Pass the Buck: The New Face of Oncology Formulary Management

June 16, 2016
Agenda

- U.S. Oncology Market Trends
- Prescriber Incentive Pathway Overview
- Oncology TA Deep-Dive
  - Non-Small Cell Lung Cancer
  - Multiple Myeloma
- Conclusions and Takeaways
U.S. Oncology Market Trends

U.S. pharmaceutical sales in the oncology space have grown 60% since 2011, putting considerable strain on the margins of U.S. payers

- Oral products in the retail and clinic spaces, as well as hospital-administered injection/infusions have seen the most growth in the last 5 years

Annual U.S. Pharmaceutical Oncology Spend by Form and Dispensing Location, 2011-2015

- Clinic Injection
- Clinic Oral
- Hospital Injection
- Hospital Oral
- Retail Injection
- Retail Oral

Source: IMS Health, MIDAS, IMS Institute for Healthcare Informatics, Dec 2015
This growth will likely not slow in the foreseeable future, as oncology products continue to dominate industry development pipelines

- In 2015, 87% of late phase oncology products in development were targeted therapies, which tend to have higher price tags than cytotoxics, the second largest development category
- Of the 586 pipeline products in development by 2015, 145 are in Phase III human trials

**Annual Growth of the Late Phase* Oncology Pipeline 2005-2015**

*late phase = post-Phase I

Source: IMS Health, R&D Focus, IMS Institute for Healthcare Informatics, May 2016
In other expensive specialty classes, payers control costs by influencing product utilization with NDC blocks and step therapies.

PBM releases annual exclusion lists that include brands in specialty TAs like autoimmune, HCV and MS—payers do not list oncology brands on exclusion lists.

Payers also control utilization with step therapy requirements—typically only label-indicated steps are used on oncology brands.

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**2016 Preferred Drug List Exclusions**

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>Excluded Medications</th>
<th>Preferred Alternatives</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hepatitis C (Genotype 1)</td>
<td>Harvoni, Olysio, Sowaldi*</td>
<td>Viekira Pak</td>
</tr>
<tr>
<td>INFLAMMATORY CONDITIONS</td>
<td>Cimzia, Simponi 50 MG, Xeljanz</td>
<td>Cosentyx, Enbrel, Humira, Simponi 100 MG (for ulcerative colitis only), Stelara</td>
</tr>
</tbody>
</table>

**Formulary Drug Removals**

- **Anti-infectives, Antivirals**
  - Hepatitis C Agents: VIEKIRA PAK, HARVONI
- **Multiple Sclerosis Agents**: AVONEX, EXTAVIA, PLEGRIDY, AUBAGIO, BETASERON, COPAXONE, GILENYA, REBIF

Source: Payer websites
Caught in between the PR challenge of controlling access to cancer therapy and significant medical losses, payers have had to alter their strategy.

Some payers have innovated their approaches to cost control in the oncology space by targeting physician prescribing behavior instead of patient utilization.

Use Formulary Control on Patient to Lower Oncology Costs

Incentivize Physician to Prescribe in a Cost-Effective Way

Incentivizing physicians to treat in a cost-effective way falls well in-line with the overall movement towards value-based care models.
Physicians are easier to target and influence than ever before, as the majority of U.S. providers now fall within an affiliated network

- Only 16% of the oncologists in the U.S. operate within independent, unaffiliated practices
- Physicians that are consolidated into large, affiliated groups are more likely to have their prescribing behavior informed by incentivizing programs rather than their independent standard of care practices

**U.S. Oncology Provider Affiliations by Delivery Systems Type, 2010 & 2015**

- **2010**
  - Integrated Delivery Network: 57%
  - Corporate Parent: 28%
  - Independent: 15%

- **2015**
  - Integrated Delivery Network: 70%
  - Corporate Parent: 16%
  - Independent: 13%

The shift toward a consolidated U.S. prescribing population provides a great opportunity for payers to introduce incentivizing programs, known as prescriber pathways

*Source: IMS Health, Healthcare Organizational Services; May 2016  
Notes: IDN = healthcare system or network with at least 1 acute care hospital; Corporate Parent = healthcare system or network that does not include an acute care hospital; independent = facility not part of a broader healthcare system*
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Prescriber incentive pathway programs represent one form of influence on prescriber behavior, along with more traditional factors.

