Gemeinsamer Bundesausschuss

Justification

for the Resolution of the Federal Joint Committee (G-BA) on an Amendment of the Pharmaceuticals Directive:
Annex XII – Benefit Assessment of Medicinal Products with New Active Ingredients according to Section 35a SGB V
Momelotinib (reassessment of an orphan drug after exceeding the EUR 30 million limit (myelofibrosis))

of 16 April 2026

Contents

1. Legal basis

According to Section 35a paragraph 1 German Social Code, Book Five (SGB V), the Federal Joint Committee (G-BA) assess the benefit of all reimbursable medicinal products with new active ingredients. This includes in particular the assessment of the additional benefit and its therapeutic significance. The benefit assessment is carried out on the basis of evidence provided by the pharmaceutical company, which must be submitted to the G-BA electronically, including all clinical studies the pharmaceutical company have conducted or commissioned, at the latest at the time of the first placing on the market as well as the marketing authorisation of new therapeutic indications of the medicinal product, and which must contain the following information in particular:

1. approved therapeutic indications,
2. medical benefit,
3. additional medical benefit in relation to the appropriate comparator therapy,
4. number of patients and patient groups for whom there is a therapeutically significant additional benefit,
5. treatment costs for the statutory health insurance funds,
6. requirements for a quality-assured application,

The G-BA may commission the Institute for Quality and Efficiency in Health Care (IQWiG) to carry out the benefit assessment. According to Section 35a, paragraph 2 SGB V, the assessment must be completed within three months of the relevant date for submission of the evidence and published on the internet.

According to Section 35a paragraph 3 SGB V, the G-BA decide on the benefit assessment within three months of its publication. The resolution is to be published on the internet and is part of the Pharmaceuticals Directive.

2. Key points of the resolution

The active ingredient momelotinib (Omjjara) was listed for the first time on 15 February 2024 in the “LAUER-TAXE®”, the extensive German registry of available drugs and their prices. Omjjara for the treatment of myelofibrosis is approved as a medicinal product for the treatment of rare diseases under Regulation (EC) No 141/2000 of the European Parliament and the Council of 16 December 1999.

At their session on 15 August 2024, the G-BA decided on the benefit assessment of momelotinib in the "myelofibrosis" therapeutic indication in accordance with Section 35a SGB V.

If the sales of the orphan drug through the statutory health insurance at pharmacy sales prices and outside the scope of SHI-accredited medical care, including value-added tax, exceed an amount of € 30 million in the last twelve calendar months, the pharmaceutical company must submit evidence in accordance with Chapter 5 Section 5, paragraphs 1 to 6 Rules of Procedure

(VerfO) within three months of being requested to do so by the Federal Joint Committee, and in this evidence, must demonstrate the additional benefit compared to the appropriate comparator therapy.

By letter dated 16 July 2025, the pharmaceutical company was requested to submit a dossier for the benefit assessment according to Section 35a SGB V by 1 November 2025, due to exceeding EUR 30 million turnover limit within the period from April 2024 to March 2025. Pursuant to Section 4, paragraph 3, No. 4 of the Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV) in conjunction with Chapter 5 Section 8, paragraph 1, No. 6 Rules of Procedure (VerfO), the pharmaceutical company submitted the final dossier to the G-BA on 31 October 2025.

The G-BA commissioned the IQWiG to carry out the assessment of the dossier. The benefit assessment was published on 2 February 2026 on the G-BA website (www.g-ba.de), thus initiating the written statement procedure. In addition, an oral hearing was held.

The G-BA came to a resolution on whether an additional benefit of momelotinib compared to the appropriate comparator therapy could be determined on the basis of the dossier of the pharmaceutical company, the dossier assessment prepared by the IQWiG and the statements submitted in the written statement and oral hearing procedure. In order to determine the extent of the additional benefit, the G-BA have evaluated the data justifying the finding of an additional benefit on the basis of their therapeutic relevance (qualitative), in accordance with the criteria laid down in Chapter 5 Section 5, paragraph 7 VerfO. The methodology proposed by the IQWiG in accordance with the General Methods [1] was not used in the benefit assessment of momelotinib.

In the light of the above, and taking into account the statements received and the oral hearing, the G-BA have made the following assessment:

2.1 Additional benefit of the medicinal product in relation to the appropriate comparator therapy

2.1.1 Approved therapeutic indication of Momelotinib (Omjjara) in accordance with the product information

Omjjara is indicated for the treatment of disease-related splenomegaly or symptoms in adult patients with moderate to severe anaemia who have primary myelofibrosis, post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis and who are Janus Kinase (JAK) inhibitor naïve or have been treated with ruxolitinib.

Therapeutic indication of the resolution (resolution of 16.04.2026):

See the approved therapeutic indication

[1] General Methods, version 8.0 from 19.12.2025. Institute for Quality and Efficiency in Health Care (IQWiG), Cologne.

2.1.2 Appropriate comparator therapy

The appropriate comparator therapy was determined as follows:

a) Adults with moderate to severe anaemia who have primary myelofibrosis, post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis and who are Janus Kinase (JAK) inhibitor naïve; for the treatment of disease-related splenomegaly or symptoms

Appropriate comparator therapy for momelotinib:

− Ruxolitinib

or

− Fedratinib

b) Adults with moderate to severe anaemia who have primary myelofibrosis, post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis and who have been treated with ruxolitinib; for the treatment of disease-related splenomegaly or symptoms

Appropriate comparator therapy for momelotinib:

− Fedratinib

Criteria according to Chapter 5 Section 6 of the Rules of Procedure of the G-BA and Section 6 paragraph 2 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV):

The appropriate comparator therapy must be an appropriate therapy in the therapeutic indication according to the generally recognised state of medical knowledge (Section 12 SGB V), preferably a therapy for which endpoint studies are available and which has proven its worth in practical application unless contradicted by the guidelines under Section 92, paragraph 1 SGB V or the principle of economic efficiency.

In determining the appropriate comparator therapy, the following criteria, in particular, must be taken into account as specified in Chapter 5 Section 6, paragraph 3 VerfO:

1. To be considered as a comparator therapy, the medicinal product must, principally, have a marketing authorisation for the therapeutic indication.
2. If a non-medicinal treatment is considered as a comparator therapy, this must be available within the framework of the SHI system.
3. As comparator therapy, medicinal products or non-medicinal treatments for which the patient-relevant benefit has already been determined by the G-BA shall be preferred.
4. According to the generally recognised state of medical knowledge, the comparator therapy should be part of the appropriate therapy in the therapeutic indication.

