CURRENT REIMBURSEMENT SITUATION OF ATMPS IN GERMANY

DIFFERENT PATHWAYS AND THEIR STRATEGIC IMPLICATIONS

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BACKGROUND

- Advanced therapy medicinal products (ATMPs) are new medicinal products based on genes (gene therapy), cells (cell therapy) and tissues (tissue engineering). Legal framework for ATMPs is provided by Regulation (EC) 1394/2007 (ATMP Regulation) which has been designed to ensure the free movement of ATMPs within Europe, to facilitate access to the EU market and to foster the competitiveness of European companies in the field, while guaranteeing the highest level of health protection for patients.
- As of September 2016, 12 ATMPs are approved in Germany either through the Community centralized approval or the national approval pursuant to art. 28 of the ATMP Regulation („hospital exemption“).
- Their reimbursement status depends whether they are used in an outpatient or inpatient setting and whether they are considered as a medicinal product and are reimbursed by law, or as part of a therapy. If it is part of an outpatient therapy the Federal Joint Committee (G-BA) has to decide on funding on a case-by-case basis before it can be applied.

OBJECTIVES

The aim of the study is to review current reimbursement situation of the 12 ATMPs approved in Germany by focusing on the opportunity of reimbursement by law as well as implications of a classification as an innovative inpatient therapy (so-called NUB procedure) securing inpatient reimbursement through later inclusion in the Diagnosis-related group (DRG) system.

METHODS

For each ATMP available in Germany, reimbursement status and funding issues have been analyzed in official sources and databases taking into account regulatory status, class specificities and inpatient or outpatient setting.

Our analysis represents data as of September 2016.

RESULTS

GENE THERAPIES

Brand name	Approval	Status	Orphan Status	Outpatient	Inpatient
Glybera®	EU (2012)	medicinal product	Yes	additional benefit not quantifiable	NUB-Status 4**)
Imlygic®	EU (2015)	medicinal product	Yes	expected 12.2016	NUB-Status 4**)
Strimvelis®	EU (2016)	/ *)	No	unknown	unknown

SOMATIC CELL THERAPIES (Tumor vaccines)

Brand name	Approval	Status	Outpatient	Inpatient
Provenge®	*approval revoked*	*medicinal product*	*additional benefit not quantifiable*	/
Dcvax®	PEI (2014)	/ *)	hospital exemption	NUB-Status 2***)
Cytokine-induced killer cell	PEI (2014)	/ *)	hospital exemption	no information – no reimbursement

TISSUE ENGINEERED PRODUCTS

Brand name	Approval	Status	Outpatient	Inpatient
BioSeed®	PEI (2014)	/ *)	hospital exemption	**OPS-Code 5-801k****: Matrix-associated chondrocyte tranplantation **+ Additional OPS-Code 5-936-X**: Use of ATMPs – **+ Additional remuneration nr. 126**: Autogenous/Autologous Matrix-associated chondrocyte association (3079,31 €)
co.don®	PEI (2013)	/ *)	hospital exemption	
NOVOCART 3D®	PEI (2014)	/ *)	hospital exemption	
NOVOVART Inject®	PEI (2016)	/ *)	hospital exemption	
Chondro-Celect®	*withdrawn by 30.11.16*	/ *)	/	
MACI®	*approval suspended*	*part of therapy*	/	/
Holoclar®	EU (2015)	part of therapy	not reimbursed	NUB-Status 4**)
MukoCell®	PEI (2013)	/ *)	hospital exemption	NUB-Status 2***)
T2c001®	PEI (2014)	/ *)	hospital exemption	NUB-Status 4**)

Outpatient setting
- Entitlement to be reimbursed by law
- AMNOG assessment of advantage for Orphan Drugs

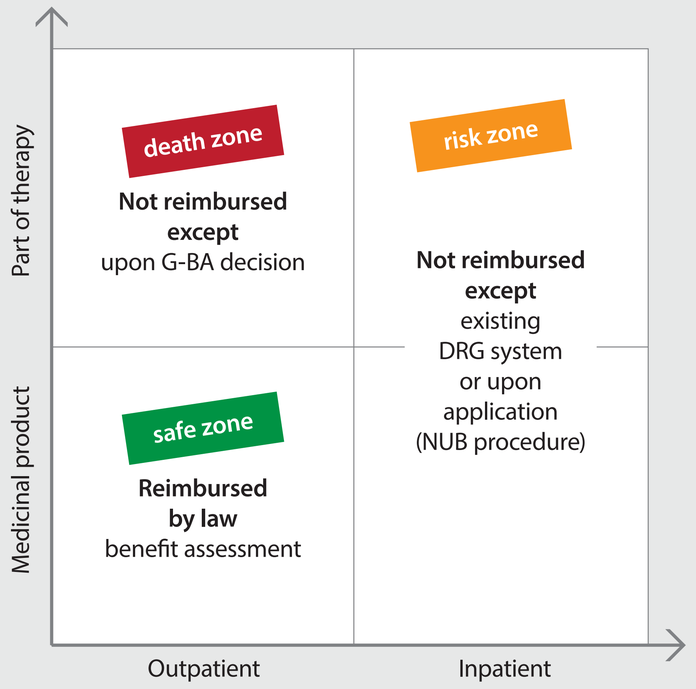
Inpatient setting
- Inpatient outcome reimbursement so far negative
- Reference to outpatient reimbursement

Outpatient setting
- No reimbursement available when medicinal products not sold outpatient

Inpatient setting
- No successful reimbursement for somatic cell therapies so far

Outpatient setting
- Tissue-engineered products most likely to be considered as “parts of a therapy” by G-BA
- No AMNOG assessment but prohibition subject to authority approval

Inpatient setting
- Reimbursement in inpatient setting only for matrix-associated chondrocyte transplantation (MACT)



*) No decision taken by G-BA so far.

**) NUB-Status 4 means that information provided is insufficient to meet the eligibility criteria for an additional reimbursement according to the NUB procedure.

***) NUB-Status 2 means that the product does not fulfill the requirements for a NUB, Institute for Hospital Fee Systems (InEK) 2016

CONCLUSIONS

- Reimbursement of ATMPs is a challenge in Germany
  - 7 out of 12 ATMPs are reimbursed in Germany
  - Glybera®, Imlygic® (and Provenge®) are reimbursed outpatient
  - Matrix-associated chondrocyte transplantation is the only method reimbursed in the inpatient setting
- So far, only ATMPs being medicinal products used outpatient do have a clear reimbursement

REFERENCES

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- Institut für das Entgeltsystem im Krankenhaus, www.g-drg.de/cms/Neue_Untersuchungs-_und_Behandlungsmethoden_NUB (last accessed: 09.2016)
- Final decisions on early benefit assessment were taken from the G-BA website: www.g-ba.de/informationen/nutzenbewertung/ (English version [less recent]: www.english.g-ba.de/benefitassessment/resolutions/) (last accessed 09.2016)

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