

Resolution
by the Federal Joint Committee
on an amendment to the Pharmaceutical Directive (AM-RL):
Appendix XII – Resolutions on the benefit assessment of pharmaceuticals
with new active ingredients, in accordance with the German Social Code,
Book Five (SGB V), section 35a
Albiglutide

From 19 March 2015

In its session on 19 March 2015, the Federal Joint Committee resolved to amend the Pharmaceutical Directive (AM-RL), version published 18 December 2008/22 January 2009 (Federal Gazette, number 49a of 31 March 2009), last amended on 24 February 2015 (Federal Gazette, AT 27 March 2015 B2) as follows:

I.

Appendix XII shall be amended in alphabetical order to include the active ingredient albiglutide:

Albiglutide

Therapeutic indication:

Albiglutide (Eperzan[®]) is indicated for the treatment of type 2 diabetes mellitus in adults to improve glycaemic control as:

Monotherapy

When diet and exercise alone do not provide adequate glycaemic control in patients for whom use of metformin is considered inappropriate due to contraindications or intolerance.

Add-on therapy

In combination with other glucose-lowering medicinal products including basal insulin, when these, together with diet and exercise, do not provide adequate glycaemic control (see section 4.4 and 5.1 for available data on different combinations)¹.

1. Additional benefit of the pharmaceutical over appropriate comparator

- a) In monotherapy, when diet and exercise alone do not provide adequate glycaemic control in patients for whom use of metformin is considered inappropriate due to contraindications or intolerance

Appropriate comparator: A sulfonylurea
(glibenclamide or glimepiride)

Extent and probability of additional benefit of albiglutide over a sulfonylurea (glibenclamide or glimepiride):

An additional benefit has not been proved.

- b) In combination with other glucose-lowering medicinal products (except insulin), when these, together with diet and exercise, do not provide adequate glycaemic control

b1) In dual combination with metformin

Appropriate comparator:

Metformin + a sulfonylurea (glibenclamide or glimepiride)

(Please note: if metformin is inappropriate when used according to product information, human insulin is to be used as a treatment option)

¹ Eperzan[®] product information (effective: December 2014).

Extent and probability of additional benefit of albiglutide in combination with metformin over metformin and a sulfonylurea (glibenclamide or glimepiride):

Indication of a minor additional benefit.

b2) In dual combination with another glucose-lowering pharmaceutical other than metformin and insulin

Appropriate comparator:

Metformin + a sulfonylurea (glibenclamide or glimepiride)

(Please note: if metformin is inappropriate when used according to product information, human insulin is to be used as a treatment option)

Extent and probability of additional benefit of albiglutide in combination with another glucose-lowering pharmaceutical (other than metformin and insulin) over metformin and a sulfonylurea (glibenclamide or glimepiride):

An additional benefit has not been proved.

c) In combination with at least two other glucose-lowering medicinal products when these, together with diet and exercise, do not provide adequate glycaemic control

Appropriate comparator:

Metformin + human insulin

(Please note: therapy only with human insulin if metformin as used according to product information is insufficiently effective or not tolerated.)

Extent and probability of additional benefit of albiglutide in combination with at least two other glucose-lowering pharmaceuticals over metformin and human insulin:

An additional benefit has not been proved.

d) In combination with insulin (with or without an oral anti-diabetic medication)

Appropriate comparator:

Metformin + human insulin

(Please note: therapy only with human insulin if metformin as used according to product information is insufficiently effective or not tolerated.)

Extent and probability of additional benefit of albiglutide in combination with insulin (with or without an oral anti-diabetic medication) over metformin and human insulin:

An additional benefit has not been proved.

Study results according to endpoints:

a) In monotherapy, when diet and exercise alone do not provide adequate glycaemic control in patients for whom use of metformin is considered inappropriate due to contraindications or intolerance

No data were submitted.

b) In combination with other glucose-lowering medicinal products (except insulin), when these, together with diet and exercise, do not provide adequate glycaemic control

b1) In dual combination with metformin study

GLP 112753 (HARMONY 3)²

Endpoint category Endpoint ^a	Intervention albiglutide + metformin N=302 Patients with events n (%)	Control glimepiride + metformin N=307 Patients with events n (%)	Intervention vs. control RR [95% CI] p-value ^b
Mortality			
All-cause mortality	4 (1.3) ^c	6 (2.0) ^c	0.68 [0.19; 2.38] ^d 0.568
Morbidity			
Strokes (all, adjudged) ^e	3 (1.0)	1 (0.3)	3.05 [0.32; 29.15] 0.330

² Data from the IQWiG benefit assessment A 14-36 of 23 December 2014; study GLP 112753 (HARMONY 3); RCT, direct comparison: albiglutide + metformin vs. glimepiride + metformin.

