



Radium-223 dichloride

Resolution of: 17 October 2019
Entry into force on: 17 October 2019
Federal Gazette, BAnz AT 11 111 2019 B6

Valid until: unlimited

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 |
| 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 |
| 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