Insights from payers, organized providers, and specialty pharmacy providers

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The Metastatic Prostate Cancer Trend Report aims to provide pertinent information on current and anticipated trends in the metastatic prostate cancer (MPC) marketplace. It contains questionnaire and interview responses from various stakeholders as well as information obtained from reports and publications. Specifically, this document strives to

**Quantify**
- current and future utilization patterns of MPC therapies

**Gauge**
- stakeholder awareness of future MPC pipeline therapies

**Explore**
- perceptions of oral and intravenous (IV) oncolytics within the MPC space

**Identify**
- key influences and trends among payers, organized providers, and specialty pharmacy providers (SPPs)
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The Metastatic Prostate Cancer Trend Report was developed by Precision for Value (Precision), a Precision for Medicine company. The data contained in this report were generated through extensive literature reviews as well as online questionnaires and in-depth interviews with key stakeholders in the MPC space: payers, organized providers, SPPs, and employers. All questionnaires and in-depth interviews were developed and conducted by Precision in consultation with an internal advisory board composed of 13 managed care experts with an average of 20 years’ experience.

The final report was developed by Precision and reviewed by an independent editorial board composed of leading managed care opinion leaders. Any statements and opinions contained within the report reflect the responses of the questionnaire and interview participants and do not necessarily reflect those of Precision, the editorial board, or any other party participating in the development of this document.

**Questionnaires and Interviews**

The majority of data for The Metastatic Prostate Cancer Trend Report were generated from 3 multiple-choice questionnaires targeting 3 audience groups perceived to have the most market influence: payers, organized providers, and SPPs. Independent in-depth interviews were conducted with these audiences to supplement and qualify the data collected from the multiple-choice questionnaires. Additionally, in-depth interviews with employer stakeholders were conducted to provide perspectives on the current state of the MPC environment and anticipated trends.

Questionnaires (mean questions: 34, range: 30 to 38) and interviews (mean questions: 24, range: 20 to 26) varied in length. Although questionnaire and interview questions were tailored toward target audiences, most focused on the following central themes:

- Perceptions of oral and IV MPC therapies
- Formulary decision making and trends in utilization management
- Anticipated market trends and impact of future therapies
- Perspectives on healthcare delivery pathways and patient support services
- Key considerations for optimal MPC treatment outcomes

Questionnaires were developed based on extensive literature searches to uncover current issues in the MPC space. These questionnaires were vetted through the internal advisory board and market research experts before being pretested with target stakeholders to ensure question appropriateness.

**Respondents**

Questionnaire and interview participants were drawn from an extensive, proprietary, internal database composed of top managed care organization (MCO), pharmacy benefit manager (PBM), organized provider, specialty pharmacy, and employer decision makers. Completers received honoraria based on fair market value assessment.

Ninety-nine payers, 50 organized providers, and 10 SPPs completed online multiple-choice questionnaires. Further, 10 members from each specialty and 10 employers participated in one-on-one interviews with a member of the Precision Advisory Board; these interviews supplied deeper qualitative perspectives of key market issues.

**Data Aggregation and Analysis**

Data were generated from literature searches, questionnaires, and in-depth stakeholder interviews. No information about specific MPC therapies was
solicited at any time. Precision collected, clarified, aggregated, analyzed, and reported the resulting data using Qualtrics® survey software and Microsoft® Excel®. All questionnaires and in-depth interviews were double-blinded to minimize confounding factors.

The data reflect participants’ best knowledge of the services and features of the organizations they represent. However, the dataset is limited, and responses were not verified with participant organizations. Therefore, the findings in this report should be interpreted with caution, as they may not be representative of general stakeholder populations.

**Role of the Funding Source**
This trend report was funded by Astellas Pharma US, Inc. (Astellas) and Medivation.

Data collection and interpretation and report development were led by the Precision Advisory Board. All members of the advisory board were employed by Precision at the time of its involvement with this trend report. As a company, Precision received compensation from Astellas and Medivation for their role in data and report generation. In an effort to minimize potential bias, Precision employees did not receive any direct forms of compensation, commission, or any other financial incentives from the funding sources.

The final report was reviewed and validated by an independent editorial board; members of the independent editorial board did not receive compensation from Precision, Astellas, or Medivation for their roles. Editorial board members received honoraria based on fair market value assessment for their contributions.

**How to Use This Report**
This report offers different perspectives on topics and challenges in oncology specific to MPC. Refer to the following pages for audience-specific trends and insights:
The MPC space continues to be a source of innovation and evolution. In an effort to transition toward a more cost-conscious and value-driven system, many stakeholders have started considering new cost containment strategies that do not sacrifice care quality. Our analysis indicates that these approaches are varied across stakeholder types and are rooted in organization priorities. For example, our payer sample conveyed a focus on utilization strategies, with many expected to increase their use of complex formulary designs, product exclusions, and step therapies. On the other hand, our organized provider respondents indicated that they are adopting coordinated care delivery models at a rapid pace. Specialty pharmacies are taking patient-centric approaches to improve outcomes through increased use of patient navigation programs, home care visits, and other offerings. Even employers, who have traditionally taken a relaxed approach to the management of oncology therapies, are beginning to use management techniques similar to those commonly seen in MCOs and PBMs. These multifaceted approaches represent the evolving nature of how stakeholders approach MPC.

One unique aspect of cancer care, and MPC care in particular, is the differential coverage models of oral and IV oncolytics. Analysis of questionnaire responses confirms the belief that IV therapies are typically covered under less restrictive medical benefits, whereas oral therapies tend to be covered under more restrictive pharmacy benefits. Despite this, most respondents (regardless of specialty) expect the utilization of oral oncolytics to increase relative to IV oncolytics in the near future. An oral oncolytic pipeline, where more than 60% of all therapies are expected to be oral formulations, and changing paradigms toward preferential oral therapy use may be causative factors for this shift. Organized providers appear to be the largest supporters of this trend, with approximately 85% of all respondents reporting a preference for oral oncolytics when costs and clinical outcomes are constant. Conversely, IV oncolytic utilization is expected to remain the same or decrease, which may symbolize the inverse relationship between oral and IV therapies.

Achieving quality outcomes is an important objective for MPC stakeholders. However, our respondents noted different priorities for achieving outcomes based on specialty. Payers, organized providers, and SPPs tended to agree that patient adherence to therapy is one of the most critical barriers preventing optimized outcomes. Relatedly, respondents also noted that ongoing patient dialogue and education are important variables in achieving quality outcomes. In general, SPP respondents and organized provider respondents tended to align regarding priorities for obtaining ideal outcomes. On the other hand, payer respondents tended to be less aligned with the other major stakeholders on this issue (Figure 1).
Payers institute a wide array of management strategies in efforts to steer therapy selection toward cost-effective products with validated clinical profiles. However, some of the most widely employed management strategies may be among the least influential when it comes to prescriber choice. Our payer respondents noted that clinical criteria requirements (ie, prior authorization [PA] criteria) and quantity limits are used almost uniformly for MPC therapies; yet our organized provider group noted that these measures are not among the most influential strategies they encounter. Other strategies such as step therapy requirements and high patient out-of-pocket costs were more likely to influence prescribing.

**Figure 1. Key Predictors of Optimal Outcomes by Stakeholder**

Payers tended to be less aligned with other stakeholders on the importance of open access, healthcare provider (HCP) education, financial assistance, and easy access to products as they relate to outcomes.
decisions than clinical criteria requirements and quantity limits (Figure 2). It is worth noting that our payer group anticipates increased use of step therapy in the near future as payers try to increase their autonomy over therapy selection."

Results from our online questionnaires and interviews suggested that nurse and financial navigators may play a substantial role in achieving quality outcomes. These groups are viewed favorably among all stakeholders, especially when employed internally. However, many of those interviewed expressed hesitation about using external navigators, especially those employed by pharmaceutical manufacturers, due to perceived unavoidable bias. Overall, navigators were viewed more favorably by SPP respondents and organized provider respondents than by payer respondents.

