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Science & INNOVATION THEATER  
Developed for Managed Care Pharmacy  
by AMCP Corporate Members  
WEBINARS

# Payer Needs for Specialty Pharma Oncology Pipeline: What's Needed and When?

January 29, 2019

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Presented By

AMCP eDossier SYSTEM<sup>®</sup> FormularyDecisions.com<sup>™</sup> dymaxium

**Moderator: Jackie Gladman, BPE**  
Vice President, Sales and Marketing, Dymaxium

**Elizabeth Sampsel, PharmD, MBA, BCPS**  
Vice President, Payer Strategy and Relations, Dymaxium

**Jeremy Lee, PharmD, BCPS**  
Director, Drug Information, MedImpact

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## Webinar Objective

- To discuss the evolving landscape of reviewing oncology pipeline drugs for formulary coverage and reimbursement decisions.
- 2018-19 US syndicated survey review – based on payer responses from the FormularyDecisions.com® community
- Provide payer perspective on reviewing oncology drugs for P&T and the challenges associated with coverage decisions
- PBM perspective on accommodating payer requirements for oncology product P&T reviews
- Discussion of the challenges in the near and long term with oncology product reviews and potential solutions to optimize the decision-making process and facilitate access to these important therapies

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Syndicated Survey Review - FormularyDecisions.com®

**Elizabeth Sampsel, PharmD, MBA, BCPS**  
Vice President, Payer Strategy and Relations  
Dymaxium

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Central platform connecting health care decision makers to the **evidence, resources,** and their **peer community**, so they can work more effectively and collaboratively.

**Data collected on:**

- 1900+ US PAYERS/HCDMs
- 900+ organizations
- 86% of covered lives
- 150,000 + evidence links
- 2300 + products



Active evidence review and assessment to make informed formulary and reimbursement decisions.

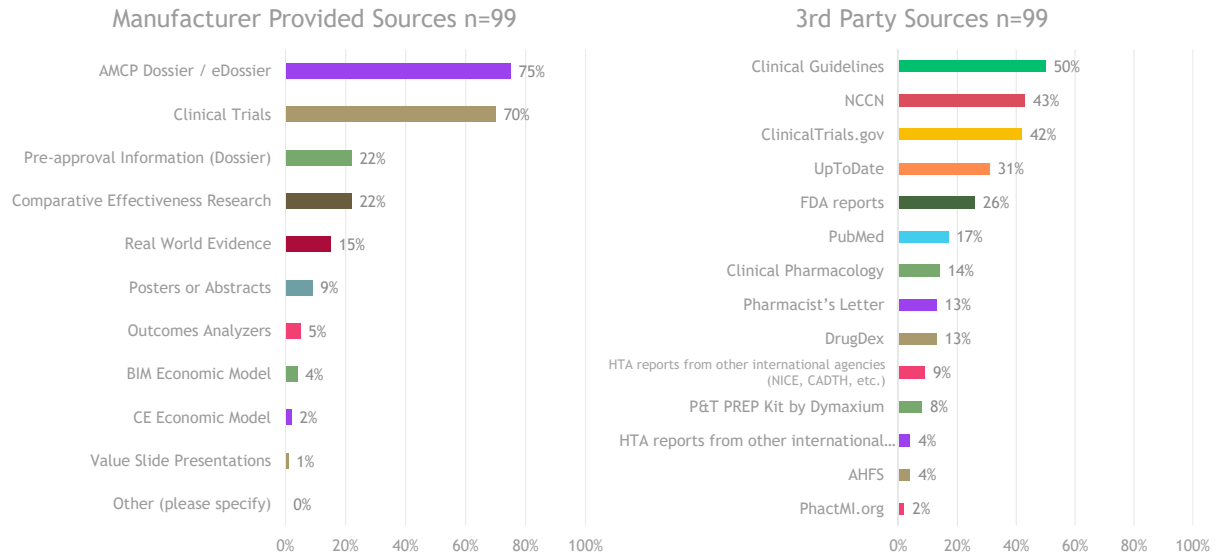
A closed payer only environment.