According to Section 6, paragraph 2, sentence 2 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV), the determination of the appropriate comparator therapy must be based on the actual medical treatment situation as it would be without the medicinal product to be assessed. According to Section 6, paragraph 2, sentence 3 Ordinance on the

Benefit Assessment of Pharmaceuticals (AM-NutzenV), the G-BA may exceptionally determine the off-label use of medicinal products as an appropriate comparator therapy or as part of the appropriate comparator therapy if they determine by resolution on the benefit assessment according to Section 7, paragraph 4 that, according to the generally recognised state of medical knowledge, this is considered a therapy standard in the therapeutic indication to be assessed or as part of the therapy standard in the medical treatment situation to be taken into account according to sentence 2, and

1. for the first time, a medicinal product approved in the therapeutic indication is available with the medicinal product to be assessed,
2. according to the generally recognised state of medical knowledge, the off-label use is generally preferable to the medicinal products previously approved in the therapeutic indication, or
3. according to the generally recognised state of medical knowledge, the off-label use for relevant patient groups or indication areas is generally preferable to the medicinal products previously approved in the therapeutic indication.

An appropriate comparator therapy may also be non-medicinal therapy, the best possible add-on therapy including symptomatic or palliative treatment, or monitoring wait-and-see approach.

Justification based on the criteria set out in Chapter 5 Section 6, paragraph 3 VerfO and Section 6, paragraph 2 AM-NutzenV:

On 1. In addition to momelotinib, the active ingredients fedratinib and ruxolitinib are approved in the present therapeutic indication.

On 2. Allogeneic stem cell transplantation, splenic irradiation and splenectomy are, in principle, considered to be non-medicinal treatments in the present therapeutic indication.

On 3. Resolutions of the G-BA on the benefit assessment of medicinal products with new active ingredients according to Section 35a SGB V:

- Momelotinib: Resolution of 15 August 2024
- Fedratinib: Resolution of 2 September 2021 and 21 August 2025
- Ruxolitinib: Resolution of 6 November 2014

On 4. The generally recognised state of medical knowledge was illustrated by a systematic search for guidelines as well as systematic reviews of clinical studies in the present indication and is presented in the "Research and synopsis of the evidence to determine the appropriate comparator therapy according to Section 35a SGB V".

The scientific-medical societies and the Drugs Commission of the German Medical Association (AkdÄ) were also involved in writing on questions relating to the comparator therapy in the present indication according to Section 35a paragraph 7 SGB V (see "Information on Appropriate Comparator Therapy"). A written statement of the scientific-medical societies or Drugs Commission of the German Medical Association (AkdÄ) is not available.

The available evidence on therapy options for primary myelofibrosis, post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis is

limited overall. The guidelines presented in the evidence synopsis do not fully meet the methodological quality criteria applicable to the drafting of guidelines. However, they are used as a supplementary measure in the absence of higher-quality evidence.

For the present therapeutic indication, it is assumed that an allogeneic stem cell transplantation is not indicated at the time of therapy.

Splenectomy, as a non-medicinal treatment option, is not determined as an appropriate comparator therapy, particularly due to therapy-related mortality and morbidity.

The current guidelines consistently recommend the use of Janus kinase (JAK) inhibitors for the treatment of disease-related splenomegaly or symptoms associated with myelofibrosis. Based on the marketing authorisations, the JAK inhibitors ruxolitinib, fedratinib and momelotinib are available.

Furthermore, the current guidelines also recommend momelotinib - the medicinal product to be assessed here. According to Section 6, number 2, sentence 2 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV), the appropriate comparator therapy must be based on the actual medical treatment situation as it would be without the medicinal product to be assessed. For this reason, momelotinib is ineligible as the appropriate comparator therapy.

Taking into account the fact that the present therapeutic indication includes both patients who are JAK inhibitor naïve and those who have been pretreated with ruxolitinib, the G-BA consider it appropriate to form two patient populations for the determination of the appropriate comparator therapy.

<u>On patient population a)</u>

Current guidelines consistently recommend therapy with the Janus kinase (JAK) inhibitors ruxolitinib or fedratinib for previously untreated symptomatic patients in the present therapeutic indication.

By resolution of 6 November 2014, the G-BA found a hint for a considerable additional benefit of ruxolitinib, which is approved regardless of pretreatment with JAK inhibitors, compared to best supportive care.

By resolution of 2 September 2021, the G-BA found a hint for a non-quantifiable additional benefit of fedratinib in patients, who have not been pretreated with a JAK inhibitor, since the scientific data did not allow quantification. The underlying study compared fedratinib with placebo.

In the overall analysis, the G-BA determined ruxolitinib or fedratinib as the appropriate comparator therapy for patient population a).

This appropriate comparator therapy thus includes several therapeutic alternatives. These therapeutic alternatives are equally appropriate for the comparator therapy.

On patient population b)

It can be inferred from the current guideline recommendations that patients, who have already been pretreated with ruxolitinib and who continue to be indicated for therapy, should switch to a different JAK inhibitor. Fedratinib or momelotinib are available for this purpose. As momelotinib is the medicinal product to be assessed here, it cannot be considered as a comparator therapy for the research question of the benefit assessment.

In the new benefit assessment of fedratinib following the expiry of the time limit, a hint for a non-quantifiable additional benefit was found for the reassessed patient group b) "Adults who have primary myelofibrosis, post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis and who have been treated with ruxolitinib, for the treatment of disease-related splenomegaly or symptoms" (resolution of 21 August 2025). The underlying study compared fedratinib with best available therapy (primarily ruxolitinib, transfusions with red blood cells and hydroxyurea).

In patient group b), it is assumed that pretreatment with ruxolitinib has been administered for a sufficient duration (or has been discontinued due to intolerance) and, consequently, further therapy with ruxolitinib is not an option and a change of therapy is indicated. According to the product information of ruxolitinib, treatment with ruxolitinib should be continued as long as the benefits outweigh the risks. Treatment should nevertheless be discontinued after 6 months if there has been no reduction in spleen size or improvement in symptoms since the start of therapy. The guidelines recommend continuing therapy with ruxolitinib for at least 6 months prior to definitive assessment of the response.

In the overall analysis, the G-BA determined fedratinib as the appropriate comparator therapy for patient population b).

Further information:

Ruxolitinib and fedratinib are not primarily indicated in the presence of thrombocytopenia. In this respect, ruxolitinib and fedratinib should only be used from a platelet count of ≥ 50,000/µl according to the product information and the therapy recommendations in guidelines.

Furthermore, it is assumed for the present therapeutic indication that patients in this therapeutic indication have anaemia requiring treatment, which however does not preclude treatment with JAK inhibitors. In this regard, it is assumed that appropriate supportive measures for the treatment of moderate/ severe anaemia will be implemented in both study arms of a clinical study.

Based on the available evidence, epoetin alfa, corticosteroids and transfusion therapy on demand with red blood cell concentrates, in combination with chelation therapy, are relevant options for the treatment of moderate/ severe anaemia. Furthermore, it is assumed that additional supportive measures to treat splenomegaly and/or other symptoms will be implemented as needed in both study arms of a clinical study.

The relevant findings in Annex XII do not restrict the scope of treatment required to fulfil the medical treatment mandate.

Any change to the appropriate comparator therapy requires a decision by the G-BA based on a prior review of the criteria set out in Chapter 5 Section 6, paragraph 3 VerfO.