Advanced prostate cancer remains a significant burden to the healthcare system. External pressure and increasing innovation are catalyzing significant shifts in the MPC landscape. Payers, organized providers, and SPPs are all initiating novel and heterogeneous approaches to achieve quality- and value-based objectives. The trends outlined in this report represent a snapshot of those observed in the MPC community as a whole and show that the treatment and management of MPC is changing. Understanding the trends, innovations, and philosophies to address issues facing stakeholders will be important in improving the quality of care delivered to the thousands of men forced to confront the disease on a daily basis.

**Figure 2. Utilization Strategy Prevalence and Impact on Prescribing Decisions**

![Image of Figure 2 showing utilization strategy prevalence and impact on prescribing decisions. The most commonly used utilization strategies are not always the most influential when it comes to prescribing decisions.]

The most commonly used utilization strategies are not always the most influential when it comes to prescribing decisions.
Cost containment approaches are varied across stakeholder types and are rooted in organization priorities.
The United States healthcare system continues to be in the midst of a significant evolution. Legislation at the beginning of this decade sought to reduce spending while encouraging value-based healthcare by linking reimbursement to quality outcomes. However, recent transitions of power at the federal level have created uncertainty about the future direction of the United States healthcare system. Whatever the future may hold, healthcare will likely remain a focal point of public perception and will continue to garner significant attention from healthcare professionals, patients, the media, politicians, and other stakeholders alike.

One particular sector of healthcare that has experienced recent significant changes is the prostate cancer space. Changes in treatment and screening guidelines and the emergence of new treatment options have led to shifts in how prostate cancer is managed. Since 2005, annual diagnoses and deaths from prostate cancer have decreased by 22% and 14%, respectively. However, significant unmet needs in the space still exist. Prostate cancer remains the most prevalent cancer among men, with nearly 1 in 7 being diagnosed in their lifetime. Further, prostate cancer is the third-deadliest cancer in men. Some of this burden can be attributed to the high mortality associated with late-stage disease. When all cases of prostate cancer are considered, 5-year survival rates from 2005 through 2011 were nearly 100%. Conversely, when only metastatic disease is considered, 5-year survival rates dropped below 30% (Figure 3).

The economic burden of prostate cancer is substantial. According to a retrospective analysis of claims from the Surveillance, Epidemiology, and End Results-Medicare database conducted from 1975 to 2005, prostate cancer may account for up to 10% of all oncology spend. The primary driver of this trend is end-of-life care, which may approach an annualized cost of $100,000 per patient. In comparison, annual costs for non–end-of-life care are less than $30,000. Further, the majority of MPC-specific costs are linked to inpatient and ambulatory expenditures. In fact, these 2 categories alone may be responsible for more than 90% of all castration-resistant prostate cancer (CRPC) spend.

Our research described herein examined the shifting nature of the MPC space. We found that managed care stakeholders are exploring new strategies to improve clinical outcomes and promote cost savings in MPC. Our analysis indicates that high-deductible health plans, multi-tier formularies, and coordinated care delivery systems are strategies that are expected to increase in prevalence in the near future. The Metastatic Prostate Cancer Trend Report details these specific findings and others that may impact MPC treatment and management in the near future.

When all stages are considered, 5-year survival rates for prostate cancer approach 100%; however, the 5-year survival rate for metastatic disease is less than 30%.
Figure 3. Five-Year Relative Survival Rates by Stage at Diagnosis: Prostate Cancer (2005-2011 Data)

- **Local**: An invasive malignant cancer confined entirely to the organ of origin
  - Survival rate: > 99%

- **Regional**: A malignant cancer that 1) has extended beyond the limits of the organ of origin directly into surrounding organs or tissues; 2) involves regional lymph nodes; or 3) has both regional extension and involvement of regional lymph nodes
  - Survival rate: > 99%

- **Distant**: A malignant cancer that has spread to parts of the body remote from the primary tumor either by direct extension or by discontinuous metastasis to organs and tissues or via the lymphatic system to distant lymph nodes
  - Survival rate: 28%
Needs and Challenges Associated With Oral and Intravenous Therapies

IV therapies (eg, chemotherapy infusion) have long been considered a standard of care in oncology. However, advances in research and understanding of disease have led to advances in drug development—notably, the proliferation of oral oncolytics. In the MPC space, we estimate that more than two-thirds of all late-stage pipeline products are oral formulations (Table 1, Figure 4). This figure is approximately double general estimates of the entire oncology pipeline.

Survey respondents indicated that the management of oral and IV therapies can vary substantially (Figure 5). They noted that IV therapies have been traditionally covered under a health plan’s medical benefit, often requiring minimal out-of-pocket patient costs and allowing providers to profit on drug administration under buy-and-bill models. Conversely, oral agents have traditionally fallen under a pharmacy benefit and profitability, often requiring high out-of-pocket patient costs. This disparity may influence prescribers to make decisions based on benefit designs rather than clinical rationale, a trend that may impact clinical practice.

The issue of disparate cost coverage and benefit design has become so prevalent that some policymakers have taken legislative action to address it. In June 2015, US Senator Mark Kirk (R-IL) and US Representative Leonard Lance (R-NJ-7) introduced the Cancer Drug Coverage Parity Act of 2015 to their respective branches of Congress. Although many states have already enacted similar legislation at the local level, this bill would be the first of its kind and would set national precedent for standards on equivalent oncology medication coverage regardless of route of administration.
**Expectations of Future Metastatic Prostate Cancer Therapies**

**Current Landscape**
Since 2010, 5 drugs have been approved by the Food and Drug Administration (FDA) for the treatment of metastatic CRPC (Figure 6).46-50

**Metastatic Prostate Cancer Pipeline**
The MPC pipeline is diverse and robust. Many MPC pipeline therapies seek to improve on existing mechanisms, whereas others represent novel approaches to MPC care. These therapies range from cancer vaccines with prostate-specific selectivity to novel small molecules that alter gene expression at the nuclear level. A brief overview of notable late-stage pipeline agents (ie, therapies in phase 2 or phase 3 trials) is presented in Table 1.1-38

