OBJECTIVES
- For the mandatory assessment of the benefit of new drugs in Germany, an appropriate comparator is defined by the Federal Joint Committee (FJC).
- Appropriate comparators can be categorized into four classes: (1) one specific drug; (2) a list of drugs; (3) best supportive care (BSC); and (4) patient individual therapy.
- The goal of this analysis was to determine which methodological challenges come along with the assignment of patient individual therapy as an appropriate comparator and how this comparator impacts the outcome of the benefit assessment.

METHODS
- Information was retrieved from all non-orphan AMNOG-dossiers in the field of oncology published at the FJC website (https://www.g-ba.de) until the end of 2015.
- Information concerning indication, size of target population, line of therapy, and outcome was obtained. In addition, it was examined whether the pharmaceutical companies followed the definition of the appropriate comparator by the FJC in their dossiers or not.

RESULTS
- 42 relevant AMNOG-dossiers in the field of oncology were published within the years 2011-2015 and exclusively assessed by the FJC. These dossiers included 73 separately evaluated sublabels.
- The assignment of appropriate comparators was distributed as follows: 26 (36%) specific drug; 16 (22%) list of drugs; 20 (27%) BSC; and 11 (15%) patient individual therapy (Figure 1).
- Patient individual therapy was named as the appropriate comparator in 11 cases (15%) (Figure 1).
- The most common appropriate comparator was a specific drug (36%) (Figure 1).

CONCLUSIONS
- Patient individual therapy (i.e., all relevant drugs can be used to the discretion of the study physician) is not defined as an appropriate comparator by the FJC for drugs designated for frontline therapy and in only 3% of the dossiers in that period (Figure 4).
- If a specific drug or a list of drugs is assigned as the appropriate comparator, an added benefit could only be achieved, if the company’s choice of the comparator matched the FJC requirements.
- In the case of patient individual therapy and BSC, there seems to be more flexibility regarding the choice of the comparator. In this category the likelihood of achieving an added benefit was comparably high (Figure 4).

Figure 1: Patient individual therapy is the least common appropriate comparator in oncological AMNOG-dossiers.

Figure 2: In frontline therapies, patient individual therapy was not assigned as appropriate comparator.

Figure 3: Patient individual therapy was assigned as appropriate comparator in small target populations only.

Figure 4: Patient individual therapy was increasingly assigned as appropriate comparator in the last three years.

Figure 5: Labels with patient individual therapy as appropriate comparator less often achieved an added benefit.

Figure 6: Patient individual therapy: There may be proof of an added benefit irrespective of compliance with FJC’s definition of the appropriate comparator.