CB PARTNERS

THE RESULTANT IMPACT OF HEOR DATA ON US PAYER FORMULARY COVERAGE

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INTRODUCTION

- Health economics and outcomes research (HEOR) has consistently been an important component of communicating overall value to US managed care organization stakeholders throughout the lifecycle of a therapeutic, particularly for high-cost drugs (e.g., cell & gene therapies, biologics) and in categories with high levels of branded and generic competition.
- Further understanding US payer perceptions of the value associated with various types of HEOR analyses and endpoints, and the degree to which they have influenced formulary coverage decisions can help shape future manufacturer HEOR strategies to optimize US access and formulary positioning.

OBJECTIVE

- The objective of this research was to identify instances where manufacturer HEOR data and/or pharmacoeconomic models either influenced positive changes, or had limited tangible impact on resultant US payer coverage decisions.
- This analysis provided an understanding of the underlying payer rationale shaping value perceptions of manufacturer HEOR data.

METHODS

- The study employed a pragmatic literature, industry, and US payer policy review to determine instances of HEOR datasets tangibly impacting or having limited impact on US payer formulary coverage, supplemented by prior CBPartners HEOR-focused US payer primary research.
- Additionally, a survey was conducted with a curated list of N=15 US payers across MCO (N=9), IDN (N=3), and PBM (N=3) organizations to provide further context surrounding recent examples of manufacturer HEOR data materially influencing decisions at P&T committee meetings, different ways HEOR data can subsequently change formulary coverage, and the extent to which organizational philosophies towards HEOR data can shape payer perceptions of this evidence.

RESULTS

PAYER UTILIZATION OF HEOR DATA IS INCREASING FOR A MINORITY OF HEALTH PLANS:

- While the majority of payers (N=10/15, 67%) indicated their organizations have not changed the frequency in their use of HEOR evidence in making formulary decisions, some payers (N=5/15, 33%) noted their organizations are incorporating HEOR data into management decisions to a greater extent today compared to 3 years ago.
- For payers who are utilizing HEOR to a greater extent today relative to 3 years ago, the most commonly cited rationale include high list-to-net prices and high total cost of care per patient associated with recent innovative therapeutics, as well as increasingly crowded categories providing more opportunities to manage within a therapeutic class.

