GBA
Gemeinsamer
Bundesausschuss

Justification

for the Resolution of the Federal Joint Committee (GBA) on an Amendment of the Pharmaceuticals Directive:
Annex XII – Benefit Assessment of Medicinal Products with New Active Ingredients according to Section 35a SGB V
Finerenone (new therapeutic indication: chronic heart failure with LVEF ≥ 40%)

of 15 October 2026

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1. Legal basis

According to Section 35a, paragraph 1 German Social Code, Book Five (SGB V), the Federal Joint Committee (GBA) 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 GBA 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 GBA 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 GBA 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 finerenone (Kerendia) was listed for the first time on 1 October 2022 in the "LAUER-TAXE®", the extensive German registry of available drugs and their prices.

On 26 March 2026, finerenone received marketing authorisation for a new therapeutic indication to be classified as a major type 2 variation as defined according to Annex 2, number 2, letter a to Regulation (EC) No. 1234/2008 of the Commission of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products (OJ L 334 from 12.12.2008, sentence 7).

On 21 April 2026, i.e. at the latest within four weeks of informing the pharmaceutical company about the approval for a new therapeutic indication, the pharmaceutical company submitted a dossier in due time in accordance with Section 4, paragraph 3, number 2 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV) in conjunction with Chapter 5, Section

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8, paragraph 1, number 2 of the Rules of Procedure (VerfO) of the GBA concerning the active ingredient finerenone with the new therapeutic indication "Kerendia is indicated for the treatment of symptomatic chronic heart failure with left ventricular ejection fraction (LVEF) ≥ 40% in adults".

The GBA commissioned the IQWiG to carry out the assessment of the dossier. The benefit assessment was published on 3 August 2026 on the GBA website (www.g-ba.de), thus initiating the written statement procedure. In addition, an oral hearing was held.

The GBA came to a resolution on whether an additional benefit of finerenone compared with the appropriate comparator therapy could be determined on the basis of the dossier of the pharmaceutical company, the dossier assessment prepared by the IQWiG, the statements submitted in the written statement and oral hearing procedure, and the addendum to the benefit assessment prepared by IQWiG. In order to determine the extent of the additional benefit, the GBA 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 finerenone.

In the light of the above, and taking into account the statements received and the oral hearing, the GBA 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 Finerenone (Kerendia) in accordance with the product information

Kerendia is indicated for the treatment of symptomatic chronic heart failure with left ventricular ejection fraction (LVEF) ≥ 40% in adults.

Therapeutic indication of the resolution (resolution of 15.10.2026):

See the approved therapeutic indication

2.1.2 Appropriate comparator therapy

The appropriate comparator therapy was determined as follows:

Adults with symptomatic chronic heart failure with preserved ejection fraction HFpEF (LVEF ≥ 50%) or with midrange ejection fraction HFmrEF (LVEF 40 to 49%)

Appropriate comparator therapy for finerenone:

- An optimised standard therapy for the treatment of symptomatic chronic heart failure with preserved ejection fraction or midrange ejection fraction, as well as the underlying diseases, such as hypertension, cardiac arrhythmias, coronary artery heart disease, diabetes mellitus, chronic kidney disease, dyslipoproteinaemia and the concomitant symptoms.

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

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Criteria according to Chapter 5, Section 6 of the Rules of Procedure of the GBA 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 GBA 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 GBA 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 for 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 for the therapeutic indication.

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

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

On 1. ACE inhibitors, AT1 receptor blockers, beta-blockers, among other medicinal products, are generally approved for the treatment of chronic heart failure. Furthermore, the SGLT2 inhibitors empagliflozin and dapagliflozin are approved for the treatment of symptomatic, chronic heart failure – regardless of measurement of left ventricular ejection fraction. Both active ingredients were also specifically investigated in the therapeutic indication to be assessed in adults with symptomatic chronic heart failure with left ventricular ejection fraction ≥ 40%.

