

Selumetinib (plexiform neurofibromas in neurofibromatosis type 1, 1 to < 3 years)

Benefit assessment according to §35a SGB V¹

A decorative horizontal bar composed of 20 small squares in various shades of blue and grey. The word 'EXTRACT' is centered in a dark blue rectangle that spans the width of the bar.

EXTRACT

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Patient and family involvement

No feedback was received within the framework of this dossier assessment.

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Part I: Benefit assessment

I Table of contents

	Page
I List of tables	I.3
I List of abbreviations.....	I.4
I 1 Executive summary of the benefit assessment	I.5
I 2 Research question.....	I.9
I 3 Information retrieval and study pool.....	I.10
I 3.1 Evidence provided by the company	I.11
I 3.2 Assessment of the evidence presented by the company	I.12
I 4 Results on added benefit.....	I.14
I 5 Probability and extent of added benefit	I.15
I 6 References for English extract	I.16

I List of tables²

	Page
Table 2: Research question for the benefit assessment of selumetinib.....	I.5
Table 3: Selumetinib – probability and extent of added benefit.....	I.8
Table 4: Research question for the benefit assessment of selumetinib.....	I.9
Table 5: Selumetinib – probability and extent of added benefit.....	I.15

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 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 selumetinib. 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 05 February 2026.

Research question

The aim of this report is to assess the added benefit of selumetinib in comparison with best supportive care as the appropriate comparator therapy (ACT) for symptomatic, inoperable plexiform neurofibromas in paediatric patients with neurofibromatosis type 1, aged 1 to < 3 years.

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 selumetinib

Therapeutic indication	ACT ^a
Treatment of symptomatic, inoperable plexiform neurofibromas in paediatric patients with neurofibromatosis type 1, aged 1 to < 3 years	BSC ^b
a. Presented is the ACT specified by the G-BA. b. BSC refers to the therapy that provides the patient with the best possible, individually optimized, supportive treatment to alleviate symptoms and improve the quality of life. ACT: appropriate comparator therapy; BSC: best supportive care; G-BA: Federal Joint Committee	

The company followed the G-BA’s specification of the ACT.

The assessment was conducted by means of patient-relevant outcomes on the basis of the data provided by the company in the dossier. Studies with a minimum duration of 24 weeks were used for the derivation of the added benefit.

Results

Consistent with the findings of the company, a review of the completeness of the study pool did not identify any randomized controlled trials (RCTs) for the comparison of selumetinib with the ACT.

As the company did not identify any studies for a direct comparison either, it conducted information retrievals for further studies on selumetinib and identified the single-arm approval study SPRINKLE, which it used for the benefit assessment. The SPRINKLE study is an

ongoing, single-arm phase I/II study with selumetinib in children aged ≥ 1 to < 7 years with symptomatic, inoperable plexiform neurofibromas associated with neurofibromatosis type 1. Primary outcomes of the SPRINKLE study are pharmacokinetics, as well as safety and tolerability of selumetinib. Further outcomes were recorded in the categories of morbidity and health-related quality of life. However, no analyses on efficacy outcomes were carried out for this first data cut of 8 April 2024. For the SPRINKLE study, the company's dossier therefore only contains results on mortality and outcomes in the side effects category.

In addition to the assessment of the SPRINKLE study, the company also aims to transfer the study results from source populations with older age groups (children aged 3 years and older and adolescents; adults) to the target population relevant for the benefit assessment (children aged 1 to < 3 years). In addition to the SPRINKLE study identified for this therapeutic indication, it therefore also used the single-arm SPRINT study in children aged 3 years and older and adolescents, as well as the RCT KOMET in adults.

The data presented by the company were unsuitable for the benefit assessment of selumetinib in comparison with the ACT. The evidence is described below, and the reasons for its unsuitability for the benefit assessment are provided.

Assessment of the evidence presented by the company

The SPRINKLE study

For the population of the therapeutic indication to be assessed, the company's dossier only contains results from the single-arm SPRINKLE study, which does not permit a comparison with the ACT. Furthermore, no analyses were conducted on outcomes of the categories morbidity and health-related quality of life for the presented first data cut of the study; such analyses would be necessary for the overall assessment required as part of the benefit assessment. Overall, the SPRINKLE study is therefore not suitable for the benefit assessment.