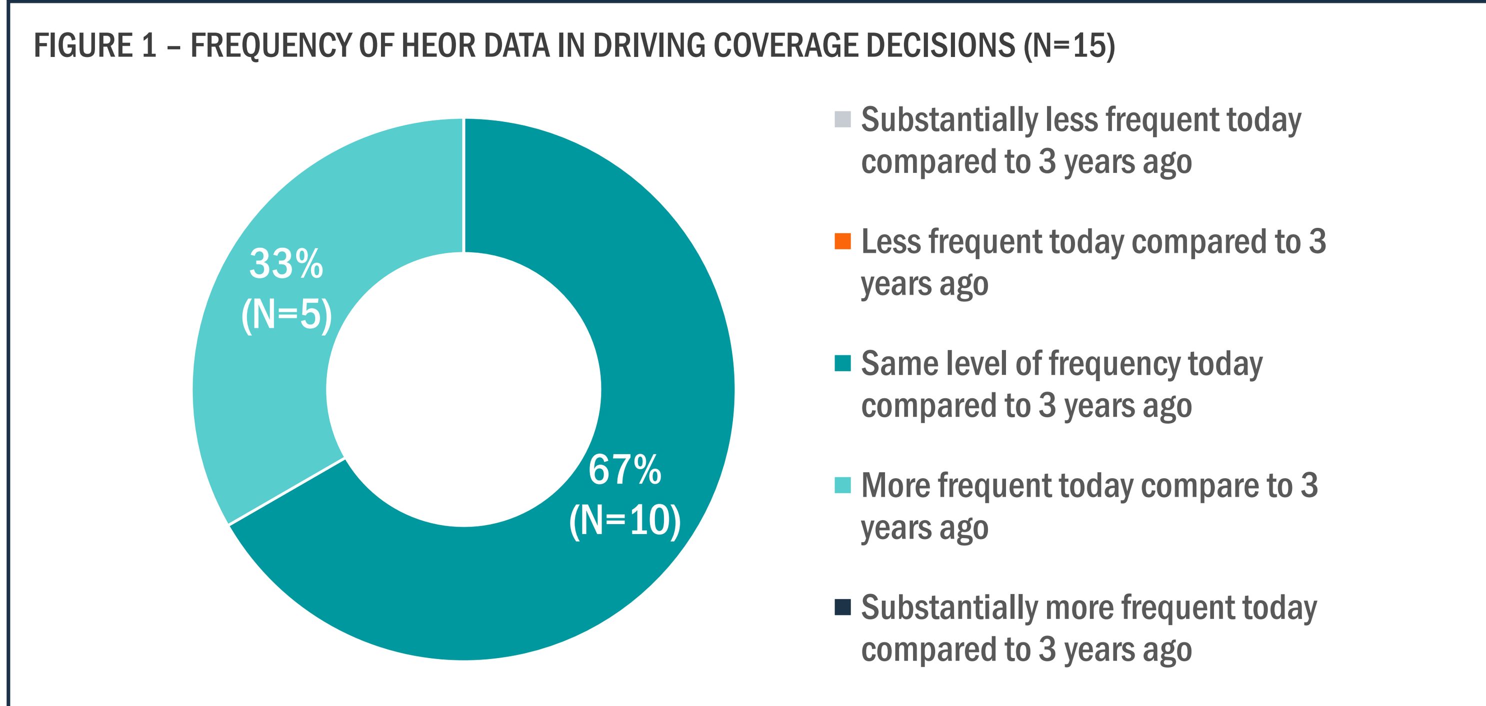


FIGURE 1 – FREQUENCY OF HEOR DATA IN DRIVING COVERAGE DECISIONS (N=15)

PAYERS VIEW CELL & GENE THERAPIES AND BIOLOGICS AS AREAS WHERE HEOR DATA COULD LIKELY INFLUENCE COVERAGE DECISIONS:

- Payers provided insights into the types of drugs that are most likely to benefit from supplemental HEOR data from a formulary management perspective; survey results show payers are most keen on evaluating HEOR data in relation to high-cost therapeutic classes such as cell & gene therapies (N=13/15, 87%) and biologics (N=12/15, 80%); and to a slightly lesser extent orphan therapies (N=10/15, 67%) and drugs in crowded disease categories (N=8/15, 53%).
- Importantly, the drug categories payers perceive as most likely to achieve tangible benefit in terms of formulary coverage are aligned with areas of substantial manufacturer investment, highlighting the need for drug sponsors to have a clear understanding of payer HEOR value drivers.