2.1.3 Extent and probability of the additional benefit

In summary, the additional benefit of momelotinib is assessed as follows:

a) Adults with moderate to severe anaemia who have primary myelofibrosis, post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis and who are Janus Kinase (JAK) inhibitor naïve; for the treatment of disease-related splenomegaly or symptoms

An additional benefit is not proven.

Justification:

For the benefit assessment, the pharmaceutical company presented the results of the multicentre, randomised, double-blind, phase III SIMPLIFY- 1 study, which compared momelotinib to ruxolitinib. The study consists of a 24-week randomised, controlled and blinded treatment phase. This was followed by a single-arm, open-label extension phase in which participants from both study arms could receive momelotinib after completion of the 24-week treatment phase. The 24-week blinded treatment phase was used for the benefit assessment.

The study population of the SIMPLIFY-1 study comprises adults with myelofibrosis and splenomegaly who are JAK inhibitor naïve. With regard to myelofibrosis, the study population included patients who have primary myelofibrosis, post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis, as defined by the diagnostic criteria of the World Health Organization (WHO) or the International Working Group for Myeloproliferative Neoplasms Research and Treatment (IWG-MRT). A total of 432 subjects were enrolled in the study and randomised in a 1:1 ratio, stratified by transfusion dependence (yes/ no) and platelet count ($< 100 \times 10^9$/l / $\geq 100 \times 10^9$/l and $\leq 200 \times 10^9$/l / $> 200 \times 10^9$/l) (intention-to-treat-(ITT)-population). The ITT population comprises 215 subjects in the momelotinib arm and 217 subjects in the ruxolitinib arm.

In order to limit the study population to the therapeutic indication, which includes subjects with moderate or severe anaemia, a modified ITT (mITT) population, which represents subjects with a haemoglobin (Hb) level < 10 g/dl and is used for the benefit assessment, was defined post hoc.

The mITT population comprises 180 subjects (momelotinib arm N = 86; ruxolitinib arm N = 94).

The baseline transfusion burden averaged 3.1 units of transfused red blood cell concentrate in the momelotinib arm and 2.8 units in the ruxolitinib arm, based on the 12-week period prior to randomisation.

In the SIMPLIFY-1 study, the patient's overall condition, including anaemia-related symptoms, laboratory parameters and the patient's subjective well-being were taken into account to decide on whether transfusion was indicated. Criteria determining the time of transfusion were not pre-specified in the study.

The primary endpoint of the study was spleen response at week 24, defined as the percentage of patients with a reduction in spleen volume by ≥ 35%. The study, which was completed in May 2019, was conducted in 131 study sites across North America, Europe, Asia and Australia.

A total of 3 data cut-offs are available:

- 12 September 2016: predefined analysis of the primary endpoint following the 24-week treatment phase
- 12 September 2017: Analysis after 48 weeks of treatment
- 1 July 2019: Final data cut-off

The final data cut-off from 1 July 2019 was used for the benefit assessment of momelotinib.

On the implementation of the appropriate comparator therapy:

The G-BA determined ruxolitinib or fedratinib as the appropriate comparator therapy.

The appropriate comparator therapy thus includes several therapeutic alternatives. These therapeutic alternatives are equally appropriate for the comparator therapy. The additional benefit can be proven compared to one of the therapeutic alternatives mentioned; usually, this can be done within the framework of a single-comparator study.

The active ingredient ruxolitinib used as a comparator is therefore considered appropriate.

With regard to supportive measures for the treatment of anaemia, amongst others, epoetin alfa, whose use was however prohibited in the SIMPLIFY-1 study, represents a relevant therapy option.

Extent and probability of the additional benefit

Mortality
In the SIMPLIFY-1 study, the endpoint of overall survival was operationalised as the time span (in months) from the first dose in the blinded treatment phase to death, regardless of the cause of death.

There was no statistically significant difference between the treatment arms.

Morbidity

Leukaemic transformation

In the SIMPLIFY-1 study, the time to the onset of leukaemic transformation was assessed as a subcomponent of the composite endpoint of leukaemia-free survival and presented in the dossier as a post-hoc analysis. In the SIMPLIFY-1 study, leukaemic transformation is operationalised as the time from randomisation to the occurrence of leukaemic transformation, defined as an increase in the blast count in the bone marrow by ≥ 20% or a blast count in the peripheral blood by ≥ 20% in conjunction with an absolute blast count ≥ 1 × 10^9/l for at least 2 weeks.

The transformation of myelofibrosis into acute myeloid leukaemia is a poor prognostic factor for overall survival and is considered to be patient-relevant. The selection of definition criteria is considered an adequate representation of leukaemic transformation.

The results of the SIMPLIFY-1 study show no statistically significant difference between the treatment arms with only one event observed overall.

Transfusion independence

The pharmaceutical company presented several endpoints on transfusion independence with varying operationalisations from the SIMPLIFY-1 study. Post-hoc analyses of transfusion independence of the percentage of patients, who did not receive any transfusion of red blood cell concentrates throughout the observation period of the 24-week randomised controlled treatment phase, were presented for the present benefit assessment.

Other pharmaceutical company's analyses of transfusion-related endpoints, such as transfusion dependence, mainly relate to shorter periods of 12 or 8 weeks, and are therefore considered unsuitable for the present benefit assessment.

Long-term or sustained avoidance of transfusions (transfusion independence) is generally a relevant therapeutic goal. In principle, transfusion independence of ≥ 24 weeks may represent a patient-relevant endpoint.

The present therapeutic indication includes both patients who are dependent on regular transfusions and those who do not require any or only occasional supportive red blood cell transfusions for anaemia-related symptoms. 51.1% of patients in the mITT population were classified as transfusion-dependent at baseline as the characteristic of transfusion dependence was used as a stratification factor for randomisation.

In addition, the average transfusion burden at baseline is low.

Furthermore, no criteria were pre-specified in the study documents as to when blood transfusions should be given. As a rule, the indication for a blood transfusion is not only based on laboratory values (e.g. haemoglobin), but also takes into account the overall clinical picture. Information on detailed criteria for the administration of transfusions was not presented by the pharmaceutical company. The lack of information results in uncertainty about the extent to which transfusions were administered under comparable conditions in different study sites and whether this corresponds to the German healthcare context.

Due to the relevant uncertainty mentioned above, the results of SIMPLIFY-1 are considered insufficiently robust to derive an additional benefit from them. The results are presented additionally.

