Gemeinsamer Bundesausschuss

Resolution

of the Resolution of the Federal Joint Committee (G-BA) on an Amendment of the Pharmaceuticals Directive (AM-L):

Annex XII - Benefit Assessment of Medicinal Products with New Active Ingredients according to Section 35a SGB V: Pertuzumab/trastuzumab (breast cancer, HER2-positive, metastatic or locally recurrent (unresectable), first-line, combination with docetaxel)

of 15 July 2021

At its session on 15 July 2021, 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 on DD. 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 pertuzumab/trastuzumab as follows:

Pertuzumab/trastuzumab

Resolution of: 15 July 2021
Entry into force on: 15 July 2021
BAnz AT TT. MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 21 December 2020):

Phesgo is indicated for use in combination with docetaxel in adult patients with HER2-positive metastatic or locally recurrent unresectable breast cancer, who have not received previous anti-HER2 therapy or chemotherapy for their metastatic disease.

Therapeutic indication of the resolution (resolution of 15 July 2021):

see therapeutic indication according to marketing authorisation.

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

Adult patients with HER2-positive metastatic or locally recurrent, unresectable breast cancer who have not received previous anti-HER2 therapy or chemotherapy for their metastatic disease

Appropriate comparator therapy for pertuzumab/trastuzumab in combination with docetaxel:

- Pertuzumab in combination with trastuzumab and docetaxel

Extent and probability of the additional benefit of pertuzumab/trastuzumab in combination with docetaxel compared to pertuzumab + trastuzumab in combination with docetaxel:

An additional benefit is not proven

Study results according to endpoints:[1]

Adult patients with HER2-positive metastatic or locally recurrent, unresectable breast cancer who have not received previous anti-HER2 therapy or chemotherapy for their metastatic disease

No data are available to allow an assessment of the additional benefit.

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
∅: there are no usable data for the benefit assessment.
n.a.: not assessable

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

Adult patients with HER2-positive metastatic or locally recurrent, unresectable breast cancer who have not received previous anti-HER2 therapy or chemotherapy for their metastatic disease

approx. 2,470 to 4,000 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

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A21-09) unless otherwise indicated.

product characteristics, SmPC) for Phesgo (active ingredient: pertuzumab/trastuzumab) at the following publicly accessible link (last access: 07 April 2021): https://www.ema.europa.eu/en/documents/product-information/phesgo-epar-product-information_de.pdf

Treatment with pertuzumab/trastuzumab should only be initiated and monitored by specialists in internal medicine, haematology, and oncology, obstetrics and gynaecology, and specialists participating in the Oncology Agreement are experienced in the treatment of adults with breast cancer.

Pertuzumab/trastuzumab should be used by medical professionals trained in the treatment of anaphylaxis and in an environment where full resuscitation equipment is immediately available.

4. Treatment costs

Annual treatment costs:

Designation of the therapy	Annual treatment costs/patient
Medicinal product to be assessed:	
Pertuzumab/trastuzumab	€ 90,954.03
in combination with the chemotherapeutic agent:	
Docetaxel	€ 18,968.09 - € 24,066.46
Total	€ 109,922.12- € 115,020.49
Appropriate comparator therapy:	
Pertuzumab	€ 48,244.43
Trastuzumab	€ 36,257.21
Docetaxel	€ 18,968.09 - € 24,066.46
Total	€ 103,469.73- € 108,568.10

Costs after deduction of statutory rebates (LAUER-TAXE® as last revised: 15 June 2021)

Costs for additionally required SHI services: not applicable

if necessary: Other SHI services:

Designation of therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Medicinal product to be assessed					
Pertuzumab/ trastuzumab	not applicable				
In combination with the chemotherapeutic agent:					
Docetaxel	b	€ 81	1	17.4	€ 1,409.40
Appropriate comparator therapy:					
Pertuzumab	a	€ 71	1	17.4	€ 1,235.40
Trastuzumab	a	€ 71	1	17.4	€ 1,235.40
Docetaxel	b	€ 81	1	17.4	€ 1,409.40
a: Surcharge for the preparation of a parenteral solution containing monoclonal antibodies b: Surcharge for the preparation of a parenteral preparation containing cytostatic agents					

II. The resolution will enter into force on the day of its publication on the internet on the website of the G-BA on 15 July 2021.

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

Berlin, 15 July 2021

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

Prof. Hecken