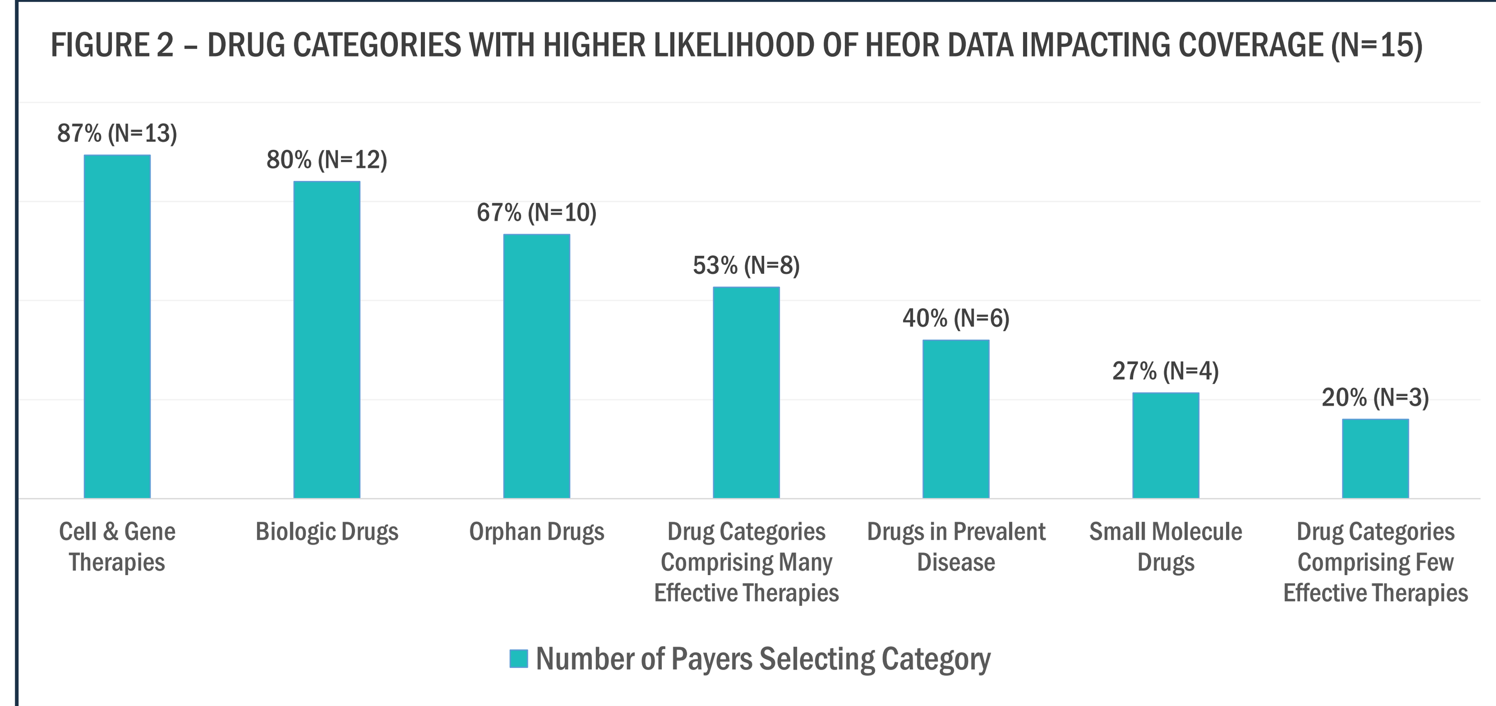