Transfer of study results from older age groups

In order to transfer study results from a source population to a target population, a complete comparison of all relevant data is necessary to assess whether such transfer is possible. As previously described, the dossier presents only results from the single-arm SPRINKLE study relating to mortality and the side effects category for the target population under assessment. As there are no data available on outcomes of the categories morbidity and health-related quality of life, it is not possible to adequately assess the transferability of the results.

Furthermore, in the present situation, in order to transfer evidence from one age group to another, data are required from the age group immediately adjacent to the target population as source population. This is the age group of children aged 3 and older and adolescents. However, the dossier only provides the results of the single-arm SPRINT study for this

population. It is therefore not possible to transfer evidence from this population to the target population under assessment, as this would require comparative data on the source population.

Comparative data for the adult population are available from the KOMET study. However, an evidence transfer also requires sufficient similarity between the source population and the target population, also with regard to the course of the disease. In this indication, the course of the disease is particularly influenced by the further growth of the plexiform neurofibromas. Tumour growth is chronic progressive. It should be noted that the growth velocity of plexiform neurofibromas is age-dependent, and that the most significant increase in volume is predominantly observed in early childhood. Consequently, a further increase in the symptoms caused by plexiform neurofibromas is to be expected particularly in younger patients. Overall, there are thus uncertainties as to whether the course of the disease in the source populations used by the company (children aged 3 years and older and adolescents; adults) and the target population (children aged 1 to < 3 years) is sufficiently comparable to allow for a transfer of evidence. For this reason, the data on the adult population cannot be used for the benefit assessment either, despite the availability of a comparative study.

In summary, it is not possible to transfer the study results from the age group of children aged 3 years and older, adolescents and adults, presented by company to the population under assessment, i.e. children aged 1 to < 3 years; consequently, the data cannot be used for the benefit assessment.

Results on added benefit

Since no suitable data were available for the benefit assessment, there is no hint of an added benefit of selumetinib in comparison with the ACT; an added benefit is therefore not proven.

Probability and extent of added benefit, patient groups with therapeutically important added benefit³

Table 3 summarizes the probability and extent of added benefit of selumetinib.

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 lesser benefit). For further details see [1,2].

Table 3: Selumetinib – probability and extent of added benefit

Therapeutic indication	ACT ^a	Probability and extent of added benefit
Treatment of symptomatic, inoperable plexiform neurofibromas in paediatric patients with neurofibromatosis type 1, aged 1 to < 3 years	BSC ^b	Added benefit not proven
a. Presented is the ACT specified by the G-BA. b. BSC refers to the therapy that provides the patient with the best possible, individually optimized, supportive treatment to alleviate symptoms and improve the quality of life. BSC: best supportive care; G-BA: Federal Joint Committee		

The G-BA decides on the added benefit.

I 2 Research question

The aim of this report is to assess the added benefit of selumetinib in comparison with best supportive care as the ACT for symptomatic, inoperable plexiform neurofibromas in paediatric patients with neurofibromatosis type 1, aged 1 to < 3 years.

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 selumetinib

Therapeutic indication	ACT ^a
Treatment of symptomatic, inoperable plexiform neurofibromas in paediatric patients with neurofibromatosis type 1, aged 1 to < 3 years	BSC ^b
a. Presented is the ACT specified by the G-BA. b. BSC refers to the therapy that provides the patient with the best possible, individually optimized, supportive treatment to alleviate symptoms and improve the quality of life. ACT: appropriate comparator therapy; BSC: best supportive care; G-BA: Federal Joint Committee	

The company followed the G-BA's specification of the ACT.

The assessment was conducted by means of patient-relevant outcomes on the basis of the data provided by the company in the dossier. Studies with a minimum duration of 24 weeks were used for the derivation of the added benefit. This deviates from the company's inclusion criteria, which did not specify a minimum duration.

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 selumetinib (status: 17 November 2025)
- Bibliographical literature search on selumetinib (last search on 17 November 2025)
- Search of trial registries / trial results databases for studies on selumetinib (last search on 17 November 2025)
- Search on the G-BA website for selumetinib (last search on 17 November 2025)

To check the completeness of the study pool:

- Search of trial registries for studies on selumetinib (last search on 24 February 2026); for search strategies, see I Appendix A of the full dossier assessment

Consistent with the findings of the company, a review of the completeness of the study pool did not identify any RCTs for the comparison of selumetinib with the ACT.

