Patient Access & Reimbursement: Current Challenges & Strategies

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Disclaimer

- The information and views shared in this presentation are my own and do not necessarily represent any official positions of EMD Serono or Merck KGaA, Darmstadt, Germany.
Topics for Today’s Discussion

This session will review the following:

● the current *access and reimbursement landscape* for community oncology and strategies to deal with emerging challenges

● the role of *government and commercial payers*, as well as Pharmacy Benefit Managers (PBMs) and the changing ways that we work with them

● the new opportunities presented by the Administration’s focus on *value-based agreements* and its implications for community oncology

● the growing *funding gaps for patients* and strategies for working with assistance programs to help them meet their needs
1 LANDSCAPE OVERVIEW
Since Peaking in the Early 1990s, Cancer Death Rates Have Declined by About 25 Percent

Increases in cancer survival are estimated to translate to the avoidance of nearly 2.1 million cancer deaths.

Introduction of Novel Cancer Medicines Associated with Survival Increases

Medicines are one factor driving increased survival, along with screening, earlier diagnosis, and lifestyle changes.

Promise in the Pipeline: More than 800 Medicines in Development for Various Cancers

Number of Medicines in Development in the United States, September 2015, Selected Cancer Types

1 Some medicines are being explored in more than one therapeutic category.

Cancer Drugs Account for About One Percent of U.S. Healthcare Spending

Cancer Medicines as a Portion of NHE Projected Total U.S. Health Care Spending, 2016

- $45.5 Billion
- $3.3 Trillion*


1 2016 CMS total National Health Expenditures is a projection
2 Cancer drug invoice spending and does not include discounts
Cancer Medicines Represent About 20 Percent of Cancer Spending

The trend of volume-weighted Average Sales Price (ASP) for cancer drugs administered through Medicare Part B has been growing in line with medical inflation.

Better Use of Cancer Medicines Can Reduce Health Care Costs

Advanced melanoma patients who were adherent to immunotherapy experienced 10 percent lower health care costs.

Source: Gupte-Singh K, Lin J, Lingohr-Smith M, Menges BL, Rao S. Adherence to cancer therapies and the impact on healthcare costs among patients with advanced melanoma in the USA. Proceedings of the 22nd Annual International Meeting International Society of Pharmacoeconomics and Outcomes Research (May 2017); Available at https://www.ispor.org/ScientificPresentationsDatabase/Presentation/70971?pdfid=49558.
2 PATIENT BURDEN
Patients Face Medical and Non-Medical Cost Burdens

More than 40 percent of patients say medical and non-medical costs cause equal financial hardship.

1 Among patients (n=110) diagnosed with cancer in the past five years and surveyed by CancerCare in April 2017.

A Cancer Diagnosis Impacts Productivity and Employment for Patients and Caregivers

Patients

67% of patients who were employed full-time when diagnosed either stopped working or reduced their work hours

Caregivers

More than 25% of cancer caregivers made extended employment changes

Out-of-Network (OON) Utilization Contributes to High of OOP Costs

Out-of-pocket (OOP) costs can be high when insurance does not cover the services patients need. For cancer patients with high OOP spending, a large portion of their costs are due to OON services.

Benefit Design Is a Barrier for Some Cancer Patients

Percentage of Silver Plans Placing All Drugs per Class on Specialty Tier, 2016

Molecular Target Inhibitors*: 23%

Antiangiogenics*: 50%

*There are no generic drugs available in this class. All products are single-source.

Some plans place treatments for certain high-cost conditions on the highest drug formulary cost sharing tier (sometimes called adverse tiering).

Source: Avalere Health PlanScape®, a proprietary analysis of exchange plan features, April 2016. This analysis is based on data collected by Managed Markets Insight & Technology, LLC.
High Cost Sharing Leads to Abandonment or Delays in Cancer Treatment

Oral Oncolytic Abandonment Rate by Patient Out-of-Pocket Amount

- <$10: 9%
- $50.01-$100: 13%
- $100.01-$500: 29%
- $500.01-$2000: 38%
- >$2000: 45%

Highest cost sharing group was six times more likely to delay treatment than the lowest cost-sharing group.

