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 Naldemedin (Treatment of Opioid-induced Constipation in Adult Patients who Have Previously Been Treated with a Laxative)

of 5 November 2020

On 5 November 2020, the Federal Joint Committee (G-BA) resolved by written statement 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 naldemedin as follows:

Naldemedin

Resolution of: 5 November 2020
Entry into force on: 5 November 2020
Federal Gazette, BAnz AT DD MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 18 February 2019):

Rizmoic is indicated for the treatment of opioid-induced constipation (OIC) in adult patients who have previously been treated with a laxative.

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

a) Adult patients with opioid-induced constipation who have previously been treated with a laxative

Appropriate comparator therapy:

- Another non-prescription laxative (in accordance with AM-RL Annex I No. 1) or a prescribable medical product to treat constipation (in accordance with AM-RL Section J and Annex V) or combinations thereof

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

An additional benefit is not proven.

b) Adult patients with opioid-induced constipation for whom a non-prescription laxative or a prescribable medical product to treat constipation are no longer suitable

Appropriate comparator therapy:

- Methylnaltrexone or naloxegol

Extent and probability of the additional benefit of naldemedin compared with naloxegol:

An additional benefit is not proven.

Study results according to endpoints:

a) Adult patients with opioid-induced constipation who have previously been treated with a laxative

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

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ Risk of bias	Summary
Mortality	∅	No data available.
Morbidity	∅	No data available.
Health-related quality of life	∅	No data available.
Side effects	∅	No data available.

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

b) Adult patients with opioid-induced constipation for whom a non-prescription laxative or a prescribable medical product to treat constipation are no longer suitable

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

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ Risk of bias	Summary
Mortality	n.a.	No relevant data are available.
Morbidity	n.a.	No relevant data are available.
Health-related quality of life	n.a.	No relevant data are available.
Side effects	n.a.	No relevant data are available.

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

a) Adult patients with opioid-induced constipation who have previously been treated with a laxative

and

b) Adult patients with opioid-induced constipation for whom a non-prescription laxative or a prescribable medical product to treat constipation are no longer suitable

approx. 65,000 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 product characteristics, SmPC) for Rizmoic (active ingredient: naldemedin) at the following publicly accessible link (last access: 15 October 2020):

https://www.ema.europa.eu/en/documents/product-information/rizmoic-epar-product-information_en.pdf

4. Treatment costs

Annual treatment costs:

a) Adult patients with opioid-induced constipation who have previously been treated with a laxative

Designation of the therapy	Annual treatment costs/patient
Medicinal product to be assessed:	
Naldemedin	€ 1,505.88
Appropriate comparator therapy:	
Bisacodyl	€ 19.89–39.79
Escherichia coli	€ 667.15–1,334.29
Psyllium husks, Indian	€ 159.63–239.44
Lactulose	€ 43.80–175.20
Macrogol 4000	€ 203.45–406.90

Designation of the therapy	Annual treatment costs/patient
Macrogol, electrolytes	€ 165.05–495.16
Sodium picosulphate	€ 69.35–138.70

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 October 2020

Costs for additionally required SHI services: not applicable

b) Adult patients with opioid-induced constipation for whom a non-prescription laxative or a prescribable medical product to treat constipation are no longer suitable

Designation of the therapy	Annual treatment costs/patient
Medicinal product to be assessed:	
Naldemedin	€ 1,505.88
Appropriate comparator therapy:	
Methylnaltrexone	€ 8,013.84
Naloxegol	€ 1,386.31

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 October 2020

Costs for additionally required SHI services: not applicable

II. The resolution will enter into force with effect from the day of its publication on the internet on the website of the G-BA on 5 November 2020.

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

Berlin, 5 November 2020

Federal Joint Committee
in accordance with Section 91 SGB V
The Chair

Prof. Hecken