Endpoint category Endpoint ^a	Intervention albiglutide + metformin N=302 Patients with events n (%)	Control glimepiride + metformin N=307 Patients with events n (%)	Intervention vs. control RR [95% CI] p-value ^b
Strokes (not fatal, adjudged) ^e	3 (1.0)	1 (0.3)	3.05 [0.32; 29.15] 0.330
Cardiac morbidity	12 (4.0)	5 (1.6)	2.44 [0.87; 6.84] ^d 0.081
Body weight	N=296 MV (SD) in kg	N=302 MV (SD) in kg	DM [95% CI] p-value ^f
Start of study	89.61 (18.38)	91.88 (20.51)	-2.37 [-3.03; -1.71] < 0.0001
Week 104	88.43 ^g (18.47)	93.03 ^g (20.77)	
Health-related quality of life			
Endpoint not ascertained			
Side effects			
AE	263 (87.1)	261 (85.0)	
SAE	44 (14.6)	36 (11.7)	1.24 [0.82; 1.87] ^d 0.309
Withdrawal due to AE	24 (7.9)	17 (5.5)	1.44 [0.79; 2.62] ^d 0.246
Severe hypoglycaemia	0 (0)	1 (0.3)	n.i. 0.343
Symptomatic hypoglycaemia (PG ≤ 54 mg/dl) ^h	3 (1.0)	24 (7.8)	0.13 [0.04; 0.42] < 0.001
Symptomatic hypoglycaemia (PG ≤ 70 mg/dl)	12 (4.0)	66 (21.5)	0.18 [0.10; 0.33] ^d < 0.001
Reactions at the injection site	55 (18.2)	26 (8.5)	2.15 [1.39; 3.33] ^d < 0.001

^a If not indicated otherwise, all events from the beginning and within 56 days after completion of treatment until week 164 are included.

^b IQWiG calculation, unconditioned exact test (CSZ method according to Martin Andrés A, Silva Mato A. Choosing the optimal unconditioned test for comparing two independent proportions. Computat Stat Data Anal 1994; 17(5): 555-574).

^c IQWiG calculation.

^d IQWiG calculation of effect estimates and confidence interval (asymptotic).

^e Events to the point in time at which all patients achieved week 104.

^f Effect estimates, confidence interval, and p-value result from an ANCOVA, adjusted for body weight, HbA1c category (< 8.0 %/≥ 8.0 %), prior myocardial infarctions (yes/no), age category (< 65/≥ 65 years) and region (ex-USA, USA north, USA south Atlantic, USA south central, USA west), each at study begin.

^g LOCF for missing post-baseline scores and body weights after emergency medication.

^h Events at least until week 104 irrespective of observations on and following emergency medication.

Abbreviations: ANCOVA: covariance analysis; HbA1c: glycohaemoglobin; n.i.: no information; CI: confidence interval; LOCF: last observation carried forward; MV: mean value, DM: difference of means; N: number of patients evaluated; n: number of patients with events; PG: plasma glucose; RCT: randomized controlled trial; RR: relative risk; SD: standard deviation; SAE: serious adverse event; AE: adverse event; vs: versus

b2) In dual combination with another glucose-lowering pharmaceutical other than metformin and insulin

No data were submitted.

c) In combination with at least two other glucose-lowering medicinal products when these, together with diet and exercise, do not provide adequate glycaemic control

No data were submitted.

d) In combination with insulin (with or without an oral anti-diabetic medication)

No data were submitted.

2. Number of patients and criteria for defining patients eligible for treatment

a) In monotherapy, when diet and exercise alone do not provide adequate glycaemic control in patients for whom use of metformin is considered inappropriate due to contraindications or intolerance

approx. 221,400 patients

b) In combination with other glucose-lowering medicinal products (except insulin), when these, together with diet and exercise, do not provide adequate glycaemic control

b1) In dual combination with metformin approx.