Symptomatology assessed using the Myeloproliferative Neoplasm Symptom Assessment Form (MPN-SAF)

Symptomatology was assessed in the SIMPLIFY-1 study using the MPN-SAF at baseline and subsequently in a 4-week cycle. In the dossier, the pharmaceutical company presented post-hoc analyses of improvement by at least 15% of the scale range at week 24. These are post-hoc responder analyses of both improvement in the total score and improvement in the 17 individual items on symptomatology. The items relating to myelofibrosis-associated symptoms and to overall health-related quality of life are presented and used individually in this benefit assessment since the calculation of a total score from all 27 items (17 individual items of the MPN-SAF, overall quality of life and 9 items from the Brief Fatigue Inventory) of the MPN-SAF is not described in the questionnaire's validation. In addition, the pharmaceutical company presented analyses of a modified version of the MPN-SAF TSS (Total Symptom Score) in the dossier. The presented version differs from the validated version of the questionnaire, and the information provided by the pharmaceutical company does not indicate the basis on which the items in the modified version were selected. Consequently, the analyses relating to the MPN-SAF TSS are not included in the present benefit assessment.

For the individual items of the MPN-SAF, there was no statistically significant difference between the treatment arms.

Brief Fatigue Inventory (BFI)

In the SIMPLIFY-1 study, the "fatigue" symptom was assessed using the BFI. In the dossier, the pharmaceutical company presented analyses of improvement and deterioration by at least 15% of the scale range at week 24, each using the total BFI score as well as the fatigue score and interference score subdomains.

For the present benefit assessment, the analyses of improvement in the total score at week 24 are used, as treatment with momelotinib can, in principle, lead to an improvement in symptomatology.

There were no differences between the treatment arms.

Symptomatology using Patient Global Impression of Change (PGIC)

In the dossier, the pharmaceutical company presented responder analyses of any improvement ("very much improved" to "minimally improved") and any deterioration ("minimally worse" to "very much worse") at week 24.

For the present benefit assessment, the analyses of improvement at week 24 are used, as treatment with momelotinib can, in principle, lead to an improvement in symptomatology.

There was no statistically significant difference between the treatment arms.

EQ-5D VAS

Health status was assessed in the SIMPLIFY-1 study using the visual analogue scale (VAS) of the EuroQoL-5 dimension (EQ-5D). In the dossier, the pharmaceutical company presented post-hoc analyses of both improvement and deterioration by at least 15% of the scale range at week 24.

The analyses of improvement at week 24 are used for the present benefit assessment.

There was no statistically significant difference between the two treatment arms.

Quality of life

In the SIMPLIFY-1 study, quality of life was assessed using the Short Form Health Survey Version 2 (SF-36v2). In the dossier, the pharmaceutical company presented post-hoc analyses of both improvement and deterioration by at least 15% of the scale range at week 24.

The analyses of improvement at week 24 are used for the present benefit assessment.

With regard to quality of life, there was no difference between the treatment arms.

Side effects

In the SIMPLIFY-1 study, the collection and monitoring of adverse events (AEs) began with the first dose of the study medication and was continued during the blinded 24-week treatment phase up to the first study medication with momelotinib in the open-label extension phase or up to 30 days after the last administration of the study treatment.

Adverse events (AEs) in total

AEs occurred in almost all study participants. The results are only presented additionally.

Serious AEs (SAE) and severe AEs (CTCAE grade ≥ 3)

For SAEs and severe AEs, there were no statistically significant differences between the treatment arms.

Therapy discontinuation due to AEs

For the endpoint of therapy discontinuation due to AEs, there was a statistically significant difference to the disadvantage of momelotinib compared to ruxolitinib.

Specific AEs

Detailed analysis of the results for severe AEs (CTCAE grade ≥ 3) showed a statistically significant effect in favour of momelotinib over ruxolitinib for the PT "Anaemia".
In the PT "Nausea", there was a statistically significant effect to the disadvantage of momelotinib compared with ruxolitinib.
In the specific AE "Peripheral neuropathy", the relevant sub-population of the SIMPLIFY-1 study predominantly experienced events of "Peripheral sensory neuropathy", the majority of which were events of CTCAE grade 1, which are not directly patient-relevant according to the CTCAE classification. During the written statement procedure, the pharmaceutical company submitted analyses that exclude events of CTCAE grade 1, meaning that only events of CTCAE grade ≥2 are included in the analysis. This analysis includes a total of only 4 events of grade 2 and therefore has no bearing on the present assessment.

Conclusion on side effects

For SAEs and severe AEs in the endpoint category of side effects, the overall assessment did not show any statistically significant differences between the treatment arms. For the endpoint "Therapy discontinuation due to AEs", there was a disadvantage of momelotinib. Detailed analysis of specific AEs showed both an advantage and a disadvantage of momelotinib. A disadvantage is derived overall in the endpoint category of side effects due to the disadvantage in "Therapy discontinuation due to AEs".

<u>Overall assessment</u>

Results on mortality, morbidity, quality of life and adverse events from the SIMPLIFY-1 study comparing momelotinib with ruxolitinib are available for the benefit assessment of momelotinib for the treatment of disease-related splenomegaly or symptoms in adults with moderate to severe anaemia who have primary myelofibrosis, post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis and who are Janus Kinase (JAK) inhibitor naïve.

For the endpoint of overall survival, there was no statistically significant difference between the treatment groups.

In the endpoint category of morbidity, there were no relevant differences with regard to leukaemic transformation, with only 1 event observed. There were also no relevant differences in the endpoints on symptomatology (MPN-SAF, BFI, PGIC) and health status (EQ-5D VAS).

No relevant difference was found with regard to quality of life which was surveyed using the SF-36v2.

For the overall rate of SAEs and severe AEs in terms of the endpoint category of side effects, there were no statistically significant differences between the treatment arms. For "Therapy discontinuation due to AEs", there was a disadvantage of momelotinib. Detailed analysis of specific AEs showed both an advantage and a disadvantage of momelotinib. A disadvantage is derived overall in the endpoint category of side effects due to the disadvantage in "Therapy discontinuation due to AEs".
The overall assessment showed that an additional benefit of momelotinib over ruxolitinib in patients, who are Janus Kinase (JAK) inhibitor naïve, is not proven.

b) Adults with moderate to severe anaemia who have primary myelofibrosis, post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis and who have been treated with ruxolitinib; for the treatment of disease-related splenomegaly or symptoms

   An additional benefit is not proven.

Justification:

For the benefit assessment, the pharmaceutical company presented the results of the SIMPLIFY-2 study and additionally presented the results of the MOMENTUM study.

SIMPLIFY-2 study

The SIMPLIFY-2 study is a multicentre, randomised, open-label, phase III study which compared momelotinib with the best available therapy (BAT). The study consists of a 24-week randomised treatment phase. This was followed by an optional extension phase in which participants from both study arms could receive momelotinib after completion of the 24-week treatment phase. BAT was administered in the comparator arm at the discretion of the investigators and could be adjusted at any point of time in the study. As part of the BAT, treatment options included ruxolitinib, chemotherapy, anagrelide, corticosteroids, haematopoietic growth factors, immunomodulatory agents, androgens, interferon alfa, or no treatment. The study, which was completed in April 2019, was conducted in 55 study sites in North America and Europe.