Medicinal products approved for the respective therapeutic indications are an option for the treatment of common comorbidities such as hypertension, coronary heart disease, diabetes mellitus, dyslipoproteinaemia, chronic kidney disease or secondary diseases. Diuretics such as the mineralocorticoid receptor antagonist (MRA) spironolactone are indicated for the treatment of concomitant symptoms, such as oedema resulting from heart failure.

On 2. Non-medicinal treatment options are not considered in the present therapeutic indication as a rule.

On 3. The following GBA resolutions on the early benefit assessment of medicinal products with new active ingredients according to Section 35a SGB V (Annex XII of the Pharmaceuticals Directive) are available for the therapeutic indication of chronic heart failure with preserved ejection fraction (HFpEF) or midrange ejection fraction (HFmrEF):

- empagliflozin (resolution of 15 September 2022)
- dapagliflozin (resolution of 17 August 2023).

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 therapeutic indication according to Section 35a, paragraph 7 SGB V.

Different forms of chronic heart failure are distinguished on the basis of the left ventricular ejection fraction (LVEF). Adults with symptomatic chronic heart failure with preserved ejection fraction HFpEF (LVEF ≥ 50%) and with midrange ejection fraction HFmrEF (LVEF 40 to 49%) are considered in the present therapeutic indication.

In contrast to the treatment of heart failure with reduced ejection fraction HFrEF (LVEF < 40%), for which various active ingredients or product classes are approved, there is less evidence available for the treatment of heart failure with preserved ejection fraction. The SGLT2 inhibitors empagliflozin and dapagliflozin, which were investigated as part of the relevant extension of the marketing authorisation in adults with heart failure with LVEF > 40%, are approved - according to the marketing authorisation - for the treatment of symptomatic chronic heart failure, regardless of the ejection fraction, and are therefore also indicated for HFpEF and HFmrEF. In accordance with the guideline recommendations on the treatment of heart failure, an SGLT2 inhibitor (empagliflozin, dapagliflozin) should be recommended for adults with heart failure with

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LVEF > 40%. In addition, empagliflozin and dapagliflozin are also approved for the treatment of type 2 diabetes mellitus and chronic kidney disease.

According to the guideline recommendations, the relevant comorbidities of patients within the present therapeutic indication should, in particular, be adequately treated. The use of a diuretic is recommended if there are signs of fluid retention.

In accordance with national and international guidelines, the GBA therefore consider it appropriate to determine the appropriate comparator therapy to be an optimised standard therapy for the treatment of symptomatic chronic heart failure with preserved ejection fraction or midrange ejection fraction, as well as the underlying diseases, such as hypertension, cardiac arrhythmias, coronary artery heart disease, diabetes mellitus, chronic kidney disease, dyslipoproteinaemia and the concomitant symptoms. In this context, it is assumed that patient-individual treatment is carried out in accordance with the generally recognised state of medical knowledge for heart failure, as well as for the underlying diseases and concomitant symptoms. According to the guidelines, an SGLT2 inhibitor should be recommended for patients with symptomatic chronic heart failure. Furthermore, an additional benefit of each of the SGLT2 inhibitors empagliflozin and dapagliflozin compared with an optimised standard therapy for the treatment of heart failure was identified in the present therapeutic indication.

The marketing authorisations and product information of the medicinal products must be observed.

The 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 GBA based on a prior review of the criteria set out in Chapter 5, Section 6, paragraph 3 VerfO.

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2.1.3 Extent and probability of the additional benefit

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

Adults with symptomatic chronic heart failure with preserved ejection fraction HFpEF (LVEF ≥ 50%) or with midrange ejection fraction HFmrEF (LVEF 40 to 49%)

An additional benefit is not proven.

Justification:

The pharmaceutical company presented the label-enabling FINEARTS-HF study for the assessment of the additional benefit of finerenone within the new therapeutic indication for the treatment of adults with symptomatic chronic heart failure with LVEF ≥ 40%. In addition, the pharmaceutical company identified the FIDELIO-DKD and FIGARO-DKD studies conducted in the therapeutic indication of kidney disease associated with type 2 diabetes mellitus. From each of these two studies, they draw on data relating to a sub-population of patients with heart failure. The pharmaceutical company presented a pre-specified meta-analysis based on the FINEARTS-HF total study population and the sub-populations identified in the FIDELIO-DKD and FIGARO-DKD studies.

