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 Regadenoson (new therapeutic indication: measurement of the fractional flow reserve)

of 15 August 2019

At its session on 15 August 2019, 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. In Annex XII, the following information shall be added after No. 4 to the information on the benefit assessment of regadenoson in accordance with the resolution of 29 March 2012:

Regadenoson

Resolution of: 15 August 2019
Entry into force on: 15 August 2019
Federal Gazette, BAnz AT DD MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 23 January 2019):

Rapiscan® is a selective coronary vasodilator for use in adults as a pharmacological stress agent for:

- […]
- the measurement of fractional flow reserve (FFR) of a single coronary artery stenosis during invasive coronary angiography when repeated FFR measurements are not anticipated

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

Patients in whom the fractional flow reserve (FFR) of a single coronary artery stenosis is measured using a pharmacological stress agent during invasive coronary angiography when repeated FFR measurements are not anticipated

Appropriate comparator therapy:

Pharmacological stress agent according to the physician's instructions

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

The additional benefit is deemed not to have been proven

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

Patients in whom the fractional flow reserve (FFR) of a single coronary artery stenosis is measured using a pharmacological stress agent during invasive coronary angiography when repeated FFR measurements are not anticipated

approx. 780,000 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 Rapiscan® (active ingredient: regadenoson) at the following publicly accessible link (last access: 1 July 2019):

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

Treatment with Rapiscan® may only take place in a medical facility where equipment is available for monitoring cardiac function and for cardiac resuscitation.

4. Treatment costs

Annual treatment costs:

Patient population

Designation of the therapy
Medicinal product to be assessed:
Regadenoson[1]
Appropriate comparator therapy:
Pharmacological stress agent according to the physician's instructions

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 July 2019

Costs for additionally required SHI services: not applicable[2]

II. The resolution will enter into force on the day of its publication on the internet on the website of the G-BA on 15 August 2019.

1 The medicinal product is not subject to the Pharmaceutical Price Ordinance (AMPreisV).
2 The costs for the implementation of an FFR are incurred both on the part of the medicinal product to be evaluated and on the part of the appropriate comparator therapy and are therefore not shown in the cost breakdown.

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

Berlin, 15 August 2019

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

Prof Hecken