**Relationships**



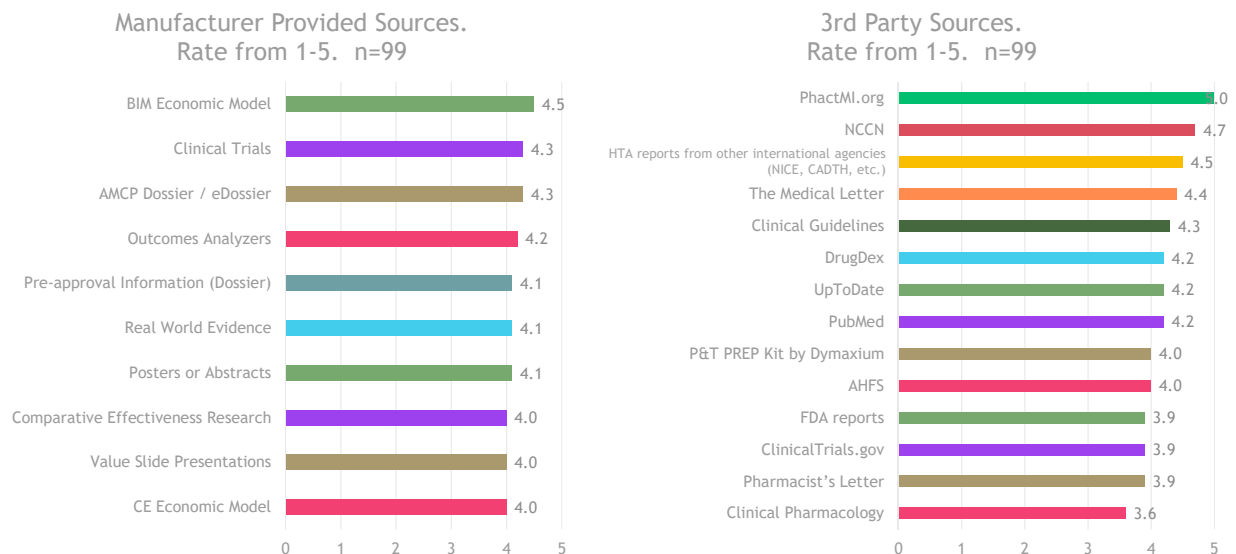
- Purpose: To better understand the payer perspective on new oncology product reviews and the quality of evidence used to inform formulary placement.
- Response timeline: 07/06/18 to 01/22/19
- Respondents (n = 115):
  - Directors/Managers/Supervisors (28%), Clinical Pharmacists (72%)
  - MCOs (39%), also represents PBM, Providers, Government, Other

## Evidence Used as Part of Review Process?



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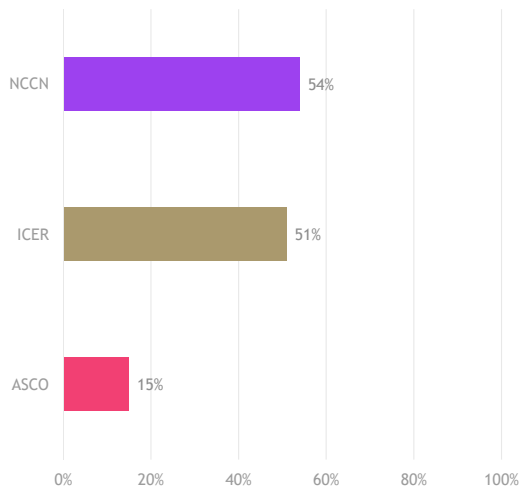
## Usefulness of Evidence Sources



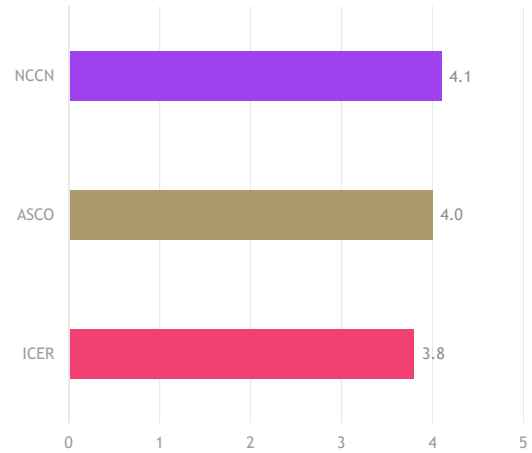
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## Value Frameworks

Value Frameworks used for Review n=99



Usefulness of Value Frameworks.  
Rate from 1-5. n=99

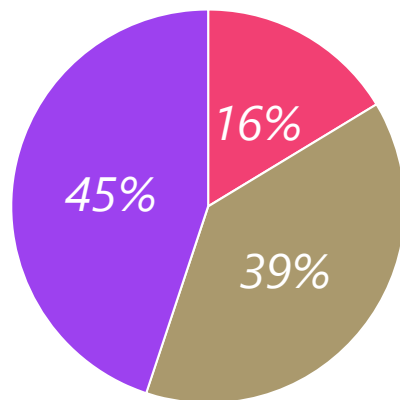


Sd|hw2FGP #h#vbj #yoch#up hz runv#r#khl#hyhz v#lqg#lgbj #khp #vnxk

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## Payer Use of ICER

Used ICER as Part of Review n=98



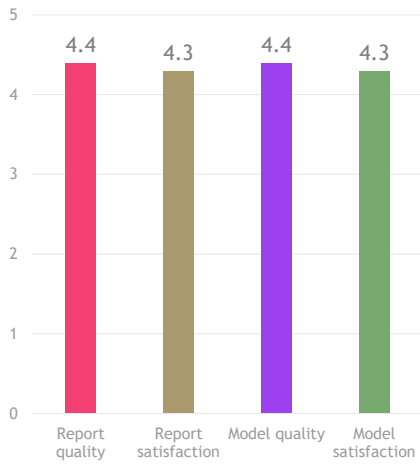
- Yes, I used the ICER report in my formulary review
- Yes, I will use the ICER report for this formulary review but I have not yet reviewed it
- No

