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
Tafasitamab (new therapeutic indication: follicular lymphoma, after ≥ 1 prior therapy, combination with lenalidomide and rituximab)

From 2 July 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.

For medicinal products for the treatment of rare diseases (orphan drugs) that are approved according to Regulation (EC) No. 141/2000 of the European Parliament and the Council of 16 December 1999, the additional medical benefit is considered to be proven through the grant of the marketing authorisation according to Section 35a, paragraph 1, sentence 11, 1st half of the sentence SGB V. Evidence of the medical benefit and the additional medical benefit in relation to the appropriate comparator therapy do not have to be submitted (Section 35a, paragraph 1, sentence 11, 2nd half of the sentence SGB V). Section 35a, paragraph 1, sentence 11, 1st half of the sentence SGB V thus guarantees an additional benefit of an approved orphan drug, although an assessment of the orphan drug in accordance with the principles laid down in Section 35a, paragraph 1, sentence 3, numbers 2 and 3 SGB V in conjunction with Chapter 5, Sections 5 et seqq. of the Rules of Procedure (VerfO) of the G-BA has not been carried out. In accordance with Section 5, paragraph 8 AM-NutzenV, only the extent of the additional benefit is to be quantified indicating the significance of the evidence.

However, the restrictions on the benefit assessment of orphan drugs resulting from the statutory obligation to the marketing authorisation do not apply if the turnover of the medicinal product with the SHI at pharmacy sales prices and outside the scope of SHI-accredited medical care, including VAT exceeds € 30 million in the last 12 calendar months. In accordance with Section 35a, paragraph 1, sentence 12 SGB V, the pharmaceutical company shall provide evidence - within three months of being requested to do so by the G-BA - in accordance with Chapter 5, Section 5, paragraphs 1 to 6 VerfO, in particular regarding the additional medical benefit in relation to the appropriate comparator therapy specified by the G-BA in accordance with Chapter 5, Section 6 VerfO, and in this evidence, demonstrate the additional benefit over the appropriate comparator therapy.

In accordance with Section 35a, paragraph 2 SGB V, the G-BA decide whether to carry out the benefit assessment itself or to commission the Institute for Quality and Efficiency in Health Care (IQWiG). Based on the legal requirement in Section 35a, paragraph 1, sentence 11 SGB V that the additional benefit of an orphan drug is considered to be proven through the grant of the marketing authorisation, the G-BA modified the procedure for the benefit assessment of orphan drugs at their session on 15 March 2012 to the effect that, for orphan drugs, the G-BA initially no longer independently determine an appropriate comparator therapy as the basis for the solely legally permissible assessment of the extent of an additional benefit to be assumed by law. Rather, the extent of the additional benefit is assessed exclusively on the basis of the approval studies by the G-BA indicating the significance of the evidence.

Accordingly, at their session on 15 March 2012, the G-BA amended the mandate issued to the IQWiG by the resolution of 1 August 2011 for the benefit assessment of medicinal products with new active ingredients in accordance with Section 35a, paragraph 2 SGB V to that effect that, in the case of orphan drugs, the IQWiG is only commissioned to carry out a benefit assessment in the case of a previously defined comparator therapy when the sales volume of the medicinal product concerned has exceeded the turnover limit according to Section 35a, paragraph 1, sentence 12 SGB V and is therefore subject to an unrestricted benefit assessment. According to Section 35a, paragraph 2 SGB V, the assessment by the G-BA 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 relevant date for the start of the benefit assessment procedure was the first placing on the (German) market of the active ingredient tafasitamab on 15 January 2026 in accordance with Chapter 5, Section 8, paragraph 1, number 2 of the Rules of Procedure of the G-BA (VerfO). Pursuant to Section 4, paragraph 3, number 2 of the Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV) in conjunction with Chapter 5, Section 8, paragraph 1, number 2 Rules of Procedure (VerfO), the pharmaceutical company submitted the final dossier to the G-BA on 12 January 2026.

Tafasitamab for the treatment of relapsed or refractory follicular lymphoma is approved as a medicinal product for the treatment of rare diseases under Regulation (EC) No. 141/2000 of the European Parliament and of the Council of 16 December 1999.

