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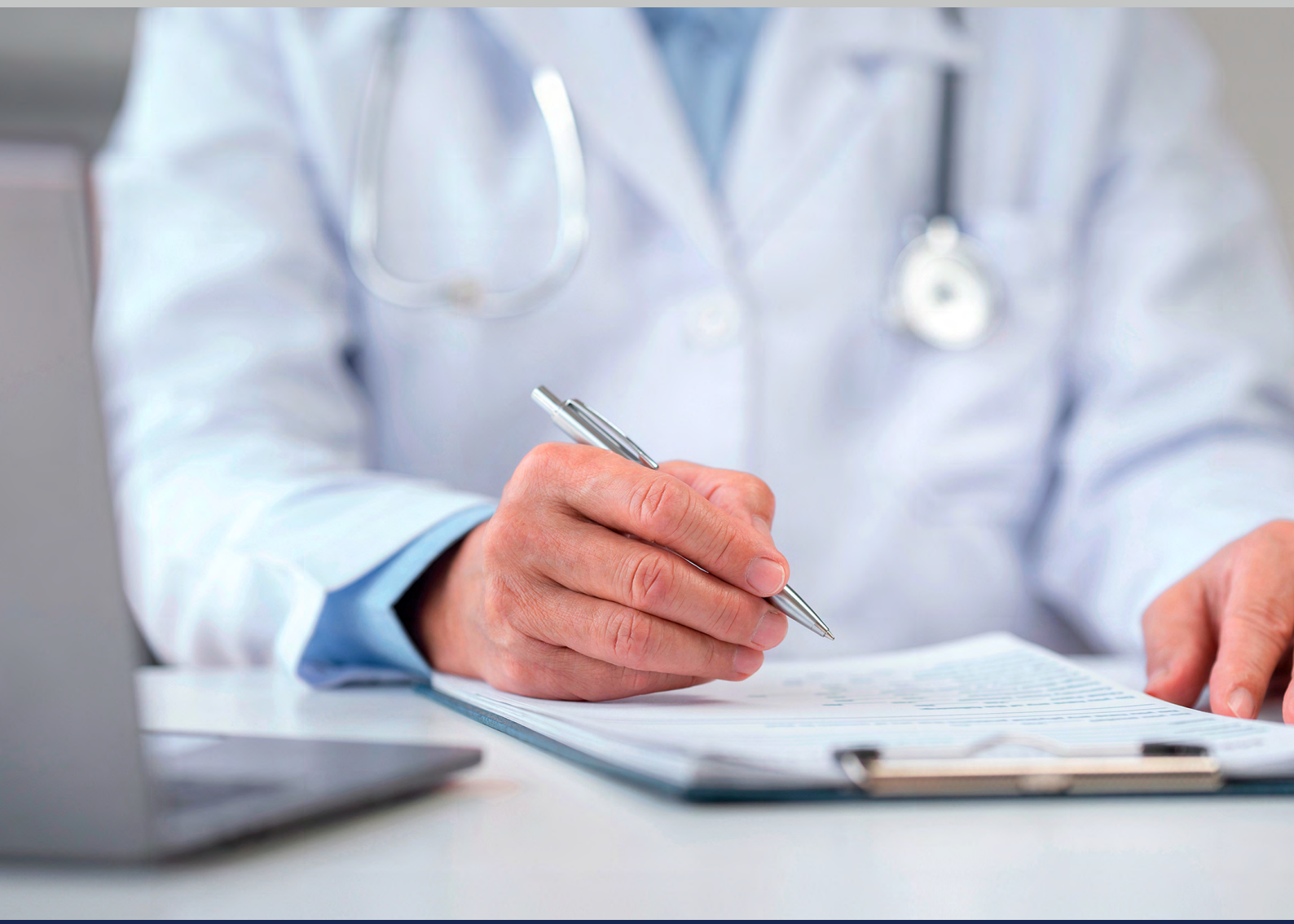

