AMCP MARCH 2017

3 Key Themes

Staying current in the dynamic managed care pharmacy landscape is more important than ever. Entrée Health attended nearly 45 sessions at the AMCP Managed Care and Specialty Pharmacy Annual Meeting. Here's what we think you should know.

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THEME 1

Management of specialty therapeutics:

Payers are still a long way from a consensus on the best way to manage

THEME 2

Oncology care management:

Payers are looking to evaluate the possible benefits of value-based risk-sharing arrangements with manufacturers

THEME 3

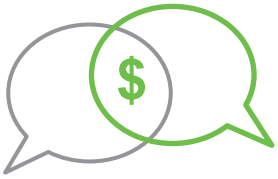
Uncertainty about government policies:

AMCP has recommendations for payer communications, pre- and post-FDA approval

Management of specialty therapeutics

With the FDA approving more specialty drugs than traditional drugs in the last 7 years, this area is of major interest to the managed care industry.

However, payers have not reached a consensus on how to manage specialty products. Coverage policies differ across payer types and from plan to plan due to variations in the types of evidence selected for review by P&T committees.



From discussions we heard throughout the conference, we learned that payers use very few cost-effectiveness analyses to inform specialty drug management decisions. This could be due to the fact that not enough analyses exist, or that they aren't developed in a way that can assist them in the decision-making process.

Looming patent expirations will add management complexity

2017

from 2017 through 2021, there is a

$23.7 **billion** opportunity for specialty generics, as **64 patents on specialty brands will expire** over the next 4 years.

A similar opportunity is ahead for biosimilars, with **73 biologic patent expirations** anticipated by 2021 with a US sales value of **$46.2 billion.**

2021

Source: IMS health data, 2016. Patent expiration dates of specialty brands and biologics are current as of March 2017.

TURN INSIGHTS INTO ACTION

With no consensus on management strategy emerging, the value framework for your product will need to be flexible enough to meet the needs of many different payers. Therapeutic impact, patient adherence, cost-effectiveness, and management collaborations are a few of the ways payers told us they're looking for manufacturers to demonstrate value.

THEME 2
Oncology care management

With more than 800 drugs and vaccines estimated in the oncology pipeline (80% potentially first in class) and costs projected to rise 8% to 12% annually through 2020, it's no surprise that oncology care management dominated several sessions at this year's meeting.

In a costly and rapidly changing environment, payers are looking to evaluate the possible benefits of value-based risk-sharing arrangements with manufacturers.

Results presented at AMCP from a January 2017 survey of 21 payers and 10 IDNs found 3 different perspectives regarding payer/manufacturer value-based oncology contracting:

OPTIMISTIC

- Believe a model should be implemented in which the provider and manufacturer to take on more risk for patients whose risk can be controlled and whose outcomes can be influenced
- Create financial incentives to use the most cost-effective alternative, provided the clinical outcomes are similar
- Tier payment models with payers for pathway compliance

CAUTIOUS

- Require several large trials of value-based risk sharing with a transparent structure and publicly shared results to better inform future programs based on real experiences
- Believe utility of risk sharing must be demonstrated in a broad setting before it is adocpted

NOT INTERESTED

- Do not believe risk sharing is a useful concept in oncology due to patient and disease variability

Although most of the respondents were cautious about value-based contracting, the optimistic perspective was a close second. An emphasis on value permeated the majority of sessions this year.

Be on the lookout for an increase in customer willingness to engage in contracts that push beyond standard rebates.

TURN INSIGHTS INTO ACTION

Opportunities exist for manufacturers to take a bolder approach to value-based contracts. This topic came up in multiple sessions at AMCP, and payers seem willing to develop contracts with competing therapies in order to see which performs best in the real world. Innovate alongside your customers to improve oncology product access for the patients who need it most.

THEME 3
Uncertainties about government policies

While the question of how to redirect healthcare reform continues to challenge policymakers, the AMCP and like-minded stakeholders offer two consensus recommendations to empower population health decision makers in other areas of great interest to drug manufacturers:

AMCP RECOMMENDATION 1

Clarification and expansion of FDAMA section 114 should occur post-FDA approval and permit:

- Truthful information
- Transparent communications that are reproducible and accurate
- Economic and clinical information
- Information applicable to healthcare decision makers and influencers
- Using a consistent format and process
- Leave-behind models

AMCP RECOMMENDATION 2

Permit pre-approval information exchange by creating a pre-approval safe harbor to allow biopharmaceutical companies to proactively share clinical and economic information on emerging therapies

A pre-approval safe harbor should:

- Apply to a period of pre-FDA approval, 12 to 18 months in advance
- Apply to population health decision makers only
- Be specific to new molecules and expanded indications
- Include information only, not evidence

TURN INSIGHTS INTO ACTION

The recommendations put forth by AMCP allow for a crucial flow of information between manufacturers and their payer customers. Having the opportunity to clearly define the economic outcomes of therapies and to share information on emerging therapies could redefine the crux of these relationships. Ultimately, the industry is looking for ways to increase communication and produce meaningful strategies that improve the lives of members. But until the FDA finalizes their guidance on this topic, manufacturers are left struggling to determine how much of the draft guidance (issued earlier this year) and the AMCP recommendations they can implement.