# The Mosaic Project

The American Cancer Society offers a place where cancer patients and their caregivers can find help and hope when home is far away from the treatment they need—an American Cancer Society Hope Lodge. The AstraZeneca Hope Lodge Center in Boston, MA, offers free lodging and a supportive community in a comfortable environment for those undergoing treatment.

Various missions help make this vision a reality. One such mission is “art as therapy.” When guests are engaged creatively, they focus less on their troubles and can think and act in a more positive manner. The mosaic project was designed to meet this end. As many as 60 guests contributed to the mosaics, chatting through the night while working together toward a common, cooperative goal. Whether large or small, these projects served as therapy for many and gave the guests a creative outlet during their time of need.

The mosaic pictured on the cover, along with several others created at the Hope Lodge, served as auction items at the American Cancer Society: 2013 Boston Key Gala to raise funds for the organization.

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Message from James E. Hoyes, President, EMD Serono, Inc.

Dear health care colleagues:

At EMD Serono, we are driven by an enduring commitment to create value and benefit patients by striving to provide specialty medicines and high-value solutions to health care payers and their network providers. We are focused on strengthening our presence in our core therapeutic areas of expertise within neurodegenerative diseases, fertility, and metabolic endocrinology. Additionally, we are committed to developing new, best delivery systems to meet the needs of patients and providers, so that we can optimize the treatment outcomes. At the same time, we are seeking new clinical breakthroughs within areas of high unmet medical need, as well as exploring opportunities to bring appropriate biosimilars to the market place.

We are very pleased to share the 9th edition of the EMD Serono Specialty Digest. The insights and trends that are presented within its pages are meant to provide greater clarity to those working in the industry, as strategic and challenging decisions are made with regard to the care of members and patients. Additionally, these outputs should support day-to-day efforts in managing the overall challenges of specialty pharmacy.

We’ve built this publication over the past 8 years and, as always, continue to work to develop a resource that meets the needs of our clientele and better equips them to understand and respond to the ever-changing landscape of specialty pharmacy. As we move forward with this effort, we will persist in seeking out opportunities to expand the Digest and maximize the impact of this resource.

Sincerely,

James E. Hoyes
President and Head of US Operations
EMD Serono, Inc.
Message from Michael Dezelan, Senior Vice President, Managed Markets, EMD Serono, Inc.

Dear managed care colleagues:

As we launch the 9th edition of the EMD Serono Specialty Digest, we hope that this year’s insights and outputs will continue to address the needs of those in the industry to more effectively understand the complexity of this health care channel and how to improve upon it in the future. It is our vision that this resource truly reflects our desire to work with health care organizations and specialty pharmacies to develop mutually effective solutions to address the needs of today while anticipating those that may arise in the future.

As readers review this year’s edition, they will notice the enhanced visuals within the document and call-outs of new and interesting insights. Based on feedback from our readers and the Editorial Advisory Board, the Digest survey has been updated to include the following new topics of interest to managed care:

- Medical specialty site of care delivery
- Oncology clinical pathway programs
- Adherence management goals and strategies
- Newly identified utilization management strategies

These efforts are meant to better support the ongoing desire of readers to more effectively understand specialty pharmacy and how to improve upon what is currently being done to address membership as a whole. At the end of the day, we are all committed to improving upon health care, improving upon access, and achieving improved outcomes.

Moving forward, please do not hesitate to reach out to EMD Serono, the account managers, or directly to myself with new ideas, needs, or solutions that will enhance the experience even more.

Best regards,

Michael Dezelan
Senior Vice President, Managed Markets
EMD Serono, Inc.
Message from the Editorial Advisory Board

To the readers:

As members of the Editorial Advisory Board for the EMD Serono Specialty Digest™, 9th Edition, we have reviewed the findings and offer comments and observations on the following topics:

Medical Benefit Specialty Drug Management: Despite a number of operational challenges, payers are continuing to develop and refine strategies to manage specialty drugs covered under the medical benefit. Strategies focus on 3 main areas of management: (1) site of care, (2) provider reimbursement and incentives, and (3) clinical pathways and guidelines. Further engagement with medical providers may result in workable solutions to decrease costs where appropriate and ensure quality patient care.

Member Cost Share: It is interesting to note that only 51% of the participating commercial plans (representing 32% of lives) have developed separate tiers for specialty drugs, while the remainder of plans utilize their standard cost share tiers. At the same time, more plans are assessing cost share for specialty drugs under the medical benefit. Cost share methodologies under the pharmacy benefit and medical benefit are moving along parallel paths but do not seem to be converging to create a more uniform cost share for specialty drugs regardless of the benefit under which they are covered.

Adherence: Adherence to specialty drug therapy is a major concern for payers, physicians, patients, and the pharmaceutical industry. Non-adherence leads to waste, as many dollars are spent on patient care, yet the desired outcomes are not achieved. Survey results indicate that improved adherence and persistency is the number-one priority for health plans related to specialty pharmaceutical management. Payers will need to develop a multi-pronged approach to engage their members in the battle against non-adherence.

The Digest has continually led the way to identify new payer specialty pharmacy strategies that shape the future management of specialty pharmaceuticals. We appreciate the opportunity to review the results of this year’s Digest and look forward to sharing this information with our colleagues.

Sincerely,

Randy Falkenrath, MBA
Senior Vice President, Specialty Pharmacy Services, CVS Caremark, Northbrook, IL

Michael Fine, MD
Medical Director, Health Net, Huntington Beach, CA

John Fox, MD, MHA
Associate Vice President of Medical Affairs Priority Health, Grand Rapids, MI

Raulo Frear, PharmD
General Manager, RegenceRx, Boise, ID

Larry Georgopoulos, PharmD, PhC
Associate Dean of Clinical Affairs and Professor of Pharmacy Practice and Administrative Science, University of New Mexico, College of Pharmacy, Albuquerque, NM

Suzanne Tschida, PharmD, BCPS
Vice President, Specialty Benefit and Outcomes Strategy, OptumRx, Eden Prairie, MN
# Glossary: Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASCO</td>
<td>American Society of Clinical Oncology</td>
</tr>
<tr>
<td>ASP</td>
<td>Average Sales Price</td>
</tr>
<tr>
<td>AWP</td>
<td>Average Wholesale Price</td>
</tr>
<tr>
<td>CD</td>
<td>Crohn's Disease</td>
</tr>
<tr>
<td>CER</td>
<td>Comparative Effectiveness Research</td>
</tr>
<tr>
<td>CLIA</td>
<td>Clinical Laboratory Improvement Amendments</td>
</tr>
<tr>
<td>DMARD</td>
<td>Disease Modifying Antirheumatic Drug</td>
</tr>
<tr>
<td>e-PA</td>
<td>Electronic Prior Authorization</td>
</tr>
<tr>
<td>ESA</td>
<td>Erythropoietin Stimulating Agent</td>
</tr>
<tr>
<td>G-CSF</td>
<td>Granulocyte Colony Stimulating Factor</td>
</tr>
<tr>
<td>GH</td>
<td>Growth Hormone</td>
</tr>
<tr>
<td>HAE</td>
<td>Hereditary Angioedema</td>
</tr>
<tr>
<td>HA</td>
<td>Hyaluronic Acid</td>
</tr>
<tr>
<td>HCV</td>
<td>Hepatitis C Virus</td>
</tr>
<tr>
<td>IM</td>
<td>Intramuscular</td>
</tr>
<tr>
<td>IV</td>
<td>Intravenous</td>
</tr>
<tr>
<td>LS Diseases</td>
<td>Lysosomal Storage Diseases</td>
</tr>
<tr>
<td>MA-PD</td>
<td>Medicare Advantage Prescription Drug plan</td>
</tr>
<tr>
<td>MOOP</td>
<td>Maximum Out of Pocket</td>
</tr>
<tr>
<td>MS</td>
<td>Multiple Sclerosis</td>
</tr>
<tr>
<td>NCCN</td>
<td>National Comprehensive Cancer Network</td>
</tr>
<tr>
<td>NDC</td>
<td>National Drug Code</td>
</tr>
<tr>
<td>OAA</td>
<td>Office-Administered Agent</td>
</tr>
<tr>
<td>P&amp;T</td>
<td>Pharmacy and Therapeutics</td>
</tr>
<tr>
<td>PA</td>
<td>Prior Authorization</td>
</tr>
<tr>
<td>PAH</td>
<td>Pulmonary Arterial Hypertension</td>
</tr>
<tr>
<td>PBM</td>
<td>Pharmacy Benefit Manager</td>
</tr>
<tr>
<td>RA</td>
<td>Rheumatoid Arthritis</td>
</tr>
<tr>
<td>RSV</td>
<td>Respiratory Syncytial Virus</td>
</tr>
<tr>
<td>SAA</td>
<td>Self-Administered Agent</td>
</tr>
<tr>
<td>SC</td>
<td>Subcutaneous</td>
</tr>
<tr>
<td>SPP</td>
<td>Specialty Pharmacy Provider</td>
</tr>
<tr>
<td>SVR</td>
<td>Sustained Viral Response</td>
</tr>
<tr>
<td>WAC</td>
<td>Wholesale Acquisition Cost</td>
</tr>
</tbody>
</table>
Executive Summary

The 9th edition of the EMD Serono Specialty Digest includes information independently gathered and evaluated via an online survey by Rxperts, Inc., from 102 health plans representing over 106 million covered lives. Topics include benefit design, clinical and utilization management, provider reimbursement, oncology management, specialty pharmacy providers, and management goals and strategies.
Methodology

The EMD Serono Specialty Digest™, 9th Edition, contains objective market data on the management of pharmacy and medical benefit specialty pharmaceuticals by health plans in 2012.

