Payer perceptions on the use of patient-reported outcomes in oncology decision making

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What is already known about this subject

- Patient-reported outcome (PRO) evidence for oncology therapies may be reported as part of clinical trials or may be gathered during real-world studies after products launch.
- Collecting PRO data enables direct measurement of patient experiences with cancer therapies.

What this study adds

- PRO evidence is helpful for payers' formulary decision making in oncology, especially in the incurable/metastatic scenario, where treatment is palliative rather than curative and health-related quality of life is an important goal of treatment.
- Payers want to evaluate PRO evidence from clinical trials to help with formulary decision making and from real-world studies for postlaunch formulary reviews and validation within their health plan populations.
- A better understanding of PRO evidence can impact care delivery models and ultimately factor into health resource utilization and total cost of care, which are of paramount interest to payers.

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J Manag Care Spec Pharm.
2022;28(2):188-95

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ABSTRACT

BACKGROUND: In oncology, especially with accelerated regulatory approvals and niche populations, US payers appreciate all evidence that can help support formulary decision making, including evidence beyond traditional safety and efficacy data from clinical trials. Research suggests payers incorporate patient-reported outcome (PRO) evidence in their decision making and expect the importance of PRO evidence to grow. Greater understanding on payers' use of PRO information in oncology is needed.

OBJECTIVE: To assess US payer perceptions regarding the use of PRO evidence in informing oncology formulary decision making.

METHODS: A multidisciplinary steering committee involving a measurement specialist, health economics and outcomes research experts, and payers developed a survey containing single-answer, multiple-answer, and free-response questions. The pilot survey was tested at a mini-advisory board with 5 US payers and revised based on feedback. In February 2020, the survey was distributed to 221 US payers through the AMCP Market Insights program and 10 additional payer panelists who were invited to discuss and contextualize the survey results. Results were presented primarily as frequencies of responses and evaluated by plan size, type of health plan, and geography (regional vs national). Differences in categorical data responses were compared using Pearson chi-square or Fisher exact tests. Two-tailed

values are reported and a *P* value less than or equal to 0.05 was used to indicate statistical significance.

RESULTS: Overall, 106 of 231 payers (45.9%) completed the survey; 45.5% represented small plans (<1 million lives), and 54.5% represented large plans (≥1 million lives). Respondents were largely pharmacists (89.9%), with 55.6% of all respondents indicating their job was pharmacy administrator. The majority of payers (60.0% of small health plans and 57.8% of large plans) felt PRO evidence from clinical trials is useful. Similarly, the majority of payers (57.8% of small plans and 51.9% of large plans) felt PRO evidence from real-world studies is useful. Almost half (47.1%) suggested formulary review would be influenced by a lack of PRO evidence from oncology clinical trials either somewhat,

much, or a great deal. Most payers (78.2%) thought PRO evidence is useful for providing additional context for safety of oncology therapies. More than one-third of payers (34.3%) valued PRO evidence when comparing 2 similar therapies, and 51.5% felt PRO evidence may help in measuring value for value-based agreements. Panelists indicated PRO evidence can be useful for developing treatment pathways for addressing health-related quality of life, informing provider-patient dialogues, and defining progression-free survival length and quality.

CONCLUSIONS: US payers view PRO evidence from both clinical trials and real-world studies as useful for supplementing traditional clinical trial data when making oncology formulary decisions and for refining treatment pathways and care delivery models. Manufacturers of oncology therapies should collect and consider leveraging PRO evidence from both settings when engaging with US payers.

