Reimbursement system and strategies

DRG-System, NUB and Germany on coverage with evidence development (CED) for non-drug interventions.

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Innovations-strategies

New diagnostic and therapeutic methods or innovative medical devices are successful,

if there is an higher medical need in comparing of existing methods/ products and the need

> is reached with the same costs
> or is reached with lower costs
> or the need growth is bigger than the cost growth

Innovation: medical <u>and</u> economic need

Innovation hurdle?

> Increasingly no longer sufficient actuarial remuneration

> Trial regulation

> Draft of an european regulation for medical devices

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Funding overview different settings

Inpatient	All German inpatient procedures are funded through G-DRGs. A G-DRG is a lump sum payment that is supposed to cover the hospital costs during the patients entire stay, including device costs.
Outpatient	German outpatient procedures are funded under the EBM catalogue (public) or GOÄ catalogue (private).
Home care	The German Medical Aids list, *Hilfsmittelverzeichnis,* contains medical devices and other medical supplies that are to be covered for by the payers, mainly.

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Funding within Inpatient Care

Inpatient

All German inpatient procedures are funded through G-DRGs. A G-DRG is a lump sum payment that is supposed to cover the hospital costs during the patients entire stay, including device costs.

- G-DRGs are never device specific. Hence, brand specific registrations are not needed if an appropriate G-DRG already exists.

- G-DRGs are retrieved by a G-DRG-grouper by entering the patients' diagnosis code(s) (ICD-10 German Version), procedure code(s) (OPS) and some patient specific parameters, such as gender, length of stay etc.

- G-DRG reimbursement is based on historical cost data and is updated yearly by InEK, the Institute for the Hospital Remuneration System.

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Funding within Inpatient Care

- Clinical Evidence
  - There is no formal evaluation of evidence in the process of changing / updated the DRG-system.

- Innovation Funding: The German DRG system has a feature called NUB (Neue Untersuchungs- und Behandlungsmethoden) that is designed to fund new methods in the German inpatient setting. NUB facts

  - NUB approval require a certain application to be submitted to InEK.
  - Each hospital need to submit their own application.
  - An approved NUB application does not imply guaranteed funding. It only gives the hospital the possibility to negotiate an additional amount for a certain method.