A quantitative survey was fielded to health plan pharmacy and medical directors who are responsible for specialty drug-related services in their health plans.

- The survey was administered through a feedback management software platform providing access to a shared, secure environment via the web.
- The general survey topics were identified by the Editorial Advisory Board, and survey questions were independently developed by Rxperts, Inc., which had sole control over the survey content.
- Surveying was conducted between December 6, 2012, and January 9, 2013.
- 76% of respondents for the 9th edition Digest also provided responses to the 8th edition Digest. Trend data include all survey respondents.

Data were analyzed based on the percent of plans responding to each survey question as well as the percent of lives that are represented by those plans. The majority of the data within the Specialty Digest are displayed as the percent of responding plans; however, in select questions, the responses based on percent of lives are included if there is significant variation between the two analyses.
New to This Issue

This Digest builds upon information gathered in previous editions and feedback provided by the Editorial Advisory Board and the general audience of readers. New features in the 9th edition Digest are listed below.

Utilization Management

Newly identified utilization management strategies are examined, including grandfathering the coverage of non-preferred drugs, manufacturer copay coupons, grace period fills at retail prior to mandatory use of specialty pharmacy, and extended day’s supply for chronic therapy.

Oncology

Oncology management strategies are updated to reflect current practices, including oncology clinical pathways, provider incentives, and site of care management.

Adherence

Strategies specific to therapy adherence management are identified and prioritized.

Benefit Design

Commercial health plans that have developed separate cost share for specialty drugs versus traditional drugs are analyzed to drill into the unique benefit structures available for specialty drugs.

Weighting by Number of Lives

All questions have been analyzed by the number of responding plans and the number of lives impacted by these plans. Select survey data are presented based on the number of lives where significant variation is identified between the two analyses.

Trend Analysis

Where possible, trends in strategies across previous years are measured and analyzed.
Demographics

Data were collected from 102 health plans representing over 106 million covered lives. The survey targeted health plan pharmacy directors (n=87) and medical directors (n=15) who are primarily responsible for overseeing specialty drugs and specialty pharmacy-related services in their organizations.

102 health plans that participated in the survey

Table 1: Distribution of Covered Lives by Line of Business

<table>
<thead>
<tr>
<th>Number of Lives</th>
<th>Commercial</th>
<th>MA–PD</th>
<th>Medicaid</th>
<th>Other*</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Small (400,000 or less)</td>
<td>8%</td>
<td>34%</td>
<td>36%</td>
<td>22%</td>
<td>8%</td>
</tr>
<tr>
<td>Medium (400,001–999,999)</td>
<td>15%</td>
<td>10%</td>
<td>16%</td>
<td>16%</td>
<td>12%</td>
</tr>
<tr>
<td>Large (1,000,000 or more)</td>
<td>77%</td>
<td>56%</td>
<td>48%</td>
<td>62%</td>
<td>80%</td>
</tr>
<tr>
<td>Total number of lives covered</td>
<td>65,189,157</td>
<td>10,901,976</td>
<td>16,970,244</td>
<td>13,910,914</td>
<td>106,972,291</td>
</tr>
</tbody>
</table>

*Other may include indemnity plans, military health care, state and local low income plans, and Medicare Supplemental and non-Medicare retiree programs

Table 2: Distribution of Number of Plans by Line of Business

<table>
<thead>
<tr>
<th>Number of Lives</th>
<th>Commercial</th>
<th>MA–PD</th>
<th>Medicaid</th>
<th>Other*</th>
<th>Total Number/Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Small (400,000 or less)</td>
<td>47</td>
<td>66</td>
<td>52</td>
<td>32</td>
<td>53/52%</td>
</tr>
<tr>
<td>Medium (400,001–999,999)</td>
<td>17</td>
<td>2</td>
<td>5</td>
<td>4</td>
<td>22/22%</td>
</tr>
<tr>
<td>Large (1,000,000 or more)</td>
<td>16</td>
<td>3</td>
<td>5</td>
<td>5</td>
<td>27/26%</td>
</tr>
<tr>
<td>Total number of plans</td>
<td>80</td>
<td>71</td>
<td>62</td>
<td>41</td>
<td>102</td>
</tr>
<tr>
<td>Mean lives covered per plan</td>
<td>814,864</td>
<td>153,549</td>
<td>273,714</td>
<td>339,291</td>
<td>1,048,748</td>
</tr>
</tbody>
</table>

*Other may include indemnity plans, military health care, state and local low income plans, and Medicare Supplemental and non-Medicare retiree programs
Geographic Distribution

Health plans participating in the survey represent all regions of the United States and all types of plans, including national plans, regional plans, and statewide plans. 15% of survey respondents (48% of lives) represent national plans, 40% (21% of lives) represent regional plans, and 45% (31% of lives) represent statewide plans.

Total is greater than 100% due to business in more than one region.
WHAT ARE SPECIALTY PHARMACEUTICALS?

Despite their growing number and importance to the US health care system, specialty pharmaceuticals lack a standard or commonly accepted definition. As a result, payers develop their own definition for the classification of specialty drugs in order to direct member cost share, clinical management, and distribution requirements.

Systematic Literature Review

A recent systematic review of literature and websites confirms the lack of consensus in defining specialty pharmaceuticals. However, this analysis did suggest 3 key elements to define specialty drugs: high cost, difficult medication delivery, and/or complex treatment maintenance.

AMCP Format for Formulary Submissions, Version 3.1

In January 2013, the Academy of Managed Care Pharmacy (AMCP) released Version 3.1 of the AMCP Format for Formulary Submissions, which includes a definition of specialty pharmaceuticals. Similar to the elements identified in the systematic review, a product can be classified as a specialty pharmaceutical if it includes either of these two requirements: difficult or unusual process of delivery or requires patient management.

The AMCP Format definition does not include high cost and leaves it up to the payer or manufacturer to determine if cost plays a role in the definition. According to the Format guidelines, drugs for any disease may carry complex and demanding requirements that would qualify for the definition of specialty pharmaceuticals.

It is anticipated that today’s definition for specialty pharmaceuticals will evolve as innovative therapies continue to enter the market.

References

Benefit Design

Specialty drugs have become the standard of care for many complex diseases, including GH disorders, hemophilia, hepatitis C, MS, RA, and various cancers. Specialty drugs may be administered by various routes of administration, including oral, injection, and infusion, some of which require the oversight and expertise of a health care provider.

Unlike traditional oral pharmaceuticals, specialty drugs may be covered under the pharmacy or medical benefit and may be distributed or administered to the patient by a retail pharmacy, a specialty pharmacy, a physician’s office, an outpatient hospital facility, or a home infusion company. These characteristics pose unique challenges to health plans related to coverage, patient cost share, provider reimbursement, clinical management, and patient access. The complex nature of specialty drugs has resulted in most health plans creating specific rules regarding their coverage, cost share, and/or benefit management.
Coverage of Specialty Drugs

Most health plans make a determination on whether the drug is covered under the pharmacy benefit or medical benefit at the time a new drug is approved by the FDA. Factors influencing this decision may include the route of administration, the provider that would distribute the drug, the physical location of drug administration, the requirement for health care provider administration, and specific patient care needs.

Q. Describe how SAAs, OAAs, and home infusion specialty drugs are typically covered for your most common benefit structure.

Consistent with previous years, SAAs are typically covered under the pharmacy benefit, while OAAs and home infusion drugs are typically covered under the medical benefit. A minority of plans may not follow this benefit coverage methodology or do not have strict coverage rules and may cover a drug under either benefit, depending upon which provider purchases or administers the drug.

- More than 85% of plans cover SAAs exclusively under the pharmacy benefit
- More than 76% of plans cover OAAs exclusively under the medical benefit
- Less than 6% of plans cover OAAs under the pharmacy benefit

>85% plans that cover self-administered agents (SAAs) under the RX benefit
Pharmacy Benefit Cost Share

Health plans typically require their members to pay a portion of the cost of their prescriptions under the pharmacy benefit. Drugs classified as specialty may have the same cost share as non-specialty drugs, or the health plan may create a separate cost share benefit for these drugs. Within the various benefit design offerings, there are two distinct types of cost share structures: single tier cost share, where the member pays the same cost share amount for preferred and non-preferred drugs, or multi-tier cost share, where the member pays a lower cost share for preferred drugs and a higher cost share for non-preferred drugs. The cost share can be a fixed dollar copay or a coinsurance, where a member pays a percent of the drug cost, with or without a maximum out-of-pocket (MOOP) amount per prescription.