In accordance with Section 35a, paragraph 1, sentence 11, 1st half of the sentence SGB V, the additional benefit is considered to be proven through the grant of the marketing authorisation. The extent of the additional benefit and the significance of the evidence are assessed by the G-BA on the basis of the approval studies.

The G-BA carried out the benefit assessment and commissioned the IQWiG to evaluate the information provided by the pharmaceutical company in Module 3 of the dossier on treatment costs and patient numbers. The benefit assessment was published on 15 April 2026 together with the IQWiG assessment 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 adopted their resolution on the basis of the pharmaceutical company's dossier, the dossier assessment carried out by the G-BA, the IQWiG assessment of treatment costs and patient numbers (IQWiG G26-01) and the statements made in the written statement and oral hearing procedure, as well as the amendment drawn up by the G-BA on the benefit assessment.

In order to determine the extent of the additional benefit, the G-BA have assessed the studies relevant to the marketing authorisation on the basis of their therapeutic relevance (qualitative), in accordance with the criteria laid down in Chapter 5, Section 5, paragraph 7, sentence 1, numbers 1 to 4 VerfO. The methodology proposed by the IQWiG in accordance with the General Methods [1] was not used in the benefit assessment of tafasitamab.

2.1 Additional benefit of the medicinal product

2.1.1 Approved therapeutic indication of tafasitamab (Minjuvi) in accordance with the product information

Minjuvi is indicated in combination with lenalidomide and rituximab for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL) (Grade 1-3a) after at least one line of systemic therapy.

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

Therapeutic indication of the resolution (resolution of 2 July 2026):

See the approved therapeutic indication

2.1.2 Extent of the additional benefit and significance of the evidence

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

a) Adults with relapsed or refractory, grade 1-3a follicular lymphoma after one line of systemic therapy

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

Hint for a non-quantifiable additional benefit since the scientific data does not allow quantification.

b) Adults with relapsed or refractory, grade 1-3a follicular lymphoma after at least two lines of systemic therapy

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

Hint for a non-quantifiable additional benefit since the scientific data does not allow quantification.

Justification:

For the assessment of the additional benefit of tafasitamab, the pharmaceutical company submitted data from the randomised, controlled, double-blind phase III inMIND study. The inMIND study compared tafasitamab in combination with lenalidomide and rituximab with the combination of lenalidomide and rituximab. This is an ongoing study that has been taking place at 199 study sites across Europe, Australia, Asia and North America since April 2021. The end of the study is planned for August 2028. The treatment phase of the study lasts a maximum of 48 weeks (12 cycles, each spanning 28 days).

Patients with relapsed or refractory, grade 1-3a follicular lymphoma, as well as patients with marginal zone lymphoma, were recruited into the study and randomised in a 1:1 ratio. Stratification was based on the presence of disease progression within 24 months of the initial diagnosis (yes/no), refractoriness to a previous anti-CD20-targeted therapy (yes/no) and the number of previous systemic therapies (1 vs ≥ 2). A total of 548 subjects with follicular lymphoma were randomised, with 273 subjects assigned to the tafasitamab arm and 275 subjects to the control arm. The need for treatment was assessed using the GELF criteria (GELF, Groupe d'Etude des Lymphomes Folliculaires) at the time of enrolment in the study. All study participants have received at least 1 previous anti-CD20-targeted immunotherapy or chemoimmunotherapy.

The primary endpoint of the study is progression-free survival (PFS), which is assessed by the investigators on the basis of the 2014 Lugano criteria. Endpoints in the categories of mortality, morbidity, health-related quality of life and side effects were also assessed in the study.

The following data cut-offs are available or have been planned:

- Interim analysis of safety data following 2 treatment cycles involving 60 subjects
- Interim analysis of futility on 7 November 2022
- Primary data cut-off from 23 February 2024
- Data cut-off from 31 December 2024, requested by the European Medicines Agency (EMA), for the endpoint category of side effects
- Final data cut-off planned for August 2028

The primary data cut-off from 23 February 2024 is used for the present benefit assessment.

