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) Vibegron (overactive bladder)

of 21 August 2025

At their session on 21 August 2025, 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. Annex XII shall be amended in alphabetical order to include the active ingredient Vibegron as follows:

Vibegron

Resolution of: 21 August 2025
Entry into force on: 21 August 2025
Federal Gazette, BAnz AT DD. MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 27 June 2024):

Obgemsa is indicated in symptomatic treatment of adult patients with overactive bladder (OAB) syndrome.

Therapeutic indication of the resolution (resolution of 21 August 2025):

See therapeutic indication according to marketing authorisation.

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

Adults with an overactive bladder

Appropriate comparator therapy:

- Darifenacin or desfesoterodine or fesoterodine or mirabegron or propiverine or solifenacin or tolterodine or trospium chloride

Extent and probability of the additional benefit of vibegron compared to tolterodine:

An additional benefit is not proven.

Study results according to endpoints:[1]

Adults with an overactive bladder

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	↔	No deaths occurred.
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. In detail, advantage in the endpoint dry mouth.

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

RVT-901-3003 study and RVT-901-3004 extension study: Vibegron vs tolterodine

Relevant sub-population: Patients who were treated with vibegron or tolterodine continuously over a period of 52 weeks during both studies

Mortality

Endpoint	Vibegron		Tolterodine		Vibegron vs tolterodine
	N[a]	Patients with event n (%)	N[a]	Patients with event n (%)	RR [95% CI]; p value
Overall mortality[b]					
	181	0 (0)	141	0 (0)	–[c]

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A25-39) unless otherwise indicated.

Morbidity

Endpoint	Vibegron			Tolterodine			Vibegron vs tolterodine
	N[a]	Patients with event n (%)		N[a]	Patients with event n (%)		RR [95% CI]; p value[e]
Health status – improvement at week 52[h]							
EQ-5D VAS	166	39 (23.5)		134	27 (20.1)		1.16 [0.75; 1.78]; 0.525
Symptomatology – improvement at week 52							
Symptom bother score[d]	166	121 (72.9)		134	87 (64.9)		1.12 [0.97; 1.30]; 0.160
PGI change[f]	166	140 (84.3)		134	112 (83.6)		1.02 [0.93; 1.12]; 0.923
PGI severity[g]	166	123 (74.1)		134	87 (64.9)		1.13 [0.97; 1.32]; 0.092
	N[l]	Values at the start of the study MV (SD)	Change at week 52 MV[m] (SE)	N[l]	Values at the start of the study MV (SD)	Change at week 52 MV[m] (SE)	MD [95% CI]; p value[m]
Symptomatology (PGI control)[n]	166	3.3 (0.9)	MV (SD): -1.1 (1.0)	134	3.2 (0.8)	MV (SD): -1.0 (1.1)	−0.10 [−0.33; 0.13]; 0.399[o]
Incontinence[p]	152	3.1 (3.2)	-2.1 (0.1)	120	2.9 (2.7)	-1.6 (0.2)	-0.48 [-0.84; -0.12]; 0.009
Urge incontinence[q]	152	2.6 (2.8)	-1.8 (0.1)	120	2.4 (2.2)	-1.4 (0.1)	-0.47 [-0.79; -0.14]; 0.005
Micturition frequency[r]	152	11.1 (3.3)	-2.4 (0.2)	120	11.3 (3.2)	-2.0 (0.3)	-0.43 [-1.06; 0.20]; 0.183
Imperative urge to urinate[s]	152	7.9 (4.6)	-3.4 (0.3)	120	8.1 (3.7)	-3.2 (0.4)	-0.15 [-1.07; 0.77]; 0.749
Nycturia[t]	152	1.4 (1.1)	-0.6 (0.1)	120	1.5 (1.2)	-0.5 (0.1)	-0.13 [-0.32; 0.07]; 0.202

Health-related quality of life

Endpoint	Vibegron		Tolterodine		Vibegron vs tolterodine
	N[a]	Patients with event n (%)	N[a]	Patients with event n (%)	RR [95% CI]; p value
OAB-q LF – improvement at week 52[i]					
Total score	166	92 (55.4)	134	68 (50.8)	1.10 [0.89; 1.35]; 0.486[e]
Effect modification age					
< 65 years	*81[u]*	*41 (50.6)*	*72[u]*	*41 (56.9)*	*0.89 [0.66; 1.19]; 0.435[j]*
≥ 65 years	*85[u]*	*51 (60.0)*	*62[u]*	*27 (43.5)*	*1.38 [0.99; 1.92]; 0.049[j]*
Total					*Interaction: 0.049[v]*
Coping with illness	166	104 (62.6)	134	76 (56.7)	1.14 [0.95; 1.38][e]; -
Concern	166	94 (56.6)	134	72 (53.7)	1.06 [0.87; 1.30][e]; -
Sleep	166	94 (56.6)	134	72 (53.7)	1.06 [0.87; 1.30][e]; -
Social limita-tion	166	67 (40.4)	134	48 (35.8)	1.13 [0.84; 1.50][e] ; -

Side effects

Endpoint	Vibegron		Tolterodine		Vibegron vs tolterodine
	N[a]	Patients with event n (%)	N[a]	Patients with event n (%)	RR [95% CI]; p value[j]
Adverse events in total					
	181	119 (65.8)	141	86 (61.0)	-
Serious adverse events (SAE)					