New to this year’s Digest, commercial health plans that have established separate cost share for specialty drugs versus traditional drugs are identified and analyzed to drill into the unique benefit structures available for specialty drugs. Additionally, the specialty drug benefit designs are viewed as a percent of the responding plans and as a percent of the total lives represented in this Digest to fully understand the impact of cost share on health plan membership overall. Due to the different methodology to analyze cost share, trend data across previous Digests are not available.
Standard vs. Specialty Cost Share

51% percent of the commercial plans participating in this survey have unique cost share tiers for specialty drugs compared to non-specialty drugs; however, this represents only 32% of the health plan lives. As a result, 68% of the health plan lives are not subject to specialty tiers, and the health plans utilize their standard cost share tiers for specialty drugs (tiers 2 or 3).

Note: Of the 80 commercial plans responding to the survey, 70 reported their cost share information for specialty drugs covered under the pharmacy benefit.
The following pages (17–21) analyze the cost share only for commercial plans that charge a separate or unique cost share for specialty drugs vs. non-specialty drugs.

Pharmacy Benefit Cost Share for Commercial Plans with Specialty Tiers

**Q. Describe the benefit structure according to your most common benefit structure for pharmacy benefit specialty drugs in your commercial line of business with separate cost share from non-specialty drugs.**

*Note: A distinction between PPO and HMO lines of business was not specified in the survey questions; therefore the data presented in the Digest represent the most common benefit designs offered by the participants.*

<table>
<thead>
<tr>
<th>Commercial Cost Share Structures for Plans with Specialty Tiers (n=36)</th>
<th>% of Plans</th>
<th>% of Lives</th>
<th>Mean Cost Share</th>
<th>Min Cost Share</th>
<th>Max Cost Share</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plans with Single Tier Specialty Cost Share (n=24)</td>
<td>67%</td>
<td>55%</td>
<td></td>
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<td></td>
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<tr>
<td>Specialty Tier with Dollar Copay</td>
<td>38%</td>
<td>34%</td>
<td>$103</td>
<td>$40</td>
<td>$250</td>
</tr>
<tr>
<td>Tier 4</td>
<td>89%</td>
<td>99%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tier 5</td>
<td>11%</td>
<td>1%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Specialty Tier with Coinsurance</td>
<td>63%</td>
<td>66%</td>
<td>23%</td>
<td>10%</td>
<td>50%</td>
</tr>
<tr>
<td>Tier 4</td>
<td>87%</td>
<td>89%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tier 5</td>
<td>13%</td>
<td>11%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coinsurance with MOOP</td>
<td>87%</td>
<td>96%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coinsurance without MOOP</td>
<td>13%</td>
<td>4%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Plans with Multi-Tier Specialty Cost Share (n=12)</td>
<td>33%</td>
<td>45%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preferred Specialty Tier</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dollar Copay</td>
<td>58%</td>
<td>33%</td>
<td>$50</td>
<td>$25</td>
<td>$75</td>
</tr>
<tr>
<td>Coinsurance with MOOP</td>
<td>71%</td>
<td>67%</td>
<td>18%</td>
<td>10%</td>
<td>20%</td>
</tr>
<tr>
<td>Non-Preferred Specialty Tier</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dollar Copay</td>
<td>33%</td>
<td>22%</td>
<td>$100</td>
<td>$50</td>
<td>$150</td>
</tr>
<tr>
<td>Coinsurance with MOOP</td>
<td>58%</td>
<td>78%</td>
<td>30%</td>
<td>20%</td>
<td>50%</td>
</tr>
<tr>
<td>Coinsurance without MOOP</td>
<td>8%</td>
<td>0%</td>
<td>20%</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Total Plans with Specialty Tiers (n=36)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dollar Copay</td>
<td>44%</td>
<td>34%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>% Coinsurance</td>
<td>56%</td>
<td>66%</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Commercial Pharmacy Benefit: Copay vs. Coinsurance

For commercial plans utilizing unique specialty drug cost share, 56% of plans use coinsurance for specialty drugs, representing 66% of covered lives. Copay is used by 44% of plans, representing 34% of covered lives.

n=36
Commercial Pharmacy Benefits: Single vs. Multi-Tier

For commercial plans utilizing unique specialty drug cost share, 67% of plans use a single tier for specialty drugs, representing 55% of covered lives. Multi-tier cost share is used by 33% of plans, representing 45% of covered lives.

<table>
<thead>
<tr>
<th></th>
<th>HEALTH PLANS</th>
<th>MEMBER LIVES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single tier</td>
<td>67%</td>
<td>45%</td>
</tr>
<tr>
<td>Multi-tier</td>
<td>33%</td>
<td>55%</td>
</tr>
</tbody>
</table>

n=36
Commercial Pharmacy Benefit Cost Share: Single Tier

As noted earlier, 67% of plans (55% of lives) with unique specialty pharmacy cost share tiers utilize a single tier cost share for their specialty drugs.

- 38% of plans (36% of lives) use copay for single tier cost share, while 62% of plans (65% of lives) use coinsurance.
- Tier 4 is the most common tier for single tier specialty benefits, with 87% of plans (89% of lives) placing specialty drugs in tier 4.
- Tier 5 is used by only 13% of plans (11% of lives).
- Coinsurance is more commonly used than copay for both tier 4 and tier 5.
- For single tier cost share, the average copay is $103, and the average coinsurance is 23%.
- Survey data indicate that most plans using coinsurance limit the member’s cost share with a MOOP per RX, which is present in 87% of plans (87% of lives).

$n=24$
Commercial Multi-Tier Pharmacy Benefit Cost Share

33% of plans (45% of lives) with unique specialty pharmacy cost share utilize a multi-tier cost share.

- The most common tier design is tier 4 for preferred drugs and tier 5 for non-preferred drugs (50% of plans and 75% of lives)
- For preferred drugs, the average copay is $50, and the average coinsurance is 18%
- For non-preferred drugs, the average copay is $100, and the average coinsurance is 30%

$n=12$
MA-PD Part D Cost Share

Q. Describe the benefit structure according to your most common benefits for MA–PD Part D members.

Medicare Part D plans as a part of the MA-PD benefit have a unique benefit structure that may vary by plan, yet must conform to specific requirements laid out by federal regulation.

<table>
<thead>
<tr>
<th>Cost Share Structures (n=58)</th>
<th>% of Plans</th>
<th>% of Lives</th>
<th>Mean Cost Share</th>
<th>Min Cost Share</th>
<th>Max Cost Share</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single Tier Cost Share</td>
<td>93%</td>
<td>71%</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Dollar Copay</td>
<td>23%</td>
<td>7%</td>
<td>$52</td>
<td>$10</td>
<td>$85</td>
</tr>
<tr>
<td>% Coinsurance</td>
<td>77%</td>
<td>93%</td>
<td>29%</td>
<td>20%</td>
<td>33%</td>
</tr>
<tr>
<td>Multi-Tier Cost Share</td>
<td>7%</td>
<td>29%</td>
<td></td>
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<tr>
<td>Preferred</td>
<td></td>
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<tr>
<td>Dollar Copay</td>
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<td>100%</td>
<td>$38</td>
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<tr>
<td>Non-preferred</td>
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</tr>
<tr>
<td>Dollar Copay</td>
<td>100%</td>
<td>100%</td>
<td>$64</td>
<td>$45</td>
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<td>Total All Benefits</td>
<td></td>
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<tr>
<td>Dollar Copay</td>
<td>28%</td>
<td>32%</td>
<td>$48</td>
<td>$10</td>
<td>$100</td>
</tr>
<tr>
<td>% Coinsurance</td>
<td>72%</td>
<td>68%</td>
<td>29%</td>
<td>20%</td>
<td>35%</td>
</tr>
</tbody>
</table>
MA-PD Part D Single Tier Cost Share by Tier

The majority of MA-PD plans place specialty drugs in a single tier benefit (93% of plans and 71% of lives).

- Only 7% of MA-PD plans (29% of lives) have a multi-tier cost share for specialty drugs
- Tier 4 is the most common tier for single tier MA-PD benefits, with 46% of plans (51% of lives) placing specialty drugs in tier 4, while tier 5 is used by 28% of plans (36% of lives)

MA-PD Part D Single Tier Cost Share: Copay vs. Coinsurance

- Consistent with previous years, 77% of MA-PD plans assess coinsurance under single tier benefits
- For single tier cost share, the average copay is $52, and the average coinsurance is 29%

\[ n=54 \]
Medical Benefit Cost Share

Health plans may charge a separate cost share for specialty drugs covered under the medical benefit: the cost share can be a fixed dollar copay or a coinsurance, where a member pays a percent of the drug cost. Cost share for specialty drugs covered under the medical benefit typically does not have a MOOP/RX, as this out-of-pocket expense accumulates to an annual out-of-pocket maximum that includes all other medical benefit cost share.

