GBA
Gemeinsamer
Bundesausschuss

# Resolution

of the Federal Joint Committee 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

At their session on 15 October 2026, the Federal Joint Committee (GBA) resolved to amend the Pharmaceuticals Directive (AM-RL) in the version dated 18 December 2008 / 22 January 2009 (Federal Gazette, BAnz. No. 49a of 31 March 2009), as last amended by the publication of the resolution of D Month YYYY (Federal Gazette, BAnz AT DD.MM.YYYY BX), as follows:

I. **In Annex XII, the following information shall be added after number 5 (stages 1 and 2 chronic kidney disease (with albuminuria) associated with type 2 diabetes) to the information on the benefit assessment of Finerenone in accordance with the resolution of 17 August 2023:**



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**Finerenone**

Resolution of: 15 October 2026
Entry into force on: 15 October 2026
Federal Gazette, BAnz AT DD. MM YYYY Bx

**New therapeutic indication (according to the marketing authorisation of 26 March 2026):**

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 October 2026):**

See new therapeutic indication according to marketing authorisation.

## 1. Additional benefit of the medicinal product in relation to 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%)

**Appropriate comparator therapy:**

- 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

**Extent and probability of the additional benefit of finerenone compared to the optimised standard therapy for heart failure and the underlying diseases:**

An additional benefit is not proven.



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**Study results according to endpoints:**[1]

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

**Summary of results for relevant clinical endpoints**

| Endpoint category | Direction of effect/ risk of bias | Summary |
|---|---|---|
| Mortality | ↔ | No relevant differences for the benefit assessment. |
| Morbidity | ↔ | No relevant differences for the benefit assessment. |
| Health-related quality of life | ↔ | No relevant differences for the benefit assessment. |
| Side effects | ↔ | No relevant differences for the benefit assessment. |
| Explanations:<br>↑: statistically significant and relevant positive effect with low/unclear reliability of data<br>↓: statistically significant and relevant negative effect with low/unclear reliability of data<br>↑↑: statistically significant and relevant positive effect with high reliability of data<br>↓↓: statistically significant and relevant negative effect with high reliability of data<br>↔: no statistically significant or relevant difference<br>∅: No data available.<br>n.a.: not assessable | | |

**FINEARTS-HF study:** an event-driven RCT comparing finerenone with placebo, each in addition to background therapy for heart failure and concomitant diseases

**Mortality**

| Endpoint | Finerenone + background therapy | | Placebo + background therapy | | Finerenone vs placebo |
|---|---|---|---|---|---|
| | N | Median time to event in months [95% CI]<br>Patients with event n (%) | N | Median time to event in months [95% CI]<br>Patients with event n (%) | HR [95% CI]; p value[a] |
| **Overall mortality** | | | | | |
| | 3,003 | n.r.<br>491 (16.4) | 2,998 | n.r.<br>522 (17.4) | 0.93 [0.83; 1.06]; 0.279 |

[1] Data from the dossier assessment of the IQWiG (A26-42) and from the addendum (A26-42), unless otherwise indicated.



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| | | | | | |
|---|---|---|---|---|---|
| **Cardiovascular death** *(presented additionally)* | | | | | |
| | 3,003 | n.r.<br>242 (8.1) | 2,998 | n.r.<br>260 (8.7) | 0.93<br>[0.78; 1.11];<br>0.412 |

**Morbidity**

| **Endpoint** | **Finerenone + background therapy** | | **Placebo + background therapy** | | **Finerenone vs placebo** |
|---|---|---|---|---|---|
| | N | Median time to event in months [95% CI]<br>Patients with event n (%) | N | Median time to event in months [95% CI]<br>Patients with event n (%) | HR [95% CI]; p value |
| **Hospitalisation due to heart failure** | | | | | |
| | 3,003 | n.r.<br>450 (15.0) | 2,998 | n.r.<br>514 (17.1) | 0.86<br>[0.76; 0.97];<br>0.018 |
| **Total hospitalisation** | | | | | |
| | 3,003 | 33.53<br>[31.07; 35.60]<br>1,433 (47.7) | 2,998 | 31.40<br>[28.03; 34.07]<br>1,481 (49.4) | 0.94<br>[0.88; 1.02];<br>0.126 |
| **Myocardial infarction**[b] | | | | | |
| | 3,003 | n.r.<br>99 (3.3) | 2,998 | n.r.<br>82 (2.7) | 1.21<br>[0.91; 1.63];<br>0.195 |
| **Stroke**[b] | | | | | |
| | 3,003 | n.r.<br>118 (3.9) | 2,998 | n.r.<br>107 (3.6) | 1.11<br>[0.85; 1.44];<br>0.437 |
| **New-onset of atrial fibrillation** | | | | | |
| | 1,355 | n.r.<br>76 (5.6) | 1,373 | n.r.<br>99 (7.6) | 0.78<br>[0.58; 1.05];<br>0.097 |
| **Severe renal function impairment or renal failure (composite endpoint)**[c] | | | | | |
| | 3,003 | n.r.<br>41 (1.4) | 2,998 | n.r.<br>31 (1.0) | 1.28<br>[0.80; 2.05];<br>0.296 |
| **Sustained decline in eGFR by ≥ 57%**[d] | | | | | |
| | 3,003 | n.r.<br>35 (1.2) | 2,998 | n.r.<br>26 (0.9) | 1.29<br>[0.77; 2.15];<br>0.327 |



