G-BA vs. InEK: Navigating divergent requirements between the two key bodies behind inpatient drug reimbursement in Germany

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Introduction

In Germany, there are two national bodies that determine the pricing and reimbursement of inpatient drugs. The G-BA conducts an HTA that precedes a price negotiation, whilst InEK establishes the price and funding route (e.g., via NUB). This research explores the relationship between the G-BA and InEK in driving successful pricing and reimbursement outcomes.

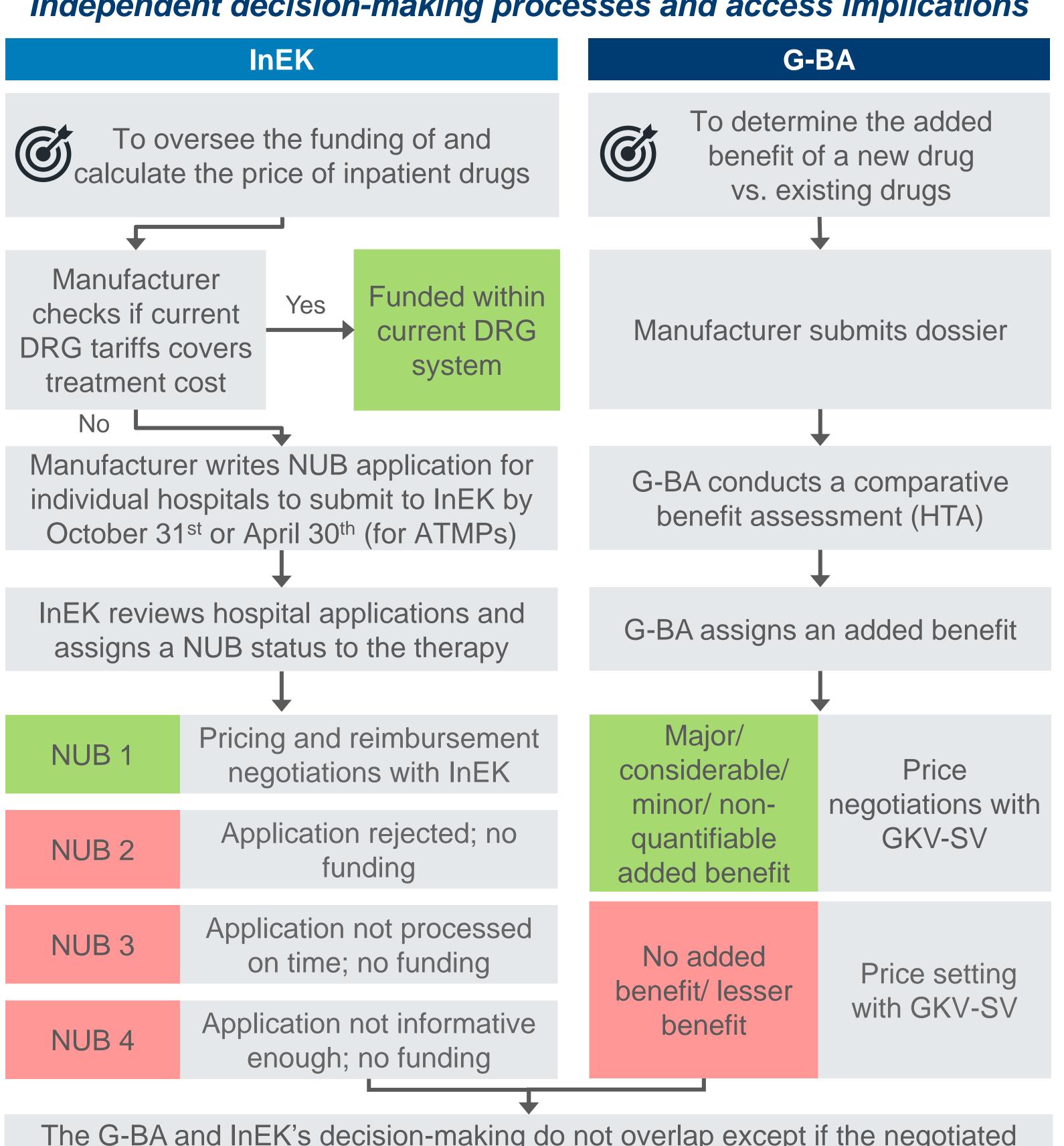
Methods

A quantitative analysis of inpatient drugs in the 2022 NUB list plus a 60minute 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 be aware of and successful in utilizing both pathways to optimize reimbursement and uptake of inpatient drugs.

