Targeted Cancer Therapies

What Is It:
• Targeted cancer therapies encompass many classes of infusion and oral chemotherapeutics that specifically affect tumor cells. Therapies have significantly increased progression-free survival for patients with certain cancers.

How Does it Work:
• The variety of therapies available target processes specific to cancer growth, such as blocking tumor cell growth receptors or interfering with the action of tyrosine kinase enzymes, which spur cell division. Others induce apoptosis or deliver targeted radiotherapy directly to cells.

Adoption Status:
• Early majority; targeted therapies are available at most community cancer centers

FDA Status:
• First therapy (tamoxifen) approved in 1990; currently more than 40 approved; most recent drug approved Xofigo (May 2013) for prostate cancer bone metastases

Major Vendors:
• Genentech/Roche, Novartis, Eli Lily, Bristol-Myers Squibb

Competing Products:
• Standard chemotherapies such as doxorubicin, radiation therapy, minimally-invasive surgery, immunotherapy

Technology Insights

Consideration | Technology Insights’ Take
---|---
Clinical | • Targeted therapies may be used as adjuvant therapies, first-line therapies, or last-resort therapies after cancer has progressed
• Providers must use molecular diagnostics to assess suitability of targeted therapies for a patient’s cancer
• Combinations of targeted therapies are not always effective and can even result in worse outcomes for some patients
• Shortages of cancer drugs remain a major challenge for providers

Reimbursement | • Payment is based upon the Average Sales Price (ASP) for each drug plus 6% to cover general and administrative costs

Cost | • Oncology drugs are a significant financial outlay for cancer clinics, which must either purchase the drugs then bill for administration or rely upon specialty pharmacies to procure the drugs
• Targeted therapies cost anywhere from $5,000 to $30,000 or more per month
• 340B prescription drug program gives providers that treat low-income patients discounts of 20-50% off the manufacturer price for drugs

Payer Coverage | • Medicare covers drugs that are FDA-approved and commercial payers typically follow, but some require prior authorization
• Often, companion diagnostic tests inconsistently covered by Medicare
• Strict standards for adherence to guidelines make reimbursement for off label indications challenging

Market Potential | • With the projected growth in cancer incidence and use of outpatient chemotherapy, the use of targeted therapies is likely to grow significantly

Operational Needs | • Providers need sufficient infrastructure for infusion therapies (chairs, oncology nurses, etc.) and processes to ensure effective use of oral chemotherapeutics

Impact in Accountable Care | • Targeted therapies improve patient outcomes but at a high cost. Many do not meet quality-adjusted life year cost effectiveness standards, so some providers may reduce utilization of expensive targeted therapies to improve gainsharing under ACO contracts if they do not improve outcomes

Competitive Take | • For AMCs: Appropriate patient accrual to clinical trials for new targeted therapies should be emphasized
• For community hospitals: Offering targeted therapies increasingly seen as standard of care, though providers must be wary of increased costs

Position on the Adoption Curve | • Early majority

Source: Technology Insights interviews and analysis.
Targeted Therapies Extend Progression Free Survival With Less Toxicity

Market & Financial Overview

National Market Estimates

<table>
<thead>
<tr>
<th>Year</th>
<th>Outpatient Chemotherapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012</td>
<td>866,594</td>
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<tr>
<td>2017</td>
<td>929,425</td>
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</tbody>
</table>

7% Overall Market Growth

Sample Drug Reimbursement Rates

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<thead>
<tr>
<th>CPT Code</th>
<th>Name</th>
<th>2012 Rate</th>
<th>2013 Rate</th>
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<tbody>
<tr>
<td>J9035</td>
<td>Bevacizumab injection 10mg</td>
<td>$62.32</td>
<td>$63.56</td>
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<tr>
<td>J9355</td>
<td>Trastuzumab injection 10mg</td>
<td>$76.40</td>
<td>$78.55</td>
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<tr>
<td>J9055</td>
<td>Cetuximab injection 10mg</td>
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Clinical Considerations

Results of Five-Year Follow Up Study for Imatinib for Chronic Myelogenous Leukemia

- 98% Cumulative Rate of Complete Remission
- 95% Overall Survival
- 17% Drug-Related Adverse Events

Often considered the paradigm of targeted therapy efficacy, imatinib (Gleevec®) completely changed the prognosis for chronic myelogenous leukemia. Imatinib, which is administered orally, disrupts tyrosine kinase enzyme activity that is crucial for cancer cell development. However, some concerns have been raised over the drug’s continued high cost ($92,000 per year) even after the development company, Novartis, has long recovered its research expenses.

Keys for Investment Success

- If purchasing drugs directly (i.e. not relying on a specialty pharmacy) providers must have sufficient reserve capital to purchase sometimes expensive drugs and protect against risk of non-payment
- Develop clinical pathways that incorporate the use of companion diagnostics for targeted therapies
- Outreach and educational initiatives for oncologists are crucial to ensure appropriate use of targeted therapies
- For advanced centers, participate in commercial and government-sponsored clinical trials to make cutting-edge therapies available to patients with limited options

Source: Druker et al. “Five Year Follow Up of Patients Receiving Imatinib for Chronic Myeloid Leukemia. NEJM. 2006 Dec 7;355(23):2408-2417