Division of the total population into sub-populations

The pharmaceutical company presented the results of the inMIND study in the dossier, distinguished into two sub-populations, based on the number of previous systemic therapies, and accordingly provided evidence of the extent of the additional benefit separately for each sub-population. The number of previous systemic therapies was a stratification factor in the study (1 vs ≥ 2).

Given that the number of previous systemic therapies is directly linked to the number of recurrences, which makes a difference in terms of patients' prognosis, the division into the relevant sub-populations is understandable.

Consequently, the present benefit assessment is based on patient group a) subjects who have received prior systemic therapy and patient group b) subjects who have received at least two prior systemic therapies.

Mortality

In the inMIND study, overall survival was operationalised as the time between randomisation and death from any cause.

Given the indolent disease progression of follicular lymphoma and the low number of events, the observation period for overall survival as of the present primary data cut-off is considered too short. According to information provided by the pharmaceutical company, the main analysis of overall survival is planned with the final data cut-off.

There was no statistically significant difference between the treatment arms for patient group a).

There was no statistically significant difference between the treatment arms for patient group b).

Morbidity

Progression-free survival (PFS)

PFS assessed by the investigators is the primary endpoint of the inMIND study and is operationalised as the time from randomisation to first documented disease progression or death from any cause, whichever occurs first.

For each patient groups a) and b), there was a statistically significant difference in favour of the tafasitamab combination compared with the comparator arm.

The PFS endpoint is a composite endpoint composed of endpoints of the categories "mortality" and "morbidity". The endpoint component "mortality" is already assessed via the endpoint "overall survival" as an independent endpoint. The morbidity component "disease

progression" is assessed according to the criteria for Lugano classification of non-Hodgkin lymphomas and thus, not in a symptom-related manner but by means of laboratory parametric, imaging, and haematological procedures. Taking into account the aspects mentioned above, there are different opinions within the G-BA regarding the patient relevance of the PFS endpoint. The overall statement on the additional benefit remains unaffected.

Cross-endpoint note on Patient-Reported Outcomes (PROs)

A change to the study protocol implemented by Amendment 6 resulted in a rescheduling of the visit to the end of treatment (EOT). Prior to Amendment 6, the EOT visit took place 90 days after the end of treatment. Amendment 6 introduced a final visit at the end of treatment, meaning that the EOT visit now takes place on the last day of the final cycle. The information in the dossier did not indicate in how many subjects the EOT visit occurred according to the old definition and how many according to the new one.

In the written statement procedure, the pharmaceutical company stated the number of subjects in which the EOT visit occurred according to the definition prior to Amendment 6 and those thereafter. Accordingly, 24 subjects received the EOT visit 90 days after the end of treatment, and 524 subjects on the last day of the final cycle.

The subsequently submitted information does not indicate any factors that would distort the assessment, either before or after Amendment 6, meaning that the analyses can be used for the benefit assessment.

Furthermore, the pharmaceutical company did not present any results on PROs for the sub-populations they had proposed in the dossier, but merely provided supplementary analyses at month 6 without effect estimators for the total population, justifying this on the basis of return rates <70%. Patients, who were still undergoing treatment at the time of the data cut-off and therefore could not yet have made certain visits including that at the end of treatment (EOT), were excluded from the calculation of the return rate.

Among the subjects who have already completed treatment, the return rate at the end of treatment is over 70%, meaning that these results can, in principle, be used for the benefit assessment.

In the written statement procedure, the pharmaceutical company submitted analyses of the mean change relative to baseline, distinguished into individual sub-populations.

Consequently, the analyses of the PROs subsequently submitted by the pharmaceutical company in the written statement procedure and presented for the respective sub-population are used for the present benefit assessment.

Health status (EQ-5D VAS)

In the inMIND study, health status is assessed using the visual analogue scale (VAS) of the European Quality of Life Questionnaire 5 Dimensions (EQ-5D).

For the health status, there was no statistically significant difference between the study arms in patient group a).

For the health status, there was no statistically significant difference between the study arms in patient group b).