The German NUB proposal process

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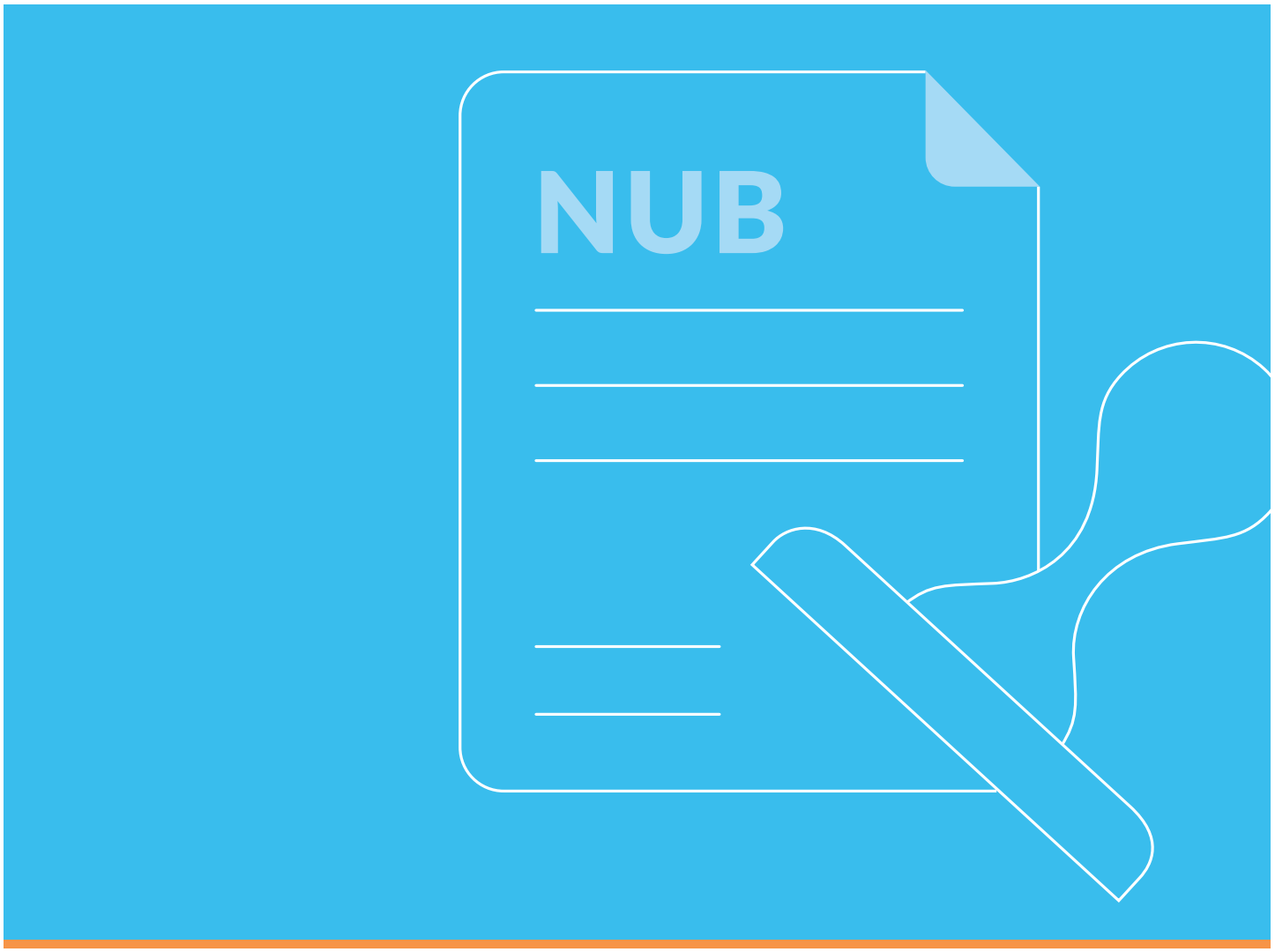
WHITEPAPER

The German NUB proposal process

The proposal process for new examination and treatment methods in the in-patient sector in Germany



1. Executive Summary

The NUB process is a proposal process organized by InEK which examines whether German hospitals can negotiate an additional payment for new examination and treatment methods with the payers.

The proposal process is executed annually for the following year, from the beginning of September to the end of October. In the context of this process, InEK proves whether the requested method is "new" and whether it is "not sufficiently reimbursed"[1] via the G-DRG-system.

In addition to the examination of these two criteria by InEK, the Joint Federal Committee (Gemeinsamer Bundesausschuss; G-BA) also conducts a benefit assessment under certain requirements for methods performed with products of high-risk classes.

Although the industry is not officially involved, the industry's participation in the NUB process by supporting hospitals with relevant information and a smart proposal management is, in our view, of great importance for the success of the proposal and the market acceptance of the respective products. In addition to formal criteria, the evaluation of NUB proposals also takes into account economic and linguistic aspects that require expert knowledge in the preparation of proposals.

