Rimegepant
(migraine, acute treatment)

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

EXTRACT

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[1] Translation of Sections I 1 to I 4 of the dossier assessment *Rimegepant (Migräne, Akutbehandlung) – 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.

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Keywords

Rimegepant, Migraine Disorders, Benefit Assessment

Medical and scientific advice

- No advisor on medical and scientific questions was available for the present dossier assessment.

Patient and family involvement

The questionnaire on the disease and its treatment was answered by two persons.

IQWiG thanks the respondents for participating in the written exchange about how they experienced the disease and its treatment and about the treatment goals. The respondents were not involved in the actual preparation of the dossier assessment.

IQWiG employees involved in the dossier assessment

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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)
NSAIDs	non-steroidal anti-inflammatory drugs
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 V, the Federal Joint Committee (G-BA) has commissioned the Institute for Quality and Efficiency in Health Care (IQWiG) to assess the benefit of the drug rimegepant. 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 30 May 2025.

Research question

The aim of this report was to assess the added benefit of rimegepant in comparison with the appropriate comparator therapy (ACT) for adults with migraine with or without aura who require acute treatment.

The research question shown in Table 2 was defined in accordance with the ACT specified by the G-BA.

Table 2: Research question for the benefit assessment of rimegepant

Therapeutic indication	**ACT[a]**
Adults with migraine with or without aura who require acute treatment	Individualized treatment[b] taking into account the pretreatment, the severity of the attack and existing concomitant diseases, choosing from selective serotonin 5-HT_1 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 treatment in a study of direct comparison, the investigators are 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, benefit assessments are used, in part, to ascertain the extent to which conclusions can be drawn about a subpopulation.

ACT: appropriate comparator therapy; G-BA: Federal Joint Committee; 5-HT_1: 5-hydroxytryptamine-1

The company deviates from the ACT specified by the G-BA in that it adds lasmiditan to the ACT for patients who have contraindications to triptans or for whom analgesics/non-steroidal anti-inflammatory drugs (NSAIDs)/triptans are not sufficiently effective.

The company's approach to determining the ACT will not be commented on further, as suitable data for the benefit assessment are lacking. The benefit assessment was conducted in comparison with the ACT specified by the G-BA.

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

Results

The review of the information retrieval did not identify any relevant study for assessing the added benefit of rimegepant 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 rimegepant 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 rimegepant.

Table 3: Rimegepant – probability and extent of added benefit

Therapeutic indication	ACT[a]	Probability and extent of added benefit
Adults with migraine with or without aura who require acute treatment	Individualized treatment[b] taking into account the pretreatment, the severity of the attack and existing concomitant diseases, choosing from selective serotonin 5-HT_1 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 treatment in a study of direct comparison, the investigators are 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, benefit assessments are used, in part, to ascertain the extent to which conclusions can be drawn about a subpopulation.

ACT: appropriate comparator therapy; G-BA: Federal Joint Committee; 5-HT_1: 5-hydroxytryptamine-1

The G-BA decides on the added benefit.

[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].

I 2 Research question

The aim of this report was to assess the added benefit of rimegepant in comparison with the ACT for adults with migraine with or without aura who require acute treatment.

The research question shown in Table 4 was defined in accordance with the ACT specified by the G-BA.

Table 4: Research question for the benefit assessment of rimegepant

Therapeutic indication	**ACT**[a]
Adults with migraine with or without aura who require acute treatment	Individualized treatment[b] taking into account the pretreatment, the severity of the attack and existing concomitant diseases, choosing from selective serotonin 5-HT_1 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 treatment in a study of direct comparison, the investigators are 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, benefit assessments are used, in part, to ascertain the extent to which conclusions can be drawn about a subpopulation.

ACT: appropriate comparator therapy; G-BA: Federal Joint Committee; 5-HT_1: 5-hydroxytryptamine-1

The company deviates from the ACT specified by the G-BA in that it adds lasmiditan to the ACT for patients who have contraindications to triptans or for whom analgesics/NSAIDs/triptans are not sufficiently effective.

The company's approach to determining the ACT will not be commented on further, as suitable data for the benefit assessment are lacking. The benefit assessment was conducted in comparison with the ACT specified by the G-BA.

The assessment was conducted by means of patient-relevant outcomes on the basis of the data provided by the company in the dossier. RCTs with a minimum duration of 12 weeks are used for the derivation of added benefit. This concurred with the company’s inclusion criteria.

I 3 Information retrieval and study pool

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

Sources used by the company in the dossier:

- Study list on rimegepant (status: 22 April 2025)
- Bibliographical literature search on rimegepant (last search on 24 March 2025)
- Search in trial registries/trial results databases for studies on rimegepant (last search on 24 March 2025)
- Search on the G-BA website for rimegepant (last search on 24 March 2025)

To check the completeness of the study pool:

- Search in trial registries for studies on rimegepant (last search on 12 June 2025); for search strategies, see I Appendix A of the full dossier assessment

The review of the information retrieval did not identify any relevant study for assessing the added benefit of rimegepant in comparison with the G-BA's ACT. This concurs with the company's assessment.

However, in Module 4 A Section 4.4, the company supplementarily presents the results of the approval studies BHV3000-301 [3], BHV3000-302 [4] and BHV3000-303 [5] to characterize the medical benefit. The 3 RCTs compare the treatment of migraine attacks with rimegepant versus placebo in adults with migraine (with or without aura). Due to the lack of comparison with the ACT, the studies BHV3000-301, BHV3000-302, and BHV3000-303 are assessed as unsuitable for the benefit assessment of rimegepant in the present therapeutic indication (concurring with the company).

