NEW GUIDANCE IN GERMANY ON QUALITY ASSURED USE OF ATMPS - IS EVIDENCE ON IMPACT ON CARE PRACTICE BECOMING EVER MORE IMPORTANT FOR HTA SUBMISSIONS?

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1. CONTEXT

- In November 2021 the G-BA released a regulation on quality assured use of ATMPs in Germany.
- The basis for the guidance is to permit use of ATMPs only to health care service practices that have the sufficient experience and qualifications to handle the treatments.

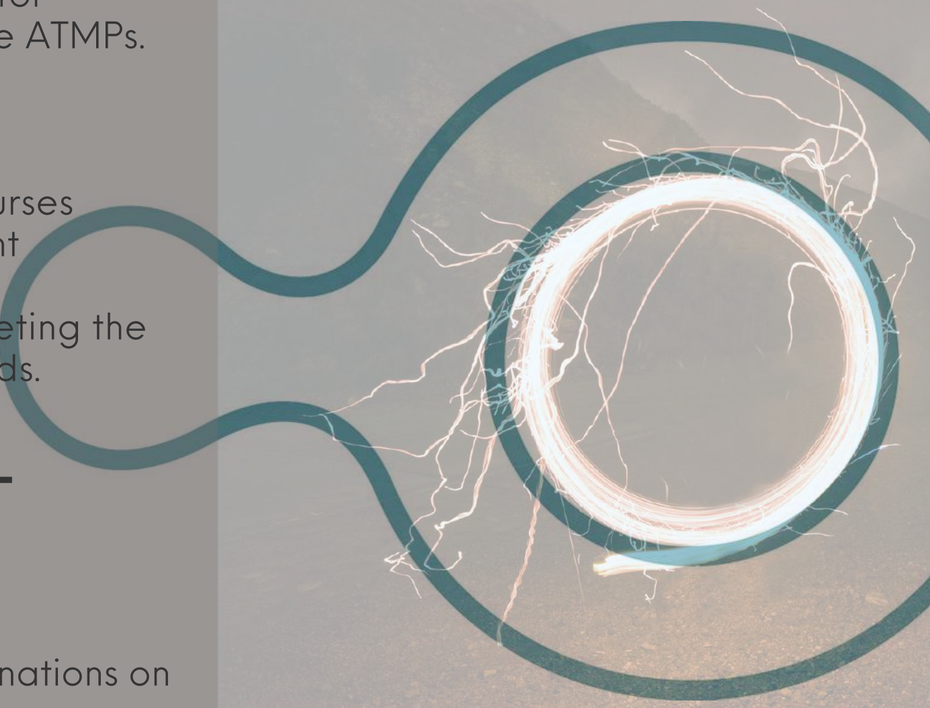
2. DETAILS

- The regulation covers the minimum requirements for ambulatory practices and hospital wards to handle ATMPs.
- This includes:
- Minimum case numbers
- Medical equipment
- Requirements related to staff – physicians and nurses
- Requirements related to the practice environment
- Reporting requirements

Only ambulatory practices and hospital wards meeting the requirements can claim reimbursement via sick funds.

3. CONCLUSIONS & POTENTIAL DIRECTION

This new regulation may affect:
- The G-BA dossier will require evidence and explanations on quality assured use
- Development of evidence to demonstrate impact of a new ATMP to the health care delivery system will become more important and ensures manufacturers demonstrate knowledge to understand how the new product will be brought to patients
- It could potentially present a restriction in use.



CONTACT:

MICHAEL.EPSTEIN@ASCENIAN-CONSULTING.COM

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