The NUB process offers great opportunities in the context of Market Access of new medical devices – but it might also carry immense risks. The medical device industry should take the chance to participate in this complex issue, making it essential to take advantage of the opportunities to be supported by competent local consultants, ideally as part of a Market Access strategy.

1 The exact German wording is "sachgerecht". In this paper, we will use the translation "sufficiently"; according to our understanding, this translation reflects the meaning most explicitly to the reader. In its report of 2006, InEK uses "appropriately" for the translation of "sachgerecht". However, the understanding of this translation requires specific knowledge of the G-DRG-system of the reader.

2. What is a NUB?

NUB is the German acronym for „Neue Untersuchungs- und Behandlungsmethode" which can be translated as "new examination and treatment method".

New examination and treatment methods can occur in the out-patient or in-patient sector. This refers to innovative diagnostic or therapeutic methods that seek entry into regular healthcare.

While new examination and treatment methods in the out-patient sector require a positive assessment of the existing evidence in the context of a benefit assessment, the remuneration for NUB in the in-patient sector can be achieved via a proposal process at InEK which is based on sec 6 (2) KHEntG.

For this process, the term "NUB proposal process" has become established exclusively for the in-patient sector.

This whitepaper deals exclusively with the NUB proposal process for the in-patient sector in Germany.

3. The NUB proposal process

3.1 What is the NUB proposal process?

In 2004, the NUB proposal process was introduced allowing hospitals to negotiate an individual Reimbursement with the payers for new examination and treatment methods that are not yet sufficiently reimbursed via the G-DRG-system.

According to sec 6 (2) KHEntgG, hospitals should be able to negotiate temporary additional payments for new examination and treatment methods with the payers. Hospitals must appropriately calculate the Reimbursement for these procedures themselves and agree on them with the payers, typically as part of the budget negotiations. The contracting parties at the federal level (which means payers and hospital federations) authorized InEK to handle the NUB proposal process as the representative.

In the context of this process, individual hospitals can submit a NUB proposal to InEK by the end of October each year. If InEK confirms that the requested procedure is „new“ and „not sufficiently reimbursed“, InEK assigns the so-called NUB status 1. With this status 1, hospitals who submitted a proposal to InEK by October 31, can negotiate a Reimbursement for the method with the payers for the following year.

In the context of the NUB proposal, information on the applicant (the hospital), the respective examination or treatment method, encoding OPS-codes, Reimbursement, innovation and the cost of the method will be transmitted to InEK. Based on this information, InEK decides whether the respective method is “new” and whether it is still “not sufficiently reimbursed” via the G-DRG-system.

The result of the InEK decision is assigned to each requested method via the so-called “NUB status”. The following NUB statuses are available[2]:

NUB status 1:
Status 1 will be assigned if the proposal meets the requirements. Status 1 corresponds to a positive decision and hospitals are eligible to negotiate a NUB fee for the requested method with the payers (desired result).

NUB status 2:
Status 2 is assigned if the requested method does not meet the criteria for a NUB.

NUB status 3:
Status 3 is assigned if the proposals could not be completely processed by InEK within the deadline.

NUB status 4:
Status 4 is assigned if the forwarded information in the proposal was implausible or incomprehensible.

The validity of the NUB payments is limited to one year. This means that a successful NUB proposal has to be submitted by the hospitals each year in order to be able to re-negotiate a Reimbursement in the following year, until an appropriate Reimbursement has been established in the G-DRG-system. In addition, the annual cycle of the pro-

2 https://www.g-drg.de/aG-DRG-System_2021/Neue_Untersuchungs-_und_Behandlungsmethoden_NUB/Aufstellung_der_Informationen_nach_6_Abs._2_KHEntgG_fuer_2021

posal process may also offer the opportunity to improve the outcome of the InEK evaluation with a modified NUB proposal (status 4 or 2 to status 1).

3.2 Why is the NUB proposal process necessary in Germany?

Any new method used in German hospitals can be billed via a DRG („permission with prohibition reservation“) with the payers. The requirement is the approval of the method (CE mark) and that the method has not been excluded from Reimbursement by the G-BA. If there is no specific OPS-code for the method yet, there is always a non-specific OPS-code available. This means that, already with the introduction of a new method, a Reimbursement via the G-DRG-system exists; however, this may be too low and does not sufficiently reimburse the method.

