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 Radium-223 dichloride (reassessment due to new scientific knowledge: prostate carcinoma)

of 17 October 2019

At its session on 17 October 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 will be amended as follows:

1. The information on radium-223 dichloride in accordance with the resolution of 19 June 2014 (BAnz AT 18 July 2014 B4) as last amended on 1 November 2018 (BAnz AT 16 November 2018 B5) shall be repealed.

2. Annex XII shall be amended in alphabetical order to include the active ingredient radium-223 dichloride as follows:

Radium-223 dichloride

Resolution of: 17 October 2019
Entry into force on: 17 October 2019
Federal Gazette, BAnz AT DD MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 28 September 2018):

Xofigo monotherapy or in combination with an LHRH analogue (LHRH: luteinising hormone-releasing hormone) is indicated for the treatment of adult patients with metastatic castration-resistant prostate cancer (mCRPC), symptomatic bone metastases and no known visceral metastases, in progression after at least two prior lines of systemic therapy for mCRPC (other than LHRH analogues), or ineligible for any available systemic mCRPC treatment (see Section 4.4).

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

a) Adult patients with metastatic castration-resistant prostate cancer (mCRPC), symptomatic bone metastases and no known visceral metastases who are in progression after at least two prior lines of systemic therapy for the treatment of mCRPC (other than LHRH analogues)

Appropriate comparator therapy:

Patient-individual therapy taking into account previous therapies and selecting abiraterone, enzalutamide, cabazitaxel, and docetaxel

Extent and probability of the additional benefit of radium-223 dichloride compared with the appropriate comparator therapy:

An additional benefit is not proven.

b) Adult patients with metastatic castration-resistant prostate cancer (mCRPC), symptomatic bone metastases and no known visceral metastases who are ineligible for any available systemic mCRPC treatment

Appropriate comparator therapy:

Best supportive care (especially adequate pain therapy, treatment with bisphosphonates, denosumab, and/or radionuclides)

Extent and probability of the additional benefit of radium-223 dichloride compared with the appropriate comparator therapy:

An additional benefit is not proven.

Study results according to endpoints:

a) Adult patients with metastatic castration-resistant prostate cancer (mCRPC), symptomatic bone metastases and no known visceral metastases who are in progression after at least two prior lines of systemic therapy for the treatment of mCRPC (other than LHRH analogues)

There is no suitable data that would allow for the assessment of the additional benefit.

b) Adult patients with metastatic castration-resistant prostate cancer (mCRPC), symptomatic bone metastases and no known visceral metastases who are ineligible for any available systemic mCRPC treatment

There is no suitable data that would allow for the assessment of the additional benefit.

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

a) Adult patients with metastatic castration-resistant prostate cancer (mCRPC), symptomatic bone metastases and no known visceral metastases who are in progression after at least two prior lines of systemic therapy for the treatment of mCRPC (other than LHRH analogues)

Approx. 2,840 patients

b) Adult patients with metastatic castration-resistant prostate cancer (mCRPC), symptomatic bone metastases and no known visceral metastases who are ineligible for any available systemic mCRPC treatment

Approx. 970–1,720 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 Xofigo® (active ingredient: radium-223 dichloride) at the following publicly accessible link (last access: 26 August 2019):

https://www.ema.europa.eu/en/documents/product-information/xofigo-epar-product-information_de.pdf

Treatment with radium-223 dichloride should only be initiated and monitored by specialists in internal medicine, haematology, and oncology, specialists in urology, and other specialists participating in the Oncology Agreement who are experienced in the treatment of patients with prostate carcinoma.

The medicinal product may only be used by persons authorised to handle radioactive medicinal products in a designated clinical area.

The regulations of the Radiation Protection Ordinance must be observed.

4. Treatment costs

Annual treatment costs:

a) Adult patients with metastatic castration-resistant prostate cancer (mCRPC), symptomatic bone metastases and no known visceral metastases who are in progression after at least two prior lines of systemic therapy for the treatment of mCRPC (other than LHRH analogues)

Designation of the therapy	Annual treatment costs/patient
Medicinal product to be assessed:	
Monotherapy	
Radium-223 dichloride	€ 33,450.90
In combination with LHRH analogue	
Radium-223 dichloride	€ 33,450.90
LHRH analogue	€ 1,283.50 – € 1,939.48
Total In combination with LHRH analogue:	€ 34,734.40 – € 35,390.38
Additionally required SHI services	€ 602.34
Appropriate comparator therapy:	
Abiraterone acetate + prednisone or prednisolone + LHRH analogue	
Abiraterone acetate	€ 45,841.91
Prednisone or prednisolone	€ 55.47 – € 69.82
LHRH analogue	€ 1,283.50 – € 1,939.48
Total	€ 47,180.88 – € 47,851.22
Enzalutamide + LHRH analogue	
Enzalutamide	€ 45,603.10
LHRH analogue	€ 1,283.50 – € 1,939.48
Total	€ 46,886.60 – € 47,542.58
Cabazitaxel + prednisone or prednisolone	
Cabazitaxel	€ 63,568.78
Prednisone or prednisolone	€ 55.47 – € 69.82
Total	€ 63,624.25 – € 63,638.60
Docetaxel + prednisone or prednisolone	
Docetaxel	€ 20,741.53
Prednisone or prednisolone	€ 94.94 – € 103.74
Total	€ 20,836.47 – € 20,845.27

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

b) Adult patients with metastatic castration-resistant prostate cancer (mCRPC), symptomatic bone metastases and no known visceral metastases who are ineligible for any available systemic mCRPC treatment

Designation of the therapy	Annual treatment costs/patient
Medicinal product to be assessed:	
Monotherapy	
Radium-223 dichloride	€ 33,450.90
In combination with LHRH analogue	
Radium-223 dichloride	€ 33,450.90
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Total In combination with LHRH analogue:	€ 34,734.40 – € 35,390.38
Additionally required SHI services	€ 602.34
Best supportive care	different for each individual patient
Appropriate comparator therapy:	
Best supportive care	different for each individual patient

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

II. The resolution will enter into force on the day of its publication on the internet on the website of the G-BA on 17 October 2019.

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

Berlin, 17 October 2019

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

Prof. Hecken