468,700 patients

b2) In dual combination with another glucose-lowering pharmaceutical other than metformin and insulin

approx. 35,900 patients (dual combination with a sulfonylurea)

c) In combination with at least two other glucose-lowering medicinal products when these, together with diet and exercise, do not provide adequate glycaemic control

approx. 77,400 patients

d) In combination with insulin (with or without an oral anti-diabetic medication)

approx. 450,000 – 650,000 patients

3. Requirements for quality-assured administration

The specifications outlined in the product information are to be followed. The European Medicines Agency (EMA), the European regulatory authority, provides the product information for Eperzan® (active ingredient: albiglutide) at the following public link (last accessed: 10 February 2015):

http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/002735/WC500165117.pdf

The use of GLP1 receptor antagonists (including albiglutide) is associated with a risk of developing acute pancreatitis. Patients must be informed of the characteristic symptoms of acute pancreatitis.

According to an EMA statement on pancreatic cancer in the context of a GLP1-based therapy (including albiglutide), although clinical data do not indicate an increased risk of these substances, an evaluation of the risk cannot be made at this time due to the short duration of the study and the low number of cases.

4. Costs of treatment

a) In monotherapy, when diet and exercise alone do not provide adequate glycaemic control in patients for whom use of metformin is considered inappropriate due to contraindications or intolerance

Duration of treatment:

Description of therapy	Mode of treatment	Number of treatments per patient	Duration per treatment (days)	Number of treatment days per patient per
Pharmaceutical evaluated (albiglutide)				
Albiglutide	ongoing, 1 x weekly ³	ongoing	1	52
Appropriate comparator (sulfonylurea (glibenclamide or glimepiride))				
Glibenclamide or	ongoing, 1 – 2 x daily	ongoing	365	365
glimepiride	ongoing, 1 x daily	ongoing	365	365

³ Subcutaneous application.

Consumption:

Description of therapy	Strength	Number/amount per pack ⁴	Average annual consumption
Pharmaceutical evaluated (albiglutide)			
Albiglutide	30 or 50 mg	3 x 4 pens	52 pens
Appropriate comparator (sulfonylurea (glibenclamide or glimepiride))			
Glibenclamide ⁵ or glimepiride	3.5 mg 1 – 6 mg	180 tablets 180 tablets	182,5 – 1,095 tablets 365 tablets

Costs:

Cost of pharmaceutical:

Description of therapy	Cost (pharmacy retail price)	Cost after legally mandated rebates
Pharmaceutical evaluated (albiglutide)		
Albiglutide 30 mg or 50 mg	€356.14	€335.26 [€1.77 ⁶ ; €19.11 ⁷]
Appropriate comparator (sulfonylurea (glibenclamide or glimepiride))		
Glibenclamide ⁸ or glimepiride ⁸	€14.93 €16.87 – 82.53	€12.85 [€1.77 ⁶ ; €0.31 ⁷] €14.63 – 75.10 [€1.77 ⁶ ; €0.47 – 5.66 ⁷]

"Lauer-Taxe", effective: 1 March 2015

Costs for additional, necessary SHI benefits: none

Annual treatment costs:

Description of therapy	Annual treatment costs per patient
Pharmaceutical evaluated (albiglutide)	
Albiglutide	€1,452.79
Appropriate comparator (sulfonylurea (glibenclamide or glimepiride))	
Glibenclamide or glimepiride	€13.03 – 78.17 €29.67 – 152.29

b) In combination with other glucose-lowering medicinal products (except insulin), when these, together with diet and exercise, do not provide adequate glycaemic control

b1) In dual combination with metformin

Duration of treatment:

Description of therapy	Mode of treatment	Number of treatments per patient per year	Duration per treatment (days)	Number of treatment days per patient
Pharmaceutical evaluated (albiglutide in combination with metformin)				
Albiglutide	ongoing, 1 x weekly ³	ongoing	1	52
Metformin	ongoing, 2 – 3 x daily	ongoing	365	365
Appropriate comparator metformin + sulfonylurea (glibenclamide or glimepiride)				
Glibenclamide or glimepiride	ongoing, 1 – 2 x daily	ongoing	365	365
glimepiride	ongoing, 1 x daily	ongoing	365	365
Metformin	ongoing, 2 – 3 x daily	ongoing	365	365

⁴ Largest pack.

⁵ Calculation is based on a strength of 3.5 mg. Dosage according to product information 1.75 – 10.5 mg.

⁶ Rebate in accordance with SGB V, section 130.

⁷ Rebate in accordance with SGB V, section 130a.

⁸ Reference price.

