HTA84

Is our evidence enough?

A review of G-BA's ongoing evidentiary requirements in the oncology space

Perez-Kempner, Lucia; Rocha, Jessica

Background

- As increasing health expenditures call for a maximization of the value-per-dollar spent, health technology assessments (HTA) agencies, such as the German Gemeinsamer Bundesausschuss (G-BA), are requesting long-term, mature, comparative clinical data. The aim of this research was to identify additional data requests by G-BA in oncology that relate to uncertainties in the clinical evidence package at launch and, subsequently, in the value-per-dollar spent

Methods

- We selected two hematologic (chronic lymphocytic leukemia [CLL], multiple myeloma [MM]) and two solid (ovarian cancer [OC], triple-negative breast cancer [TNBC]) oncology indications. We identified all G-BA assessments conducted between Jan 2014 - Jul 2023 on therapies for these indications and analyzed the data-driven reassessments requests and time-limit impositions. Finally, we analyzed the decisions over time, identifying the trends across years.

Results

- 44 completed appraisals/re-appraisals were identified (**Figure 1**).
- **Seven appraisals** (OC: n=2; CLL: n=1; MM: n=4) involved **reassessments** (**Figure 2**). Most reassessments (5/7) related to clinical uncertainties at the initial assessment. Two reassessments were required because, as orphan drugs, the products exceeded the €50 million threshold (**Figure 2**). Of the five reassessments related to clinical uncertainties at the initial assessment, two did not present appropriate comparative data, and most did not present patient-relevant endpoints. Out of the seven re-assessments, four involved orphan drugs (MM: n=3; OC: n=1). Upon the reassessments, a hint of considerable additional benefit was proven in four products, proof of considerable additional benefit was demonstrated in one product, and no additional benefit was proven in two products.
- **Ten appraisals** (OC: n=3; TNBC: n=1; CLL: n=2; MM: n=4) involved **time-limit resolutions** related to clinical uncertainties at the initial assessment (**Figure 3**), which involved time limits between 1.5 and 4.5 years. None of these time-limit resolutions were imposed in the reassessments. Out of the ten re-assessments, six involved orphan drugs (MM: n=4; OC: n=1; CLL: n=1).
- Most reassessments (6/7) and some time-limit impositions (7/10) involved resolutions published after 2019 **(Figure 4**)