**Figure 6.** Metastatic CRPC Therapies Approved by the FDA Since 201046-50

The metastatic CRPC landscape experienced rapid proliferation of available therapies at the beginning of this decade; however, no new branded therapies have been approved by the FDA since 2013.
Targeted therapies (eg, anti-androgens, protein kinase inhibitors, and monoclonal antibodies) comprise a majority of MPC pipeline agents.¹⁻³⁸
<table>
<thead>
<tr>
<th>Drug Category</th>
<th>Drug</th>
<th>Mechanism of Action</th>
<th>Route of Administration</th>
<th>Sponsor</th>
<th>Phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Angiogenesis Inhibitor (Combination)</td>
<td>Cyclophosphamide, diclofenac, sulfasalazine, cimetidine (Hamsa-1 TL-118)</td>
<td>DNA replication inhibitor, cyclooxygenase inhibitor, nuclear factor κ-light-chain-enhancer of activated B-cell inhibitor, histamine type 2-receptor blocker</td>
<td>Oral</td>
<td>Tiltan Pharma Ltd</td>
<td>Phase 2</td>
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<tr>
<td>Cancer Vaccines</td>
<td>Rilimogene galvacirepvec</td>
<td>Vaccine with PSMA selectivity</td>
<td>Subcutaneous injection</td>
<td>Bavarian Nordic, Bristol-Myers Squibb</td>
<td>Phase 3</td>
</tr>
<tr>
<td></td>
<td>pTVG-HP</td>
<td>Vaccine with prostatic acid phosphatase selectivity</td>
<td>Intradermal injection</td>
<td>Dendreon</td>
<td>Phase 2</td>
</tr>
<tr>
<td>Cellular Pathway Inhibitors</td>
<td>Buparlisib (BKM120)</td>
<td>PI3K inhibitor</td>
<td>Oral</td>
<td>Novartis</td>
<td>Phase 2</td>
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<tr>
<td></td>
<td>GDC-0980</td>
<td>PI3K inhibitor, mTOR kinase inhibitor</td>
<td>Oral</td>
<td>Genentech</td>
<td>Phase 2</td>
</tr>
<tr>
<td></td>
<td>Ipatasertib (GDC-0068)</td>
<td>Serine-threonine protein kinase B inhibitor</td>
<td>Oral</td>
<td>Genentech</td>
<td>Phase 2</td>
</tr>
<tr>
<td></td>
<td>LY3023414</td>
<td>PI3K inhibitor, mTOR kinase inhibitor</td>
<td>Oral</td>
<td>Eli Lilly and Company</td>
<td>Phase 2</td>
</tr>
<tr>
<td>Hormone Therapies</td>
<td>Apalutamide (ARN-509, JNJ-56021927)</td>
<td>AR antagonist</td>
<td>Oral</td>
<td>Aragon Pharmaceuticals, Johnson &amp; Johnson</td>
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<td>Oral</td>
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<td>Anti-PSMA antibody</td>
<td>IV infusion</td>
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<td>Poly adenosine diphosphate ribose polymerase inhibitor</td>
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<td>Chromosome region maintenance 1 protein inhibitor, exportin 1 inhibitor</td>
<td>Oral</td>
<td>Karyopharm Therapeutics</td>
<td>Phase 2</td>
</tr>
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</table>

mTOR, mechanistic target of rapamycin; PI3K, phosphoinositide 3-kinase; PSMA, prostate-specific membrane antigen

This table is not intended to be a comprehensive list of all prostate cancer pipeline therapies. Since clinical development information changes rapidly, no guarantees can be made regarding the status of the agents listed. This table was generated through extensive review of publicly available information from Clinicaltrials.gov, prescribing information (where available), and peer-reviewed literature. It consists of therapies being evaluated in phase 2 or phase 3 industry-initiated clinical trials. Drugs with terminated, withdrawn, or suspended clinical development programs as well as those without updates since 2011 are not included.
Stakeholder Awareness of Pipeline Products

Payers

Payers are generally most aware or engaged with pipeline products when developing formularies. To this end, payers are most interested in pipeline products that are expected to come to market within 1 year. In-depth interviews indicate that payers are most likely to prepare for new products entering the market approximately 3 to 6 months before launch.

The most commonly mentioned class of therapeutic agents that piqued interest among those interviewed was the immunomodulatory agents. However, interviewees noted that these products were generally associated with high costs that can limit product utilization. Specifically, sipuleucel-T was commonly cited as a therapy whose utilization was hindered by cost burden. Further, some of those interviewed also noted that the approval of new generic formulations is not always associated with significant cost savings. These concerns should be noted as some current MPC specialty medications approach the end of their life cycle.
**Organized Providers**

Information gathered from organized providers during in-depth interviews indicated that this group is generally aware that many oral oncolytic agents are in the MPC pipeline. Further, they expect that prescribing rates of oral MPC oncolytics will rise in the future because of the pipeline composition. Although most providers are not aware of specific pipeline products, immunotherapies and oral agents tend to be among the most highly anticipated therapies in the pipeline. In general, organized providers do not take significant action in anticipation of pipeline products coming to market unless they are directly involved in the therapy’s clinical development (ie, acting as investigators in clinical trials).

**Specialty Pharmacy Providers**

Our discussions with SPPs indicated that they are more proactive than other key stakeholders when it comes to monitoring the MPC pipeline. Many organizations actively engage with manufacturers and monitor clinical development programs as far as 2 years out from approval. However, most preparations for pipeline products coming to market do not occur until the drug is fewer than 6 months from FDA approval. This time frame provides specialty pharmacies with critical insights into the product’s clinical profile, necessary patient services, and anticipated distribution model.

SPPs cited immunotherapy, oral drugs, and generic medications as the most highly anticipated therapies in the MPC pipeline. However, some SPPs stated that they expect shifts in guidelines or pathway placement of currently available therapies to more drastically affect the MPC market than approval of new therapeutics.
**Trends and Observations: Payers**

**Demographics**

Ninety-nine payers completed the online questionnaire, which consisted of multiple-choice questions on MPC topics. Responses from these questionnaires form the basis for a majority of the data summarized within this section. Further, 10 payers were selected to participate in live in-depth interviews with a member of the Precision Advisory and Editorial Board in order to obtain a deeper understanding of payer perspectives on MPC. This section represents the combined trends, insights, and outcomes of questionnaire and interview responses.

The majority of questionnaire respondents (N = 99) served as pharmacy directors and medical directors (78.8%) within their organizations (Figure 7). The sample was composed of high-level influencers with most having some role in formulary decision making (82%). Other common responsibilities include pharmacy and therapeutic (P&T) committee membership (71%) and PA or precertification criteria input (71%).

Representatives from regional MCOs comprised the largest subset of the analyzed sample (39%) with the remainder of respondents representing national MCOs (23%), national PBMs (17%), MCOs affiliated with integrated delivery systems (12%), and regional PBMs (5%). The median number of total lives covered was 2 million; of those, 73% were commercial lives, 16% were Medicare lives, and 12% were Medicaid lives.

**Figure 7.** Payer Respondents by Organization Type and Primary Discipline (N = 99)
**Trends Among Intravenous and Oral Oncolytics**

Results from our questionnaire indicate that payers expect acquisition costs for all MPC agents to increase over the next 5 years ([Figure 8](#)). Results also suggest that utilization of oral oncolytics is expected to increase over the next 5 years, while the utilization of IV therapies is expected to decrease over the same time frame. These trends may suggest a paradigm shift in MPC treatment toward increased oral oncolytic use.39

**Figure 8.** Anticipated MPC Therapy Cost and Utilization Trends: Payers39

Utilization and acquisition costs of oral oncolytics are expected to rise more dramatically than those of IV therapies over the next 5 years.

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**Acquisition Cost Trends**

- **Oral**
  - Increase Greatly: 1%
  - Increase Slightly: 7%
  - Remain the Same: 36%
  - Decrease Slightly: 5%
  - Decrease Greatly: 10%
  - Unsure, Unable to Predict: 2%

- **IV**
  - Increase Greatly: 9%
  - Increase Slightly: 7%
  - Remain the Same: 30%
  - Decrease Slightly: 18%
  - Decrease Greatly: 5%
  - Unsure, Unable to Predict: 30%

---

Percentages may not equate to 100% as a result of rounding.
Formulary Management and Utilization Strategies
The management of therapies for metastatic cancer is often considered high priority among payers. Breast, lung, and colorectal cancers were ranked as the highest management priorities among major metastatic cancers by those completing the questionnaire (Figure 9). MPC also ranked highly, with nearly two-thirds of respondents rating MPC as a “very high” or “above average” management priority.9

Payer questionnaire respondents indicate that formulary designs are expected to shift in the next 3 years. Our sample suggests that most payers currently structure their formularies under 3- or 4-tier benefit designs (59.2%).