Patient-reported outcomes (PROs) can be an important tool for payers in oncology decision making. PROs are useful for assessing the status of a patient's health and treatment experiences via direct report from the patient, without bias from the physician.¹ PROs often address patients' symptoms, treatment side effects, productivity, and health-related quality of life (HRQOL), as well as physical, social, cognitive, or other types of functional outcomes.^{2,3}

The consideration of patient perspectives of oncology treatments can help manufacturers, providers, and payers identify therapies that address patients' HRQOL, productivity, and functional concerns, which can lead to better outcomes, improved costs, and better patient-centered care.⁴ Studies have shown that incorporating PROs into treatment decisions is associated with improvements in overall survival, symptom management, and HRQOL in oncology.⁵⁻⁷

As payers look for evidence to help inform formulary decisions, both at launch and at postlaunch reviews, they may find that PRO evidence can complement the traditional efficacy and safety data available from clinical trials. However, there are limited data on how payers perceive PRO evidence for use in oncology decision making. Therefore, we conducted a survey of US payers to examine payers' perceptions of the utility of PRO evidence in oncology decision making.

Methods

To gauge US payer understanding of the value and use of PRO evidence in oncology decision making, an interdisciplinary steering committee of payers, academic and industry health

economics and outcomes research experts, and a measurement specialist was formed to develop a survey.

The steering committee created a pilot survey based on literature reviews and current understanding of the payer landscape regarding the use of PRO evidence in oncology decision making. The pilot survey was distributed via email to 5 US payers in October 2019, which were representative of the larger survey group. The results were tallied, then a follow-up in-person discussion was held a week later with the steering committee and the 5 payers. Discussions focused on questions where the answers showed disagreement or confusion. Survey questions were revised based on feedback from the payers and then refined by the authors.

The revised survey questions included 10 questions about payer perceptions and use of PRO evidence. Five questions asked for yes/no responses, and 3 asked respondents to rate choices on a scale (a great deal to not at all, very high to very low, and extremely useful to not useful at all). Of the 10 questions, 2 explored payers' impression of the usefulness of PRO evidence from clinical trials and from real-world studies, respectively. Four asked payers about the impact of PRO evidence from clinical oncology trials or real-world evidence on formulary decisions. Two questions asked about payers' perception of the patient-reported outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE). One question asked if PRO evidence from clinical trials could help in providing context for safety data, and 1 asked whether respondents thought PRO evidence could play a role in measuring value in innovative or value-based agreements.

Subsequently, in February 2020, the national online survey was distributed through the AMCP Market Insights program to a panel of 221 payers. This managed care panel consisted of AMCP members who were pharmacy leaders involved in medication product evaluation and/or utilization management who agreed up front to participate in payer-based survey research. Results of the online survey were collected using SurveyMonkey.

The same survey was also distributed to 10 additional representative US payers who were not in the AMCP Market Insights panel and who agreed to participate in a live panel discussion about the aggregate survey results. The survey results from these 10 panelists were combined with the results from the broader payer panel mentioned above. After the panelists filled out the survey, but before the panel discussion, the 10 panelists were sent a 2017 article on the use of PRO evidence in US payer decision making to provide a common basic level of understanding around PRO evidence.⁸ The panel of 10 payers and the steering committee

TABLE 1 Demographics of Survey Respondents

	Total n (%)	Small (<1 million lives covered) n (%)	Large (≥1 million lives covered) n (%)	P value
Organization type (n=99)^a				
Managed care organization	47 (47.5)	24 (53.3)	23 (42.6)	0.317
Pharmacy benefit manager	37 (37.4)	11 (24.4)	26 (48.1)	0.021
Employer group	12 (12.1)	8 (17.8)	4 (7.4)	0.134
Government	9 (9.1)	8 (17.8)	1 (1.9)	0.010
Integrated delivery network	10 (10.1)	7 (15.6)	3 (5.6)	0.178
Health management organization	8 (8.1)	5 (11.1)	3 (5.6)	0.463
Accountable care organization	5 (5.1)	3 (6.7)	2 (3.7)	0.657
Other	5 (5.1)	3 (6.7)	2 (3.7)	0.657
US region (n=89)				
Northeast	26 (29.2)	9 (21.4) ^b	17 (36.2)	0.253
Midwest	25 (28.1)	10 (23.8)	15 (31.9)	0.644
West	25 (28.1)	14 (33.3)	11 (23.4)	0.251
South	13 (14.6)	9 (21.4)	4 (8.5)	0.079
Regional vs national (n=99)				
Regional	49 (49.5)	35 (77.8)	14 (25.9)	<0.001
National	47 (47.5)	8 (17.8)	39 (72.2)	<0.001
Other	3 (3.0)	2 (4.4)	1 (1.9)	0.589
Payer type (n=99)				
Commercial+government	64 (64.6)	21 (46.7)	43 (79.6)	0.001
Government	19 (19.2)	13 (28.9)	6 (11.1)	0.039
Commercial	16 (16.2)	11 (24.4)	5 (9.3)	0.055