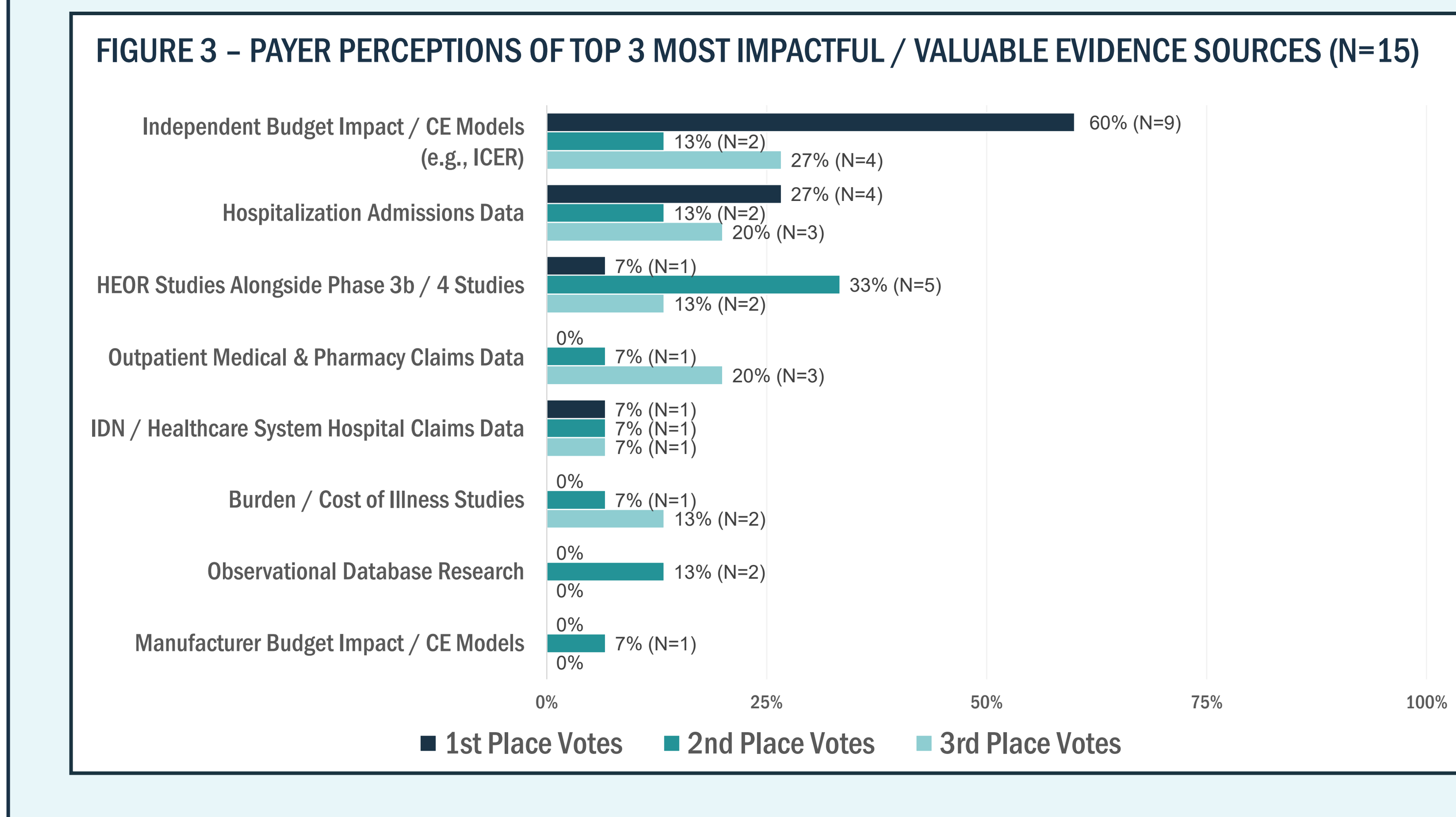