In Germany, it takes at least three years for an innovative therapy to access the G-DRG-system via the regular procedures of the so-called „structured dialogue“ (application for a specific OPS-code, via the regular calculation of the InEK, etc.). In order to bridge this so-called „innovation gap“, the NUB proposal process has been introduced.

For examination and treatment methods which are on the one hand new and on the other hand not yet sufficiently reimbursed via the G-DRG-system, the negotiation of a Reimbursement – outside the G-DRG-system – between hospitals and payers is allowed, based on the NUB proposal process.

The NUB proposal process thus closes the above-mentioned innovation gap that emerges from the introduction of new methods until their appropriate representation and sufficient Reimbursement in the G-DRG-system.

HcH Top Tip:

Are you unsure whether the NUB proposal process is relevant for you? Contact an expert with the appropriate experience to clarify the requirements in advance.

3.3 How does the NUB proposal process work?

In the context of the NUB proposal process, individual hospitals can submit a NUB proposal to InEK by the end of October each year. The application must be submitted electronically to InEK. The InEK data portal is available for this purpose. After the proposal submission in due time and formally correct, the proposals are screened and assigned to the different treatment categories. All proposals for a therapy category are used jointly for the assessment. Relevant for the assessment is whether the respective therapy is „new“ and whether it is „not sufficiently“ reimbursed via the G-DRG-system. On the one hand, InEK uses the information provided on the therapy and procedure in the NUB proposal and on the other hand, information on therapies and methods already available in the InEK or all information that is available to InEK as part of the G-DRG development, are used.

As part of the assessment at InEK, each proposal is assigned an analysis result, a so-called NUB status.

The InEK submits the assessments to the self-governing bodies for decision. At the end of the process, applicants (hospitals) will be informed on the results and, at the end of January of the following year, the therapy categories with the associated status will be published on the website of InEK.

HcH Top Tip:

The NUB proposal process is a regulated application procedure and can be well planned in advance. A good preparation takes time – so let yourself be expertly supported in the planning of your NUB proposal.

4. The NUB- proposal

4.1 Who can apply for NUB?

A NUB proposal cannot be collected and submitted by several hospitals for one method, but only submitted by each individual hospital that wants to use the new method. It varies from hospital to hospital, in some cases from department to department, whether a NUB proposal is submitted by medical controlling or by physicians. In any case, coordination between physicians and administration is necessary. The industry or consultants authorized by the industry can support this. In many cases, NUB proposals are prepared by consultants authorized by the industry and provided to hospitals.

HcH Top Tip:

Find an expert consultant with a good network to the hospitals who can support you in the strategic preparation and the administration of the NUB proposal process.

4.2 How to submit a NUB proposal?

In order to participate in the NUB proposal process, a NUB proposal must be submitted to InEK which set up a data portal for this purpose.
https://daten.inek.org/DataPortal/

This data portal is used to communicate with InEK, i. e. for the submission of proposals and data by the applicants (hospitals) to InEK.

A NUB proposal can only be submitted by hospitals. However, it has proved its worth that consultants prepare NUB proposals on behalf of the industry and provide them to the various hospitals. After completion with the hospital-specific data (contact data, etc.), the hospitals can then conveniently submit the NUB proposal via the data portal.

Typically, the NUB proposal process starts in the beginning of September each year and ends on October 31 (deadline). Methods for which a NUB proposal has been submitted in due time and formally correct will be published by InEK in the following year on the basis of sec 6 (2) KHEntgG on the website of InEK. *https://www.g-drg.de/*

4.3 Is the timely submission of a NUB proposal sufficient to achieve NUB status 1?

Based on our 15 years of experience regarding NUB, in the self-governmental bodies as well as in the industry, we do not consider the exclusive proposal submission to be sufficient.

The reasons for this are manifold and require a differentiated analysis in individual cases.

- According to our understanding, the assessment for NUB at InEK itself must be considered. All NUB proposals submitted to InEK are screened or categorized via the data portal. This allows a joint review and assessment of all proposals concerning the respective method. On the one hand, this ensures that all proposals for an identical method also receive the same assessment, regardless of whether the content of the proposals is the same or not. On the other hand, this means that a method may receive NUB status 2 or 4 if the proposals differ in the data relevant for the assessment.

