Lasmiditan (migraine)

Benefit assessment according to §35a SGB V[1]

EXTRACT

Project: A23-35 Version: 1.0 Status: 22 June 2023

[1] Translation of Sections I 1 to I 4 of the dossier assessment *Lasmiditan (Migräne) – Nutzenbewertung gemäß § 35a SGB V*. 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.

Publishing details

Publisher

Institute for Quality and Efficiency in Health Care

Topic

Lasmiditan (migraine) – Benefit assessment according to §35a SGB V

Commissioning agency

Federal Joint Committee

Commission awarded on

17 April 2023

Internal Project No.

A23-35

Address of publisher

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No advisor on medical and scientific questions was involved in the present dossier assessment.

Patient and family involvement

No patients or families were involved in the present dossier assessment.

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Keywords

Lasmiditan, Migraine Disorders, Benefit Assessment

Part I: Benefit assessment

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[2] Table numbers start with “2” as numbering follows that of the full dossier assessment.

I List of abbreviations

Abbreviation	Meaning
ACT	appropriate comparator therapy
G-BA	Gemeinsamer Bundesausschuss (Federal Joint Committee)
IQWiG	Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (Institute for Quality and Efficiency in Health Care)
RCT	randomized controlled trial
SGB	Sozialgesetzbuch (Social Code Book)

I 1 Executive summary of the benefit assessment

Background

In accordance with § 35a Social Code Book (SGB) V, the Federal Joint Committee (G-BA) commissioned the Institute for Quality and Efficiency in Health Care (IQWiG) to assess the benefit of the drug lasmiditan. The assessment is based on a dossier compiled by the pharmaceutical company (hereinafter referred to as the "company"). The dossier was sent to IQWiG on 17 April 2023.

Research question

The aim of the present report was to assess the added benefit of lasmiditan in comparison with the appropriate comparator therapy (ACT) for adult patients who need acute treatment in the headache phase of migraine attacks with or without aura.

The research question presented in Table 2 results from the ACT specified by the G-BA.

Table 2: Research question of the benefit assessment of lasmiditan

Therapeutic indication	**ACT**[a]
Adults who need acute treatment in the headache phase of migraine attacks with or without aura	Individualized treatment[b] taking into account the pretreatment, the severity of the attack and existing concomitant diseases, choosing from selective serotonin 5-HT1 receptor agonists (almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, sumatriptan, zolmitriptan) and nonsteroidal anti-inflammatory drugs (acetylsalicylic acid, diclofenac, ibuprofen)

a. Presented is the ACT specified by the G-BA.
b. For the implementation of individualized therapy in a study of direct comparison, the investigator is expected to have a selection of several treatment options at disposal to permit an individualized treatment decision taking into account the listed criteria (multicomparator study). A rationale must be provided for the choice and any limitation of treatment options. The decision on individualized treatment with regard to the comparator therapy should be made before group allocation (e.g. randomization). This does not apply to necessary therapy adjustments during the course of the study. In single-comparator studies, the extent to which conclusions can be drawn about a subpopulation is examined as part of the benefit assessment.

ACT: appropriate comparator therapy; G-BA: Federal Joint Committee; 5-HT1: 5-hydroxytryptamine-1

The present assessment was conducted in comparison with the ACT specified by the G-BA. The company deviates from the ACT specified by the G-BA by adding drug and/or non-drug prophylactic measures. This is not appropriate. The present therapeutic indication covers the specific situation of treatment of an acute migraine attack with the aim of short-term relief of the headache, the most distressing accompanying symptoms and restoration of the patient's functioning, but not the treatment of episodic or chronic migraine over the course.

Furthermore, the company's deviation from the G-BA's ACT is not commented on further, as it presented no data on the comparator therapy named by it or on the ACT specified by the G-BA.

The assessment is conducted by means of patient-relevant outcomes on the basis of the data presented by the company in the dossier. Randomized controlled trials (RCTs) with a minimum duration of 12 weeks were used for the derivation of added benefit.