- **81%** would recommend ICER to their peers
- **41%** did not use ICER reports because they were not available in time to prepare for P&T decision

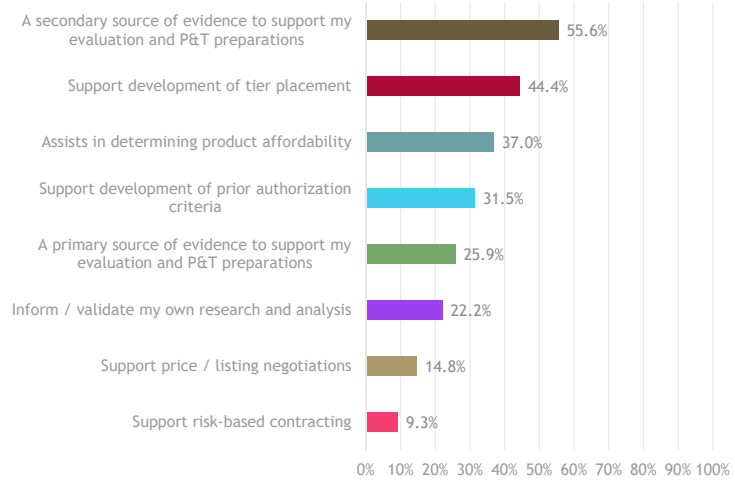
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## ICER Satisfaction and Usefulness

Please rate quality and level of satisfaction with the ICER report used. n=16



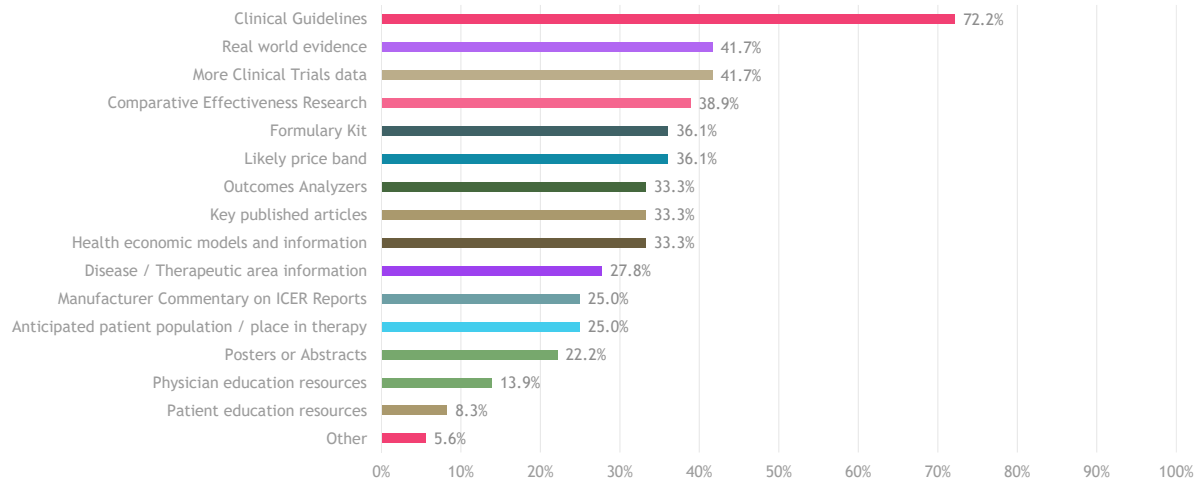
How is the ICER Report used in your product assessment and formulary decision process? n=54



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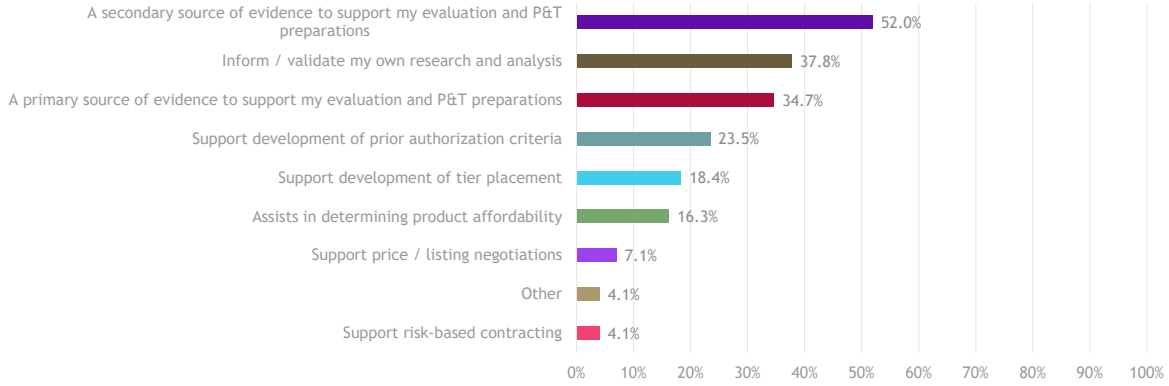
## Information Requested in a Manufacturer Resource Center