Endpoint	Vibegron		Tolterodine		Vibegron vs tolterodine
	N[a]	Patients with event n (%)	N[a]	Patients with event n (%)	RR [95% CI]; p value[j]
	181	4 (2.2)	141	4 (2.8)	0.78 [0.20; 3.06]; 0.720
Severe adverse events[k] (CTCAE grade ≥ 3)					
	181	4 (2.2)	141	5 (3.5)	0.62 [0.17; 2.28]; 0.471
Therapy discontinuation due to adverse events					
	181	3 (1.7)	141	4 (2.8)	0.58 [0.13; 2.57]; 0.472
Specific adverse events					
Urinary tract infection (PT, AEs)	181	10 (5.5)	141	13 (9.2)	0.60 [0.27; 1.33]; 0.202
Dry mouth (PT, AEs)	181	3 (1.7)	141	10 (7.1)	0.23 [0.07; 0.83]; 0.014

a. Number of patients evaluated. For endpoints in the morbidity and health-related quality of life category, patients with baseline value and observation at week 52 were considered.
b. The results on overall mortality are based on the data on fatal AEs.
c. Being non-informative, the effect estimate has not been presented
d. Symptom scale of the OAB-q LF (symptom bother score); lower values indicate an improvement in symptoms. A decrease in symptom bother score by ≥ 15 points compared to the start of the study is considered clinically relevant improvement (scale range: 0 to 100).
e. RR and CI: logistic regression, adjusted for OAB type and sex; p value: Cochran-Mantel-Haenszel test, stratified by OAB type and sex
f. Percentage of patients with any improvement ("very much improved", "much improved" or "slightly improved")
g. Percentage of patients with any improvement in symptom severity on a four-point scale ("no symptoms", "mild", "moderate" and "severe") compared to the start of the study
h. An increase in EQ-5D VAS score by ≥ 15 points compared to the start of study is considered clinically relevant improvement (scale range: 0 to 100).
i. An increase in OAB-q LF score by ≥ 15 points compared to the start of the study is considered a clinically relevant improvement (scale range: 0 to 100).
j. RR and CI: logistic regression, unadjusted; p value: Cochran-Mantel-Haenszel test, unstratified
k. Severe AEs are operationalised as severe or medically significant, not immediately life-threatening; hospitalisation or prolongation of hospitalisation indicated; disability; limitation of self-care activities of daily living; or life-threatening consequences; urgent intervention indicated; or death due to an adverse event. This definition corresponds in wording to the criteria according to NCI CTCAE grade ≥ 3.

Endpoint	Vibegron		Tolterodine		Vibegron vs tolterodine
	N[a]	Patients with event n (%)	N[a]	Patients with event n (%)	RR [95% CI]; p value[j]

l. Number of patients included in the effect estimate (patients with baseline value and observation at week 52). Values at the start of the study may be based on other patient numbers.
m. Unless otherwise stated: mixed model with repeated measures with covariates OAB type and sex
n. Lower (decreasing) values mean better symptomatology; negative effects mean an advantage for the intervention (scale range: 1 to 5).
o. IQWiG calculation from information on the change at week 52
p. Number of total incontinence episodes/24 h (measured in the 7 days before the last visit)
q. Number of urge incontinence episodes/24 h (measured in the 7 days before the last visit). Urge incontinence is a component of the incontinence endpoint and is therefore interpreted together with this endpoint.
r. Number of micturitions/24 h (measured in the 7 days before the last visit)
s. Number of imperative urge-to-urinate episodes/24 h (measured in the 7 days before the last visit)
t. Number of nocturnal micturitions/24 h (measured in the 7 days before the last visit)
u. Number of patients evaluated in the subgroups. Patients with a baseline value and observation at week 52 were considered.
v. Interaction p value: Test for interaction between treatment group and subgroup from the generalised linear model

Abbreviations used:
CTCAE: Common Terminology Criteria for Adverse Events; CI: confidence interval; MV: mean value; MD: mean difference; n: number of patients with (at least 1) event; N: number of patients evaluated; NCI: National Cancer Institute; OAB-q LF: overactive bladder symptom and health-related quality of life questionnaire long form; PGI: Patient Global Impression; PT: preferred term; RCT: randomised controlled trial; RR: relative risk; SD: standard deviation; SE: standard error; SAE: serious adverse event; OAB = overactive bladder; AE: adverse event; VAS: visual analogue scale; vs: versus

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

Adults with an overactive bladder

Approx. 587,900 to 1,270,000 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 Obgemsa (active ingredient: vibegron) at the following publicly accessible link (last access: 5 August 2025):

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

4. Treatment costs

Annual treatment costs:

Adults with an overactive bladder

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Vibegron	€ 606.83
Appropriate comparator therapy:	
Darifenacin	€ 194.12 - € 233.75
Desfesoterodine	€ 202.28 - € 243.43
Fesoterodine	€ 189.91 - € 228.23
Mirabegron	€ 226.23
Propiverine	€ 218.44 - € 243.92
Solifenacin	€ 197.59 - € 236.80
Tolterodine	€ 205.18
Trospium chloride	€ 179.62 - € 199.58

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 August 2025)

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 an overactive bladder

- 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.

II. The resolution will enter into force on the day of its publication on the website of the G-BA on 21 August 2025.

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

Berlin, 21 August 2025

Federal Joint Committee (G-BA)
in accordance with Section 91 SGB V
The Chair

Prof. Hecken