# US Payer assessment of the utility and impact of value dossier content, format, and impact on decision-making

**HTA 343**

Keep Space Clear for QR Code

Mary Fletcher-Louis*[1], Sophie Doran[1], Abigail Silber[1], Matthew O'Hara[1]

[1] Trinity Life Sciences, London, United Kingdom, US; *Presenting Author
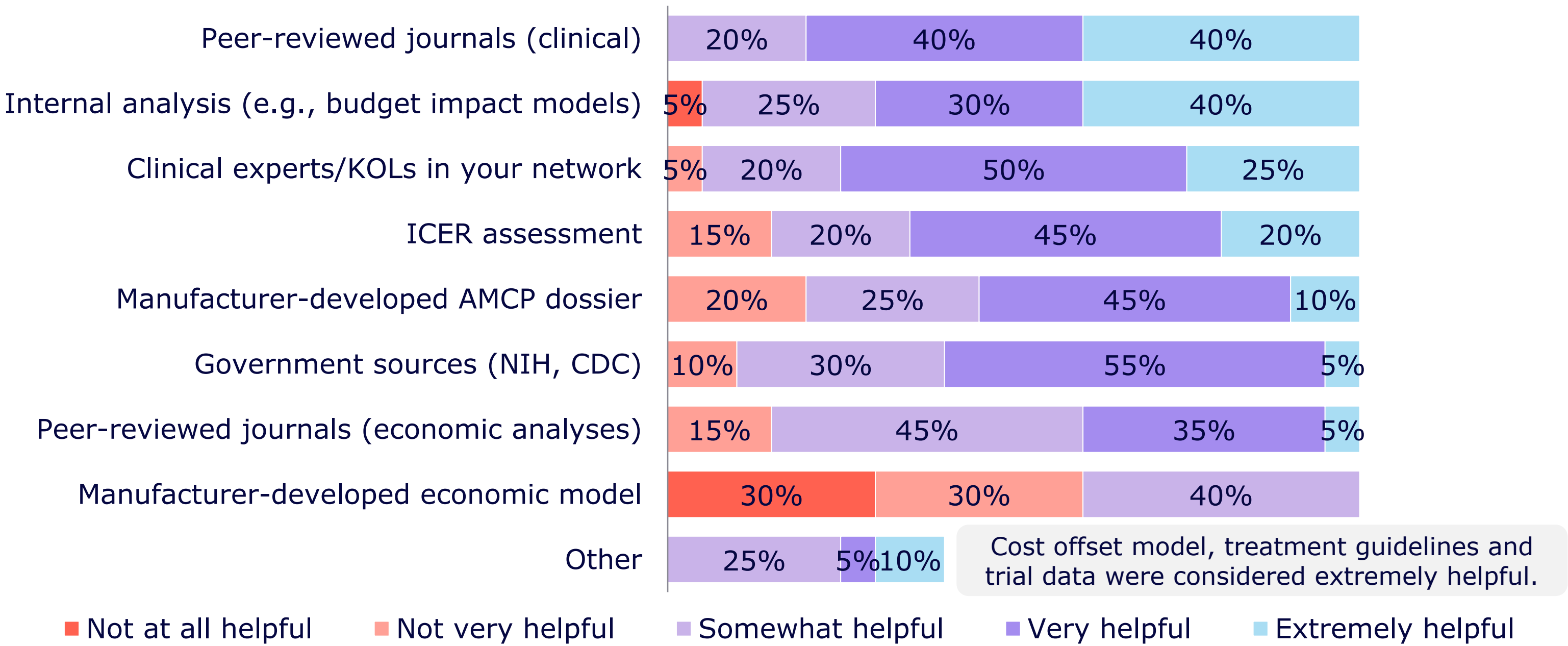
## Introduction & Objectives

The Academy of Managed Care Pharmacy (AMCP) Dossier Format 5.0 is the standard for presenting clinical, economic, and humanistic evidence to support formulary reviews, but its impact on payer decision making remains uncertain. The objective of this research was to understand US payer perspectives on use/impact of AMCP Dossiers.

## Methods

A survey was fielded among U.S. payers, who were required to be involved in pharmacy and therapeutics (P&T) decision making for a managed care organization (MCO), integrated delivery network (IDN) or pharmacy benefit manager (PBM) covering >10 million lives. The sample included n=20 payers, 40% representing large national MCOs, 40% regional MCOs, 10% from IDNs, and 10% from PBMs (average covered lives ranged from 136M [large national MCO] to 11M[IDNs]). The majority (85%) were pharmacy directors, 15% were medical directors. After analyzing survey findings, Trinity Life Sciences conducted 1-hour interviews with 4 US pharmacy directors to explore their perspectives on the survey findings.

