

From Vague to Valid – Chances and Risks of Benefit Re-Assessments Due to New Scientific Evidence in Germany



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Objectives

In the German HTA, the G-BA assesses the added benefit of pharmaceuticals based on the evidence submitted by the pharmaceutical manufacturer, which is the basis for the price negotiations. However, the available evidence is often (considered) limited and/or not mature. The G-BA's rules of procedure (chapter 5 sect. 14 VerfO) allow manufacturers to request a re-assessment based on "new scientific findings", which – if accepted – consequently leads to a re-negotiation as well. This precedence analysis aims at identifying the evidence level required for a re-assessment in general, the respective outcome and ultimately the impact on the price negotiations with the GKV-SV.

Methods

Using a comprehensive database, all benefit re-assessments according to chapter 5 section 14 of the G-BA's rules of procedure (VerfO) and their respective previous assessment(s) were analyzed regarding the methodology, G-BA rating(s) and rationale(s) as well as the impact on the reimbursed costs of the drug. The used database is based on publicly available data, combining all dossier assessments in Germany and IQWiG/G-BA rulings with GKV-SV price negotiation outcomes (LAUER-TAXE®).

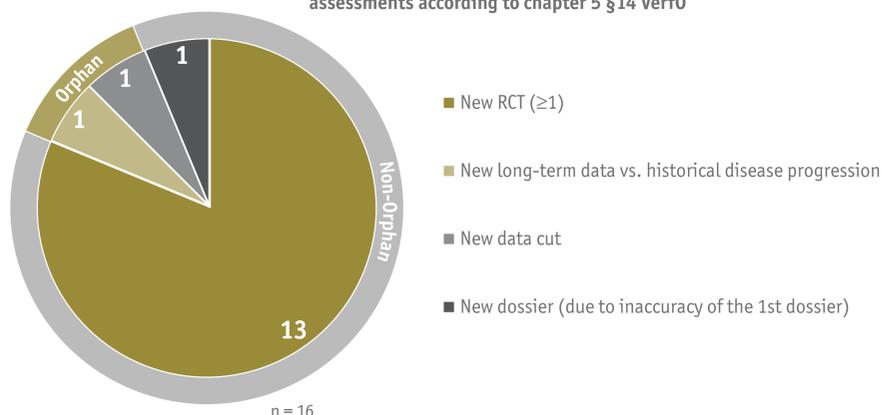
Results

Characterization of the "new scientific findings" sufficient for a benefit re-assessments by the G-BA

Out of 16 G-BA accepted request for re-assessments due to "new scientific findings", 13 were based on new RCTs submitted by the manufacturer.

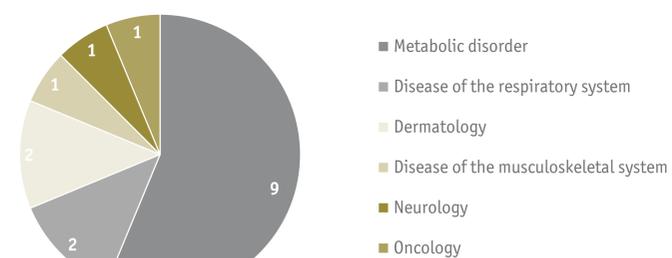
The indication areas are scattered, while more than half were in the metabolic disease setting.

Figure 1: Level of evidence of granted requests for new benefit assessments according to chapter 5 §14 VerfO



- 13 out of 16 granted requests for a new benefit assessment submitted ≥1 new RCTs as new scientific evidence (Figure 1).
- Only two orphan drug were re-assessed.
- Apart from submitted RCTs, rather specific individual situations led to an acceptance for re-assessment.
- One outlier was excluded due to discontinuation of sales.
- Due to the non-disclosure of not accepted requests, only accepted requests for benefit re-assessments according to chapter 5 §14 VerfO are publicly available and were included in the research. Therefore, an analysis vice versa is not possible.

Figure 2: Indication areas of requests for new benefit assessments according to chapter 5 §14 VerfO

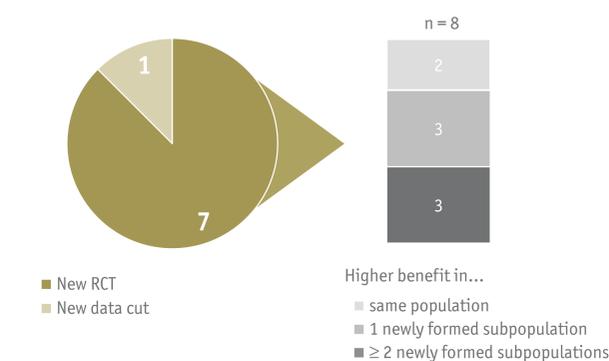


- With 9 out of 16 re-assessments, the majority was in the metabolic disease setting (Figure 2).
- Only one oncological drug was re-assessed due to new scientific findings per request by the manufacturer.

