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
Tezepelumab (new therapeutic indication: chronic rhinosinusitis with nasal polyps (CRSwNP))

dated 7 May 2026

At their session on 7 May 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, the following information shall be added after No. 5 to the information on the benefit assessment of Tezepelumab in accordance with the resolution of 12 May 2023 last modified on 21 December 2023:

Tezepelumab

Resolution of: 7 May 2026
Entry into force on: 7 May 2026
Federal Gazette, BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 20 October 2025):

Tezspire is indicated as an add-on therapy with intranasal corticosteroids for the treatment of adult patients with severe CRSwNP for whom therapy with systemic corticosteroids, and/or surgery do not provide adequate disease control.

Therapeutic indication of the resolution (resolution of 7 May 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 severe chronic rhinosinusitis with nasal polyps (CRSwNP) for whom therapy with systemic corticosteroids, and/or surgery do not provide adequate disease control

Appropriate comparator therapy for tezepelumab as an add-on therapy to intranasal corticosteroids:

- Dupilumab or mepolizumab or omalizumab, each in combination with intranasal corticosteroids (budesonide or mometasone furoate)

Extent and probability of the additional benefit of tezepelumab compared to mepolizumab, each in combination with intranasal corticosteroids:

Hint for a non-quantifiable additional benefit.

Study results according to endpoints:[1]

Adults with severe chronic rhinosinusitis with nasal polyps (CRSwNP) for whom therapy with systemic corticosteroids, and/or surgery do not provide adequate disease control

[1] Data from the dossier assessment of the IQWiG (A25-145) and from the addendum (A26-32), unless otherwise indicated.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	n.a.	There are no assessable data.
Morbidity	↑	Advantages in the endpoints of nasal congestion, sense of smell and nasal discharge.
Health-related quality of life	↔	No relevant differences for the benefit assessment.
Side effects	n.a.	There are no assessable data.
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		

Adjusted indirect comparison - according to Bucher - of tezepelumab + INCS (WAYPOINT study) vs mepolizumab + INCS (SYNAPSE study) via the bridge comparator placebo + INCS, with a study duration of 52 weeks in each case.

Mortality

Endpoint	Tezepelumab + INCS or mepolizumab + INCS, respectively		Placebo + INCS (bridge comparator)		Group difference
	N	Patients with event n (%)	N	Patients with event n (%)	RR [95% CI] p value
Overall mortality[a] (week 52)					
Tezepelumab + INCS vs placebo + INCS					
WAYPOINT	144	0 (0)	147	1 (0.7)	–[b] > 0.999[c]
Mepolizumab + INCS vs placebo + INCS					
SYNAPSE	206	0 (0)	201	0 (0)	–
Indirect comparison via bridge comparators[d]: Tezepelumab + INCS vs mepolizumab + INCS					–

Morbidity[e]

Endpoint	Tezepelumab + INCS or mepolizumab + INCS, respectively		Placebo + INCS (bridge comparator)		Group difference
	N	Patients with event n (%)	N	Patients with event n (%)	RR [95% CI] p value
Nasal congestion / obstruction (week 52)					
Tezepelumab + INCS vs placebo + INCS					
WAYPOINT (NPSD [NRS])[f]	144	134 (93.1)	147	97 (66.0)	0.71 [0.63; 0.81][g] < 0.001[h]
Mepolizumab + INCS vs placebo + INCS					
SYNAPSE (VAS)[i]	206	155 (75.0)	201	132 (66.0)	0.87 [0.76; 0.99][g] 0.037[j]
Indirect comparison via bridge comparators[d]: Tezepelumab + INCS vs mepolizumab + INCS					0.82 [0.69; 0.98][g] 0.032
Reduction / loss of sense of smell (week 52)					
Tezepelumab + INCS vs placebo + INCS					
WAYPOINT (NPSD [NRS])[f]	144	94 (65.3)	147	40 (27.2)	0.41 [0.31; 0.54][g] < 0.001[h]
Mepolizumab + INCS vs placebo + INCS					
SYNAPSE (VAS)[i]	206	100 (49.0)	201	71 (35.0)	0.73 [0.57; 0.95][g] 0.007[j]
Indirect comparison via bridge comparators[d]: Tezepelumab + INCS vs mepolizumab + INCS					0.56 [0.38; 0.82][g] 0.003
Nasal discharge (week 52)					
Tezepelumab + INCS vs placebo + INCS					
WAYPOINT (NPSD [NRS])[f]	144	126 (87.5)	147	83 (56.5)	0.65 [0.56; 0.76][g] < 0.001[h]
Mepolizumab + INCS vs placebo + INCS					
SYNAPSE (VAS)[i]	206	155 (75.0)	201	132 (66.0)	0.87 [0.76; 0.99][g] 0.037[j]
Indirect comparison via bridge comparators[d]: Tezepelumab + INCS vs mepolizumab + INCS					0.75 [0.61; 0.92][g] 0.005