EORTC QLQ-C30 symptom scales

In the inMIND study, disease symptomatology was assessed using the symptom scales of the cancer-specific Quality of Life Questionnaire – Core Questionnaire of the European Organisation for Research and Treatment of Cancer (EORTC QLQ-C30).

For patient group a), there were no statistically significant differences between the treatment arms in the symptom scales.

For patient group b), there were no statistically significant differences between the treatment arms in the symptom scales.

Quality of life

EORTC QLQ-C30 functional scales

In the inMIND study, health-related quality of life was assessed using the functional scales of the cancer-specific EORTC QLQ-C30 questionnaire.

In patient group a), there was no statistically significant difference between the study arms for each one of the scales of health-related quality of life of the EORTC QLQ-C30.

In patient group b), there was no statistically significant difference between the study arms for each one of the scales of health-related quality of life of the EORTC QLQ-C30.

FACT-Lym

In addition, health-related quality of life was assessed in the inMIND study using the lymphoma-specific Functional Assessment of Cancer Therapy - Lymphoma (FACT-Lym) questionnaire.

No statistically significant difference between the study arms could be observed for patient group a).

No statistically significant difference between the study arms could be observed for patient group b).

Side effects

In the inMIND study, the assessment of adverse events (AEs) began after the start of administration of the study treatment and ended 90 days after the last dose of the study treatment.

In accordance with the study protocol, events related to the underlying disease or to the progression of the cancer under investigation should not be classified as AEs. The study protocol does not provide any further guidelines in this regard, so it is unclear which events should have been taken into account.

The benefit assessment is based on the analyses, distinguished into sub-populations, as of the relevant data cut-off from 23 February 2024; these analyses were submitted subsequently with the pharmaceutical company's written statement.

Adverse events (AEs)

In the inMIND study, almost all study participants in patient groups a) and b) experienced an AE. The results were only presented additionally.

Serious AEs (SAEs), severe AEs and therapy discontinuation due to AEs

With regard to patient group a), the inMIND study did not show any statistically significant differences between the study arms for the endpoints of SAEs, severe AEs and therapy discontinuation due to AEs respectively.

With regard to patient group b), the inMIND study did not show any statistically significant differences between the study arms for the endpoints of SAEs, severe AEs and therapy discontinuation due to AEs respectively.

AE of special interest

In the dossier, the pharmaceutical company provided information on severe AEs and SAEs occurring at an incidence ≥ 5%.

For patient group a), the results on severe AEs (CTCAE grade ≥ 3) occurring at an incidence ≥ 5% show significant differences to the disadvantage of the tafasitamab combination compared with the comparator arm at the Preferred Terms (PT) level of "COVID-19 pneumonia" and "Pneumonia", and at the System Organ Class (SOC) level of "Infections and infestations".

For patient group a), SAEs occurring at an incidence ≥ 5% show a significant difference to the disadvantage of the tafasitamab combination compared with the comparator arm for the PT "COVID-19 pneumonia" and the SOC "Infections and infestations".

For patient group b), the results on severe AEs (CTCAE grade ≥ 3) occurring at an incidence ≥ 5% show a significant difference to the disadvantage of the tafasitamab combination compared with the comparator arm for the PT "Febrile neutropenia".

For patient group b), SAEs occurring at an incidence ≥ 5% show a significant difference in favour of the tafasitamab combination compared with the comparator arm for the SOC "Gastrointestinal disorders".

Overall, neither an advantage nor a disadvantage is derived for the patient groups a) and b) in the endpoint category of side effects. Detailed analysis shows differences in individual AEs of special interest, which imply disadvantages of the tafasitamab combination for patient group a) and both an advantage and a disadvantage thereof for patient group b).