FIGURE 2 – DRUG CATEGORIES WITH HIGHER LIKELIHOOD OF HEOR DATA IMPACTING COVERAGE (N=15)

PAYERS ATTRIBUTE INDEPENDENT / 3RD-PARTY HEOR DATA SOURCES AS MOST VALUABLE IN FORMULARY DECISION-MAKING:

- Payer responses indicate a clear preference towards independent Budget Impact / Cost Effectiveness Models (e.g., ICER) (N=15/15, 100%) to have the greatest impact in decision-making due to the neutrality of the source, followed by Hospitalization Admissions Data (N=9/15, 60%), and HEOR Studies Alongside Phase 3b / 4 Studies (N=8/15, 53%) as among the most frequently cited influential HEOR data sources.
- Payers view manufacturer-generated HEOR as less compelling, with only N=1/15 (7%) payer identifying this as a top 3 selection; payers perceived manufacturer-generated HEOR analyses as less credible given the bias of manufacturers to frequently demonstrate favorable economic data for their therapy.

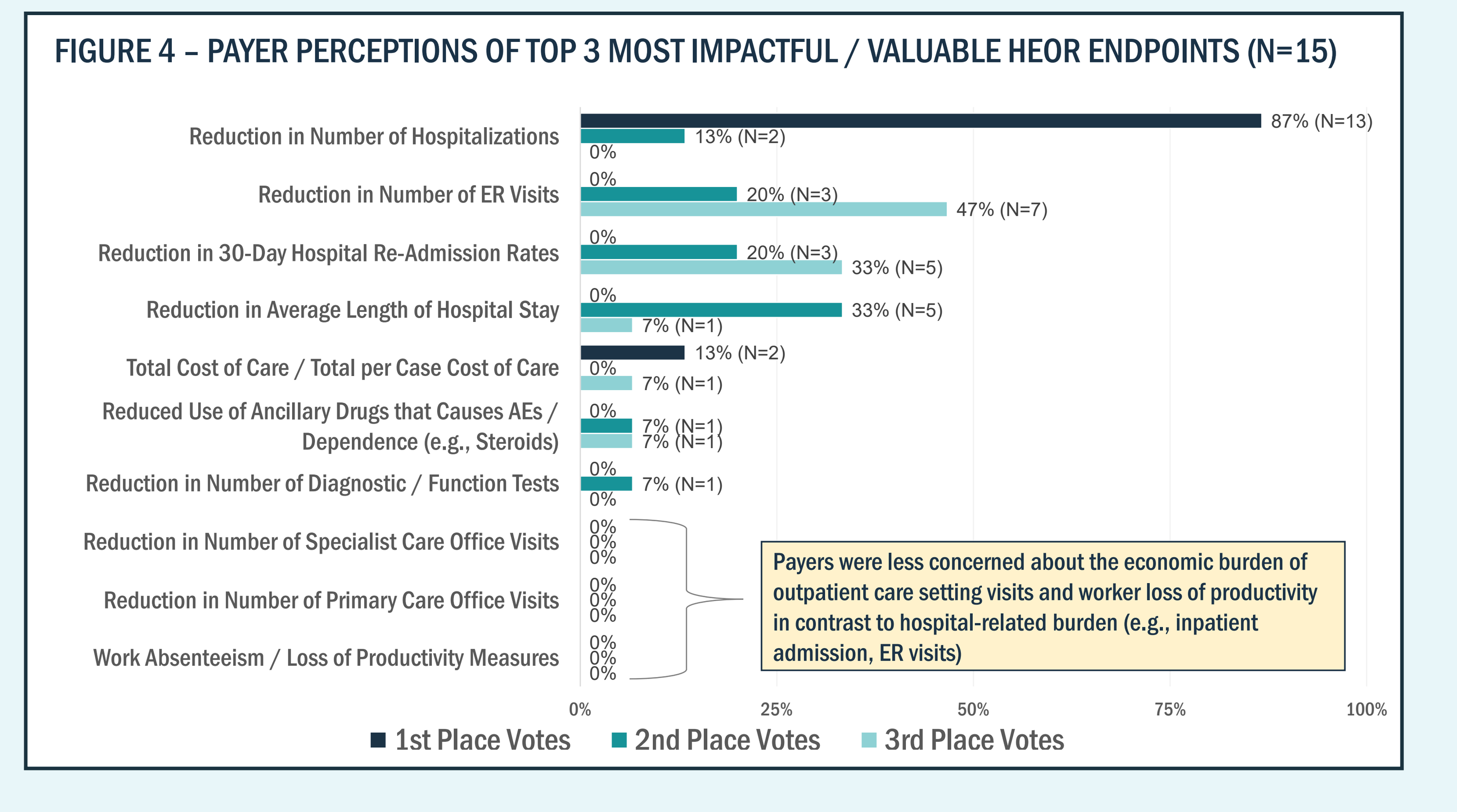
FIGURE 3 – PAYER PERCEPTIONS OF TOP 3 MOST IMPACTFUL / VALUABLE EVIDENCE SOURCES (N=15)