**Figure 9. Payer Management Priority by Metastatic Disease**

MPC therapies are a top 5 management priority among major metastatic cancers.
However, respondents expect formularies to shift toward more complicated designs over the next 3 years, culminating in a significant increase in the prevalence of formularies with 5 or more tiers (Figure 10). Discussions with those interviewed revealed that these progressive formulary designs are engineered to give payers greater control over utilization and patient cost-share to encourage use of more cost-effective medications. Further, interviewees indicated that many of these new specialty tiers may be based on coinsurance cost-share models rather than traditional copay models.39

Figure 10. Current and Expected Prevalence of Formulary Benefit Designs

A. 3- and 4-tier formularies comprise the majority of current designs.

B. Payers are expected to shift toward more complex formulary designs, with more than one-quarter of all formularies expected to have 5 or more tiers by 2018.
Payers use a variety of utilization strategies to help manage the use of therapies on their formularies. Among those completing our questionnaire, PA requirements, quantity limits, and preferred pharmacies were listed as the most frequently enforced utilization strategies to manage claims for MPC oncolytics under pharmacy benefits. Interviews with these stakeholders suggest that they plan to implement additional utilization strategies in the near future because of increasing costs in the space. Results from our questionnaire support this idea, as the incidence of new step therapy requirements and product exclusions are anticipated to increase in volume the most over the next 3 years (Figure 11).

**Figure 11.** Relative Frequency of Utilization Strategies Used by Payers in MPC

<table>
<thead>
<tr>
<th></th>
<th>Medical Benefit</th>
<th>Pharmacy Benefit</th>
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<tr>
<td><strong>Current Relative Frequency of Use</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Always</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Future Plan</strong></td>
<td>Decrease</td>
<td>Increase</td>
</tr>
</tbody>
</table>

- **PA requirements**
- **Quantity limits**
- **Preferred pharmacy**
- **Clinical pathway, compendia, or clinical guideline requirements**
- **Mandated use of specialty pharmacy**
- **Tiered formularies with preferred products**
- **Biomarkers or diagnostic requirements**
- **Step therapy requirements**
- **Case management requirements**
- **Variable patient out-of-pocket costs**
- **Product exclusions from formulary**
Utilization strategies are expected to increase in the future, regardless of whether therapies fall under pharmacy or medical benefits.\textsuperscript{39}
Results from our questionnaire analysis indicated that the management of MPC therapies covered under medical benefits may become stricter in the future. Currently enforced management strategies are similar to those of pharmacy benefits, with PA requirements and quantity limits cited as the top 2 management strategies. Strategies that are expected to increase most drastically in the future include product exclusions, tiered formularies with preferred products, and mandated use of specialty pharmacies (Figure 11).

Coverage decisions for MPC therapies involve a variety of complex influences that are known only to plan sponsors. We asked questionnaire participants to rank common resources based on their perceived value in formulary decision making (Figure 12). Nearly 80% of respondents ranked clinical guidelines or compendia listings as “very important” or “absolutely essential.” Approximately 77% of payers ranked primary publications of clinical trial results as “very important” or “absolutely essential.” Economic factors, such as rebates and health economics data, were rated as

**Figure 12.** Relative Importance of Select Factors in Formulary Decisions Regarding MPC Therapies.

Validated clinical literature and Centers for Medicare & Medicaid Services (CMS) rulings are the most important resources used when making formulary decisions.
less influential in coverage decisions, which supports the notion that a therapy must meet a clinical need before being considered for formulary coverage. These data suggest that the clinical profile, and not the economic impact, of drugs has a greater influence over formulary placement. However, in-depth discussions with payers revealed that economic factors can play a large role in differentiating products with similar clinical profiles.\textsuperscript{39}

Most P&T committees meet at regular intervals to review high-priority situations. However, there are certain events that are likely to trigger ad hoc P&T committee meetings. Results from those sampled indicate that FDA approval of new branded or generic drugs, release of updated clinical guidelines, and updates to the safety profile of an FDA-approved pharmaceutical are the events most likely to trigger an unscheduled P&T committee meeting to review MPC therapies (Figure 13). Approximately 42% and 32% of participants would be “extremely likely” to have an immediate review upon approval of a new branded or generic MPC agent, respectively.\textsuperscript{39}

\textbf{Figure 13.} Events Most Likely to Trigger Nonroutine P&T Committee Meeting Regarding MPC\textsuperscript{39}

\begin{itemize}
\item FDA approval of new branded drug
\item FDA approval of new generic options
\item Updated clinical guidelines
\item Updated safety profile (eg, boxed warning, contraindications) of FDA-approved drug
\item Updated coverage decisions from CMS
\item Expanded indication of existing drug already FDA-approved for other indications
\item Greater than anticipated pricing of 1 or more products
\item Contracting/rebate offers
\item New clinical trial data for an existing FDA-approved drug
\end{itemize}

\textbf{Relative Likelihood}

Unlikely \hspace{2cm} Very Likely

\textbf{FDA approvals and clinical guideline revisions are events that are most likely to trigger ad hoc P&T committee meetings.}
**Perspectives on Other Healthcare Stakeholders**

Specialty pharmacies work closely with payers to deliver some of the most important and costly MPC medications to patients and members. Payer questionnaire respondents indicated that they find their SPP relationships to be most valuable when pharmacies are able to provide cost savings, improve patient adherence to medication, and improve provider adherence to established pathways *(Figure 14)*.39

Integrated delivery systems such as accountable care organizations (ACOs) and oncology medical homes (OMHs) are becoming increasingly utilized in today’s value-based system. Although the payer group interviewed for this analysis generally understood the potential value and utility of such organizations, some cited a lack of outcomes data as the primary reason for not presently pursuing these models. Still, the group expressed some optimism surrounding the

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**Figure 14.** Payers’ Perceived Value Added by Specialty Pharmacies as They Relate to MPC

Payers highly value specialty pharmacies because they are perceived to provide cost savings and improve adherence to therapy, clinical guidelines, and pathways.
potential utility of ACOs and OMHs. Our data indicate that ACOs are perceived to be most valuable when they are able to improve quality of care and performance, increase the use of lower-cost treatment alternatives, and enhance interdisciplinary coordination (Figure 15). Nurse and financial navigators were generally viewed in a favorable light among those interviewed. However, many interviewees expressed skepticism when it comes to navigators who are employed by pharmaceutical manufacturers, perhaps fearful of an unintentional bias toward the manufacturer’s products. Still, the group felt that these stakeholders play an important role in healthcare, especially in the MPC space where numerous HCPs interact to deliver complex treatment plans. Nurse navigators ranked highest among PBMs, and financial navigators ranked highest among Medicare plans.

Figure 15. Payers’ Perceived Value Added by Integrated Delivery Systems as They Relate to MPC

Payers expect coordinated care models to provide value by improving healthcare quality and enhancing use of low-cost treatment options.
Factors Influencing Treatment Outcomes
Questionnaire respondents indicated that nonadherence is a major concern among payer stakeholders (Figure 16). Therefore, it shouldn’t come as a surprise that payers perceive ongoing patient evaluation and counseling as an extremely valuable measure for achieving optimal outcomes. In fact, an overwhelming majority of this group (73%) felt that patient follow-up within 15 days of initial prescription fill of an oral oncolytic is vital. However, it remains unclear if strategies and tactics to support this philosophy have been implemented by payers on a large scale. 39
Some interviewees expressed interest in the development of genetic biomarkers that more accurately reflect disease progression. This approach has been proven effective in other cancer types such as chronic myelogenous leukemia and breast cancer, but payers warned that such tests

Figure 16. Key Predictors of Optimal MPC Outcomes From Payer Perspective

Payers note that patient medication adherence was the most important aspect in achieving ideal outcomes.
can be cost prohibitive and don’t always lead to a “Yes/No” decision, thereby marginally affecting treatment choice.

Payers completing the questionnaire believe HCPs are the most well equipped to provide support services to patients receiving IV infusions but feel that specialty pharmacies are the most well equipped to provide those services to patients receiving oral oncolytics. MCOs and PBMs rated themselves as only adequately equipped to provide patient support services. Pharmaceutical manufacturers were viewed as the least equipped to provide such services.39

The process of tracking quality outcomes within healthcare stakeholders has become increasingly important with the nearly universal adoption of accepted measures such as the National Committee for Quality Assurance (NCQA) Healthcare Effectiveness Data and Information Set® (HEDIS®) and the CMS’ 5-Star Quality Rating System. Our discussions with payer stakeholders indicate that quality tracking for advanced prostate cancer remains unstandardized across many payer organizations. Although HEDIS was the most commonly cited measure used, other measures to track the delivery of advanced prostate cancer care, such as overall or progression-free survival, were also mentioned as alternatives. Naturally, some organizations were better at tracking quality than others, with some participants revealing that their organizations have no infrastructure for tracking quality.