Overall assessment

Results on mortality, morbidity, quality of life and side effects from the double-blind, randomised controlled inMIND study, which compared tafasitamab in combination with lenalidomide and rituximab with the combination of lenalidomide and rituximab, are available for the benefit assessment of tafasitamab in the treatment of relapsed or refractory, grade 1-3a follicular lymphoma after at least one line of systemic therapy. The pharmaceutical company presented the results of the inMIND study in the dossier, distinguished into two sub-populations, based on the number of previous systemic therapies, which form the basis of the assessment.

a) Adults with relapsed or refractory, grade 1-3a follicular lymphoma after one line of systemic therapy

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

With regard to health status (EQ-5D VAS) and the EORTC QLQ-C30 symptom scales in the endpoint category of morbidity, there were no statistically significant differences between the treatment arms.

With regard to quality of life, as measured using the functional scales of the EORTC QLQ-C30 and the FACT-Lym, there were no statistically significant differences between the treatment arms.

With regard to the endpoint category of side effects, there were no statistically significant differences between the treatment arms in the overall rates of SAEs and severe AEs, as well as for "Therapy discontinuation due to AEs". Detailed analysis shows disadvantages of the tafasitamab combination for some "AEs of special interest". In the category of side effects, neither an advantage nor a disadvantage can be derived overall.

In the overall assessment, a non-quantifiable additional benefit of tafasitamab in combination with lenalidomide and rituximab compared to lenalidomide and rituximab is identified for patients, who have received one line of systemic therapy, since the scientific data does not allow quantification.

Significance of the evidence

The randomised, double-blind inMIND study forms the basis of the present benefit assessment.

Overall, the risk of bias at the study level is rated as low.

For the overall survival, the risk of bias at the endpoint level is rated as low.

For the endpoints of morbidity and quality of life, the risk of bias is classified as high, as return rates fluctuated over the course of the treatment period and, as of the primary data cut-off, not all randomised patients, but only those who had reached the end of treatment/ safety follow-up time point could be analysed according to the ITT principle.

With regard to the side effects, the risk of bias is rated as low.

Overall, a hint is derived for the significance of the evidence.

b) Adults with relapsed or refractory, grade 1-3a follicular lymphoma after at least two lines of systemic therapy

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

With regard to health status (EQ-5D VAS) and the EORTC QLQ-C30 symptom scales in the endpoint category of morbidity, there were no statistically significant differences between the treatment arms.

With regard to quality of life, as measured using the functional scales of the EORTC QLQ-C30 and the FACT-Lym, there were no statistically significant differences between the treatment arms.

With regard to the endpoint category of side effects, there were no statistically significant differences between the treatment arms in the overall rates of SAEs and severe AEs, as well as for "Therapy discontinuation due to AEs". Detailed analysis shows a disadvantage and an advantage of the tafasitamab combination for some "AEs of special interest". In the category of side effects, neither an advantage nor a disadvantage can be derived overall.

In the overall assessment, a non-quantifiable additional benefit of tafasitamab in combination with lenalidomide and rituximab compared to lenalidomide and rituximab is identified for patients, who have received at least two lines of systemic therapy, since the scientific data does not allow quantification.

Significance of the evidence

The randomised, double-blind inMIND study forms the basis of the present benefit assessment.

Overall, the risk of bias at the study level is rated as low.

For the overall survival, the risk of bias at the endpoint level is rated as low.

For the endpoints of morbidity and quality of life, the risk of bias is classified as high, as return rates fluctuated over the course of the treatment period and, as of the primary data cut-off, not all randomised patients, but only those who had reached the end of treatment/ safety follow-up time point could be analysed according to the ITT principle.

With regard to the side effects, the risk of bias is rated as low.

Overall, a hint is derived for the significance of the evidence.

2.1.3 Summary of the assessment

The present assessment is the benefit assessment of a new therapeutic indication for the medicinal product Minjuvi with the active ingredient tafasitamab.

Minjuvi was approved as an orphan drug.

The therapeutic indication assessed here is as follows: Minjuvi is indicated in combination with lenalidomide and rituximab for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL) (Grade 1-3a) after at least one line of systemic therapy.

For the benefit assessment, the pharmaceutical company presented data on mortality, morbidity and side effects from the ongoing, randomised, controlled, double-blind inMIND study comparing tafasitamab in combination with lenalidomide and rituximab to lenalidomide in combination with rituximab.