Prescriber Incentive Pathway Overview

Clinical Pathway Recommendations

National oncology organizations recommend certain treatments in a particular order based on clinical outcomes (typically QALYs and ICERs*)

Prescriber -Incentive Pathway Program

Payers incentivize oncologists to treat their patients with a particular regimen of medication

Clinical Evidence-Based Step Therapies

Payers may require patients to step through specific therapies based on clinical efficacy and/or preferred status before moving on to other products

This presentation will focus on the ways U.S. payers are outsourcing control of the oncology space to sub-contracted entities that create treatment pathways

*QALY= Quality Adjusted Life Year; ICER = Incremental Cost-Effectiveness Ratios
A variety of companies provide clinical expertise to inform physician pathway programs or support their usage

Three of the largest of these organizations include....

AIM Specialty Health designed the oncology pathways solutions for the Anthem Cancer Care Quality Program

- AIM Specialty Health reviews published scientific literature, product costs, and solicits input from experts in order to create the pathway programs, but these can be tailored by the payer.

- Pathways are selected based on 1) clinical benefit, 2) side effects/toxicities, 3) strength of national guideline recommendations and 4) cost of regimens and associated supportive care.

- AIM grants registered physicians provides access to quarterly analytics, clinical experts for peer-to-peer discussion, as well as access to its ProviderPortal™ to request validation of treatment regimens and to access summarized reports on new publications.

Prescriber Incentive Pathway Overview

The AIM Oncology ProviderPortalSM provides physicians with a step-by-step online tool for logging treatment pathways and tracking reimbursement.

1. **Input Patient/Provider Info.**

2. **Clinical Regimen Entry**

3. **Regimen Alternative**

Both patients and providers need to be registered through the portal.

The physician enters in their preferred treatment pathway based on a number of documented factors relevant to each case.

If an entered pathway does not match one specified by AIM/Anthem, the portal shows the physician a list of regimens that are.

Source: Anthem/AIM Oncology Provider Tutorials, https://anthem.aimoncology.com/Tutorial.html#
At the initiation of the Anthem Cancer Care Quality Program, Anthem became the largest U.S. payer to offer an oncology pathway program.

Anthem Cancer Care Quality Program Specifics:

- The first Anthem pathway programs went live on July 1, 2014 and applied to both Commercial and Part D plans
  - Initially, the program was instated in Indiana, Kentucky, Missouri, Ohio, Wisconsin, and Georgia, but expanded nationally throughout 2015
- Oncologists complying with this program receive additional compensation: $350 at treatment initiation and then $350/month for each patient they treat
  - This incentive payment is meant to offset the financial gains oncologists would have gotten by potentially prescribing more numerous or expensive treatments
- The pathways are specific to each patient case where applicable
  - There are pathways for cancer sub-types (i.e. non-squamous vs. squamous non-small cell lung cancer) and genetic marker-positive cases (i.e. EGFR+, ALK+, HER2+) where applicable
- Pathway adherence does not impact coverage determination for a patient
  - Anthem formulary restrictions do not necessarily mirror preferred pathway products

Sources: Anthem.org
The roll-out of the Anthem Cancer Care Quality Program happened in stages of Anthem regional additions and new oncology TA offerings.

**Prescriber Incentive Pathway Overview**

*Anthem Central* includes the following states: IN, OH, WI, KY, MO; **Anthem Northeast** includes the following states: CT, ME, NH

**Timeline of Anthem Regional and TA Pathway Entrance July 2014-Sept 2015:**

- *Regions Launched:*
  - Anthem Central*, BCBS GA
    - Est. Lives: 4.0m
  - BC CA, BCBS CO, BCBS NV
    - Est. Lives: 2.9m
- *Regions Launched:*
  - National Out-Area Plans
    - Est. Lives: 1.1m
  - Empire (NY BCBS)
    - Est. Lives: 1.4m
- *Regions Launched:*
  - Anthem VA
    - Est. Lives: 1.4m
- *Regions Launched:*
  - Anthenn Northeast**
    - Est. Lives: 1.3m

**Pathways Launched:**
- **Breast, non-small cell lung cancer & colorectal cancer**
- **Melanoma, brain & endocrine breast**
- **Prostate, neoadjuvant breast & CML**
- **Lymphoma, leukemia, myeloma, ovarian & pancreatic**

*By Sept 2015, an estimated 14.7 million Anthem lives and >14 oncology classes were eligible for enrollment in the Anthem Cancer Care Quality Program.*

Just six months following the initial launch of the Anthem Cancer Care Quality Program, over 5,500 patients were enrolled.