- It must be pointed out that the different submitting persons of the different hospitals – in some hospitals the proposals are submitted by physicians, in others by the medical controlling – have different interests, different knowledge about the methods and data to be submitted and possibly also about the NUB process itself. As a consequence, this can lead to proposals for identical methods being submitted with very different information or with prepared information being subsequently modified and, despite careful preparation, can even be submitted incorrectly to InEK.

- It should be noted that not products are evaluated with the NUB proposal process but examination or treatment methods. This means that different companies with different products (used for an identical method), different interests, different costs, and possibly even different indication areas support the submission of NUB proposals for the same method with different proposals.

HcH Top Tip:

Take the opportunity to increase the chances of success of your NUB proposal by a smart management. We recommend managing the NUB process by experts with experience and to prepare the relevant information in an appropriate manner for all parties involved.

- The risk class of the medical device also plays an important role in answering this question. There are additional requirements for medical devices of high-risk classes. An „agreement“ between the hospital requesting the NUB and the company of the medical device is required and information prepared as a dossier must be submitted to the G-BA for examination. This process is relatively new and not all persons involved in the submission of a NUB proposal are aware of this fact and the possible consequences.

- Additionally, it is unclear which information is exchanged between G-BA and InEK and how these different processes influence each other. The first NUB proposal process according to para 6 sec 2 sentence 3 KHEntgG (the process described in this Whitepaper) for the use of a medical device with a high risk class needs more time and preparation. Hospitals should not pass this process without any support of the medical device manufacturer.

- Furthermore, the success of a NUB proposal includes not only the assessment with status 1, but also the successful negotiation of a NUB payment in the hospital in the course of time. Experience shows that negotiation with the payers is another challenge for hospitals.

As a result, this means that a correct and in time submitted NUB proposal is a necessary prerequisite for its successful assessment with NUB status 1, but also the entire process of proposal preparation, submission, and communication – e.g. hospitals, medical societies and InEK – up to the negotiation of the NUB payment should be organized and accompanied.

5. Further relevance of the NUB proposal process

5.1 Which role does the industry play in the NUB proposal process?

The industry plays a significant role in the NUB proposal process, even if it is not formally involved in the proposal process. On the one hand, some self-governmental bodies are sensitive when they have the impression that NUB proposals are supported by the industry. On the other hand, in our opinion, the NUB proposal process cannot be conducted without the support of the industry.

The self-governmental bodies are in parts critical concerning the involvement of the industry because of its potential interdependence with economic interests. There is a fear that economic rather than clinical reasons could ultimately play a role in indication identification. Since the evaluation of InEK is subject to approval by the self-governmental bodies, this aspect is relevant for the proposal process. InEK itself uses very differentiated formulations for the presentation of the factual and data situation and availability, which can almost be described as an "own language". A good proposal should therefore take these linguistic specificities into account in order to communicate the information as clearly as possible to InEK.

Furthermore, in some cases, the industry plays a role in the benefit assessment by the G-BA in accordance with sec 137 h (1) SGB V.

HcH Top Tip:

A good NUB proposal is characterized by a differentiated presentation of the relevant information. A NUB proposal is much more complex than "only" ticking the right boxes. Therefore, have your proposal supported by experienced consultants who master the linguistic intricacies and differentiations of the "InEK language".

This procedure is linked to the NUB process at InEK but is separate from this organization and content and concerns only a few methods. The G-BA conducts a benefit assessment in certain circumstances for methods using high-risk medical devices based on a "new theoretical-scientific concept". In this respect, the requesting hospitals are obliged to an "agreement" with the company of the products concerned. As part of the G-BA process, the respective companies are also given the opportunity to transmit information on the product or the method to the G-BA themselves.

HcH Top Tip:

There has to be an "agreement" between the hospitals and the manufacturers which assigns a new and important role to the medical device industry. Check together with an experienced consultant whether your product is classified as high-risk, whether your evidence meets the requirements and what information you need to provide to hospitals before starting the NUB .

5.2 What is the significance of the method's benefit and the risk class of the medical device for the NUB proposal process?

Unlike the benefit assessments according to sec 137h SGB V at the G-BA, the benefit as well as the risk class of the method do not play a role in the NUB process pending in the InEK according to sec 6 (2) of the KHEntgG.

In accordance with the legal requirements according to sec 6 (2) KHEntgG, the NUB proposal process does not distinguish the methods neither regarding benefit nor regarding risk class of the underlying medical device. The status that InEK assigns refers to the method – regardless of the specific medical device used and a possible proof of benefit. Both parameters, benefit and risk class, have only become relevant later in an additional process separate from the NUB proposal process by InEK.