PAYERS UNAMINOUSLY AGREE THAT A REDUCTION IN HOSPITALIZATIONS IS THE MOST IMPACTFUL HEOR ENDPOINT THAT DRIVES FORMULARY DECISION-MAKING:

- When considering a set of HEOR endpoints typically found across manufacturer-submitted analyses, payers noted that reduction in hospitalizations was the HEOR endpoint most likely to tangibly influence coverage decisions, with N=15/15 (100%) payers selecting this as among the top 3, including N=13/15 (87%) of the 1st place votes.
- The findings indicate a clear payer preference towards HEOR data that can be credibly linked to direct cost-offsets, with reduction in number of ER visits (N=10/15, 67%) as 2nd among the top 3, followed by reduction in 30-day hospital re-admission rates (N=8/15, 53%) ranked 3rd among the top 3 most compelling HEOR endpoints.

FIGURE 4 – PAYER PERCEPTIONS OF TOP 3 MOST IMPACTFUL / VALUABLE HEOR ENDPOINTS (N=15)



HEOR DATA THAT DEMONSTRATED DIRECT COST OF CARE OFFSETS CAN IN SOME INSTANCES IMPROVE FORMULARY ACCESS:

- In instances where manufacturer-submitted HEOR data led to a positive change in payer coverage, the evidence sources and endpoints tended to be objective, direct measures of medical costs that provided payers a clear picture of how patient economics or outcomes data can support downstream cost offsets.
- **FIGURE 5** summarizes several recent examples of products that benefitted from submitted HEOR data, highlighting how evidence connected to direct cost offsets (e.g., reduction in hospitalizations) can elicit positive payer action such as removal of the PA / relaxation of PA restrictions, removal of a step edit, or moving the product to a lower tier / preferential tier positioning vs. competitors.

FIGURE 5 – INSTANCES OF HEOR DATA DRIVING POSITIVE CHANGE TO FORMULARY COVERAGE (N=15)

THERAPY	DISEASE AREA	PERTINENT HEOR DATA SUBMITTED	SUBSEQUENT IMPACT ON PAYER COVERAGE
Entresto (sacubitril/valsartan) tablets	***Cardiovascular Disease***	Payers frequently indicated reduction in hospitalizations (N=8), reduction in mortality risk (N=5), and H2H data vs. enalapril (N=4) as the HEOR data that were most impactful in driving positive formulary changes*	**Payers provided a variety of formulary changes, from moving ENTRESTO to a lower / preferred formulary tier (N=7), relaxing the PA criteria (N=5), or removing a step edit (N=1)**
Praluent (alirocumab) Injection; Repatha (evolocumab)	***Cardiovascular Disease / LDL Cholesterol Lowering***	PCSK9 data demonstrating CV risk prevention was most commonly cited (N=5), with cost effectiveness (N=2) and reduction in hospitalizations (N=1) as additional mentions by payers	**In response, payers moved products to a lower / preferred formulary tier (N=4), removed a step edit (N=2), or added the PCSK9 to formulary when otherwise it would not be covered (N=1)****
SPIRIVA RESPIMAT (tiotropium bromide) inhalation spray	***COPD***	HEOR data demonstrating a reduction in exacerbations was perceived as compelling by N=4 payers, with additional mention of reduction in hospitalizations by N=1 payer	**N=2 payers moved SPIRIVA to a lower / preferred formulary tier**
ORKAMBI (lumacaftor/ivacaftor)	***Cystic Fibrosis***	One payer (N=1) noted a reduction in hospitalizations while another payer (N=1) mentioned a reduction in respiratory exacerbations	**No Change: N=1 payer's organizational philosophy is to apply HEOR data minimally (if at all) when generally deciding the health plan's coverage of products**
Hepatitis C Direct-Acting Antivirals (DAAs)	***Hepatitis C***	One payer (N=1) listed real-world cure rates and cost offsets from later-generation Hepatitis C products	**N=1 payer relaxed the PA, and patient continuation criteria**
Vascepa (icosapent ethyl)	***Cardiovascular Disease***	One payer (N=1) noted MACE data	**N=1 payer moved VASCEPA to a lower / preferred formulary tier**