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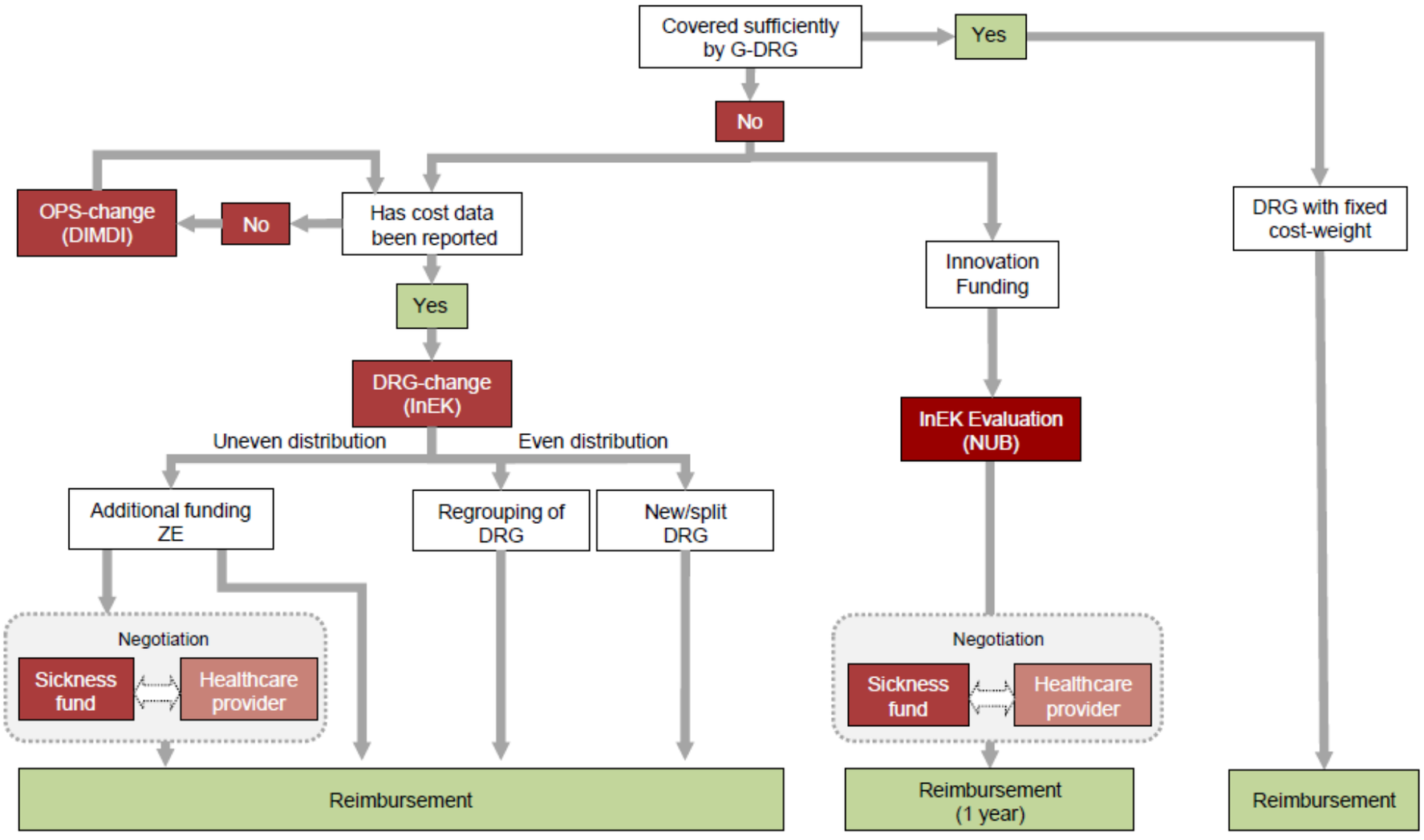
Reimbursement Pathways - Inpatient



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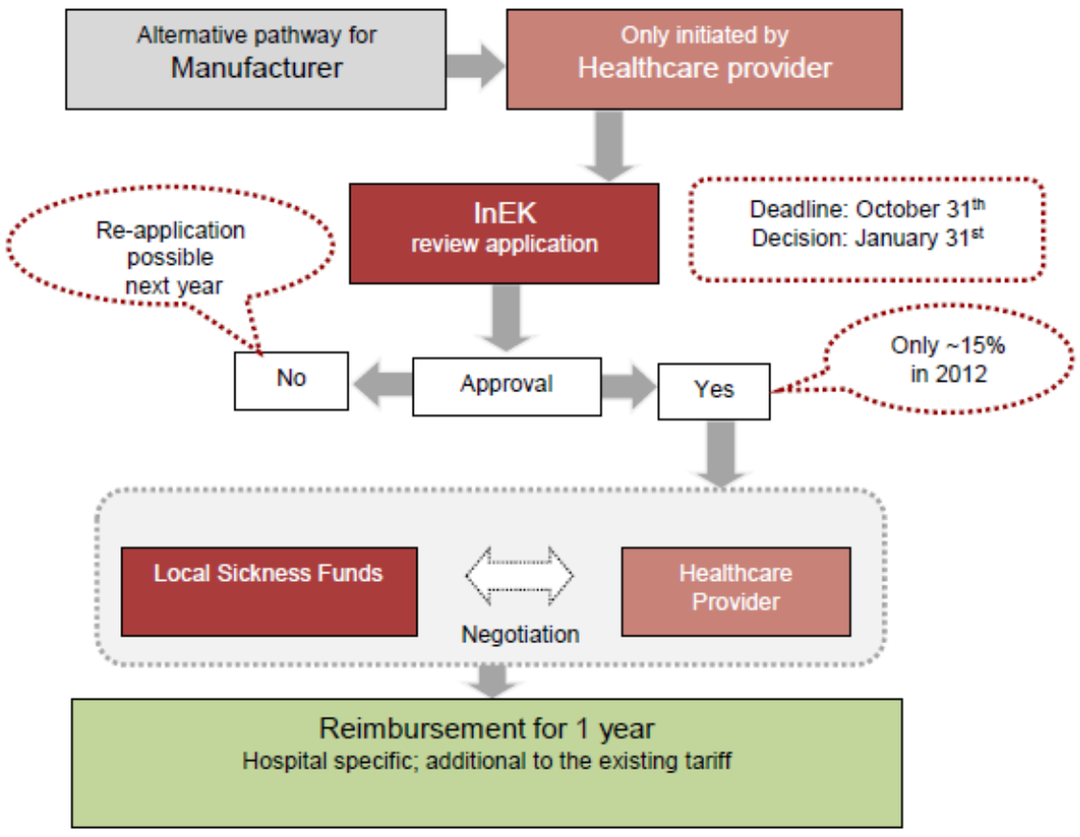
Innovation Funding - Inpatient