# Results

## Figure 1| U.S. Payer Evaluation of the Value of Key Evidence Sources in Making Formulary Coverage and Access Decisions



| | Not at all helpful | Not very helpful | Somewhat helpful | Very helpful | Extremely helpful |
|---|---|---|---|---|---|
| Peer-reviewed journals (clinical) | | | 20% | 40% | 40% |
| Internal analysis (e.g., budget impact models) | 5% | | 25% | 30% | 40% |
| Clinical experts/KOLs in your network | 5% | | 20% | 50% | 25% |
| ICER assessment | | 15% | 20% | 45% | 20% |
| Manufacturer-developed AMCP dossier | | 20% | 25% | 45% | 10% |
| Government sources (NIH, CDC) | 10% | | 30% | 55% | 5% |
| Peer-reviewed journals (economic analyses) | | 15% | 45% | 35% | 5% |
| Manufacturer-developed economic model | | 30% | 30% | 40% | |
| Other | | | 25% | 5% 10% | |

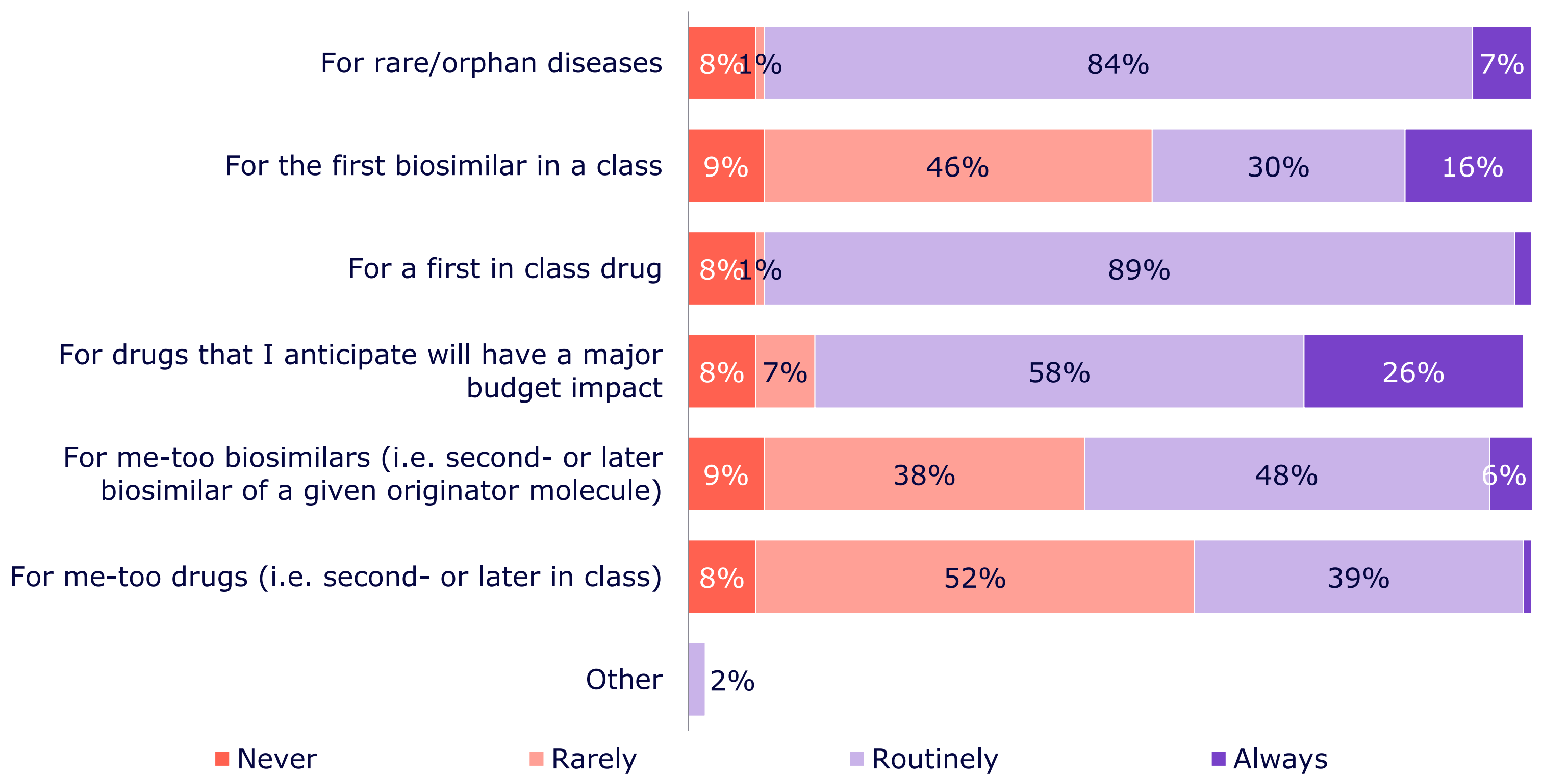Cost offset model, treatment guidelines and trial data were considered extremely helpful.