FIGURE 2: NUMBER OF HTA REASSESSMENTS

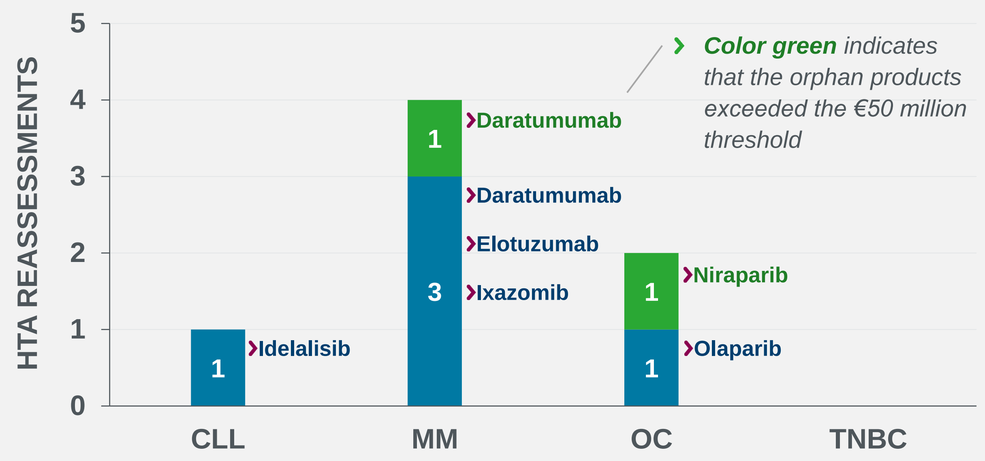


FIGURE 3: NUMBER OF HTA REASSESSMENTS WITH TIME LIMIT RESOLUTIONS

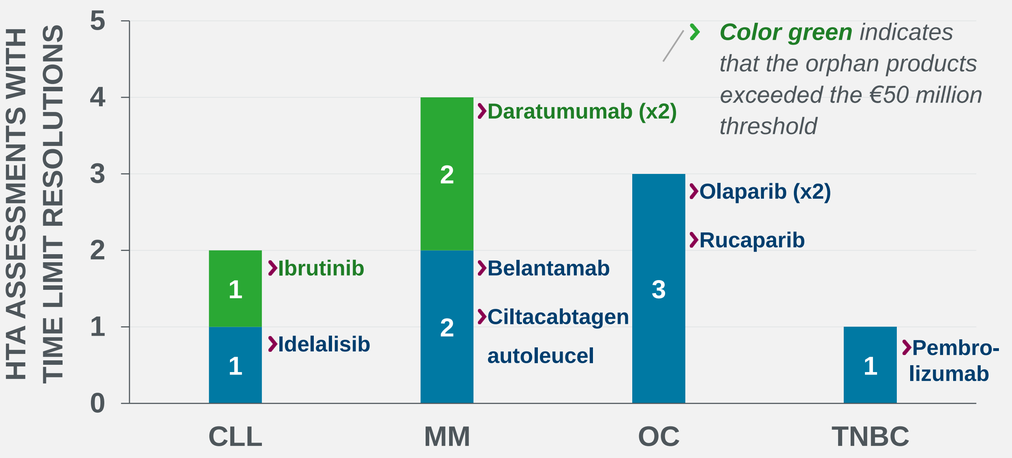


FIGURE 1: NUMBER OF HTA APPRAISALS

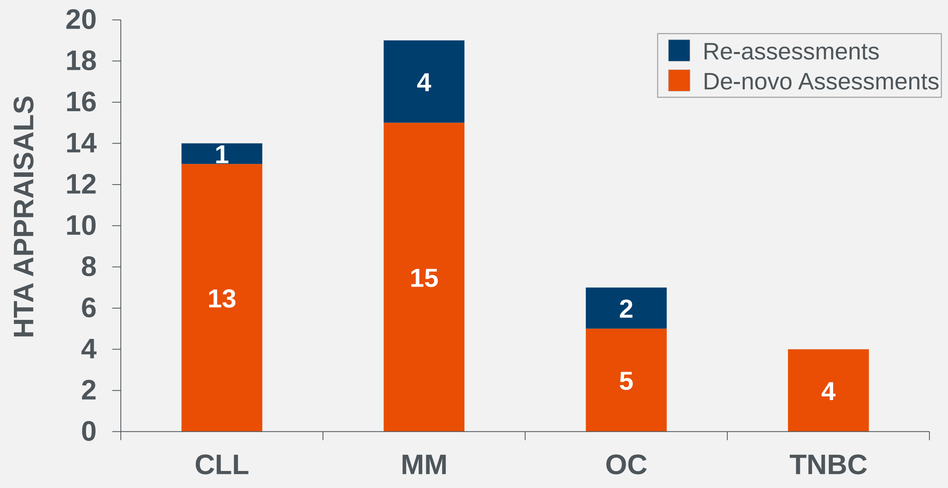
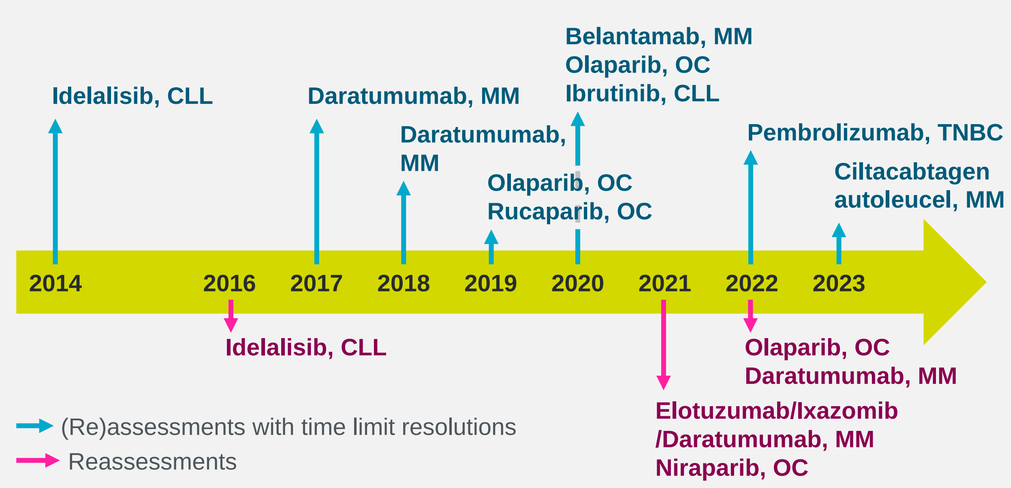


FIGURE 4: TIMELINES OF APPRAISALS



Conclusions

- As pressures to control expenditure increases, so does the need to provide meaningful evidence directly relevant to patient experience and clinical practice. This evidence is critical in order to support investments in healthcare. This research shows how risk is being managed in Germany through reassessments and time-limited approvals as the demand for value increases. Early payer engagement that allows the understanding of evidentiary requirements together with evidence packages at- and post-launch can help mitigate the access risks posed by clinical uncertainties.

REFERENCES

G-BA assessments for drugs launched in CLL, MM, TNBC, and OC

ABBREVIATIONS

CLL: chronic lymphocytic leukemia; G-BA: Gemeinsamer Bundesausschuss; HTA: Health Technology Assessment; MM: multiple myeloma; OC ovarian cancer; TNBC: triple-negative breast cancer.