### Medical Benefit Cost Share for Specialty Drugs

**Q. Describe the benefit structure according to your most common benefit structure for all medical benefit specialty drugs in your commercial and MA-PD lines of business.**

**Note:** A distinction between PPO and HMO lines of business was not specified in the survey questions; therefore the data presented in the Digest represent the most common benefit designs offered by the participants.

![Chart](image-url)

<table>
<thead>
<tr>
<th></th>
<th>% of Plans</th>
<th>% of Lives</th>
<th>Mean Cost Share</th>
<th>Range of Cost Share</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>Commercial</td>
<td>MA-PD</td>
<td>Commercial</td>
<td>MA-PD</td>
</tr>
<tr>
<td>No Cost Share</td>
<td>45%</td>
<td>40%</td>
<td>64%</td>
<td>36%</td>
</tr>
<tr>
<td>Cost Share</td>
<td>55%</td>
<td>60%</td>
<td>36%</td>
<td>64%</td>
</tr>
<tr>
<td>Dollar Copay</td>
<td>30%</td>
<td>18%</td>
<td>41%</td>
<td>18%</td>
</tr>
<tr>
<td>% Coinsurance</td>
<td>70%</td>
<td>82%</td>
<td>59%</td>
<td>82%</td>
</tr>
</tbody>
</table>

55% commercial plans that require separate cost share for medical benefit specialty drugs
Health Plans with Medical Benefit Cost Share (2009–2012)

The use of cost share for specialty drugs under the medical benefit has increased over the past years.

- In 2009, only 37% of commercial plans and 52% of MA-PD plans charged separate cost share for specialty drugs under the medical benefit.
- In 2012, 55% of commercial plans and 60% of MA-PD plans charge separate cost share for specialty drugs under the medical benefit.

Commercial Medical Benefit Cost Share: Copay vs. Coinsurance (2009–2012)

The use of copay vs. coinsurance for specialty drugs under the commercial medical benefit has increased over the past years.

- 30% of plans assess copay in 2012 vs. 17% in 2010.
- 70% of plans assess coinsurance in 2012 vs. 83% in 2010.
Benefit Management

Additional benefit design strategies are identified by payers who are currently implementing or planning to implement in the next 12 months. The strategies focus on day’s supply limitations, cost share changes, and new cost share tiers.

Benefit Design Strategies (Commercial Plans)

Q. Indicate whether you currently implement or are planning to implement any of the following benefit design strategies in the next 12 months.

- 34% of commercial plans expect to create additional cost share tiers for specialty drugs under the pharmacy benefit
- Less than 20% of commercial plans expect to add cost share for medical benefit specialty drugs
- 28% of commercial and MA-PD plans and 16% of Medicaid plans currently or plan to allow 90-day supplies of specialty drugs for patients if clinically appropriate

34% commercial plans that expect to create more cost share tiers under the RX benefit
Clinical and Utilization Management

Health plans utilize a number of management tools to ensure appropriate use of specialty drugs that follow plan guidelines, including prior authorization, selection of preferred products, implementing online step edits, and developing coverage criteria.

Prior Authorization

>90% plans that require PA for GH, RA, and oral HCV

Medical Benefit Prior Authorization

15% plans that provide oncologists with an e-PA system through a web portal

Preferred Products

15 therapeutic categories with possible preferred products

Other Utilization Management Strategies

45% plans that currently or will block coverage of non-preferred drugs with coupons
Prior Authorization

Plans may require that a provider obtain prior authorization (PA) to prescribe a drug to a specific patient. The primary objectives of PA are to verify that the drug is being prescribed according to plan guidelines, monitor response to therapy, drive usage to preferred products, or require trial and failure of other therapies.


Q. Indicate which of the therapeutic classes/products require PA in order to be covered under each benefit.

The top drug classes requiring PA have not changed from 2011 to 2012; however, the use of PA for all drug categories has increased from 2011 to 2012, with the largest increase for oral HCV, oral MS, and ESA therapy classes. Over 80% of plans require PA for 7 therapy categories under the pharmacy benefit and for 6 therapy categories under the medical benefit.

<table>
<thead>
<tr>
<th>Pharmacy Benefit</th>
<th>Medical Benefit</th>
<th>% of plans</th>
</tr>
</thead>
<tbody>
<tr>
<td>GH Disorders</td>
<td>RA/Crohn's Disease (SC)</td>
<td>96%</td>
</tr>
<tr>
<td></td>
<td>Hepatitis C (Oral)</td>
<td>92%</td>
</tr>
<tr>
<td></td>
<td>MS (Oral)</td>
<td>91%</td>
</tr>
<tr>
<td></td>
<td>Hepatitis C (SC)</td>
<td>84%</td>
</tr>
<tr>
<td></td>
<td>ESAs</td>
<td>82%</td>
</tr>
<tr>
<td></td>
<td>MS (SC)</td>
<td>82%</td>
</tr>
<tr>
<td>RA/Crohn's Disease (IV)</td>
<td>Psoriasis</td>
<td>88%</td>
</tr>
<tr>
<td>RSV</td>
<td>85%</td>
<td></td>
</tr>
<tr>
<td>MS (IV)</td>
<td>Immune Globulin (IV)</td>
<td>83%</td>
</tr>
<tr>
<td>Immune Globulin (SC)</td>
<td>82%</td>
<td></td>
</tr>
</tbody>
</table>

>90% plans that require PA for GH, RA, and oral HCV
Plans utilize various departments or vendors to administer PA for specialty drugs. The pharmacy department is primarily responsible for PAs for self-administered drugs and has some level of responsibility for medical benefit drugs and diagnostics; however, this varies between oncology- and non-oncology-related categories.

**Departments Responsible for Managing Prior Authorization**

**Q. Who is primarily responsible for administering the PA?**

PA requirements vary by drug type and are less common for drugs covered under the medical benefit than those covered under the pharmacy benefit.

- 99% of plans require PA for some or all self-administered non-oncology specialty drugs, while 88% of plans require PA for medical benefit non-oncology specialty drugs
- 95% of plans require PA for oral oncology agents, compared to 74% of plans requiring PA for infused oncology drugs
- 11% of plans do not require PA for oncology companion diagnostics
PBM Responsibility for PA (2011–2012)

Pharmacy benefit managers (PBMs) have typically had a minor role in administering PA for specialty drugs. The 2012 data indicate that plans are relying more on their PBMs to administer PA for specialty drugs under the pharmacy and medical benefit, when compared to 2011 data.
Medical Benefit Prior Authorization Management

Traditional tools used to manage specialty drugs under the pharmacy benefit may not be as readily available for managing specialty drugs under the medical benefit, as medical providers are less likely to have an online claims processing system to streamline the process. In spite of administrative challenges, the majority of plans have developed processes to manage medical benefit PAs.

Prior Authorization Under the Medical Benefit

Q. How is PA typically managed for medical benefit specialty drugs?

For those plans that require PA under the medical benefit, the majority use prospective PA for both oncology and non-oncology specialty drugs, although some plans utilize a retrospective post-payment review (9%) for infused oncology rather than prospective PA.
Due to the challenges previously identified with managing specialty drugs covered under the medical benefit, payers may not be able to optimally manage these drugs. Survey respondents were asked to identify what services are of most importance to their organizations to most effectively manage specialty drugs covered under the medical benefit.

**Importance of Medical Benefit Management Services**

**Q. Indicate which medical benefit management services are most important to your organization, using a scale of 1–5, where 1=not at all important and 5=extremely important.**

50% or more payers identify the following services as most important (rating of 4 or 5) to their organization:

- Obtain NDC level claims data
- Direct patients to preferred site of care
- Reprice claims according to fee schedule
- Contract for medical benefit rebates
- Develop custom fee schedule

![Graph showing the percentage of plans (top 4+5) for each service.]

- Obtain NDC level claims data: 64%
- Direct patient to preferred site of care: 56%
- Reprice claims according to fee schedule: 50%
- Contract for medical benefit rebates: 48%
- Develop custom fee schedule: 35%
Preferred Products

Plans may select preferred products in therapy categories where there are several therapeutic options to ensure quality patient care based on safety, efficacy, and cost.

Therapy Categories with Preferred Products

Q. Indicate which therapy categories have preferred products.

Survey data indicate that 91% of plans have designated at least 1 therapy category with preferred products, compared to 88% in 2011 and 2010. Responding plans have selected an average of 6 therapy categories with preferred products (range 1–14).

Although not as common, survey respondents indicate they have also selected preferred products in the following categories (based on percent of plans):

- G-CSF (20%)
- IVIG (15%)
- Infertility (15%)
- Hemophilia factor (14%)
- Botulinum toxin (11%)
Other Utilization Management Strategies

Additional utilization management strategies are identified by payers who are currently implementing or planning to implement in the next 12 months. The strategies focus on grandfathering use of non-preferred drugs, grace period fills at retail prior to mandatory specialty pharmacy (SP), and manufacturer coupons for non-preferred drugs.

Current and Future Utilization Management Strategies (Commercial Plans)

Q. Indicate whether you currently implement or are planning to implement any of the following utilization management strategies in the next 12 months.