The pharmaceutical company presented the results of the inMIND study in the dossier, distinguished into two sub-populations, based on the number of previous systemic therapies, which form the basis of the assessment.

a) Adults with relapsed or refractory, grade 1-3a follicular lymphoma after one line of systemic therapy

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

With regard to health status (EQ-5D VAS) and the EORTC QLQ-C30 symptom scales in the endpoint category of morbidity, there were no statistically significant differences between the treatment arms.

With regard to quality of life, as measured using the functional scales of the EORTC QLQ-C30 and the FACT-Lym, there were no statistically significant differences between the treatment arms.

With regard to side effects, there were no statistically significant differences between the treatment arms in the overall rates of SAEs and severe AEs, as well as for "Therapy discontinuation due to AEs". Detailed analysis shows disadvantages of the tafasitamab combination for some "AEs of special interest". In the endpoint category of side effects, neither an advantage nor a disadvantage can be derived overall.

The significance of the evidence is classified as a hint overall.

In the overall assessment, a hint for a non-quantifiable additional benefit of tafasitamab in combination with lenalidomide and rituximab compared to lenalidomide and rituximab is identified for patients, who have received one line of systemic therapy, since the scientific data does not allow quantification.

b) Adults with relapsed or refractory, grade 1-3a follicular lymphoma after at least two lines of systemic therapy

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

With regard to health status (EQ-5D VAS) and the EORTC QLQ-C30 symptom scales in the endpoint category of morbidity, there were no statistically significant differences between the treatment arms.

With regard to quality of life, as measured using the functional scales of the EORTC QLQ-C30 and the FACT-Lym, there were no statistically significant differences between the treatment arms.

With regard to side effects, there were no statistically significant differences between the treatment arms in the overall rates of SAEs and severe AEs, as well as for "Therapy discontinuation due to AEs". Detailed analysis shows a disadvantage and an advantage of the tafasitamab combination for some "AEs of special interest". In the endpoint category of side effects, neither an advantage nor a disadvantage can be derived overall.

The significance of the evidence is classified as a hint overall.

In the overall assessment, a hint for a non-quantifiable additional benefit of tafasitamab in combination with lenalidomide and rituximab compared to lenalidomide and rituximab is identified for patients, who have received at least two lines of systemic therapy, since the scientific data does not allow quantification.

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).

The resolution is based on the information from the dossier of the pharmaceutical company.

The information is based on an incidence rate from 2021, which was determined by the Institute for Applied Health Research Berlin (InGef) and was also used in the resolution on the benefit assessment of zanubrutinib (resolution of 6 June 2024). In the written statement procedure, the pharmaceutical company determined the number of patients in patient group a) using a 2023 incidence rate, based on data from the German Centre for Cancer Registry Data (ZfKD), which however does not exclusively cover SHI-insured patients, nor those with grade 1–3a follicular lymphoma. As the estimated number of patients in patient group b) is also based on data from the InGef, the information from the pharmaceutical company's dossier is used here.

With regard to patient group a), the number of patients estimated by the pharmaceutical company is subject to uncertainties arising, for example, from the length of the observation period in the studies on which the percentages are based.

With regard to patient group b), uncertainties arise, for example, from the length of the observation period, uncertainties in the definition of specific follicular lymphoma therapies and a lack of information on the frequency of individual therapies.

Overall, against the backdrop of a uniform data basis for the incidence rates of both patient groups and by analogy with the previous procedure for zanubrutinib (resolution of 6 June 2024), the information from the pharmaceutical company's dossier is used.

Approximately 680 to 1,510 patients result for patient group a), i.e. subjects who have received one line of systemic therapy.

Approximately 370 to 840 patients result for patient group b), i.e. subjects who have received at least two lines of systemic therapy.

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 Minjuvi (active ingredient: tafasitamab) at the following publicly accessible link (last access: 30 April 2026):

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

Therapy with tafasitamab should only be initiated and monitored by specialists in internal medicine, haematology and oncology experienced in the treatment of patients with follicular lymphoma.

This medicinal product received a conditional marketing authorisation. This means that further evidence of the benefit of the medicinal product is anticipated. The EMA will assess new information on this medicinal product at least annually and update the product information as necessary.

