Gemeinsamer Bundesausschuss

Resolution

of the Federal Joint Committee on an Amendment of the Pharmaceuticals Directive:
Annex XII – Benefit Assessment of Medicinal Products with New Active Ingredients according to Section 35a (SGB V)
Decitabine/ cedazuridine (acute myeloid leukaemia, first-line)

of 15 August 2024

At its session on 15 August 2024, the Federal Joint Committee (G-BA) resolved to amend the 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 by the publication of the resolution of D 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 Decitabine/ cedazuridine as follows:

Decitabine/ cedazuridine

Resolution of: 15 August 2024
Entry into force on: 15 August 2024
Federal Gazette, BAnz AT DD. MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 15 September 2023):

Inaqovi is indicated as monotherapy for the treatment of adult patients with newly diagnosed acute myeloid leukaemia (AML) who are ineligible for standard induction chemotherapy.

Therapeutic indication of the resolution (resolution of 15 August 2024):

See therapeutic indication according to marketing authorisation.

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

Adult patients with newly diagnosed acute myeloid leukaemia (AML) who are ineligible for standard induction chemotherapy

Appropriate comparator therapy:

– azacitidine

or

– decitabine

or

– glasdegib in combination with low-dose cytarabine

or

– venetoclax in combination with azacitidine

or

– venetoclax in combination with decitabine

Extent and probability of the additional benefit of decitabine/ cedazuridine compared to the appropriate comparator therapy:

An additional benefit is not proven.

Study results according to endpoints:[1]

Adult patients with newly diagnosed acute myeloid leukaemia (AML) who are ineligible for standard induction chemotherapy

There are no assessable data.

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 ∅: No data available. n.a.: not assessable		

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

Adult patients with newly diagnosed acute myeloid leukaemia (AML) who are ineligible for standard induction chemotherapy

Approx. 560 – 840 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 Inaqovi (active ingredient: decitabine/ cedazuridine) agreed upon in the context of the marketing authorisation at the following publicly accessible link (last access: 24 July 2024):

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

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A24-29) unless otherwise indicated.

Treatment with decitabine/ cedazuridine should only be initiated and monitored by specialists in internal medicine, haematology and oncology experienced in the treatment of patients with acute myeloid leukaemia.

4. Treatment costs

Annual treatment costs[2]:

Adult patients with newly diagnosed acute myeloid leukaemia (AML) who are ineligible for standard induction chemotherapy

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Decitabine - cedazuridine	€ 88,570.69
Appropriate comparator therapy:	
Azacitidine	€ 45,434.48
Decitabine	€ 80,624.70
Glasdegib in combination with low-dose cytarabine	
Glasdegib	€ 106,498.73
Cytarabine	€ 418.60
Total	€ 106,917.33
Venetoclax in combination with azacitidine	
Venetoclax	€ 76,963.13
Azacitidine	€ 45,434.48
Total	€ 122,397.61
Venetoclax in combination with decitabine	
Venetoclax	€ 76,963.13
Decitabine	€ 80,624.70
Total	€ 157,587.83

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 July 2024)

[2] Only the costs for the first year of treatment are presented.

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Appropriate comparator therapy					
Azacitidine	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	7	91	€ 9,100
Cytarabine	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	10	130	€ 13,000
Decitabine	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	5	65	€ 6,500

5. Designation of 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 the assessed medicinal product

In the context of the designation of medicinal products with new active ingredients pursuant to Section 35a, paragraph 3, sentence 4 SGB V, the following findings are made:

Adult patients with newly diagnosed acute myeloid leukaemia (AML) who are ineligible for standard induction chemotherapy

- No designation of medicinal products with new active ingredients that can be used in combination therapy pursuant to Section 35a, paragraph 3, sentence 4 SGB V, as the active ingredient to be assessed is an active ingredient authorised in monotherapy.

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.

II. The resolution will enter into force on the day of its publication on the website of the G-BA on 15 August 2024.

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

Berlin, 15 August 2024

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

Prof. Hecken