Impact of GKV Financial Stabilization Act on Drug Pricing in Germany – Early Experiences of the Reform

HPR62

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CONCLUSIONS

- **Prices** for **drugs** with **no** or **minor added benefit** are generally **within** the **pricing guardrails** introduced by the **GKV Financial Stabilization Act** (GKV-FinStG), i.e., a minimum 10% discount from patented appropriate comparator therapy (ACT) for drugs with no added benefit, and no price premium from the patented ACT for drugs with non-quantifiable or minor added benefit.
- **Manufacturer pricing** for drugs with **minor added benefit** was **18.9% to 23.2% discount** from the ACT price and **45% discount to 13.9% premium** from the ACT price for drugs with no added benefit.

INTRODUCTION

- The GKV-FinStG, introduced in November 2022, imposed stricter drug pricing rules for drugs with no or limited added benefit:
  - a minimum 10% discount from patented ACT for drugs with no added benefit;
  - no price premium from the patented ACT for drugs with minor or non-quantifiable additional benefit.
- Considering the new regulations, we studied how manufacturers approached their list pricing upon G-BA assessment.

METHODS

- We identified added benefit ratings at the subpopulation level for non-orphan drugs assessed post-GKV-FinStG. All assessment types were considered (first, indication extension, re-assessment).
- We compared annual per-patient therapy costs (pharmacy sales prices deducted by mandatory manufacturer and pharmacy rebates) with patented ACT from G-BA decisions to quantify list price differences (discount/premium).
- We calculated average costs if multiple patented ACTs were available, excluding combination therapies to avoid bias. We calculated cost ranges for assessments with multiple subpopulations.