An overwhelming majority of payers felt that patient follow-up within 15 days of initial prescription fill of an oral oncolytic is vital to patient outcomes.39
Trends and Observations: Organized Providers

Demographics
Fifty organized providers completed the online questionnaire, which consisted of multiple-choice questions on MPC topics. Responses from these questionnaires form the basis for a majority of the data summarized within this section. Further, 10 organized providers were selected to participate in live in-depth interviews with a member of the Precision Advisory and Editorial Board in order to obtain a deeper understanding of organized provider perspectives on MPC.

Of the organized providers who completed a questionnaire, most were practicing physicians (44%) who were most frequently affiliated with hospitals (42%), medical groups (18%), cancer treatment centers (16%), or oncology medical groups (14%) (Figure 17). Most respondents were affiliated with larger practices, with 48% noting that their affiliates housed more than 10 oncology or urology specialists.

Figure 17. Provider Respondents by Organization Type and Specialty (N = 50)
Questionnaire participants oversaw a variety of patient lives that were insured in a number of ways. Commercially insured lives represented 43% of total lives covered within the sample, while a sizable portion of lives were covered by Medicare Advantage (17%) or Managed Medicaid (13%). Further, feedback from participants indicated that insurance coverage was highly heterogeneous across the sample depending on healthcare delivery models; however, these data should be interpreted with caution as the small sample size may not be representative of national averages (Figure 18).

**Figure 18.** Organized Provider Patient Base by Insurance Type (N = 50)

Patient insurance coverage type was highly heterogeneous across organization types.
**Trends Among Intravenous and Oral Oncolytics**

Those completing the questionnaire overwhelmingly identified oral oncolytics as their preferred route of administration for MPC treatments within their organizations. In fact, 86% of respondents believe that their practice/network would prefer the use of oral medications to IV infusions or self-administered injections if clinical and economic characteristics were constant.

Most questionnaire respondents (72%) believed that oral MPC therapies will experience increased utilization over the next 5 years. Conversely, this group expects utilization of IV MPC therapies to decrease or remain the same over the same time frame. These expectations may be reflective of professional bias toward oral oncology agents and comprehension of the MPC pipeline, where the majority of new agents are expected to be oral formulations (Figure 19).

Responses to questionnaires indicate that acquisition costs for all MPC oncolytics are expected to rise in the future. Expenditures are expected to rise more significantly in the oral oncolytic space. Conversely, a substantial proportion of respondents believe that acquisition costs for IV MPC therapies will decrease in the near future. Overall, these trends may signal a potential paradigm shift in MPC therapy preference among organized providers.

**Figure 19.** Anticipated MPC Therapy Cost and Utilization Trends: Organized Providers

Organized providers expect the utilization of oral oncolytics to rise dramatically in the future.
Factors Influencing Prescribing Habits
Analysis of our payer questionnaire responses suggests that PA requirements are perceived to be the most common utilization management strategy used by payers. In order to quantify the impact of PAs on prescribing, we asked organized providers a series of questions pertaining to PA denials and appeals. Results from that analysis indicate that PA requests for MPC therapies are rarely denied as long as the request meets prerequisite criteria (Figure 20). In fact, an overwhelming majority of respondents (82%) did not view PA denials as a significant issue in today’s healthcare space. Nonetheless, almost all respondents acknowledged that PA requests for MPC therapies are denied on occasion. In such cases, the frequency of submitting coverage appeals is highly dependent upon the individual organization: 42% of participants responded that they “never” or “rarely” appeal a coverage decision, while 40% of participants responded that they “often” or “always” appeal such decisions. According to respondent experience, PA appeals lead to approval roughly half of the time.\textsuperscript{a}

Figure 20. Rates of MPC PA Denials and Postdenial Appeals (Percentage of Responses)\textsuperscript{a}

Organized providers report that PAs based on clinical criteria are rarely denied but are often appealed in rare occurrences of PA denial.
Analysis from our payer questionnaire indicates that quantity limits and the designation of preferred pharmacies are also commonly used utilization strategies (Figure 11). Despite this, organized provider questionnaire responses suggest that these strategies are perceived to be among the least influential strategies for impacting MPC prescribing choices (Figure 21). Instead, organized provider respondents ranked step therapy requirements, high patient cost-shares, and clinical pathway requirements as utilization strategies with the greatest chance of impacting prescribing decisions. Specifically, three-fourths of the sample rated step therapy requirements as “likely” or “very likely” to influence prescribing decisions.39

Although utilization strategies may influence prescribing decisions in some situations, prescribers ultimately aim to provide their patients with the best possible therapy available. To determine the clinical value of MPC therapies, organized providers consider a wide array of source information. Primary publications of clinical trials and clinical guidelines or compendia listings ranked highest among those surveyed in terms of value added when considering the clinical utility of MPC therapies (Figure 22). Nearly all (88%) organized providers ranked primary publications of clinical trial results as having “above average importance” or “very high importance,” and 86% ranked clinical guidelines or compendia listings as having “above average importance” or

**Figure 21.** Utilization Strategies Most Likely to Impact MPC Prescribing Decisions

- Step therapy requirement
- Increased patient out-of-pocket cost
- Clinical pathway, compendia, or clinical guideline requirements
- Biomarkers or diagnostic requirements
- Product exclusion from formulary
- PA requirement
- Placement of product on nonpreferred formulary tier
- Mandated use of specialty pharmacy
- Case management requirements
- Quantity limits

Organized providers reported step therapy requirements as the utilization strategy most likely to influence MPC prescribing choices.
“very high importance.” External clinical consultant opinions, pharma-provided resources, and HCP surveys were ranked as the least important data sources, suggesting that HCPs are more apt to consider highly validated information from sources that they feel are trustworthy. These data provide insight into what types of data are used when constructing professional clinical preferences or developing clinical pathways.

**Figure 22. Relative Perceived Value of Select Resources in Evaluating Clinical Utility of MPC Therapies**

Validated clinical sources were generally viewed as the most influential factor when determining the clinical utility of MPC therapies.
An ACO is a system of HCPs with reimbursement care delivery models tied to quality and cost metrics. The goal of an ACO is to provide patients with optimal care while avoiding unnecessary services and spending. In short, ACOs aim to improve care quality across the entire care continuum. ACOs also change the financial relationship between payers and providers. Specifically, they shift financial responsibility from payer to provider. This approach is intended to incentivize providers to increase efficiency, decrease redundancy, and minimize costs.

