

# GUIDELINES IN GERMAN EARLY BENEFIT ASSESSMENT – WHICH GUIDELINES ARE CONSIDERED BY FEDERAL JOINT COMMITTEE FOR DETERMINING THE APPROPRIATE COMPARATOR?

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## Objectives

- 1) Evaluate how often Federal Joint Committee (Gemeinsamer Bundesausschuss, G-BA) considers evidence in guidelines
- 2) Determine therapeutic areas where the majority of considered guidelines were exclusively non-German
- 3) Explore reasons for G-BA for not considering any guidelines when determining the appropriate comparator for German early benefit assessment.

## Methods

All completed German early benefit assessments with procedure start date between 01/07/2014 and 01/06/2017 were selected. Documents necessary for analysis were retrieved from the G-BA website. Frequency of assessments in which G-BA considered German guidelines, non-German guidelines exclusively, and no guidelines at all were determined. Therapeutic areas wherein G-BA considered non-German guidelines exclusively in >50% of cases were identified. Reasons for not considering any guidelines were explored.

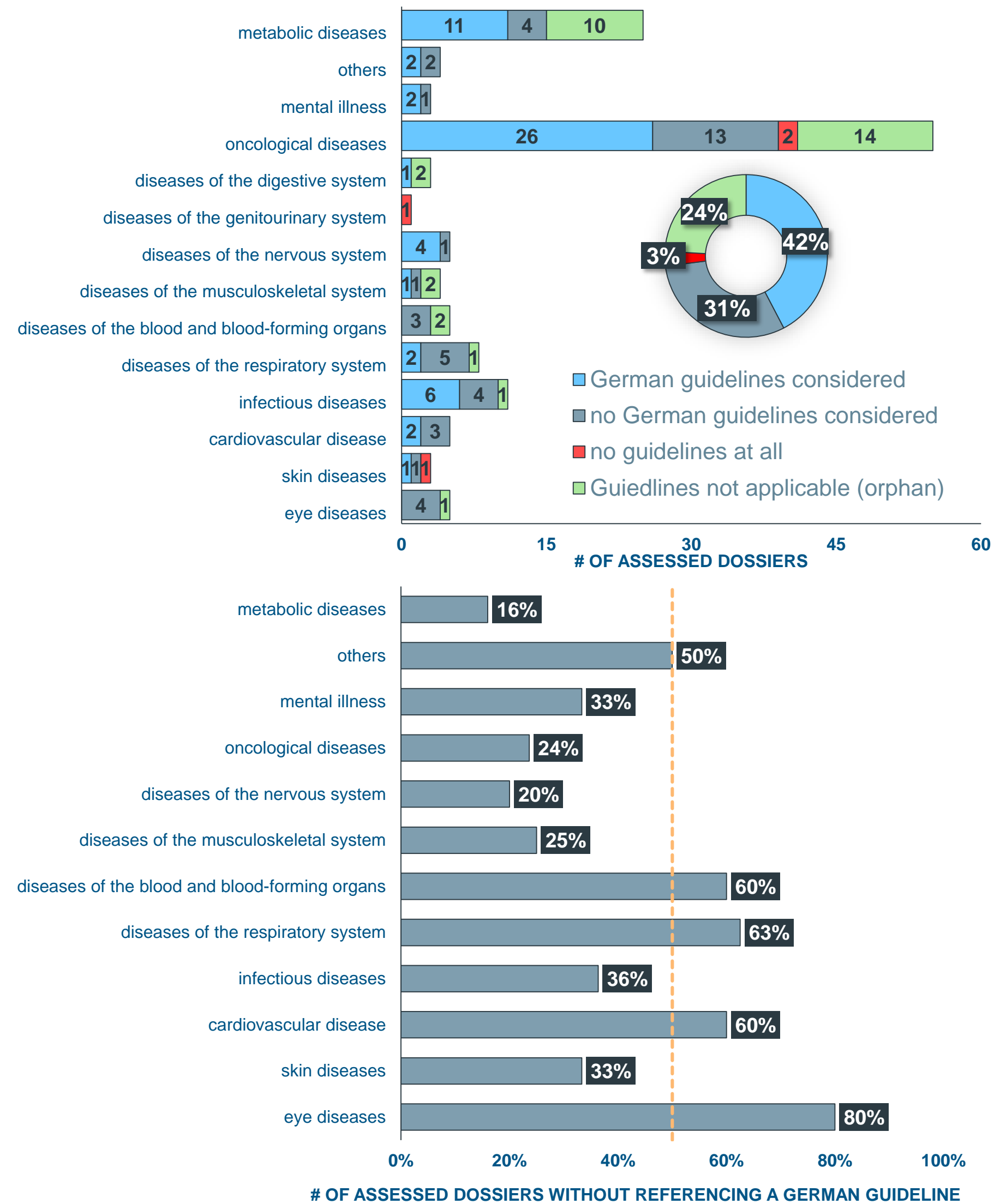
## Results:

Of 137 relevant assessments, the G-BA referred to German guidelines in 42% of cases when determining the appropriate comparator for early benefit assessment, while in 31% exclusively non-German guidelines were considered. For the following therapeutic areas, this was the case in >50% for eye diseases (80%), diseases of respiratory system (63%), cardiovascular diseases (60%), and diseases of blood and blood forming organs (60%). In 27%, the G-BA referred to no guidelines at all. Of these, 24% corresponded to pharmaceuticals with orphan drug designation and one diagnostic tool, while 3% corresponded to regular pharmaceuticals. In oncology, making up for 40% of the submitted dossiers, a similar trend as in the main analysis was observed with reference of the G-BA to German guidelines in 47% of cases, while in 24% exclusively non-German guidelines were considered. G-BA's main reason to not consider any guidelines for regular pharmaceuticals was that no relevant guidelines were detected during the systematic guideline search. This might be due to low incidence/prevalence diseases in combination with very narrow drug indications.

