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 Andexanet Alfa

of 20 February 2020

At its session on 20 February 2020, the Federal Joint Committee (G-BA) resolved 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 andexanet alfa as follows:

Andexanet alfa

Resolution of: 20 February 2020
Entry into force on: 20 February 2020
Federal Gazette, BAnz AT DD MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 26 April 2019):

Andexanet alfa (Ondexxya®) is indicated for adult patients treated with a direct factor Xa (FXa) inhibitor (apixaban or rivaroxaban) when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding.

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

Adult patients treated with a direct factor Xa (FXa) inhibitor (apixaban or rivaroxaban) when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding.

Appropriate comparator therapy:

- An optimised standard therapy for life-threatening or uncontrolled bleeding.

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

An additional benefit is not proven.

Study results according to endpoints:

Adult patients treated with a direct factor Xa (FXa) inhibitor (apixaban or rivaroxaban) when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding.

No data suitable for the benefit assessment were submitted.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/risk of bias	Summary
Mortality	∅	No data suitable for the benefit assessment.
Morbidity	∅	No data suitable for the benefit assessment.
Health-related quality of life	∅	No data suitable for the benefit assessment.
Side effects	∅	No data suitable for the benefit assessment.

Explanations:
↑, ↓: statistically significant and relevant positive or negative effect with high or unclear risk of bias
↑↑, ↓↓: statistically significant and relevant positive or negative effect with low risk of bias
↔: no relevant difference
∅: no data available
n.a.: not assessable

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

Adult patients treated with a direct factor Xa (FXa) inhibitor (apixaban or rivaroxaban) when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding.

approx. 4,200–27,600 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 Ondexxya® (active ingredient: andexanet alfa) at the following publicly accessible link (last access: 7 November 2019):

https://www.ema.europa.eu/documents/product-information/ondexxya-epar-product-information_de.pdf

This medicinal product was approved with "specific obligations". This means that further evidence of the benefit of the medicinal product is anticipated. The EMA will evaluate new information on this medicinal product at a minimum once per year and update the product information where necessary.

Andexanet alfa is intended exclusively for use in hospitals.

After the administration of andexanet alfa, monitoring for signs and symptoms of thrombosis is highly recommended.

4. Treatment costs

Annual treatment costs:

Adult patients treated with a direct factor Xa (FXa) inhibitor (apixaban or rivaroxaban) when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding.

Designation of the therapy	Annual treatment costs/patient
Medicinal product to be assessed:	
Andexanet alfa[1]	€ 19,040 – 34,272
An optimised standard therapy for life-threatening or uncontrolled bleeding	different for each individual patient
Appropriate comparator therapy:	
An optimised standard therapy for life-threatening or uncontrolled bleeding	different for each individual patient

Pharmaceutical retail price (LAUER-TAXE®) as last revised: 1 February 2020

Costs for additionally required SHI services: not applicable

[1] Andexanet alfa is intended exclusively for use in hospitals.

II. Entry into force

1. **The resolution will enter into force on the day of its publication on the internet on the website of the G-BA on 20 February 2020.**

2. **The period of validity of the resolution is limited to 1 November 2023.**

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

Berlin, 20 February 2020

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

Prof. Hecken