The ACO model has become increasingly popular in today’s healthcare market and represents a shift toward incentivizing efficient care and moving away from traditional volume-based models. Recent estimates show more than 740 ACOs exist across all 50 states and provide care for more than 20 million people. Further, initial analyses show that these coordinated care models are producing measurable cost savings. As of November 2014, Medicare ACOs alone had generated $877 million in savings, $460 million of which has been returned to ACOs as part of their shared savings contract.”
Perspectives on Other Healthcare Stakeholders

Overall, organized providers had neutral stances on the value of specialty pharmacies. On one hand, specialty pharmacies are perceived to provide some value by improving adherence to accepted clinical and utilization protocols. On the other hand, some organized providers expressed that involvement of specialty pharmacies may place an additional burden on organized providers. Specifically, some interviewees viewed specialty pharmacies as an unnecessary middleman and/or a financial impediment to billing physicians (Figure 23).39

The rise of integrated delivery systems such as ACOs and OMHs has been catalyzed by recent national shifts toward value-based care. Nearly 65% of organized providers surveyed noted that they are currently a member of or plan to join a coordinated delivery system in the next 5 years. Among the sample, ACOs were more prevalent than patient-centered medical homes (PCMHs) and OMHs, with 20% of organized providers reporting they belong to an ACO and another 16% reporting that they are in the process of joining an ACO. Conversely, only 12% of respondents are current members or are pursuing membership within a PCMH

Figure 23. Providers’ Perceived Value Added by Specialty Pharmacies as They Relate to MPC39

Organized provider perceptions of specialty pharmacies were neutral, with adherence support cited as a positive clinical factor and increased organized provider burden cited as a potential drawback.
or OMH. Further, only 14% of respondents stated that they have no plans of joining such a system, and a large percentage (22%) of respondents abstained from committing one way or another. These data suggest that organized providers see value in these new coordinated care delivery models but that additional data are required to fully validate their utility in the MPC space (Table 2).\textsuperscript{39}

Patient support services, including patient advocacy groups and financial and nurse navigators, were viewed favorably among questionnaire respondents. Overall, 78% of respondents ranked financial navigators as “very important” or “absolutely essential.” Advocacy groups and nurse navigators were viewed as slightly less valuable, with 64% of respondents rating these groups as “very important” or “absolutely essential.” It is important to note that many of those interviewed maintain that these perceptions are only in reference to navigators employed by their health system because most had little or no contact with payer- or manufacturer-employed navigators. These data suggest that these forms of ancillary support services may play a key role in the evolving healthcare landscape.\textsuperscript{39}

### Table 2. Organized Provider Membership in Coordinated Care Delivery Models\textsuperscript{39}

<table>
<thead>
<tr>
<th>Integrated Delivery System Status</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Currently unsure</td>
<td>22%</td>
</tr>
<tr>
<td>Already a member of an ACO or already have an ACO</td>
<td>20%</td>
</tr>
<tr>
<td>Currently in the process of joining or forming an ACO</td>
<td>16%</td>
</tr>
<tr>
<td>Already a member of a coordinated delivery system not listed here</td>
<td>14%</td>
</tr>
<tr>
<td>No plans to join or form a coordinated delivery system model at this time</td>
<td>14%</td>
</tr>
<tr>
<td>Currently in the process of joining or forming a PCMH/OMH</td>
<td>8%</td>
</tr>
<tr>
<td>Already a member of a PCMH/OMH or already a PCMH/OMH</td>
<td>4%</td>
</tr>
<tr>
<td>Currently in the process of joining or forming a coordinated delivery system not listed here</td>
<td>2%</td>
</tr>
</tbody>
</table>

A majority of organized providers are currently members of a coordinated care delivery model or are planning to become members within 5 years.
Factors Influencing Treatment Outcomes

Questionnaire respondents indicated that nonadherence is a major concern among organized providers (Figure 24). Approximately 86% of those surveyed ranked patient adherence to therapy as “very important” or “absolutely essential” in achieving optimal outcomes. To this end, the majority (60%) of respondents indicated that follow-up time after initial prescription of oral MPC therapy should occur within 30 days. The 30-day time frame is more relaxed than the 15-day time frame associated with the findings from the payer and SPP questionnaires. Nevertheless, it underscores the perceived need to monitor patients during the initial therapy period. Other factors that respondents rated as critical to optimal outcomes include patient financial assistance and easy access to MPC therapies.

Quantifying the quality of healthcare being provided is becoming increasingly important in a healthcare system that places high value on quality-based care. Review of questionnaire responses from organized providers indicates that quality of care measurements remain highly variable among healthcare systems. Regarding quality measurements in MPC, general health measurements are the most commonly used, while cancer- and prostate-specific measures for MPC are used only sparingly. Specifically, the Nottingham Health Profile (NHP) and

Figure 24. Key Predictors of Optimal MPC Outcomes From Provider Perspective

Organized providers view oncolytic adherence and access as key contributors to quality outcomes.
Medical Outcomes Study (MOS) Short Form (SF)-36-Item and SF-12-Item surveys are the most commonly used quality of life measurement tools to assess MPC outcomes. Nearly half (48%) of respondents always use the NHP, while 44% always use the MOS-SF-36 and 32% always use the MOS-SF-12. Among cancer-specific quality of life measures, only the Functional Assessment of Cancer Therapy-General (FACT-G) and CAncer Rehabilitation Evaluation System–Short Form (CARES-SF) are used consistently. Prostate-specific quality of life measures are less frequently used than both general health and cancer-specific quality of life measures. Among the prostate-specific measures, the most commonly used tools are the University of California, Los Angeles Prostate Cancer Index (UCLA-PCI) and Functional Assessment of Cancer Therapy-Prostate (FACT-P) (Table 3). The heterogeneity of these findings is somewhat concerning because not all of these measurements are directly comparable. These data highlight a potential need to standardize medical outcomes measurement requirements across healthcare systems.39

Surveyed organized providers believe that infusion centers and HCP organizations are best equipped to provide patient support services to patients receiving IV oncolytics for MPC. Regarding oral MPC therapy, HCP organizations and patient advocacy foundations are viewed as the stakeholders most well equipped to provide support to patients. Notably, respondents viewed pharmaceutical manufacturers and MCOs/PBMs as the least well equipped for providing such services.39

General health quality measures are commonly used to evaluate the quality of MPC care; however, specific measures are diverse. Cancer- and prostate-specific quality measures are used much less frequently.39
Table 3. Prevalence of Quality Measures Used Among Organized Providers to Assess MPC Care

<table>
<thead>
<tr>
<th>Quality of Life Measure</th>
<th>Mean Frequency (Range: 1-5)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>General Health Measures</strong></td>
<td></td>
</tr>
<tr>
<td>Nottingham Health Profile (NHP)</td>
<td>4.32</td>
</tr>
<tr>
<td>Medical Outcomes Study (MOS) 36-Item Survey (SF-36)</td>
<td>4.24</td>
</tr>
<tr>
<td>MOS-SF-12</td>
<td>4.16</td>
</tr>
<tr>
<td>Quality of Well-Being Scale (QWB)</td>
<td>4.14</td>
</tr>
<tr>
<td>Sickness Impact Profile (SIP)</td>
<td>3.98</td>
</tr>
<tr>
<td>Profile of Mood States (POMS)</td>
<td>3.82</td>
</tr>
<tr>
<td>Mental Health Inventory (MHI)</td>
<td>3.54</td>
</tr>
<tr>
<td>McGill-Melzack Pain Questionnaire</td>
<td>3.48</td>
</tr>
<tr>
<td><strong>Cancer-Specific Measures</strong></td>
<td></td>
</tr>
<tr>
<td>Functional Assessment of Cancer Therapy-General (FACT-G)</td>
<td>3.24</td>
</tr>
<tr>
<td>CAncer Rehabilitation Evaluation System–Short Form (CARES-SF)</td>
<td>2.94</td>
</tr>
<tr>
<td>Rotterdam Symptom Checklist</td>
<td>2.50</td>
</tr>
<tr>
<td>European Organization for Research and Treatment of Cancer Quality-of-Life Questionnaire C30 (EORTC QLQ-30)</td>
<td>2.40</td>
</tr>
<tr>
<td><strong>Prostate-Specific Measures</strong></td>
<td></td>
</tr>
<tr>
<td>University of California, Los Angeles Prostate Cancer Index (UCLA-PCI)</td>
<td>2.93</td>
</tr>
<tr>
<td>Functional Assessment of Cancer Therapy-Prostate (FACT-P)</td>
<td>2.84</td>
</tr>
<tr>
<td>Prostate Cancer-Specific Quality-of-Life Instrument (PROS-QOLI)</td>
<td>2.70</td>
</tr>
<tr>
<td>HEDIS Non-Recommended Prostate-Specific Antigen (PSA)-Based Screening in Older Men</td>
<td>2.48</td>
</tr>
<tr>
<td>Prostate Cancer Treatment Outcome Questionnaire (PCTO-Q)</td>
<td>2.44</td>
</tr>
<tr>
<td>Expanded Prostate Cancer Index Composite-50 (EPIC-50)</td>
<td>2.42</td>
</tr>
</tbody>
</table>

Based on the question “How frequently does your organization utilize any of the following quality-of-life measurements to assess the quality of metastatic prostate cancer care being delivered to your patients?”

