Pricing and Reimbursement Decisions in Germany

CDDF MULTI-STAKEHOLDER WORKSHOP
Access to Innovative Oncology Drugs in Europe
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Federal Joint Committee (G-BA)
• The Federal Joint Committee (G-BA)
• The AMNOG procedure
• Price negotiation and arbitration process
• Recent social court decision on pricing
• Amount of AMNOG-savings
• Summary
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The Federal Joint Committee (G-BA)

Highest decision-making body of the statutory health insurance system
- Established in 2004
- Binding decisions for healthcare providers, the insured and sickness funds
- Ministry of Health: control of legality
The Federal Joint Committee (G-BA)

13 Voting Members:
- Impartial Chairman
- 2 Impartial Members

Federal Joint Committee as per Social Code Book
(§ 91 SGB V)

5 Sickness Fund Representatives:
- GKV-SV

5 Provider Representatives:
- DKG, KBV, KZBV

5 Patient Representatives
(Consultation and application rights. No voting rights)

Subcommittees (total 9)
Office / Academic Staff
Academic & Methodological Institutes (IQWIG, IQTIQ)

Impartial members appointed by Parliament (Bundestag)
- GKV-SV: sickness funds umbrella organization
- DKG: German hospital organization
- KBV: German doctor association
- KZBV: German dentist association
• The Federal Joint Committee (G-BA)
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Act on the Reform of the Market for Medicinal Products (AMNOG)

Free pricing of new drugs until 2010
Patented drugs: 13% share in volume but 45% share in sales in 2009
Increase in sales from 18.8 bn (€) in 1999 to 28.5 bn (€) in 2009

➢ Need for action

AMNOG-law on drug pricing and HTA in 2011
• Assessment of drugs on additional benefits compared to the benefits of an appropriate comparator by the Federal Joint Committee (G-BA)
• Free pricing was replaced by negotiation between manufacturer and National Association of Statutory Health Insurance Funds (GKV-SV)
Reform of the Market for Medicinal Products (AMNOG)
The early benefit assessment - sequence

1. Submission of the dossier
2. Publication of the dossier and the assessment
3. Resolution on the benefit

6 months

- 3 months: Benefit assessment (proposal by the IQWiG)
- 3 months: Hearing procedure and resolution
Resolution on the additional benefit

Resolution is part of the Pharmaceutical Directive and includes

- Additional benefit over an appropriate comparator
- Number of patients
- Requirements for quality-assured administration
- Costs of treatment, also in comparison to the appropriate comparator
  …for each therapeutic indication
Resolution on the additional benefit

Transparency: Resolution is published same-day on the G-BAs website

Nutzenbewertungsverfahren zum Wirkstoff Nivolumab (Neues Anwendungsgebiet: Nierenzellkarzinom)

Steckbrief
- **Wirkstoff:** Nivolumab
- **Handelsname:** Opdivo®
- **Therapeutisches Gebiet:** Nierenzellkarzinom (onkologische Erkrankungen)
- **Pharmazeutischer Unternehmer:** Bristol-Myers Squibb GmbH & Co. KGaA

Fristen
- Beginn des Verfahrens: 01.05.2016
- Veröffentlichung der Nutzenbewertung und Beginn des schriftlichen Stellungnahmeverfahrens: 01.08.2016
- Fristende zur Abgabe einer schriftlichen Stellungnahme: 22.08.2016
- Verfahrensstatus: Verfahren abgeschlossen

Bemerkungen
Nutzenbewertung nach § 1 Abs. 2 Nr. 2 VerfO

<table>
<thead>
<tr>
<th>Dossier</th>
<th>Zweckmäßige Vergleichstherapie</th>
<th>Nutzenbewertung</th>
<th>Stellungnahmeverfahren</th>
<th>Beschlüsse</th>
<th>Zugehörige Verfahren</th>
</tr>
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<tbody>
<tr>
<td>Arzneimittel-Richtlinie/Anlage XII: Nivolumab (neues Anwendungsgebiet – Nierenzellkarzinom)</td>
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</table>
Appropriate comparator is determined by the GBA

- Defined criteria per law:
  - Licensed (off-label-use is not allowed)
  - Standard of care
  - Best evidence
- Can differ from the comparator used in a study
- Can be requested within a consultation with the G-BA
Extent of the additional benefit

Differences in patient-relevant endpoints are crucial

- Mortality
- Morbidity
- Quality of life
- Adverse events

The primary endpoint is not the focus of interest!

Asymptomatic findings (PFS, ORR…) are not per se patient-relevant!

