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)
Trastuzumab deruxtecan (new therapeutic indication: gastric or gastroesophageal junction adenocarcinoma, HER2+, after trastuzumab-based therapy)

of 20 July 2023

At its session on 20 July 2023, 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 is added after no. 5 to the information on the benefit assessment of Trastuzumab deruxtecan according to the resolution version of 2 February 2023 on the therapeutic indication "unresectable or metastatic HER2-positive breast cancer, after at least one anti-HER2-based pretreatment":

Trastuzumab deruxtecan

Resolution of: 20 July 2023
Entry into force on: 20 July 2023
Federal Gazette, BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 12 December 2022):

Enhertu as monotherapy is indicated for the treatment of adult patients with advanced HER2-positive gastric or gastroesophageal junction (GEJ) adenocarcinoma who have received a prior trastuzumab-based regimen.

Therapeutic indication of the resolution (resolution of 20 July 2023):

See new therapeutic indication according to marketing authorisation.

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

a) Adults with advanced HER2-positive gastric or gastroesophageal junction (GEJ) adenocarcinoma; after prior trastuzumab-based first-line therapy

Appropriate comparator therapy:

- Docetaxel cf. Annex VI to Section K of the Pharmaceuticals Directive

or

- Irinotecan cf. Annex VI to Section K of the Pharmaceuticals Directive

or

- Paclitaxel cf. Annex VI to Section K of the Pharmaceuticals Directive

or

- Ramucirumab in combination with paclitaxel

Extent and probability of the additional benefit of trastuzumab deruxtecan compared to the appropriate comparator therapy:

An additional benefit is not proven.

b) Adults with advanced HER2-positive gastric or gastroesophageal junction (GEJ) adenocarcinoma; after at least two prior treatment regimens, including trastuzumab

Appropriate comparator therapy:

- Trifluridine/ tipiracil

Extent and probability of the additional benefit of trastuzumab deruxtecan compared to the appropriate comparator therapy:

An additional benefit is not proven.

Study results according to endpoints:

a) Adults with advanced HER2-positive gastric or gastroesophageal junction (GEJ) adenocarcinoma; after prior trastuzumab-based first-line therapy

There are no assessable data.

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	n.a.	There are no assessable data.
Health-related quality of life	n.a.	There are no assessable data.
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		

b) Adults with advanced HER2-positive gastric or gastroesophageal junction (GEJ) adenocarcinoma; after at least two prior treatment regimens, including trastuzumab

There are no assessable data.

Summary of results for relevant clinical endpoints

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

a) Adults with advanced HER2-positive gastric or gastroesophageal junction (GEJ) adenocarcinoma; after prior trastuzumab-based first-line therapy

approx. 360 - 600 patients

b) Adults with advanced HER2-positive gastric or gastroesophageal junction (GEJ) adenocarcinoma; after at least two prior treatment regimens, including trastuzumab

approx. 110 - 270 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 Enhertu (active ingredient: trastuzumab deruxtecan) at the following publicly accessible link (last access: 17 May 2023):

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

Treatment with trastuzumab deruxtecan should only be initiated and monitored by specialists in internal medicine, haematology and oncology as well as specialists in internal medicine and gastroenterology and other specialists participating in the Oncology Agreement, all of whom are experienced in the treatment of patients with gastric cancer.

This medicinal product was approved under "special conditions". This means that further evidence of the benefit of the medicinal product is anticipated. The European Medicines Agency will evaluate new information on this medicinal product at least once a year and update the product information where necessary.

4. Treatment costs

Annual treatment costs:

a) Adults with advanced HER2-positive gastric or gastroesophageal junction (GEJ) adenocarcinoma; after prior trastuzumab-based first-line therapy

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Trastuzumab deruxtecan	€ 189,123.21
Appropriate comparator therapy:	
Ramucirumab + paclitaxel	
Ramucirumab	€ 71,031.74

Designation of the therapy	Annual treatment costs/ patient
Paclitaxel	€ 17,573.79
Additionally required SHI services	€ 241.99
Total	€ 88,847.52
Monotherapies cf. Annex VI to Section K of the Pharmaceuticals Directive	
Paclitaxel	
Paclitaxel	€ 23,476.78
Additionally required SHI services	€ 241.99
Total	€ 23,718.77
Docetaxel	€ 13,734.17
Irinotecan	€ 15,482.52

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 July 2023)

Other SHI services:

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Medicinal product to be assessed:					
Trastuzumab deruxtecan	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	17.4	€ 1,740
Appropriate comparator therapy:					
Paclitaxel (in combination with ramucirumab)	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	3	39.0	€ 3,900
Paclitaxel (Monotherapy, cf. Annex VI to Section K of the Pharmaceuticals Directive)	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	52.1	€ 5,210
Docetaxel (cf. Annex VI to Section K of the Pharmaceuticals Directive)	Surcharge for production of a parenteral preparation	€ 100	1	17.4	€ 1,740

	containing cytostatic agents				
Irinotecan (cf. Annex VI to Section K of the Pharmaceuticals Directive)	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	26.1	€ 2,610
Ramucirumab (cf. Annex VI to Section K of the Pharmaceuticals Directive)	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	2	26.0	€ 2,600

b) Adults with advanced HER2-positive gastric or gastroesophageal junction (GEJ) adenocarcinoma; after at least two prior treatment regimens, including trastuzumab

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Trastuzumab deruxtecan	€ 189,123.21
Appropriate comparator therapy:	
Trifluridine/ tipiracil	€ 42,230.98

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 July 2023)

Costs for additionally required SHI services: not applicable

Other SHI services:

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Medicinal product to be assessed:					
Trastuzumab deruxtecan	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	17.4	€ 1,740

5. 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 Trastuzumab deruxtecan

Medicinal products with new active ingredients pursuant to Section 35a, paragraph 3, sentence 4 SGB V are medicinal products with the following new active ingredients, which, on the basis of the marketing authorisation granted under Medicinal Products Act, can be used in a combination therapy with trastuzumab deruxtecan for the treatment of adults with advanced HER2-positive gastric or GEJ adenocarcinoma:

a) Adults with advanced HER2-positive gastric or gastroesophageal junction (GEJ) adenocarcinoma; after prior trastuzumab-based first-line therapy

- No designation of medicinal products with new active ingredients that can be used in combination therapy pursuant to Section 35a, paragraph 3, sentence 4 SGB V, as the active ingredient to be assessed is an active ingredient authorised in monotherapy.

b) Adults with advanced HER2-positive gastric or gastroesophageal junction (GEJ) adenocarcinoma; after at least two prior treatment regimens, including trastuzumab

- No designation of medicinal products with new active ingredients that can be used in combination therapy pursuant to Section 35a, paragraph 3, sentence 4 SGB V, as the active ingredient to be assessed is an active ingredient authorised in monotherapy.

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 website of the G-BA on 20 July 2023.

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

Berlin, 20 July 2023

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

Prof. Hecken