Endpoint	Tezepelumab + INCS or mepolizumab + INCS, respectively		Placebo + INCS (bridge comparator)		Group difference
	N	Patients with event n (%)	N	Patients with event n (%)	RR [95% CI] p value
Post-nasal drip (week 52)					
Tezepelumab + INCS vs placebo + INCS					
WAYPOINT (NPSD [NRS])[f]	144	103 (71.5)	147	85 (57.8)	0.81 [0.69; 0.97][g] 0.019[h]
Mepolizumab + INCS vs placebo + INCS					
SYNAPSE (VAS)[i]	206	148 (72.0)	201	130 (65.0)	0.90 [0.78; 1.03][g] 0.129[j]
Indirect comparison via bridge comparators[d]: Tezepelumab + INCS vs mepolizumab + INCS					0.90 [0.73; 1.13][g] 0.373
Facial pain (week 52)					
Tezepelumab + INCS vs placebo + INCS					
WAYPOINT (NPSD [NRS])[f]	144	90 (62.5)	147	76 (51.7)	0.83 [0.68; 1.02][g] 0.074[h]
Mepolizumab + INCS vs placebo + INCS					
SYNAPSE (VAS)[i]	206	141 (68.0)	201	119 (59.0)	0.86 [0.74; 1.00][g]; 0.054[j]
Indirect comparison via bridge comparators[d]: Tezepelumab + INCS vs mepolizumab + INCS					0.97 [0.75; 1.25][g] 0.802
SNOT-22 total score[k] (week 52)					
Tezepelumab + INCS vs placebo + INCS					
WAYPOINT	144	129 (89.6)	147	97 (66.0)	0.74 [0.65; 0.84][g] < 0.001[h]
Mepolizumab + INCS vs placebo + INCS					
SYNAPSE	205	157 (76.6)	198	122 (61.6)	0.80 [0.69; 0.93][g] 0.001[j]
Indirect comparison via bridge comparators[d]: Tezepelumab + INCS vs mepolizumab + INCS					0.92 [0.76; 1.12][g] 0.412

Health-related quality of life

Endpoint	Tezepelumab + INCS or mepolizumab + INCS, respectively		Placebo + INCS (bridge comparator)		Group difference
	N	Patients with event n (%)	N	Patients with event n (%)	RR [95% CI] p value
SF-36v2 (week 52)					
Physical Component Summary (PCS) score[l]					
Tezepelumab + INCS vs placebo + INCS					
WAYPOINT	144	69 (47.9)	147	49 (33.3)	0.70 [0.52; 0.93][g] 0.013[h]
Mepolizumab + INCS vs placebo + INCS					
SYNAPSE	205	86 (42.0)	198	46 (23.2)	0.55 [0.39; 0.76][g] < 0.001[j]
Indirect comparison via bridge comparators[d]: Tezepelumab + INCS vs mepolizumab + INCS					1.27 [0.82; 1.96][g] 0.294
Mental Component Summary (MCS) score[m]					
Tezepelumab + INCS vs placebo + INCS					
WAYPOINT	144	48 (33.3)	147	46 (31.3)	0.94 [0.67; 1.31][g] 0.710[h]
Mepolizumab + INCS vs placebo + INCS					
SYNAPSE	205	62 (30.2)	198	41 (20.7)	0.68 [0.47; 0.99][g] 0.030[j]
Indirect comparison via bridge comparators[d]: Tezepelumab + INCS vs mepolizumab + INCS					1.38 [0.84; 2.28][g] 0.206

