Integrated Care in Germany
A potential route to market access for medical devices?
ISPOR 17th Annual European Congress

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DAK-Gesundheit: Germany's longest-standing and third-largest SHI company is a quality leader

- Germany's third largest nationwide statutory health insurance company
- 6.3 million insured, (approx. 9.0% market share)
- Annual expenditures: EUR 19.5 billion in health insurance
- Drug spendings: EUR 3.5 billion (approx. 12% of GKV drug costs)
- MedTech spendings: approx. 2.1 Billion € (estimate based on DAK-G, BMG and MVMed Data)
Different health care markets in Germany: Statutory Health Insurance covers 87% of German health care

Statutory Health Insurance (SHI) market:
› 70 million insurees (87% of BRD population)
› **ambulatory health care sector** / outpatients
  o **EBM** = Einheitlicher Bewertungsmaßstab:
    Uniform Value Scale for SHI outpatient services
› **hospital sector** / inpatients
  o **DRG** = Diagnosis Related Groups
  o **ZE** = Zusatzentgelte: additional payments for special services
    e.g. very expensive treatments / drugs

Private health insurance insurance sector:
> 10,5 million insurees (13% of BRD population)
  > **GOÄ** = Gebührenordnung für Ärzte: German Scale of Medical fees

**IGEL = Individuelle Gesundheitsleistungen:**
> individual health care services, to be paid by insuree (out of pocket)
From market access to the reimbursement: Different sectors and different ways in the SHIS

Medical devices / CE-marking
New diagnostic and treatment method (NUB)

Hospital
- NUB remuneration
  - InEK
  - SHIC
  - MDK
- DRG / additional payment (ZE)
  - Prime principle: if it is not explicitly forbidden, it is allowed

Selective contracts

Ambulatory care
- GBA
  - § 135 SGB V
- NUB status
  - Prime principle: if it is not explicitly allowed, it is forbidden
Consequences for reimbursement: Different options and possibilities in the different sectors

**Hospital** sector:

- everything can be reimbursed via DRG / ZE / NUB by SHI-System* unless explicitly excluded from reimbursement by G-BA**

  - excluded methods: proton therapy e.g. brain metastases
  - necessary methods: proton therapy e.g. chondrosarcomas at the skull base
  - assessment procedure suspended: proton therapy e.g. prostate cancer

**Ambulatory care** sector:

- nothing can be reimbursed via EBM by SHI-System* unless explicitly included in reimbursement scheme by G-BA

  - approved methods: MRI female breast, dual energy X ray densitometry, capsule endoscopy, PET (certain indications)
  - excluded methods: refractive eye surgery, soft- / mid-power-laser, PET other indications than mentioned above, holmium laser ablation in BPS
  - assessment procedure suspended: Vacuum sealing therapy / PET or PET/CT in malignant lymphoma

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* SHI-System = Statutory Health Insurance System (Gesetzliche Krankenversicherung (GKV))
** G-BA = Federal Joint Committee (Gemeinsamer Bundesausschuss)
Integrated care concepts have to be in line with §§ 140a-d SCB V**: cross sectoral or interdisciplinary

SHIC* plus health care providers

SHIC plus management company

* SHIC = Statutory Health Insurance Company

** SCB V = Social Code Bokk V (five)
Integrated care concepts have to be in line with §§ 140a-d SCB V**: cross sectoral or interdisciplinary

SHIC* plus health care providers

SHIC plus management company

To only one out of 1,800 contracts examined by the Bundesversicherungsamt*** recently a pharmaceutical company was party. No MedTech company was party to any contract.

BVA press release 07.03.2014

* SHIC = Statutory Health Insurance Company  
** SCB V = Social Code Book V (five)  
*** Bundesversicherungsamt (BVA) = German Federal Insurance Office
DAK-G selective contracts focus on three major goals and on benefits for all involved

- Adequate access to specialist
- Interconnection of ambulatory and stationary care
- Process acceleration / workflow optimizing

QUALITY

- Innovative care concepts
- Guideline orientation
- Service provision in line with requirements

COST EFFICIENCY

- Containing cost increases
- Reducing healthcare service consumption over time
- Ensuring risk structure equalization (RSA) margins