Outcomes of the benefit re-assessments and price negotiations with the "new scientific evidence"

8 re-assessments received a higher added benefit; 6 of them in newly sliced subpopulations

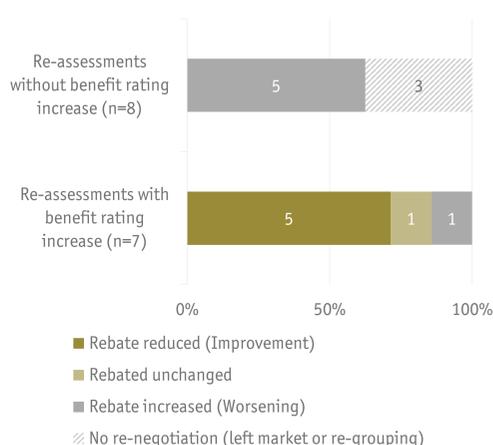
Figure 3: Benefit re-assessments resulting in a higher added benefit



- 7 out of the 8 re-assessments resulting in a higher added benefit were based on ≥ 1 new RCT, while one was based on a new data cut of an RCT used in the 1st assessment.
- In 6 re-assessments, the original population was sliced into (more) subpopulations. In half of the procedures, a higher benefit was granted in more than one newly formed subpopulations.
- In only two re-assessments procedures, the same population was assessed and rated by the G-BA with the new scientific evidence submitted.

Only 5 drugs with ≥1 new RCT improved their price negotiation outcome by negotiating an increased reimbursed price with the GKV-SV.

Figure 4: Re-assessments with higher benefit and without an added benefit associated with changes in rebate*



- No drugs have achieved a lower or consistent rebate without enhancing their benefit rating.
- *One benefit re-assessment "new data cut" excluded due to ongoing price negotiations (as of Sep 2022).

Table 1: Development of rebate per package after re-assessment resulting in a higher benefit*

Drug name	Number of populations and benefit rating of 1 st procedure	Number of populations and benefit rating of re-assessment	New evidence included	Original rebate per package (net)	New rebate per package (net)
Acridiniumbromid (Eklira Genuair/Bretaris Genuair)	2 pop. 2x no added benefit	4 pop. 3x no added benefit 1x considerable	New RCT	22.95%	22.95%
Dapagliflozin (Forxiga)	4 pop. 4x no added benefit	8 pop. 3x Minor 5x no added benefit	New RCT	Discontinuation of sales; re-assessment: 58.46%	28.99%
Dapagliflozin/Metformin (Xigduo)	3 pop. 3x no added benefit	6 pop. 3x no added benefit 3x minor	New RCT	33.39%	7.69%
Empagliflozin (Jardiance)	5 pop. 5x no added benefit	10 pop. 5x no added benefit 1x minor 4x considerable	New RCT	Average: 48.68%	5.59%
Ingenolmebutat (Picato)	1 pop. 1x no added benefit	2 pop. 1x non-quantifiable 1x no added benefit	New RCT	150 µg: 33.83% 500 µg: 42.75%	150 µg: 29.41% 500 µg: 38.93%
Secukinumab (Cosentyx)	3 pop. 1x no added benefit 1x considerable 1x minor	3 pop. 2x considerable 1x minor	New RCT	7.2%	3.49%
Sekucinumab (Cosentyx)	2 pop. 2x no added benefit	3 pop. 2x no added benefit 1x minor	New RCT	7.2%	18.29%

Conclusion

- A re-assessment due to new scientific evidence gives the opportunity to obtain increased reimbursement if the submitted evidence is of high quality and/or specifically addresses the G-BA's initial criticism.
- In oncology, evidence especially over survival data is often not mature when the study is submitted to the G-BA. These procedures are usually time-limited by the G-BA, demanding a 2nd dossier after the next relevant data cut. Since this is requested by the G-BA, these procedures are not part of the re-assessments requested by the manufacturer due to new scientific evidence.
- In several cases, the updated evidence led to slicing: New subpopulations were formed and assessed separately. A more in-depth analysis of the individual procedures could reveal, whether this approach was part of the pricing strategy of the manufacturer OR was performed by the German HTA bodies to weaken the manufacturers overall position, potentially as a result of payers influence.
- Based on the analyzed data, a higher added benefit rating based on the "new scientific findings" appears to be essential to receive a better reimbursement in the negotiations with the GKV-SV. Since in several re-assessments the negotiated rebate increased (worsening), an upfront anticipation of the outcome of the G-BA and GKV-SV interactions is essential to prevent effort and waste in resources or, in the worst case, a higher rebate.



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All analyses have been conducted with our own comprehensive MAIS database that contains and links AMNOG information of all completed and ongoing benefit assessment procedures according to §35a SGB V of the German Federal Joint Committee (G-BA).