Commercial plans are developing strategies to limit the use of manufacturer copay coupons for select non-preferred drugs:

- 45% currently or plan to block coverage of non-preferred drugs with coupons
- 31% currently or plan to block use of coupons for non-preferred drugs

A small number of payers are considering the elimination of grandfathering of patients on non-preferred therapies and eliminating grace period fills at retail prior to mandatory SP.

45% plans that currently or will block coverage of non-preferred drugs with coupons
Provider Reimbursement

Specialty drugs are distributed through a number of different providers depending on the specific drug.

Key factors influencing access and distribution include:
- Distribution sites authorized by the manufacturer
- Requirements of the health plan
- Route of administration

<table>
<thead>
<tr>
<th>Reimbursement Methods</th>
<th>&gt;45% plans that reimburse oncologists based on ASP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reimbursement Rates</td>
<td>8.9% average % over ASP reimbursement for MDs across all lines of business</td>
</tr>
<tr>
<td>Other Reimbursement Strategies</td>
<td>61% plans that currently or intend to implement a preferred infusion network</td>
</tr>
</tbody>
</table>
Provider Reimbursement Methods

The actual reimbursement rate to each provider is determined by the health plan and can be based on the average wholesale price (AWP) plus or minus a discount, the average sales price (ASP) plus a percentage, or the wholesale acquisition cost (WAC) plus or minus a percentage. Additionally, some payers may have capitation arrangements with medical providers where they are paid on a per-member, per-month basis.

Q. What is the most common reimbursement basis for single-source brand specialty pharmacy products through the various distribution channels?

The reimbursement methodology is highly influenced by the type of provider and the site of care. ASP-based reimbursement is the most common form of reimbursement for physicians for all lines of business, while AWP-based reimbursement is the most common form of reimbursement for all non-physician-administered drugs.

<table>
<thead>
<tr>
<th></th>
<th>Commercial</th>
<th>MA-PD</th>
<th>Medicaid</th>
</tr>
</thead>
<tbody>
<tr>
<td>MD: Non-Oncology</td>
<td>42%</td>
<td>47%</td>
<td>41%</td>
</tr>
<tr>
<td>MD: Oncology</td>
<td>46%</td>
<td>57%</td>
<td>49%</td>
</tr>
<tr>
<td>Home Infusion</td>
<td>33%</td>
<td>29%</td>
<td>24%</td>
</tr>
<tr>
<td>Infusion Center</td>
<td>34%</td>
<td>40%</td>
<td>32%</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Providers</th>
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<th>MA-PD</th>
<th>Medicaid</th>
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<tbody>
<tr>
<td>MD: Non-Oncology</td>
<td>42%</td>
<td>47%</td>
<td>41%</td>
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<tr>
<td>MD: Oncology</td>
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<tr>
<td>Home Infusion</td>
<td>33%</td>
<td>29%</td>
<td>24%</td>
</tr>
<tr>
<td>Infusion Center</td>
<td>34%</td>
<td>40%</td>
<td>32%</td>
</tr>
</tbody>
</table>

>45% plans that reimburse oncologists based on ASP
Average AWP Discount by Provider and Line of Business

Specialty pharmacies receive the lowest AWP-based reimbursement, and oncologists receive the highest AWP-based reimbursement. The most variation in AWP-based reimbursement by line of business is seen for medical benefit providers, and the least variation in AWP-based reimbursement is seen for specialty and retail pharmacies.
Provider Reimbursement Rates

The average percent over ASP for specialty pharmacy products reimbursed through physician offices across all lines of business has not changed significantly from previous Digests, with oncologists receiving the highest reimbursement and home infusion providers receiving the lowest ASP reimbursement, although there is not a large variation between providers.

Mean and Range of ASP-Based Reimbursement

Commercial plans reimburse most providers at a higher ASP-based rate than MA-PD or Medicaid plans. ASP reimbursement ranges from lows between 5% and 6%, and highs between 15% and 25%.
**Additional Provider Reimbursement Strategies**

As payers become more involved in managing medical benefit providers who are being reimbursed for specialty drugs, new strategies are emerging to optimize efficiencies and ensure competitive pricing for specialty drugs and their administration.

### Current and Future Provider Reimbursement Strategies (Commercial Plans)

Q. Indicate whether you currently implement or are planning to implement any of the following provider reimbursement and management strategies in the next 12 months.

Strategies payers are most likely to implement in the next 12 months include:

- Creating a preferred infusion network
- Leveraging 340B pricing with hospitals

![Bar chart showing the percentage of plans currently implementing or planning to implement various strategies in the next 12 months.](chart)

- **Create preferred infusion network**
  - Currently implement: 32%
  - Plan to implement in next 12 months: 29%

- **Match provider reimbursement to SPP rate**
  - Currently implement: 38%
  - Plan to implement in next 12 months: 16%

- **Leverage 340B pricing with hospitals**
  - Currently implement: 20%
  - Plan to implement in next 12 months: 33%

- **Variable fee schedule for oncology**
  - Currently implement: 24%
  - Plan to implement in next 12 months: 16%

- **Performance based contracts with SPPs**
  - Currently implement: 15%
  - Plan to implement in next 12 months: 18%

- **Fee schedule managed by vendor**
  - Currently implement: 13%
  - Plan to implement in next 12 months: 6%
Oncology Management

With over 900 oncology-targeted therapies in the pipeline, payers are developing and refining their strategies to manage the cost of treatment while at the same time ensuring their members achieve optimal outcomes.

Payer management strategies typically include:

- Methods to ensure appropriate use based on FDA-labeled indication or compendia listing
- Competitive contracting with pharmacies and physicians for drug reimbursement
- Reducing variability in treatment regimens for common cancers
- Directing patients to the lowest cost site of care
- Providing patients with choice about how to manage their serious illness

---

**Oncology Management Strategies**

<table>
<thead>
<tr>
<th>Methodology</th>
<th>Benefit Design</th>
<th>Clinical &amp; Utilization Management</th>
<th>Provider Reimbursement</th>
</tr>
</thead>
<tbody>
<tr>
<td>40%</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Oncology Pathways**

- MA–PD plans that offer financial incentives to oncologists

**Palliative Care and Advance Care Planning**

- MA–PD plans that currently or intend to provide communication skills training to oncologists

**Companion Diagnostics**

- Plans that restrict the use of drugs based on companion diagnostic test results
Oncology Management Strategies

Most oncology therapies are administered via infusion in the oncologist's office or at an infusion center and are covered under the medical benefit. With the introduction of many new oral oncology drugs, payer oncology management has expanded to include the pharmacy benefit. Oncology management may vary not only by the benefit under which it is covered but also by the line of business.

| Current and Future Oncology Management Strategies by Line of Business |

Q. Indicate whether you currently implement or are planning to implement any of the following oncology management strategies in the next 12 months.

Commercial and MA-PD payers plan to implement more of the following strategies: promote the use of palliative care/end-of-life programs, adopt national guidelines, limit therapy according to guidelines or label, and incent use of lower cost drugs through the fee schedule.

Medicaid payers plan to implement more of the following strategies: adopt national guidelines and limit lines of therapy according to guidelines or label.

---

75% MA–PD plans that limit therapy according to guidelines or FDA-approved label

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<tr>
<th>Promote use of palliative care/end-of-life programs</th>
<th>0%</th>
<th>20%</th>
<th>40%</th>
<th>60%</th>
<th>80%</th>
<th>100%</th>
</tr>
</thead>
<tbody>
<tr>
<td>% of lives</td>
<td>82%</td>
<td>84%</td>
<td>41%</td>
<td>74%</td>
<td>82%</td>
<td>76%</td>
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<thead>
<tr>
<th>Adopt NCCN/ASCO guidelines</th>
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<th>60%</th>
<th>80%</th>
<th>100%</th>
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</thead>
<tbody>
<tr>
<td>% of lives</td>
<td>74%</td>
<td>82%</td>
<td>68%</td>
<td>76%</td>
<td>82%</td>
<td>68%</td>
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</table>

<table>
<thead>
<tr>
<th>Limit therapy according to guidelines or label</th>
<th>0%</th>
<th>20%</th>
<th>40%</th>
<th>60%</th>
<th>80%</th>
<th>100%</th>
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<tbody>
<tr>
<td>% of lives</td>
<td>68%</td>
<td>75%</td>
<td>68%</td>
<td>69%</td>
<td>75%</td>
<td>68%</td>
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<table>
<thead>
<tr>
<th>Create MD performance incentives for following pathways</th>
<th>0%</th>
<th>20%</th>
<th>40%</th>
<th>60%</th>
<th>80%</th>
<th>100%</th>
</tr>
</thead>
<tbody>
<tr>
<td>% of lives</td>
<td>15%</td>
<td>33%</td>
<td>61%</td>
<td>59%</td>
<td>62%</td>
<td>59%</td>
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<table>
<thead>
<tr>
<th>Incent use of lower cost drugs through fee schedule</th>
<th>0%</th>
<th>20%</th>
<th>40%</th>
<th>60%</th>
<th>80%</th>
<th>100%</th>
</tr>
</thead>
<tbody>
<tr>
<td>% of lives</td>
<td>32%</td>
<td>52%</td>
<td>62%</td>
<td>52%</td>
<td>52%</td>
<td>53%</td>
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</table>

<table>
<thead>
<tr>
<th>Rely on oncologists to follow their own pathways</th>
<th>0%</th>
<th>20%</th>
<th>40%</th>
<th>60%</th>
<th>80%</th>
<th>100%</th>
</tr>
</thead>
<tbody>
<tr>
<td>% of lives</td>
<td>25%</td>
<td>32%</td>
<td>52%</td>
<td>52%</td>
<td>52%</td>
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<table>
<thead>
<tr>
<th>Develop proprietary clinical pathways with oncologists</th>
<th>0%</th>
<th>20%</th>
<th>40%</th>
<th>60%</th>
<th>80%</th>
<th>100%</th>
</tr>
</thead>
<tbody>
<tr>
<td>% of lives</td>
<td>28%</td>
<td>45%</td>
<td>56%</td>
<td>56%</td>
<td>56%</td>
<td>56%</td>
</tr>
</tbody>
</table>
Oncology Clinical Pathways

Clinical pathways are detailed, evidence-based treatment algorithms to standardize the treatment of specific cancer types and stages of disease. The scope, granularity, and available options of pathways vary based on the source of the pathway and the disease state. Pathways may be created by third-party vendors, groups of oncologists, or health plans.