What manufacturer information would you like to see in the Manufacturer Resource Center? n=36



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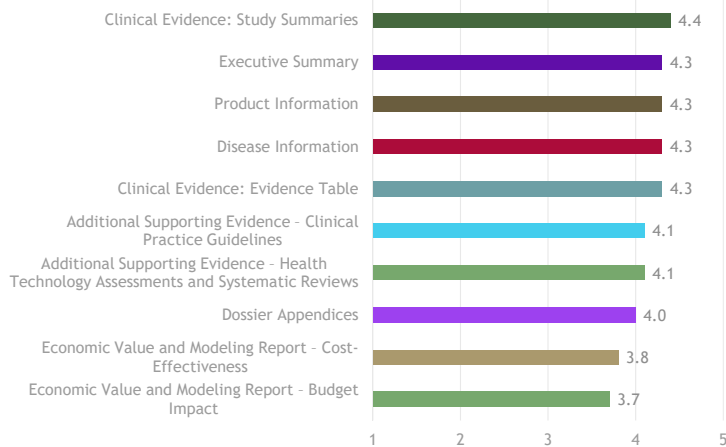
How is a dossier used as part of the review process? n=98



• 4 out of 5 level of dossier satisfaction (n=98)

• 4 out of 5 dossier quality (n=98)

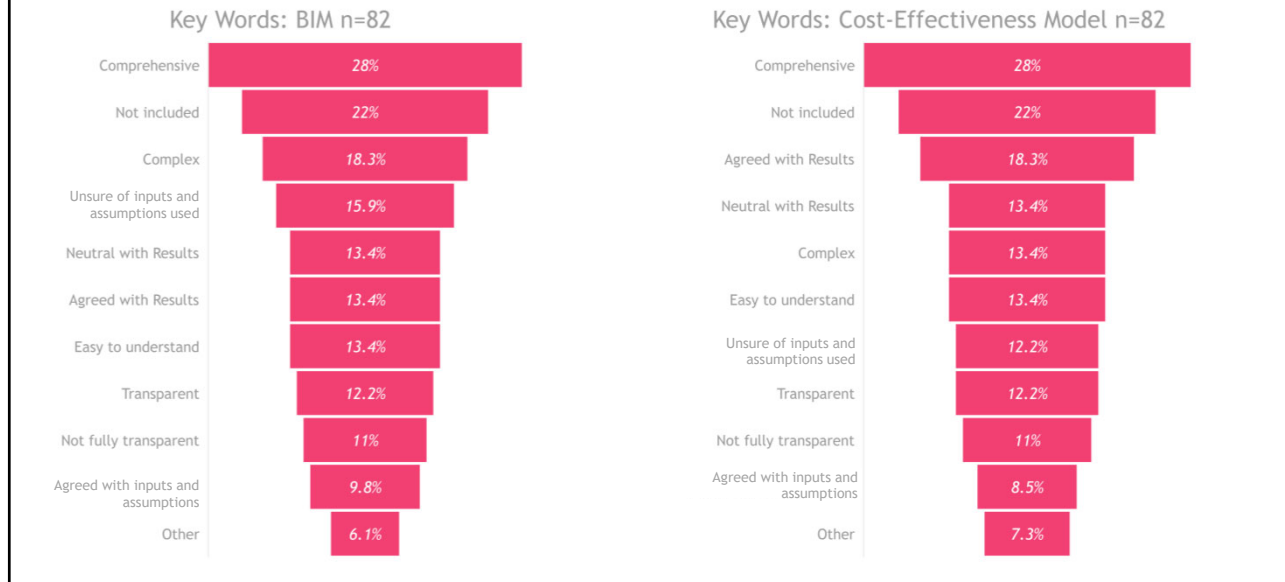
Please rate the usefulness of the sections of the product dossier.  
Rate from 1-5. n=83



What is your opinion of the dossier?  
What descriptive words do you associate with it? n=83



## Key Words Describing Manufacturer Economic Information



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## Reimbursement Decision Insights