FINEARTS-HF study

The FINEARTS-HF study was conducted as a double-blind, placebo-controlled, randomised, parallel-group study between September 2020 and June 2024. Patients aged 40 years and older with symptomatic heart failure in NYHA classes II to IV with LVEF ≥ 40% were enrolled. In accordance with the inclusion criteria, subjects participating in the study had to be suffering from structural heart disease (enlargement of the left atrium and/or left ventricular hypertrophy), as well as elevated NT-proBNP[2] values ≥ 300 pg/ml. Patients who required treatment with more than one ACE inhibitor, ARB[3] or ARNI[4] at the time of randomisation were excluded from the study. Treatment with potassium-sparing diuretics and MRA[5], such as eplerenone or spironolactone, was not permitted during the study.

A total of 6,001 adults with LVEF ≥ 40% were enrolled in the study and randomised in a 1:1 ratio to the finerenone arm (N = 3,003) and the placebo arm (N = 2,998), respectively. The treatment with finerenone was carried out according to the recommendations in the product information. The FINEARTS-HF study was conducted on an event-driven basis and was to be terminated once 2,375 events relating to the primary endpoint had occurred. Patients were treated with the study medication for a median period of 28 months and were followed up for approximately 33 months from the time of randomisation until their final visit. The primary endpoint was the composite endpoint comprising cardiovascular death and all heart failure events (first-time or recurrent hospitalisations or emergency doctor consultations).

Implementation of the appropriate comparator therapy in the FINEARTS-HF study

The appropriate comparator therapy was determined to be an optimised standard therapy for the treatment of symptomatic chronic heart failure with preserved or midrange ejection fraction, as well as the underlying diseases and concomitant symptoms. In the FINEARTS-HF

[2] NT-proBNP: N-terminal pro-B-type natriuretic peptide
[3] ARB: angiotensin receptor blocker
[4] ARNI: angiotensin receptor-neprilysin inhibitor
[5] MRA: mineralocorticoid receptor antagonist

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study, all patients were required to receive *standard of care* as background therapy, which was defined by the study protocol as the best possible medical care at the doctor's discretion.

The FINEARTS-HF study did not include any restrictions on change of therapy or dose adjustments for the treatment of heart failure. Treatment with RAAS inhibitors, such as ACE inhibitors, ARBs or ARNIs, as well as with beta-blockers, is considered appropriate. The majority of patients received loop diuretics. However, the administration of potassium-sparing diuretics and MRAs was prohibited in the study.

In accordance with the guidelines in force at the time of the benefit assessment, treatment with an SGLT2 inhibitor is indicated for patients with symptomatic chronic heart failure. The pharmaceutical company stated that they specifically drew the attention of the treating doctors to the potential use of SGLT2 inhibitors in the FINEARTS-HF study at an early stage, namely before the marketing authorisation of empagliflozin and dapagliflozin and before the guidelines were updated. Nevertheless, at the time of randomisation, just under 15% of study participants were receiving SGLT2 inhibitors; this percentage increased over the course of the study to 29% in the intervention arm and 32% in the comparator arm, respectively.

The subgroup analyses of the sub-population receiving SGLT2 inhibitor treatment at the start of the study, which were submitted as part of the written statement procedure, lack data on patient characteristics, concomitant medication and progression scores for key parameters (blood pressure, HbA1c value), meaning that the relevance of this sub-population cannot be conclusively assessed. However, based on the subgroup analyses submitted, no statistically significant interactions were found for the characteristic "treatment with an SGLT2 inhibitor at the start of the study" in the endpoints analysed. There is no effect modification due to this characteristic.[6]

A small percentage of patients received treatment with SGLT2 inhibitors, making it difficult to fully assume that treatment was in line with guidelines and creating uncertainties, particularly regarding the transferability of results to the German healthcare context. Nevertheless, the GBA consider the *Standard of Care* therapy administered in the comparator arm of the FINEARTS-HF study to constitute an adequate implementation of the appropriate comparator therapy. Therefore, the results of the FINEARTS-HF study are used for the benefit assessment.