Oncology Clinical Pathway Programs

Q. Indicate whether you currently implement or are planning to implement oncology clinical pathway programs in the next 12 months.

Approximately 50% of commercial, MA-PD, and Medicaid plans currently implement or intend to implement cancer clinical pathways in the next 12–24 months. When viewed as percent of lives, the data indicate that 71% of MA-PD lives from the surveyed plans will be impacted by cancer clinical pathways.

90% plans using oncology pathways that offer financial incentives to oncologists
Current or Future Clinical Pathway Development by Disease

Q. Indicate whether you currently implement or are planning to implement specific oncology clinical pathway programs in the next 12 months.

Of those plans with clinical pathways, more than 70% of commercial, MA-PD, and Medicaid health plans currently implement or intend to implement clinical pathways for breast, prostate, colorectal, and lung cancer. Additional cancer types under consideration for pathways by over 40% of plans include:

- Bladder
- Renal cell
- Leukemia
- Lymphoma
- Ovarian

<table>
<thead>
<tr>
<th>Cancer Type</th>
<th>Commercial (n=37)</th>
<th>MA-PD (n=33)</th>
<th>Medicaid (n=27)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breast</td>
<td>89%</td>
<td>94%</td>
<td></td>
</tr>
<tr>
<td>Prostate</td>
<td>85%</td>
<td>81%</td>
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</tr>
<tr>
<td>Colorectal</td>
<td>70%</td>
<td>54%</td>
<td></td>
</tr>
<tr>
<td>Lung</td>
<td>81%</td>
<td>82%</td>
<td></td>
</tr>
<tr>
<td>Leukemia</td>
<td>72%</td>
<td>56%</td>
<td></td>
</tr>
<tr>
<td>Melanoma</td>
<td>74%</td>
<td>67%</td>
<td></td>
</tr>
</tbody>
</table>
Physician Incentives for Clinical Pathways

Q. Which physician incentives have you built into your organization's clinical pathway programs?

As health plans adopt clinical pathways, they are looking at ways to create physician incentives based on better patient outcomes and cost savings. 90% of surveyed plans with clinical pathways offer some type of financial incentive for participating in pathway programs. The most commonly cited incentives include:

- A bonus for adherence to guidelines
- Shared savings or bonus from medical cost reductions
- Financial incentives to use lower cost drugs

Only 10% of surveyed plans using clinical pathways do not provide any financial incentives to oncologists.

n=48 (subset of respondents who indicated they have clinical pathways)
CANCER THERAPY PIPELINE

Researchers’ understanding of the etiology and pathobiology of cancer has dramatically increased. At the same time, there has been significant progress in the screening, diagnosis, and treatment of cancer. These combined resources have resulted in a significant decline in cancer deaths. Cancer survivors living in the US have increased from 3 million in 1971 to nearly 12 million in 2008. Despite recent progress, cancer remains the second leading cause of death by disease in the US, exceeded only by heart disease. In 2012, more than 1.6 million new cases of cancer were expected, and more than 500,000 Americans were expected to die of cancer—which translates into more than 1,500 people a day.

Pipeline

PhRMA documents more than 900 medicines and vaccines in clinical testing for cancer, along with a number of molecular diagnostic tools to target therapy and personalize treatment. In 2012 alone, there were 15 novel cancer agents approved, which represents 40% of the 39 novel products approved that year.

Among specialty therapeutic categories, cancer drug costs account for the highest per member, per month spend. As cancer disproportionately affects the elderly, the aging Baby Boomer population will accelerate the demand for treatment. As noted throughout this Digest, health plans have a high degree of interest in managing oncology therapy with the end result of improved treatment outcomes and controlling cost.

References
Palliative Care and Advance Care Planning

Palliative care in general is an approach that focuses on providing patients with relief from the symptoms, pain, and stress of a serious illness. Advance care planning involves learning about the types of decisions that might need to be made if a person is incapacitated and unable to make his or her own health care decisions, and documenting those preferences, typically in an advance directive.

Oncology Palliative Care Strategies (MA-PD)

Q. Indicate whether you currently implement or are planning to implement any of the following palliative care strategies in the next 12 months.

The most commonly used strategies relate to educating providers on the use of palliative care when appropriate and educating all members, including members currently being treated for cancer, on advance care planning. Some newly emerging strategies include:

- Increasing member benefits for palliative care
- Providing financial incentives to providers to discuss treatment options
- Utilizing external vendors to consult with patients on palliative care options and advance care/end-of-life planning

44% MA-PD plans that currently or intend to provide communication skills training to oncologists
Companion Diagnostics

Companion diagnostics are developed where safe and effective use of the drug depends on a specific diagnostic test, which can be predictive or monitoring. Predictive companion diagnostics determine which patients will respond to treatment, the appropriate dose, or those at risk for specific adverse events. Monitoring companion diagnostics evaluate a patient’s response to treatment over time to enable changes in dosage or treatment schedule.

Companion Diagnostic Strategies

Q. Indicate whether you currently implement or are planning to implement any of the following companion diagnostic management strategies in the next 12 months.

Health plans are at various stages of management with respect to companion diagnostics. On average, approximately 50% of payers require companion diagnostic testing before approval of the related drug; restrict use of the drug based on the test results; require submission of test results from providers; and require PA for the test itself.

Recently, several oncology drugs have been approved with a label stating that an FDA-approved test must be used to detect the related genetic mutation. Survey results indicate that 40% of plans currently allow use of a CLIA lab-developed test, while 26% of plans require use of the specific test as indicated in the FDA label for a drug.
Health plans are continuing to develop and implement strategies to ensure appropriate oncology therapy, manage drug cost for plan sponsors, and improve the quality of patient care. To this end, several key strategies have been embraced by payers and show continued adoption across time, including:

- Mandatory use of specialty pharmacy provider (SPP) for oral oncology
- Increased focus on palliative care and end-of-life programs
- More oversight on the use of drugs with companion diagnostics

### Trends in Oncology Management (2010–2012)

- **Mandate use of SPP for some or all oral oncology drugs**
  - 2010: 41%
  - 2011: 46%
  - 2012: 56%

- **Promote use of palliative care and end-of-life programs**
  - 2010: 23%
  - 2011: 42%
  - 2012: 55%

- **Require companion diagnostic test before approval of drug**
  - 2010: 40%
  - 2011: 53%
  - 2012: 53%

- **Restrict use of drug based on results of companion diagnostic**
  - 2010: 32%
  - 2011: 47%
  - 2012: 50%

- **Require PA for oncology companion diagnostics**
  - 2010: 40%
  - 2011: 47%
  - 2012: 46%
ONCOLOGIST CONSOLIDATION AND SHIFT IN SITE OF CARE

A recent trend resulting in increased cost to payers is the shift in site of care for cancer treatment from community practices to hospitals. As few as 6 years ago, the generally accepted split between community clinics versus hospital site of care for infused oncology was 80:20, respectively. In 2013, the ratio is approximately 50:50, with an even greater shift to hospital outpatient and integrated delivery networks (IDNs) predicted by 2015.

Three primary factors are contributing to this trend:

1. Reduced drug and administration reimbursement to oncologists from payers, including Medicare
2. The expansion of 340B discounts to hospitals (explained below)
3. The purchase of oncologist clinical practices by 340B hospitals

340B Program

Congress created the 340B program in 1992 to offer uninsured indigent patients better access to prescription drugs by helping facilities serving large numbers of uninsured, low-income patients purchase outpatient drugs at discounted prices. Today, all outpatients of a 340B facility, both insured and uninsured, may be treated using drugs purchased via the 340B program, resulting in 340B entities using 340B-discounted drugs for insured patients and billing insurers at a much higher contracted rate.

According to a recent study, chemotherapy costs are on average 24% more in a hospital-based outpatient setting than in a doctor’s office and vary by length of therapy time.