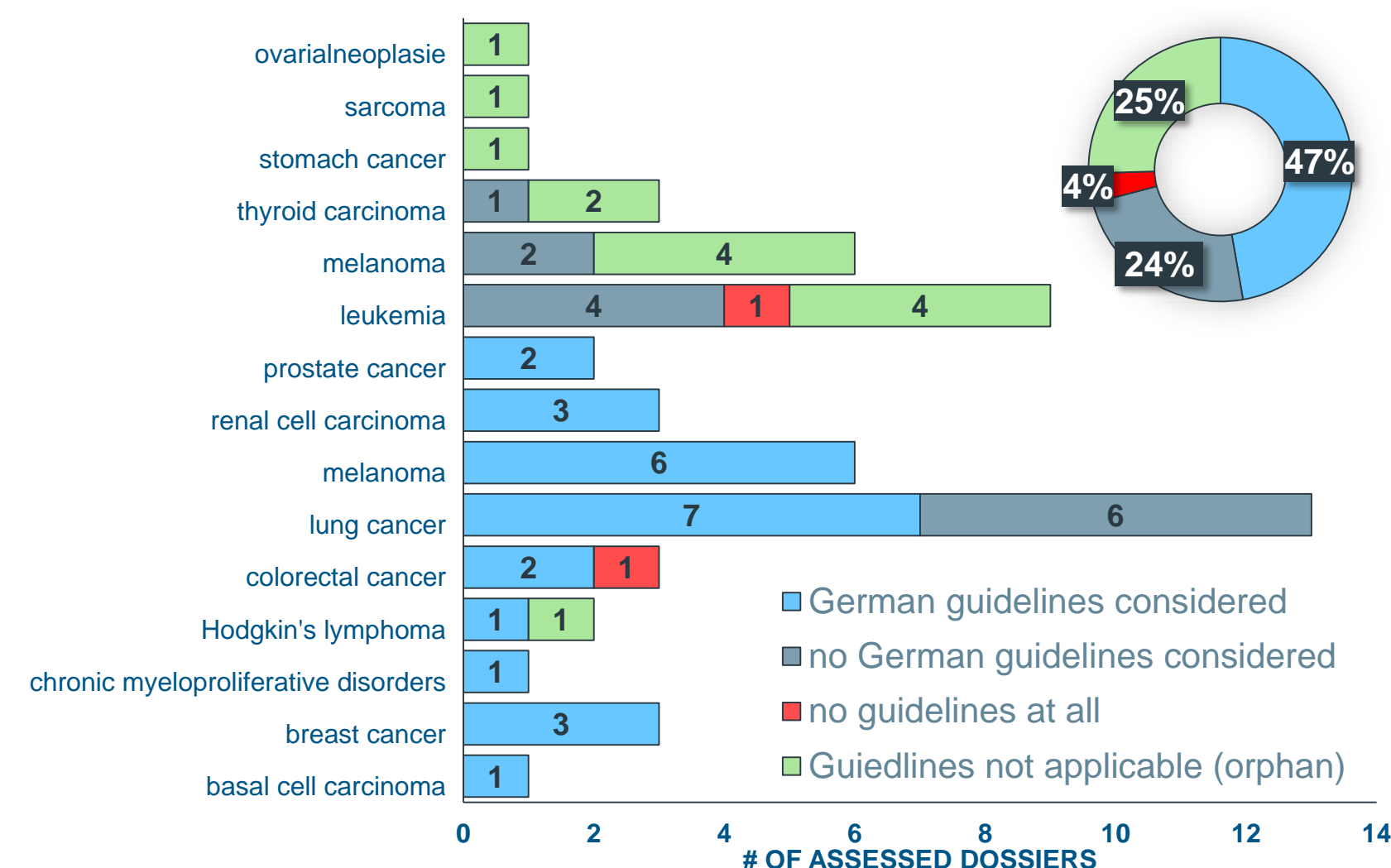
## Key findings

- 1) G-BA considers German guidelines where available.
- 2) The therapeutic field with the highest proportion of G-BA considering exclusively non-German guidelines is eye diseases.
- 3) G-BA's main reasons for considering no guidelines are orphan designations and failure to identify relevant guidelines, possibly due to low disease incidence/ prevalence.

## Overview of guidelines taken into consideration by the G-BA in 137 assessments between 01/07/2014 – 01/06/2017



## Oncology: Guideline considerations of 55 different dossiers



Sources:  
1. <https://www.g-ba.de/>  
2. HTA Database by IQVIA Commercial GmbH & Co. OHG.

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