FIDELIO-DKD and FIGARO-DKD studies

For the purpose of the marketing authorisation in the therapeutic indication of chronic kidney disease (stages 1 and 2, as well as 3 and 4, each with albuminuria) associated with type 2 diabetes mellitus, the FIDELIO-DKD and FIGARO-DKD studies were conducted between September 2015 and April 2020 and between September 2015 and February 2021, respectively. Adults who mainly had chronic kidney disease associated with type 2 diabetes mellitus were enrolled in these studies. The primary endpoint of the FIDELIO-DKD study was a composite renal endpoint, whilst in the FIGARO-DKD study it was a composite cardiovascular endpoint.

For the present assessment of finerenone in the therapeutic indication of symptomatic chronic heart failure with LVEF ≥ 40%, the pharmaceutical company identified a sub-population from the FIDELIO-DKD and FIGARO-DKD studies using a MedDRA classification for heart failure. For this purpose, a MedDRA labelling group derived from the medical history of the analysed subjects in both studies was used. The PTs enrolled, amongst others, congestive heart failure, acute heart failure, acute left ventricular failure, ventricular failure and cardiac

[6] See the data from the addendum (A26-42) to the IQWiG's dossier assessment

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oedema. In contrast to the therapeutic indication considered here, certain PTs in the MedDRA labelling group indicate non-chronic heart failure. In addition, no criterion was used to define the sub-population that would allow for the classification of symptomatic heart failure. Furthermore, no information on either the NYHA classification or the type of heart failure, i.e. HFmrEF or HFpEF is available for the sub-population. In the overall analysis, it cannot be assumed with certainty that the patients in the DKD studies actually fall within the therapeutic indication of symptomatic chronic heart failure with LVEF ≥ 40%. The data from the sub-populations are therefore not taken into account in the benefit assessment. Nor is the meta-analysis submitted taken into account.

Summary of the evidence presented

In the overall assessment, the results of the FINEARTS-HF study are used for the benefit assessment, taking the total population into account.

Results of the FINEARTS-HF study

Extent and probability of the additional benefit

Mortality

Overall mortality and cardiovascular death

For the endpoint of overall mortality, there were no statistically significant differences between the treatment arms. Even for the additionally presented endpoint "cardiovascular death", there were no statistically significant differences.

Morbidity

Hospitalisation due to heart failure

In patients with chronic heart failure, "hospitalisation due to heart failure" usually occurs in the case of deterioration of symptomatology as a result of the disease. Therefore, hospitalisation due to heart failure in this context can be considered an approximation of the clinical condition of symptom deterioration. This endpoint therefore allows conclusions to be drawn about the disease-specific morbidity of the patients analysed.

In the FINEARTS-HF study, events relating to the endpoint "hospitalisation due to heart failure" were adjudicated by a Clinical Event Committee (CEC). The endpoint "hospitalisation due to heart failure", operationalised as the time to the first event, was used in the benefit assessment.

For the endpoint "hospitalisation due to heart failure", there was a statistically significant advantage of finerenone over the comparator arm.

Total hospitalisation

For the endpoint "total hospitalisation", operationalised as the time to the first occurrence of hospitalisation for any cause, there were no statistically significant differences between the treatment arms.

Myocardial infarction and stroke

For the endpoints "myocardial infarction" and "stroke", there were no statistically significant differences between the treatment arms in either case.

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Atrial fibrillation

The occurrence of atrial fibrillation was collected in the study using an electrocardiogram and assessed by a CEC. The endpoint "atrial fibrillation", operationalised as the first occurrence of atrial fibrillation in patients with no history of atrial fibrillation, was used in the benefit assessment.

For the endpoint "new-onset of atrial fibrillation", there were no statistically significant differences between the treatment arms.