**Respondents provided multiple answers in the payer survey; **PCSK9 contracting could have been an additional factor contributing to less restrictive payer coverage*

PAYERS STILL PERCEIVE A NUMBER OF LIMITATIONS WITH HEOR DATA:

- When probed on the reasons why HEOR data may ultimately not have any impact on formulary decisions, payer justification tended to fall into two common themes:
- **HEOR DATA NOT CONSIDERED RELEVANT** – The rationale provided most often by payers (N=8/15, 53%) was that their organization's operating philosophy does not consistently incorporate analysis of HEOR data into their formulary decision-making process.
  - N=6/15 (40%) respondents noted HEOR evidence has not influenced changes to formulary decisions in the past due to a primary focus on clinical considerations, while N=2/15 (13%) payers viewed HEOR data as generally less usable given their organizational philosophy to implement strict utilization management protocols for all high-cost therapies.
    - In many instances, these minority of payers do not experience overall offsets in the total cost of care even when the HEOR data demonstrates medical cost reductions (e.g., high drug cost >> reduction in medical costs).
  - *Examples provided by payers: Some payers tend to place less emphasis on the value of manufacturer-submitted HEOR data given their unique institutional resources to produce more reliable in-house economic analyses (e.g., leverage internal claims / cost data).*
- **HEOR DATA NOT CONSIDERED COMPELLING ENOUGH** – For organizations more willing to formally incorporate HEOR data into decision-making, these payers (N=7/15, 47%) still highlight the inability of HEOR data to consistently demonstrate compelling evidence that warranted changes to the formulary, with payers noting medical cost offsets are often minimal relative to the drug acquisition costs.
  - *Examples cited by payers include: severe asthma / COPD biologics, PCSK9s, multiple sclerosis oral medications, hereditary angioedema medications.*
- Payers were split in terms of believing HEOR data could differentiate a product within a class (N=8/15, 53%) versus being viewed as a class effect (N=7/15, 47%).

ABBREVIATIONS: HEOR: Health Economics and Outcomes Research; **MCO**: Managed Care Organization; **IDN:** Integrated Delivery Network; **PBM:** Pharmacy Benefit Manager; **P&T:** Pharmacy and Therapeutics; **ICER:** Institute for Clinical and Economic Review; **CE:** Cost Effectiveness; **ER:** Emergency Room; **AEs:** Adverse Events; **PA:** Prior Authorization; **H2H:** Head-to-Head; **CV:** Cardiovascular; **COPD:** Chronic Obstructive Pulmonary Disease; **MACE:** Major Adverse Cardiac Events

CONCLUSION

- Payers are more likely to perceive manufacturer-submitted data favorably and implement positive formulary changes when the HEOR data is generated via credible, independent 3rd-party sources (e.g., ICER, RAND Corporation) and when it includes HEOR analysis / endpoints that can objectively be linked to direct downstream cost offsets (e.g., reduction in hospitalizations, ER visits).
- However, payers also flagged a number of limitations with manufacturer HEOR data that have in the past prevented a tangible change to formulary coverage, such as organizational philosophies that deprioritizes HEOR evidence (i.e., reluctance to stray beyond clinical data in shaping management approach), and a lackluster HEOR performance that is sometimes shown, as general indicators that did not warrant a change in coverage.
- The variation across MCO, IDN, and PBM payer organizations regarding their approach and willingness to incorporate HEOR data in formulary decisions highlights the benefit in studying evolving payer interpretations of manufacturer-submitted HEOR analyses to ensure HEOR studies are optimized and the appropriate payers are approached with HEOR value story presentations, which can help increase the likelihood of achieving positive formulary changes.

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