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
Colchicine (known active ingredient with new data protection: for the prevention of ischaemic cardiovascular events in patients with atherosclerotic CHD following a myocardial infarction)

From 20 August 2026

At their session on 20 August 2026, the Federal Joint Committee (G-BA) 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, information on the active ingredient colchicine shall be added in alphabetical order as follows:

Colchicine

Resolution of: 20 August 2026
Entry into force on: 20 August 2026
Federal Gazette, BAnz AT DD. MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 2 August 2025):

Adults

Prevention of ischaemic cardiovascular events in patients with atherosclerotic coronary heart disease and a recent myocardial infarction (MI), in addition to standard therapies.

Therapeutic indication of the resolution (resolution of 20 August 2026):

See therapeutic indication according to marketing authorisation.

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

Adults with atherosclerotic coronary heart disease and a recent myocardial infarction (MI) who are indicated for the prevention of ischaemic cardiovascular events

Appropriate comparator therapy:

- An optimised standard therapy for the secondary prevention of ischaemic cardiovascular events in patients with atherosclerotic coronary heart disease and a recent myocardial infarction (MI), as well as for the treatment of any existing concomitant diseases, e.g., hypertension, heart failure, diabetes mellitus and relevant concomitant symptoms

Extent and probability of the additional benefit of colchicine in combination with an optimised standard therapy compared with an optimised standard therapy:

Hint of a minor additional benefit.

Study results according to endpoints:[1]

Adults with atherosclerotic coronary heart disease and a recent myocardial infarction (MI) who are indicated for the prevention of ischaemic cardiovascular events

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	↔	No relevant difference for the benefit assessment.
Morbidity	↑	Advantage in terms of the primary composite endpoint "major adverse cardiovascular events (MACE)", comprising the individual components "non-fatal stroke" and "urgent hospital admission for angina pectoris requiring coronary revascularisation (non-fatal)".
Health-related quality of life	∅	No data available.
Side effects	↔	No relevant differences for the benefit assessment were observed for the endpoint of SAEs. No data are available for the endpoints of severe AEs and discontinuation due to AEs.

Explanations:
↑: statistically significant and relevant positive effect with low/unclear reliability of data
↓: statistically significant and relevant negative effect with low/unclear reliability of data
↑↑: statistically significant and relevant positive effect with high reliability of data
↓↓: statistically significant and relevant negative effect with high reliability of data
↔: no statistically significant or relevant difference
∅: no data available
n.a.: not assessable

[1] Data from the dossier assessment of the IQWiG (A26-16) and from the addendum (A26-82), unless otherwise indicated.

COLCOT study: RCT, colchicine vs placebo (in each case in addition to optimised standard therapy)

Mortality

Endpoint	Colchicine + optimised standard therapy		Placebo + optimised standard therapy		Colchicine vs placebo (in each case + optimised standard therapy)
	N	Patients with event n (%)	N	Patients with event n (%)	HR [95% CI] p value[a]
Overall mortality	2,366	43 (1.8)	2,379	44 (1.8)	0.98 [0.64; 1.49] 0.930

Morbidity

Endpoint	Colchicine + optimised standard therapy		Placebo + optimised standard therapy		Colchicine vs placebo (in each case + optimised standard therapy)
	N	Patients with event n (%)	N	Patients with event n (%)	HR [95% CI] p value[a] AD[b]
Major adverse cardiovascular events[c] (primary composite endpoint)	2,366	131 (5.5)	2,379	170 (7.1)	0.77 [0.61; 0.96] 0.022 AD = 1.6%
Cardiovascular death	2,366	20 (0.8)	2,379	24 (1.0)	0.84 [0.46; 1.52] 0.560
Stroke (non-fatal)	2,366	5 (0.2)	2,379	19 (0.8)	0.26 [0.10; 0.70] 0.004 AD = 0.6%
Resuscitated cardiac arrest (non-fatal)	2,366	5 (0.2)	2,379	6 (0.3)	0.83 [0.25; 2.73] 0.762
Acute myocardial infarction (non-fatal)[d]	2,366	89 (3.8)	2,379	98 (4.1)	0.91 [0.68; 1.21] 0.521
Urgent hospital admission due to	2,366	25 (1.1)	2,379	50 (2.1)	0.50 [0.31; 0.81]

angina pectoris requiring coronary revascularisation (non-fatal)							0.004 AD = 1.0%
	N	n_E	Event rate [95% CI][e]	N	n_E	Event rate [95% CI][e]	Rate ratio [95% CI]; p value[f] AD[b]
Major adverse cardiovascular events[c], including recurrent events *(presented additionally)*	2,366	154	0.29 [n.d.]	2,379	223	0.42 [n.d.]	0.66 [0.51; 0.86] 0.002 AD = 0.13
Severe heart failure events	No suitable data[g]						

Health-related quality of life

The endpoint of health-related quality of life was not assessed in the COLCOT study.