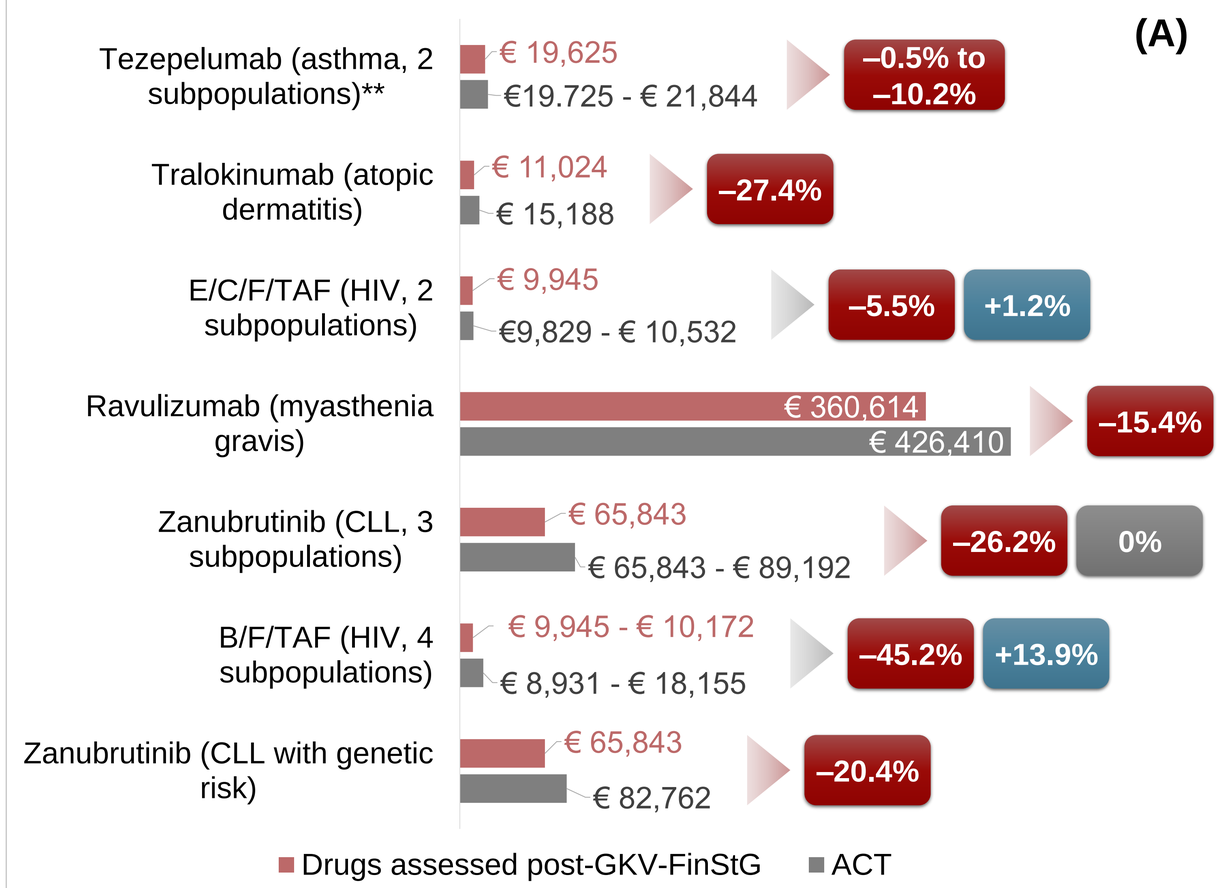
RESULTS

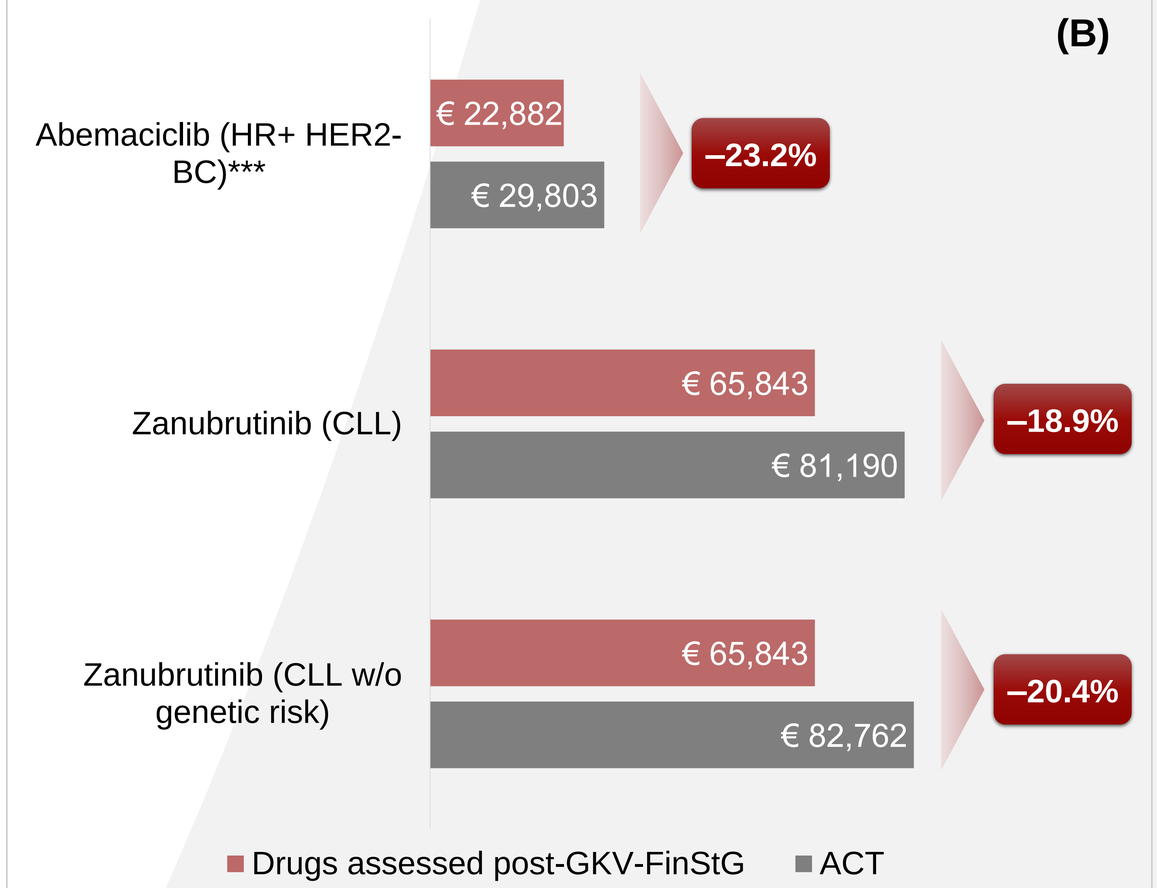
- Eight assessments were eligible for our analysis with a minor added benefit for two drugs (three subpopulations), and no added benefit for six drugs with 14 subpopulations (June 15, 2023 data cut).
- Indication extension was the most prevalent assessment type, reported for seven drugs.
- For drugs with minor added benefit, discounts ranged from 18.9% to 23.2%. For drugs with no added benefit, price differences ranged from 45.2% discount to 13.9% premium versus ACT (**Figure 1).**

DISCUSSION

- Pricing premiums are not permitted by the GKV-FinStG for drugs with no added benefit; however, we identified two such instances in our research. A potential explanation for the observed price premiums is that the manufacturers did not expect ‘no added benefit’ rating with their list pricing approach.
- Given that the GKV-FinStG was introduced several months ago, our study did not look at prices 3 to 6 months after G-BA decisions, when GKV pricing negotiations are typically concluded.

FIGURE1. THERAPY COSTS (€) FOR DRUGS ASSESSED WITHIN THE GKV-FINSTG*: (A) DRUGS WITH NO ADDITIONAL BENEFIT; (B) DRUGS WITH MINOR ADDITIONAL BENEFIT





* Indication extension assessment (unless stated otherwise); ** First assessment; *** Re-assessment

BC = breast cancer; B/F/TAF = bictegravir/emtricitabine/tenofovir alafenamide; CLL = chronic lymphocytic leukemia; E/C/F/TAF = elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide; HR = hormone receptor; HER2 = human epidermal growth factor receptor 2; w/o = without

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