Cost Effectiveness & Pricing/Reimbursement A Biotech Case Study

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Biotech Business Model

- High costs
- High risks
- Small target populations

- Business model dictates high prices
- Value based pricing
- Comparative, defensible, and sustainable pricing
- Next generation pricing models

Herceptin Background

- HER2 gene was first cloned in 1985
- Herceptin® (Trastuzumab) developed from 1990-1997 and launched in 1998
- In vitro, Herceptin has been shown to bind to HER2+ tumor cells, leading to tumor cell stasis and death and continuous suppression of HER2 activity
- Approved to treat HER2+ first line and second or third line metastatic breast cancer
- Now approved for the adjuvant treatment of HER2 positive, node-positive breast cancer

Initial Trial and Cost Effectiveness

Patient Population	MBC HER2+ patients receiving chemotherapy (1st line)
Outcome	Median overall survival time: +4.8 months
Incremental cost effectiveness	$145,000/QALY[1]

[1] Elkin E, Weinstein M, Winer E, et al. "HER-2 Testing and Trastuzumab Therapy for Metastatic Breast Cancer: A Cost-Effectiveness Analysis." J Clin Oncol 2004;5: 854-863.

Adjuvant Trials and Cost Effectiveness

Clinical trial	NCCTG N9831 and NSABP B-31
Patient population	ABC HER2+ node+ patients receiving chemotherapy
Outcomes	Risk of recurrence: -52% Reduction in mortality: -33%* Disease free survival: +3 yrs
Incremental cost effectiveness	$26,417/QALY[1]

NOTE: risk of making coverage and reimbursement decisions based on snapshots of data

* P value = NS

[1]Garrison L, Lubeck D, Lalla D, et al. "Cost-Effectiveness Analysis of Trastuzumab in the Adjuvant Setting for Treatment of HER2-Positive Breast Cancer."

A “Cost-Effective” Pricing Model

Condition	Cost per month	Cost-Effectiveness (per QALY)	“Cost-Effective Price” per month (@ $75,000/QALY)
HER2+ MBC (population = 10K)	$3,243	$145,000	$1,677
HER2+ ABC (population =30K)	$3,670	$26,417	$10,419

Question: what would be stakeholder reactions to such price increases?

Delivery System Obstacles to Implementation

- ASP based reimbursement
- J codes
- Claims processing system logic
- Drug distribution
- What of the wisdom of markets?

The Challenge of Healthcare Affordability

- Drug costs and profits are a very small portion of overall healthcare spending
- Addressing fundamental inefficiencies in administration and delivery of care is key to long term success
- Let’s not risk undermining medical innovation only to achieve a false sense of security

Indications and Usage

- Herceptin as part of a treatment regimen containing doxorubicin, cyclophosphamide, and paclitaxel, is indicated for the adjuvant treatment of patients with HER2-overexpressing, node-positive breast cancer.
- Herceptin as a single agent is indicated for the treatment of patients with metastatic breast cancer whose tumors overexpress the HER2 protein and who have received one or more chemotherapy regimens for their metastatic disease.
- Herceptin in combination with paclitaxel is indicated for treatment of patients with metastatic breast cancer whose tumors overexpress the HER2 protein and who have not received chemotherapy for their metastatic disease.

Herceptin administration can result in left ventricular dysfunction and congestive heart failure. Serious infusion reactions and pulmonary toxicity have occurred; rarely these have been fatal. Exacerbation of chemotherapy-induced neutropenia has also occurred. The most common adverse reactions associated with Herceptin use were fever, nausea, vomiting, infusion reactions, diarrhea, infections, increased cough, headache, fatigue, dyspnea, rash, neutropenia, anemia, and myalgia.

References

- Romond EH, Perez EA, Bryant J, et al. “Trastuzumab plus adjuvant chemotherapy for operable HER2-positive breast cancer”. N Engl J Med 2005;353:1673-1684.