Results

In line with the company's assessment, the check of the information retrieval identified no relevant study for the assessment of the added benefit of lasmiditan in comparison with the G-BA's ACT.

Results on added benefit

Since no relevant study is available for the benefit assessment, there is no hint of an added benefit of lasmiditan in comparison with the ACT; an added benefit is therefore not proven.

Probability and extent of added benefit, patient groups with therapeutically important added benefit[3]

Table 3 shows a summary of probability and extent of the added benefit of lasmiditan.

[3] On the basis of the scientific data analysed, IQWiG draws conclusions on the (added) benefit or harm of an intervention for each patient-relevant outcome. Depending on the number of studies analysed, the certainty of their results, and the direction and statistical significance of treatment effects, conclusions on the probability of (added) benefit or harm are graded into 4 categories: (1) "proof", (2) "indication", (3) "hint", or (4) none of the first 3 categories applies (i.e., no data available or conclusions 1 to 3 cannot be drawn from the available data). The extent of added benefit or harm is graded into 3 categories: (1) major, (2) considerable, (3) minor (in addition, 3 further categories may apply: non-quantifiable extent of added benefit, added benefit not proven, or less benefit). For further details see [1,2].

Table 3: Lasmiditan – probability and extent of added benefit

Therapeutic indication	**ACT**[a]	**Probability and extent of added benefit**
Adults who need acute treatment in the headache phase of migraine attacks with or without aura	Individualized treatment[b] taking into account the pretreatment, the severity of the attack and existing concomitant diseases, choosing from selective serotonin 5-HT1 receptor agonists (almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, sumatriptan, zolmitriptan) and nonsteroidal anti-inflammatory drugs (acetylsalicylic acid, diclofenac, ibuprofen)	Added benefit not proven

a. Presented is the ACT specified by the G-BA.
b. For the implementation of individualized therapy in a study of direct comparison, the investigator is expected to have a selection of several treatment options at disposal to permit an individualized treatment decision taking into account the listed criteria (multicomparator study). A rationale must be provided for the choice and any limitation of treatment options. The decision on individualized treatment with regard to the comparator therapy should be made before group allocation (e.g. randomization). This does not apply to necessary therapy adjustments during the course of the study. In single-comparator studies, the extent to which conclusions can be drawn about a subpopulation is examined as part of the benefit assessment.

ACT: appropriate comparator therapy; G-BA: Federal Joint Committee; 5-HT1: 5-hydroxytryptamine-1

The G-BA decides on the added benefit.

I 2 Research question

The aim of the present report was to assess the added benefit of lasmiditan in comparison with the ACT for adult patients who need acute treatment in the headache phase of migraine attacks with or without aura.

The research question presented in Table 4 results from the ACT specified by the G-BA.

Table 4: Research question of the benefit assessment of lasmiditan

Therapeutic indication	**ACT**[a]
Adults who need acute treatment in the headache phase of migraine attacks with or without aura	Individualized treatment[b] taking into account the pretreatment, the severity of the attack and existing concomitant diseases, choosing from selective serotonin 5-HT1 receptor agonists (almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, sumatriptan, zolmitriptan) and nonsteroidal anti-inflammatory drugs (acetylsalicylic acid, diclofenac, ibuprofen)

a. Presented is the ACT specified by the G-BA.
b. For the implementation of individualized therapy in a study of direct comparison, the investigator is expected to have a selection of several treatment options at disposal to permit an individualized treatment decision taking into account the listed criteria (multicomparator study). A rationale must be provided for the choice and any limitation of treatment options. The decision on individualized treatment with regard to the comparator therapy should be made before group allocation (e.g. randomization). This does not apply to necessary therapy adjustments during the course of the study. In single-comparator studies, the extent to which conclusions can be drawn about a subpopulation is examined as part of the benefit assessment.

ACT: appropriate comparator therapy; G-BA: Federal Joint Committee; 5-HT1: 5-hydroxytryptamine-1

The present assessment was conducted in comparison with the ACT specified by the G-BA. The company deviates from the ACT specified by the G-BA by adding drug and/or non-drug prophylactic measures. This is not appropriate. The present therapeutic indication covers the specific situation of treatment of an acute migraine attack with the aim of short-term relief of the headache, the most distressing accompanying symptoms and restoration of the patient's functioning, but not the treatment of episodic or chronic migraine over the course.

