AiM

Reimbursement Update Germany

Michael Weißer, AiM GmbH

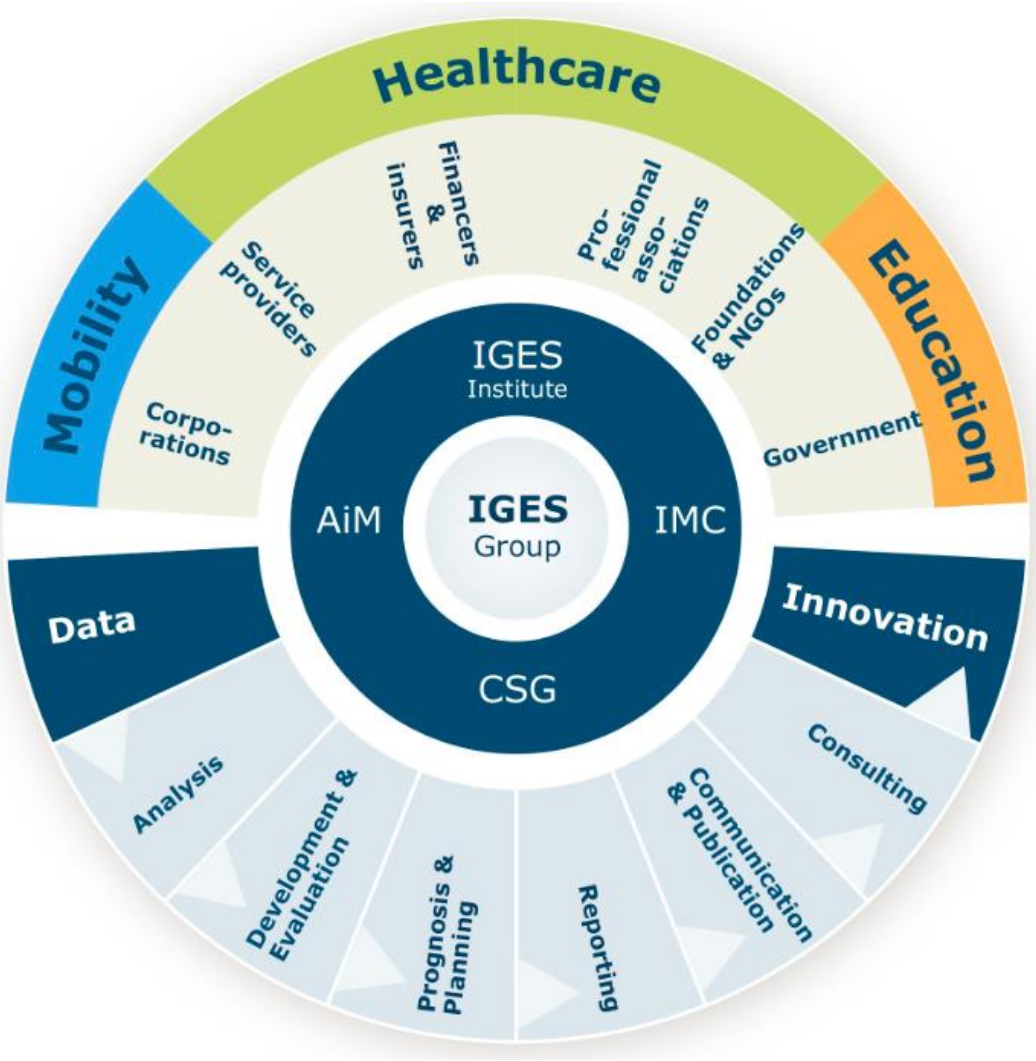
GTAI Webinar, 14 July 2016

Who we are

AiM

IGES Group

The Knowledge Corporation



Contents

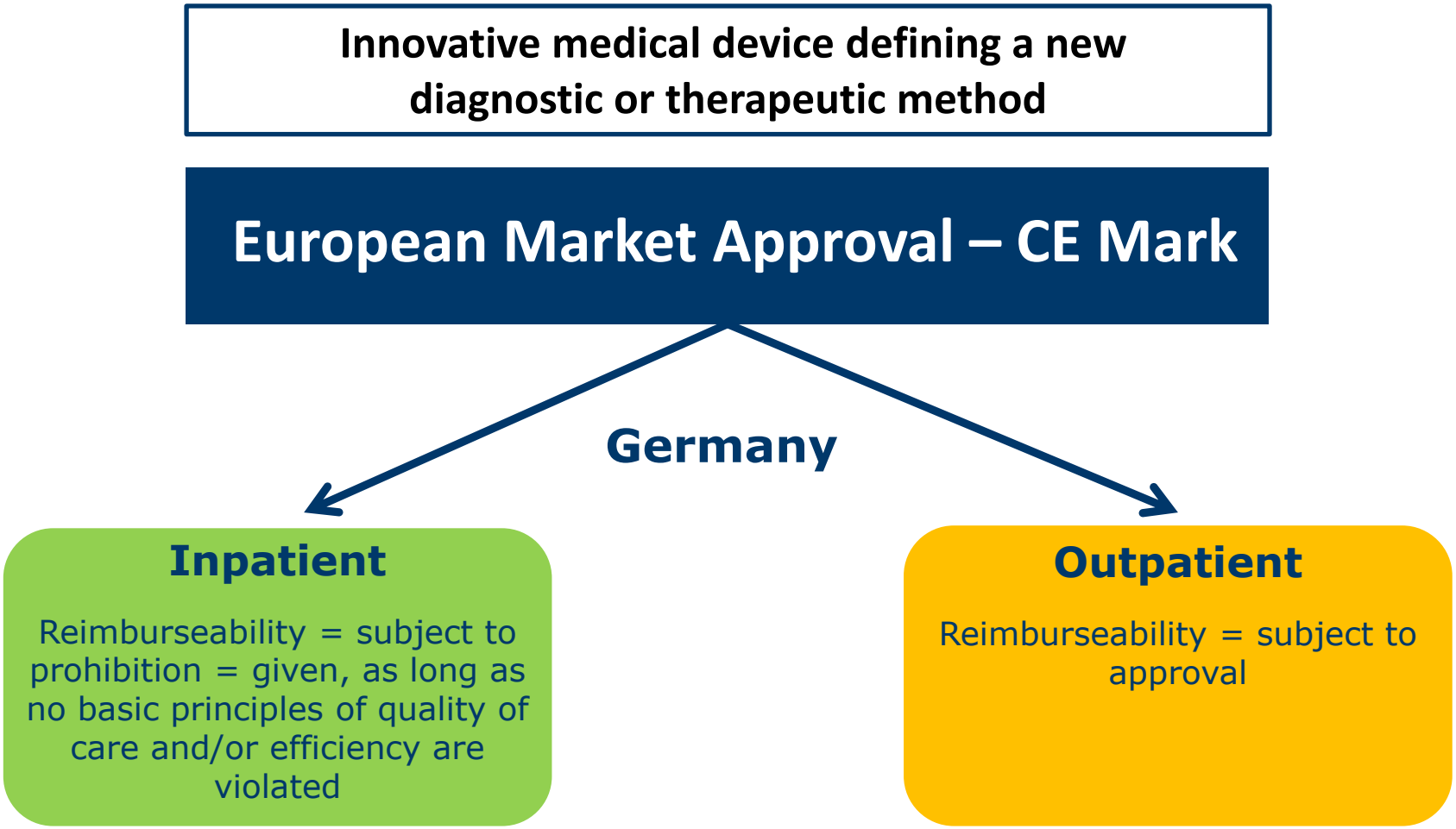
AiM

1. Reimbursement Update Germany

1.1 Overview of inpatient and outpatient settings

