Access Briefing: Germany Q4/24

All resolutions by G-BA for HTA procedures of pharmaceuticals published in the fourth quarter of 2024:

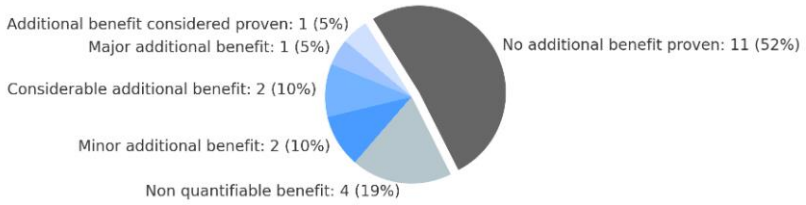
Medicinal product	Company	Indication	Resolution date	Result	Note
Abaloparatid (Eladynos®)	Theramex Germany GmbH	Osteoporosis, postmenopausal women	02.10.2024	Additional benefit is not proven	
Etrasimod (Velsipity®)	Pfizer Pharma GmbH	Ulcerative colitis, pretreated, ≥ 16 years	02.10.2024	Additional benefit is not proven	
Abrocitinib (Cibinqo®)	Pfizer Pharma GmbH	Atopic dermatitis, ≥ 12 to ≤ 17 years	17.10.2024	Additional benefit is not proven	New therapeutic indication
Dabrafenib (Finlee®)	Novartis Pharma GmbH	Malignant glioma, BRAF V600E mutation, ≥ 1 year, low-grade (LGG)/ high-grade (HGG) after at least 1 prior therapy; combination with trametinib	17.10.2024	Hint for a considerable additional benefit and hint for a non-quantifiable additional benefit since the scientific data does not allow quantification.	Orphan drug; assessment of known substance due to new regulatory data protection
Luspatercept (Reblozyl®)	Bristol-Myers Squibb GmbH & Co. KGaA	Myelodysplastic syndromes with transfusion-dependent anaemia, non-pretreated, and without ringed sideroblasts, pretreated	17.10.2024	Hint for a minor additional benefit and additional benefit is not proven	Orphan drug; assessment after exceeding 30 Mio €; new therapeutic indication
Pembrolizumab (Keytruda®)	MSD Sharp & Dohme GmbH	Non-small cell lung carcinoma, adjuvant treatment, after prior chemotherapy	17.10.2024	Additional benefit is not proven	New therapeutic indication; **33rd assessment**
Pembrolizumab (Keytruda®)	MSD Sharp & Dohme GmbH	Non-small cell lung carcinoma, high risk of recurrence, neoadjuvant and adjuvant treatment, monotherapy or combination with platinum-based chemotherapy	17.10.2024	Additional benefit is not proven	New therapeutic indication; **34th assessment**
Trametinib (Spexotras®)	Novartis Pharma GmbH	Malignant glioma, BRAF V600E mutation, ≥ 1 year, low-grade (LGG)/ high-grade (HGG) after at least 1 prior therapy; combination with dabrafenib	17.10.2024	Hint for a considerable additional benefit and hint for a non-quantifiable additional benefit since the scientific data does not allow quantification	Orphan drug; new therapeutic indication; new approval under existing data protection
Selpercatinib (Retsevmo®)	Lilly Deutschland GmbH	Thyroid cancer, RET fusion-positive, refractory to radioactive iodine, first-line or after prior systemic therapy, ≥ 12 years	07.11.2024	Additional benefit is not proven	New therapeutic indication
Selpercatinib (Retsevmo®)	Lilly Deutschland GmbH	Solid tumours, RET fusion-positive	07.11.2024	Additional benefit is not proven	New therapeutic indication
Bimekizumab (Bimzelx®)	UCB Pharma GmbH	Hidradenitis suppurativa (acne inversa)	22.11.2024	Additional benefit is not proven	New therapeutic indication
Danicopan (Voydeya®)	Alexion Pharma Germany GmbH	Paroxysmal nocturnal haemoglobinuria with residual haemolytic anaemia, add-on to ravulizumab or eculizumab	22.11.2024	Hint for a non-quantifiable additional benefit since the scientific data does not allow quantification	Orphan drug
Futibatinib (Lytgobi®)	Taiho Pharma Netherlands	Cholangiocarcinoma, with FGFR2 fusion or FGFR2 rearrangement, after at least 1 prior therapy	22.11.2024	Additional benefit is not proven	
Pegcetacoplan (Aspaveli®)	Swedish Orphan Biovitrum GmbH	Paroxysmal nocturnal haemoglobinuria, non-pretreated patients	22.11.2024	Hint for a non-quantifiable additional benefit since the scientific data does not allow quantification	Orphan drug; new therapeutic indication
Vadadustat (Vafseo®)	MEDICE Arzneimittel Pütter GmbH & Co. KG	Symptomatic anaemia in dialysis-dependent chronic kidney disease	22.11.2024	Additional benefit is not proven	
Cefepim/ Enmetazobactam (Exblifep®)	Advanz Pharma Germany GmbH	Bacterial infections, multiple therapeutic indications	05.12.2024	The additional benefit is considered proven	**Antibiotic of last resort**
Axicabtagen-Ciloleucel (Yescarta®)	Gilead Sciences GmbH	Diffuse large B-cell lymphoma, high-grade B-cell lymphoma, after 1 prior therapy, relapsed within 12 months or refractory	19.12.2024	Hint for a minor additional benefit	Orphan drug; assessment after exceeding 30 Mio €; reassessment after deadline; ATMP
Iptacopan (Fabhalta®)	Novartis Pharma GmbH	Paroxysmal nocturnal haemoglobinuria	19.12.2024	Hint for a non-quantifiable additional benefit since the scientific data does not allow quantification	Orphan drug; **reimbursement with data generation**
Nivolumab (Opdivo®)	Bristol-Myers Squibb GmbH & Co. KGaA	Urothelial carcinoma, first-line, combination with cisplatin and gemcitabine	19.12.2024	Additional benefit is not proven	New therapeutic indication; **26th assessment**
Osimertinib (Tagrisso®)	AstraZeneca GmbH	Non-small cell lung cancer, EGFR mutations, adjuvant treatment	19.12.2024	**Hint for a major additional benefit** and additional benefit is not proven	Reassessment after deadline
Tofersen (Qalsody®)	Biogen GmbH	Amyotrophic lateral sclerosis (ALS)	19.12.2024	Hint for a non-quantifiable additional benefit since the scientific data does not allow quantification	Orphan drug

Source: www.g-ba.de; compilation: Ecker+Ecker GmbH (as of: 23.02.2025); contact: t.ecker@ecker-ecker.de

Highlights:

- Osimertinib: Hint for major additional benefit for one subpopulation (highest category)
- Pembrolizumab: 33rd and 34th assessment
- Nivolumab: 26th assessment
- One assessment led to reimbursement with data generation
- One assessment for antibiotic of last resort

Statistics:



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