

**Selinexor** (multiple myeloma (after at least 4 prior therapies, combination with dexamethasone))

Resolution of: 16 March 2023/23. May 2023

valid until: unlimited

Entry into force on: 16 March 2023/25. May 2023

Federal Gazette, BAnz AT 27.04.2023 B3/ BAnz AT 03.07.2023 B2

**Therapeutic indication (according to the marketing authorisation of 26 March 2021):**

Nexpovio is indicated in combination with dexamethasone for the treatment of multiple myeloma in adult patients who have received at least four prior therapies and whose disease is refractory to at least two proteasome inhibitors, two immunomodulatory agents and an anti-CD38 monoclonal antibody, and who have demonstrated disease progression on the last therapy.

**Therapeutic indication of the resolution (resolution of 16 March 2023):**

See therapeutic indication according to marketing authorisation.

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

Adults with multiple myeloma who have received at least four prior therapies and whose disease is refractory to at least two proteasome inhibitors, two immunomodulatory agents and an anti-CD38 monoclonal antibody, and who have demonstrated disease progression on the last therapy

**Appropriate comparator therapy:**

A patient-individual therapy under selection of:

- Bortezomib monotherapy
- Bortezomib + pegylated liposomal doxorubicin
- Bortezomib + dexamethasone
- Carfilzomib + lenalidomide and dexamethasone
- Carfilzomib + dexamethasone
- Daratumumab + lenalidomide + dexamethasone
- Daratumumab + bortezomib + dexamethasone
- Daratumumab + pomalidomide + dexamethasone
- Daratumumab monotherapy
- Elotuzumab + lenalidomide + dexamethasone
- Elotuzumab + pomalidomide + dexamethasone
- Isatuximab + pomalidomide + dexamethasone
- Ixazomib + lenalidomide + dexamethasone
- Lenalidomide + dexamethasone

- Panobinostat + bortezomib and dexamethasone
- Pomalidomide + bortezomib and dexamethasone
- Pomalidomide + dexamethasone
- Cyclophosphamide (in combination with other antineoplastic medicinal products)
- Melphalan
- Doxorubicin
- Carmustine (in combination with other cytostatic agents and a corticosteroid, especially prednisone)
- Vincristine
- Dexamethasone
- Prednisolone
- Prednisone
- Best supportive care

taking into account prior therapies as well as the severity and duration of the response.

**Extent and probability of the additional benefit of selinexor in combination with dexamethasone compared to the appropriate comparator therapy:**

An additional benefit is not proven.

**Study results according to endpoints:<sup>1</sup>**

Adults with multiple myeloma who have received at least four prior therapies and whose disease is refractory to at least two proteasome inhibitors, two immunomodulatory agents and an anti-CD38 monoclonal antibody, and who have demonstrated disease progression on the last therapy

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

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<sup>1</sup> Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A22-101) unless otherwise indicated.

## 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

Adults with multiple myeloma who have received at least four prior therapies and whose disease is refractory to at least two proteasome inhibitors, two immunomodulatory agents and an anti-CD38 monoclonal antibody, and who have demonstrated disease progression on the last therapy

approx. 570 – 1130 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 Nexpovio (active ingredient: selinexor) at the following publicly accessible link (last access: 7 February 2023):

[https://www.ema.europa.eu/en/documents/product-information/nexpovio-epar-product-information\\_en.pdf](https://www.ema.europa.eu/en/documents/product-information/nexpovio-epar-product-information_en.pdf)

Treatment with selinexor should only be initiated and monitored by specialists in internal medicine, haematology and oncology, experienced in the treatment of patients with multiple myeloma.

#### 4. Treatment costs

##### Annual treatment costs:

The annual treatment costs shown refer to the first year of treatment.

Adults with multiple myeloma who have received at least four prior therapies and whose disease is refractory to at least two proteasome inhibitors, two immunomodulatory agents and an anti-CD38 monoclonal antibody, and who have demonstrated disease progression on the last therapy

