Commercial Plans Seek More Control over Oral Oncolytics

Increased utilization, costs, competition and payor confidence shift access strategies in this growing category.

by Susan Weber, director of brand access analysis, Health Strategies Group

In the words of one health plan executive, a “tsunami” is brewing in the oral oncolytics category.

Although these agents escaped payors’ focus in the past, more plans fear the combined pressures of increasing utilization and high drug costs. But it’s not all bad news for payors. Many new brands are likely to enter the market in the next few years, offering new options to treat previously unmanageable cancers. In addition to filling unmet clinical needs, these new treatments provide more competition among drugs — and more opportunities for payors to ride out the storm.

COMMERCIAL PLANS: AT THE READY
Over the past 10 years, the U.S. Food and Drug Administration (FDA) has approved more than 15 oral oncology agents treating a wide range of cancers. The pipeline for oral oncolytics is also bursting, accounting for more than half of the 300 oncology drugs currently in phase 2 or 3 clinical trials (Figure 1). As a result, health plans have more options for convenient, cost-effective administration — as well as greater opportunities to influence treatment selections for specific cancer indications.

We have identified several trends in this increasingly important category, based on surveys and interviews with 52 pharmacy executives and medical directors representing 38 health plans and 153.8 million lives, as well as

Figure 1. FDA Approval Dates for Oncology Indications*

*Timeline represents a subset of oral oncolytics on the market.
five executives from pharmacy benefit managers (PBMs) representing 63.5 million lives. While PBMs and specialty pharmacy managers (SPMs) are influencers, it is the commercial plans that are driving this market. This is particularly true for new agents.

While tenured drugs, such as Xeloda and Temodar, face fewer access barriers at commercial plans, it’s a different story for agents that have won approval in the past five years. Most plans are implementing access barriers for late-to-market agents not demonstrating significant improvements in survival. Specifically, these plans are increasing cost-sharing burdens and use of restrictions — typically prior authorizations (PAs) — for these oral oncolytics (Figure 2).

Simply put, the days of low member cost-sharing are over. Cost-sharing is rising in the oral oncolytics category, as it is in other categories. Newer oral oncolytics, in particular, face high cost-sharing requirements at commercial plans. Most commercial plans reimburse the four newest oral oncolytics on the highest tier. One of these drugs is Xalkori (Figure 3). Beyond price, lack of comparative efficacy data and lack of post-launch marketing experience offer plans two rationales for limiting access to Xalkori and other recently approved drugs. Wary of safety issues that go unnoticed during accelerated FDA approval processes, payors may wait years to get the significant evidence of benefit they feel is necessary to make changes.

However, cost-sharing is just a piece of the access puzzle, particularly for commercial members. Typically, these patients aren’t sensitive to copays, due to their strong desire for treatment and the fact that many patient assistance programs eliminate copay differentials for commercial members. As a result, plans primarily rely on restrictions like PAs to influence use. For example, recently approved agents such as Zelboraf, Zytiga, Xalkori and Caprelsa are facing more PA requirements as plans complete formal product reviews. We expect the use of such restrictions to grow in the coming years.

While PAs remain plans’ most effective tool to reduce inappropriate use, payors realize that their current utilization management efforts aren’t cutting it. As one executive at a regional independent pharmacy admitted, “We use PAs to limit use to the indication, study or compendia listing. That’s about it.”

One example of how plans are using cost-sharing, restrictions and other strategies to control access is Gleevec. Most plans place Gleevec on the second tier due to its strong efficacy, tenure and market share. Fifteen percent of plans use copay differentials to advantage Gleevec over two competitive agents, Sprycel and Tasigna. Another 14 percent use copay differentials to advantage Gleevec and Sprycel over Tasigna. In addition,
some plans encourage Gleevec use by limiting restrictions on it while requiring PAs for Sprycel and Tasigna.

While plans have typically shielded away from system-based step edits because they lack the clear, defensible evidence they need to limit access to these oral oncolytics, some have implemented step edits to further increase Gleevec use. As commercial plans step up their management efforts, however, they continue to lack tactics that effectively balance cost management and clinical imperatives. And that’s what worries them. As one plan executive said, initiatives such as “cost-sharing, specialty pharmacy, pathways and medical necessity are all high on payor lists, but there’s no credible solution that will limit the long-term cost impact of the extraordinary oral oncolytic pipeline.”

GOVERNMENT PAYORS TEST THE WATERS
While commercial plans drive access decisions for oral oncolytics, Part D plans are also employing management tactics. Most require higher member cost-sharing for oral oncolytics. Part D plans consider drugs that cost more than $600 to be “specialty” drugs, allowing them to reimburse these agents on the coinsurance tier. This may be the fourth or fifth tier, depending on the plan’s benefit design.

