Hamburg, 2017

Germany’s new benefit assessment of health technologies based on medical devices

Benefit dossier for Volanesorsen in the indication Familial Chylomicronemia Syndrome
This document was compiled by Ecker + Ecker GmbH.

Distribution, citation and reproduction of this document or extracts thereof are not permitted except by prior agreement with Ecker + Ecker GmbH.

This document is intended to give a short overview and does not constitute full documentation or consultation of the topic.
New law aims at enhancing both the quality and efficacy of health technologies based on medical devices

Background

Patient safety

Scandal involving medical devices

Promoting safe high risk medical devices

Enhancing price regulation

Cost-efficient patient care

Intransparent prices

Mandatory systematic assessment of health technologies based on medical devices
Hospital applying for reimbursement starts the assessment procedure

Overview of the procedure pursuant to § 137h SGB V¹

¹ German Social Code Book Five

Hospital intends to use a new health technology (so-called „NUB“) based on a high-risk medical device

Compilation of scientific information in consultation with the manufacturer

„NUB“ application

Scientific information for assessment

(Institute for Hospital Fee Systems)

(Federal Joint Committee)
Procedure by G-BA follows the schedule of reimbursement requests

Timetable of the procedure

- **Start**
  - Early consultation process

- 31/10
  - Check for plausibility

- ~15/11
  - Call for additional information

- ~15/12
  - Assessment and benefit approval

- ~15/03
  - End of yearly reimbursement requests and confirmation of receipt

- Decision on initiation of assessment

- Result of initial formal check

- Assessment result
Three assessment scenarios are possible

**Application**
Hospital provides information on the current state of scientific knowledge on health technology under investigation and the use of the medical device (in consultation with the manufacturer)

**Assessment of potential**
G-BA assesses within three months the health technology using a medical device

**Outcome**

1. Benefit substantiated with sufficient evidence
2. Benefit not substantiated with sufficient evidence but potential of an essential treatment alternative
3. No potential, as harmful or ineffective

**Assessment**

- **Check if quality requirement are needed**
  - **Within six months**
    - Decision on a clinical trial
  - **Within two years**
    - Clinical trial completed

**Reimbursement Decision**

- **Reimbursement (Contract between a and b)**
  - **Within three months**
    - Reimbursement yes/no (depending on outcome)
  - **No Reimbursement**
Statutory Regulation defines which medical devices are covered by the assessment pursuant to § 137h SGB V

Class I and IIa
- Low to medium level of risk
- **Never** covered by the assessment pursuant to § 137h SGB V

Class IIb and III
- Higher to high level of risk
- **Partially** covered by the assessment pursuant to § 137h SGB V
  (when their use is particularly invasive)

Active implantable medical devices (AIMD)
- High to very high level of risk
- **Always** covered by the assessment pursuant to § 137h SGB V
Advice to manufacturers

• G-BA advice is strongly recommended
• Dossier is of key importance for reimbursement decision
• Dossier preparation is mainly with the manufacturer
• Required data is to be understood in a comprehensive way, in order not to fail due to formal hurdles