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
<i>Selinexor in combination with dexamethasone</i>	
Selinexor	€ 206,009.44
Dexamethasone	€ 243.52
Total	€ 206,252.96
Appropriate comparator therapy	
<i>Bortezomib monotherapy</i>	
<i>Bortezomib</i>	€ 5,602.24
<i>Bortezomib in combination with pegylated liposomal doxorubicin</i>	
Bortezomib	€ 5,602.24
Doxorubicin (pegylated, lysosomal)	€ 17,454.00
Total	€ 23,056.24
<i>Bortezomib in combination with dexamethasone</i>	
Bortezomib	€ 2,801.12 - € 5,602.24
Dexamethasone	€ 104.10 - € 168.90
Total	€ 2,905.22 - € 5,771.14
<i>Carfilzomib in combination with lenalidomide and dexamethasone</i>	
Carfilzomib	€ 76,695.24
Lenalidomide	€ 774.93
Dexamethasone	€ 193.44
Total	€ 77,663.61
Additionally required SHI services	€ 106.40
<i>Carfilzomib in combination with dexamethasone</i>	
Carfilzomib	€ 144,716.22
Dexamethasone	€ 243.05
Total	€ 144,959.27
Additionally required SHI services	€ 106.40
<i>Daratumumab in combination with lenalidomide and dexamethasone</i>	

Designation of the therapy	Annual treatment costs/ patient
Daratumumab	€ 128,183.14
Lenalidomide	€ 774.93
Dexamethasone	€ 107.88
Total	€ 129,065.95
Additionally required SHI services	€ 341.49 - € 344.80
<i>Daratumumab in combination with bortezomib and dexamethasone</i>	
Daratumumab	€ 117,036.78
Bortezomib	€ 5,602.24
Dexamethasone	€ 147.23
Total	€ 122,786.25
Additionally required SHI services	€ 292.01 - € 295.02
<i>Daratumumab monotherapy (only for subjects with disease progression on last therapy)</i>	
Daratumumab	€ 128,183.14
Additionally required SHI services	€ 399.30 - € 649.54
<i>Elotuzumab in combination with lenalidomide and dexamethasone</i>	
Elotuzumab	€ 84,540.00
Lenalidomide	€ 774.93
Dexamethasone	€ 185.70
Total	€ 85,500.63
Additionally required SHI services	€ 359.57 - € 363.88
<i>Elotuzumab + pomalidomide + dexamethasone (only for subjects with disease progression on last therapy)</i>	
Elotuzumab	€ 84,540.00
Pomalidomide	€ 106,253.29
Dexamethasone	€ 188.54
Total	€ 190,981.83
Additionally required SHI services	€ 266.74 - € 269.47
<i>Isatuximab in combination with pomalidomide and dexamethasone (only for subjects with disease progression on last therapy)</i>	
Isatuximab	€ 73,272.92
Pomalidomide	€ 106,253.29
Dexamethasone	€ 89.28
Total	€ 179,615.49
Additionally required SHI services	€ 106.40
<i>Ixazomib in combination with lenalidomide and dexamethasone</i>	
Ixazomib	€ 75,468.38

Designation of the therapy	Annual treatment costs/ patient
Lenalidomide	€ 774.93
Dexamethasone	€ 193.44
Total	€ 76,436.75
Additionally required SHI services	€ 106.40
<i>Lenalidomide in combination with dexamethasone</i>	
Lenalidomide	€ 774.93
Dexamethasone	€ 312.48
Total	€ 1,087.41
Additionally required SHI services	€ 106.40
<i>Panobinostat in combination with bortezomib and dexamethasone</i>	
Panobinostat	€ 33,633.12 - € 67,266.24
Bortezomib	€ 5,602.24 - € 8,403.36
Dexamethasone	€ 168.90 - € 233.70
Total	€ 39,404.26 - € 75,903.30
<i>Pomalidomide in combination with bortezomib and dexamethasone</i>	
Pomalidomide	€ 94,810.63
Bortezomib	€ 8,893.56
Dexamethasone	€ 237.44
Total	€ 103,941.62
Additionally required SHI services	€ 106.40
<i>Pomalidomide in combination with dexamethasone (only for subjects with disease progression on last therapy)</i>	
Pomalidomide	€ 106,253.29
Dexamethasone	€ 193.44
Total	€ 106,446.73
Additionally required SHI services	€ 106.40
<i>Cyclophosphamide (in combination with other antineoplastic medicinal products)</i>	
Cyclophosphamide	€ 198.28
Melphalan	€ 332.40
Carmustine	€ 38,015.12
Vincristine	€ 357.55
Prednisone	€ 132.64
Total	€ 39,035.99
<i>Melphalan</i>	
Melphalan	€ 603.20