### % of Surveyed U.S. Payers (n=20)

AMCP dossiers were considered extremely/very/somewhat helpful by 80% of payers. The most helpful evidence for making decisions was from peer-reviewed journals with a clinical focus (considered very helpful by 80%). Payer-generated economic analyses were considered very helpful by 70%, in contrast to manufacturer-developed economic models (considered not at all or not very helpful by 60%).

**Interview findings**
- US payers are using their own EHR data and population demographics, and external sources for claims data to model budget impact. BIMs that allow payers to input their own data are most valuable
- They appreciate the summary value frameworks provided by ICER and NCCN

## Figure 2| AMCP Dossier Content Used in Formulary Decision Making (% of respondents)



| | |
|---|---|
| Clinical practice guidelines | 90% |
| Clinical evidence | 88% |
| Executive summary | 70% |
| Product information | 60% |

**Above 50%**

---
**50% or below**

| | |
|---|---|
| Summaries of HTA and systematic reviews | 48% |
| Economic value and modelling report | 45% |
| Compendia information | 37% |
| Effect on equity | 33% |
| Effect on quality measures | 33% |
| Patient information | 19% |

Note that 57% of surveyed formulary decision makers refer to the cost per average treatment duration, and 43% use the PMPM data (next slide)

The clinical evidence section was the most frequently used content, with 90% relying on it, followed by clinical practice guidelines (75%).

**Interview findings:**
- The economic section is used but the assumptions and references are the most helpful because of strong perception of bias, 'We always create our own BIM.'
- US payers are increasingly exploring how comparative effectiveness plays into the 'matched-adjusted total cost of care and want pharmacy and medical benefit insights

## Figure 3| Circumstances Driving AMCP Dossier Requests (% of respondents)



| | Never | Rarely | Routinely | Always |
|---|---|---|---|---|
| For rare/orphan diseases | 8% | 1% | 84% | 7% |
| For the first biosimilar in a class | 9% | 46% | 30% | 16% |
| For a first in class drug | 8% | 1% | 89% | |
| For drugs that I anticipate will have a major budget impact | 8% | 7% | 58% | 26% |
| For me-too biosimilars (i.e. second- or later biosimilar of a given originator molecule) | 9% | 38% | 48% | 6% |
| For me-too drugs (i.e. second- or later in class) | 8% | 52% | 39% | |
| Other | | | 2% | |