The study population of the SIMPLIFY-2 study comprises adults with myelofibrosis and splenomegaly who have been pretreated with the JAK inhibitor ruxolitinib. With regard to myelofibrosis, the study population included subjects who have primary myelofibrosis, post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis, as defined by the diagnostic criteria of WHO or IWG-MRT. A total of 156 subjects were enrolled in the study and randomised in a 2:1 ratio, stratified by transfusion dependence (yes/ no) and total symptom score in the modified MPN-SAF at baseline (< 18 / ≥ 18) (ITT population). The ITT population comprises 104 subjects in the momelotinib arm and 52 subjects in the control arm.

In order to limit the study population to the therapeutic indication that includes patients with moderate or severe anaemia, a population was defined post hoc that represents subjects with a haemoglobin (Hb) level < 10 g/dl (mITT population) - 105 subjects (momelotinib arm N = 66; control arm N = 39). Approximately 90% of patients in the comparator arm of this relevant sub-population received treatment with ruxolitinib. No patient received treatment with fedratinib.

The primary endpoint of the study was spleen response at week 24, defined as the percentage of patients with a reduction in spleen volume by ≥35% compared with baseline value.

For the study, a total of three data cut-offs were performed:

- 25 June 2019 (final data cut-off)
- 28 July 2016 (end of the randomised treatment phase; interim analysis week 24)
- 12 September 2017 (interim analysis at week 48)

On the implementation of the appropriate comparator therapy:

According to the product information of ruxolitinib, treatment should be discontinued after 6 months if there has been no reduction in spleen size or improvement in symptoms since the start of therapy. In the SIMPLIFY-2 study, patients were required to have previously received ruxolitinib only for at least 28 days. Further administration of ruxolitinib was not excluded in the comparator arm as part of best available therapy (BAT).

When determining the appropriate comparator therapy for patient population b), it is assumed that pretreatment with ruxolitinib has been administered for a sufficient duration (or has been discontinued due to intolerance) and, consequently, further therapy with ruxolitinib is not an option and a change of therapy is indicated. Prior therapy with ruxolitinib for at least 28 days therefore does not comply with the provisions of the product information of ruxolitinib.

Notwithstanding this, the G-BA determined fedratinib as the appropriate comparator therapy. The comparator in the SIMPLIFY-2 study therefore does not correspond to the appropriate comparator therapy.

MOMENTUM study

The MOMENTUM study presented additionally is a multicentre, randomised, double-blind, phase III study, which compared momelotinib to danazol. The study consists of a 24-week randomised, controlled and blinded treatment phase. This is followed by an optional extension phase, during which all participants could receive momelotinib and participants in the danazol arm could continue to receive danazol. The study, which was completed in December 2022, was conducted in 107 study sites across North America, Europe, Asia and Australia.

The study population of the MOMENTUM study comprises adults pretreated with JAK inhibitors who have symptomatic myelofibrosis (primary myelofibrosis, post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis, as defined by the diagnostic criteria of WHO or IWG-MRT) and anaemia (Hb < 10 g/dl). Symptomatic myelofibrosis was defined as a total symptom score ≥ 10 on the Myelofibrosis Symptom Assessment Form (MFSAF). A total of 195 subjects were enrolled in the study and randomised in a 2:1 ratio, stratified by MFSAF total symptom score at baseline (< 22/ ≥ 22), palpable spleen length below the left costal margin (< 12 cm vs ≥ 12 cm) and transfusion burden at baseline (no unit of red blood cell concentrate vs 1 to 4 units of red blood cell concentrate vs ≥ 5 units of red blood cell concentrate within the 8 weeks prior to randomisation).

The primary endpoints of the study were symptom response after 24 weeks, defined as a ≥ 50% reduction in the MFSAF total symptom score during the 28 days immediately preceding the end of week 24 from baseline, and transfusion independence at week 24.

For the study, the following data cut-offs were performed:

- 17 January 2023 (data cut-off for closing the database)
- 3 December 2021 (end of the double-blind treatment phase)

On the implementation of the appropriate comparator therapy:

Danazol, the comparator selected in the MOMENTUM study presented additionally by the pharmaceutical company, does not correspond to the appropriate comparator therapy determined by the G-BA.

Conclusion

The therapy options used in the comparator arms of the SIMPLIFY-2 and MOMENTUM studies do not correspond to the appropriate comparator therapy determined by the G-BA.

The SIMPLIFY-2 and MOMENTUM studies presented by the pharmaceutical company are thus unsuitable for demonstrating the additional benefit of momelotinib. An additional benefit of momelotinib for the treatment of adults with moderate to severe anaemia who have primary myelofibrosis, post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis and who have been treated with ruxolitinib, is thus not proven.

2.1.4 Summary of the assessment

The present assessment is the new benefit assessment of the active ingredient momelotinib due to exceeding the EUR 30 million turnover limit.

Momelotinib was approved as an orphan drug for the treatment of disease-related splenomegaly or symptoms in adult patients with moderate to severe anaemia who have primary myelofibrosis, post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis and who are Janus Kinase (JAK) inhibitor naïve or have been treated with ruxolitinib.

In the therapeutic indication to be considered, two patient groups were distinguished, depending on prior therapy:

a) Adults with moderate to severe anaemia who have primary myelofibrosis, post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis and who are Janus Kinase (JAK) inhibitor naïve; for the treatment of disease-related splenomegaly or symptoms

   and

b) Adults with moderate to severe anaemia who have primary myelofibrosis, post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis and who have been treated with ruxolitinib; for the treatment of disease-related splenomegaly or symptoms

Patient group a)

The G-BA determined the appropriate comparator therapy to be treatment with ruxolitinib or fedratinib.

For this patient group, the pharmaceutical company presented the multicentre, randomised, controlled, double-blind, phase III SIMPLIFY-1 study which compared momelotinib to ruxolitinib. The comparator therapy in the study corresponds to the appropriate comparator therapy for the present therapeutic indication.

For the endpoint of overall survival, there was no statistically significant difference between the treatment groups.

In the endpoint category of morbidity, there were no relevant differences with regard to leukaemic transformation, with only 1 event observed overall. There were also no relevant differences in the endpoints on symptomatology (MPN-SAF, BFI, PGIC) and health status (EQ-5D VAS).

No relevant difference was found with regard to quality of life which was surveyed using the SF-36v2.

For the overall rate of SAEs and severe AEs in terms of the endpoint category of side effects, there were no statistically significant differences between the treatment arms. For "Therapy discontinuation due to AEs", there was a disadvantage of momelotinib. A disadvantage is derived overall in the endpoint category of side effects due to the disadvantage in "Therapy discontinuation due to AEs".

The overall assessment showed that an additional benefit of momelotinib over ruxolitinib in patients, who are Janus Kinase (JAK) inhibitor naïve, is not proven.

Patient group b)

The G-BA determined the appropriate comparator therapy to be treatment with fedratinib.

