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)
Dalbavancin (repeal of exemption: acute bacterial skin and skin structure infections (ABSSSI), ≥ 3 months)

of 1 February 2024

At its session on 1 February 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 Dalbavancin as follows:

Dalbavancin

Resolution of: 1 February 2024
Entry into force on: 1 February 2024
Federal Gazette, BAnz AT DD. MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 05.12.2022):

Xydalba is indicated for the treatment of acute bacterial skin and skin structure infections (ABSSSI) in adults and paediatric patients aged 3 months and older.

Consideration should be given to official guidance on the appropriate use of antibacterial agents.

Therapeutic indication of the resolution (resolution of 1 February 2024):

See therapeutic indication according to marketing authorisation.

1. Extent of the additional benefit and significance of the evidence

For the medicinal product Xydalba with the active ingredient dalbavancin, an exemption from the obligation to submit the evidence according to Section 35a, paragraph 1, sentence 3, number 2 and 3 SGB V was granted by resolution of 20 April 2023, as it is a reserve antibiotic within the meaning of Section 35a, paragraph 1c, sentence 1 SGB V. The additional benefit is deemed to be proven if the Federal Joint Committee has decided on an exemption for a reserve antibiotic in accordance with Section 35a, paragraph 1c, sentence 1 SGB V; the extent of the additional benefit and its therapeutic significance are not to be assessed by the Federal Joint Committee. By resolution pursuant to Section 35a, paragraph 3, sentence 1 SGB V, the Federal Joint Committee shall specify requirements for a quality-assured application of the reserve antibiotic, taking into account the effects on the resistance situation.

Adults and children aged 3 months and older with acute bacterial skin and skin structure infections (ABSSSI)

Additional benefit of dalbavancin:

The additional benefit is considered proven.

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

Adults and children aged 3 months and older with acute bacterial skin and skin structure infections (ABSSSI)

approx. 190 – 9,800 patients

3. Requirements for a quality-assured application

Notes on 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 Xydalba (active ingredient: dalbavancin) at the following publicly accessible link (last access: 17 October 2023):

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

The requirements for a quality-assured application of dalbavancin apply to the approved therapeutic indications as of September 2023.

Dalbavancin is approved for the treatment of acute bacterial skin and skin structure infections (ABSSSI) in adults and paediatric patients aged 3 months and older. Dalbavancin may only be used if there is evidence or, in exceptional cases, strong suspicion that the infection is caused by methicillin-resistant Staphylococcus aureus (MRSA) and only limited treatment options are available.

Treatment options are limited, particularly in the presence of simultaneous resistance to linezolid and/or vancomycin and for children under 8 years of age.

Dalbavancin should be used with caution in patients with known hypersensitivity to other glycopeptides due to the potential occurrence of a cross-reaction. If an allergic reaction to dalbavancin occurs, use should be discontinued and appropriate therapy initiated.

For restarting treatment with Dalbavancin, consult a specialist with an additional qualification in infectiology, a specialist in internal medicine and infectiology, or a specialist in microbiology, virology and epidemiology of infectious diseases. In case of unavailability of the above-mentioned groups of specialists at the time of use, a specialist with appropriate experience in the treatment of infectious diseases with multi-drug resistant pathogens must be consulted.

Notes on pathogen detection

The reserve antibiotic may only be used as part of a targeted therapy. Before use, the causative pathogen and sensitivity to pathogen must always be proven by microbiological diagnostics of appropriate clinical material.

A calculated (empirical) use of dalbavancin without pathogen detection should only be carried out in exceptional cases. These include a known resistance problem in the treatment facility or in the case of a transfer from a facility with a known resistance problem, as well as in the case of a lack of therapeutic response to standard antibiotic therapy in the case of a serious infection and urgent suspicion that the infection is caused by MRSA.

Samples for pathogen detection must be taken before the start of treatment. The calculated therapy must usually be adjusted after a maximum of 72 hours, if necessary, when an antibiogram is available.

Dalbavancin may not be used if the pathogen shows sensitivity to other antibiotics (without reserve status), unless other antibiotics cannot be used, for example because of contraindications or expected severe complications.

Notes on implementation

The current guidelines of the AWMF and medical and, if applicable, also international scientific-medical societies for the appropriate use of antibiotics must be taken into account.

Furthermore, reference should be made to the listed requirements for a quality-assured application of dalbavancin in the locally available treatment guidelines and regulations of the measures for restrictive antibiotic use.

Outpatient implementation:

The appropriate handling of MRSA patients and the corresponding conditions in the practice must be carried out in accordance with the current recommendations of the RKI (Robert Koch Institute).

In order to ensure the overarching surveillance of resistance data on dalbavancin, the participation of the laboratory supplying the practice in ARS (antibiotic resistance surveillance) should be guaranteed.

The G-BA will review the reports on resistance data from the outpatient sector within 12 months of the resolution being passed.

Inpatient implementation:

The aforementioned specifications are to be implemented within the framework of regulations of the hospital's Drug Commission. Implementation should take place in particular within the framework of the in-house Antibiotic Stewardship Programme (ABS)[1].

The treatment facility must have a local clearance policy for the use of dalbavancin in the respective treatment facility.

Consumption and resistance surveillance in accordance with Section 23, paragraph 4 Infection Protection Act must be implemented. This is to be done through participation in the AVS (Antibiotic Consumption Surveillance) and ARS (Antibiotic Resistance Surveillance) or ARVIA (ARS and AVS – Integrated Analysis) systems.

The reporting of consumption and resistance data on dalbavancin to the above-mentioned systems should be ensured within six months of the entry into force of this resolution. Until participation in the mentioned systems, consumption and resistance situation must be ensured via the existing systems.

The principles of antibiotic therapy of the Commission on Anti-infectives, Resistance and Therapy (ART) at the Robert Koch Institute must be observed (last access: 28 August 2023):

https://www.rki.de/DE/Content/Kommissionen/ART/Links/Grundsaetze-der-Therapie.html

4. Treatment costs

Annual treatment costs:

Adults and children aged 3 months and older with acute bacterial skin and skin structure infections (ABSSSI)

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Dalbavancin	€ 1,011.34 - € 3,034.02

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

Costs for additionally required SHI services: not applicable

[1] See S3 guideline: strategies to ensure rational antibiotic use in hospitals, 2018 update: https://www.awmf.org/uploads/tx_szleitlinien/092-001l_S3_Strategien-zur-Sicherung-rationaler-Antibiotika-Anwendung-im-Krankenhaus_2020-02.pdf

Other SHI services:

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ Number/ patient/ year	Costs/ patient/ year
Dalbavancin	Surcharge for production of a antibiotic and virustatic-containing infusion solution	€ 39	1	1 - 2	€ 39 - € 78

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:

<u>Adults and children aged 3 months and older with acute bacterial skin and skin structure infections (ABSSSI)</u>

- No designation of medicinal products with new active ingredients that can be used in combination therapy in accordance with Section 35a, paragraph 3, sentence 4 SGB V, as the G-BA has decided to exempt the assessed medicinal product as a reserve antibiotic in accordance with Section 35a, paragraph 1c, sentence 1 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.

II. The resolution will enter into force on the day of its publication on the website of the G-BA on 1 February 2024.

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

Berlin, 1 February 2024

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

Prof. Hecken