Side effects

Endpoint	Tezepelumab + INCS or mepolizumab + INCS, respectively		Placebo + INCS (bridge comparator)		Group difference
	N	Patients with event n (%)	N	Patients with event n (%)	RR [95% CI] p value
Adverse events (AEs, presented additionally)[n]					
Tezepelumab + INCS vs placebo + INCS					
WAYPOINT	144	113 (78.5)	147	111 (75.5)	–
Mepolizumab + INCS vs placebo + INCS					

SYNAPSE	206	169 (82.0)	201	168 (83.6)	–
Endpoint	**Tezepelumab + INCS or mepolizumab + INCS, respectively**		**Placebo + INCS (bridge comparator)**		**Group difference**
	N	**Patients with event n (%)**	**N**	**Patients with event n (%)**	**RR [95% CI] p value**
Serious adverse events (SAE)[o]					
Tezepelumab + INCS vs placebo + INCS					
WAYPOINT	144	8 (5.6)	147	10 (6.8)	0.82 [0.33; 2.01] 0.809[c]
Mepolizumab + INCS vs placebo + INCS					
SYNAPSE	206	12 (5.8)	201	13 (6.5)	0.90 [0.42; 1.93] 0.839[c]
Indirect comparison via bridge comparators[d]: Tezepelumab + INCS vs mepolizumab + INCS					–[p]
Therapy discontinuation due to adverse events					
Tezepelumab + INCS vs placebo + INCS					
WAYPOINT	144	1 (0.7)	147	2 (1.4)	0.51 [0.05; 5.57] > 0.999[c]
Mepolizumab + INCS vs placebo + INCS					
SYNAPSE	206	4 (1.9)	201	4 (2.0)	0.98 [0.25; 3.85] > 0.999[c]
Indirect comparison via bridge comparators[d]: Tezepelumab + INCS vs mepolizumab + INCS					–[p]

[a] The results on overall mortality are based on the data on fatal AEs.
[b] No presentation of effect estimate and CI, as not informative
[c] Unadjusted RR, CI from Wald test, p value from Fisher's exact test. In the case of 0 events in one study arm, the correction factor 0.5 was used in both study arms when calculating effect.
[d] Indirect comparison according to Bucher et al. 1997
[e] Responder imputation for patients with missing values following NP surgery, and LOCF imputation for patients with missing values who have not undergone NP surgery
[f] Percentage of patients with a decrease in scores by ≥ 0.45 points of the mean value from week 49 to 52 compared with the start of the study (mean value of the last 14 days prior to randomisation). A decrease in the NRS score of the NPSD by ≥ 0.45 points compared to the start of the study is considered as clinically relevant improvement (scale range: 0 to 3).
[g] Data based on comparison of placebo + INCS vs tezepelumab + INCS for the WAYPOINT study or placebo + INCS vs mepolizumab + INCS for the SYNAPSE study or mepolizumab + INCS vs tezepelumab + INCS for the indirect comparison.
[h] A binomial regression model including the following terms: treatment arm, region, baseline value, and log(e) of the baseline blood eosinophil count. The log-link function was used for the RR. 95% CI and p value from Wald test.
[i] Percentage of patients with a decrease in scores by ≥ 1.5 points of the mean value from week 49 to 52 compared with the start of the study (mean value of the last 7 days prior to randomisation). A decrease in

the VAS score by ≥ 1.5 points compared to the start of the study is considered as clinically relevant improvement (scale range: 0 to 10).

[j] Unconditional exact CI, calculated by inverting 2 separate one-sided tests based on the score statistics. p value from the unconditional exact test (CSZ method).

