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: Avatrombopag (immune thrombocytopenia)

of 16 September 2021

At its session on 16 September 2021, 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 TT. Month YYYY (Federal Gazette, BAnz AT DD.MM.YYYY BX), as follows:

I. In Annex XII, the following information shall be added after point 4 to the information on the benefit assessment of avatrombopag, as amended by the resolutions of 16 September 2021, for the therapeutic indication "[...] used for the treatment of severe thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo an invasive procedure.":

Avatrombopag

Resolution of: 16 September 2021
Entry into force on: 16 September 2021
BAnz AT DD. MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 20 June 2019):

Doptelet is indicated for the treatment of severe thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo an invasive procedure.

Therapeutic indication (according to the marketing authorisation of 18 January 2021):

Doptelet is indicated for the treatment of primary chronic immune thrombocytopenia (ITP) in adult patients who are refractory to other treatments (e.g. corticosteroids, immunoglobulins).

Therapeutic indication of the resolution (resolution from the 16 September 2021):

Doptelet is indicated for the treatment of primary chronic immune thrombocytopenia (ITP) in adult patients who are refractory to other treatments (e.g. corticosteroids, immunoglobulins).

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

Adult patients with primary chronic immune thrombocytopenia (ITP) who are refractory to other treatments (e.g. corticosteroids, immunoglobulins)

Appropriate comparator therapy:

Eltrombopag or romiplostim

Extent and probability of the additional benefit of avatrombopag compared to the appropriate comparator therapy:

An additional benefit is not proven.

Study results according to endpoints:

Adult patients with primary chronic immune thrombocytopenia (ITP) who are refractory to other treatments (e.g. corticosteroids, immunoglobulins)

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

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

Adult patients with primary chronic immune thrombocytopenia (ITP) who are refractory to other treatments (e.g. corticosteroids, immunoglobulins)

approx. 4,260 – 10,830 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 Doptelet® (active ingredient: avatrombopag) at the following publicly accessible link (last access: 11 June 2021):

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

Treatment with avatrombopag should be started and continuously monitored by doctors experienced in the treatment of haematological diseases.

4. Treatment costs

Annual treatment costs:

Adult patients with primary chronic immune thrombocytopenia (ITP) who are refractory to other treatments (e.g. corticosteroids, immunoglobulins)

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Avatrombopag	€ 6,034.50 - 84,715.04
Appropriate comparator therapy:	
Eltrombopag	€ 8,297.73 - € 49,303.20
Romiplostim	€ 23,307.46 - 146,233.37

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 September 2021)

Costs for additionally required SHI services: not applicable

II. The resolution will enter into force on the day of its publication on the website of the G-BA on 16 September 2021.

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

Berlin, 16 September 2021

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

Prof. Hecken