For this patient group, the pharmaceutical company presented the randomised, controlled, open-label phase III SIMPLIFY-2 study, as well as the randomised, controlled, double-blind phase III MOMENTUM study. In the SIMPLIFY-2 study, momelotinib was compared with best available therapy (BAT). Active ingredients commonly used in the BAT were ruxolitinib, hydroxyurea and prednisolone; fedratinib was not used. In the MOMENTUM study, momelotinib was compared with danazol.

The therapy options used in the comparator arms of the SIMPLIFY-2 and MOMENTUM studies therefore do not correspond to the appropriate comparator therapy.

Thus, no suitable data for the benefit assessment of momelotinib are available.

An additional benefit is therefore not proven.

2.2 Number of patients or demarcation of patient groups eligible for treatment

The information on the number of patients is based on the target population in statutory health insurance (SHI).

In the dossier submitted by the pharmaceutical company, there was uncertainty regarding the patient numbers due to the lack of consideration of potential diagnostic codes and a lack of consideration of some of the symptomatic patients. In order to ensure a consistent determination of the patient numbers in the present therapeutic indication, the G-BA refer to the derivation of the target population used as a basis in the resolution on the benefit assessment of momelotinib (resolution of 15 August 2024). Based on the updated population figures and the SHI share, the following patient numbers result:

Approx. 470 to 1,500 patients for patient group a) patients who are Janus Kinase (JAK) inhibitor naïve and approx. 210 to 1,180 patients for patient group b) patients who were treated with ruxolitinib.

The resolution on momelotinib (resolution of 15 August 2024) includes a more valid derivation of the patient numbers in the SHI target population, which can be used despite existing uncertainty.

Based on the derivation of the patient numbers from the procedure for momelotinib (resolution of 15 August 2024) with the changes described above, the following patient numbers result:

Baseline (procedure D-1040 for momelotinib, lower limit): prevalence of myelofibrosis in Germany in 2025: 8 / 100,000 (6,680)

1. Patients with disease-related splenomegaly or symptoms 53.0% to 73.8% (3,540 to 4,930)
2. Application of the SHI share 89.2%; sub-population of ill insured patients (3,157 to 4,396)

3a. Patients with myelofibrosis and treatment with ruxolitinib: 0.0023% of all SHI-insured patients in 2025 (1,726)

3b. Patients with myelofibrosis and discontinuation of treatment with ruxolitinib 37.4% (646)

For the upper limit (100.0%), it is assumed that all patients receiving treatment with ruxolitinib (step 3a) switch to momelotinib and are eligible for treatment with momelotinib.

3. Patient group b): Patients who were fully or partially treated with ruxolitinib (646 to 1,726)
4. Patient group a): therapy naïve patients (sub-population of ill insured patients minus patient group b) (1,431 to 3,750)

   Consideration of patients with anaemia (percentage values from information provided by the pharmaceutical company for momelotinib):

5a. Patient group a): 33 to 40% with moderate to severe anaemia (472 to 1,500)

5b. Patient group b): 33 to 68.18% with moderate to severe anaemia (213 to 1,177)

The prevalence rate (baseline) and the percentages for anaemia (steps 5a and 5b) from the pharmaceutical company's dossier are subject to uncertainty and may be higher in each case. Furthermore, the share of 0.0023% used in step 3a is based on data from 2013.

In summary, this results in 3,157 to 4,396 patients with disease-related splenomegaly or symptoms covered by the SHI in 2025. This target population is divided between the two research questions as follows:

Patient group a) Adult patients who have not been pretreated with a JAK inhibitor: approximately 470 to 1,500 patients

Patient group b) Adult patients treated with ruxolitinib: approximately 210 to 1,180 patients.

2.3 Requirements for a quality-assured application

The requirements in the product information are to be taken into account. The European Medicines Agency (EMA) provides the contents of the product information (summary of product characteristics, SmPC) for Omjjara (active ingredient: momelotinib) at the following publicly accessible link (last access: 22 January 2026):

https://www.ema.europa.eu/en/documents/product-information/omjjara-epar-product-information_en.pdf

Treatment with momelotinib should only be initiated and monitored by specialists in internal medicine, haematology and oncology experienced in the treatment of patients with myelofibrosis.

2.4 Treatment costs

The treatment costs are based on the requirements in the product information and the information listed in the LAUER-TAXE® (last revised: 15 February 2026). The calculation of treatment costs is generally based on the last revised LAUER-TAXE® version following the publication of the benefit assessment.

For the cost representation, only the dosages of the general case are considered. Patient-individual dose adjustments (e.g. because of side effects or comorbidities) are not taken into account when calculating the annual treatment costs.

If no maximum treatment duration is specified in the product information, the treatment duration is assumed to be one year (365 days), even if the actual treatment duration is different from patient to patient and/or is shorter on average. The time unit "days" is used to calculate the "number of treatments/ patient/ year", time intervals between individual treatments and for the maximum treatment duration, if specified in the product information.

a) Adults with moderate to severe anaemia who have primary myelofibrosis, post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis and who are Janus Kinase (JAK) inhibitor naïve; for the treatment of disease-related splenomegaly or symptoms

Treatment period:

Designation of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
Medicinal product to be assessed				
Momelotinib	Continuously, 1 x daily	365.0	1	365.0
Appropriate comparator therapy				
Ruxolitinib or fedratinib				
Ruxolitinib	Continuously, 2 x daily	365.0	1	365.0
Fedratinib	Continuously, 1 x daily	365.0	1	365.0

Consumption:

Designation of the therapy	Dosage/ application	Dose/ patient/ treatment days	Consumption by potency/ treatment day	Treatment days/ patient/ year	Average annual consumption by potency
Medicinal product to be assessed					
Momelotinib	200 mg	200 mg	1 x 200 mg	365.0	365 x 200 mg
Appropriate comparator therapy					
Ruxolitinib or fedratinib					
Ruxolitinib	5 mg – 25 mg	10 mg – 50 mg	2 x 5 mg – 2 x 20 mg + 2 x 5 mg	365.0	730 x 5 mg – 730 x 20 mg + 730 x 5 mg
Fedratinib	400 mg	400 mg	4 x 100 mg	365.0	1,460 x 100 mg

b) Adults with moderate to severe anaemia who have primary myelofibrosis, post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis and who have been treated with ruxolitinib; for the treatment of disease-related splenomegaly or symptoms

Treatment period:

Designation of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
Medicinal product to be assessed				
Momelotinib	Continuously, 1 x daily	365.0	1	365.0
Appropriate comparator therapy				
Fedratinib				
Fedratinib	Continuously, 1 x daily	365.0	1	365.0

Consumption:

Designation of the therapy	Dosage/ application	Dose/ patient/ treatment days	Consumption by potency/ treatment day	Treatment days/ patient/ year	Average annual consumption by potency
Medicinal product to be assessed					
Momelotinib	200 mg	200 mg	1 x 200 mg	365.0	365 x 200 mg
Appropriate comparator therapy					
Fedratinib					
Fedratinib	400 mg	400 mg	4 x 100 mg	365.0	1,460 x 100 mg

a) Adults with moderate to severe anaemia who have primary myelofibrosis, post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis and who are Janus Kinase (JAK) inhibitor naïve; for the treatment of disease-related splenomegaly or symptoms

b) Adults with moderate to severe anaemia who have primary myelofibrosis, post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis and who have been treated with ruxolitinib; for the treatment of disease-related splenomegaly or symptoms

Costs:

In order to improve comparability, the costs of the medicinal products were approximated both on the basis of the pharmacy sales price level and also deducting the statutory rebates in accordance with Section 130 and Section 130a SGB V. To calculate the annual treatment costs, the required number of packs of a particular potency was first determined on the basis of consumption. Having determined the number of packs of a particular potency, the costs of the medicinal products were then calculated on the basis of the costs per pack after deduction of the statutory rebates. Any reference prices shown in the cost representation may not represent the cheapest available alternative.

