



This document contains attendee questions related to the webinar:

Payer Needs for Specialty Pharma Oncology Pipeline: What's Needed and When? Presented Jan 29, 2019.

Responses have been provided by the speakers Dr. Elizabeth Sampsel Vice President, Payer Strategy and Relations, Dymaxium, and Dr. Jeremy Lee, Director, Drug Information, MedImpact.

Syndicated survey-related questions

1. Why is response rate for use of BIMs low but rate them highly useful?
 - a. The discrepancy could be attributed to the availability of a BIM for a specific product or the usefulness for a specific product, since this data was only a subset of all syndicated responses.
2. How many respondents had medical oncologists or board-certified oncology pharmacists on staff? If not, did they report consulting external experts?
 - a. Our survey doesn't gather that data.
3. One slide read that only 4% and 2% reported using BIMs and CEAs respectively, but n=82 had commentary on them. Could you explain disparity?
 - a. The commentary was based on overall vs the specifics for the products.
4. Is there a reason the proportions of value frameworks useful to payers do not add up to 100%? Does that mean some payers use two or more sources?
 - a. Yes, it was a check all that apply question.
5. How was term "value slide presentation" defined?
 - a. The term represents value messaging provided by manufacturers to payers in a slide deck.

Payer-focused questions

6. What are some ways that manufacturers can reduce the OOP costs for Medicare Part D patients for high cost oral cancer therapies e.g. greater than \$5000 per month?
 - Manufacturers can (and do) provide copay assistance cards. Most manufacturers also have patient assistance programs for un/under-insured patients.

7. The cost is key - no matter what model I use I can't demonstrate the value of any oncology product - in the short term - we need more long-term models and models that prove that the spend outcome just like an agent for asthma or diabetes-I think the current models are not appropriate - please comment
 - a. We agree that the current models consistently produce outputs that imply cancer drugs do not provide sufficient value to justify their use. Part of it is due to the fact that we usually input "list price" into the model, which often does not reflect the true combined price paid by the plan and patient. We agree that oncology is very different than chronic disease states like diabetes or asthma, and developing the cancer-specific frameworks to accommodate for this, and subsequently achieving consensus on what reasonable value thresholds should be utilized has to be a top priority for our industry.
8. Should also mention "cost is key" is from the patient perspective how to consider their copays, deductibles and coinsurance depending on their plan type
 - a. Agree. There are considerable patient assistance programs made available by manufacturer organizations, oncology associations and foundations to assist patients with this financial burden.
9. How about lowering the costs instead of copay assistance cards (of course information for manufacturer would be lost) comment?
 - a. The manufacturers would have to consider pricing adjustments. One concern with this approach is that, in order to work, it would require all health plans to reduce/eliminate their patient cost-sharing amounts to correspond with the price decrease from the manufacturer. This would be very challenging to coordinate.
10. We contract with a few manufacturers making them half of the cost the first year allowing the manufacturer and the plan to develop models to continue the drugs use.
 - a. Thank you for sharing your approach. This is an excellent way to mitigate costs for the health plan when a new drug is launched and may be particularly useful for drugs that receive accelerated approval, allowing time for the follow up study results to be released before the plan has to pay the full market price.
11. Many states have policies in place to require coverage of FDA approved oncology drugs. This is different from non-oncology specialty drugs. Does this mean that formulary decisions for specialty oncology drugs are mainly decisions on restrictions or prior authorization, rather than denial of coverage? Is there any data on how economic evidence is considered for decisions on restrictions and prior authorizations? I am interested in learning how often AMCP dossier, budget impact model and value frameworks are utilized in restrictions and prior authorization decisions.
 - a. Regulations on benefits vary based on the lines of business and careful consideration would need to be made to address those regulations. If a state requires coverage of FDA approved oncology drugs, it is possible that formulary restrictions are allowed. It is important to review each state regulations carefully to ensure compliance.
 - We have not surveyed specifically how economic evidence, AMCP dossier, BIM and PA is used for decisions on restrictions and prior authorization, but this is a good question that we may consider for future research.

12. How are the pharmacists evaluating the drugs that are paid in the medical benefit? Is there an evaluation/selection process in other to decide which are going to be paid?
 - a. At health plans and PBMs, it is common that specialty drugs that are being considered for medical and/or pharmacy benefits are evaluated similarly with regards to evidence, safety and economic evaluation. When medications require healthcare professional administration, site of care is an important factor that influences coverage on medical versus pharmacy benefits.
13. Regarding evidence used for review process. Can you further speak about why tools such as RWE or CE Economic modeling aren't being used as often? Is it the lack of availability of these tools or more preference?
 - a. It is typically an availability issue with use of RWE and CE Economic modeling.

General questions

14. What information is typically included in the Pre-approval information?
 - a. Generally, within our System we see publicly available information, posters, presentations, disease models, etc. AMCP Format 4.0 has good guidance.
15. This question is a little off the tangent from the presentation but still important. When Liz talked about when she was a director at SFHP, it was important to plan to avoid delaying access to high cost medications to patients, can Liz talk a little more about what she meant by "planning"? As a Medi-Cal health plan you would get money from the state. So how would you allocate the funds to be able to cover oncology drugs?
 - a. Planning would include notifying the state during the budget forecasting process that a new product may be approved during the budget year that could potentially have a high impact on the population, both clinically and financially. BIM and CEA could be included as documentation when the budget forecast is submitted with the goal to follow up once the product is FDA approved and more information is available. It is also important to consider operational planning. For instance, if a new product will require a significant amount of time for the health plan and provider teams to gather information for prior authorization requirements for the coverage determination process, staffing considerations may be needed.
16. Since the dossier seems to be the core strength of evaluating oncology products how confident is Dymaxium in the transparency of information from each individual manufacturer and are some of the manufacturers less transparent than others.
 - a. We can't really comment on the transparency, as we do not evaluate the dossiers, but rather support the exchange of information. However, our data suggests that payers do utilize dossiers, so perhaps the continued usage is a better barometer.
17. Any suggestions to make BIM flexible? Maybe interactive tool in addition to paper-based dossier?
 - a. Dymaxium has been involved in making BIMs interactive for a long time and it certainly provides the user with the most flexibility. If there are other ways, beyond technology, that would be a question for a consultant.