Patient Enrollment in Pathway by Cancer Type

- **Breast Cancer**: 29%
- **Colon Cancer**: 13%
- **Lung Cancer**: 15%
- **Lymphoma**: 10%
- **Other**: 33%

These patients were treated at 616 unique oncology practices, medical groups or hospitals.

Despite lymphoma and “other” cancers, only being available for pathway enrollment for a maximum of 4 months at the time of this data capture, their registered patient population was about 2,380, making up 43% of the overall distribution of patients.

In the first six months of availability, Anthem reported that pathway adherence for breast, NSCL lung, and colon cancer was 63%, 72%, and 63%, respectively.

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The Anthem Cancer Care Quality Program specifies the standard of care treatment regimens for patients with non-small cell lung cancer.

**Anthem Care Quality Program NSCLC Treatment Pathway:**
*(bolded products are disadvantaged)*

**Adjuvant Therapy (with surgery)**
- cisplatin and vinorelbine
- gemcitabine and cisplatin
- paclitaxel and carboplatin

**First-Line – Metastatic Disease ALK+**
- Xalkori

**First-Line – Metastatic Disease EGFR+**
- Gilotrif
- Tarceva

**First-Line – Metastatic Disease Non-squamous**
- carboplatin and paclitaxel
- cisplatin and gemcitabine
- cisplatin and Alimta
- paclitaxel, carboplatin and Avastin

**First-Line – Metastatic Disease Squamous**
- carboplatin and paclitaxel
- cisplatin and gemcitabine

**Maintenance – Metastatic Disease Non-Squamous**
- Avastin
- Alimta

**Second Line – Metastatic Disease ALK+ or EGFR+**
- carboplatin and paclitaxel
- cisplatin and gemcitabine
- cisplatin and Alimta
- Tagrisso

**Second Line – Metastatic Disease Non-squamous**
- docetaxel
- Opdivo
- Alimta

**Second Line – Metastatic Disease Squamous**
- Opdivo

**Omitted:** Zykdia, Erbitux, etoposide, fluorouracil, irinotecan, oxaliplatin, temozolomide, topotocan, vincristine, vinorelbine, doxorubicin

*Source: Anthem Cancer Care Quality Program; https://anthem.aimoncology.com/*
Tarceva, Gilotrif, and Xalkori are used as monotherapies more often in the six original pathway states, but did not increase post-pathway therein.

**Percent of New Lung Cancer-Diagnosed Patients Taking Tarceva, Gilotrif or Xalkori as a Monotherapy, 2012-2015**

<table>
<thead>
<tr>
<th>Non-Original Pathway States</th>
<th>Original Pathway States</th>
</tr>
</thead>
<tbody>
<tr>
<td>% of new NSCLC patients*</td>
<td></td>
</tr>
<tr>
<td>Anthem</td>
<td>Non-Anthem Payers</td>
</tr>
<tr>
<td>80%</td>
<td>82%</td>
</tr>
<tr>
<td>81%</td>
<td>85%</td>
</tr>
</tbody>
</table>

*original pathway-active states include OH, KY, IN, WI, GA, MO

Note: patients can have > 1 drug in their line of therapy, so the % of new patients taking each product would sum to > 100%

Source: IMS LAAD Integrated Dataset, IMS/Amundsen Analysis; Payer and Specialty Provider Websites

- While monotherapy use of these products did not increase in the original pathway states, it was higher in these states than the rest of the nation.
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Anthem Care Quality Program MM Treatment Pathway:

**First-Line Therapy (ASCT candidate)**
- VAD: Velcade, doxorubicin, dexamethasone
- VD: Velcade, dexamethasone
- VCD: Velcade, dexamethasone, cyclophosphomide
- VRD: Velcade, Revlimid, dexamethasone (2016)

**Second+ Line**
- Velcade
- CRD: **Kyprolis**, Revlimid, dexamethasone
- VCD: Velcade, cyclophosphomide, dexamethasone
- VD: Velcade, dexamethasone

**First-Line Therapy (non-ASCT candidate*)**
- MPB: **melphalan**, prednisone, Velcade
- R+: **Revlimid**, dexamethasone
- VD: Velcade, dexamethasone

**Third+ Line**
- **Kyprolis**
- **Darzalex**
- **Emplicit**, Revlimid, dexamethasone

**Omitted:** Pomalyset, thalidomide

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*generally only patients over 65 or in very poor health do not receive ASCT at treatment outset; some achieve complete remission from the ASCTs

Source: Anthem Cancer Care Quality Program; https://anthem.aimoncology.com/
Velcade first-line utilization decreased minimally among Anthem patients in the original six pathway states

Anthem Cancer Care Quality MM pathways: Advantaged Product

Percent of New MM-Diagnosed Patients Taking Velcade as a First-Line Treatment, 2013-2015

- Non-Original Pathway States
  - Non-Anthem Payer: 40% → 29%
  - Anthem: 44% → 32%

- Original Pathway States
  - Non-Anthem Payer: 30% → 24%
  - Anthem: 50% → 48%

In the time period following pathway initiation, Velcade first-line utilization decreased nationally, but did so less in the original six pathways states, especially among Anthem patients.

*original pathway-active states include OH, KY, IN, WI, GA, MO

Note: patients can have > 1 drug in their line of therapy, so the % of new patients taking each product would sum to > 100%

Source: IMS LAAD Integrated Dataset, IMS/Amundsen Analysis; Payer and Specialty Provider Websites
Whereas Revlimid first-line utilization increased nationally, it decreased in the original pathway states among Anthem and non-Anthem patients.

Anthem Cancer Care Quality MM pathways: In-Pathway Disadvantaged Product

- In the time period following pathway initiation, Revlimid first-line utilization increased nationally, but decreased in the six states where the Anthem pathways were in place the longest.

- Prior to 2016, Revlimid was only listed as a viable product for non-ASCT candidates, typically only made up of the very ill, which supports the decreased 2015 utilization of the product despite a national upswing.

*original pathway-active states include OH, KY, IN, WI, GA, MO

Note: patients can have >1 drug in their line of therapy, so the % of new patients taking each product would sum to >100%

Source: IMS LAAD Integrated Dataset, IMS/Amundsen Analysis; Payer and Specialty Provider Websites
All states where the Anthem Cancer Care Quality Program was initially rolled out showed below-average Revlimid growth

- Revlimid is a growing first-line brand nationally, but states who have been exposed to the ACCQR longest and also have relatively large Anthem footprints showed stifled growth for the product
- This indicates that longer physician exposure to pathway availability could influence the prescribing paradigm

**Change in Revlimid First-Line Share (2013 to 2015) vs. MM Anthem Share by State (2015)**

- Non-original Anthem Pathway State
- Original Anthem Pathway State

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**Note:** Only states with >10 new patients in 2015, and with pathways implemented between 09/2014 – 01/2015 were included

Source: IMS LAAD Data (2013-2015); IMS MM Strategy Analysis
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Oncology treatment costs are causing increasing strain on payers’ medical loss ratios, and this does not look to be slowing down

- Costs expected to more than double by 2020 ($37Bn to $79Bn)
- Pipelines are full and valuations on oncology companies are among highest in biotech

Due to these pressures, payers have begun to innovate their strategies at controlling costs in the oncology TAs

- IDNs, staff models and corporate practices become more rational financial actors
- The use of Pathways has expanded to numerous Payers and nearly 20 tumor types and disease

Pathways have demonstrated effectiveness on both in-network and “spillover” behaviors

- The pathway correlated with decreased use of Revlimid in first-line Pathway patients while overall use of Revlimid skyrocketed
- Not only did Anthem patients see effects of Pathways, non-Anthem patients in the same states did as well
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Questions?

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