[k] Percentage of patients with a decrease in the SNOT-22 total score by ≥ 16.5 points at week 52 compared with baseline. A decrease in the SNOT-22 total score by ≥ 16.5 points compared to the start of the study is considered as clinically relevant improvement (scale range: 0 to 110).

[l] Percentage of patients with an increase in the PCS score by ≥ 9.4 points at week 52 compared with the start of the study (randomisation in the SYNAPSE study; in the WAYPOINT study, it is unclear whether it was during randomisation or at the start of the run-in phase in week −2). An increase in the PCS score by ≥ 9.4 points compared to the start of the study is considered as clinically relevant improvement (scale range: 7.3 to 70.1; calculated on the basis of the 2009 normative sample.

[m] Percentage of patients with an increase in the MCS score by ≥ 9.6 points at week 52 compared with the start of the study (randomisation in the SYNAPSE study; in the WAYPOINT study, it is unclear whether it was during randomisation or at the start of the run-in phase at week −2). An increase in the MCS score by ≥ 9.6 points compared to the start of the study is considered as clinically relevant improvement (scale range: 5.8 to approx. 69.9; calculated on the basis of the 2009 normative sample.

[n] Includes disease-related events

[o] Without deaths

[p] The reliability of data requirement for carrying out an adjusted indirect comparison is not met.

Abbreviations used:
INCS = intranasal corticosteroids; CI = confidence interval; LOCF = last observation carried forward; MCS = Mental Component Summary; N = number of patients evaluated; n = number of patients with (at least one) event; NP = nasal polyps; NPSD = Nasal Polyposis Symptom Diary; NRS = Numerical Rating Scale; PCS = Physical Component Summary; RR = relative risk; SF-36v2 = Short Form-36 Health Survey Version 2; SNOT-22 = 22-Item Sinonasal Outcome Test; VAS = visual analogue scale; vs = versus

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

Adults with severe chronic rhinosinusitis with nasal polyps (CRSwNP) for whom therapy with systemic corticosteroids, and/or surgery do not provide adequate disease control

Approx. 10,500 to 12,600 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 Tezspire (active ingredient: tezepelumab) at the following publicly accessible link (last access: 26 February 2026):

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

Treatment with tezepelumab should only be initiated and monitored by specialists experienced in treating patients with CRSwNP.

4. Treatment costs

Annual treatment costs:

Adults with severe chronic rhinosinusitis with nasal polyps (CRSwNP) for whom therapy with systemic corticosteroids, and/or surgery do not provide adequate disease control

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Tezepelumab	€ 13,833.17
Intranasal corticosteroids	€ 60.93 - € 243.72
Total	€ 13,894.10 - € 14,076.89
Appropriate comparator therapy:	
Dupilumab or omalizumab or mepolizumab, each in combination with intranasal corticosteroids (budesonide or mometasone furoate)	
Dupilumab	€ 15,946.67
Intranasal corticosteroids	€ 60.93 - € 243.72
Total	€ 16,007.60 - € 16,190.39
Mepolizumab	€ 16,163.98
Intranasal corticosteroids	€ 60.93 - € 243.72
Total	€ 16,224.91 - € 16,407.70
Omalizumab	€ 5,116.06 - € 41,085.89
Intranasal corticosteroids	€ 60.93 - € 243.72
Total	€ 5,176.99 - € 41,329.61

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 March 2026)

Costs for additionally required SHI services: not applicable

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

In the context of the designation of medicinal products with new active ingredients pursuant to Section 35a, paragraph 3, sentence 4 SGB V, the following findings are made:

Adults with severe chronic rhinosinusitis with nasal polyps (CRSwNP) for whom therapy with systemic corticosteroids, and/or surgery do not provide adequate disease control

- 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.

The designation of combinations exclusively serves the implementation of the combination discount according to Section 130e SGB V between health insurance funds and pharmaceutical companies. 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.

II. The resolution will enter into force on the day of its publication on the G-BA website on 7 May 2026.

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

Berlin, 7 May 2026

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

Prof. Hecken