(1 = never; 2 = rarely; 3 = sometimes; 4 = very often; 5 = always)
Delivering quality healthcare has become a high priority in today’s society. To this end, it is becoming increasingly important for stakeholders to track healthcare quality. Quality measures are tools that help stakeholders measure or quantify healthcare processes, outcomes, patient perceptions, and organizational structure. They are playing increasingly important roles in accreditation and reimbursement.

One of the most commonly used and widely accepted quality measures is the NCQA’s HEDIS. HEDIS is a tool used by more than 90% of America’s health plans to measure performance on important dimensions of care and service. Altogether, HEDIS consists of 81 measures across 5 domains of care:

- Effectiveness of care
- Access/availability of care
- Experience of care
- Utilization and risk-adjusted utilization
- Relative resource use

Similar quality measurements are being used in other areas of healthcare, especially in the Medicare and Medicaid spaces where the CMS has developed numerous quality measures tailored to specific organization types.
Potential Measures for Tracking Prostate Cancer Treatment Quality*

- Percentage of patients with clinically localized prostate cancer receiving counseling on (at a minimum) the following treatment options before treatment begins: active surveillance, interstitial prostate brachytherapy, external beam radiotherapy, radical prostatectomy
- Percentage of patients with a new diagnosis with documented evaluation of prostate-specific antigen (PSA), primary tumor stage, and Gleason score
- Percentage of patients who are at high risk of recurrence and are receiving external beam therapy and who receive adjuvant hormonal therapy
- Percentage of patients with low-risk prostate cancer receiving interstitial prostate brachytherapy, external beam radiotherapy to the prostate, radical prostatectomy, or cryotherapy who receive unnecessary imaging
- Percentage of patients receiving external beam radiotherapy who also receive 3D conformal radiation therapy or intensity-modulated radiation therapy
- Percentage of patients with a diagnosis of high-risk prostate cancer who receive a bone scan and a computed tomography scan prior to treatment
- Percentage of patients invited to meet with a urologic oncologist and radiation oncologist prior to treatment

*T Based on National Comprehensive Cancer Network® Guidelines in Oncology on Prostate Cancer and the American Medical Association’s Physician Reporting Quality Initiative.
Demographics
Ten SPPs completed the online questionnaire, which consisted of multiple-choice questions on MPC topics. Responses from these questionnaires form the basis for a majority of the data summarized within this section. Further, 10 SPPs were selected to participate in live in-depth interviews with a member of the Precision Advisory and Editorial Board in order to obtain a deeper understanding of payer perspectives on MPC. This section represents the combined trends, insights, and outcomes of questionnaire and interview responses.

It is important to note that the views expressed by this sample are likely not representative of all specialty pharmacies because of the low number of participants. Nevertheless, pharmacies included in this analysis account for nearly 1.4 billion total prescriptions annually (median: 175,000 prescriptions annually). Most questionnaire respondents were employed by independently owned pharmacies (40%).

Responsibilities of those participating in the questionnaire include pharmacy or general management (30%), pharmaceutical contracting or procurement (30%), sales and account management (30%), clinical duties (30%), and pharmacy program development (20%). Half of those surveyed had daily responsibilities that included the management of oral oncolytics for MPC. The majority of MPC prescriptions fulfilled by specialty pharmacies represented in the sample were reimbursed by commercial insurance, but Medicare Advantage, Medicare Part D, and Managed Medicaid populations comprised significant segments as well (Figure 25).

**Figure 25.** Percentage of MPC Prescriptions Adjudicated by Insurance Coverage

Many MPC claims filled by specialty pharmacies are commercially insured.
Trends Among Intravenous and Oral Oncolytics

Nearly all SPPs responding to the questionnaire handled oral MPC therapies (80%), and nearly half (40%) handled both oral and IV oncolytics for MPC. Oral oncolytics made up a majority of MPC therapies dispensed by these specialty pharmacies, with approximately two-thirds of all MPC-related dispensations being oral formulations. An overwhelming majority (80%) believe that acquisition costs for oral MPC therapies will increase in the near future, while only half foresee an increase in acquisition costs of IV therapies. Respondents also anticipate the utilization of oral agents will increase in the near future; however, no consensus exists among the sample regarding the future utilization of IV MPC therapies.

Figure 26. Anticipated MPC Therapy Cost and Utilization Trends: SPPs

SPPs expect the utilization of oral oncolytics to increase more than IV oncolytics in the future.
SPPs reported that most MPC oncolytics are paid for at least in part by a payer entity (Table 4). Questionnaire responses indicate that the utilization of a patient assistance program is more likely to occur in patients who have been prescribed an oral oncolytic for MPC. Overall, the most common payment model for oral MPC oncolytics is insurance-based with supplemental support from patient assistance programs.  

**Trends in Specialty Pharmacy Practice and Utilization**

Questionnaire respondents identified lung, breast, melanoma, and prostate cancers as the most likely metastatic cancers to be associated with payer-mandated specialty pharmacy use (Figure 27). For the most part, these data are aligned with metastatic cancer management priorities reported by our payer sample (Figure 9). It is worth noting that mandated specialty pharmacy use may be largely influenced by the volume of oral oncolytics available for each disease state, as these formulations are more likely to be managed by specialty pharmacies and the pharmacy benefit than are IV oncolytics.  

Questionnaire respondents stated that they rarely offer alternative treatment suggestions to prescribers of MPC oncolytics. Specifically, 40% report never offering alternatives, and 30% suggested that this practice occurs less than 10% of the time.  

**Table 4. Common Payment Structures for MPC Therapies as Reported by Specialty Pharmacies**

<table>
<thead>
<tr>
<th>Method of Payment</th>
<th>Oral</th>
<th>IV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insurance coverage; patient uses patient assistance program</td>
<td>40.8%</td>
<td>27.5%</td>
</tr>
<tr>
<td>Insurance coverage; patient pays fixed copay</td>
<td>36.5%</td>
<td>35.0%</td>
</tr>
<tr>
<td>Insurance coverage; patient pays coinsurance</td>
<td>20.7%</td>
<td>24.3%</td>
</tr>
<tr>
<td>No insurance; patient uses patient assistance program</td>
<td>1.6%</td>
<td>1.8%</td>
</tr>
<tr>
<td>No insurance; patient pays cash price</td>
<td>0.4%</td>
<td>1.4%</td>
</tr>
<tr>
<td>Other</td>
<td>0%</td>
<td>10.0%</td>
</tr>
</tbody>
</table>

Most MPC claims are paid for, at least in part, by insurance companies; the use of patient assistance programs to cover patient cost-share is more common when patients are prescribed oral therapy.
**Figure 27.** Perceived Priority of Mandated Specialty Pharmacy Use for Metastatic Cancer Therapies

Mandated specialty pharmacy use for MPC therapies is perceived to be a high payer priority by specialty pharmacies.
SPPs sometimes encounter obstacles that prevent them from fully adjudicating MPC claims. Results from our questionnaire indicated that the most common barriers of this nature include the use of payer pharmacy network restrictions, patients’ inability to pay for drugs, and the use of PA criteria (Figure 28). Seven out of 10 respondents ranked payer pharmacy network restrictions as “often” or “always” a barrier, while at least half ranked patient inability to pay for drugs and PA criteria as “often” or “always” a barrier. Pharmacy benefit coverage was perceived as having the least impact on adjudication of initial MPC prescriptions.