Independent decision-making processes and access implications



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



"If you have a high-cost drug that is significantly over the DRG, then it's very unlikely that a hospital will buy it, unless it's absolutely necessary like a life-saving drug for newborn babies." - DE payer

Differing decision-making criteria

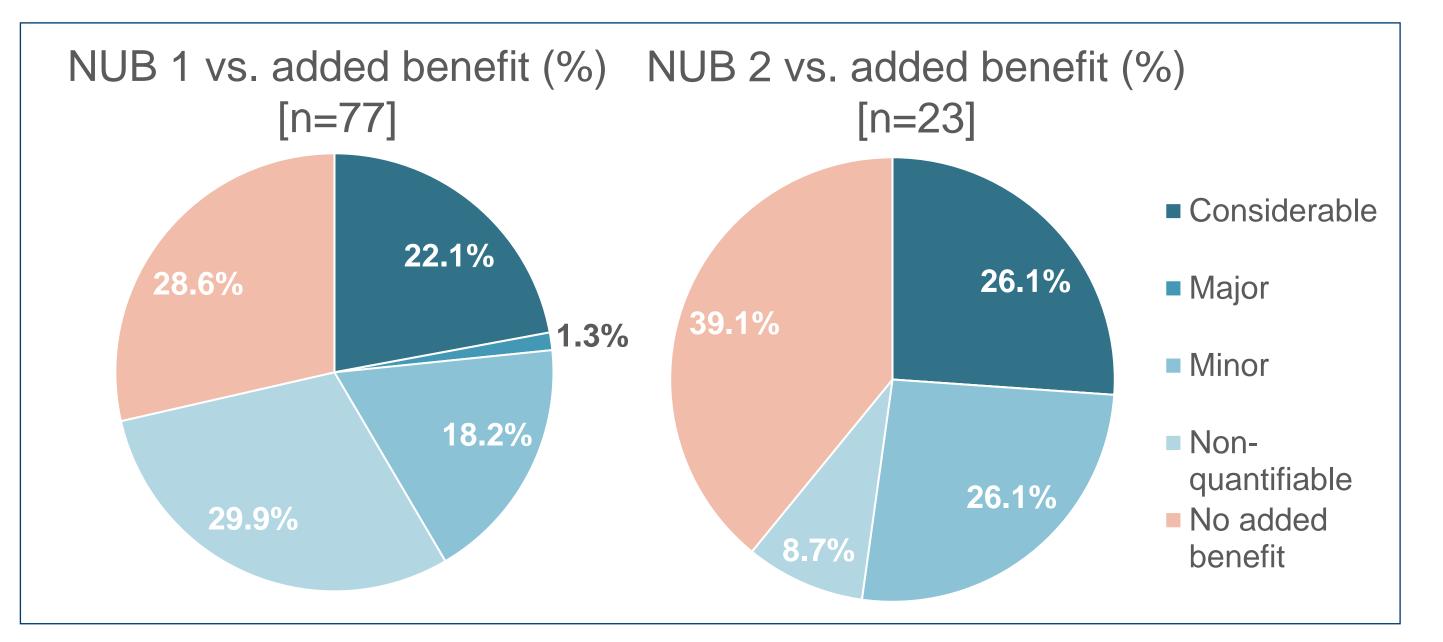
Criteria	InEK	G-BA
Supporting a positive outcome	 Drug is considered new (MA granted in last 4 yrs) 	 Additional clinical benefit is demonstrated via patient-relevant outcomes and validated QoL measures vs. a relevant comparator
	 Cost differential vs. DRG, generally 1 S.D. over DRG 	
	 Added costs vs. DRG are clearly justified 	
Risking a failed 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

"Manufacturers are encouraged to be transparent about high development costs and treatment complexities, e.g., stem cell harvesting. If the treatment is very expensive and for a lot of patients, an extra good application is required." - DE payer

Discrepancies in NUB vs. HTA outcomes (2018 – 2022)

100 NUB outcomes were identified: 77% achieved NUB 1 and 23% received NUB 2. Of these, 69% received an added benefit and 31% received no added benefit. Notably, there were discrepancies between favourable outcomes by InEK vs. the GBA: 29% of therapies with NUB 1 received no added benefit, but 61% of therapies with NUB 2 received added benefit.



Conclusions

The contrasting decision-making processes complicate patient access to inpatient drugs in Germany, with the G-BA and InEK performing their assessments according to different criteria. To secure inpatient reimbursement following the G-BA's HTA, manufacturers must also ensure they meet InEK's criteria, assess and justify their drug's cost-differential, prepare a well-written submission, and ensure all hospitals apply annually with the same application.

Abbreviations: ATMP: advanced therapeutic medicinal product; DRG: diagnostic-related group; EMA: European Medicines Agency; 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.