

Background

Digital health applications (DiGAs) in Germany, introduced in 2019, have been gaining physician and patient acceptance with prescriptions tripling to ~125,000 between 2021-22. DiGAs are covering an increasing number of therapeutic areas, enhancing usual care and providing innovative treatment options for patients and physicians. Manufacturers can apply for either a permanent or provisional listing for their DiGA based on evidence package available at the time of application. DiGAs with satisfactory evidence requirements* are permanently listed in the directory while DiGAs which need additional evidence are provisionally listed with a trial period of ~1-2 years to gather additional data.

Objective

Purpose of this analysis was to evaluate pricing trends of all available DiGAs in Germany since inception and identify differences in initial manufacturer price vs final negotiated price

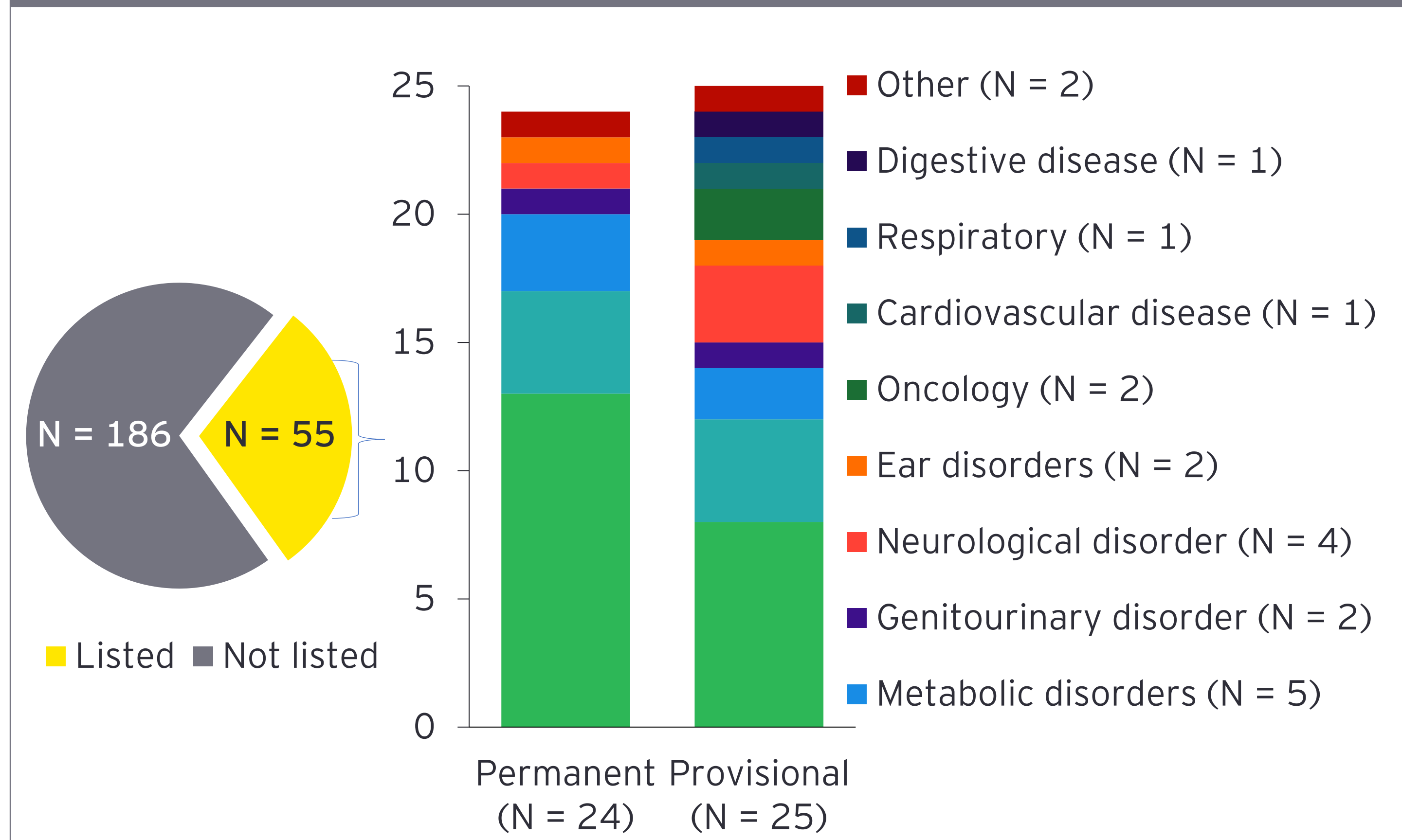
Methods

All assessments listed on the DiGA directory were reviewed individually to extract relevant information such as the DiGA name, indication, therapy area, listing status, manufacturer's price and negotiated price as of 20 September 2023. Price differential calculations were conducted on the permanently listed DiGAs where both manufacturer and negotiated prices are available to identify discount percentages. Data extraction and analysis was reviewed by two independent reviewers for accuracy.