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members convened virtually in March 2020 to discuss survey findings and offer additional insight into the survey results.

The survey results were presented primarily as frequencies of responses. For multiple-response questions, each response was coded as Yes or No. Categorical responses were evaluated using the Pearson chi-square or Fisher exact test by plan size, plan type, and scope of service (regional vs national). Statistical significance was based on 2-tailed values with P value less than or equal to 0.05.

Results

DEMOGRAPHICS OF RESPONDENTS

From the national sample of 221 AMCP survey recipients plus the 10 payer panelists (231 total), 106 completed the survey, resulting in a 45.9% response rate. Table 1 shows key demographics of the respondents, including geography and plan type. Completion of demographic questions was not required, and 7 of the 106 respondents did not answer the demographic questions. The most common organizations

represented were managed care organizations (MCOs; 47.5%) and pharmacy benefit managers (PBMs; 37.4%). Plans were evenly divided between regional plans (49.5%) and national plans (47.5%). Private payer plans covering commercial and government lives represented 64.6% of the respondents' organizations. All sizes of health plans were well represented, with 24.2% of respondents representing plans with at least 10 million members. Further analysis by plan type did not reveal any statistically significant results, most likely due to small numbers. Most respondents were pharmacists (89.9%). The most common roles included pharmacy administrators (55.6%) and pharmacists/clinical pharmacists (30.3%). More than half of respondents (58.6%) had been with their current organization for 5 years or less.

CURRENT PAYER PERCEPTION AND USE OF PRO EVIDENCE

More than half of the US payers who responded to the survey felt that PRO evidence is useful for formulary decision making (Figure 1). Specifically, 60.0% of small health plans (<1 million covered lives) and 57.4% of large plans (≥1 million covered lives; $P=0.794$) felt PRO evidence from clinical trials is useful. Similarly, both small and large plans felt PRO evidence from real-world studies is useful (57.8% vs 51.9%; $P=0.555$). In addition, almost half of payers (48.2% of large plans and 42.2% of small plans, $P=0.538$) suggested that formulary review would be negatively influenced by a lack of PRO evidence from oncology clinical trials either somewhat, much, or a great deal (Figure 2).

Payers considered PRO evidence useful in a variety of applications, including providing additional context for safety (78.2% agreed) and in impacting formulary decision making

TABLE 1 Demographics of Survey Respondents (continued)

	Total n (%)	Small (<1 million lives covered) n (%)	Large (≥ 1 million lives covered) n (%)	P value
Degrees (n=99)^a				
RPh, PharmD	89 (89.9)	39 (86.7)	50 (92.6)	0.505
MS, MBA, MPH	30 (30.3)	13 (28.9)	17 (31.5)	0.829
MD, DO	4 (4.0)	2 (4.4)	2 (3.7)	1.000
PhD	2 (2.0)	1 (2.2)	1 (1.9)	1.000
Other	3 (3.0)	3 (6.7)	0 (0.0)	0.090
Position (n=99)				
Pharmacy administrator	55 (55.6)	26 (57.8)	29 (53.7)	0.839
Pharmacist	30 (30.3)	12 (26.7)	18 (33.3)	0.516
Medical director	5 (5.1)	2 (4.4)	3 (5.6)	1.000
Other	9 (9.1)	5 (11.1)	4 (7.4)	0.728
Time in position (n=99)				
<1 year	8 (8.1)	5 (11.1)	3 (5.6) ^b	0.463
1-5 years	50 (50.5)	23 (51.1)	27 (50.0)	1.000
6-10 years	18 (18.2)	5 (11.1)	13 (24.1)	0.120
>10 years	23 (23.2)	12 (26.7)	11 (20.4)	0.483

Note: N=the number of respondents to answer the question (of 106 total respondents).

