Who we are

IGES Group

The Knowledge Corporation

IGES Institute

IMC

CSG

Analysis
Development & Evaluation
Prognosis & Planning
Reporting
Communication & Publication
Consulting
Innovation

Data

Healthcare

Mobility

Service providers
Corporations

Government
Foundations & NGOs
Professional associations
Insurers

Financers

Education
1. Reimbursement Update Germany

1.1 Overview of inpatient and outpatient settings

1.2 How to maximize reimbursement on top of German DRG lump sums: the “NUB” strategy

1.3 Summary
1. Reimbursement Update Germany

1.1 Overview of inpatient and outpatient settings
Coverage principles Germany

Inpatient
Reimburseability = subject to prohibition = given, as long as no basic principles of quality of care and/or efficiency are violated

Outpatient
Reimburseability = subject to approval

Innovative medical device defining a new diagnostic or therapeutic method

European Market Approval – CE Mark

Source: Own Illustration
Reimbursement: Inpatient setting

Running costs per case

**ICD-10 GM** + **OPS** = **DRG**

- Diagnosis Codes
- Procedure Codes
- One DRG (lump sum payment) per case

Potentially applicable in addition to the DRG payment:

- **Innovation payments, new diagnostic or therapeutic methods (NUB)**
- **Extra rates (ZE)**

Source: Own Illustration
Reimbursement: Outpatient setting

- SHI Scheme
- EBM
- Regulations / Payment schemes
- Insurances
  - Health Care Providers
- KBV
  - GKV-Spitzenverband
- Initiators
- Single insurances
  - Health Care Providers
- G-BA
  - Centralized coverage decision

GKV-Spitzenverband: Federal association of statutory health insurances, KBV: GKV-registered physician association, G-BA: Joint Federal Committee, EBM: Physician Fee Schedule under the statutory health insurance scheme

Source: Own Illustration
1. Reimbursement Update Germany

1.2 How to maximize reimbursement on top of German DRG lump sums: the “NUB” strategy
The NUB process so far

- Two step approach:
  1. Application by hospitals (to the DRG institute, InEK) September / October
  2. If application approved: negotiations (individual hospital vs. insurances)

- So far: no official assessment of benefit / clinical evidence in this process

Source: Own illustration
The NUB process of the future

- “Health Care Strengthening Law” introducing §137h Social Code Book (SGB) V

  - From 2016 onwards: benefit assessment conducted by G-BA
    - For methods using... medical devices of “risk” class IIb and III or active implants with an especially invasive character ...providing a... new scientific theoretical concept ...for which a (first-ever) NUB application ...is submitted.
The NUB process of the future

If method is subject to the new process, two assessment lines apply:

1. **InEK** → **DRG-related NUB assessment** → **Reimbursement Level = NUB negotiations yes/no**
   Result by Jan. 31st

   **No communication / no interaction between InEK and G-BA**

2. **G-BA** → **Rapid Benefit Assessment** → **Coverage status = Will GKV pay for it at all?**
   Result 3 months after start of assessment

Source: Own Illustration
The G-BA NUB assessment outcomes

**Benefit proven**
Potentially official quality guideline, § 137 SGB V

**No benefit proven but attested “potential to be a necessary treatment alternative”**
Decision about testing regulation guideline, § 137e SGB V, within 6 months & “commonly” testing within 2 years & coverage decision on the basis of trial results

**Neither “potential” nor benefit proven**
Immediate decision about exclusion from SHI coverage, § 137c SGB V

Source: Own Illustration
Coverage with evidence development

Based upon § 137e SGB V, in existence since 2012

No benefit proven but attested “potential to be a necessary treatment alternative”

Decision about testing regulation guideline, § 137e SGB V, within 6 months
& “commonly” testing within 2 years
& coverage decision on the basis of trial results

Trial

Trial data

Co-funded by the relevant manufacturers (overhead costs)
German centers only
High evidence requirements expected

Federal-wide coverage decision, inpatient setting

Source: Own illustration
1. Reimbursement Update Germany

1.3 Summary
Summary

- In general, more clinical evidence required than ever
- First bricks in the wall of the inpatient „subject to prohibition“ principle in Germany
- Manufacturers have to prepare more carefully before entering the German inpatient market
- If subject to the new NUB process, clinical evidence will play a crucial role now – either existing (lacking) evidence, or evidence to be developed via the CED program