340B participation also incentivizes hospitals to acquire community oncology practices. The Community Oncology Alliance reports that during the last 4.5 years:

- 241 community oncology clinics have closed
- 392 practices have entered into a contractual relationship with a hospital or have been acquired by a hospital

Successful payer/physician oncology strategies based on collaborative business partnerships may provide workable solutions to engage physicians, decrease costs where appropriate, and ensure quality patient care.
Specialty Pharmacy Providers

The complexity of specialty drug distribution, handling, and patient support leads most health plans to adopt a custom specialty pharmacy network that may contain one or more specialty pharmacy providers (SPPs). Since specialty drugs treat populations that are relatively small, centralizing the dispensing of these medications is a common strategy for payers who wish to manage their specialty pharmacy expenditures most effectively.

| Mandatory Use of Specialty Pharmacy Providers | 66% | commercial and Medicaid plans that mandate the use of SPP for self-administered agents (SAAs) |
| Specialty Pharmacy Services | 44% | plans that are satisfied with their SPP’s adherence measurements |
| Performance Guarantees | 68% | plans that are offered performance guarantees for on-time delivery |
| Therapy Management Programs | 50% | plans that state their SPP provides a therapy management program for oral oncology |
Mandatory Use of Specialty Pharmacy Providers

Each health plan establishes its own SPP network and rules regarding the use of its contracted SPPs. The use of SPPs to dispense and distribute specialty drugs may be voluntary, where the patient has the option to obtain the medication from a variety of sources, or mandatory, where the health plan requires the patient to obtain specialty drugs from a limited network of specialty pharmacies. For specialty drugs covered under the medical benefit, health plans may allow medical benefit providers to maintain their own drug inventory and bill the health plan at their contracted rate (commonly referred to as "buy and bill"), or they may require the providers to order the drug from a specialty pharmacy and bill the health plan for their administration— and procedure–related costs only. In this case, the specialty pharmacy bills the health plan and collects any applicable cost share from the patient.
Mandatory Use of Specialty Pharmacy

Q. Indicate whether the use of SPPs is mandatory for some/all drugs within these categories.

Some states do not allow health plans to mandate the use of a limited pharmacy network. In these states, a payer must allow all providers into the network as long as the provider is willing to accept the network rate and complies with network performance requirements. As a result, only 66% of commercial and Medicaid plans mandate the use of SPPs for self-administered specialty drugs. The mandatory use of SPPs is much less common for medical benefit providers, with less than 22% of plans mandating the use of SPPs for MD infused drugs.

Survey data also reveal that 30% of commercial plans do not mandate the use of SPPs but charge a higher cost share when members use a non-network provider.

<table>
<thead>
<tr>
<th></th>
<th>Commercial (n=80)</th>
<th>MA-PD (n=71)</th>
<th>Medicaid (n=62)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Self-Administered Specialty</td>
<td>66%</td>
<td>35%</td>
<td>66%</td>
</tr>
<tr>
<td>Oral Oncology</td>
<td>56%</td>
<td>31%</td>
<td>60%</td>
</tr>
<tr>
<td>Home Infused</td>
<td>52%</td>
<td>24%</td>
<td>26%</td>
</tr>
<tr>
<td>MD Infused: Non-Oncologists</td>
<td>16%</td>
<td>21%</td>
<td>18%</td>
</tr>
<tr>
<td>MD Infused: Oncologist</td>
<td>15%</td>
<td>13%</td>
<td>13%</td>
</tr>
<tr>
<td>Stand-alone Infusion Center</td>
<td>13%</td>
<td>15%</td>
<td>10%</td>
</tr>
</tbody>
</table>
Specialty Pharmacy Services

Due to the complex nature of specialty drugs, SPPs offer a broad range of services to meet their clinical, billing, distribution, and service requirements and, as such, serve a highly specialized role within health care delivery.

Most Valuable Services Provided by SPPs

Q. Indicate the value of specific SPP services to your organization, where 1=not at all valuable and 5=extremely valuable, and indicate whether your SPP(s) provide the service to your organization.

The SPP services identified as most important (rating of 4 or 5) by respondents include ensure dose accuracy; manage drug waste and abuse; adherence programs and measurement; access to limited distribution drugs; savings measurement; and tracking patient interventions and subsequent outcomes.

Based on the most valuable services, health plans find the following service offerings lacking from their SPPs: adherence measurement, savings measurement, and tracking patient interventions and subsequent outcomes. Some specialty pharmacies also offer a retail pharmacy option. Survey data indicate that only 27% of payers find the availability of a retail pharmacy option valuable.
Health Plan Satisfaction with SPP Services

Q. Indicate the value of specific SPP services to your organization, and rate your satisfaction with each service provided to your organization, where 1=not at all satisfied and 5=extremely satisfied.

Based on the services previously identified as most valuable, survey results indicate that health plans are only moderately satisfied with their SPP’s performance. Approximately 60% of health plans are satisfied with their SPP’s ability to ensure dose accuracy, access limited distribution drugs, and provide adherence programs. 50% or less of health plans are satisfied with their SPP’s ability to manage drug waste and abuse, measure adherence, measure savings, and track patient interventions and subsequent outcomes.
Performance Guarantees

Survey participants provided feedback on what type of performance guarantees are most valuable to their organizations and whether their SPPs offer these services.

Performance Guarantees Provided by SPPs

Q. Indicate the value of specific SPP performance guarantees to your organization, where 1=not at all valuable and 5=extremely valuable and whether your SPP(s) provide these guarantees to your organization.

Survey data indicate that payers highly value a variety of performance measures; however, they are most likely to have performance guarantees only for prescription fill accuracy, on-time delivery, and customer service. Less than 44% of plans have been offered performance guarantees for adherence, pharmacy and medical cost savings, and outcomes.
Therapy Management Programs

Most SPPs have developed therapy management programs to enhance the value of the services they provide. For the purposes of this report, therapy management programs were defined to survey participants as targeted programs by therapy area to assess patients, manage side effects, optimize medication adherence, and provide disease-specific patient education.

Therapy Management Programs Offered by Specialty Pharmacy Providers

Q. Indicate whether your SPP(s) offers therapy management programs for the following conditions and whether you utilize the programs.

From the viewpoint of survey respondents, two-thirds of SPPs provide therapy management programs for HCV and MS; however, other therapy management programs are less commonly offered. When asked whether the plans utilize the programs where offered, only 40% of plans utilize these programs for HCV and MS, and fewer plans utilize therapy management programs for RA, hemophilia factor, GH, oral oncology, or RSV.
**Therapy Management Program Goals**

Q. If you utilize therapy management programs, identify the major program goals of the specific programs.

Health plans that utilize their SPP’s therapy management programs do so with one or more specific goals. For example, payers indicate their primary goals for HCV and MS therapy management are to improve clinical outcomes and improve adherence and persistency.

Therapy management programs for oral oncology drugs are implemented to improve clinical outcomes, reduce drug costs, manage side effects, and reduce product waste.

<table>
<thead>
<tr>
<th>Therapy Category</th>
<th>Improve clinical outcomes</th>
<th>Reduce drug costs</th>
<th>Improve adherence and persistency</th>
<th>Manage side effects</th>
<th>Reduce product waste</th>
</tr>
</thead>
<tbody>
<tr>
<td>GH</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Hemophilia Factor</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>HCV</td>
<td>✓</td>
<td></td>
<td></td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>MS</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral Oncology</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>RSV</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RA/Crohn's Disease</td>
<td>✓</td>
<td></td>
<td></td>
<td>✓</td>
<td></td>
</tr>
</tbody>
</table>
SPECIALTY PHARMACY PROVIDERS: IMPACT ON OUTCOMES

Specialty pharmacy is a growing area of pharmacy practice focused on providing drug therapy management and dispensing services for patients requiring treatment with specialty pharmaceuticals. Patients taking these medications require frequent monitoring and training, coordination of care with multiple health care providers, comprehensive patient education, and adherence management.

The increasing need for detailed information on patient adherence, quality of care, and outcomes measurements is changing the role of specialty pharmacies. This change in focus reflects the increased expectations of payers and the pharmaceutical industry. Several studies published within the last year highlight the role that specialty pharmacies can play in increasing therapy adherence, improving outcomes, and impacting overall health care utilization and cost (see below).

Payers will continue to look to specialty pharmacies to provide comprehensive data on the real-world effectiveness of specialty pharmaceuticals and to demonstrate their ability to influence patient outcomes.

Outcomes of a Specialty Pharmacy Program for Oral Oncology Medications¹

OBJECTIVE: Evaluate whether the use of specialty pharmacy services compared with retail services is associated with improved oncology medication use and reduced overall health care costs.

RESULTS: Specialty pharmacy services increased patient adherence and lowered overall health care costs.

Role of Pharmacy Channel in Adherence to Hepatitis C Regimens²

OBJECTIVE: Determine whether there are differences in hepatitis C regimen adherence between specialty and retail pharmacy patients.