Side effects

Endpoint	**Colchicine + optimised standard therapy**		**Placebo + optimised standard therapy**		**Colchicine vs placebo (in each case + optimised standard therapy)**
	N	Patients with event n (%)	N	Patients with event n (%)	RR [95% CI] p value
Total adverse events *(presented additionally)*	Endpoint not assessed[h]				
Severe adverse events (CTCAE grade 3 or 4)	Endpoint not assessed[h]				
Serious adverse events (SAEs)[i]	2,330	259 (11.1)	2,346	268 (11.4)	0.97 [0.83; 1.14] 0.805[j]
Therapy discontinuation due to adverse events	No suitable data[h]				
Specific adverse events					

Endpoint	Colchicine + optimised standard therapy		Placebo + optimised standard therapy		Colchicine vs placebo (in each case + optimised standard therapy)
	N	Patients with event n (%)	N	Patients with event n (%)	RR [95% CI] p value
Gastrointestinal disorders (SOC, AEs)	2,330	396 (17.0)	2,346	401 (17.1)	0.99 [0.88; 1.13] 0.946[j]

a. HR and 95% CI from an unstratified Cox proportional hazards model; p value from the log-rank test
b. Indication of absolute difference (AD) only in case of statistically significant difference; own calculation.
c. Composite cardiovascular endpoint comprising the components "cardiovascular death", "stroke", "resuscitated cardiac arrest", "acute myocardial infarction" and "urgent hospital admission for angina pectoris requiring coronary revascularisation"; following review by an endpoint committee
d. The operationalisation also includes type 3 myocardial infarction events (fatal myocardial infarctions in the absence of cardiac biomarkers). One type 3 myocardial infarction occurred in the control arm of the study.
e. Event rate according to the pharmaceutical company was calculated as the crude event rate and expressed per 100 patient-months, i.e. calculated as 100 × nE / tFU, where tFU is the sum of the patient-individual follow-up times in months
f. Rate ratio and p value according to the pharmaceutical company, based on a negative binomial model with the patient-individual follow-up time in months as an offset term; 95% CI according to the pharmaceutical company, based on normal approximation
g. The operationalisation presented here includes urgent, unscheduled visits to the outpatient clinic/ doctor's surgery or the accident and emergency department. There is no information available on how many patients were actually hospitalised following a visit to their doctor or the accident and emergency department. No suitable data are therefore available for the endpoint of severe heart failure events.
h. Potentially incomplete assessment: AEs (regardless of severity) were collected only selectively in the COLCOT study.
i. Without disease-related events
j. IQWiG calculation of RR, CI (asymptotic) and p value (unconditional exact test, CSZ method according to Andrés et al, 1994).

Abbreviations used:

AD = absolute difference; CTCAE = Common Terminology Criteria for Adverse Events; HR = hazard ratio; CI = confidence interval; MedDRA = Medical Dictionary for Regulatory Activities; N = number of patients evaluated; n = number of patients with (at least one) event; n_E = number of events (multiple events per patient possible); PT = preferred term; pU = pharmaceutical company; RR = relative risk; SOC = system organ class; SAE = serious adverse event; t_{FU}: total patient-individual follow-up times in months; AE = adverse event; vs = versus

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

Adults with atherosclerotic coronary heart disease and a recent myocardial infarction (MI) who are indicated for the prevention of ischaemic cardiovascular events

Approx. 125,000 to 132,000 patients

3. Requirements for a quality-assured application

The requirements in the product information are to be taken into account.

Colchicine has a narrow therapeutic index and is therefore associated with a significant risk of severe overdose. The recommended maximum dose must not be exceeded. Therefore, a review of any concomitant medication and an assessment of kidney and liver function should be carried out before initiation of therapy.

4. Treatment costs

Annual treatment costs:

Adults with atherosclerotic coronary heart disease and a recent myocardial infarction (MI) who are indicated for the prevention of ischaemic cardiovascular events

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Colchicine	€ 1,333.89
+ 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 June 2026)

Costs for additionally required SHI services: not applicable

II. The resolution will enter into force on the day of its publication on the G-BA website on 20 August 2026.

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

Berlin, 20 August 2026

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

Dr Optendrenk