## Are Clinical Guidelines Informed by HTA Decision Making? A German Analysis by IQWiG

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Linical guidelines influence clinical decisions on diagnostics and treatments, rules of operation at hospitals and clinics, and in some countries healthcare spending by governments and insurers is also being influenced by guidelines. As defined by the Institute of Medicine, clinical guidelines are "statements that include recommendations, intended to optimize patient care, that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options."<sup>1</sup>They may offer concise instructions on which diagnostic or screening tests to offer, how to provide medical or surgical services, how long patients should stay in the hospital, or other details of clinical practice.

The type of information included in a clinical guideline should come from a systematic review of the available evidence. To most 'market access' savvy audiences it may seem appropriate that information from health technology assessments (HTAs) be included in national clinical guidelines. However, an investigation conducted by the Institute for Quality and Efficiency in Health





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Care (IQWiG) in 2016 found that information from the Pharmaceuticals Market Reorganisation Act (AMNOG) benefit assessments have not been included in German S3-guidelines to date.<sup>2,3</sup> IQWiG scientists investigated the extent to which AMNOG findings are cited/ considered in the German guidelines. As of 2 October 2015, 133 dossier assessments have been conducted. At the same time, there were 141 up-to-date S3, 28 of which focused on indications where AMNOG-assessed medicines are used. Of these 28 guidelines, 12 were updated after the publication of Germany's Federal Joint Committee (G-BA) resolution on related medicines and could potentially include G-BA's findings and recommendations.

**Results:** Only 3 out of 12 guidelines mentioned the respective AMNOG assessments with none of the 3 presenting the content of AMNOG documents.

## For more information, email info@evidera.com.

- <sup>1</sup> The National Academies of Sciences Engineering Medicine, Health and Medicine Division. Clinical Practice Guidelines We Can Trust. March 23, 2011. Available at: http://nationalacademies.org/hmd/reports/2011/clinical-practice-guidelines-we-can-trust.aspx. Accessed March 29, 2017.
- <sup>2</sup> Auf den Punkt gebracht, Zahlen und Fakten aus dem IQWiG 2016; IQWiG January 2017. Available at: https://www.iqwig.de/download/2016\_IQWiG\_Auf\_den\_Punkt\_gebracht.pdf. Accessed March 29, 2017.
- <sup>3</sup> AWMF Online. AWMF-Regelwerk Leitlinien: Graduierung der Empfehlungen. Available at: http://www.awmf.org/leitlinien/awmf-regelwerk/llentwicklung/awmf-regelwerk-03-leitlinienentwicklung/ll-entwicklung-graduierung-der-empfehlungen.html. Accessed March 29, 2017.

## **German Guideline Information**

- S1: The guideline was developed by an expert group in an informal consensus.
- **S2k:** A formal consensus-finding has taken place.
- S2e: A systematic evidence research has taken place.
- **S3:** The guideline has gone through all elements of a systematic development (logic, decision-making and outcome analysis, evaluation of the clinical relevance of scientific studies and periodic review).

## **Citations of AMNOG Assessments in Guidelines are Very Rare**



Graphic from Auf den Punkt gebracht, Zahlen und Fakten aus dem IQWiG 2016