

HOSPITAL REIMBURSEMENT PATHWAYS FOR NEW EXAMINATION AND TREATMENT METHODS IN GERMANY

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Background

The German health care system is characterized by a sectoral division into an outpatient and an inpatient sector with separate reimbursement mechanisms. For new examination and treatment methods (German: Neue Untersuchungs- und Behandlungsmethoden, NUB) within the hospital sector, several reimbursement pathways have been created in recent years. The aim of this research is to provide a quantitative overview of success rates for inpatient NUB reimbursement pathways, including market access acc. to § 137e German Social Code V (SGB V) (Testing of Examination and Treatment Methods) and § 137h SGB V (Evaluation of new Examination and Treatment Methods with Medical Devices of High Risk Class) as well as extrabudgetary NUB payments, which are temporary payments to bridge the reimbursement gap until new technologies are included in the German DRG system.

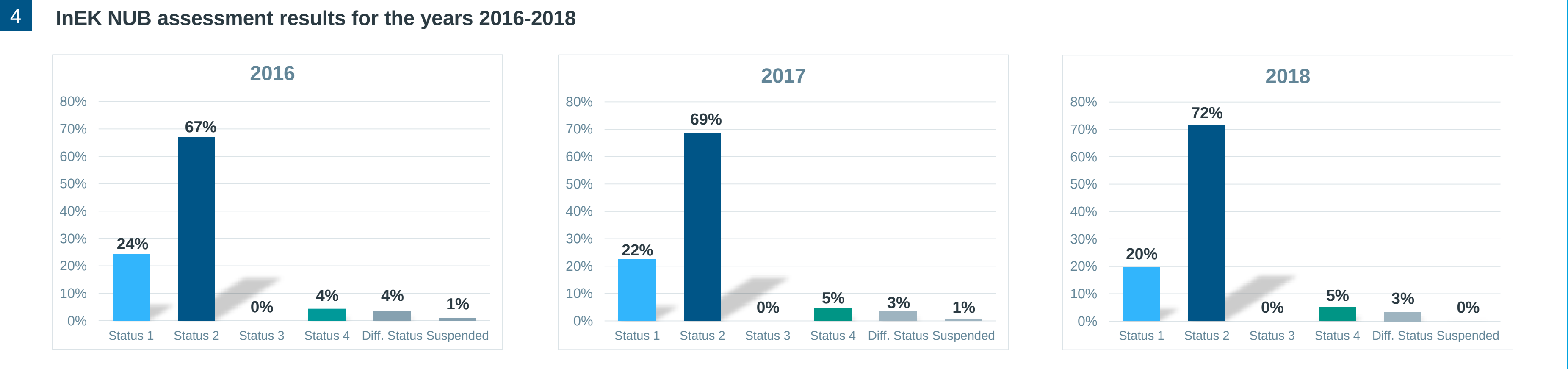
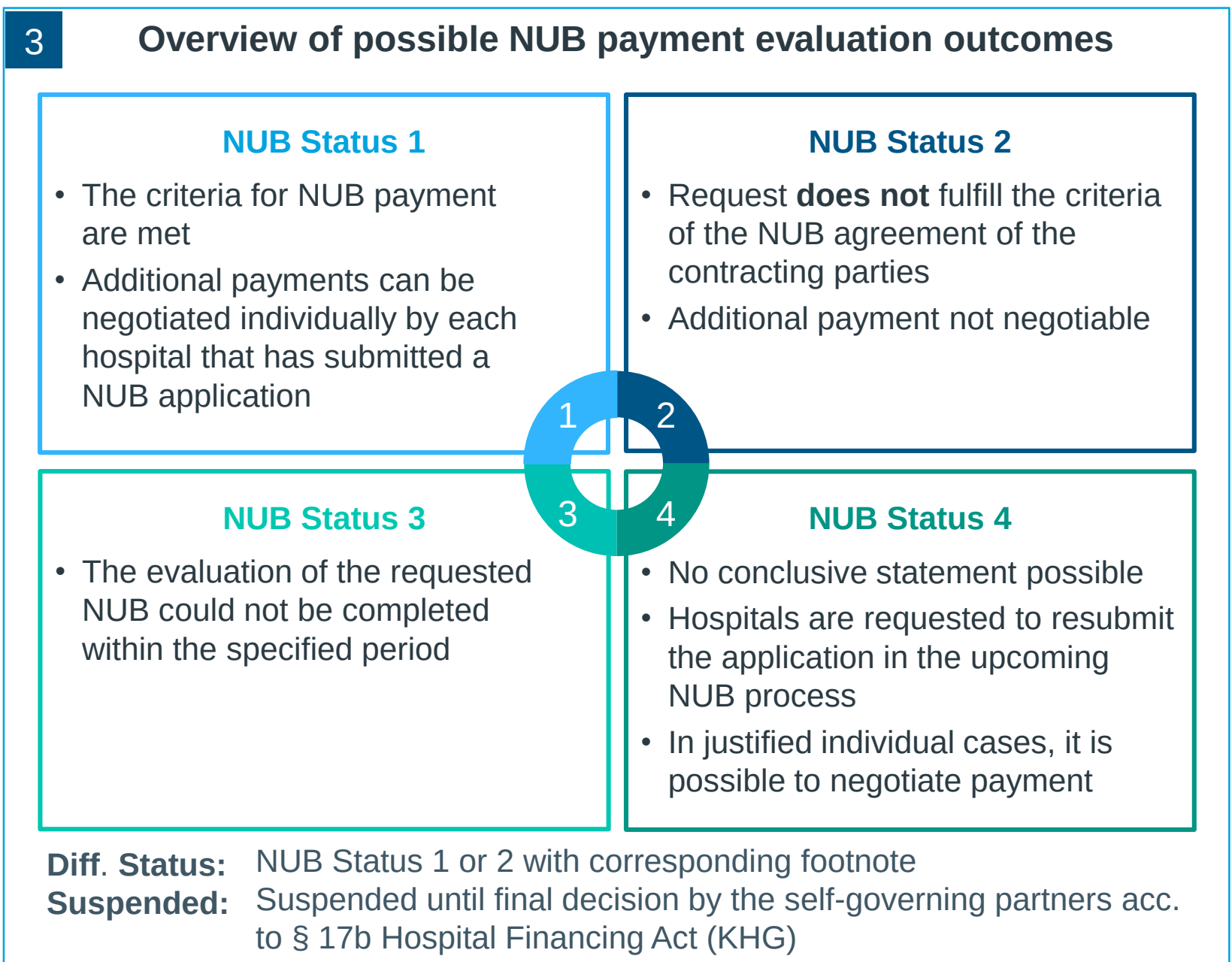
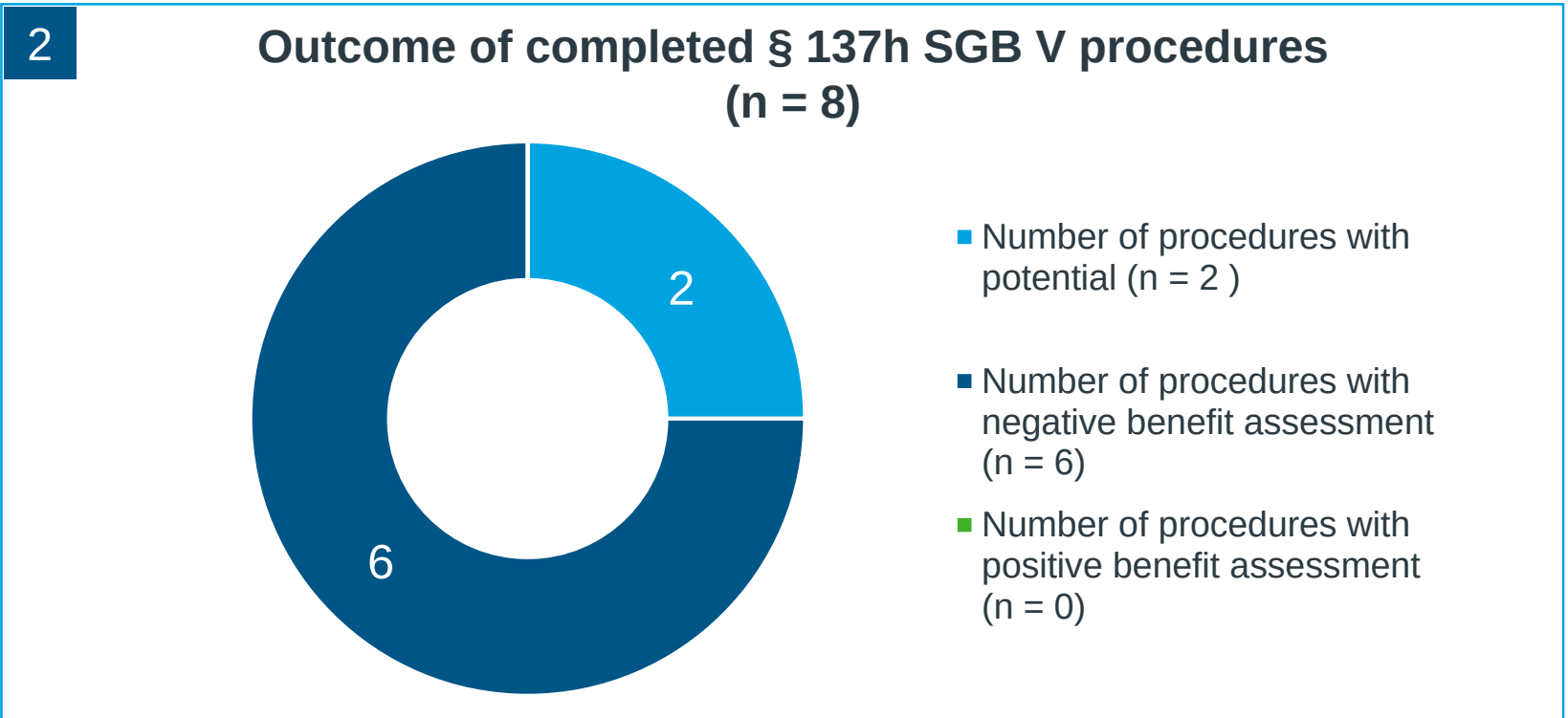
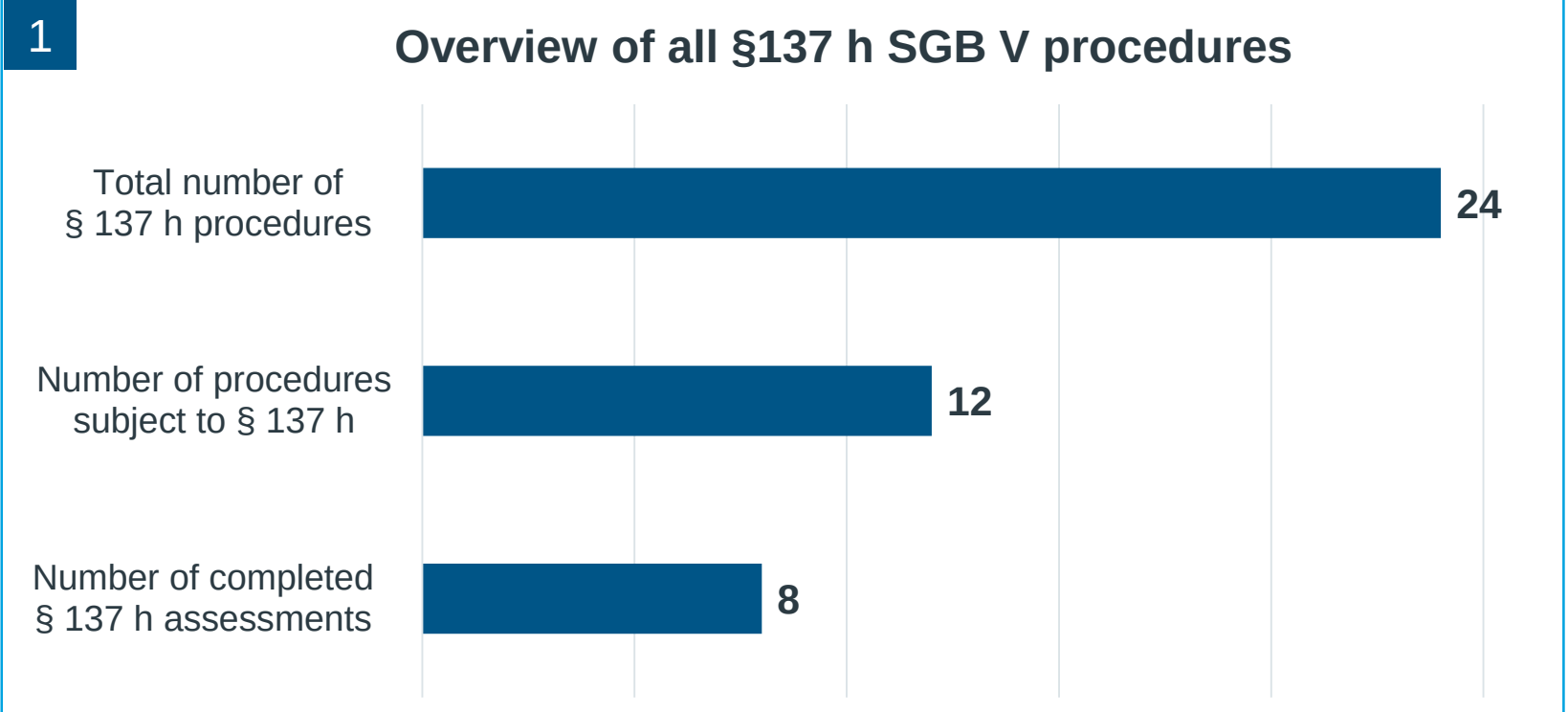
Methods