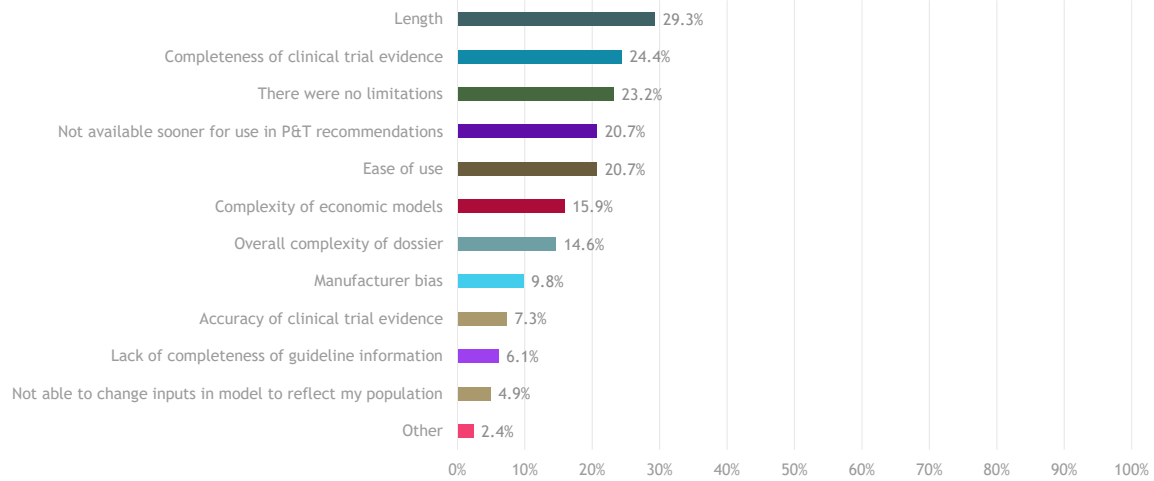
- 55% say P&T decision will be made in 0-3 months post FDA-approval; 37% say it will be 4-6 months post-FDA approval
- Coverage on pharmacy or medical benefit, or both, is common
- Prior authorization and quantity limits are the most common formulary restrictions as well as a mail order requirement.

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## Limiting Factors

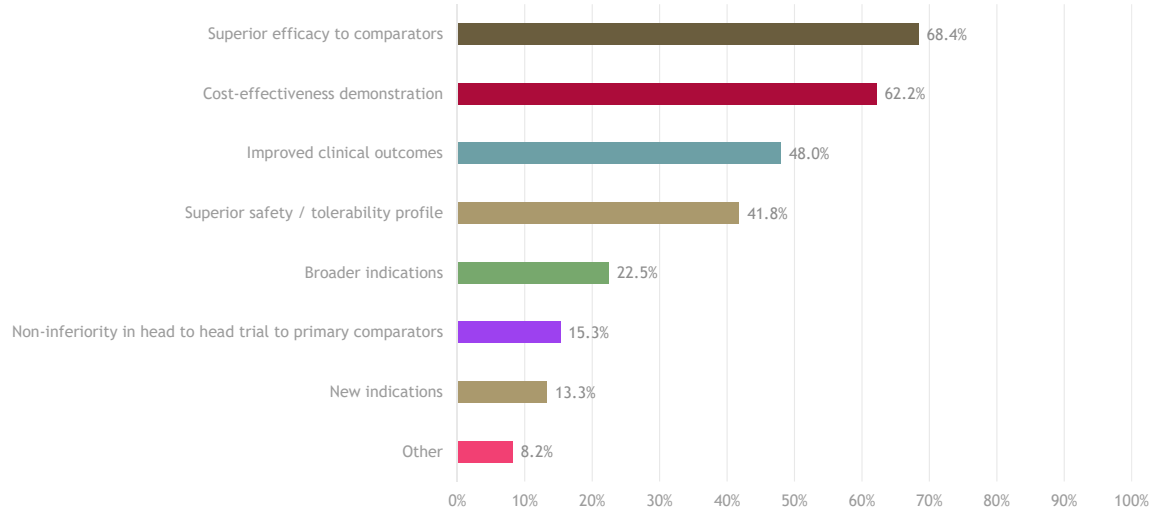
What specific factors (if any) have limited the use of the dossier during your review?  
n=82



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## Key Factors - Preferred Reimbursement

What key factors would drive this product to have PREFERRED REIMBURSEMENT? n=98



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## Feedback/Suggestions for Manufacturer

- Need additional safety studies, ongoing monitoring for adverse events
- Need real world studies
- Value-based arrangements or manufacturer rebates would improve economic assessment.

- Patient reported outcomes, comparative effectiveness studies and new indications.
- It's difficult to assess clinical efficacy and economic value when products have accelerated approval, with data from phase 3 trials pending.

- Budget impact detailing side effects and hospitalizations and quality of life measures.
- Head to head trial data.
- Consider overall survival versus tolerating side effects.
- Offer patient assistance programs to keep people on therapy by managing side effects, etc. more efficiently.



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## Syndicated Survey Review – FormularyDecisions.com®

- Key takeaways:
  - Payers are using manufacturer provided evidence in their product reviews and finding it valuable.
  - Product related economic information provided by manufacturer is rated highly.
  - NCCN and ICER are the most commonly used value frameworks in oncology; timing continues to be a challenge for ICER reports.
  - For preferred status, superior efficacy and cost-effectiveness need to be demonstrated.

