BACKGROUND

Introduction

• The implementation of the AMNOG led to the regulatory change of the German G-BA process for evaluating ACB since the inception of the AMNOG law.

METHODS

• A database was created of all the G-BA decisions on ACB through September 2012 by product and indication.

RESULTS

Overall

• The database included 30 final resolutions assessing ACB (Figure 1).

• Most of the G-BA resolved 20 (67%) submissions as having ACB, 10 (33%) final resolutions where ACB was not proven.

• In the 20 (67%) final resolutions where ACB was proven: 6 (20%) were designated as having ACB for only a subset of the indicated population, 5 (25%) were designated as having considerable clinical benefit, 8 (40%) for submitted population/indications.

• In the 10 (33%) final resolutions where ACB was not proven: 5 (25%) were designated as having no ACB for only a subset of the indicated population, 4 (20%) additional benefit in subgroup(s), 3 (10%) considered clinical benefit, effect not quantifiable.

• The database included 30 final resolutions assessing ACB. Of these, 10 (33%) final resolutions where ACB was not proven: 6 (20%) were designated as having ACB for only a subset of the indicated population, 5 (25%) were designated as having considerable clinical benefit, 8 (40%) for submitted population/indications.

CONCLUSIONS

• The percentage of submissions for which ACB was proven was higher in the last 4 months compared with the previous months.

• Since implementation of the requirement for the AMNOG dossier for assessment of clinical benefit for reimbursement in the German statutory health care system in January 2011, two-thirds of the submissions have been assessed as having some level of ACB.

• ACB was considered proven only for a subgroup of the marketing indication for 25% of these submissions, and the level of clinical benefit varied from considerable benefit to indication of benefit, effect not quantifiable.

• Assessment by direct comparison was performed in almost half of the positive assessments.

• The percentage of submissions for which ACB was proven was higher in the last 4 months compared with the previous months.

REFERENCES


CONTACT INFORMATION

Doreen McBride, MBA, PhD
Senior Director, Health Economics (Germany)
RTI Health Solutions
2nd Floor, The Pavilion
Traverse Business Park
Witham Road
Dukinfield
Manchester M20 3L5, United Kingdom
Phone: (+within Germany) (030)567.95.707
(+outside Germany) +49.30.567.95.707 or +49(0)733.76.2947
Fax: +44(0)161.434.8232
E-mail: dmcbride@rti.org

Presented at: ISPOR 15th Annual European Congress 3-7 November 2012 Berlin, Germany