Costs of the medicinal products:

Designation of the therapy	Packaging size	Costs (pharmacy sales price)	Rebate Section 130 SGB V	Rebate Section 130a SGB V	Costs after deduction of statutory rebates
Medicinal product to be assessed					
Momelotinib	30 FCT	€ 4,649.62	€ 1.77	€ 262.25	€ 4,385.60
Appropriate comparator therapy					
Fedratinib 100 mg	120 HC	€ 3,810.55	€ 1.77	€ 214.33	€ 3,594.45
Ruxolitinib 20 mg	56 TAB	€ 3,953.87	€ 1.77	€ 222.51	€ 3,729.59
Ruxolitinib 5 mg	56 TAB	€ 2,005.76	€ 1.77	€ 111.26	€ 1,892.73
Abbreviations: FCT = film-coated tablets; HC = hard capsules; TAB = tablet					

LAUER-TAXE® last revised: 15 February 2026

Costs for additionally required SHI services:

Only costs directly related to the use of the medicinal product are taken into account. If there are regular differences in the necessary use of medical treatment or in the prescription of other services in the use of the medicinal product to be evaluated and the appropriate comparator therapy in accordance with the product information, the costs incurred for this must be taken into account as costs for additionally required SHI services.

Medical treatment costs, medical fee services, and costs incurred for routine examinations (e.g. regular laboratory services such as blood count tests) that do not exceed the standard expenditure in the course of the treatment are not shown.

Additionally required SHI services for the application of the medicinal product to be evaluated according to the product information and patient information leaflet are given by the necessity of determining the thiamine level prior to therapy initiation. According to the product information, thiamine levels should be assessed at baseline and at regular intervals thereafter, e.g. monthly for the first 3 months and every 3 months thereafter (and as clinically indicated). Accordingly, 7 determinations per year are assumed.

The calculation of the additionally required SHI services is based on the fee structure items (FSI) as of the 3rd quarter of 2025 of the uniform value scale (UVS 2025/Q3).

Designation of the therapy	Packaging size	Costs (pharmacy sales price)	Rebate Section 130 SGB V	Rebate Section 130a SGB V	Costs after deduction of statutory rebates	Treatment days/ year	Costs/ patient/ year
Medicinal product to be assessed:							
Fedratinib							
Determination of the thiamine level							
Quantitative chromatographic determination(s) of one or more	-	-	-	-	€ 20.52	7	€ 143.64

Designation of the therapy	Packaging size	Costs (pharmacy sales price)	Rebate Section 130 SGB V	Rebate Section 130a SGB V	Costs after deduction of statutory rebates	Treatment days/ year	Costs/ patient/ year
substance(s) – Vitamins FSI 32306							

2.5 Designation of medicinal products with new active ingredients according to Section 35a, paragraph 3, sentence 4 SGB V that can be used in a combination therapy with the assessed medicinal product

According to Section 35a, paragraph 3, sentence 4, the G-BA designate all medicinal products with new active ingredients that can be used in a combination therapy with the assessed medicinal product for the therapeutic indication to be assessed on the basis of the marketing authorisation under Medicinal Products Act.

Basic principles of the assessed medicinal product

A designation in accordance with Section 35a, paragraph 3, sentence 4 SGB V requires that it is examined based on the product information for the assessed medicinal product whether it can be used in a combination therapy with other medicinal products in the assessed therapeutic indication. In the first step, the examination is carried out on the basis of all sections of the currently valid product information for the assessed medicinal product.

If the assessed medicinal product contains an active ingredient or a fixed combination of active ingredients in the therapeutic indication of the resolution (assessed therapeutic indication) and is approved exclusively for use in monotherapy, a combination therapy is not considered due to the marketing authorisation under Medicinal Products Act, which is why no designation is made.

A designation is also not considered if the G-BA have decided on an exemption as a reserve antibiotic for the assessed medicinal product in accordance with Section 35a, paragraph 1c, sentence 1 SGB V. The additional benefit is deemed to be proven if the G-BA have decided on an exemption for a reserve antibiotic in accordance with Section 35a, paragraph 1c, sentence 1 SGB V; the extent of the additional benefit and its therapeutic significance are not to be assessed by the G-BA. Due to the lack of an assessment mandate by the G-BA following the resolution on an exemption according to Section 35a, paragraph 1c, sentence 1 SGB V with regard to the extent of the additional benefit and the therapeutic significance of the reserve antibiotic to be assessed, there is a limitation due to the procedural privileging of the pharmaceutical companies to the effect that neither the proof of an existing nor an expected at least considerable additional benefit is possible for exempted reserve antibiotics in the procedures according to Section 35a paragraph 1 or 6 SGB V and Section 35a paragraph 1d SGB V. The procedural privileging of the reserve antibiotics exempted according to Section 35a, paragraph 1c, sentence 1 SGB V must therefore also be taken into account at the level of designation according to Section 35a, paragraph 3, sentence 4 SGB V in order to avoid valuation contradictions.

With regard to the further examination steps, a differentiation is made between a "determined" or "undetermined" combination, which may also be the basis for a designation.

A "determined combination" exists if one or more individual active ingredients which can be

used in combination with the assessed medicinal product in the assessed therapeutic indication are specifically named.

An "undetermined combination" exists if there is information on a combination therapy, but no specific active ingredients are named. An undetermined combination may be present if the information on a combination therapy:

- names a product class or group from which some active ingredients not specified in detail can be used in combination therapy with the assessed medicinal product, or
- does not name any active ingredients, product classes or groups, but the assessed medicinal product is used in addition to a therapeutic indication described in more detail in the relevant product information, which, however, does not include data from the product information on active ingredients within the scope of this therapeutic indication.

Concomitant active ingredient

The concomitant active ingredient is a medicinal product with new active ingredients that can be used in combination therapy with the assessed medicinal product for the therapeutic indication to be assessed.

For a medicinal product to be considered as a concomitant active ingredient, it must be classified as a medicinal product with new active ingredients according to Section 2 paragraph 1 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV) in conjunction with the corresponding regulations in Chapter 5 of the Rules of Procedure of the G-BA as of the date of the present resolution. In addition, the medicinal product must be approved in the assessed therapeutic indication, whereby a marketing authorisation is sufficient only for a sub-area of the assessed therapeutic indication.