Decisions publicly available on the website of the Joint Federal Committee (German: Gemeinsamer Bundesausschuss, G-BA) up to September 12th 2019 were analyzed descriptively for all existing § 137h procedures and testing guidelines pursuant to § 137e SGB V. Furthermore, the outcomes of all NUB payment applications submitted to the Institute for the German Hospital Reimbursement System (InEK) between 2016 and 2018 were evaluated. Data were screened and analyzed by two individual reviewers.

Results

Out of 24 procedures for medical devices listed under § 137h benefit assessment, twelve (50%) met the requirements to be subject to § 137h SGB V [1]. Assessment was completed for eight (66,7%) of the twelve procedures (Figure 1). None of the procedures was given a benefit. Six (75%) received a negative benefit rating, which entails the risk of a general exclusion from reimbursement in Germany by the G-BA acc. to § 137c SGB V. “Potential” was assigned to two procedures (25%), both indicated for oncological diseases (Figure 2). Regarding the § 137e procedures, the G-BA approved six testing guidelines, none of which resulted from a previous § 137h assessment [2].

Of the NUB applications submitted in 2016, 139 out of 710 (19.6%) received NUB status 1 which enabled them to negotiate an extrabudgetary NUB payment. In contrast, 472 (67.0%) were assessed with NUB status 2 and could not negotiate additional NUB payment (detailed information on possible evaluation outcomes of the InEK and their implications are provided in Figure 3). In 2017, 154 (22,4%) of the 686 applications received NUB status 1 and 471 (68.7%) NUB status 2. In 2018, 171 (24,3%) of the 705 applications fulfilled the criteria for NUB status 1, 427 (67.0%) were rated NUB status 2 (Figure 4). Out of the 171 applications rated with NUB status 1 in 2018, 57 (33.3%) were medical devices [3]. So far, no significant influence of § 137h SGB V has been observed on the number of applications submitted for an extra-budgetary NUB payment and their evaluation results.



Key Findings

The chances of success for NUB reimbursement pathways in the inpatient sector are rather moderate and hold many hurdles for the manufacturer. Only an average of 20% of the NUB applications between 2016-2018 received NUB status 1 and none of the § 137e and § 137h procedures had a positive outcome so far. Especially for market access acc. to § 137h SGB V high evidence is required for a positive benefit assessment and successful reimbursement. A negative benefit assessment can lead to a general exclusion from reimbursement in Germany. Thus, a well-prepared market access strategy is essential.

Sources

- [1] G-BA (2019a): Procedures according to § 137h SGB V. URL: <https://www.g-ba.de/informationen/verfahren-137h>. Last access date: 12.09.2019.
[2] G-BA (2019b): Guidelines method assessment. URL: <https://www.g-ba.de/richtlinien/zum-unterausschuss/5/>. Last access date: 30.08.2019.
[3] InEK (2019): InEK Institute for the German Hospital Reimbursement System. URL: <https://www.g-drg.de/>. Last access date: 17.09.2019