Cost-sharing tactics have a greater impact in this market because the Centers for Medicare & Medicaid Services (CMS) does not allow pharmaceutical and biotech companies to provide patient assistance to Medicare Part D beneficiaries. To help pay for their medication, Medicare patients must secure assistance from nonprofit agencies, which is a more cumbersome process. As a result, Medicare members must pay more until they reach their out-of-pocket maximums. In addition, CMS’s designation of oncology agents as a protected drug class discourages Part D plans from aggressively using step edits and PAs to restrict use.

In contrast to Part D plans, managed Medicaid plans do not prioritize management of oral oncolytics, largely because state coverage mandates limit their ability to manage this category. With patient access a priority, one-half of Medicaid plans cover all 18 oral oncolytics studied in Health Strategies Group’s 2012 research. Those that cover all oral oncolytics due to state coverage mandates often rely on PAs to confirm appropriate use, including dosing. As one executive in a Medicaid-only pharmacy said, “We put a PA on every new oral oncology drug. We go beyond the labeled indication and into the literature to see if there is efficacy for the cancer.”

Another reason Medicaid plans are not motivated to manage oral oncolytics is that they have limited expertise in this area, in part because these drugs are not heavily used in their patient population. Lacking resources and expertise, some Medicaid plans delegate utilization management to a third-party expert in oncology, such as their contracted PBM, and refrain from using pathways.

However, Medicaid plans that also have commercial and Part D enrollment may extend effective policies in those populations to their Medicaid members. “We’ll be reactionary to the market,” said one Medicaid pharmacy executive. “We’ll follow commercial and Part D, for example, in managing the new targeted molecules. That’s a big concern for us.”

PBMs AND SPMs: BEST SUPPORTING PARTNERS
PBMs and SPMs play supportive roles in the management of oral oncolytics, particularly in the areas of distribution and the promotion of compliance goals.

Currently, most PBMs lack control over formulary decisions for oral
oncology. Most include all oral oncology on their preferred drug lists, deferring to health plan and employer clients to customize their access approaches. However, expanding oncology expertise at national PBMs may translate to increased influence on access. Today, many PBMs are collaborating with their health plan clients to expand SPM distribution in an effort to reduce waste and keep patients on their therapies. “SPMs help us keep a pulse on the member in terms of tolerability,” said an executive with a regional independent plan. “We’re not gangbusters on specialty, but we’ll use them to enhance compliance and adherence. That will help improve outcomes.” To address compliance and adherence, some SPMs use specially trained pharmacists and nurses who contact members every two weeks to address side effects and other issues that can interfere with treatment plans.

Plans also rely on SPMs to improve adherence by supplying “short fills” to patients receiving their first prescriptions. This also reduces the costly exposure plans face if patients fail to refill their prescriptions.

Still, plans typically limit SPMs to distribution and compliance tasks, reducing their opportunity to influence access. However, as SPMs expand distribution volume and internal capabilities, their influence may slowly rise (Figure 4). We expect most national and regional independent plans to mandate SPM distribution of oral oncology by 2014. Here’s why: SPMs are the most cost-effective distribution channel, and SPMs can help plans improve patient compliance while reducing costs. Payors often negotiate lower reimbursement rates when drugs are distributed through SPMs rather than retail pharmacies.

**FUTURE TREND:**
**PLANS PICK “PREFERRED” AGENTS**

During the next few years, a number of factors will affect how plans manage this category. For instance, pathways — which several plans are now piloting in their networks — are unproven today but may emerge as a tool for controlling access. What’s more, growing concerns about costly treatment at the end of life will prompt more plans to seek solutions in this area.

While these issues are important in determining access, so is the effect of new generic alternatives on the market (Figure 5). Plans are already taking steps to increase use of generics for aromatase inhibitors currently on the market, such as Femara and Arimidex. When generics for Gleevec and Xeloda become available, plans will have an opportunity to seize sizable cost savings. In addition, plans already have a foundation in managing small molecules in less sensitive drug categories, such as proton pump inhibitors for digestive disorders.

This year, more than twice as many plans as in 2010 say they will take some action to increase use of generic oral oncology. For example, most plans will require imatinib use prior to covering Sprycel and Tasigna. As one plan executive put it, “We’ve already taken steps to maximize Gleevec use despite Sprycel’s and Tasigna’s first-line label.” Plans that already require Gleevec-first trials will easily transition to generic-first step edits for Sprycel and Tasigna.

On the other hand, plans not currently advantaging Gleevec may refrain from requiring imatinib before these competing brands. Reluctant to create barriers to treatment, some plans are not ready for a step edit requiring imatinib before Tasigna.