Dossiers were frequently requested for rare diseases, with 85% requesting them "routinely" or "always." The clinical evidence section was the most frequently used content, with 90% relying on it, followed by clinical practice guidelines (75%).
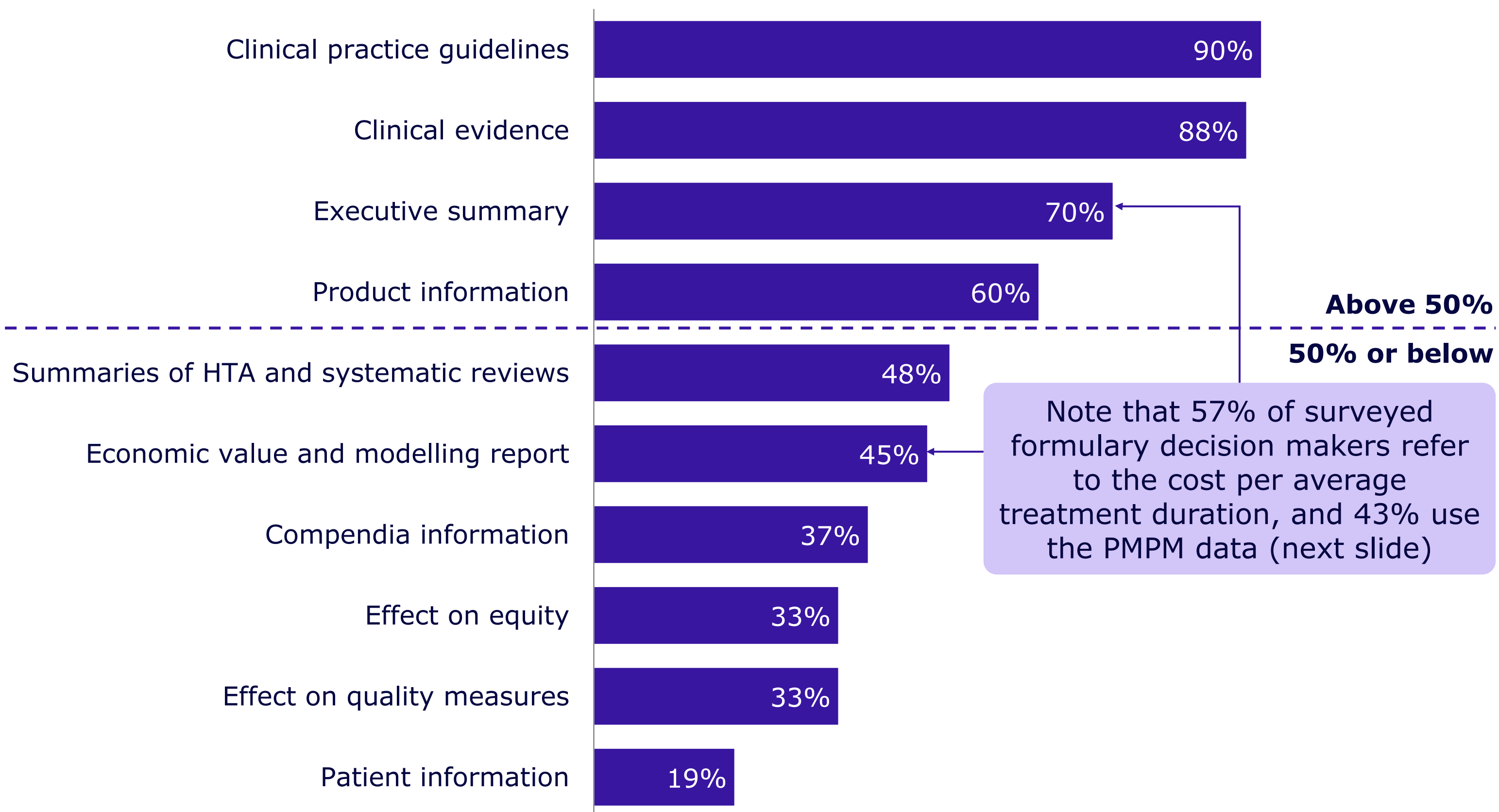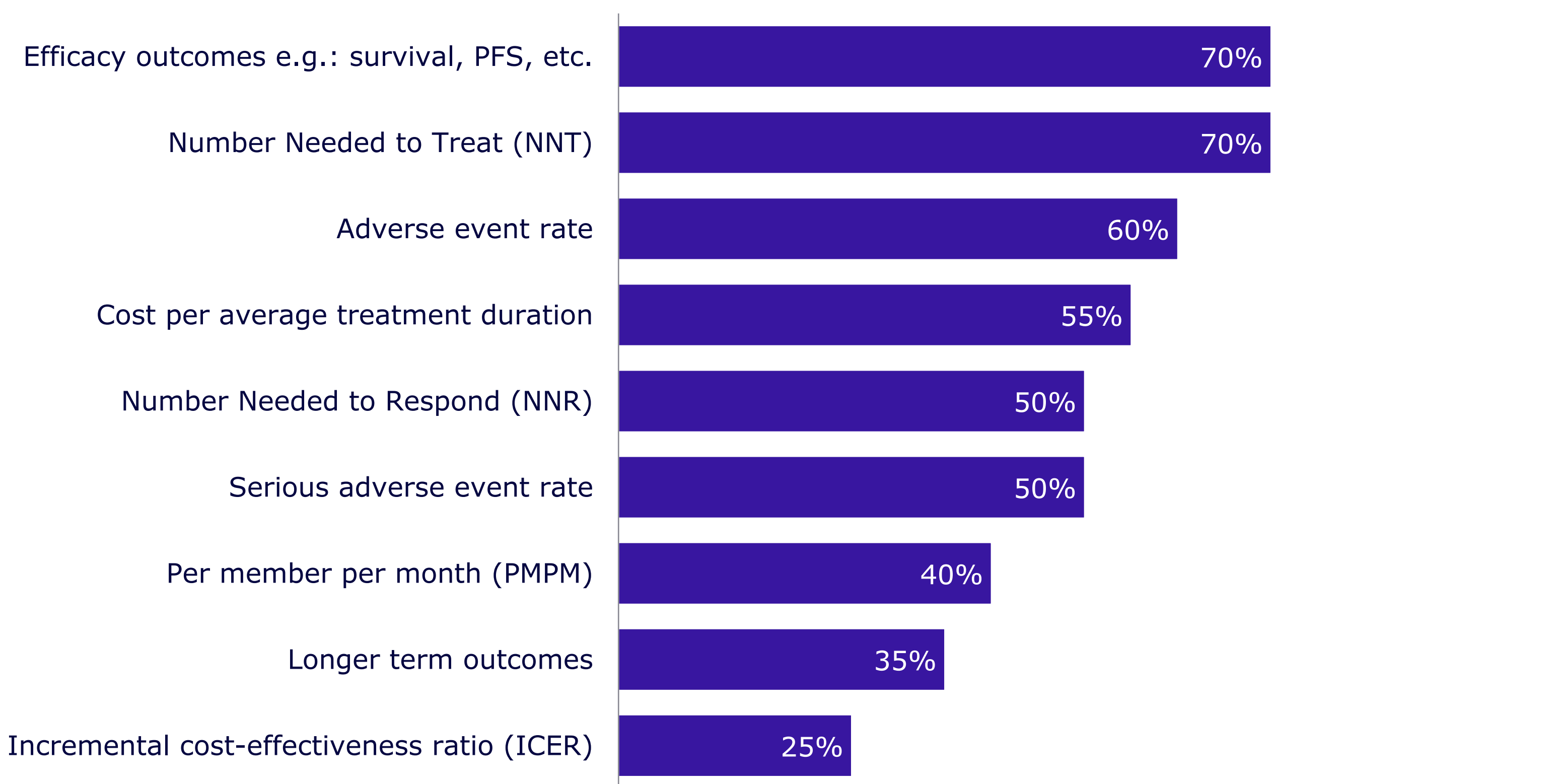
**Interview findings**
- In the case of rare diseases, US Payers welcome inclusion of KOL perspectives in AMCP dossiers, but assume a level of bias. They welcome inclusion of independent 'Peer Exchange' from a validated source (e.g. AJMC)