RESULTS: Use of specialty pharmacy was associated with significantly higher regimen adherence and likelihood of achieving optimum adherence to hepatitis C regimens compared with use of retail pharmacy.

Impact of Specialty Pharmacy on Treatment Costs for Rheumatoid Arthritis³

OBJECTIVE: Evaluate the impact of specialty pharmacy management vs. retail services on medication adherence, medical resource utilization, and health care costs for patients with RA.

RESULTS: Specialty pharmacy management services increased medication adherence and had a strong and consistent impact on medical costs.

References
Management Goals and Strategies

The management of specialty pharmacy is complex: health plans must balance the need to control health care expenditures with the achievement of improved health outcomes for their members. In this final section of the Digest, the topics of health outcomes and adherence are addressed, for without adherence to therapy, favorable health outcomes can’t be achieved. With an eye toward the future, survey participants provide a snapshot of their highest priority goals and specific strategies they want to implement within the next 12 months.

<table>
<thead>
<tr>
<th>Management Goals and Strategies</th>
<th>Health Outcomes</th>
<th>plans that highly value quality of life as an important health outcome for MS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>52%</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Adherence Management</th>
<th>plans that rely on their SPP to improve adherence</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>70%</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Specialty Pharmacy Management Goals</th>
<th>lives impacted by plans that state improved adherence is their top goal</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&gt;77%</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Future Management Strategies</th>
<th>plans that will create more cost share tiers under the RX benefit</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>34%</td>
<td></td>
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</table>
Health Outcomes

Health plans typically rely on 3 main criteria for the development of their traditional and specialty drug formularies: efficacy, safety, and cost. The degree to which a payer values outcomes may vary by the type of outcome and the specific drug category. Outcomes related to drug therapy may include specific clinical measures, the impact on overall health care resource utilization, quality of life, workplace productivity, and overall health status.

For each of the drug classes on the following pages (61–62), survey respondents identified the importance of each outcome measure to their organization's coverage and formulary decisions (using a scale of 1–5, with 1=not at all important and 5=extremely important). Each graph represents the percent of respondents who rated the specific measure as a 4 or 5 on the rating scale.
For all therapy categories, respondents identified clinical improvement measures specific to the disease or condition and impact on total health care costs as the most important outcome measures to their organizations’ coverage and formulary decisions. Improvement in quality of life was considered important to approximately 53% of plans across the therapy categories, and workplace productivity ranked lowest overall.

**Importance of Outcome Measures: Hepatitis C**

**Q. Indicate the importance of each outcome measure to your organization’s coverage and formulary decisions.**

**Importance of Outcome Measures: Multiple Sclerosis**
Importance of Outcome Measures:
Rheumatoid Arthritis

Q. Indicate the importance of each outcome measure to your organization's coverage and formulary decisions.

Importance of Outcome Measures:
Oncology

<table>
<thead>
<tr>
<th>Outcome Measure</th>
<th>% of Plans (Top 4+5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall survival</td>
<td>89%</td>
</tr>
<tr>
<td>Total health care costs</td>
<td>83%</td>
</tr>
<tr>
<td>Total drug costs</td>
<td>80%</td>
</tr>
<tr>
<td>Progression free survival</td>
<td>74%</td>
</tr>
<tr>
<td>Adherence &amp; persistency</td>
<td>67%</td>
</tr>
<tr>
<td>Improvement in QoL</td>
<td>60%</td>
</tr>
<tr>
<td>Workplace productivity</td>
<td>30%</td>
</tr>
</tbody>
</table>
Adherence Management

Adherence to drug therapy is an acknowledged issue with specialty drugs. Patients may be faced with a higher financial burden and challenged with the complexity of the disease, alternate routes of delivery and administration, and treatment side effects. Payers cite improving adherence to specialty drugs as a top priority (see page 66).

Adherence Management Strategies

Q. Indicate which strategies you currently utilize to improve adherence and persistency to specialty drug therapies.

Health plans use a variety of strategies to improve adherence and persistency to specialty drug therapies. The top 3 strategies cited by survey respondents include:

- Relying on their SPP
- Assigning patients to case management or disease management
- Implementing PA to monitor adherence

70% plans that rely on their SPP to improve adherence
Most Effective Adherence Management Strategies

Q. If you utilize an adherence strategy, indicate its effectiveness (on a scale of 1–5, where 1=not at all effective and 5=extremely effective) to improve adherence and persistency to specialty drug therapies.

Survey respondents that actually utilize their internal staff to manage adherence (25% of plans) rate this strategy as the most effective. Unfortunately, most health plans are not staffed sufficiently to manage this process in-house and must therefore delegate this responsibility to case management, disease management, or their SPP. Manufacturer patient support programs are viewed by survey respondents as the least effective method to improve adherence.
ADHERENCE TO MEDICATION THERAPY

Adherence is generally defined as the extent to which patients will follow the directions they are given for prescribed treatments. Non-adherence includes failing to fill prescriptions, delaying prescription fills, reducing the strength of the dose taken, and reducing the frequency of administration.

Poor medication adherence is increasingly recognized as a significant source of waste in our healthcare system, and the scientific and lay literature is full of reports of the clinical and economic impact of patient non-adherence to drug therapy.

Some key statistics include:¹

- An estimated third to half of all patients in the US do not take their medications as prescribed by their doctors
- Medication non-adherence is attributable to $290 billion in avoidable health care costs

Non-adherence applies to biologics:²

- 23% of prescriptions for biologics are never filled
- Only 44%–62% of patients who start a biologic DMARD remain on the medication at 1 year

There are 3 primary mechanisms to improve drug adherence:¹

- Individualize drug therapy
- Reduce cost barriers
- Address patient behaviors

Payers need to recognize that in order to improve adherence they will have to engage their members in a suite of interventions to address the various components leading to non-adherence.

References

Specialty Pharmacy Management Goals

Health plans typically develop specialty pharmacy management goals to guide their ongoing strategic planning process. This year’s survey asked respondents to rate their highest priority goals for the next 12 to 24 months.

**Priority of Specialty Pharmacy Management Goals**

Q. On a scale from 1–5, where 1=not a priority at this time and 5=extremely high priority, please rate the priority within your organization of achieving each of the following specialty pharmacy management goals within the next 12–24 months.

Top specialty pharmacy management goals vary by line of business.

For commercial and MA-PD lines of business, the highest priority goals for the next 12–24 months include improve adherence, increase rebates, and reduce variability between pharmacy and medical benefit cost share.

For Medicaid, the highest priority goals for the next 12–24 months include improve adherence, increase rebates, and manage medical benefit drugs.

>77% lives impacted by plans that state improved adherence is their top goal
Future Management Strategies

With the introduction of new specialty therapeutics and more overall utilization of specialty drugs across the pharmacy and medical benefits, health plans continue to formulate and refine strategies to enhance specialty pharmacy management. Here we look at the top strategies payers plan to implement in the next 12 months across all of the surveyed topics.

Strategies Commercial Payers Plan to Implement

Q. Indicate which strategies you plan to implement in the next 12 months.

The graph summarizes the top individual strategies that more than 25% of the respondents are planning to implement in the coming year.

The majority of strategies focus on medical benefit management, including:

- Oncology pathways
- Medical provider reimbursement
- Network contracting
- Palliative care

Additionally, commercial payers plan to create more cost share tiers under the pharmacy benefit.

34% plans that will create more cost share tiers under the RX benefit
Strategies Commercial Payers Do Not Plan to Implement in the Next 12 Months

Respondents had strong feelings about what strategies they do not plan to implement in the next 12 months. Two specific themes emerge that are not in the 12-month plan for most payers:

- **Use of external vendors to manage medical benefit components related to:**
  - Palliative care
  - Companion diagnostics
  - MD fee schedule
- **Benefit design changes related to:**
  - Grandfathering
  - Grace period fills
  - 90-day supplies
  - Cost share tiers under the medical benefit

---

<table>
<thead>
<tr>
<th>Strategy</th>
<th>% of Plans</th>
</tr>
</thead>
<tbody>
<tr>
<td>Utilize external palliative care vendor</td>
<td>86%</td>
</tr>
<tr>
<td>Utilize external vendor to manage companion diagnostics</td>
<td>81%</td>
</tr>
<tr>
<td>Utilize external vendor to manage MD fee schedule</td>
<td>81%</td>
</tr>
<tr>
<td>Add cost share tiers under MED benefit</td>
<td>76%</td>
</tr>
<tr>
<td>Allow 90-day supplies</td>
<td>72%</td>
</tr>
<tr>
<td>Eliminate grandfathering</td>
<td>71%</td>
</tr>
<tr>
<td>Eliminate grace period fills at retail</td>
<td>69%</td>
</tr>
</tbody>
</table>

---
Impact of Future Strategies on Key Stakeholders

- **PHYSICIANS**
  - Clinical pathways
  - Pathway financial incentives
  - Palliative care education

- **MEDICAL BENEFIT PROVIDERS**
  - Infusion network
  - Site of care management

- **PATIENTS**
  - New cost share structures
  - Advance care directives education

- **SPECIALTY PHARMACIES**
  - Performance guarantees
  - Documentation of interventions
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