HTA312

Inpatient Drug Reimbursement in Germany: Exploring the Differing Decision-Making Processes Between InEK and G-BA.

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INTRODUCTION

- In Germany, there are two national bodies that decide pricing and reimbursement of inpatient drugs:
  1) The G-BA conducts a benefit assessment independent of price, whilst
  2) InEK establishes the price and appropriate funding pathway
- This research investigated the relationship between the G-BA and InEK's decision-making criteria and outcomes for securing.

METHODS

- A quantitative comparison of NUB status vs. benefit assessment of inpatient drugs in the 2023 NUB list was conducted in addition to a 60-minute qualitative interview with a German payer advisor.

RESULTS

- The G-BA and InEK operate independently and vary in their processes, decision-making criteria, and outcomes.
- Manufacturers must successfully utilize both pathways to secure optimal reimbursement and uptake of inpatient drugs.

Independent decision-making processes and access implications

InEK

Manufacturer checks if current DRG covers cost → Yes → Funded within current DRG system

No → Manufacturer writes NUB application for individual hospitals to submit to InEK by Oct 31st, or Apr 30th for ATMPs

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InEK reviews hospital applications and assigns a NUB status to the therapy

NUB 1	Pricing and reimbursement negotiations with InEK
NUB 2	Application rejected; no funding
NUB 3	Application not processed on time; no funding
NUB 4	Application not informative enough; no funding

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Annual hospital-specific applications required

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Failure to achieve NUB 1 will have uptake consequences as hospitals must fund the cost differential vs. the DRG out of their own limited budgets

G-BA

Manufacturer submits dossier

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G-BA conducts a comparative benefit assessment (HTA)

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G-BA assigns an added benefit

Major/ considerable/ minor/ non-quantifiable added benefit	Price negotiations with GKV-SV
No added benefit/ lesser benefit	Price setting with GKV-SV

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Re-assessments required once new data available

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All EMA approved drugs are granted access, with the level of added benefit influencing the final reimbursement price

The G-BA and InEK's decision-making do not overlap except if the negotiated price based on the HTA is lower than the price related to NUB; **the lowest price will then be applied across the two processes**

Differing decision-making criteria

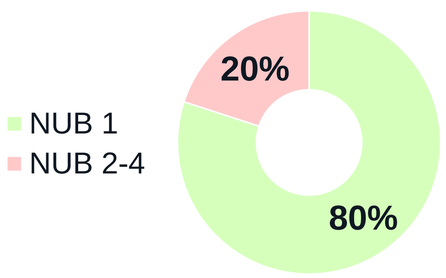
Criteria	InEK	G-BA
Supporting a positive outcome	• Drug is considered new (MA granted in last 4 yrs) • Cost differential vs. DRG, generally 1 S.D. over DRG • Added costs vs. DRG are clearly justified	• Additional clinical benefit is demonstrated via patient-relevant outcomes and validated QoL measures vs. a relevant comparator
Risking a negative outcome	• Poor quality of application, e.g., in poorly written German or inconsistencies across submissions • Too many applicants, particularly in the first year	• *N/A as all drugs are granted reimbursement in Germany*
N/A	Disease severity and unmet need	

"In the first year, a manufacturer would be well-advised to limit the number of hospital applications. The upper limit varies by disease and drug, but ~50-80 for a more common disease and ~10 for a rare disease is safe. You also have to make sure every hospital files the same text." ***– DE payer***

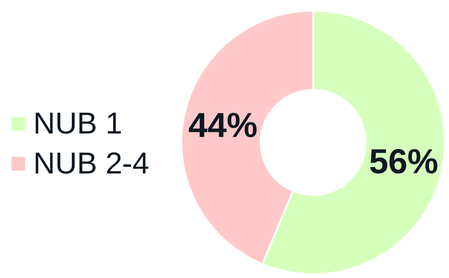
Discrepancies in NUB vs. HTA outcomes (2018 – 2023)

77.7% of drugs received NUB 1, 22.3% received NUB 2, 68.9% received an added benefit and 31.1% received no added benefit. However, 56.3% of drugs with no added benefit still received NUB 1 status, whilst 20% of drugs with added benefit received NUB 2.

Drugs with **added benefit** [n=71]



Drugs with **no added benefit** [n=32]



CONCLUSIONS

- Access to high-cost inpatient drugs in Germany is complicated by the contrasting decision-making methodologies and criteria employed by G-BA and InEK. To achieve inpatient reimbursement outside of the current DRG scheme, manufacturers must meet InEK's criteria, justify their drug's cost-differential, and ensure all hospitals apply annually with an identical application text in well-written German.

Abbreviations: ATMP: advanced therapeutic medicinal product; DRG: diagnostic-related group; G-BA: Federal Joint Committee (Gemeinsame Bundesausschuss); HTA: health technology assessment; InEK: Institute for the Hospital Remuneration System (Institut für das Entgeltsystem im Krankenhaus); MA: marketing authourisation; NUB: New Examination and Treatment Methods (Neue Untersuchungs- und Behandlungsmethoden); QoL: quality of life; S.D.: standard deviation.

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