



Integrated Care Models as a Potential Route for Market Access of Innovative Medical Devices in Germany?

Perspectives on the concept: The industry

Daniel Dröschel

MArS Market Access & Pricing Strategy GmbH, Germany

SRH FernHochschule Riedlingen, Germany

Agenda



- **INTEGRATED (MANAGED) CARE IN GERMANY**
Potential players and partners in Integrated Care Models
- **POTENTIALS OF ICMS AS MARKET ACCESS ROUTE**
Potential example in chronic wound care
- **ENVIRONMENT AND CONDITIONS FOR INTEGRATED CARE**
Current developments in Integrated Care



Integrated (Managed) Care in Germany

POTENTIAL PLAYERS AND PARTNERS IN INTEGRATED CARE MODELS

Integrated Care in Germany

Usual stakeholders eligible for selective contracting



- Selective contracts can be agreed solely with contract partners mentioned in § 140 b Abs. 2 Social Code Book V:
 - Statutory Health Insurance Companies (GKVs)
 - Individual physicians or dentists
 - Hospitals and rehabilitation clinics
 - Other providers (permitted for provision of medical care)
 - Other individual providers or their organisations

-> Explicitly not eligible: Association of the statutory health insurance physicians (KV)

Integrated Care in Germany

Potential options for the industry (manufacturer)



- Sponsors of organisations that provide integrated care services according to §140a SGB through providers permitted for provision of medical care for patients insured with the respective health insurance
 - Management organisations („Managementgesellschaften“)
 - e.g. Janssen-Cilag Germany GmbH as an integrated care organisation (e.g. management buy-in)
 - e.g. partner of MedTech company such as Mamedicon GmbH in wound care

Potentials of ICMs as Market Access
route

POTENTIAL EXAMPLE IN CHRONIC WOUND CARE

Potentials of ICMs as Market Access route



MedTech product – Example chronic wound care

- First pre-requisite is the CE-Mark approval
- Wound care therapy in the outpatient setting (G-BA approval required)
 - Reimbursement applications to the G-BA are only required for medical products which are NOT bandages and dressings and NOT aids and appliances but still should be reimbursed
 - **Potential implication:** Application of experimental coverage (in case of innovative potential)
- Bandages and dressings do not need the G-BA approval for selling purposes (reimbursement not directly granted)
 - The manufacturer of a bandage and dressing needs to label the products as a „bandage and dressing“ („Verbandmittel“) according to § 31 SGB V and lists these accordingly in the Lauertaxe (official German price registry)
- Wound dressing are individually prescribed to patients
- Wound dressings are closely followed in each practice

Potentials of ICMs as Market Access route



MedTech product – Example chronic wounds care

- There are two options for a manufacturer (outpatient setting):
 1. Inclusion of a product within existing ICMs
 2. Setting up a new ICM with potential stakeholders as partners

Potentials of ICMs as Market Access route



MedTech product – Example chronic wounds care

1. Inclusion of a product within existing ICMs:

- ICM provides a potential mid-term Market Access (MA) opportunity; inclusion within 1 – 1.5 years possible
- ICM works by allowing manufacturers proposing their product to the ICMs Medical Advisory board
- Usually a specific product cannot be included under the framework of ICM contracts, but the product category
- ICM advisory board decides on the inclusion of a specific new product...
 - ... within a new contract or
 - ... in already existing contract afterwards

Potentials of ICMs as Market Access route



MedTech product – Example chronic wounds care

1. Inclusion of a product within existing ICMs:

- **Advantage:** Involvement of almost all German stakeholders for market access which might ease the successful application in regular approval routes across health care sectors
- Potential exemption from regress claims for physicians (“Regressforderung”) e.g. in the case of diabetic foot treatment provided by specialized foot networks
- Long-term certainty on reimbursement and pricing
- Potential support by health insurance, companies and other key stakeholders for the inclusion in patient pathways

Potentials of ICMs as Market Access route



MedTech product – Example chronic wounds care

2. Setting up an ICM:

- The ICM for chronic wounds (also in general) needs to be based on an specific care process aligned with standard care process in place
- The financing can be integrated as a global budget within the management organisation (full-risk capitation) or remains at the GKV
- Contract initiation takes approx. 2-3 years and the usual initial contract phase is up to 3 years followed by a reassessment and extension agreement
- The inclusion of a product (category) is possible and the reimbursement can be back-channelled directly to the MedTech company (payment process)
- An evaluation approach can be set-up as a study design and can generate evidence on real practice



Environment and conditions for
Integrated Care

CURRENT DEVELOPMENTS IN INTEGRATED CARE

Environment and conditions for Managed Care



Current status – 10 years after introduction

- Until 2008: Most interventions included in the ICMs were moved into the regular reimbursement coverage (!)
- Beyond 2008: Health insurances try to stopp the process into the regular reimbursement coverage
 - However: up-take in the regular care is still reality due to the legal frame in German

Environment and conditions for Managed Care



- Steps required in order to have more innovative and successful ICMs:
 - Industry needs to focus on the care concepts and not only on the(ir) individual therapy
 - Payers need to install a transparent communication and application platform for ICMs
 - Evidence requirement
 - Transparent process
 - Evaluation of ICM submissions
 - e.g. through scientific institutes of the health insurances (e.g. WiDO by AOK or MDK/MDS)

Industry perspective for the future



- The stagnation needs to be overcome
 - German regulatory hurdles need to be abolished (e.g. SGB V, etc.)
 - Business concepts on the table! (from all perspectives)
- Lack of evaluation of existing ICMs
- Inclusion of medical evidence generation alongside ICMs in a standard manner
- High expectations on the newly introduced „innovation fund“



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