IQWiG Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen

IQWiG Reports - Commission No. A11-29

Aliskiren / amlodipine –

Benefit assessment according to § 35a Social Code Book V[1]

Extract

[1] Translation of Sections 2.1 to 2.6 of the dossier assessment ("Aliskiren/Amlodipin – Nutzenbewertung gemäß § 35a SGB V" (Version 1.0; Status10.02.2012). Please note: This translation is provided as a service by IQWiG to English-language readers. However, solely the German original text is absolutely authoritative and legally binding.

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2 Executive summary

2.1 Executive summary of the benefit assessment

Background

On 14.11.2011, in accordance with § 35a SGB (Social Code Book) V, the Federal Joint Committee (G-BA) wrote to IQWiG to commission the benefit assessment of the fixed combination of the drugs aliskiren and amlodipine (aliskiren / amlodipine). The assessment was based on a dossier compiled by the pharmaceutical company.

Research question

The benefit assessment of the fixed combination aliskiren / amlodipine was carried out for the therapeutic indication "treatment of essential hypertension in adults whose blood pressure is not adequately controlled with aliskiren or amlodipine used alone" [1].

The G-BA specified that the benefit assessment was to be undertaken in comparison with combination treatment consisting of an

- ACE inhibitor (lisinopril or ramipril or enalapril) and a
- calcium antagonist (amlodipine or nitrendipine).

However, in its dossier the pharmaceutical company compared the fixed combination aliskiren / amlodipine with a free combination of the same two drugs. It thus deviated from the G-BA's specifications and, in the Institute's view, did not provide adequate justification for doing so.

Results

By choosing a different comparator therapy, the dossier of the pharmaceutical company did not address the research question described above. No studies that would have been relevant for this question were submitted by the company. Therefore no proof of an added benefit of aliskiren / amlodipine in comparison with the appropriate comparator therapy specified by the G-BA can be inferred from the evaluation presented in the company's dossier.

Probability and extent of the added benefit, patient groups with therapeutically important added benefits

Based on the results presented, the extent and probability of the added benefit of aliskiren / amlodipine is assessed as follows:

- There is no proof of added benefit.

In respect of patient groups with therapeutically important added benefits, the result is as follows:

- There are no groups of patients for whom a therapeutically important added benefit is proven.

The decision regarding added benefit is made by the G-BA.

2.2 Research question

The benefit assessment of the fixed combination aliskiren / amlodipine was carried out in relation to its approved indication [1] of "treatment of essential hypertension in adults whose blood pressure is not adequately controlled with aliskiren or amlodipine used alone".

In the dossier, the pharmaceutical company designated a free combination of aliskiren and amlodipine as the appropriate comparator therapy. By doing so, it deviated from the combination therapy specified by the G-BA, consisting of an

- ACE inhibitor (lisinopril or ramipril or enalapril) and a
- calcium antagonist (amlodipine or nitrendipine)

In the Institute's view – which is presented in detail in Section 2.7.1 of the full assessment - the pharmaceutical company does not provide adequate justification for this deviation.

Therefore IQWiG used the appropriate comparator therapy specified by the G-BA for the benefit assessment.

The assessment was carried out in relation to patient-relevant outcomes.

Further information about the research question can be found in Module 3, Section 3.1 and Module 4 Section 4.2.1 of the dossier and in Sections 2.7.1 and 2.7.2.1 of the full dossier assessment.

2.3 Information retrieval and study pool

The only available study pool was the list of studies provided by the pharmaceutical company. This contained no relevant studies. The company undertook other methods of information retrieval (bibliographical literature searches, searches in trial registries) with a view to what it regarded as the pertinent questions. However it did not address the question that was actually relevant (comparison of aliskiren / amlodipine with the appropriate comparator therapy specified by the G-BA).

Overall, none of the studies were relevant for the benefit assessment.

Further information about the inclusion criteria for studies in the benefit assessment and the methods of information retrieval can be found in Module 4, Sections 4.2.2 and 4.2.3 of the dossier and in Sections 2.7.2.1 and 2.7.2.3 of the full dossier assessment.

2.4 Results concerning added benefit

Since no study of relevance for the benefit assessment was submitted, there is no proof of added benefit of aliskiren / amlodipine compared with the appropriate comparator therapy specified by the G-BA.

This differs from the approach of the pharmaceutical company, which, on the one hand presented a comparative evaluation with its chosen comparator therapy (free combination of aliskiren and amlodipine) and on the other, submitted results on the comparison of fixed combinations of any other antihypertensive drugs with the free combinations of the same drugs. This process leads the company to derive an overall added benefit of aliskiren / amlodipine.

Further information about the results concerning added benefit can be found in Module 4, Sections 4.3.1.3 and 4.3.2.1.3 of the dossier.

2.5 Extent and probability of the added benefit, patient groups with therapeutically important added benefit

The data submitted provide no proof of added benefit of aliskiren / amlodipine compared with the appropriate comparator therapy specified by the G-BA. Hence there are also no patient groups for whom a therapeutically important added benefit can be derived.

This differs from the conclusion of the pharmaceutical company, who showed a considerable added benefit of aliskiren / amlodipine in comparison with its own selected comparator therapy (free combination of aliskiren and amlodipine).

Further information about the extent and probability of the added benefit can be found in Module 4, Section 4.4 of the dossier and in Section 2.7.2.5 of the full dossier assessment.

2.6 List of included studies

In its evaluation the pharmaceutical company did not include any relevant study comparing aliskiren / amlodipine with the appropriate comparator therapy specified by the G-BA.

Keywords: aliskiren / amlodipine; essential hypertension; benefit assessment

References

1) European Medicines Agency. Assessment Report for Rasilamlo. Procedure No. EMEA/H/C/002073 (accessed on 03.03.2012). http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Public_assessment_report/human/002073/WC500107202.pdf

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