^aPercentages total to more than 100% because multiple answers were allowed.

^bPercentages do not total to 100% due to rounding.

DO=doctor of osteopathic medicine; MBA=master of business administration; MD=doctor of medicine; MPH=master of public health; MS=master of science; PharmD=doctor of pharmacy; PhD=doctor of philosophy; RPh=registered pharmacist.

in oncology when considering one therapy over another (34.3% agreed). In addition, more than half of respondents (51.5%) felt PRO evidence can help in measuring value for innovative or value-based agreements.

During the panel discussion, panelists agreed with the survey findings. The panelists indicated that PRO evidence can also be useful for developing treatment pathways to address HRQOL, especially in oncology where HRQOL is an important consideration. Panelists added that other areas where PRO evidence can help include shared decision support, care management designs, and provider-patient dialogues. They also felt that

defining progression-free survival (PFS) length and quality may lead to outcomes measures that can be used in outcomes-based or value-based contracts. The panelists reported that payers would especially like to see PRO evidence addressing patient functionality and other impacts of extended life during PFS. In addition, they stated that postprogression PRO evidence may help in the development of clinical pathways due to identification of side effects that can impact concepts measured by PROs.

Payers' awareness and perceptions of PRO-CTCAE, a PRO measurement system developed to evaluate symptomatic toxicity in patients on cancer

clinical trials,⁹ was low. The majority of payers (81.1%) said their level of awareness of PRO-CTCAE was low or very low (Figure 3). Additionally, nearly two-thirds of payers (67.7%) reported that they did not have enough information about PRO-CTCAE to answer a question about its usefulness.

When asked specifically about the utility of PRO evidence in payer decision making, panelists said they view PRO evidence from real-world studies as more generalizable and realistic than PRO evidence from clinical trials. However, panelists recognized that real-world data are not available at the time of initial formulary decision making. This is especially true with accelerated drug approvals, where the shortened time frames can further limit the amount of PRO evidence collected from clinical trials. This makes PRO evidence from real-world, post-launch studies even more valuable. However, data from real-world, post-launch studies may be more difficult for payers to find and/or incorporate into future decision reviews since payers often rely on information from the package insert and may not have the resources to thoroughly review the literature after launch. In addition, the panelists noted that PRO evidence included in the product's package insert is easier to access and is more likely to be accepted by payers without further validation than PRO evidence from other sources.

Given the emphasis on HRQOL in oncology, panelists felt PRO evidence may be more valuable in oncology than in other diseases. They felt that real-world PRO evidence can help add to the information in the literature about a treatment under review.

The panelists indicated that in addition to patient survival, payers are ultimately concerned with the total cost of care for oncology treatments. They added that a better

FIGURE 1 US Payers' Assessment of the Usefulness of PRO Data From Clinical Trials and Real-World Evidence Studies in Informing Formulary Decision Making in Oncology

Do clinical trials and RWE studies evaluating PRO data in oncology provide useful information to inform formulary decision making?

Note: Clinical trials, $P=0.794$; RWE studies, $P=0.555$.

PRO = patient-reported outcome; RWE = real-world evidence.

understanding of PRO evidence, including HRQOL, can impact treatment decisions and care delivery models used by the providers in their networks, and those decisions can affect the total cost of care.

Many of the panelists expressed interest in using PRO evidence to establish outcomes-based or value-based contracts. However, they viewed PRO evidence as subjective and preferred more objective measures. Panelists could not recall any specific examples where PRO data were used for outcomes contracts.

Acknowledging the challenges associated with incorporating more PRO evidence into decision making, the panelists suggested that technological advances are helping in the collection and analysis of PRO data.

