Resolution

Gemeinsamer Bundesausschuss

of the Federal Joint Committee (G-BA) on an Amendment of the Pharmaceuticals Directive (AM-RL): Annex XII – Benefit Assessment of Medicinal Products with New Active Ingredients According to Section 35a SGB V Lorlatinib

of 22 November 2019

At its session on 22 November 2019, the Federal Joint Committee (G-BA) resolved to amend the Directive on the Prescription of Medicinal Products in SHI-accredited Medical Care (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 lorlatinib as follows:

Lorlatinib

Resolution of: 22 November 2019
Entry into force on: 22 November 2019
Federal Gazette, BAnz AT DD MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 6 May 2019):

Lorviqua as monotherapy is indicated for the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC) whose disease has progressed after: alectinib or ceritinib as the first ALK tyrosine kinase inhibitor (TKI) therapy; or crizotinib and at least one other ALK-TKI.

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

a) Patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC) whose disease has progressed after alectinib or ceritinib as the first ALK tyrosine kinase inhibitor (TKI) therapy or crizotinib and at least one other ALK-TKI; for whom further antineoplastic systemic therapy is possible:

Appropriate comparator therapy:

A patient-individual therapy taking into account the ALK inhibitors alectinib and ceritinib as well as combination or mono-chemotherapies

Extent and probability of the additional benefit of lorlatinib compared with the appropriate comparator therapy:

An additional benefit is not proven.

b) Patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC) whose disease has progressed after alectinib or ceritinib as the first ALK tyrosine kinase inhibitor (TKI) therapy or crizotinib and at least one other ALK-TKI; for whom further antineoplastic systemic therapy is not possible:

Appropriate comparator therapy:

Best-supportive-care

Extent and probability of the additional benefit of lorlatinib compared with the appropriate comparator therapy:

An additional benefit is not proven.

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

a) Patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC) whose disease has progressed after alectinib or ceritinib as the first ALK tyrosine kinase inhibitor (TKI) therapy or crizotinib and at least one other ALK-TKI; for whom further antineoplastic systemic therapy is possible:

approx. 160 to 1,060 patients

b) Patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC) whose disease has progressed after alectinib or ceritinib as the first ALK tyrosine kinase inhibitor (TKI) therapy or crizotinib and at least one other ALK-TKI; for whom further antineoplastic systemic therapy is not possible:

approx. 40 to 250 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 Lorviqua® (active ingredient: Lorlatinib) at the following publicly accessible link (last access: 8 October 2019):
https://www.ema.europa.eu/documents/product-information/lorviqua-epar-product-information_de.pdf

Treatment with lorlatinib should be initiated and monitored by specialists in internal medicine, haematology, and oncology, specialists in internal medicine and pneumology, specialists in pulmonary medicine, and specialists participating in the Oncology Agreement who are experienced in the treatment of patients with non-small cell lung carcinoma.

This medicinal product was authorised under “special conditions”. This means that further evidence of the benefit of the medicinal product is anticipated. The European Medicines Agency (EMA) will evaluate new information on this medicinal product at a minimum once per year and update the product information where necessary.

4. Treatment costs

Annual treatment costs:

a) Patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC) whose disease has progressed after alectinib or ceritinib as the first ALK tyrosine kinase inhibitor (TKI) therapy or crizotinib and at least one other ALK-TKI; for whom further antineoplastic systemic therapy is possible:

Designation of the therapy	Annual treatment costs/patient
Medicinal product to be assessed:	
Lorlatinib	€ 89,675.15
Appropriate comparator therapy: a patient-individual therapy taking into account the ALK inhibitors alectinib and ceritinib as well as combination or mono-chemotherapies	
Alectinib	€ 73,479.06
Ceritinib	€ 66,946.23
Cisplatin in combination with a third-generation cytostatic agent (vinorelbine or gemcitabine or docetaxel or paclitaxel or pemetrexed)	
Cisplatin plus docetaxel	
Cisplatin	€ 1,959.42
Docetaxel	€ 20,741.53
Total:	€ 22,700.95
Additionally required SHI services:	€ 321.03 – € 411.93
Cisplatin plus gemcitabine	
Cisplatin	€ 1,959.42–2,427.26
Gemcitabine	€ 7,999.18
Total:	€ 9,958.60–10,426.44
Additionally required SHI services:	€ 321.03 – € 411.93
Cisplatin plus paclitaxel	
Cisplatin	€ 2,216.63
Paclitaxel	€ 20,269.78
Total:	€ 22,486.41
Additionally required SHI services:	€ 554.57 – € 645.47
Cisplatin plus pemetrexed	
Cisplatin	€ 1,959.42
Pemetrexed	€ 67,076.22
Total:	€ 69,035.64
Additionally required SHI services:	€ 444.63 – 581.63
Cisplatin plus vinorelbine	
Cisplatin	€ 1,959.42–2,427.26
Vinorelbine	€ 4,608.33 – € 5,555.19
Total:	€ 6,567.75 – € 7,982.45
Additionally required SHI services:	€ 321.03 – €411.93
Carboplatin in combination with a third-generation cytostatic agent (vinorelbine or	

Designation of the therapy	Annual treatment costs/patient
gemcitabine or docetaxel or paclitaxel or pemetrexed)	
Carboplatin plus docetaxel	
Carboplatin	€ 8,514.45
Docetaxel	€ 20,741.53
Total:	€ 29,255.98
Carboplatin plus gemcitabine	
Carboplatin	€ 8,514.45
Gemcitabine	€ 7,999.18
Total:	€ 16,513.63
Carboplatin plus paclitaxel	
Carboplatin	€ 8,514.45
Paclitaxel	€ 20,269.78
Total:	€ 28,784.23
Additionally required SHI services:	€ 233.55
Carboplatin plus pemetrexed	
Carboplatin	€ 8,514.45
Pemetrexed	€ 67,076.22
Total:	€ 75,590.67
Additionally required SHI services:	€ 123.60 – € 169.70
Carboplatin plus vinorelbine	
Carboplatin	€ 8,514.45
Vinorelbine	€ 4,608.33 – € 5,555.19
Total:	€ 13,122.78 – € 14,069.64
Carboplatin plus nab-paclitaxel	
Carboplatin	€ 8,514.45
nab-paclitaxel	€ 41,219.22
Total:	€ 49,733.67
Monotherapy with gemcitabine or vinorelbine (only for patients with ECOG performance status 2 as an alternative to platinum-based combination treatment).	
Gemcitabine	€ 7,154.55
Vinorelbine	€ 7,048.03 – € 8,496.18

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 October 2019

b) Patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC) whose disease has progressed after alectinib or ceritinib as the first ALK tyrosine kinase inhibitor (TKI) therapy or crizotinib and at least one other ALK-TKI; for whom further antineoplastic systemic therapy is not possible:

Designation of the therapy	Annual treatment costs/patient
Medicinal product to be assessed:	
Lorlatinib	€ 89,675.15
Appropriate comparator therapy:	
Best-supportive-care	different for each individual patient

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 October 2019

Other services covered by SHI funds:

Designation of the therapy	Type of service	Cost per unit	Number per cycle	Number per patient per year[1]	Cost per patient per year
Medicinal product to be assessed:					
not applicable					
Appropriate comparator therapy:					
Carboplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	1	17	€ 1,377
Cisplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	1	17	€ 1,377
Vinorelbine	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	2	34	€ 2,754
Gemcitabine	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	2	34	€ 2,754
Docetaxel	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	1	17	€ 1,377
Paclitaxel	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	1	17	€ 1,377

[1] calculated and standardised for one year

Designation of the therapy	Type of service	Cost per unit	Number per cycle	Number per patient per year[1]	Cost per patient per year
nab-paclitaxel	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	1	51	€ 4,131
Pemetrexed	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	1	17	€ 1,377
Gemcitabin (monotherapy)	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	3	39	€ 3,159
Vinorelbin (monotherapy)	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	1	52	€ 4,212

II. The resolution will enter into force on the day of its publication on the internet on the website of the G-BA on 22 November 2019.

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

Berlin, 22 November 2019

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

Prof Hecken