Future strategies for pricing and market access in oncology

Discussion document

October, 2014
We review the situation of pricing and market access (PMA) in oncology in 3 steps:

1. Historical perspective
2. Recent changes / situation today
3. Future developments
Historically, oncology PMA has been an “exception”

Value seen primarily in extending survival (OS)

Focus on US market:

- High value market (bulk of sales, “free” pricing and price increases)
- Key role of NCCN guidelines and copayment support

Ex-US focus on EU-5:

- Increasing use of patient restrictions by payers to limit budget impact/burden
- NICE often key EU market access focus, however standard “by-pass” through Cancer Drug Funds
  - Not representative of broader EU response/opportunity
- Japan often an afterthought (limited MA barriers/regulated pricing)
- Little or no focus on emerging markets (e.g. pricing mostly in line with EU)

Oncology sales 2013 by region (% of total)

- **US**: 41%
- **EU-5**: 24%
- **Japan**: 10%
- **Rest of the World (ROW)**: 25%

Total = $90.8bn in 2013

Source: IMS MIDAS

<table>
<thead>
<tr>
<th>Region</th>
<th>Percentage</th>
<th>Total Sales 2013</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>US</td>
<td>41%</td>
<td>$35.9bn</td>
<td>IMS MIDAS</td>
</tr>
<tr>
<td>EU-5</td>
<td>24%</td>
<td>$21.8bn</td>
<td>IMS MIDAS</td>
</tr>
<tr>
<td>Japan</td>
<td>10%</td>
<td>$9.1bn</td>
<td>IMS MIDAS</td>
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Historically, oncology PMA has been an “exception” (cont.)

US drug sales and price of therapies across selected therapeutic areas

Oncology products stand out in their ability to achieve “high prices” and sales

- Similar picture observed for EU-5
- Oncology top therapeutic area spend (>># 2 diabetes)
- Oncology over 30% of preclinical and phase I R&D activity
The price of oncology drugs has increased rapidly over the past 20 years, and a new launch product now typically exceeds $10,000 per month.
Oncology PMA today at a cross-road

**Historically**

Oncology PMA has been an “exception”

**Future**

Business as usual?

Oncology PMA evolves yet remains an exception?

Transition to “standard PMA”?
Oncology PMA today at a cross-road – US vs EU vs EM

Pricing in the US in the spotlight: We are now in the post-Zaltrap era

- CEOs under pressure -- may be the target of investigations (e.g. Sovaldi)

Increasing US payer appetite for managing oncology category

- Clinical pathway experimentation
- Impact of oral oncology on pharmacy budgets
- Generic substitution; biosimilar entry next?
- New ACO channel and physician practice/provider consolidation

EU = post-AMNOG world

- **Germany**: from open access to highly constrained access with AMNOG
- **France**: Introduction of economic considerations in HAS assessments
- **Italy**: Systematic use of “risk-sharing” (only reimburse for responders)
- **Spain**: Budgetary pressures on new oncology spend
- **UK**: Cancer drug funding extended till March 2016

Emerging markets

- **Brazil**: mandated coverage for oral therapies by private sector and private/government tiered-pricing
- **China**: End of high quality = “high prices”?
- **Russia**: DLO/regional access critical yet trends murky
Zaltrap demonstrated broadly KOLs’ ability to impact price and access

At Memorial Sloan-Kettering Cancer Center, we recently made a decision that should have been a no-brainer: **we are not going to give a phenomenally expensive new cancer drug to our patients.**

The reasons are simple: The drug, Zaltrap, has **proved to be no better than a similar medicine we already have for advanced colorectal cancer, while its price — at $11,063 on average for a month of treatment — is more than twice as high.**

In most industries something that offers no advantage over its competitors and yet sells for twice the price would never even get on the market. But that is not how things work for drugs. The Food and Drug Administration approves drugs if they are shown to be “safe and effective.” It does not consider what the relative costs might be once the new medicine is marketed.