Severe renal function impairment or renal failure (composite endpoint)

The pre-specified endpoint "severe renal function impairment or renal failure" comprises the individual components "sustained decline in eGFR by ≥ 57%", "sustained decline in eGFR to < 15 ml/min/1.73 m²" and "start of dialysis or kidney transplant".

The sub-component "start of dialysis or kidney transplant" was assessed by a CEC, whilst the eGFR components were determined on the basis of central laboratory measurements. Given the median eGFR baseline values of the patients (approximately 61 ml/min/1.73 m²), adequate patient relevance of the component "decline in eGFR by ≥ 57%" is assumed in this context. The analyses up to the first event are used here.

For the composite endpoint "severe renal function impairment or renal failure", as well as for the individual components "sustained decline in eGFR by ≥ 57%" and "start of dialysis or kidney transplant", there were no statistically significant differences between the treatment arms in either case. For the individual component "sustained decline in eGFR to < 15 ml/min/1.73 m²", by contrast, there was a statistically significant disadvantage of finerenone over the comparator arm.

Health status

Health status was assessed in the study using the visual analogue scale (VAS) of the EQ-5D questionnaire. The analysis up to month 12 was pre-specified.

For the improvement by ≥ 15 points at month 12, there was no statistically significant difference between the treatment arms.

Symptomatology

Symptomatology was assessed using the PGIC and PGIS in a sub-population of the study at selected study sites. As no clear justification has been provided as to the criteria used to select these study sites for the PGIC and PGIS surveys, the data on symptomatology are not taken into account in this context.

<u>Quality of life</u>

Kansas City Cardiomyopathy Questionnaire - Overall Summary Score

The KCCQ questionnaire was used for the endpoint category of health-related quality of life.

The KCCQ is a disease-specific questionnaire to assess health-related quality of life in patients with cardiomyopathy, which is completed by the affected patients themselves. 6 domains are queried: physical limitations, symptoms (symptom frequency and severity), symptom stability, social impairment, self-efficacy, and quality of life. For evaluation, the items of the respective domains are summed up and transformed to a scale from 0 to 100. Higher values correspond to a better condition. The clinical summary score KCCQ-OSS (overall summary score) is used for the benefit assessment.

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For the clinical summary score KCCQ-OSS based on mean differences up to month 12, there was a statistically significant advantage of finerenone over the comparator arm. As the standardised mean difference with the corresponding 95% confidence interval does not lie entirely outside the irrelevance range of -0.2 to 0.2, it cannot be concluded that the observed effect is clinically relevant.

Side effects

According to the study protocol, events involving a deterioration of heart failure or renal function[7], the occurrence of a myocardial infarction, stroke or atrial fibrillation or flutter (AF) were not to be classified under the endpoint category of side effects, but rather under the endpoint category of morbidity. Nevertheless, it was possible to capture these events as side effects, provided that the clinical investigators assessed them as more serious than expected given the disease progression.

In this context, "decline in eGFR by ≥ 50%", among other events, was considered to be deterioration of renal function. However, only a "decline in eGFR by ≥ 57%" in the endpoint category of morbidity was used for the benefit assessment. As a result, events involving a decline in eGFR by ≥ 50% to < 57% are not classified under the endpoint category of side effects, nor are they captured by the morbidity endpoint. These events (38 with finerenone vs 26 with placebo) should therefore be taken into account in the analysis of side effects. Otherwise, negative effects relating to the specific endpoint "renal and urinary disorders" could potentially be underestimated.

For the other events (heart failure, myocardial infarction, AF and the remaining components of renal function[7]), the classification into the endpoint category of morbidity appears plausible.

Overall, it is assumed that the analyses provided on the overall rates of adverse events and therapy discontinuation due to adverse events can be interpreted adequately; they are therefore used here.

Serious adverse events (SAEs)

For the overall rate of SAEs, there were no statistically significant differences between the treatment groups.

Therapy discontinuation due to adverse events (AEs)

For the endpoint of therapy discontinuation due to AEs, the study showed no statistically significant difference between the treatment arms.