## Figure 4| AMCP Dossier Metrics / Data Points Used in Formulary Decision Making (% of respondents)



| | |
|---|---|
| Efficacy outcomes e.g.: survival, PFS, etc. | 70% |
| Number Needed to Treat (NNT) | 70% |
| Adverse event rate | 60% |
| Cost per average treatment duration | 55% |
| Number Needed to Respond (NNR) | 50% |
| Serious adverse event rate | 50% |
| Per member per month (PMPM) | 40% |
| Longer term outcomes | 35% |
| Incremental cost-effectiveness ratio (ICER) | 25% |

57% of respondents use cost per average treatment duration, and 70% find 'number needed to treat' valuable. When asked what they would like to see in the next AMCP Format, payers noted a stronger focus on comparative effectiveness (n=6 mentions).

**Interview findings**
- Comparative clinical data is desired, including formal ITCs (NMAs, MAICs)
- Pharmacy directors are keen to see discontinuation rates, annual cost per patient, total cost of care

## Conclusions

This research elucidates how U.S. formulary decision-makers leverage AMCP dossiers in their coverage evaluations, and confirms dossiers are a critical part of payer engagement. For life sciences manufacturers, this emphasizes the importance of aligning dossier content with payer priorities to strengthen their engagement and support evidence-based coverage. In particular, payers want to see clear comparative effectiveness data including formal indirect treatment comparisons, they want to know how comparative effectiveness plays into total cost of care, they want pharmacy and medial benefit perspectives (and the interplay between these) and want budget impact models to be transparent and modifiable.

## Abbreviations

**AMCP:** Academy of Managed Care Pharmacy; **MCO:** Managed Care Organization; **IDN:** Integrated Delivery Network; **PBM:** Pharmacy Benefit Manager; **ICER:** Incremental cost-effectiveness ratio; **NIH:** National Institute of Health; **CDC:** Centers for Disease Control; **PMPM:** Per Member Per Month; **NCCN:** National Comprehensive Cancer Network; **EHR:** Electronic Health Record; **BIM:** Building Information Modeling; **AJMC:** The American Journal of Managed Care; **PFS:** Progression-Free Survival; **NNT:** Number Needed to Treat; **NNR:** Number Needed to Respond; **KOL:** Key Opinion Leader; **ITC:** Independent Treatment Centre; **NMA:** National Medical Association; **MAIC:** Matching-Adjusted Indirect Comparison; **EMA;** European Medicines Agency