As the company did not identify any studies for a direct comparison, it conducted information retrievals for further studies on selumetinib and identified the single-arm approval study SPRINKLE [3], which it used for the benefit assessment. The study is already known from an earlier dossier assessment [4]. The company did not present an information retrieval for further investigations with the ACT.

In addition to the assessment of the SPRINKLE study, the company also aims to transfer the study results from source populations with older age groups (children aged 3 years and older and adolescents; adults) to the target population relevant for the benefit assessment (children aged 1 to < 3 years). In addition to the SPRINKLE study identified for this therapeutic indication, it therefore also used the single-arm SPRINT study [5] in children aged 3 years and older and adolescents, as well as the RCT KOMET [6] in adults. The studies SPRINT and KOMET are also already known from previous benefit assessments [4,7]. This dossier does not present an information retrieval on the source populations.

The data presented by the company were unsuitable for the benefit assessment of selumetinib in comparison with the ACT. The evidence is described below, and the reasons for its unsuitability for the benefit assessment are provided.

I 3.1 Evidence provided by the company

The SPRINKLE study

The SPRINKLE study, the approval study for this therapeutic indication, is an ongoing, single-arm phase I/II trial with selumetinib in children aged ≥ 1 to < 7 years with symptomatic, inoperable plexiform neurofibromas associated with neurofibromatosis type 1. The aim of the study is to determine the dose of selumetinib in a new granule formulation, as well as to assess its pharmacokinetics, safety and tolerability.

The study is divided into a treatment phase, including an initial dose-finding period to determine the dosing regimen for selumetinib granules, and a subsequent long-term safety follow-up. During the treatment phase, patients are treated with selumetinib for 25 cycles, with each cycle lasting 28 days. Selumetinib was initially administered in granule form for at least 3 cycles. Children with a body surface area of 1.10 m^2 to 1.29 m^2 were subsequently encouraged to switch to the hard capsule formulation, which was already approved for use in other therapeutic indications. Long-term follow-up is planned until the child reaches the age of 5 or until the start of an alternative systemic treatment, whichever comes first. During this period, treatment with selumetinib may be continued provided there is clinical benefit as assessed by the investigator.

A total of 39 children from 7 different countries were included in the study, 36 of whom began treatment with selumetinib. Of these 36 patients, 13 were aged between 1 and < 3 years, in line with the therapeutic indication under assessment.

Treatment with selumetinib was carried out in accordance with the Summary of Product Characteristics (SmPC) of the granule and hard capsule formulations [8,9]. The study results of the dose-finding period for selumetinib granules show that the proposed initial dose regimen of 25 mg/m^2 body surface area twice daily proved to be adequate and that no dose adjustments were required. Accordingly, patients receive selumetinib in compliance with the SmPC, both during the dose-finding period and throughout the further course of their treatment.

Primary outcomes of the SPRINKLE study are the pharmacokinetics, as well as the safety and tolerability of selumetinib. Further outcomes were recorded in the categories of morbidity and health-related quality of life. However, no analyses on efficacy outcomes were performed at this first data cut of 8 April 2024, which was carried out after all patients had had the opportunity to complete three treatment cycles. These are not scheduled until the second data cut, once all patients have had the opportunity to complete 25 treatment cycles. For the SPRINKLE study, the company's dossier therefore only contains results on mortality and outcomes in the side effects category.

Transfer of study results from older age groups

In addition to the data from the SPRINKLE study, the company also considers the results of the single-arm SPRINT study in children aged 3 years and older and adolescents, as well as the RCT KOMET in adults, and transfers this evidence to the population of children aged 1 to < 3 years, which is relevant to this benefit assessment. These studies had already been the subject of dossier assessments as part of the benefit assessment procedure of selumetinib in children aged 3 years and older and adolescents [4] and in adults [7] in this therapeutic indication. The company's dossier presents results on outcomes in the categories mortality, morbidity, health-related quality of life (for the SPRINT study only) and side effects for these studies .

The company justifies the transferability of the evidence on the basis of what it considers to be adequate comparability between the source populations (children aged 3 years and older and adolescents; adults) and the target population (children aged 1 to < 3 years) with regard to the cause of the disease, the disease profile, the pharmacokinetics, efficacy and safety of selumetinib, and the ACT uniformly defined across the populations. Furthermore, from the company's point of view, there are no indications to suggest that differences between the patient populations in the studies presented have a relevant impact on the study results.