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Sanofi Halves Price of Cancer Drug Zaltrap After Sloan-Kettering Rejection

In an unusual move, a big drug company [Sanofi] said on Thursday that it would **effectively cut in half the price of a new cancer drug after a leading cancer center said it would not use the drug because it was too expensive.**

The move — announced by Sanofi for the colon cancer drug Zaltrap — could be a sign of resistance to the unfettered increase in the prices of cancer drugs, some of which cost more than $100,000 a year and increase survival by a few months at best.

Zaltrap came to market in August at a price of about $11,000 a month. Soon after, Memorial Sloan-Kettering Cancer Center in New York decided not to use the drug, saying it was twice as expensive but no more effective than a similar medicine, Avastin from Genentech. Both drugs improved median survival by 1.4 months, doctors there said.
Future – End of the “oncology exception”?

Pricing needs to be more rigorous, evidence-based

- Need to manage PR/advocacy opportunity/risk proactively
  - Portfolio approach needed - need to be consistent from asset to asset
- ASCO’s “value algorithm” - a significant PMA risk?
- Key role of high impact evidence development
- PMA needs to come in early - Pricing and market access considerations should be brought in the clinical decision making early in the process
- Need for integrated approaches that maximize opportunities while providing a robust/step-wise factbase for pricing decisions
- Need to prioritize – e.g. key geographies / other key issues
- Developing economies: A growing need for tier-pricing and other innovative approaches
Are KOLs/clinicians the main potential barrier to access for the future?

ASCO task force on “Value in Cancer” Care is developing an algorithm scorecard to evaluate drugs’ value based on their:

- Cost
- Efficacy
- Side effects

Right now the value framework is intended for doctors to use exclusively on an individual basis with their patients.

ASCO does not intend to publish rankings or any other generalizable information about the overall value of specific treatments.

Could ASCO’s algorithm transform the US into France or Germany?

- Timing uncertainty (i.e. 1st version may not bite but the 2nd could…)

- Post-Zaltrap, there is a significant risk that payers use physicians to reduce costs (if physicians don’t do it on their own…)

We are trying to be an honest broker in helping oncologists and patients make their best-informed treatment decisions based on effectiveness and cost.

—Lowell E. Schnipper, MD
Chair of ASCO’s Value in Cancer Care Taskforce and Chief of Hematology/Oncology at BIDMC in Boston
Evidence-based articulation of the value generated is likely to become key for a new therapy to achieve significant premium pricing, particularly in Europe.

For such value-based pricing approaches, the “monetization” is typically based on current payments made by payers for similar level of outcomes.
PMA needs to be brought in early in decision-making

**Common past PMA pitfalls**

- Late and/or rushed assessment of potential market access barriers/considerations
  - Sub-optimal pricing and launch decisions

- Poorly designed clinical programs that don’t address payer needs, particularly ex-US
  - Pursue local data initiatives (key for local advocacy)

- Lack of consistency from asset to asset, and across geographies
  - What works for today’s asset may hurt the next company’s blockbuster

**Emerging “early PMA” best practices**

- Conduct appropriate PMA situation analysis prior to initial clinical investments
  - Identify PMA-specific evidence needs
  - Update as clinical development progresses

- Establish early PMA representation on GPT and GBT teams
  - Explicit consideration of market access and pricing challenges and opportunities
  - Clear accountability for local data initiatives

- Develop common framework across portfolio
Pricing needs to be rigorous

Need for integrated approaches that maximize opportunities while providing a robust/step-wise factbase for pricing decisions

Research and Analysis Steps

1. **Payers**
   - Qualitative and Quantitative Research
     - Impact of product benefits and price on Product X market access (e.g. restrictions and – for the US - copayment tiers) by price point and payer (type)

2. **Physicians**
   - Quantitative Research (option for qualitative research)
     - Estimate preference share for Product X: impact of formulary (e.g. restrictions and – for the US - copayment tiers) on physician prescribing behavior

3. **Patients**
   - Quantitative Research (US only)
     - Impact of patient out-of-pocket costs on patient preferences and requests for a lower cost alternative therapy or non-compliance

Model Integration Steps

4. **Physician-Driven Share**
   - Physician-driven share – Apply market access outcome (e.g. restrictions and – for the US - copayment tiers) to estimate physician therapy preference shares based on price-access relationship. Combines 1 and 2.