The law "GKV-Versorgungsstärkungsgesetz" (GKV-VSG, 2015) linked for the first time a benefit assessment for high-risk medical devices with a NUB proposal process due to the introduction of sec 137h SGB V. As a result, since the NUB proposal process for 2017, hospitals have been obliged, under certain conditions, to provide information on the current state of scientific knowledge to the G-BA next to the NUB proposal submitted to InEK. Based on our experience, not every responsible person in the hospitals is aware of this relatively new situation. This means that individuals in hospitals can trigger a benefit assessment of certain medical devices.

Due to the organizational separation of the NUB proposal process at InEK and the benefit assessment at the G-BA and the different legal bases of both procedures, there is no overlap in the content of the assessments. What applies for the InEK NUB proposal process is not transferable to the G-BA assessment and vice versa. Only the careful consideration for individual cases can lead to an assessment of the extent to which one method meets the conditions of one process and the other.
Frivolously conclusions, into one direction or another, may have a very negative impact on further market launches.

The G-BA first checks whether the method meets the conditions for a benefit assessment. Which methods are covered by the benefit assessment depends on the risk class of the underlying medical device and on whether the G-BA classifies the method as a "new theoretical-scientific concept". The specific requirements are regulated in the prescription "Medizinproduktemethoden-Bewertungsverordnung" (MeM-BV).

HcH Top Tip:

The G-BA and InEK have different standards as to what exactly constitutes a NUB. If you want to clarify the importance of the different valuation standards for your product, you should consult external expertise with knowledge of the German self-governmental bodies.

If the conditions are met, the G-BA shall conduct a "rapid benefit assessment" (3 months) for the method on the basis of the documents submitted. This benefit assessment by the G-BA carries the potential risk that the method will be excluded from the GKV's catalogue and thus no longer is reimbursed by the payers – or, in the case of unclear benefits, the G-BA will perform a "trial study" at the expense of the product company.

Therefore, the benefits of the method and the risk class may have a decisive impact on the future of a medical device – if a NUB proposal is submitted.

For certain methods or medical devices, therefore, the decision on whether to submit a NUB proposal has an immense significance for the future of a medical device.

At present, however, there are hardly any opportunities for medical device manufacturers to participate in the organization of the G-BA application process.

HcH Top Tip:

Assessing whether a method is affected by the G-BA benefit assessment and, if so, what benefits and risks this entails, requires a reliable and detailed analysis. Advice from an expert on the German healthcare system with expertise in the medical-scientific field is urgently recommended here.

5.3 Which role plays evidence?

In principle, the evidence does not play a role in the assessment of NUB proposals at InEK. No evidence is necessary for a successful proposal process[3].

It should be pointed out that in the in-patient sector, following the principle of "permission with prohibition reservation", all methods are reimbursed via the G-DRG system – without prior benefit assessment.

As explained in the previous chapters, from the point of InEK's view, it is a question – after proposal submission by the hospitals – to check whether a method is so new that it is not yet sufficiently reimbursed via the G-DRG-system, so that hospitals can negotiate a payment with the payers. The basis for this is sec 6 KHEntgG, which makes no reference to the evidence, although the various quality criteria set by SGB V must be met for in-patient treatments (which is not assessed by InEK). However, the NUB proposals are submitted by the hospitals – and therefore by different persons. Under certain circumstances, these attach importance to supporting only NUB proposals for methods for which sufficient evidence already exists, and this must be examined in good time.

Furthermore, hospitals have to negotiate the Reimbursement for the corresponding NUB with the payers first. In many cases, the negotiation on the payers' side is prepared by the MDS and at least payers internally may have an evidence dossier on the method. It has proved its worth that the medical industry is offering hospitals evidence of the method, so that hospitals are also prepared for negotiation at this point.

For methods performed with products of higher risk classes and based on a new theoretical-scientific concept, the G-BA benefit assessment requires that existing evidence be submitted in the form of a dossier. However, this process is executed separately from the NUB proposal process at InEK.

Evidence is never necessary in the context of the NUB process at InEK and is rarely necessary in the benefit assessment at the G-BA. However, evidence is always helpful.

HcH Top Tipp:

Discuss the topic of possible negotiation support for NUB payments with your consultant.

3 For medical devices of high risk classes, the G-BA requires evidence in the nUB process. This special situation is explained separately in a separate section.

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