**FUTURE TREND:**
**PLANS PROMOTE GENERICS**

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**FUTURE TREND:**
**PLANS PICK “PREFERRED” AGENTS**

Over the next few years, we also expect plans to leverage growing market competition to encourage first-line use of specific agents for certain tumors. In fact, this is happening already. Some plans are advantaging certain drugs that treat chronic myelogenous leukemia,

![Figure 4. SPM Distribution Policies](image)

**Figure 4. SPM Distribution Policies**

(Average estimated percentage enrollment at plans utilizing SPMs)

<table>
<thead>
<tr>
<th></th>
<th>Optional</th>
<th>Mandated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current</td>
<td>41%</td>
<td>59%</td>
</tr>
<tr>
<td>Predicted (2014)</td>
<td>14%</td>
<td>86%</td>
</tr>
</tbody>
</table>

*Assumes generic imatinib net pricing is 50 percent lower than Gleevec.

![Figure 5. Anticipated Plan Actions to Optimize Generic Imatinib Use in 2014*](image)

**Figure 5. Anticipated Plan Actions to Optimize Generic Imatinib Use in 2014***

(Percentage plans)

<table>
<thead>
<tr>
<th>Action</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reimburse Gleevec on a higher copay tier</td>
<td>55%</td>
</tr>
<tr>
<td>Eliminate coverage for Gleevec</td>
<td>34%</td>
</tr>
<tr>
<td>Reimburse Sprycel and Tasigna on higher copay tiers</td>
<td>30%</td>
</tr>
<tr>
<td>No action</td>
<td>9%</td>
</tr>
</tbody>
</table>

*Assumes generic imatinib net pricing is 50 percent lower than Gleevec.*
and a few are using step edits to advantage drugs for advanced renal cell carcinoma, often encouraging Sutent or Nexavar as first-line therapies.

Nearly nine out of 10 plans anticipate using a mix of tactics to encourage use of a specific agent in 2014 if competition leads to more choices in treating specific tumors. Plans will apply new rigor in evaluating agents and will use PA criteria and clinical protocols to encourage trials of specific agents when treatment choice and contracting opportunities exist (Figure 6).

Certain factors will likely affect plans’ ability to advantage a particular oral oncolytic. Specifically, plans that have coverage guidelines, strong physician relations, a robust IT infrastructure and in-house clinical pharmacists specializing in oncology will be more effective with this strategy.

In the coming years, we expect plans to focus on agents that target the same receptors (e.g., vascular endothelial growth factor, epidermal growth factor), ideally relying on overall survival data comparing market entrants to current treatment standards. However, plans are waiting for overall survival data that show an improvement over the standard of care before advantaging new agents. “If there is real-world data demonstrating a meaningful difference in overall survival, it can impact our pathways,” said one executive at a regional independent plan. “We’re looking for survival to double or add more than what hospice adds, which is six months.”

However, when competing brands lack clear differentiation on patient survival rates, almost one-half of plans prioritize cost savings (up from one-third in 2011), advantaging the brand with the lowest net price (Figure 7).

Nearly half of plans say lower net pricing is one of the top three factors they consider when making access decisions on new oral agents. This means that if agents fail to have a strong clinical story, contracts may create a difference down the road. In terms of contracting, we expect plans to become more price sensitive in the next few years as they encounter growing treatment choices and gain greater influence over treatment decisions.

With more competition, savvy plans — namely, those with a greater ability to enforce step edits or PAs to require first-line use — will seek opportunities for better pricing.

Clearly, what these trends point to is that payors are preparing to meet the rising costs and utilization in this unique category. By taking advantage of increased competition and other market dynamics, plans will be able to provide more options to their growing member populations while managing their own significant business challenges.

Figure 6. Likely Plan Actions to Encourage Use of a Specific Oral Oncolytic in 2014* (Percentage plans in 2011 or 2012 predicting future action)

<table>
<thead>
<tr>
<th>Action</th>
<th>2012</th>
<th>2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Refine PA criteria</td>
<td>63%</td>
<td>59%</td>
</tr>
<tr>
<td>Use copay differentials</td>
<td>54%</td>
<td>40%</td>
</tr>
<tr>
<td>Use step edits</td>
<td>54%</td>
<td>36%</td>
</tr>
<tr>
<td>No action</td>
<td>13%</td>
<td>23%</td>
</tr>
</tbody>
</table>

n = 46

*Data assess likely plan tactics to encourage specific agent use when product choice increases within certain classes (e.g., tyrosine kinase inhibitors, aromatase inhibitors) of oral oncotics.

Figure 7. Attribute Ability to Drive Improved Access for New Oral Agent in 2014 (Percentage plans ranking as top-three driver)

<table>
<thead>
<tr>
<th>Attribute</th>
<th>2011</th>
<th>2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improved OS relative to standard</td>
<td>85%</td>
<td>80%</td>
</tr>
<tr>
<td>chemotherapy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Improved OS relative to Avastin</td>
<td>48%</td>
<td>44%</td>
</tr>
<tr>
<td>Lower net pricing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fewer side effects relative to oral</td>
<td>22%</td>
<td>20%</td>
</tr>
<tr>
<td>competitors</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contract offers</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Activity against multiple tumors</td>
<td></td>
<td></td>
</tr>
<tr>
<td>First to market of new oral agents</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

n = 46