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**Jeremy Lee, PharmD, BCPS**  
Director, Drug Information  
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Special thanks to:  
Karen Watkins, PharmD, BCOP, Emerging Therapeutics Strategy Pharmacist  
Kristi Jhangiani, PharmD, Drug Information Pharmacist

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## Agenda

MedImpact Overview

Oncology Landscape – PBM Perspective

Financial Toxicity

“Value” of Cancer Drugs

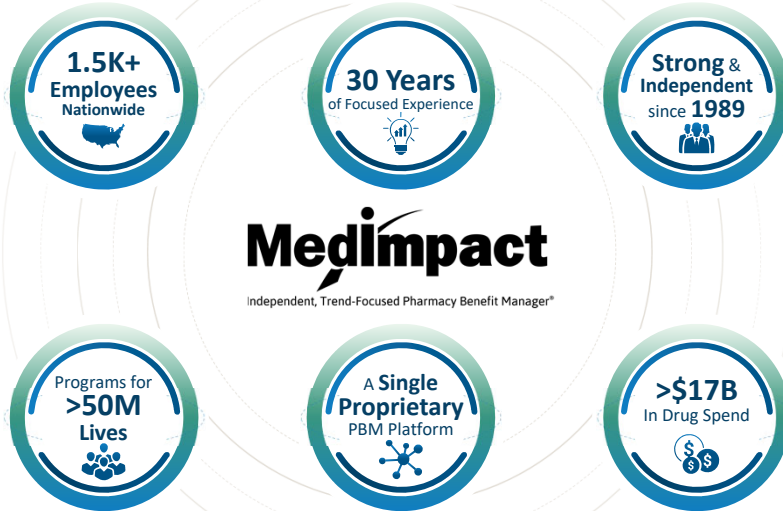
PBM Utilization Management Strategies

Challenges for Formulary Decision-Making

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## About Us



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## Overview



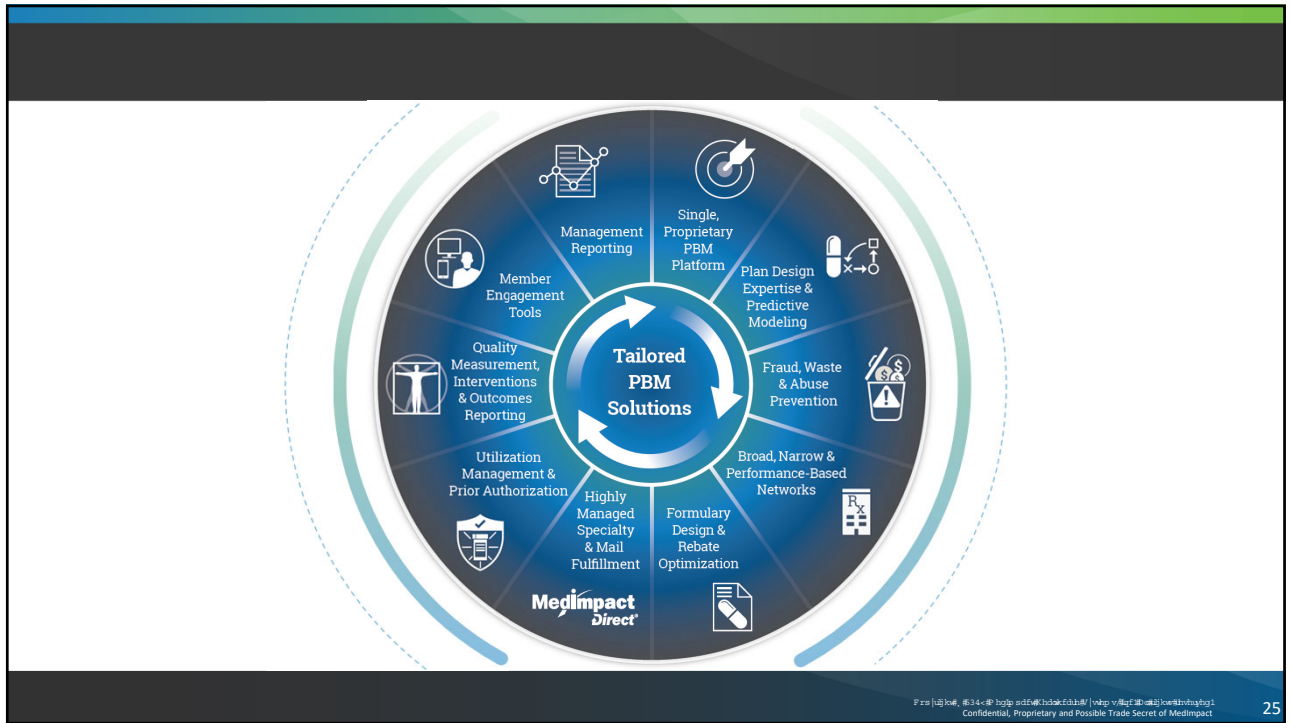
PBM of choice for self-insured employers that own pharmacies