5. **Fully Integrated Share and Price**
   - Fully integrated share – Apply impact of price on physician-driven shares to patient share based on out-of-pocket costs estimate patient demand, therapy requests, and physician compliance. Combines 3 and 4.
Need to prioritize – e.g. key geographies / other key issues

The “No brainer”: Avoid the time wasters (e.g. Australia)

“More difficult yet key”: Assess launch sequencing / timing options from a PMA perspective

- EU pricing barriers – Now bypassing/delaying entry in some EU-5 countries a real consideration
  - Challenging innovation/clinical benefit ratings and economics (Germany post-AMNOG, France, etc.)
  - Pricing spillovers on other countries (e.g. Japan)

- Japan matters (potential bigger than EU-5?, HTA risk?)

Keep it simple!

- Need flexibility as things change
- Sales volume uncertainty will remain (even for big countries like Brazil, Russia and China)
- Managing price differentials is challenging (exchange rate fluctuations, US price increases,…)

Product X expected peak net sales

<table>
<thead>
<tr>
<th>Country</th>
<th>Market Share</th>
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<tbody>
<tr>
<td>US</td>
<td>60%</td>
</tr>
<tr>
<td>EU-5</td>
<td>8%</td>
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<tr>
<td>Japan</td>
<td>11%</td>
</tr>
<tr>
<td>ROW</td>
<td>21%</td>
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PMA scenario modeling can help!

Data inputs
- Scenario analysis metrics
- Other assumptions
- Patient segment characteristics
- Distribution of access by segment
- Sensitivity analysis

Calculations
- US Calculations
- EU Calculations
- Market share by segment
- Profit forecasting

Outputs
- Financials
- Impact of price on access
- Impact of access on utilization
- Market share, revenue, profit
Developing economies: A growing need for tier-pricing and other innovative approaches

As drug budgets rise in emerging markets, so is pressure on manufacturers to enable more patients to have access to modern medicine.

In this example, high correlation between a region’s Product X performance and income per capita:
- High share performance in cities where income is highest
- Low share performance in poorer regions/rural areas

Subsequent analysis helped identify new price approaches to increase the value of Product X in India and other developing countries.
The rising importance of effective collaborations with a broader set of stakeholders

Physician/patient advocacy require formalized processes

- Critical importance of advocacy is generally recognized
- Still few companies have adequate processes for it
- Some accountability for performance of advocacy support required

Develop local data early on [for key geographies]

- Key enabler for advocacy and innovative pricing
- Can help reduce evidence hurdle (e.g. achieve access with Phase II data)

Innovative pricing approaches (MEAs, risk-sharing, etc.)

- Win-wins and PR deals?
- Italy risk-sharing model spillover to other countries?
- Need to ensure outcomes are maximized for payers

KOL advocacy can greatly facilitate achieving access with payers, particularly ex-US

Assessing and Evaluating Options both from your and payers’ perspective
In conclusion:

Move early
- Early PMA involvement, KOL/local data advocacy development

Be bold
- “High stakes” in PMA in oncology as in other high value-based pricing

Think local
- Delegate / develop effective early collaborations with key geographies (provide tools and processes to support these collaborations)
- Monitor access and key initiatives (e.g. local data generation)

Keep it simple
- You can’t do everything

Learn from other therapeutic areas!
- Oncology has traditionally been insular…However, no need to reinvent the wheel or revisiting errors from other TAs…
- If you don’t, stakeholders (e.g. payers) may do it at your expense…
THANK YOU!

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