I 3.2 Assessment of the evidence presented by the company

The data presented by the company were unsuitable for the benefit assessment of selumetinib in comparison with the ACT. The reasons for this are provided below.

The SPRINKLE study

For the population of the therapeutic indication to be assessed, the company's dossier only contains results from the single-arm SPRINKLE study, which does not permit a comparison with the ACT. Furthermore, no analyses were conducted on outcomes of the categories morbidity and health-related quality of life for the presented first data cut of the study; such analyses would be necessary for the overall assessment required as part of the benefit assessment. Overall, the SPRINKLE study is therefore not suitable for the benefit assessment.

Transfer of study results from older age groups

In support to the SPRINKLE study, the company uses data from the studies SPRINT and KOMET to transfer evidence from source populations in older age groups to the target population of the therapeutic indication under assessment. However, for various reasons, it is not possible to transfer the findings of the study. The rationale is provided below.

In order to transfer study results from a source population to a target population, a complete comparison of all relevant data is necessary to assess whether such transfer is possible. As previously described, the dossier presents only results from the single-arm SPRINKLE study relating to mortality and the side effects category for the target population under assessment.

As there are no data available on outcomes of the categories morbidity and health-related quality of life, it is not possible to adequately assess the transferability of the results.

Furthermore, in the present situation, in order to transfer evidence from one age group to another, data are required from the age group immediately adjacent to the target population as source population. This is the age group of children aged 3 and older and adolescents. However, the dossier only provides the results of the single-arm SPRINT study for this population. It is therefore not possible to transfer evidence from this population to the target population under assessment, as this would require comparative data on the source population.

Comparative data for the adult population are available from the KOMET study. However, an evidence transfer also requires sufficient similarity between the source population and the target population, also with regard to the course of the disease. In this indication, the course of the disease is particularly influenced by the further growth of the plexiform neurofibromas. Depending on their size and location, plexiform neurofibromas can cause a wide range of symptoms, such as pain, motor impairment, functional impairment of various internal organs, and disfigurement in the case of lesions in visible areas. Tumour growth is chronic progressive [10]. It should be noted that the growth velocity of plexiform neurofibromas is age-dependent, and that the most significant increase in volume is predominantly observed in early childhood [11]. Consequently, a further increase in the symptoms caused by plexiform neurofibromas is to be expected particularly in younger patients. Overall, there are thus uncertainties as to whether the course of the disease in the source populations used by the company (children aged 3 years and older and adolescents; adults) and the target population (children aged 1 to < 3 years) is sufficiently comparable to allow for a transfer of evidence. For this reason, the data on the adult population cannot be used for the benefit assessment either, despite the availability of a comparative study.

Finally, it should be noted that, for the source populations used by the company, the dossier does not describe any information retrieval. Relevant research had already been carried out as part of previous benefit assessment procedures for the indication under assessment [12,13]. However, as this research was carried out more than three months before the submission of this dossier, it would have been necessary to conduct an updated information retrieval for both source populations.

In summary, it is not possible to transfer the study results from the age group of children aged 3 years and older, adolescents and adults, presented by company to the population under assessment, i.e. children aged 1 to < 3 years; consequently, the data cannot be used for the benefit assessment.

I 4 Results on added benefit

No suitable data were available to assess the added benefit of selumetinib compared with the ACT of best supportive care for the treatment of symptomatic, inoperable plexiform neurofibromas in paediatric patients with neurofibromatosis type 1, aged 1 to < 3 years. There is thus no hint of an added benefit of selumetinib 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 selumetinib in comparison with the ACT is summarized in Table 5.

Table 5: Selumetinib – probability and extent of added benefit

Therapeutic indication	ACT ^a	Probability and extent of added benefit
Treatment of symptomatic, inoperable plexiform neurofibromas in paediatric patients with neurofibromatosis type 1, aged 1 to < 3 years	BSC ^b	Added benefit not proven
a. Presented is the ACT specified by the G-BA. b. BSC refers to the therapy that provides the patient with the best possible, individually optimized, supportive treatment to alleviate symptoms and improve the quality of life. BSC: best supportive care; G-BA: Federal Joint Committee		

The assessment described above deviates from that of the company, which, on the basis of the results of the single-arm SPRINKLE study and the transfer of results from the studies SPRINT and KOMET to the population under assessment, derives a hint of considerable added benefit.

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.

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The full report (German version) is published at

<https://www.iqwig.de/en/projects/a26-09.html>.