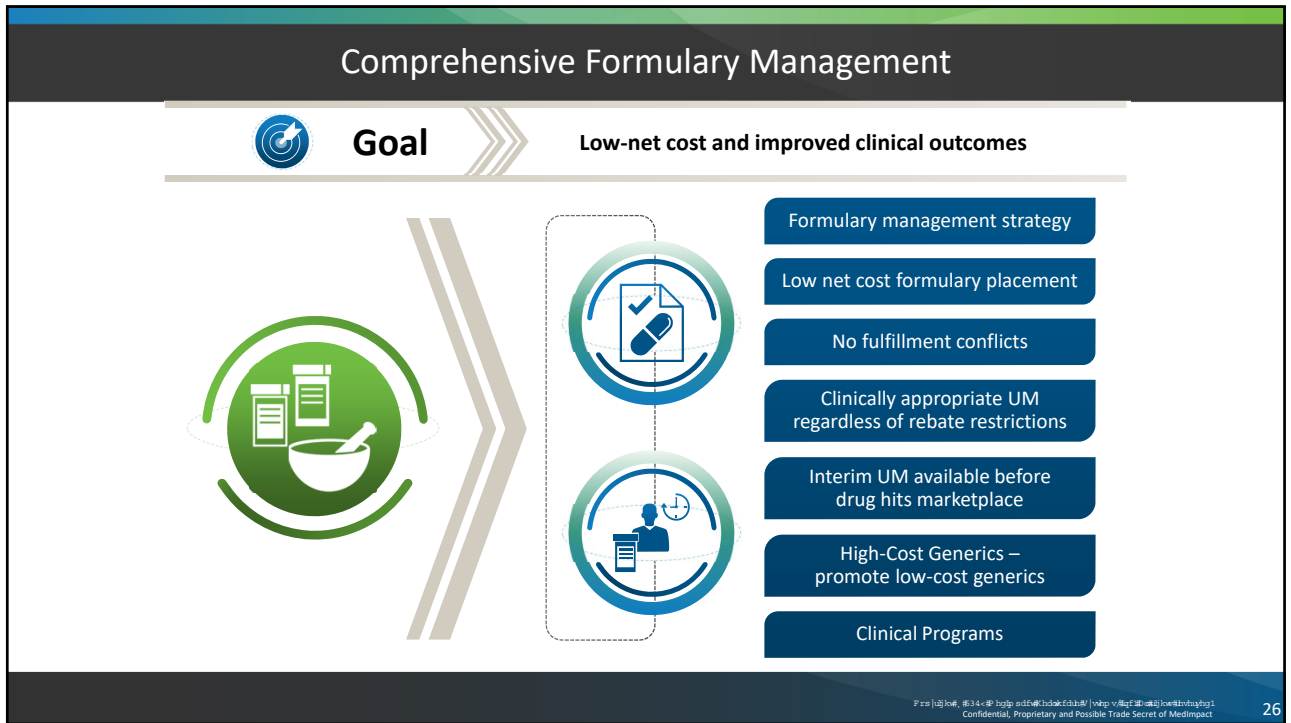
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# The Evolving Oncology Landscape

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## Clinical Trends – The Numbers

**2013 - 2017**

**14** New Active Substances (NAS) approved  
All targeted therapies  
**11** breakthrough  
**11** oral agents

**2017**

**76** new indications  
**61** NAS  
**23** Tumor types

IQVIA Institute. Global Oncology Trends 2018. May, 2018.

Pharmaceutical, Biotech and Health Care Industry | Confidential, Proprietary and Possible Trade Secret of Medi**impact**

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## Clinical Trends – The Science

**Over 700 oncology molecules in late-stage development in 2017**

Up over **60%** from a decade ago

**90%** are targeted therapies

**34%** of ongoing trials involve biomarkers

**43%** are immunotherapy drugs with **60** separate MOA's in phase I/II

**New MOA's can cause rapid market shifts.**

**Use of biomarkers increasing rapidly, enabling precision medicine**

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## Financial Trends

**19%**

of medical benefit spend is on cancer

**21%**

of pharmacy benefit spend is on cancer

**Spend is outstripping growth rate of other drugs**

**Annual U.S. spend on cancer drugs**

Year	Spend
2012	\$25b
2017	\$50b
2022	\$100b

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## Financial Trends

All drugs approved in **2017**  
had an annual list price  
above **\$50k**

The average list price  
was over **\$200k/year**

↓ patient numbers...  
↑ drug prices

Among employer plans,  
only **22%** report utilization  
of a carved out benefit design  
for cancer therapeutics

IQVIA Institute. Global Oncology Trends 2018. May, 2018.  
2018 Genentech Oncology Trend Report. 10<sup>th</sup> ed. April, 2018.

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## Financial Toxicity

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## Out of Pocket (OOP) Costs

Oncology patients spend  
**20-68%** more OOP  
than non-oncology patients

### Commercial

**13.4%**  
of oncology patients  
had OOP costs greater than  
**20%**  
of their income

### Part D

Oncology pts had OOP costs averaging  
**23.7%**  
of their annual household income  
with **10%**  
of patients having expenses exceeding  
**60%**  
of their household income

Risk factors for non-adherence due  
to OOP costs are lower income,  
younger age, uninsured

Future Oncol 2014;10:2189-99.  
J Clin Oncol 2011;29:2821-6.