Results

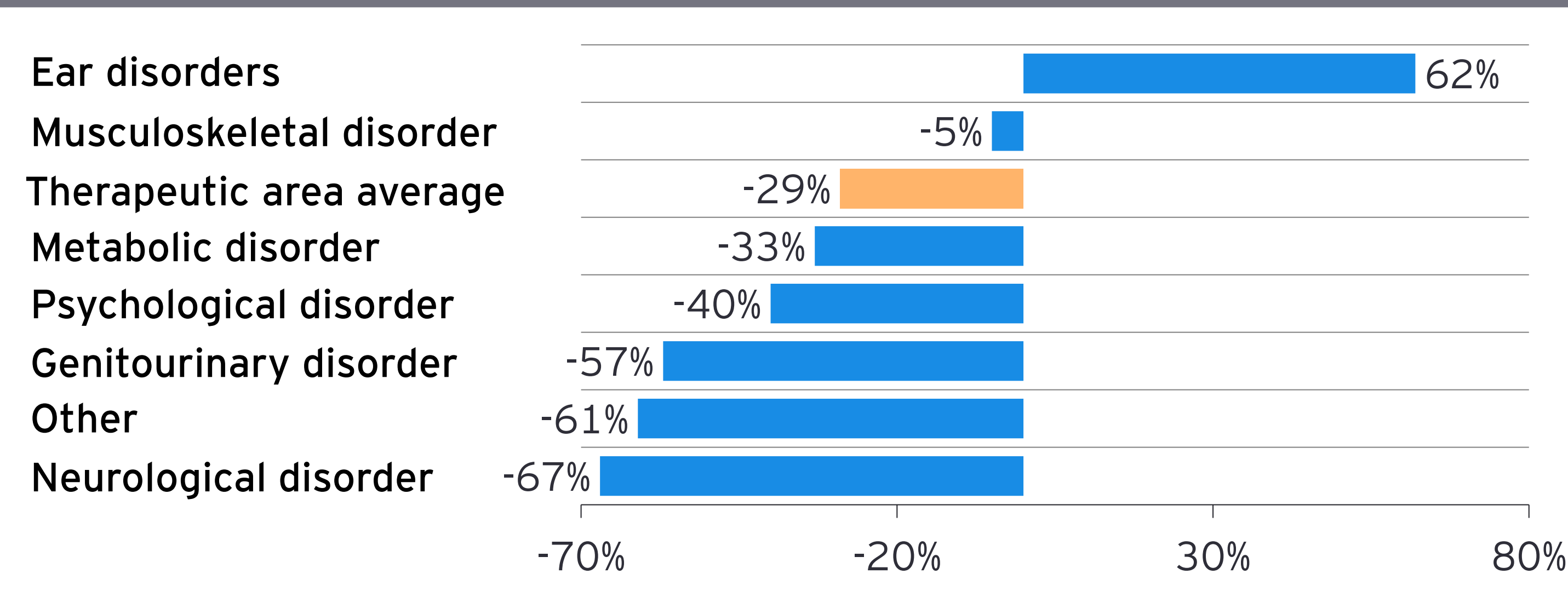
As of 20 September 2023, out of 186 applications, 55 DiGAs are either permanently or provisionally listed (figure 1). Out of total 55 DiGAs, 24 DiGAs are permanently listed while 25 are provisionally listed. Six DiGAs have been removed from the directory to date predominantly due to no positive health benefit demonstration. Top three therapy areas with most DiGAs are psychological disorders (N=21, 43%), musculoskeletal disorders (N=8, 16%) and metabolic disorders (N=5, 10%), all others (N=15, 31%).

Figure 1. Categories of permanently and provisionally listed DiGAs as of 20 September 2023