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| | | | | | |
|---|---|---|---|---|---|
| **Sustained decline in eGFR to < 15 ml/min/1.73 m² [d]** | | | | | |
| | 3,003 | n.r.<br>25 (0.8) | 2,998 | n.r.<br>12 (0.4) | 2.09<br>[1.05; 4.15];<br>0.033 |
| **Start of dialysis or kidney transplant[d]** | | | | | |
| | 3,003 | n.r.<br>7 (0.2) | 2,998 | n.r.<br>6 (0.2) | 1.14<br>[0.38; 3.40];<br>0.810 |
| **Dialysis** | | | | | |
| | 3,003 | n.r.<br>7 (0.2) | 2,998 | n.r.<br>6 (0.2) | 1.14<br>[0.38; 3.40];<br>0.810 |
| **Kidney transplant** | | | | | |
| | 3,003 | 0 (0) | 2,998 | 0 (0) | – |

| **Endpoint** | **Finerenone + background therapy** | | **Placebo + background therapy** | | **Finerenone vs placebo** |
|---|---|---|---|---|---|
| | N | Patients with event n (%) | N | Patients with event n (%) | RR [95% CI]; p value |
| **Health status EQ-5D VAS[e], month 12** | | | | | |
| | 2,841 | 800 (28.2) | 2,826 | 790 (28.0) | 1.02<br>[0.96; 1.08];<br>0.627[f] |
| **Symptomatology[g] PGIC, PGIS** | no suitable data[h] | | | | |



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**Health-related quality of life**

| Endpoint | Finerenone + background therapy | | | Placebo + background therapy | | | Finerenone vs placebo |
|---|---|---|---|---|---|---|---|
| | N[i] | Values at the start of study MV[-] (SD) | Change at month 12 LS MV[j] (SE) | N[i] | Values at the start of study MV (SD) | Change at month 12 LS MV[j] (SE) | LS MD [95% CI]; p value[j] |
| **KCCQ-OSS[k] up to month 12** | | | | | | | |
| | 2,732 | 63.15 (22.00) | 6.37 (0.31) | 2,711 | 62.44 (22.39) | 5.44 (0.31) | 0.93 [0.19; 1.67]; 0.014 SMD 0.06 [0.00; 0.11] |
| *Domains presented additionally* | | | | | | | |
| *Physical limitation* | *2,676* | *64.12 (24.62)* | *2.70 (0.35)* | *2,662* | *63.20 (25.17)* | *2.09 (0.35)* | *0.61 [-0.22; 1.45]* |
| *Psychological quality of life* | *2,731* | *57.29 (24.37)* | *8.43 (0.36)* | *2,710* | *56.98 (24.51)* | *7.51 (0.36)* | *0.92 [0.06; 1.78]* |
| *Social limitation* | *2,513* | *63.61 (28.49)* | *6.30 (0.43)* | *2,513* | *62.90 (28.63)* | *5.35 (0.44)* | *0.95 [-0.09; 1.99]* |
| *Symptoms (KCCQ-TSS)* | *2,731* | *67.55 (23.91)* | *7.99 (0.32)* | *2,710* | *66.51 (23.91)* | *6.43 (0.33)* | *1.56 [0.79; 2.34]* |

**Side effects**

| Endpoint | Finerenone + background therapy | | Placebo + background therapy | | Finerenone vs placebo |
|---|---|---|---|---|---|
| | N | Patients with event n (%) | N | Patients with event n (%) | RR [95% CI]; p value |
| **Total adverse events[l]** *(presented additionally)* | | | | | |
| | 2,993 | 2,571 (85.9) | 2,993 | 2,510 (83.9) | – |
| **Serious adverse events[l] (SAEs)** | | | | | |
| | 2,993 | 1,343 (44.9) | 2,993 | 1,359 (45.4) | 0.99 [0.93; 1.04]; 0.678[m] |