Consumption:

Description of therapy	Strength	Number/amount per pack ⁴	Average annual consumption
Pharmaceutical evaluated (albiglutide in combination with metformin)			
Albiglutide	30 or 50 mg	3 x 4 pens	52 pens
Metformin ⁹	1,000 mg	180 tablets	365 – 1,095 tablets
Appropriate comparator metformin + sulfonyleurea (glibenclamide or glimepiride)			
Glibenclamide ⁵ or glimepiride	3.5 mg 1 – 6 mg	180 tablets 180 tablets	182,5 – 1,095 tablets 365 tablets
Metformin ⁹	1,000 mg	180 tablets	365 – 1,095 tablets

Costs:

Cost of pharmaceutical:

Description of therapy	Cost (pharmacy retail price)	Cost after legally mandated rebates
Pharmaceutical evaluated (albiglutide in combination with metformin)		
Albiglutide 30 mg or 50 mg	€356.14	€335.26 [€1.77 ⁶ ; €19.11 ⁷]
Metformin ⁸	€18.78	€16.39 [€1.77 ⁶ ; €0.62 ⁷]
Appropriate comparator metformin + sulfonyleurea (glibenclamide or glimepiride)		
Glibenclamide ⁸ or glimepiride ⁸	€14.93 €16.87 – 82.53	€12.85 [€1.77 ⁶ ; €0.31 ⁷] €14.63 – 75.10 [€1.77 ⁶ ; €0.47 – 5.66 ⁷]
Metformin ⁸	€18.78	€16.39 [€1.77 ⁶ ; €0.62 ⁷]

“Lauer-Taxe”, effective: 1 March 2015

Costs for additional, necessary SHI benefits: none

Annual treatment costs:

Description of therapy	Annual treatment costs per patient
Pharmaceutical evaluated (albiglutide in combination with metformin)	
Albiglutide + metformin	€1,486.03 – 1,552.50
Appropriate comparator metformin + sulfonyleurea (glibenclamide or glimepiride)	
Glibenclamide + metformin or glimepiride + metformin	€46.27 – 177.88 €62.91 – 252.00

b2) In dual combination with another glucose-lowering pharmaceutical other than metformin and insulin

Duration of treatment:

Description of therapy	Mode of treatment	Number of treatments per patient	Duration per treatment (days)	Number of treatment days per patient per year
Pharmaceutical evaluated (albiglutide in combination with another glucose-lowering pharmaceutical besides metformin and insulin) ¹⁰				
Albiglutide	ongoing, 1 x weekly ³	ongoing	1	52

⁹ Calculation is based on a strength of 1,000 mg. Dosage according to product information 1,000 – 3,000 mg.

¹⁰ The combination with a sulfonyleurea is shown as an example of a combination therapy with another glucose-lowering pharmaceutical besides metformin and insulin.

Description of therapy	Mode of treatment	Number of treatments per patient	Duration per treatment (days)	Number of treatment days per patient per
Glibenclamide or glimepiride	ongoing, 1 – 2 x daily	ongoing	365	365
	ongoing, 1 x daily	ongoing	365	365
Appropriate comparator metformin + sulfonyleurea (glibenclamide or glimepiride))				
Glibenclamide or glimepiride	ongoing, 1 – 2 x daily	ongoing	365	365
	ongoing, 1 x daily	ongoing	365	365
Metformin	ongoing, 2 – 3 x daily	ongoing	365	365

Consumption:

Description of therapy	Strength	Number/amount per pack ⁴	Average annual consumption
Pharmaceutical evaluated (albiglutide in combination with another glucose-lowering pharmaceutical besides metformin and insulin) ¹⁰			
Albiglutide	30 or 50 mg	3 x 4 pens	52 pens
Glibenclamide ⁵ or glimepiride	3.5 mg 1 – 6 mg	180 tablets 180 tablets	182,5 – 1,095 tablets 365 tablets

Appropriate comparator metformin + sulfonyleurea (glibenclamide or glimepiride))

Glibenclamide ⁵ or glimepiride	3.5 mg 1 mg – 6 mg	180 tablets 180 tablets	182,5 – 1,095 tablets 365 tablets
Metformin ⁹	1,000 mg	180 tablets	365 – 1,095 tablets

Costs:

Cost of pharmaceutical:

Description of therapy	Cost (pharmacy retail price)	Cost after legally mandated rebates
Pharmaceutical evaluated (albiglutide in combination with another glucose-lowering pharmaceutical besides metformin and insulin) ¹⁰		
Albiglutide 30 mg or 50 mg	€356.14	€335.26 [€1.77 ⁶ ; €19.11 ⁷]
Glibenclamide ⁸ or Glimepiride ⁸	€14.93 €16.87 – 82.53	€12.85 [€1.77 ⁶ ; €0.31 ⁷] €14.63 – 75.10 [€1.77 ⁶ ; €0.47 – 5.66 ⁷]