Neue Untersuchungs- und Behandlungsmethoden (NUB)

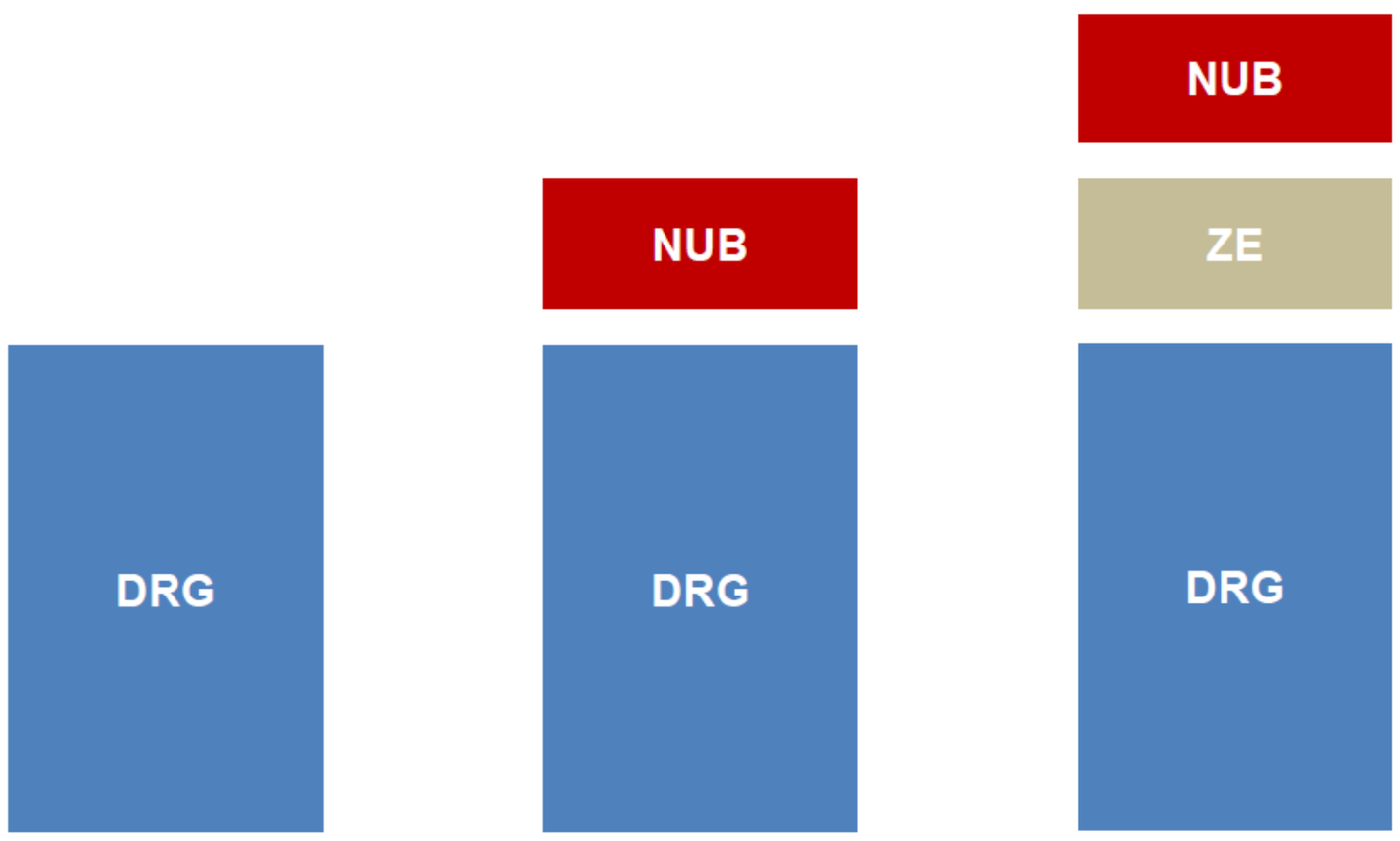


Facts of NUB arrangements
- Re-application needed each year
- Only applicable for those hospitals that apply

Some Success factors for NUB arrangements
- Understanding the criteria for approval
- Ability to appropriately answer the questions
- Submitting hospitals

Criteria for NUB arrangements
- Novelty (< 5 years)
- Suitable patient group
- Significantly higher costs (labor and material costs)

NUB is an add-on to existing payment in DRG-system



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The new CED-Legislation Framework