Specific AEs

Renal and urinary disorders (SAEs)

Detailed analysis of the specific endpoint "renal and urinary disorders (SAEs)" showed a statistically significant disadvantage of finerenone over the comparator arm.

Given the approach taken to classify renal events into the categories of morbidity or side effects (see above), it cannot be ruled out that the negative effect of finerenone may be underestimated for the specific endpoint "renal and urinary disorders (SAEs)".

[7] The deterioration in renal function comprised the events – decline in eGFR by ≥ 50%; – decline in eGFR by ≥ 57%; – decline in eGFR to < 15 ml/min/1.73 m²; or – dialysis or kidney transplant.

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Hyperkalaemia (SAEs)

Detailed analysis of the specific endpoint "hyperkalaemia (SAEs)" showed a statistically significant disadvantage of finerenone over the comparator arm.

Overall assessment

The double-blind, placebo-controlled, randomised FINEARTS-HF study was presented for the assessment of the additional benefit of finerenone within the new therapeutic indication for the treatment of adults with symptomatic chronic heart failure with LVEF ≥ 40%. In addition, data were presented from the FIDELIO-DKD and FIGARO-DKD studies for a sub-population of adults with heart failure with LVEF ≥ 40%. Only data from the label-enabling FINEARTS-HF study are used in this benefit assessment.

For the endpoint "overall mortality" in the endpoint category of mortality, there was no statistically significant difference between the treatment arms.

For the endpoint "hospitalisation due to heart failure" in the endpoint category of morbidity, there was a statistically significant advantage of finerenone over the comparator arm.

For the endpoint "sustained decline in eGFR to < 15 ml/min/1.73 m²", which was classified into the endpoint category of morbidity according to the study protocol, there was a statistically significant disadvantage of finerenone over the comparator arm.

For the other endpoints in the endpoint category of morbidity – "total hospitalisation", "myocardial infarction", "stroke", "severe renal function impairment or renal failure", "decline in eGFR by ≥ 57%", "start of dialysis or kidney transplant", as well as for health status, as assessed using the EQ-5D VAS, there were no statistically significant differences between the treatment arms.

In the endpoint category of health-related quality of life, data are available for the clinical summary score KCCQ-OSS based on mean differences up to month 12. Whilst this does indicate a statistically significant advantage of finerenone over the comparator arm, it cannot be concluded that the observed effect is clinically relevant.

For the overall rates of SAEs and for the endpoint "therapy discontinuation due to AEs" in the endpoint category of side effects, there were no statistically significant differences between the treatment arms. Detailed analysis of the specific AEs "renal and urinary disorders (SAEs)" and "hyperkalaemia (SAEs)" showed a statistically significant disadvantage of finerenone over the comparator arm in each case. These are aligned with the disadvantage for the renal function parameter "sustained decline in eGFR to < 15 ml/min/1.73 m²" depicted in the endpoint category of morbidity.

Overall, for the endpoint "hospitalisation due to heart failure", there was a statistically significant advantage of finerenone over the comparator arm despite uncertainties regarding the transferability of the study results to the current German healthcare context. However, at 2.1%, the difference in the number of occurred events between the intervention and comparator arms is small (450 versus 514 events). Furthermore, for the endpoint "sustained decline in eGFR to < 15 ml/min/1.73 m²", there was a statistically significant disadvantage of finerenone. In the overall benefit-risk assessment, the GBA therefore conclude that, for the endpoint category of morbidity, there were no relevant advantages overall that would justify the conclusion of an additional benefit.

In the overall assessment, the additional benefit of finerenone over the appropriate comparator therapy in adults with symptomatic chronic heart failure with LVEF ≥ 40% is therefore not proven.

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2.1.4 Summary of the assessment

The present assessment is the benefit assessment of a new therapeutic indication for the active ingredient finerenone. The therapeutic indication assessed here is "Kerendia is indicated for the treatment of symptomatic chronic heart failure with left ventricular ejection fraction (LVEF) ≥ 40% in adults."