Discussion

A PRO is a subjective report that comes directly from a patient in regard to his or her health condition or treatment without interpretation by a clinician or anyone else.^{1,10} Due to the perceived subjective nature of PROs, payers may

experience a conscious or unconscious bias against PRO evidence, and they may be inclined to disregard or deprioritize PRO evidence. On the surface, PRO evidence may appear to have more direct impact on physician treatment decisions, physician-patient dialogues, and care delivery models than on payer formulary decision making. Despite an earlier (2013) lack of understanding on how to use PROs in oncology decision making,¹⁰ payers are learning how PROs can affect standard-of-care guidelines, treatment decisions, and patient experience. In the future, payers will increasingly appreciate how PRO evidence can have an impact on total cost of care and health care resource utilization as more evidence is generated linking resource and cost outcomes to PROs. In fact, the trend toward recognizing the importance of PROs in health care is apparent in the Institute for Clinical and Economic Review (ICER) value assessment framework,¹¹ which identifies PROs as “potential other benefits or disadvantages” and states that they are important elements of any overall judgment on long-term value.

The US Food and Drug Administration (FDA) has recently released guidance on how to include more “meaningful” PRO data toward drug approvals¹²; these measures should also be more relevant to decision making regarding the access and reimbursement of oncology drugs for payers. Current National Comprehensive Cancer Network evidence blocks do not consider HRQOL and thus do not carry over into payer decisions.¹³ However, both the American Society of Clinical Oncology value framework and the ICER value framework do consider HRQOL in their recommendations and thus have a more direct impact on payer oncology decisions.^{14,15}

From the survey and panel discussion, it is clear that US payers felt that PRO evidence can be a useful complement to traditional clinical data for formulary decision making in oncology. PRO evidence from clinical trials can help inform initial formulary decisions. However, when accelerated FDA reviews of some innovative oncology products are based off single-arm trials, the PRO data (if collected) are noncomparative and thus difficult to contextualize and integrate into initial formulary decisions. This makes PRO evidence from postlaunch real-world studies especially valuable so that payers can validate trends within their own oncology populations, helping them make more informed decisions in later formulary reviews.

Another factor that payers saw as contributing to the value of PROs is that HRQOL plays a significant role in oncology, where care, especially in the metastatic setting, can sometimes be palliative rather than curative. Therefore, PRO evidence may be of more interest in symptomatic late stage/metastatic oncology than in some other diseases

FIGURE 2 US Payers' Assessment of How a Lack of PRO Data From Oncology Clinical Trials Would Impact Formulary Reviews

Note: $P=0.168$.

PRO=patient-reported outcome.

where HRQOL is less of a concern (eg, hypertension or hyperlipidemia). This emphasis on HRQOL may make real-world studies that prioritize HRQOL-related PROs of particular interest to both payers and providers.

Producing more PRO evidence that is meaningful to payers and actionable in their decision making may require improved methods for collecting and reporting such data. Payers recognize that providers are more likely to measure and report safety data (eg, decreasing white blood cell counts), which tend to be objective and are easier to track and pull from machine-readable chart notes than patient-reported experiences. Patients are more likely to report more tolerability information, such as pain, nausea, or fatigue, which physicians may view as more subjective and are therefore less likely to include in chart notes. The number of advances in technologies for gathering and measuring PRO data, such as member digital applications (apps) and online portals that capture patient PRO

data, is increasing.¹⁶ As technological advances become more commonplace in the oncology space, they should be developed with an eye toward making PRO data gathering and reporting more useful and actionable for payers as well as physicians and patients.

One tool for tracking PROs that is slowly gaining traction in the oncology space is the PRO-CTCAE measurement system. The PRO-CTCAE measurement system was developed to evaluate symptomatic toxicity in patients enrolled in cancer clinical trials and was designed to be used as a companion to the CTCAE, the standard lexicon for adverse event reporting in cancer clinical trials.^{9,17} The PRO-CTCAE system was developed and validated in accordance with guidelines for PRO instrument development and validation from the International Society of Quality of Life Research, the Professional Society for Health Economics and Outcomes Research, the FDA, and the European Medicines Agency.⁹ Our survey showed that most payers

(81.1%) said their level of awareness of PRO-CTCAE was low or very low. In addition, 63.2% of payers did not feel they had sufficient information about the PRO-CTCAE to rate its usefulness in informing reimbursement decisions in oncology. As the importance of patient experience data and tolerability grows, there is an opportunity to educate the payer community on the value of PRO-CTCAE and similar PRO measurement systems.