The German care structure law, Versorgungsstrukturgesetz (GKV-VStG), introduced a new instrument for testing examination and treatment methods with medical devices as of January 1st, 2012.

These are conducted by the Joint Federal Committee (JFC). During 2013 the JFC code of procedure was adapted and details of the new regulation were decided.

It provides the JFC with the opportunity of testing promising innovative medical technologies for a limited period of time under structured conditions with scientific monitoring.

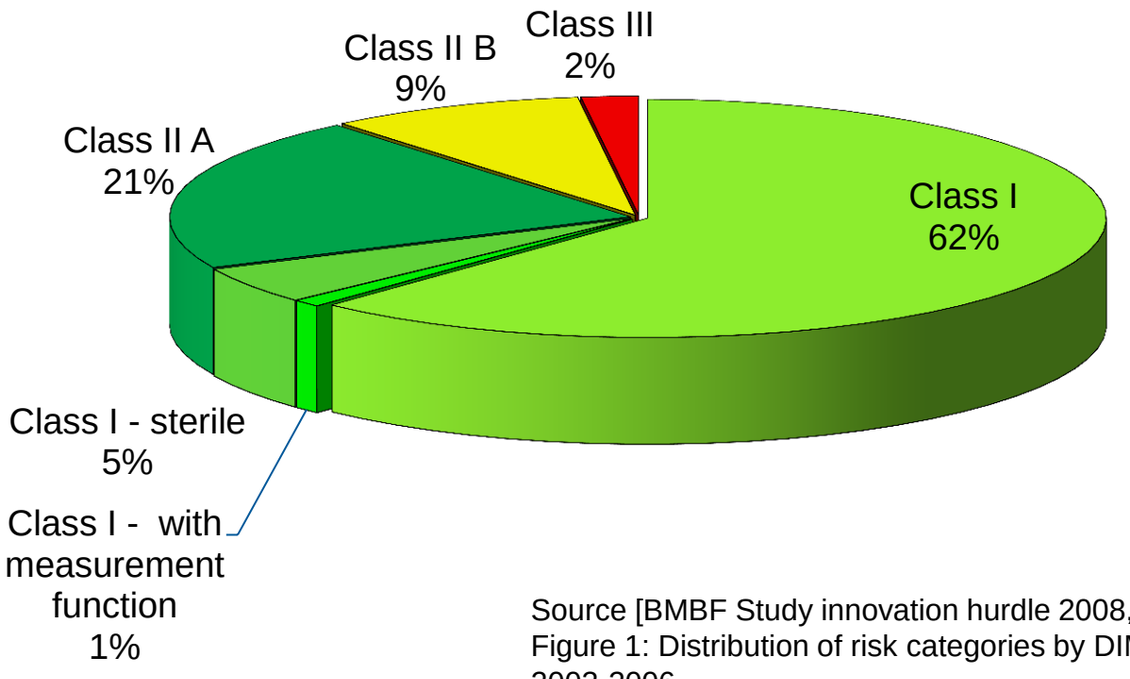
But, the costs for patient treatment incl. the MD-costs are be reimbursed by the insurances.