The GBA determined the appropriate comparator therapy to be an optimised standard therapy for the treatment of symptomatic chronic heart failure with preserved ejection fraction or midrange ejection fraction, as well as the underlying diseases, such as hypertension, cardiac arrhythmias, coronary artery heart disease, diabetes mellitus, chronic kidney disease, dyslipoproteinaemia and the concomitant symptoms.

The label-enabling FINEARTS-HF study, as well as sub-populations from the FIDELIO-DKD and FIGARO-DKD studies, which were conducted in the therapeutic indication of kidney disease associated with type 2 diabetes mellitus, were presented. Only the FINEARTS-HF study is relevant to the benefit assessment of the new therapeutic indication.

In the endpoint category of mortality, there were no statistically significant differences between the treatment arms.

For the endpoint "hospitalisation due to heart failure" in the endpoint category of morbidity, there was a statistically significant advantage of finerenone over the comparator arm. For other cardiovascular endpoints, there were no statistically significant differences between the treatment arms. In the sub-component "decline in eGFR to < 15 ml/min/1.73 m²" of the composite renal endpoint, there was a statistically significant disadvantage of finerenone. For other renal endpoints, there were no statistically significant differences between the treatment arms.

For the overall rates of SAEs and for the endpoint "therapy discontinuation due to AEs" in the endpoint category of side effects, there were no statistically significant differences in each case. Detailed analysis of the specific AEs "renal and urinary disorders (SAEs)" and "hyperkalaemia (SAEs)" showed a statistically significant disadvantage of finerenone over the comparator arm in each case.

Overall, for the endpoint "hospitalisation due to heart failure", there was a statistically significant advantage of finerenone over the comparator arm despite uncertainties regarding the transferability of the study results to the current German healthcare context. However, at 2.1%, the difference in the number of occurred events between the intervention and comparator arms is small (450 versus 514 events). Furthermore, for the endpoint "sustained decline in eGFR to < 15 ml/min/ 1.73 m²" and, in detail, for the specific AEs "renal and urinary disorders (SAEs)" and "hyperkalaemia (SAEs)" in the renal function domain, there were statistically significant disadvantages of finerenone.

In the overall benefit-risk assessment, the GBA therefore conclude that, for the endpoint category of morbidity, there were no relevant advantages overall that would justify the conclusion of an additional benefit.

In the overall assessment, the additional benefit of finerenone over the appropriate comparator therapy in adults with symptomatic chronic heart failure with LVEF ≥ 40% is therefore not proven.

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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.

The GBA take into account the patient numbers stated in the pharmaceutical company's dossier. Whilst the pharmaceutical company's calculation is methodologically and mathematically plausible, the determination of the percentage of adults with heart failure with LVEF ≥ 40% is subject to uncertainties overall.[8] Nevertheless, it is based on the information provided in the pharmaceutical company's dossier.

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 Kerendia (active ingredient: finerenone) at the following publicly accessible link (last access: 4 June 2026):

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

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: 15 August 2026). The calculation of treatment costs is generally based on the last revised LAUER-TAXE® version following the publication of the benefit assessment.

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.

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.

In general, initial induction regimens are not taken into account for the cost representation, since the present indication is a chronic disease with a continuous need for therapy and, as a rule, no new titration or dose adjustment is required after initial titration.

According to the product information, serum potassium and eGFR must be measured again 4 weeks after the start or resumption of finerenone treatment or a dose increase of finerenone. Thereafter, serum potassium must be remeasured at regular intervals and as needed, based on patient characteristics and serum potassium level. The maintenance dose (20 mg or 10 mg, maximum 40 mg) depends on the measured serum potassium and eGFR values.

The appropriate comparator therapy "An optimised standard therapy for the treatment of symptomatic chronic heart failure with preserved ejection fraction or midrange ejection

[8] IQWiG dossier assessment (A26-42), Part II: Number of patients and treatment costs

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fraction and for the treatment of the underlying diseases, such as hypertension, cardiac arrhythmias, coronary artery heart disease, diabetes mellitus, hypercholesterolaemia, as well as the concomitant symptoms" includes many treatment options that differ greatly in their nature. Symptomatic chronic heart failure is treated particularly with angiotensin-converting enzyme (ACE) inhibitors, AT1 receptor blockers (ARBs), beta-adrenoceptor antagonists, mineralocorticoid receptor antagonists (MRAs) and diuretics.