**Figure 28.** Burden of Common Barriers Encountered by Specialty Pharmacies When Adjudicating Initial MPC Claims

Pharmacy network restrictions represent the most commonly encountered burden for specialty pharmacies when adjudicating an MPC prescription.
Mandated specialty pharmacy use is a prevalent and growing trend in the MPC space.\textsuperscript{39}
SPPs are key liaisons for MPC patients. As such, they often offer a wide array of patient-centric programs and frequently counsel patients on MPC therapy. All questionnaire respondents noted that their pharmacies offer medication adherence programs and most also offer guidance on patient assistance programs and benefit coordination (Figure 29). Many pharmacies in the sample also maintain a nurse or pharmacy call center to counsel patients.39

The most frequently discussed topics between SPPs and patients with MPC included shipment or delivery dates, medication adverse reactions, and financial or payment concerns (Figure 30). Eight out of ten respondents stated that medication shipment or delivery details are “always” discussed, and 60% noted that medication adverse reactions and financial or payment concerns are “always” discussed.39

**Figure 29. Most Prevalent Specialty Pharmacy Offerings for Patients With MPC (Percentage of Respondents)**

- Medication adherence programs: 100%
- Patient assistance program guidance: 90%
- Benefit coordination: 80%
- Nursing or pharmacy call center: 80%
- Individualized patient care plans: 80%
- Patient education (live or web based): 60%
- Home care visits: 50%
- Patient navigation programs: 40%
- Mobile device programs: 40%
- Pharmaceutical compounding: 30%
- Retail pickup of specialty medications: 20%

Specialty pharmacies offer a wide range of services to their MPC patients, with medication adherence programs being universally offered across organizations.
Figure 30. Common Topics Discussed With Specialty Pharmacy Patients With MPC

MPC topics of discussion between patients and SPPs are diverse.
As the name implies, PSA is a protein secreted by the prostate. Since PSA is unique to the prostate, it can be a useful biomarker in tracking prostate cancer progression. However, reliance on PSA level alone is often not a sufficient criterion for measuring disease progression. According to the Prostate Cancer Clinical Trials Working Group 3 (PCWG3) guidelines, increases in serum PSA levels should not be considered disease progression if they occur within the first 12 weeks of treatment. This is because PSA levels may continue to rise for a period before declining, even with effective therapy. This phenomenon is known as a PSA flare. Further, the PCWG3 guidelines recommend confirming disease progression through radiographic measures (eg, magnetic resonance imaging or computed tomography).

PSA screening emerged as a useful diagnostic tool for the early detection of prostate cancer in the 1990s. However, this practice has become controversial in recent years following the recommendation from the US Preventive Services Task Force (USPSTF) against global PSA screening in healthy men. Nonetheless, early detection remains an important factor in predicting long-term survival. Identifying and validating an appropriate biomarker for prostate cancer remains one of the largest challenges in the prostate cancer space.
1986
PSA test approved for monitoring disease progression

American Urological Association (AUA) releases Prostate-Specific Antigen (PSA) Best Practice Policy; routine PSA screening recommended in men aged 50+ with ≥ 10-year life expectancy

2009
AUA expands routine PSA testing recommendation to all men aged 40+ with ≥ 10-year life expectancy

2010
ACS revises guidelines; routine PSA screening not recommended

2012
USPSTF and ACS release guidance; routine PSA screening not recommended

2013
AUA releases 2013 Early Detection of Prostate Cancer Guideline; routine PSA screening not recommended

1980s
PSA test in combination with digital rectal examination approved for prostate cancer diagnosis

1994

1990s

2000s

2010s

Factors Influencing Treatment Outcomes

The surveyed SPPs viewed patient advocacy groups, nurse navigators, and financial navigators more positively than any other stakeholder group. Almost all respondents (90%) scored financial navigators as “very important” or “absolutely essential”; patient advocacy groups were also rated highly, with 70% of respondents rating those organizations as “very important” or “absolutely essential.” The positive perceptions of these stakeholders may be related to the patient-centric focus of specialty pharmacies and the dependence of specialty pharmacies on these groups to administer patient assistance programs.39

Similar to other stakeholders, the SPPs completing questionnaires rated patient adherence to therapy as the most critical factor in achieving optimal MPC outcomes. Almost all respondents (80%) rated medication adherence as “very important” or “absolutely essential” to optimal outcomes (Figure 31). With this in mind, we explored the topic of patient adherence further. When asked about ideal follow-up times after an initial MPC prescription fill, all SPPs noted that the ideal time frame is less than 15 days. SPPs were also asked about medication possession ratio (MPR), a commonly used measure of adherence. A majority of them (60%) defined adherence as an MPR greater than or equal to 90%; the lowest accepted MPR value deemed as adherent was 75%.39

Surveyed SPPs believed that infusion centers, SPPs, and HCP organizations are all well equipped to provide patient support services to patients receiving IV oncolytics for MPC. Not surprisingly, these stakeholders overwhelming felt that SPPs were the best equipped party to provide patient services to those receiving oral oncolytics. Respondents ranked MCOs and PBMs as the least equipped to provide such services.39

Figure 31. Key Predictors of Optimal Outcomes in MPC From Specialty Pharmacy Perspective39

Specialty pharmacies feel that medication adherence and continued patient touchpoints are essential to achieving optimal outcomes.
Employer-sponsored healthcare insurance plans make up a considerable proportion of commercial health insurance plans in the United States, accounting for nearly 150 million lives. This makes employers some of the most important decision makers in the insurance marketplace. As part of our analysis of the MPC marketplace, we conducted 10 in-depth interviews with employer decision makers to obtain broader understanding of these key stakeholders’ perspectives. These interviews comprise the foundation of insights and trends discussed in this section.

Employers have traditionally been hesitant to actively manage oncology therapies due to the gravity of the disease. However, our discussions with employers indicate that escalating overall costs have incited shifts toward more aggressive management of oncolytics. Prostate cancer presents unique challenges to employers because many of these patients are not actively employed.

Many of the approaches that employers are using parallel the trends observed in the payer space, perhaps a result of close collaboration between the 2 parties. Interviewees stated that they are becoming more receptive to the use of variable cost-share models (including use of coinsurance), specialty formulary tiers, nurse navigators, and high-deductible healthcare plans. Interviewees like the idea that these strategies incentivize patients to be mindful about their own healthcare decisions. However, these types of utilization strategies may be associated with significant drawbacks; namely, increased patient out-of-pocket costs may be an important influencer of patient adherence. Thus, the risks and benefits of strategies that shift responsibility to patients should be carefully considered prior to implementing them.

Employer size can significantly impact how an organization approaches healthcare. Representatives of large employers tended to exhibit greater involvement with benefit design and formulary development, a result of which may be the development of more customized benefit designs and formularies. Conversely, interviewees representing small employers tended to settle for generic plans developed by PBMs and MCOs, citing less negotiating leverage and fewer resources dedicated to plan design. Regardless, most employers expressed a heavy reliance on the expertise of their contracted MCOs and PBMs, especially as it pertains to complicated utilization issues such as PA criteria or step therapy.

Employee demographics also influence plan philosophies, especially as they pertain to oncology. Specifically, MPC is more likely to be a critical issue among employers with older and predominantly male employee populations. Interviewees also noted that a strong union presence can influence benefit management because union populations have more leverage during benefit and formulary negotiations. Nonetheless, most of those interviewed expressed interest in providing uniform plan designs across both union and nonunion populations.

As with other key stakeholders, this group also noted that costs and clinical profile are the 2 most important factors considered when making coverage decisions. Although interviewees valued productivity, it was noted that productivity measures are rarely used to make coverage decisions. This trend may be due to the scarcity of data connecting productivity with outcomes on an individual drug basis, as well as the cost of therapy being greater than the loss of productivity. Finally, as previously noted, many prostate cancer patients are no longer active members of the workforce, which may minimize the impact of disease on productivity.
References


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