2.4 Treatment costs

The treatment costs are based on the contents of the product information and the information listed in the LAUER-TAXE® (last revised: 1 May 2026).

The calculation of treatment costs is generally based on the last revised LAUER-TAXE® version following the publication of the benefit assessment.

The (daily) doses recommended in the product information were used as the calculation basis.

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.

As it is not always possible to achieve the exact target dose per day with the commercially available dosage strengths, in these cases rounding up or down to the next higher or lower available dose that can be achieved with the commercially available dosage strengths as well as the scalability of the respective dosage form.

Treatment period:

a) Adults with relapsed or refractory, grade 1-3a follicular lymphoma after one line of systemic therapy

b) Adults with relapsed or refractory, grade 1-3a follicular lymphoma after at least two lines of systemic therapy

Designation of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
Medicinal product to be assessed				
Tafasitamab in combination with lenalidomide and rituximab				
Tafasitamab	Cycles 1 – 3: day 1, 8, 15 and 22 of a 28-day cycle Cycles 4 – 12: day 1 and 15 of a 28-day cycle	12	Cycles 1 – 3: 4 Cycles 4 – 12: 2	30
Lenalidomide	Day 1 – 21 of a 28-day cycle	12	21	252
Rituximab	Cycle 1: day 1, 8, 15 and 22 of a 28-day cycle Cycles 2 to 5: day 1 of a 28-day cycle	5	Cycle 1: 4 Cycles 2 to 5: 1	8

Consumption:

a) Adults with relapsed or refractory, grade 1-3a follicular lymphoma after one line of systemic therapy

b) Adults with relapsed or refractory, grade 1-3a follicular lymphoma after at least two lines of systemic therapy

For dosages depending on body weight (BW) or body surface area (BSA), the average body measurements from the official representative statistics "Microcensus 2021 – body measurements of the population" were applied (average body height: 1.72 m; average body weight: 77.7 kg). This results in a body surface area of 1.91 m² (calculated according to Du Bois 1916)[2].

[2] Federal Health Reporting. Average body measurements of the population (2021, both sexes, 15 years and older: http://www.gbe-bund.de/

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					
Tafasitamab in combination with lenalidomide and rituximab					
Tafasitamab	12 mg/kg = 932.4 mg	932.4 mg	5 x 200 mg	30	150 x 200 mg
Lenalidomide	20 mg	20 mg	1 x 20 mg	252	252 x 20 mg
Rituximab	375 mg/m² = 716.3 mg	716.3 mg	1 x 500 mg + 3 x 100 mg	8	8 x 500 mg + 24 x 100 mg

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:

a) Adults with relapsed or refractory, grade 1-3a follicular lymphoma after one line of systemic therapy

b) Adults with relapsed or refractory, grade 1-3a follicular lymphoma after at least two lines of systemic therapy

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						
Lenalidomide [3]	63	HC	€ 117.32	€ 1.77	€ 8.38	€ 107.17
Rituximab 100 mg	2	CIS	€ 717.21	€ 1.77	€ 33.50	€ 681.94
Rituximab 500 mg	1	CIS	€ 1,777.34	€ 1.77	€ 84.18	€ 1,691.39
Tafasitamab	1	PCI	€ 654.48	€ 1.77	€ 35.61	€ 617.10
Abbreviations: HC = hard capsules; CIS = concentrate for the preparation of an infusion solution; PCI = powder for a concentrate for the preparation of an infusion solution						

LAUER-TAXE® last revised: 1 May 2026

[3] Fixed reimbursement rate

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.

Screening for hepatitis B virus (HBV)

Patients receiving therapy with lenalidomide and rituximab should be tested for the presence of HBV infection before initiating the respective treatment.

Diagnostics to rule out chronic hepatitis B requires sensibly coordinated steps. A step-by-step serological diagnosis initially consists of the examination of HBs antigen and anti-HBc antibodies. If both are negative, a past HBV infection can be excluded. In certain case constellations, further steps may be necessary in accordance with current guideline recommendations.[4]

The calculation of the additionally required SHI services is based on packs in distribution with the LAUER-TAXE® last revised on 15 September 2025 and fee structure items (FSI) - last revised in the 3rd quarter of 2025 of the uniform value scale (UVS 2025/Q3).