JAMA Oncol 2017;3:757-65.  
Ann Transl Med 2018;6(9):166.

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## Impact on Adherence

**83%**  
of practices say  
that **18%**  
of their patients  
have delayed or  
discontinued  
treatment

Part D, OOP  
**costs > \$500**  
per claim  
were associated  
with **25%**  
abandonment  
vs. **6%** for costs  
< **\$100**

Multiple  
Myeloma,  
**17%** reported  
delays in therapy,  
and **10%**  
reported  
abandonment due  
to high costs

2018 Genentech Oncology Trend Report. 10<sup>th</sup> ed. April, 2018.  
J Oncol Pract 2011;7:46-51s.

Lancet Haematol 2015;2:e408-16.

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## Manufacturer Coupons

**37%**  
of patients used  
coupons in **2017**

These average a  
value  
of **\$526**  
per claim!

**28%**  
of employers are  
changing their  
benefit design in  
response to the  
increase in  
coupons

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## MCO Perspective

**94%** of MCOs  
are concerned about the  
impact of financial toxicity  
on the quality of care

**45%** are considering  
reducing or waiving OOP costs  
for cancer drugs

**16%** of MCOs  
waive deductible  
for oncology drugs

**8%** of MCOs  
waive copays  
for oncology drugs

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## PBM Perspective

**PBMs** offer narrow-network or self-owned specialty pharmacies to health plans in order to manage both cost and quality

**PBMs** can establish quality metrics for their network SPs, including metrics around financial toxicity and adherence

For instance, only **37%** of SPs screen all of their patients for financial toxicity

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## Addressing Value of Cancer Drugs

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## Value of Targeted Therapies

**New solid tumor drugs  
2010-2015:**  
launch price did not  
correspond to efficacy

**ASCO established targets  
for clinical trial outcomes**

**42% of 71**  
new solid tumor therapies  
approved **2002-2014**  
met the ASCO guidance

**19% of 47**  
therapies approved  
**2014-2016**  
met ASCO survival goals

Cancer Treat Rev 2017;56:1-7.  
JAMA Otolaryngol Head Neck Surg 2014;140:1225-36.  
<https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm071590.pdf>

J Clin Oncol 2014;32:1277-80.  
JAMA Oncol 2016;2:1238-40.

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## Value Based Insurance Design

### Concept

Drugs with  
higher value  
should have  
lower patient  
cost-sharing

Can increase  
adherence and  
drive utilization  
towards higher  
value therapies

Commercial claims  
2007-14, OOP  
costs were not  
associated with  
oncolytic drug  
value

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## Value Based Frameworks

NCCN,  
ICER,  
ASCO,  
Memorial Sloan  
Kettering Cancer  
Center

Comparison of  
**3 MM** regimens  
produced some  
consistent results,  
but some variable  
results

Concerns over  
objectivity, utility,  
and adaptability of  
frameworks

Another study  
found that NCCN's  
affordability  
component was  
not reliable

J Manag Care Spec Pharm 2018;24(1):39-46.  
J Manag Care Spec Pharm 2018;24(6):565-71.

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## PBM Utilization Management Strategies

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## Traditional Utilization Management

PA for indication:  
**90% of MCOs**  
(Attestation vs requiring actual  
biomarker results?)

QL:  
**78%**  
(down from 92%)

Formulary tiers with differential  
cost sharing:  
**74%**

Step Therapy:  
**67%**

Ensure cost-sharing laws  
**are followed**

**Cancer is not cholesterol**

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## Other Programs

**Specialty pharmacy  
network**

Cost/quality

Recommend alternatives  
based on formulary  
preferences

**Drug Utilization Review  
clinical programs**

**Split-fill program**

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# Challenges for Formulary Decision-Making

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## Clinical Challenges

**Lack of comparative  
efficacy data**

**Place in therapy  
is ever-evolving**

**Volume and pace  
of clinical data**

**Very specific, non-overlapping  
indications**

**Accelerated approvals /  
surrogate data**

**“Ready” to use immune  
response criteria  
Oncologists: 35%  
MCOs: 14%**

2018 Genentech Oncology Trend Report. 10th ed. April, 2018

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## Other Challenges

**Consistently synthesize  
Medical benefit and Pharmacy  
benefit data**

**MCOs: 54%**

**Employers: 43%**

**Limited Distribution**

**Timeliness of eDossier**

**Adequacy of Budget  
Impact Models**

**Smaller and smaller target  
patient populations**

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## Takeaways

Oncology drugs have the highest spend, and the largest pipeline.

Health plans must be mindful of how high OOP costs impact adherence.

The cost of new cancer drugs does not always correlate with their outcomes.

The clinical uniqueness of each drug and the rapid pace of change make it difficult to design and implement aggressive UM strategies.

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Thank you for participating!

For further information on the AMCP eDossier System contact [esampsel@dymaxium.com](mailto:esampsel@dymaxium.com)