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| | | | | | |
|---|---|---|---|---|---|
| **Therapy discontinuation due to adverse events**[l] | | | | | |
| | 2,993 | 143 (4.8) | 2,993 | 121 (4.0) | 1.18 [0.93; 1.50]; 0.167[m] |
| **Specific adverse events** | | | | | |
| Renal and urinary disorders (SOC, SAE) | | | | | |
| | 2,993 | 144 (4.8) | 2,993 | 94 (3.1) | 1.53 [1.19; 1.98]; 0.001[m] |
| Renal and urinary disorders (SOC, AE) (presented additionally) | | | | | |
| | 2,993 | 662 (22.1) | 2,993 | 542 (18.1) | – |
| Hyperkalaemia (MedDRA labelling group, SAE)<br>(PT hyperkalaemia; PT elevated level of potassium in the blood) | | | | | |
| | 2,993 | 29 (1.0) | 2,993 | 7 (0.2) | 4.14 [1.82; 9.44]; < 0.001[n] |

a. HR and corresponding 95% CI calculated using a stratified Cox regression model; p value derived from a stratified log-rank test. Region and LVEF at baseline were taken into account as stratification factors.
b. Operationalised as non-fatal events and fatal events adjudicated by a Clinical Event Committee.
c. Comprising the 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".
d. The presentation of the individual components does not include the qualifying events, but all events that occurred during the study.
e. An increase by ≥ 15 points compared to the start of the study is considered as clinically relevant improvement (scale range: 0 to 100).
f. RR, CI and p value from a log-binomial regression model with the covariates treatment and baseline value, stratified by region and LVEF; for patients without a value at month 12, the value was substituted using the LOCF method.
g. Improvement: percentage of patients with a reduction in score by ≥ 1 point on a 6-point scale (from 1 "no symptoms" to 6 "very severe symptoms") at month 12 compared to the start of the study.
h. The data were collected from a sub-population at selected study sites. It is unclear on the basis of which criteria these study sites were selected.
i. Number of patients who were taken into account in the effect estimate; the values at the start of the study (and at month 12) can be based on other patient numbers.
j. MMRM with the covariates treatment group, baseline value, visit, interaction between baseline value and visit, region and LVEF.
k. Higher (increasing) values mean better health-related quality of life; positive effects (intervention minus comparison) mean an advantage for the intervention (scale range: 0 to 100).
l. Without disease-related events.
m. Discrepancy between Module 4 A (main section) and Module 4 Annex H: either effect estimation using a log-binomial regression model or the Mantel-Haenszel method, or the logit method in the case of zero events.
n. Calculation of RR by the IQWiG, RR, CI (asymptotic) and p value (unconditional exact test, CSZ method according to Andres).



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Abbreviations used:
eGFR = estimated glomerular filtration rate; HR = hazard ratio; n.d. = no data available; KCCQ = Kansas City Cardiomyopathy Questionnaire; LS = least squares; CI = confidence interval; LOCF = last observation carried forward; LVEF = left ventricular ejection fraction; MedDRA = Medical Dictionary for Regulatory Activities; MMRM: mixed model for repeated measures; MV = mean value; MD = mean difference; OSS = overall summary score; n = number of patients with (at least 1) event; N: number of patients evaluated; n.r. = not reached; PGIC = Patient Global Impression of Change; PGIS = Patient Global Impression of Severity; PT = preferred term; RCT = randomised controlled trial; RR = relative risk; SD = standard deviation; SE = standard error; SMD = standardised mean difference; SOC = system organ class; SAE = serious adverse event; TSS = total symptom score; AE = adverse event; VAS = visual analogue scale; vs = versus

## 2. Number of patients or demarcation of patient groups eligible for treatment

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

Approximately 1,270,000 to 1,600,000 patients

## 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

## 4. Treatment costs

**Annual treatment costs:**

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

| Designation of the therapy | Annual treatment costs/ patient |
|---|---|
| Medicinal product to be assessed: | |
| Finerenone | € 686.91 |
| + optimised standard therapy | Different from patient to patient |
| Appropriate comparator therapy: | |
| optimised standard therapy | Different from patient to patient |

Costs after deduction of statutory rebates (LAUER-TAXE® as last revised: 15 August 2026)

Costs for additionally required SHI services: not applicable



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**II. The resolution will enter into force on the day of its publication on the GBA website on 15 October 2026.**

The justification for this resolution will be published on the GBA website at www.g-ba.de.

Berlin, 15 October 2026

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

Dr Optendrenk



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