IQWiG: The upper limit of confidence interval defines the additional benefit

G-BA: Balanced decision-making
Extent of the additional benefit

The extent of the additional benefit over the appropriate comparator taking into account **statistical significance, clinical relevance** and the **severity of the disease**:

1) Major additional benefit

2) Considerable additional benefit

3) Minor additional benefit

4) No additional benefit

6) Non-quantifiable
Subgroup-specific decisions

**Afatinib**
- EGFR-positive NSCLC
  - EGFR-Mutation Del19: Major additional benefit
  - EGFR-Mutation L858R: No additional benefit
  - Uncommon EGFR-Mutations: No additional benefit

**Ibrutinib**
- Pretreated CLL
  - Suitable for chemotherapy
  - Not suitable for chemotherapy
  - Non-quantifiable benefit
Extent of the Additional Benefit
Highest Category per Active Ingredient

Effective: 3 August 2017

Cancer drugs (84)
- Major 1
- Considerable 30
- No additional benefit 19
- Minor 13
- Non quantifiable 21

All assessments (229)
- Major 2
- Considerable 50
- No additional benefit 99
- Minor 39
- Non quantifiable 39

All assessments (229)
- Major 2
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- Non quantifiable 39
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Price negotiations between manufacturer and National Association of Statutory Health Insurance Funds take place on the basis of the G-BA resolutions (period of 6 months after G-BA resolution):

Legal framework

§ 130b SGB V

- Cost of appropriate comparator therapy should be the upper limit for the price of the new drug if it has no additional benefit

Rahmenvereinbarung nach § 130b Abs. 9 SGB V („general agreement“)

- If an additional benefit is proven, a supplement on top of the price of the appropriate comparative therapy is negotiated
- “Real” sales price in other European countries is incorporated
- Price-volume agreements are possible
Price negotiation and arbitration process

Cost transparency: post-AMNOG rebate is published publicly available
Price negotiation and arbitration process

Decisions by 24 August 2017

- Completed price negotiations: 122
- Arbitration decisions: 26
- Market exit: 19

Only three oncology drugs are (currently) not available in Germany

<table>
<thead>
<tr>
<th>Drug</th>
<th>Disease</th>
<th>Additional Benefit</th>
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<tbody>
<tr>
<td>Regorafenib (Stivarga®)</td>
<td>CRC</td>
<td>No additional benefit</td>
</tr>
<tr>
<td>Osimertinib (Tagrisso®)</td>
<td>NSCLC</td>
<td>No additional benefit</td>
</tr>
<tr>
<td>Necitumumab (Portrazza®)</td>
<td>NSCLC</td>
<td>No additional benefit</td>
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</tbody>
</table>
Price negotiation and arbitration process

Market exits most likely if there is no additional benefit and annual therapy costs of the appropriate comparator are low.
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Recent social court decision on pricing

Guiding principle: One drug – One benefit-based-price
Problem: How to integrate different levels of additional benefit into one price per drug? A controversial concept: calculation of a „mixed price“

<table>
<thead>
<tr>
<th>Afatinib</th>
<th>Price negotiations completed</th>
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<tbody>
<tr>
<td>EGFR-positive NSCLC</td>
<td>Price per unit: 3.050 € &gt; 2.690 €</td>
</tr>
<tr>
<td>EGFR-Mutation Del19</td>
<td>Annual costs: 39.700 € &gt; 35.000 €</td>
</tr>
<tr>
<td>EGFR-Mutation L858R</td>
<td>Major additional benefit</td>
</tr>
<tr>
<td>Uncommon EGFR-Mutations</td>
<td>No additional benefit</td>
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Patients: 1.530 – 3.590

No additional benefit
Lowest annual costs: 8.960 €
Patients: 850 – 1.980

No additional benefit
Lowest annual costs: 8.960 €
Patients: 360 – 840
Recent social court decision on pricing: Problem of “mixed price” - concept

Social court decision (March 2017):
Cost of appropriate comparator therapy should be the upper limit for the price of the new drug if it has no additional benefit:

• „Mixed price“ is not cost-effective in subgroups with no additional benefit
• „Mixed price“ is too low in subgroups with an additional benefit

Prescribing drugs in subgroups without additional benefit is not per se cost-effective!
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• Price negotiations / Arbitrations / Market exits
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Top 20 Cancer Drugs in EU5 2016 by Sales
(France, Germany, Italy, Spain and UK)

- Trastuzumab
- Bevacizumab
- Lenalidomide
- Imatinib
- Rituximab (onco)
- Nilotinib
- Dasatinib
- Bortezomib
- Nivolumab
- Enzalutamid
- Pegfilgrastim
- Abirateronacetat
- Pertuzumab
- Cetuximab
- Ruxolitinib
- Azacitidin
- Pemetrexed
- Everolimus
- Ibrutinib
- Pomalidomid

Biosimilars/Generics
Completed price negotiations
Amount of AMNOG-savings

Retail price after negotiation (including mandatory rebates)

- Nivolumab: 1.247 €
- Enzalutamide: 3.642 €
- Abiraterone: 3.806 €
- Pertuzumab: 2.781 €
- Ruxolitinib: 3.730 €
- Ibrutinib: 8.514 €
- Pomalidomide: 9.095 €

Effective: 15 August 2017
(biggest package, highest dose)
The impact of indirect savings is unclear…
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The AMNOG procedure

- Free pricing for new drugs was replaced by a negotiation procedure
- Transparent evidence-based assessments at the time of market entry
- Does not constitute a hurdle: launch and assessment run in parallel
  - Free access to new medicine at time of launch
- Comprehensive information about new drugs publicly available
- Only few market exits
- Increasing amount of savings