Furthermore, the company’s deviation from the G-BA’s ACT is not commented on further, as it presented no data on the comparator therapy named by it or on the ACT specified by the G-BA.

The assessment is conducted by means of patient-relevant outcomes on the basis of the data presented by the company in the dossier. RCTs with a minimum duration of 12 weeks were used for the derivation of added benefit. This corresponds to the company’s inclusion criteria for the investigation of the effect with more than 3 subsequent migraine attacks, for which it defines a study duration of at least 3 months.

I 3 Information retrieval and study pool

The study pool of the assessment was compiled on the basis of the following information:

- study list on lasmiditan (status: 14 February 2023)
- bibliographical literature search on lasmiditan (last search on 14 February 2023)
- search in trial registries/trial results databases for studies on lasmiditan (last search on 16 February 2023)
- search on the G-BA website for lasmiditan (last search on 16 February 2023)

To check the completeness of the study pool:

- search in trial registries for studies on lasmiditan (last search on 27 April 2023); for search strategies, see I Appendix A

The check of the information retrieval did not identify any relevant study for assessing the added benefit of lasmiditan in comparison with the ACT. This concurs with the company's assessment.

However, in Module 4 of the dossier, the company presents the studies LAHJ (SAMURAI) [3], LAHK (SPARTAN) [4] and LAIJ (CENTURION) [5] conducted in the therapeutic indication. Instead of using the study to derive the added benefit, it presented its results only as supplementary information. The 3 RCTs compare the treatment of migraine attacks with lasmiditan versus placebo in adult patients with migraine (with or without aura). Since there was no comparison with the ACT, the studies LAHJ, LAHK and LAIJ, in agreement with the company, is assessed as unsuitable for the assessment of the added benefit of lasmiditan in the present therapeutic indication.

I 4 Results on added benefit

The company has not submitted any suitable data for assessing the added benefit of lasmiditan in comparison with the ACT in adult patients who need acute treatment in the headache phase of migraine attacks with or without aura. There is no hint of an added benefit of lasmiditan in comparison with the ACT; an added benefit is therefore not proven.

I 5 Probability and extent of added benefit

Table 5 summarizes the result of the assessment of added benefit of lasmiditan in comparison with the ACT.

Table 5: Lasmiditan – probability and extent of added benefit

Therapeutic indication	**ACT[a]**	**Probability and extent of added benefit**
Adults who need acute treatment in the headache phase of migraine attacks with or without aura	Individualized treatment[b] taking into account the pretreatment, the severity of the attack and existing concomitant diseases, choosing from selective serotonin 5-HT1 receptor agonists (almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, sumatriptan, zolmitriptan) and nonsteroidal anti-inflammatory drugs (acetylsalicylic acid, diclofenac, ibuprofen)	Added benefit not proven

a. Presented is the ACT specified by the G-BA.
b. For the implementation of individualized therapy in a study of direct comparison, the investigator is expected to have a selection of several treatment options at disposal to permit an individualized treatment decision taking into account the listed criteria (multicomparator study). A rationale must be provided for the choice and any limitation of treatment options. The decision on individualized treatment with regard to the comparator therapy should be made before group allocation (e.g. randomization). This does not apply to necessary therapy adjustments during the course of the study. In single-comparator studies, the extent to which conclusions can be drawn about a subpopulation is examined as part of the benefit assessment.

ACT: appropriate comparator therapy; G-BA: Federal Joint Committee; 5-HT1: 5-hydroxytryptamine-1

The assessment described above concurs with that of the company.

The G-BA decides on the added benefit.

I 6 References

The reference list contains citations provided by the company in which bibliographical information may be missing.

Please see full dossier assessment for full reference list.

The reference list contains citations provided by the company in which bibliographical information may be missing.

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The full report (German version) is published under https://www.iqwig.de/en/projects/a23-35.html.