
Health Economics and Outcomes Research (HEOR), "Reimbursement Authorities", and Market Access



Special-HEOR

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"There is no point designing world-class products if you cannot commercialize them"

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Market Access

"Not the prolonged arm of Marketing"

Peter Stegmaier, Editor-in Chief
"Market Access & Health Policy"

You open the door

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Limits of Marketing & Sales Force

Exubera® : First inhalative Insulin
High price

Investment	2 800 Mio \$
Revenue I-III/2007	12 Mio \$

Pfizer withdraws the product from the market in 2008. Official reason:
Insufficient acceptance

Source: PM-Report 11/07, Investment: 2.8 billion US-Dollar
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Operating Margins

Great Healthcare Companies

20 to 30%

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Path

→ Regulatory

→ **Market Access**

→ Marketing & Sales

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HEOR

Input ⇔ Outcome

Costs of drug
or service

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Target Group

National policy makers, reimbursement authorities, agencies and budget holders involved in decisions regarding

- market access
- reimbursement
- listing, coverage


You have to know how they think and speak

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Basis for Data

Scientific evidence, usually from clinical trials

Not all good clinical investigators have the same power to influence reimbursement decisions



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Show that you provide value
...
By improving outcomes

Clinical Economic

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HEOR: Main Types

Cost-Minimization Analysis	CMA
Cost-Benefit Analysis	CBA
Cost-Effectiveness Analysis	CEA
Cost-Utility Analysis	CUA

Case studies

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Cost Minimization Analysis

	Captopril
Original	1.00 Euro
Generic version	0.50 Euro

Theoretical savings

0.50 Euro

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Cost Benefit Analysis

ACE Inhibitors in heart failure

Hospital admissions per year	0.1 Mio
Costs per admission	5000 £
Reduction of admissions	10%

Theoretical savings

0.1 Mio x 5000 £ x 10% = 50 Mio £

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Cost Benefit Analysis

Costs and benefits are both valued in cash terms.

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Criteria to Measure the Benefit

Demonstrate potential savings:
The new product can reduce or shorten

- hospital admissions
- duration of hospital stay
- duration of ICU (Intensive Care Unit) stay
- number of diagnostic procedures
- concomitant medication
- time nurses spent on preparing the product
- number of follow-up visits ...

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Cost Effectiveness Analysis

Patients with Kidney Failure

No Therapy †
0 \$

Hemodialysis Live
One year: 80 000 \$

Cost per life year gained **80 000 \$**

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"Good Value"

More than half of the US oncologists:
Patients should have access to effective cancer treatments only if those treatments are a "good value," or less than \$100,000 per life-year gained.

Fiercepharma 21 January 2010
Cancer docs judge cost-effectiveness of drugs

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Questionable Benefit of Cancer Drugs

Kosten und Nutzen neuer Krebsmedikamente

Yondelis Pharma Mar, Spanien JAHRES-THERAPIEKOSTEN: 124 835 € LEBENSVERLÄNGERUNG IN MONATEN Durchschnitt im Vergleich zur Standardtherapie bei Weichteilkarzinom: 2,1 (13,9 statt 11,8) bei Ovarialkarzinom: 1,1 (12,3 statt 10,4)	Nexavar Bayer, Deutschland JAHRES-THERAPIEKOSTEN: 58 400 € LEBENSVERLÄNGERUNG IN MONATEN Durchschnitt im Vergleich zur Standardtherapie bei Leberzellkarzinom: 2,8 (10,7 statt 7,9) bei Nierenzellkarzinom: 3,4 (19,3 statt 15,9)	Hycamtin GlaxoSmithKline, Großbritannien JAHRES-THERAPIEKOSTEN: 23 199 € Injektion, 30-tägiger Langzeitinfusion LEBENSVERLÄNGERUNG IN MONATEN Durchschnitt im Vergleich zur Standardtherapie bei Eierstockkrebs: 2,9 (9,4 statt 6,5) bei Lungenkrebs: 3,0 (keine Angabe)
Tarceva Roche, Schweiz JAHRES-THERAPIEKOSTEN: 29 525 € LEBENSVERLÄNGERUNG IN MONATEN Durchschnitt im Vergleich zur Standardtherapie bei Lungenkrebs: 2,8 (5,7 statt 4,7) bei Magenkrebs: 0,8 (5,8 statt 5,1)	Iressa Astra Zeneca, Großbritannien JAHRES-THERAPIEKOSTEN: 42 574 € LEBENSVERLÄNGERUNG IN MONATEN Durchschnitt im Vergleich zur Standardtherapie bei Lungenkrebs: nicht nachgewiesen	Herceptin Roche, Schweiz JAHRES-THERAPIEKOSTEN: 39 394 € LEBENSVERLÄNGERUNG IN MONATEN Durchschnitt im Vergleich zur Standardtherapie bei Brustkrebs: 7,0 (25 statt 18) bei Magenkrebs: 4,2 (15 statt 10,8)