Designation of the therapy	Annual treatment costs/ patient
<i>Doxorubicin</i>	
Doxorubicin	€ 2,497.92 - € 3,746.88
<i>Carmustine (in combination with other cytostatic agents and a corticosteroid, especially prednisone)</i>	
Carmustine	€ 38,015.12
Cyclophosphamide	€ 198.28
Melphalan	€ 332.40
Vincristine	€ 357.55
Prednisone	€ 132.64
Total	€ 39,035.99
<i>Vincristine</i>	
Vincristine	€ 1,791.20
<i>Dexamethasone</i>	
Dexamethasone	€ 877.50
<i>Daratumumab in combination with pomalidomide and dexamethasone</i>	
Daratumumab	€ 128,183.14
Pomalidomide	€ 106,253.29
Dexamethasone	€ 107.88
Total	€ 234,544.31
Additionally required SHI services	€ 341.49 - € 344.80
<i>Prednisolone</i>	
Prednisolone	Incalculable
<i>Prednisone</i>	
Prednisone	Incalculable
<i>Best supportive care</i>	
Best supportive care <sup>2</sup>	Different from patient to patient

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

<sup>2</sup> When comparing selinexor with best supportive care, the costs of best supportive care must also be taken into account for the drug to be evaluated

Other SHI services:

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Appropriate comparator therapy					
<i>Bortezomib monotherapy</i>					
Bortezomib	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	4	32.0	€ 3,200
<i>Bortezomib in combination with pegylated liposomal doxorubicin</i>					
Bortezomib	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	4	32.0	€ 3,200
Doxorubicin (pegylated, liposomal)	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	Day 4 21-day cycle	8.0	€ 800
<i>Bortezomib in combination with dexamethasone</i>					
Bortezomib	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	4	16.0 - 32.0	€ 1,600 - € 3,200
<i>Carfilzomib in combination with lenalidomide and dexamethasone</i>					
Carfilzomib	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	<u>1st - 12th cycle: 6</u> <u>From 13th cycle: 4</u>	76.0	€ 7,600
<i>Carfilzomib in combination with dexamethasone</i>					
Carfilzomib	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	6	78.0	€ 7,800
<i>Daratumumab in combination with bortezomib and dexamethasone</i>					
Bortezomib	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	4	32.0	€ 3,200
<i>Elotuzumab in combination with lenalidomide and dexamethasone</i>					



Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Elotuzumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	<u>1st - 2nd cycle:</u> 4  <u>From 3rd cycle:</u> 2	30.0	€ 3,000
<i>Elotuzumab + pomalidomide + dexamethasone (only for subjects with disease progression on last therapy)</i>					
Elotuzumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	<u>1st - 2nd cycle:</u> 4  <u>From 3rd cycle:</u> 1	19.0	€ 1,900
<i>Isatuximab in combination with pomalidomide and dexamethasone (only for subjects with disease progression on last therapy)</i>					
Isatuximab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	<u>1st cycle:</u> 4  <u>From 2nd cycle:</u> 2	28.0	€ 2,800
<i>Panobinostat in combination with bortezomib and dexamethasone</i>					
Bortezomib	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	<u>1st - 8th cycle:</u> 4  <u>9th - 16th cycle:</u> 2	32.0 - 48.0	€ 3,200 - € 4,800
<i>Pomalidomide in combination with bortezomib and dexamethasone</i>					
Bortezomib	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	<u>1st - 8th cycle:</u> 4  <u>From 9th cycle:</u> 2	50.8	€ 5,800
<i>Cyclophosphamide (in combination with other antineoplastic medicinal products)</i>					

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Cyclophosphamide	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	10.4	€ 1,040
Carmustine	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	10.4	€ 1,040
Vincristine	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	10.4	€ 1,040
<i>Melphalan monotherapy</i>					
Melphalan	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	13.0	€ 1,300
<i>Carmustine</i>					
Cyclophosphamide	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	10.4	€ 1,040
Carmustine	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	10.4	€ 1,040
Vincristine	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	10.4	€ 1,040
<i>Doxorubicin monotherapy</i>					
Doxorubicin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	6.0 - 9.0	€ 6,000 - € 9,000
<i>Vincristine monotherapy</i>					
Vincristine	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	52.1	€ 5,210

**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 Selinexor**

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 under Medicinal Products Act, can be used in a combination therapy with selinexor for the treatment of adult patients with multiple myeloma who have received at least four prior therapies and whose disease is refractory to at least two proteasome inhibitors, two immunomodulatory agents and an anti-CD38 monoclonal antibody, and who have demonstrated disease progression on the last therapy:

Adults with multiple myeloma who have received at least four prior therapies and whose disease is refractory to at least two proteasome inhibitors, two immunomodulatory agents and an anti-CD38 monoclonal antibody, and who have demonstrated disease progression on the last therapy

- No active ingredient that can be used in a combination therapy that fulfils the requirements of Section 35a, paragraph 3, sentence 4 SGB V.

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.