	Current standard of care - Same as preapproved product dossier From off-label use - Real-world safety and effectiveness (single-arm or comparative studies) - External comparator - Indirect treatment comparison - Real-world data (RWD) subgroup analyses - Biomarkers - Real-world patient experience
Endpoints	Disease epidemiology - Current SOC - Comorbidities - Unmet need - Burden of illness - Drug use/treatment patterns - Adherence to treatment (eg, discontinuation or switching) - Major safety events Economics - Healthcare resource utilization (HCRU) - Cost-effectiveness/budget impact of disease or SOC - Total cost of care	Endpoints from preapproval dossier, with direct or indirect comparison to clinical trial outcomes	Clinical - Refined description of treated population - Adherence and persistence - Validation of surrogate endpoints that may have been included in product approval - Real-world effectiveness - Real-world safety Economics - HCRU - Cost-effectiveness/budget impact of disease or SOC - Total cost of care	Clinical - Refined description of treated population - Adherence and persistence - Validation of surrogate endpoints that may have been included in product approval - Real-world effectiveness - Real-world safety Economics - HCRU - Cost-effectiveness/budget impact of disease or SOC - Total cost of care

HCRU, healthcare resource utilization; RWD, real-world data; SOC, standard of care.

Table adapted and reprinted with permission from the *Journal of Managed Care & Specialty Pharmacy*; Lockhart CM et al. 2025;31(12):1230-1236.

“Real-world evidence helps us bridge evidence gaps that we weren’t able to bridge before, especially when competing oncology therapies lack any real head-to-head kind of battles or trials. Often a new treatment clinical trial is against standard of care or against doing nothing. So [RWE] shows that real-world durability, the toxicity, adherence, and utilization patterns.”

— Dr Timothy Law

Reference: 1. Lockhart CM, Powers E, Sweet B, Gleason PP, Brixner D. AMCP real-world evidence standards: overcoming barriers to using real-world evidence in US payer decision-making. *J Manag Care Spec Pharm*. 2025;31(12):1230-1236.

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