Coverage principles Germany

AiM

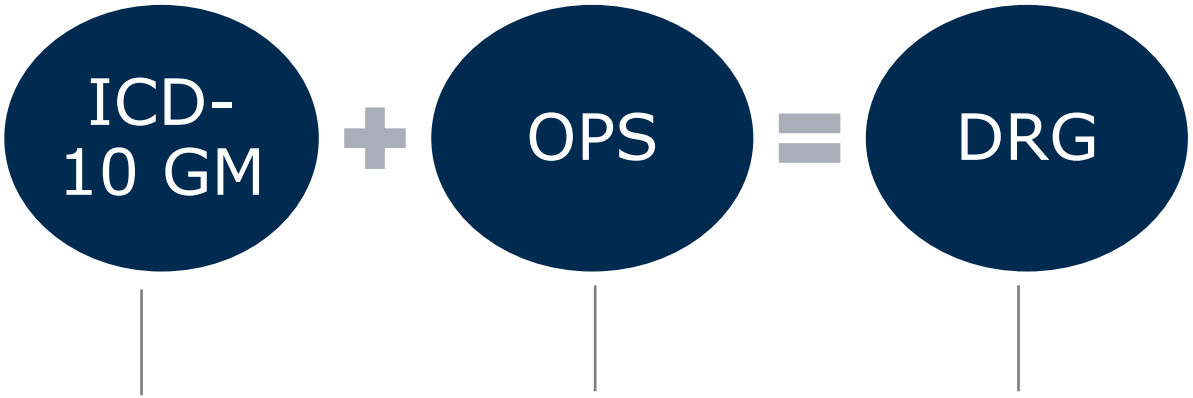


Source: Own Illustration

Reimbursement: Inpatient setting

AiM

Running costs per case



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

Potentially applicable in addition to the DRG payment:

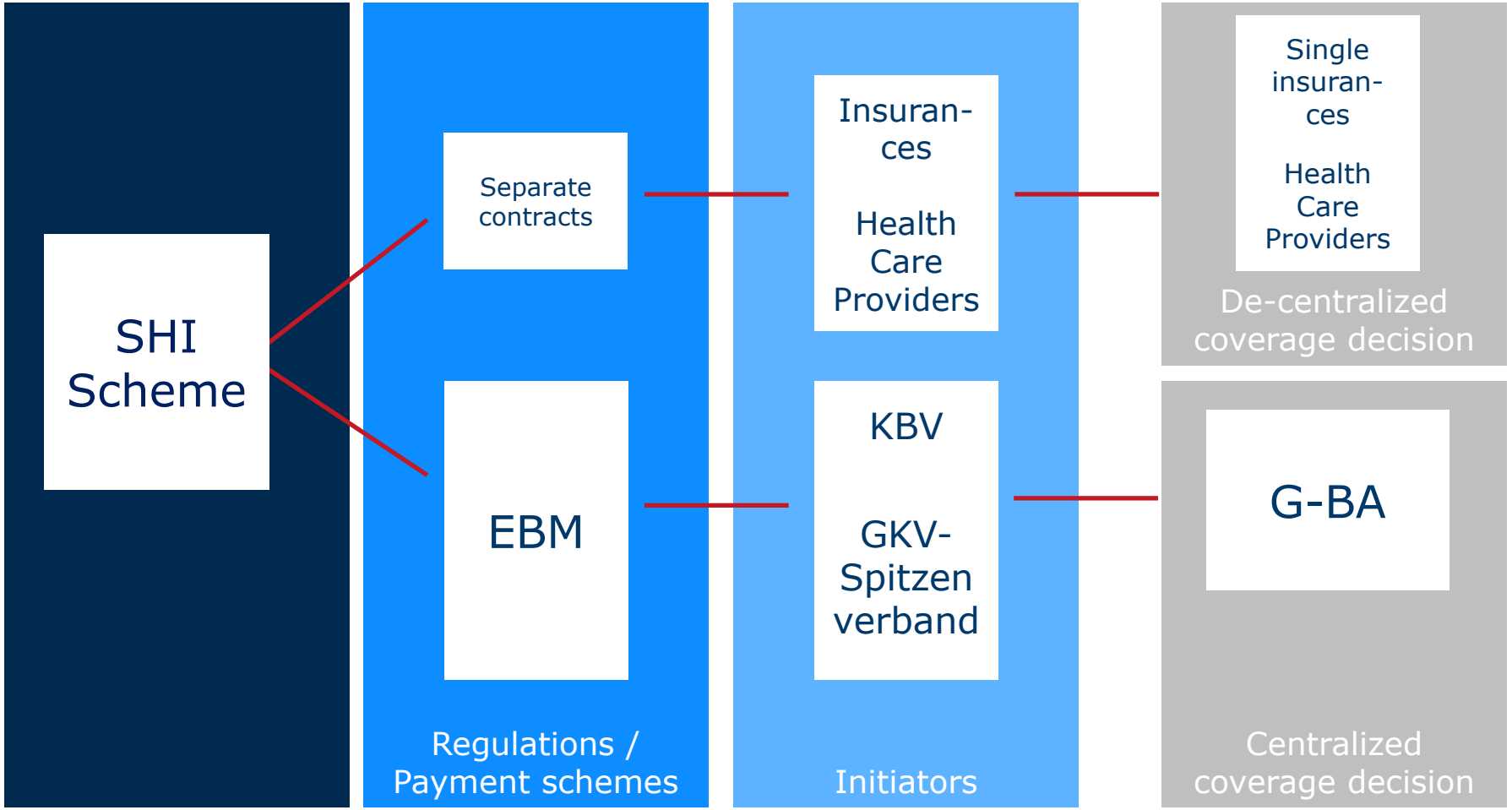
Innovation payments, new diagnostic or therapeutic methods (NUB)

Extra rates (ZE)

Source: Own Illustration

Reimbursement: Outpatient setting

AiM



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

AiM

- 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

AiM

- ”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

AiM

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

InEK → DRG-related NUB assessment → Reimbursement Level =

NUB negotiations yes/no

Result by Jan. 31st

No communication / no interaction between InEK and G-BA

G-BA → Rapid Benefit Assessment → Coverage status =

Will GKV pay for it <u>at all</u>?

Result 3 months after start of assessment

Source: Own Illustration

The G-BA NUB assessment outcomes

AiM

Benefit proven	No benefit proven but attested "potential to be a necessary treatment alternative"	Neither "potential" nor benefit proven
Potentially official quality guideline, § 137 SGB V	Decision about testing regulation guideline, § 137e SGB V, within 6 months & "commonly" testing within 2 years & coverage decision on the basis of trial results	Immediate decision about exclusion from SHI coverage, § 137c SGB V

Source: Own Illustration

Coverage with evidence development

AiM

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

AiM

- 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

AiM GmbH
Michael Weisser
- COO -

+49 7621 705 105 0
info@aim-germany.com

www.aim-germany.com