Based on an "undetermined combination", the concomitant active ingredient must be attributable to the information on the product class or group or the therapeutic indication according to the product information of the assessed medicinal product in the assessed therapeutic indication, whereby the definition of a product class or group is based on the corresponding requirements in the product information of the assessed medicinal product.

In addition, there must be no reasons for exclusion of the concomitant active ingredient from a combination therapy with the assessed medicinal product, in particular no exclusive marketing authorisation as monotherapy.

In addition, all sections of the currently valid product information of the eligible concomitant active ingredient are checked to see whether there is any information that excludes its use in combination therapy with the assessed medicinal product in the assessed therapeutic indication under marketing authorisation regulations. Corresponding information can be, for example, dosage information or warnings. In the event that the medicinal product is used as part of a determined or undetermined combination which does not include the assessed medicinal product, a combination with the assessed medicinal product shall be excluded.

Furthermore, the product information of the assessed medicinal product must not contain any specific information that excludes its use in combination therapy with the eligible concomitant active ingredient in the assessed therapeutic indication under marketing authorisation regulations.

Medicinal products with new active ingredients for which the G-BA have decided on an exemption as a reserve antibiotic in accordance with Section 35a, paragraph 1c, sentence 1 SGB V are ineligible as concomitant active ingredients. The procedural privileging of the

reserve antibiotics exempted according to Section 35a, paragraph 1c, sentence 1 SGB V also applies accordingly to the medicinal product eligible as a concomitant active ingredient.

Designation

The medicinal products which have been determined as concomitant active ingredients in accordance with the above points of examination are named by indicating the relevant active ingredient and the invented name. The designation may include several active ingredients, provided that several medicinal products with new active ingredients may be used in the same combination therapy with the assessed medicinal product or different combinations with different medicinal products with new active ingredients form the basis of the designation.

If the present resolution on the assessed medicinal product in the assessed therapeutic indication contains several patient groups, the designation of concomitant active ingredients shall be made separately for each of the patient groups.

Exception to the designation

The designation excludes combination therapies for which - patient group-related - a considerable or major additional benefit has been determined by resolution according to Section 35a, paragraph 3, sentence 1 SGB V or it has been determined according to Section 35a, paragraph 1d, sentence 1 SGB V that at least considerable additional benefit of the combination can be expected. In this context, the combination therapy that is excluded from the designation must, as a rule, be identical to the combination therapy on which the preceding findings were based.

In the case of designations based on undetermined combinations, only those concomitant active ingredients - based on a resolution according to Section 35a, paragraph 3, sentence 1 SGB V on the assessed medicinal product in which a considerable or major additional benefit had been determined - which were approved at the time of this resolution are excluded from the designation.

Legal effects of the designation

The designation of combinations is carried out in accordance with the legal requirements according to Section 35a, paragraph 3, sentence 4 and is used exclusively to implement the combination discount according to Section 130e SGB V between statutory health insurance funds and pharmaceutical companies. The designation is not associated with a statement as to the extent to which a therapy with the assessed medicinal products in combination with the designated medicinal products corresponds to the generally recognised state of medical knowledge. The examination was carried out exclusively on the basis of the possibility under Medicinal Products Act to use the medicinal products in combination therapy in the assessed therapeutic indication based on the product information; the generally recognised state of medical knowledge or the use of the medicinal products in the reality of care were not the subject of the examination due to the lack of an assessment mandate of the G-BA within the framework of Section 35a, paragraph 3, sentence 4 SGB V.

The findings made neither restrict the scope of treatment required to fulfil the medical treatment mandate, nor do they make statements about expediency or economic feasibility.

Justification for the findings on designation in the present resolution:

a) Adults with moderate to severe anaemia who have primary myelofibrosis, post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis and who are Janus Kinase (JAK) inhibitor naïve; for the treatment of disease-related splenomegaly or symptoms

- No medicinal product with new active ingredients for use in combination therapy in compliance with the requirements of Section 35a, paragraph 3, sentence 4 SGB V.

b) Adults with moderate to severe anaemia who have primary myelofibrosis, post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis and who have been treated with ruxolitinib; for the treatment of disease-related splenomegaly or symptoms

- No medicinal product with new active ingredients for use in combination therapy in compliance with the requirements of Section 35a, paragraph 3, sentence 4 SGB V.

References:
Product information for momelotinib (Omjjara); Omjjara film-coated tablets; last revised: March 2025

3. Bureaucratic costs calculation

The proposed resolution does not create any new or amended information obligations for care providers within the meaning of Annex II to Chapter 1 VerfO and, accordingly, no bureaucratic costs.

4. Process sequence

At their session on 7 October 2025, the Subcommittee on Medicinal Products determined the appropriate comparator therapy.

On 31 October 2025, the pharmaceutical company submitted a dossier for the benefit assessment of momelotinib to the G-BA in due time in accordance with Chapter 5 Section 8, paragraph 1, number 4 VerfO.

By letter dated 31 October 2025 in conjunction with the resolution of the G-BA of 1 August 2011 concerning the commissioning of the IQWiG to assess the benefits of medicinal products with new active ingredients in accordance with Section 35a SGB V, the G-BA commissioned the IQWiG to assess the dossier concerning the active ingredient momelotinib.

The dossier assessment by the IQWiG was submitted to the G-BA on 28 January 2026, and the written statement procedure was initiated with publication on the G-BA website on 2 February 2026. The deadline for submitting written statements was 23 February 2026.

The oral hearing took place on 9 March 2026.

In order to prepare a recommendation for a resolution, the Subcommittee on Medicinal Products commissioned a working group (Section 35a) consisting of the members nominated by the leading organisations of the care providers, the members nominated by the SHI umbrella organisation, and representatives of the patient organisations. Representatives of the IQWiG also participate in the sessions.

The evaluation of the written statements received and the oral hearing were discussed at the Subcommittee's session on 8 April 2026, and the draft resolution was approved.

At its session on 16 April 2026, the plenum adopted a resolution to amend the Pharmaceuticals Directive.

Chronological course of consultation

Session	Date	Subject of consultation
Subcommittee on Medicinal Products	7 October 2025	Determination of the appropriate comparator therapy
Working group Section 35a	4 March 2026	Information on written statements received; preparation of the oral hearing
Subcommittee on Medicinal Products	9 March 2026	Conduct of the oral hearing
Working group Section 35a	18 March 2026 1 April 2026	Consultation on the dossier evaluation by the IQWiG and evaluation of the written statement procedure
Subcommittee on Medicinal Products	8 April 2026	Concluding discussion of the draft resolution
Plenum	16 April 2026	Adoption of the resolution on the amendment of the Pharmaceuticals Directive

Berlin, 16 April 2026

Federal Joint Committee
in accordance with Section 91 SGB V
The Chair

Prof. Hecken