OPTIMIZED CARE PROCESS
Selective contracts: a chance to speed up the access to innovative MedTech in ambulatory care

Proton therapy: outpatient treatment in hospital for certain indications

Vacuum sealing therapy: study „wound therapy“ for future reimbursement

Video Parkinson therapy: optimising Parkinson therapy at home via video control

Telemonitoring CHF: early detection of decompensation in CHF patients

Minimally invasive spine surgery: endoscopic surgery, reduced postoperative pain, shorter recovery time

Welcome Baby: integrated care during pregnancy e.g. pH-metry test gloves

PET/CT: ambulant PET diagnostic for certain cancer indications

Hip / knee endoprosthetics: integrated care diagnosis / hospital / rehabilitation

Brachytherapy in cancer: seed implantation radiation treatment prostate cancer

Gamm knife surgery: high-precision irradiation for radiosurgical treatment of various diseases
Telemedicine 1: postoperative remote monitoring for CHF patients after discharge from hospital

Objective:
Safe transition from inpatient to outpatient treatment

• Integrated Care (cross sectoral / interdisciplinary)
• Hospital / Telemedicine Institute (IFAT), out-patient physicians (GPs, specialists)
• Postoperative telemonitoring for patients with left ventricular dysfunction (EF < 55%) and/or NYHA II – IV after cardiac surgery
• Modular intensive remote monitoring for 12 months (Electronic scale, p.r.n. mobile ECG or bloodpressure monitoring)
• If required additional 6 months basic monitoring
• Daily home check and regular telephone contacts (IFAT)
Telemedicine 2: Implantation, replacement or revision of pacemakers in outpatient care and remote CHF monitoring

Objective:
**Outpatient pacemaker treatment and integration of telemedicine**

- Integrated Care with management company (cross sectoral / interdisciplinary)
- Hospitals and out-patient specialists (cardiologist, internist, anaesthetist)
- Implantation, replacement or revision of pacemakers
- Catheter-based electrophysiological analysis
- Ablation in diagnosed tachyarrhythmia
- CardioMessenger® in case of NYHA I - IV
- since 2013: Implantation of BioMonitor® (loop recorder)
The Integrated Care as a contractual construct is dead.“
Rheinisches Ärzteblatt 11/2013

Challenges or Threats and Weaknesses

Fragmentation of IV contracts (2008)*:
- Number of contracts (C) 6407
- Participants 4,036,000
- Total volume of remuneration 811 Mio. Euro
- 32 contracts (0,5%) > 10,000 participants (P) / 3,75 Mio. P (93%)
- 168 contracts (2,6%) > 1 Mio. Euro / 426 Mio. Euro (53%)
- 138 nationwide contracts (2,1%) / 404,000 P (10%) / 50 Mio. Euro = 125 Euro / P
- Spending (per insuree per year) 11,55 Euro (2008) / 21,95 Euro (4,03 - 89,25 Euro / 2013)

Over- / misregulation
- Integrated care must be a substitute for regular care, not an add-on
- Right of accession for other care providers
- Potential entitlement to benefits for all insured
- "Internal" start-up funding (ROI required in less than one year)
- Requirement of specific adjustment of the overall remunerations of the KVs**
- Restrictive data protection regulations

* Gemeinsame Registrierungsstelle (Joint registration authority BQS140), Development of IV in Germany 2004 - 2008, 2009
** KV = Kassenärztliche Vereinigung = Association of Statutory Health Insurance Physicians

DAK 2012: 0,8 % (0,5% of total GKV spending)
(remaining Ø 45 P/C)
(remaining Ø 62,000 Euro/C)
Selective contracts make MedTech innovations accessible in ambulatory care for the benefit of DAK-G insurees

**take-away message:**

- The SHIS* covers 87% of the German population as health care insurance and is an attractive partner for selective contracting
- Selective contracts offer the chance to speed up the transfer of innovations from hospitals to ambulatory care
- DAK-G selective contracting focuses on three major goals: quality, optimized health care process and cost efficiency
- Telemedicine in various aspects is an example for innovation in outpatient care prior to regular reimbursement possibilities

*SHIS = Statutory Health Insurance System = Gesetzliche Krankenversicherung (GKV)*

Thank you for your attention.
Don’t hesitate – lets talk about it!