The company additionally names the studies BHV3000-310 [6] and BHV3000-313 [7], BHV3000-318 [8], CN170-003 [9], BHV3000-305 [10], BHV3000-201 [11] and BHV3000-401 [12], which would reflect the positive results on efficacy and safety of the above-mentioned approval studies. The company did not present any results of these studies. These studies, too, do not include a comparison of rimegepant versus the ACT, and are therefore also not suitable for the benefit assessment of rimegepant in the present therapeutic indication.

Moreover, in Section 4.4 of Module 4 A the company describes an unanchored matching-adjusted indirect comparison (MAIC) analysis on outcomes relating to side effects. This analysis compares treatment with rimegepant with treatment with lasmiditan. Data from the single-arm study BHV-3000-201 [11] were included for rimegepant, and data from the GLADIATOR study [13], which compared two dosages of lasmiditan, were included for

lasmiditan. Since lasmiditan is not part of the ACT and the comparison only addresses side effect outcomes, this comparison is also not suitable for the benefit assessment of rimegepant.

I 4 Results on added benefit

The company has not submitted any suitable data for assessing the added benefit of rimegepant in comparison with the ACT in adults with migraine with or without aura who require acute treatment. There is no hint of an added benefit of rimegepant in comparison with the ACT; an added benefit is therefore not proven.

I 5 Probability and extent of added benefit

The result of the assessment of the added benefit of rimegepant in comparison with the ACT is summarized in Table 5.

Table 5: Rimegepant – probability and extent of added benefit

Therapeutic indication	**ACT**[a]	**Probability and extent of added benefit**
Adults with migraine with or without aura who require acute treatment	Individualized treatment[b] taking into account the pretreatment, the severity of the attack and existing concomitant diseases, choosing from selective serotonin 5-HT_1 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 treatment in a study of direct comparison, the investigators are 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, benefit assessments are used, in part, to ascertain the extent to which conclusions can be drawn about a subpopulation.

ACT: appropriate comparator therapy; G-BA: Federal Joint Committee; 5-HT_1: 5-hydroxytryptamine-1

The assessment described above concurs with that by the company.

The G-BA decides on the added benefit.

I 6 References for English extract

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.

1. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen. Allgemeine Methoden; Version 7.0 [online]. 2023 [Accessed: 02.09.2024]. URL: https://www.iqwig.de/methoden/allgemeine-methoden_version-7-0.pdf.

2. Skipka G, Wieseler B, Kaiser T et al. Methodological approach to determine minor, considerable, and major treatment effects in the early benefit assessment of new drugs. Biom J 2016; 58(1): 43-58. https://doi.org/10.1002/bimj.201300274.

3. Pfizer. Safety and Efficacy Study in Adult Subjects With Acute Migraines [online]. 2023 [Accessed: 30.06.2025]. URL: https://clinicaltrials.gov/study/NCT03235479.

4. Pfizer. Safety and Efficacy in Adult Subjects With Acute Migraines [online]. 2023 [Accessed: 30.06.2025]. URL: https://clinicaltrials.gov/study/NCT03237845.

5. Pfizer. Trial in Adult Subjects With Acute Migraines [online]. 2023 [Accessed: 30.06.2025]. URL: https://clinicaltrials.gov/study/NCT03461757.

6. Pfizer. Safety and Efficacy Trial of BHV3000 (Rimegepant) 75 mg for the Acute Treatment of Migraine [online]. 2023 [Accessed: 01.07.2025]. URL: https://www.clinicaltrials.gov/study/NCT04574362.

7. Pfizer. Efficacy and Safety Study of Rimegepant for the Acute Treatment of Migraine in Japanese Subjects (Japan Only) [online]. 2025 [Accessed: 2025-07-02]. URL: https://www.clinicaltrials.gov/study/NCT05399459.

8. Pfizer. A Study to Learn About the Long-term Safety of Rimegepant for the Acute Treatment of Migraine in Chinese Participants [online]. 2025 [Accessed: 02.07.2025]. URL: https://clinicaltrials.gov/study/NCT05371652.

9. Pfizer. Dose Ranging Study of Rimegepant (BMS-927711) for the Acute Treatment of Migraine [online]. 2023 [Accessed: 02.07.2025]. URL: https://clinicaltrials.gov/study/NCT01430442.

10. Powell LC, L'Italien G, Popoff E et al. Health State Utility Mapping of Rimegepant for the Preventive Treatment of Migraine: Double-Blind Treatment Phase and Open Label Extension (BHV3000-305). Adv Ther 2023; 40(2): 585-600. https://doi.org/10.1007/s12325-022-02369-x.

11. Johnston K, Harris L, Powell L et al. Monthly migraine days, tablet utilization, and quality of life associated with Rimegepant - post hoc results from an open label safety study (BHV3000-201). J Headache Pain 2022; 23(1): 10. https://doi.org/10.1186/s10194-021-01378-5.

12. Pfizer. An Open-label, Intermediate Size, Expanded Access Study of BHV-3000 in the Acute Treatment of Migraine [online]. 2023 [Accessed: 02.07.2025]. URL: https://clinicaltrials.gov/study/NCT03934086.

13. Eli Lilly and Company. An Open-label, LonG-term, Safety Study of LAsmiDItan (100 mg and 200 mg) in the Acute Treatment Of MigRaine (GLADIATOR) [online]. 2020 [Accessed: 30.06.2025]. URL: https://clinicaltrials.gov/study/NCT02565186.

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