“What we should be doing is, those techniques that drive such good net pricing in Part D, what can we take from the learnings there into Part B?”

“I think where the government doesn’t have negotiation, it’s worth looking at that.”

Part B “was constructed a long time ago, in a different era” with different drugs and types of therapy.

“I think we need to rethink how we are structured and how we’re paying for these new drugs.”

“I think we need to rethink how we are structured and how we’re paying for these new drugs... the Part B program in particular may not have contemplated these types of new drugs coming out in the market.”

What Is CMS Going to Do?
Commercial Payers Are Using A Variety of Tools to Control Access to Oncology Therapies

Current and Anticipated Payer Measures to Manage Oncology Costs (Q1 2017)

- Utilizing one or more value frameworks* in determining reimbursement: 31%
- Using clinical pathways to determine treatment regimens: 35%
- Contracting for preferred first-line therapies: 59%

*Value Frameworks: NCCN Evidence Blocks, ASCO Value Framework, etc.

Source: Zitter Health Insights, Managed Care Oncology Index (2016).
Manufacturers and Health Insurers Are Pursuing Novel Outcomes-Based Contracts (OBCs)

About 35 percent of payers with outcomes-based contracts have or are considering OBCs in oncology. The Administration has also signaled willingness to allow OBCs for government programs.

## Enabling the Cancer Drug Market’s Move to Value

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<th>Value Based Contracts</th>
<th>Value Frameworks</th>
<th>Quality Measures</th>
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<td>Expand value-based contracts by modernizing outdated regulations.</td>
<td>Develop better data and tools to support informed decision-making by patients, physicians and payers.</td>
<td>Close gaps in clinical and patient-focused quality measures.</td>
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<td>“[R]egulatory reforms can address these concerns and encourage more robust competition within the drug market.” Scott Gottlieb &amp; Kavita Patel</td>
<td>“[E]merging approaches for assessing drug value are welcome….The frameworks will require refinement, however, before they’re ready to be broadly applied.” Peter Neumann &amp; Joshua Cohen</td>
<td>“All phases of the cancer care continuum...need new measures.” National Academy of Medicine</td>
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Payers Are Increasingly Exploring Novel Ways to Manage Specialty Drugs

Cigna recently announced that it will no longer allow buy-and-bill reimbursement for certain providers that purchase so-called “limited distribution drugs,” a term that could be applied to most oncology drugs.

Instead, the payer will mandate that these products be ordered and delivered by a specialty pharmacy provider.

Restrictions like this one can be disruptive to the practice of oncology care. Providers should be ready to express their concerns to payers that make such changes.

Pharmacy Benefit Managers (PBMs) Are Targeting Physician Dispensing

CVS Caremark

- Since 2011, PBMs have consolidated into just a handful of major corporations that control about 80 percent of covered lives in the United States.
- A leading PBM, CVS Caremark, recently attempted to decertify physicians dispensing oral oncology therapies from its pharmacy network.
- This move, which was swiftly and successfully opposed by groups like COA, would have left patients without access to their medications from the provider offices where they are treated.

FILLING GAPS
There Are Many Resources Available to Help with Patient Needs, But Keeping Track Can Be A Challenge

- A handy reference for manufacturer programs is the *ACCC Patient Assistance & Reimbursement Guide*¹

- In the past, it was hard to find a centralized resource for not-for-profit and foundation assistance programs; however, ACCC recently added these aspects as well

Your Input to Manufacturer Partners Is Absolutely Critical in Designing Patient Access Services

- Please give your manufacturer partners feedback on their patient access and reimbursement services
- We cannot design and implement these programs without your input
- Each company has different approaches, but consider taking advantage of available opportunities to provide feedback

💡 Your feedback and thoughts for improvement are greatly appreciated.
5 CLOSING THOUGHTS
With So Many Threats and Changes Looming, What Can We Do?

- There is no better advocate for community oncology than COA
- Be involved and be an advocate for your profession, and encourage your peers to do the same
- Participate in Congressional fly-ins and Hill Days and make your representatives in DC aware of your concerns

Network to amplify your voice and make your manufacturer partners aware of your concerns, so you can leverage them on issues of mutual interest.