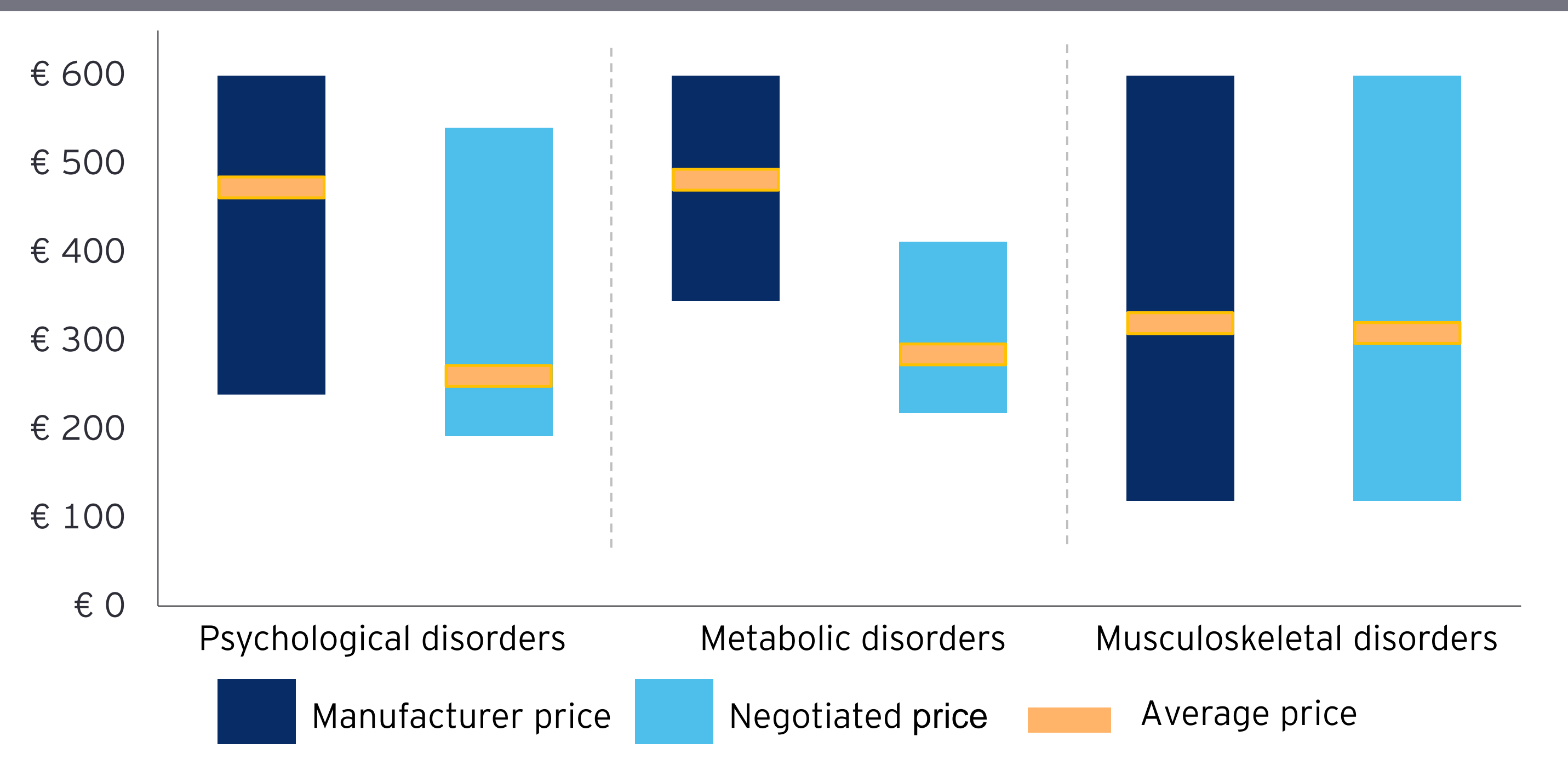
Results (continued)

Figure 2. Average price reduction of permanent DiGAs across therapeutic areas



Out of the total 24 permanently listed DiGAs, negotiated prices are available for 21 DiGAs. An average of ~29% decrease in negotiated price was observed compared to manufacturer's initial price across all the permanent listed DiGAs (figure 2). For majority (N=15, 71%) of permanent DiGAs, negotiated price is lower than initial manufacturer price with an exception of 3 DiGAs (14%) where price increased and 3 DiGAs (14%) where price remained constant. DiGAs for neurological disorders have seen the highest price reductions with an average of 67%.

Figure 3. Min-max price ranges of permanent DiGAs across therapeutic areas (TAs with >1 DiGAs considered for this analysis)



The ceiling price for permanent listed DiGAs remains at 600 euros for both the initial manufacturer and the negotiated price (figure 3). Prices of 8 DiGAs were set by the arbitration board due to non-agreement between payer and manufacturer. Despite provisional listing of DiGAs in the directory, payer organizations are critical of the high initial free price set by manufacturers.

Conclusion

Germany, although being a pioneer in the reimbursement of digital health applications, is increasingly not accepting the higher free price of DiGAs. Early payer engagement to inform evidence requirements is highly recommended. Consideration of competitive landscape and appropriate comparator in both the pricing and negotiating strategy is vital to minimize the gap between initial and final negotiated price.

References and Foot Notes

1. BfArM, Federal Institute for Drugs and Medical Devices
2. DiGA-Verzeichnis <https://diga.bfarm.de/de/verzeichnis/>
3. * Medical benefit or patient-relevant improvement