One area where payers may be able to use PRO evidence more fully is in value-based contracting with manufacturers. Although the payer panelists were not familiar with any past contracts being based fully or partially on PRO measures, other developments suggest that the industry appears to be ready to test this concept. For example, the Centers for Medicare & Medicaid Services and some commercial payers have begun implementing or investigating ways to include PRO evidence into payment and accountability programs,¹⁸ but this is not widespread yet in oncology. The continuing development and enhancement of standardized, meaningful PRO measures will contribute to the utility of PRO evidence in outcomes-based or value-based contracts.¹⁸ In a study by Schmidt et al, more than 800 patient-reported performance measurement tools were identified. Of those tools, the authors noted 515 that might be applicable to oncology, and only 18 were identified as oncology specific.¹⁸ Examples of PRO measures that would be useful in oncology could include data characterizing the duration of PFS and patient HRQOL during PFS and post-progression of disease. These data are of high interest to payers and would be useful for oncology treatment decision making; potentially they could be incorporated into outcomes measures for outcomes-based or value-based contracting purposes.

FIGURE 3 Payer Awareness of PRO-CTCAE

PRO-CTCAE = Patient-reported outcomes version of the Common Terminology Criteria for Adverse Events.

LIMITATIONS

This study has some limitations to consider. Although MCOs, PBMs, and large payers were well represented in the survey, the data may not be generalizable to all types of health plans. In particular, integrated delivery systems were not well represented in this survey (10.1%). The majority of respondents were pharmacy directors of health plans; other decision makers, such as medical directors, may have a different perspective. This survey was conducted among US payers; therefore, these results may not be generalizable outside the United States. Additionally, only a small portion (just under 10%) of the respondents participated in the virtual panel discussions; therefore, the panelists' opinions may not represent all respondents.

Conclusions

PRO evidence can be a useful complementary addition to the traditional efficacy and safety clinical trial data that payers use when making formulary decisions. This is especially true

in oncology, where HRQOL is of high importance and where traditional evidence may be limited due to accelerated approvals.

Payers see utility for PRO evidence in informing guidelines, developing treatment pathways for addressing HRQOL, enriching provider-patient dialogues, and defining PFS length and quality. Payers are especially interested in PRO evidence that can impact the total cost of care and health care resource utilization. These areas include developing or revising standard-of-care guidelines, influencing treatment decisions, and understanding the patient experience. Once relegated to patient-physician conversations, PRO evidence is becoming more valued as payers consider the patient experience and resulting HRQOL of their plan members who seek oncology treatment. PRO evidence is also being increasingly viewed as a potential mechanism that can facilitate value-based contracting, although the execution is still difficult and thus not perceived as feasible.

With both the FDA and payers showing greater interest in PRO evidence for innovative oncology

therapies, manufacturers should consider such evidence when engaging with payers before and after launch.

DISCLOSURES

Pfizer provided funding for this research, and employees of Pfizer contributed to the development of the survey instrument, were involved in the interpretation of the data, and contributed to the discussion and output as authors. Biskupiak, Oderda, and Brixner are managers of Millcreek Outcomes Group and were paid as consultants on this project. Burgoyne was a consultant for Pfizer on this project. Arondekar, Deal, and Niyazov are employees of Pfizer and own Pfizer stock. Qwek was an employee of Pfizer at the time of this project and owns Pfizer stock.

ACKNOWLEDGMENTS

The authors acknowledge medical writer Kelley JP Lindberg at Blue Raven Services, Inc., for her assistance in editing this manuscript; her work was funded by Pfizer, Inc.

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