Challenge: Appropriate Benefit Analysis

Industry‘s proposal for further actions

Requirements according to

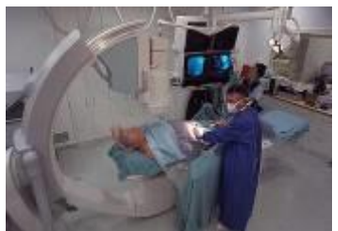
Risk class level		**and**	**modification**
Class I	low risk		> New product development (leap-innovation)
Class IIa	minor risk		
Class IIb	increased risk		> Modification (step-innovation)
Class III	high risk		> Me too (equal product)



Source [BMBF Study innovation hurdle 2008, page 12]
Figure 1: Distribution of risk categories by DIMDI 2003-2006

JFC- CED for Medical Devices ?

Bilder: GBA und Trägerorganisationen



Evaluation methods in the JFC

Different regulations in the sectors

•Contract Medical Care- Verbot mit Erlaubnisvorbehallt

Performance may only be provided at the expense of the statutory health insurance, if the JFC has taken after examination of benefits, medical necessity and viability of a positive decision.
Prohibition subject to authorization (§ 135 SGB V, Section 1)

• Inpatient care -Erlaubnis mit Verbotsvorbehalt

Benefit must always be provided at the expense of the statutory health insurance, unless the JFC has expressly pursuant to examination of benefits, medical necessity and cost-effectiveness excluded.
Authorization subject to prohibition (SGB V, § 137c)

The new CED for methods with medical devices

The experiences with the evaluation method of JFC showed, that the conditions for the acquisition of knowledge are required to improve the decision-making. The JFC will gain the possibility for future trials of innovative diagnostic and therapeutical methods with potentials within timely limited and structured conditions to gain knowledge while intermitting the evaluation method.

Source: German Bundestag, Drucksache 17/6397
July 1st, 2011

Negativ definition in the act:

The necessary potential as treatment alternative is missing especially if the JFC on the basis of available evidence decides the method is ineffective or even harmful.

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CED-Access

Access to the trial regulation can be granted through the assessment of methods conducted by the JFC if the benefit of a method has not been sufficiently demonstrated.

Alternatively, the manufacturer of a new medtech method can apply to the JFC to have the method tested. New rules were needed to give concrete form to the process.

Recomandation Deadline: Submission-Deadline April of the Year

4 Month of testing by the JFC/IQWIG

JFC: CED-Decision on September for next year (2015)

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Decision criteria

> Decision to potential within three month

> Evidence is sufficiently to accept the potential for an additional need

> The new method would be included in the context of entitlement of the SHI

> Willingness to acquisition cost of the manufacturer

Content of the dossier

> Administrative information

> Summary

> Medical devices- and methodological information

> Essential facts of the trial study (optional)

> Information about the acquisition cost

Trial study – cost order

> The **creation of the study protocol** must be paid by the manufacturer.

> The **costs of the scientific accompaniment** and evaluation of trials
must be paid by the manufacturer in an appropriate scale.

> The company can make an application of lower costs. The reduction
may be maximum 50% or 70 %.

> At first cost absorption declaration, then agreement of financing

> JFC can refuse the release of financial resources e.g. by recruiting problems

Trial study – cost bearing

Company size		SME	SME plus rar deseases
Employees [number] less than	turnover [Mio €] less than	reduction [%]	
250	**50 Mio €**	**25**	**30**
50	**10 Mio €**	**35**	**45**
10	**2 Mio €**	**50**	**70**

The new trial regulation an innovation rocket?

- ➢ Unclearly legal concepts and using by JFC
- > Cost risk of the affected companies
- > Competitive disadvantages due to missing patent protection
- > Temporally delay: creation of directive takes till 29 month years according to JFC!!! -without length of study
- > Financing subject due to limited budget of JFC