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 Fostamatinib (Chronic Immune Thrombocytopenia)

of 17 December 2020

At its session on 17 December 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 fostamatinib as follows:

Fostamatinib

Resolution of: 17 December 2020
Entry into force on: 17 December 2020
Federal Gazette, BAnz AT DD MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 9 January 2020):

Tavlesse is indicated for the treatment of chronic immune thrombocytopenia (ITP) in adult patients who are refractory to other treatments.

Therapeutic indication of the resolution (resolution of 17 December 2020):

See therapeutic indication according to marketing authorisation.

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

Adult patients with chronic immune thrombocytopenia who are refractory to other treatments

Appropriate comparator therapy for fostamatinib:

Eltrombopag or romiplostim

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

An additional benefit is not proven.

Study results according to endpoints:

Adult patients with chronic immune thrombocytopenia who are refractory to other treatments

There are no relevant data in comparison to the appropriate comparator therapy.

Summary of results for relevant clinical endpoints

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

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 chronic immune thrombocytopenia who are refractory to other treatments

approx. 4,200 to 9,700 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 Tavlesse (active ingredient: fostamatinib) at the following publicly accessible link (last access: 10 November 2020):
https://www.ema.europa.eu/en/documents/product-information/tavlesse-epar-product-information_de.pdf

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

4. Treatment costs

Annual treatment costs:

Adult patients with chronic immune thrombocytopenia who are refractory to other treatments

Designation of the therapy	Annual treatment costs/patient
Medicinal product to be assessed:	
Fostamatinib	€ 51,293.82 – 76,611.19
Appropriate comparator therapy:	
Eltrombopag	€ 8,035.74 – 47,743.69
Romiplostim	€ 22,401.96 – 141,454.11

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 December 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 17 December 2020.

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

Berlin, 17 December 2020

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

Prof. Hecken