Quelle: Ludwig Boltzmann Institut für HA, auf Grundlage der EMA-Zulassungsdaten; Ulrich Schwabe, Urs Heisenberg
 Spiegel 20/2010

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Cancer Center Says "No"

The Memorial Sloan-Kettering Cancer Center announced that it will not offer patients the cancer drug Zaltrap. Top executives do not believe the drug is worth the price tag: Zaltrap has proved to be no better than a similar medicine we already have for advanced colorectal cancer while its price - at \$11,063 for a month of treatment - is more than twice as high.

<http://www.washingtonpost.com/blog/k12a-lead/np/2012/10/15/a-cancer-center-says-no-to-an-11000-treatment-will-others-follow/>

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Cost Effectiveness Analysis

Measures outcomes in 'natural units',

Examples:

- mmHg
- symptom free days
- life years gained

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Cost Utility Analysis

Subjective quality of life is estimated to calculate *well-years* instead of *years*

Product	Life years gained	Quality of life factor	Quality of life adjusted life years (QALYs)
A	0.9	x 100%	= 0.9
B	1.0	x 80%	= 0.8

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Cost Utility Analysis

Measures outcomes in a composite metric of both length and quality of life

Note: There is some international variation in the precise definitions of each type of analysis.

Josef Hecken, head of the German G-BA plans to consider "Quality of Life" as one of their criteria.

(PIM-Report 10/13)

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Market Access Strategy

Packaging data in the right way, for the right stakeholders and payers* at the right time

* national and local decision-makers, policy makers and budget-holders

Basis: RCT = Randomized Clinical Trials

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Bayer's Nexavar Cancer Drug Fails to Win Recommendation of U.K. Agency

NICE: The price is simply too high to justify using NHS money. The cost of Nexavar couldn't be justified by its marginal benefit.

Cost-benefit info: Nexavar extended the lives of liver cancer patients by an average of 2.8 months at a cost of £27,000 (\$38,850).

To sweeten the deal, Bayer had offered a buy-three-get-one-free deal, but that wasn't enough to sway the agency.

NICE = National Institute for Health and Clinical Excellence in the UK

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Special Cases: Orphan Drugs

Examples in the EU:
Alglucosidase (Myozyme®) from Genzyme
Morbus Pompe
Bosentan (Tracleer®) from Actelion
Pulmonary Hypertension

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Market Access

Country-specific Approach
National Differences

You have to know how they think

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Germany

IQWiG = Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen

➔ G-BA

Gemeinsamer Bundes-Ausschuss

Sektorübergreifendes, oberstes Beschlussgremium der gemeinsamen Selbstverwaltung: **Kassenärztliche Bundesvereinigung**, **Kassen-zahnärztliche Bundesvereinigung**, **Deutsche Krankenhaus-Gesellschaft**, **Spitzenverband Bund** der gesetzlichen Krankenkassen, Patienten-organisationen, unparteiischer Vorsitzender

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France: La Haute Autorité de Santé

Drugs: Commission de la Transparence
measures
Amélioration du Service Médical Rendue
Price Negotiations with
Comité Economique des Produits de Santé

Medical Devices: CNEDiMTS
La Commission nationale d'évaluation des dispositifs médicaux et des technologies de santé

http://www.has-sante.fr/portail/jcms/c_5267/acces-medicaments-dispositifs-medicaux?cid=c_5267

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Italy

Agenzia Italiana del Farmaco (AIFA)
- Technical-Scientific Committee (CTS)
- Pricing- and Reimbursement Committee (CPR)

Pharmind 74, Nr. 5, 2012

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UK

NICE
National Institute for Health and
Clinical Excellence

PRPS
Pharmaceutical Price Regulation Scheme

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New Zealand

Core Services Committee
National Health Committee



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Market Access Strategy

(Repetition)

Packaging data in the right way,
for the right stakeholders and payers*
at the right time

* national and local decision-makers,
policy makers and budget-holders

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Where you could save money

More prevention: Change in life style
Less administrative procedures
Less diagnostic procedure (cardiology ...)
Less surgical procedures (hips, knees)
Less hospitalizations
Less prescriptions

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