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 Glecaprevir/Pibrentasvir (new therapeutic indication: chronic hepatitis C, adolescent patients 12 to < 18 years)

of 17 October 2019

At its session on 17 October 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 glecaprevir/pibrentasvir in accordance with the resolution of 1 February 2018:

Glecaprevir/Pibrentasvir

Resolution of: 17 October 2019
Entry into force on: 17 October 2019
Federal Gazette, BAnz AT DD MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 11 March 2019):

Maviret is indicated for the treatment of chronic hepatitis C virus (HCV) infection in adults and in adolescents aged 12 to <18 years (see Sections 4.2, 4.4, and 5.1).[1]

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

a) Patients with chronic hepatitis C aged 12 to < 18 years, genotype 1, 4, 5, or 6

Appropriate comparator therapy:

Ledipasvir/sofosbuvir.

Extent and probability of the additional benefit of glecaprevir/pibrentasvir compared with the appropriate comparator therapy:

An additional benefit is not proven.

a) Patients with chronic hepatitis C aged 12 to < 18 years, genotype 2 or 3

Appropriate comparator therapy:

Sofosbuvir plus ribavirin.

Extent and probability of the additional benefit of glecaprevir/pibrentasvir compared with the appropriate comparator therapy:

An additional benefit is not proven.

[1] This resolution relates exclusively to the patient group of adolescent patients aged 12 to < 18 years approved on 13 March 2017 .

Study results according to endpoints:[2]

a) Patients with chronic hepatitis C aged 12 to < 18 years, genotype 1, 4, 5, or 6

Results of the DORA study:

Endpoint	Glecaprevir/Pibrentasvir	
	N	Patients with event n (%)
Mortality		
Overall mortality	40	0 (0)
Morbidity		
SVR12	40	40 (100)
Side effects		
AE	40	34 (85.0)
SAE	40	0 (0)
Severe AE (CTCAE grade ≥ 3)	40	1 (2.5)[a]
Discontinuation because of AE	40	0 (0)

a) One patient was depressed. The patient already had a history of depression or bipolar disorder at the start of study.

Abbreviations:
CTCAE = Common Terminology Criteria for Adverse Events; N = number of patients evaluated; n = number of patients with (at least one) event; SAE: serious adverse event; SVR12: permanent virological response 12 weeks after end of therapy; AE: adverse event

a) Patients with chronic hepatitis C aged 12 to < 18 years, genotype 2 or 3

Results of the DORA study:

Endpoint	Glecaprevir/Pibrentasvir	
	N	Patients with event n (%)
Mortality		
Overall mortality	7	0 (0)
Morbidity		
SVR12	7	7 (100)
Side effects		

[2] Data from the dossier evaluation of the IQWiG (A19-33) unless otherwise indicated.

Endpoint	Glecaprevir/Pibrentasvir	
	N	Patients with event n (%)
AE	7	7 (100)
SAE	7	0 (0)
Severe AE (CTCAE grade ≥ 3)	7	0 (0)
Discontinuation because of AE	7	0 (0)
Abbreviations: CTCAE = Common Terminology Criteria for Adverse Events; N = number of patients evaluated; n = number of patients with (at least one) event; SAE: serious adverse event; SVR12: permanent virological response 12 weeks after end of therapy; AE: adverse event		

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

a) Patients with chronic hepatitis C aged 12 to < 18 years, genotype 1, 4, 5, or 6

Approx. 420 patients

a) Patients with chronic hepatitis C aged 12 to < 18 years, genotype 2 or 3

Approx. 120 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 Maviret® (active ingredient combination: glecaprevir/pibrentasvir) at the following publicly accessible link (last access: 14 August 2019):

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

Treatment with glecaprevir/pibrentasvir should be performed only by a physician experienced in the treatment of chronic hepatitis C.

4. Treatment costs

Annual treatment costs:

a) Patients with chronic hepatitis C aged 12 to < 18 years, genotype 1, 4, 5, or 6

Designation of the therapy	Annual treatment costs/patient
Medicinal product to be assessed:	
Glecaprevir/Pibrentasvir (8 weeks)	€ 29,986.46
Glecaprevir/Pibrentasvir (12 weeks)	€ 44,979.69
Appropriate comparator therapy:	
Ledipasvir/Sofosbuvir (8 weeks)	€ 29,986.46
Ledipasvir/Sofosbuvir (12 weeks)	€ 44,979.69
Ledipasvir/Sofosbuvir (24 weeks)	€ 89,959.38

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

Costs for additionally required SHI services: not applicable

b) Therapy-naïve patients with chronic hepatitis C aged 12 to < 18 years, genotype 2 or 3

Designation of the therapy	Annual treatment costs/patient
Medicinal product to be assessed:	
Glecaprevir/Pibrentasvir (8 weeks)	€ 29,986.46
Glecaprevir/Pibrentasvir (12 weeks)	€ 44,979.69
Glecaprevir/Pibrentasvir (16 weeks)	€ 59,972.92
Appropriate comparator therapy:	
Sofosbuvir + Ribavirin (12 weeks) Total:	€ 43,041.63 € 1,061.58 – € 1,769.30 € 44,103.21 – € 44,810.93
Sofosbuvir + Ribavirin (24 weeks) Total:	€ 86,083.26 € 2,123.16 – € 3,538.60 € 88,206.42 – € 89,621.86

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

Costs for additionally required SHI services: not applicable

II. The resolution will enter into force on the day of its publication on the internet on the website of the G-BA on 17 October 2019.

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

Berlin, 17 October 2019

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

Prof Hecken