Designation of the therapy	Costs after deduction of statutory rebates	Treatment days/ year	Costs/ patient/ year
HBV screening			
Hepatitis B surface antigen status (FSI 32781)	€ 5.06	1.0	€ 5.06
Anti-HBc antibody (FSI 32614)	€ 5.43	1.0	€ 5.43

Other SHI services:

The special agreement on contractual unit costs of retail pharmacist services (Hilfstaxe) (Sections 4 and 5 of the Pharmaceutical Price Ordinance) from 01.10.2009 is not fully used to calculate costs. Alternatively, the pharmacy sales price publicly accessible in the directory services according to Section 131, paragraph 4 SGB V is a suitable basis for a standardised calculation.

According to the special agreement on contractual unit costs of retail pharmacist services (Hilfstaxe) in its currently valid version, surcharges for the production of parenteral solutions with monoclonal antibodies amount to a maximum of € 100 per ready-to-apply unit. These additional other costs are not added to the pharmacy sales price but rather follow the rules for calculating in the Hilfstaxe. The cost representation is based on the pharmacy retail price and the maximum surcharge for the preparation and is only an approximation of the treatment costs. This presentation does not take into account, for example, the rebates on

[4] S3 guideline on prevention, diagnosis and therapy of hepatitis B virus infection; AWMF registry no.: 021/011 https://register.awmf.org/assets/guidelines/021-011l_S3_Prophylaxe-Diagnostik-Therapie-der-Hepatitis-B-Virusinfektion_2021-07.pdf

the pharmacy purchase price of the active ingredient, the invoicing of discards, the calculation of application containers, and carrier solutions in accordance with the regulations in Annex 3 of the Hilfstaxe.

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 relapsed or refractory, grade 1-3a follicular lymphoma after one line of systemic therapy

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 relapsed or refractory, grade 1-3a follicular lymphoma after at least two lines of systemic therapy

No medicinal product with new active ingredients that can be used in a combination therapy that fulfils the requirements of Section 35a, paragraph 3, sentence 4 SGB V.

References:
Product information for tafasitamab (Minjuvi); Minjuvi 200 mg powder for a concentrate for the preparation of an infusion solution; last revised: December 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

On 12 January 2026, the pharmaceutical company submitted a dossier for the benefit assessment of tafasitamab to the G-BA in due time in accordance with Chapter 5, Section 8, paragraph 1, number 2 VerfO.

The benefit assessment of the G-BA was published on 15 April 2026 together with the IQWiG assessment of treatment costs and patient numbers on the G-BA website (www.g-ba.de), thus initiating the written statement procedure. The deadline for submitting written statements was 6 May 2026.

The oral hearing was held on 26 May 2026.

An amendment to the benefit assessment with a supplementary assessment of data submitted in the written statement procedure was submitted on 12 June 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 was discussed at the Subcommittee's session on 23 June 2026, and the draft resolution was conclusively discussed.

At their session on 2 July 2026, the plenum adopted a resolution to amend the Pharmaceuticals Directive.

Chronological course of consultation

Session	Date	Subject of consultation
Subcommittee on Medicinal Products	8 April 2026	Information of the benefit assessment of the G-BA
Working group Section 35a	20 May 2026	Information on written statements received; preparation of the oral hearing
Subcommittee on Medicinal Products	26 May 2026	Conduct of the oral hearing
Working group Section 35a	3 June 2026 17 June 2026	Consultation on the dossier assessment by the G-BA, the assessment of treatment costs and patient numbers by the IQWiG, and the evaluation of the written statement procedure
Subcommittee on Medicinal Products	23 June 2026	Concluding discussion of the draft resolution
Plenum	2 July 2026	Adoption of the resolution on the amendment of the Pharmaceuticals Directive

Berlin, 2 July 2026

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

Dr Optendrenk