Since the optimised standard therapy of heart failure is patient-individual, no specific costs for the appropriate comparator therapy can be mentioned here. In addition, optimised standard therapy for the treatment of symptomatic chronic heart failure and the underlying diseases is provided in the context of both the medicinal product finerenone to be assessed and the appropriate comparator therapy.

Adults with symptomatic chronic heart failure with preserved ejection fraction HFpEF (LVEF ≥ 50%) or with midrange ejection fraction HFmrEF (LVEF 40 to 49%)

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				
Finerenone	Continuously, 1 x daily	365	1	365
+ optimised standard therapy	Different from patient to patient			
Appropriate comparator therapy				
optimised standard therapy	Different from patient to patient			

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					
Finerenone	10 mg – 40 mg	10 mg – 40 mg	1 x 10 mg – 1 x 40 mg	365	365 x 10 mg – 365 x 40 mg
+ optimised standard therapy	Different from patient to patient				
Appropriate comparator therapy					
optimised standard therapy	Different from patient to patient				

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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					
Finerenone 10 mg	98 FCT	€ 196.40	€ 1.77	€ 10.20	€ 184.43
Finerenone 20 mg	98 FCT	€ 196.40	€ 1.77	€ 10.20	€ 184.43
Finerenone 40 mg	98 FCT	€ 196.40	€ 1.77	€ 10.20	€ 184.43
+ optimised standard therapy	Different from patient to patient				
Appropriate comparator therapy					
optimised standard therapy	Different from patient to patient				
Abbreviations: FCT = film-coated tablets					

LAUER-TAXE® last revised: 15 August 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.

Because there are no 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, no costs for additionally required SHI services had to be taken into account.

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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 6 May 2026, the Subcommittee on Medicinal Products determined the appropriate comparator therapy.

On 21 April 2026, the pharmaceutical company submitted a dossier for the benefit assessment of finerenone to the GBA in due time in accordance with Chapter 5, Section 8, paragraph 1, number 2 VerfO.

By letter dated 22 April 2026 in conjunction with the resolution of the GBA of 1 August 2011 concerning the commissioning of the IQWiG to assess the benefit of medicinal products with new active ingredients in accordance with Section 35a SGB V, the GBA commissioned the IQWiG to assess the dossier concerning the active ingredient finerenone.

The dossier assessment by the IQWiG was submitted to the GBA on 30 July 2026, and the written statement procedure was initiated with publication on the GBA website on 3 August 2026. The deadline for submitting written statements was 24 August 2026.

The oral hearing was held on 7 September 2026.

By letter dated 8 September 2026, the IQWiG was commissioned with a supplementary assessment. The addendum prepared by the IQWiG was submitted to the GBA on 25 September 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 6 October 2026, and deliberation of the draft resolution was concluded.

At their session on 15 October 2026, the plenum adopted a resolution to amend the Pharmaceuticals Directive.

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Chronological course of consultation

Session	Date	Subject of consultation
Subcommittee on Medicinal Products	6 May 2026	Determination of the appropriate comparator therapy
Working group Section 35a	2 September 2026	Information on written statements received; preparation of the oral hearing
Subcommittee on Medicinal Products	7 September 2026	Conduct of the oral hearing, commissioning of the IQWiG with the supplementary assessment of documents
Working group Section 35a	16 September 2026 30 September 2026	Consultation on the dossier assessment by the IQWiG and evaluation of the written statement procedure
Subcommittee on Medicinal Products	6 October 2026	Concluding discussion of the draft resolution
Plenum	15 October 2026	Adoption of the resolution on the amendment of the Pharmaceuticals Directive

Berlin, 15 October 2026

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

Dr Optendrenk

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