Appropriate comparator metformin + sulfonyleurea (glibenclamide or glimepiride))

Glibenclamide ⁸ or glimepiride ⁸	€14.93 €16.87 – 82.53	€12.85 [€1.77 ⁶ ; €0.31 ⁷] €14.63 – 75.10 [€1.77 ⁶ ; €0.47 – 5.66 ⁷]
Metformin ⁸	€18.78	€16.39 [€1.77 ⁶ ; €0.62 ⁷]

“Lauer-Taxe”, effective: 1 March 2015

Costs for additional, necessary SHI benefits: none

Annual treatment costs:

Description of therapy	Annual treatment costs per patient
Pharmaceutical evaluated (albiglutide in combination with another glucose-lowering pharmaceutical besides metformin and insulin) ¹⁰	
Albiglutide + glibenclamide or albiglutide + glimepiride	€1,465.82 – 1,530.96 €1,482.46 – 1,605.08
Appropriate comparator metformin + sulfonyleurea (glibenclamide or glimepiride))	
Glibenclamide + metformin or glimepiride + metformin	€46.27 – 177.88 €62.91 – 252.00

c) In combination with at least two other glucose-lowering medicinal products when these, together with diet and exercise, do not provide adequate glycaemic control

Duration of treatment:

Description of therapy	Mode of treatment	Number of treatments per patient	Duration per treatment (days)	Number of treatment days per patient per
Pharmaceutical evaluated (albiglutide as a combination therapy with at least two other glucose-lowering pharmaceuticals) ¹¹				
Albiglutide	ongoing, 1 x weekly ³	ongoing	1	52
Glibenclamide or Glimepiride	ongoing, 1 – 2 x daily ongoing, 1 x daily	ongoing ongoing	365 365	365 365
Metformin	ongoing, 2 – 3 x daily	ongoing	365	365
Appropriate comparator (metformin + human insulin; therapy only with human insulin if metformin is insufficiently effective or not tolerated)				
Human insulin (NPH insulin)	ongoing, 1 – 2 x daily	ongoing	365	365
Metformin	ongoing, 2 – 3 x daily	ongoing	365	365
Therapy only with human insulin if metformin is insufficiently effective or not tolerated				
Conventional insulin therapy (combination insulin)	ongoing, 1 – 2 x daily	ongoing	365	365

Consumption:

Description of therapy	Strength	Number/amount per pack ⁴	Average annual consumption
Pharmaceutical evaluated (albiglutide as a combination therapy with at least two other glucose-lowering pharmaceuticals) ¹¹			
Albiglutide	30 or 50 mg	3 x 4 pens	52 pens
Glibenclamide ⁵ or glimepiride	3.5 mg 1 – 6 mg	180 tablets 180 tablets	182,5 – 1,095 tablets 365 tablets
Metformin ⁹	1,000 mg	180 tablets	365 – 1,095 tablets
Appropriate comparator (metformin + human insulin; therapy only with human insulin if metformin is insufficiently effective or not tolerated)			
Human insulin (NPH insulin) ¹²	100 IU/ml	3,000 IU	13,924.75 – 27,849.50 IU
Metformin	1,000 mg	180 tablets	365 – 1,095 tablets
Therapy only with human insulin if metformin is insufficiently effective or not tolerated			

¹¹ The combination with a sulfonyleurea and metformin is shown as an example of combination therapy with at least two other glucose-lowering medicinal products.

¹² Average insulin need: 0.5 – 1 IU/kg BW/day; reference body weight: 76.3 kg BW ("microcensus 2013").

Description of therapy	Strength	Number/amount per pack ⁴	Average annual consumption
Conventional insulin therapy (combination insulin) ¹²	100 IU/ml	3,000 IU	13,924.75 – 27,849.50 IU

Costs:

Cost of pharmaceutical:

Description of therapy	Cost (pharmacy retail price)	Cost after legally mandated rebates
Pharmaceutical evaluated (albiglutide as a combination therapy with at least two other glucose-lowering pharmaceuticals) ¹¹		
Albiglutide 30 mg or 50 mg	€356.14	€335.26 [€1.77 ⁶ ; €19.11 ⁷]
Glibenclamide ⁸ or glimepiride ⁸	€14.93 €16.87 – 82.53	€12.85 [€1.77 ⁶ ; €0.31 ⁷] €14.63 - 75.10 [€1.77 ⁶ ; €0.47 – 5.66 ⁷]
Metformin ⁸	€18.78	€16.39 [€1.77 ⁶ ; €0.62 ⁷]
Appropriate comparator (metformin + human insulin; therapy only with human insulin if metformin is insufficiently effective or not tolerated)		
Human insulin (NPH insulin) ⁸	€89.64	€81.65 [€1.77 ⁶ ; €6.22 ⁷]
Metformin ⁸	€18.78	€16.39 [€1.77 ⁶ ; €0.62 ⁷]
Therapy only with human insulin if metformin is insufficiently effective or not tolerated		
Conventional insulin therapy (combination insulin) ⁸	€89.64	€81.65 [€1.77 ⁶ ; €6.22 ⁷]

"Lauer-Taxe", effective: 1 March 2015

Costs for additional, necessary statutory health insurance (SHI) benefits:

Description of therapy	Additional necessary SHI expense items				
	Designation	Cost/pack ¹³	Number/day	Consumption/year	Cost/year
Appropriate comparator Human insulin plus metformin (or treatment only with human insulin)	Blood sugar strips	€12.00	1 – 3	365 – 1,095	€87.60 – €262.80
	Lancets	€3.80	1 – 3	365 – 1,095	€6.94 – 20.80
	Single-use needles	€22.80	1 – 2	365 – 730	€83.22 – 166.44

Annual treatment costs:

Description of therapy	Annual treatment costs per patient
Pharmaceutical evaluated (albiglutide as a combination therapy with at least two other glucose-lowering pharmaceuticals) ¹¹	
Albiglutide + metformin + glibenclamide or albiglutide + glimepiride	€1,499.06 – 1,630.67 €1,515.70 – 1,704.79
Appropriate comparator (metformin + human insulin; therapy only with human insulin if metformin is insufficiently effective or not tolerated)	
Human insulin (NPH insulin) + metformin	€412.22 – €857.68
Therapy only with human insulin if metformin is insufficiently effective or not tolerated	
Conventional insulin therapy (combination insulin)	€378.99 – 757.97

¹³ Number of test strips/pack = 50; Number of lancets/pack = 200; Number of single-use needles/pack = 100; least expensive pack according to "Lauer-Taxe"; effective: 1 March 2015.

Description of therapy	Annual treatment costs per patient
Costs for additional, necessary SHI benefits:	
Blood sugar test strips	€87.60 – 262.80
Lancets	€6.94 – 20.80
Single-use needles	€83.22 – 166.44

d) In combination with insulin (with or without an oral anti-diabetic medication) Duration of treatment:

Description of therapy	Mode of treatment	Number of treatments per patient per year	Duration per treatment (days)	Number of treatment days per patient per year
Pharmaceutical evaluated (albiglutide as a combination therapy with insulin (with or without an oral anti-diabetic medication)) ¹⁴				
Albiglutide	ongoing, 1 x weekly ³	ongoing	1	52
Human insulin (NPH insulin)	ongoing, 1 – 2 x daily	ongoing	365	365
Metformin	ongoing, 2 – 3 x daily	ongoing	365	365

Appropriate comparator (human insulin with metformin; therapy only with human insulin if metformin is insufficiently effective or not tolerated)

Human insulin (NPH insulin)	ongoing, 1 – 2 x daily	ongoing	365	365
Metformin	ongoing, 2 – 3 x daily	ongoing	365	365

Therapy only with human insulin if metformin is insufficiently effective or not tolerated

Conventional insulin therapy (combination insulin)	ongoing, 1 – 2 x daily	ongoing	365	365
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Consumption:

Description of therapy	Strength	Number/amount per pack ⁴	Average annual consumption
Pharmaceutical evaluated (albiglutide as a combination therapy with insulin (with or without an oral anti-diabetic medication)) ¹⁴			
Albiglutide	30 or 50 mg	3 x 4 pens	52 pens
Human insulin (NPH insulin) ¹²	100 IU/ml	3,000 IU	13,924.75 – 27,849.50 IU
Metformin ⁹	1,000 mg	180 tablets	365 – 1,095 tablets

Appropriate comparator (human insulin with metformin; therapy only with human insulin if metformin is insufficiently effective or not tolerated)

Human insulin (NPH insulin) ¹²	100 IU/ml	3,000 IU	13,924.75 – 27,849.50 IU
Metformin ⁹	1,000 mg	180 tablets	365 – 1,095 tablets

Therapy only with human insulin if metformin is insufficiently effective or not tolerated

Conventional insulin therapy (combination insulin) ¹²	100 IU/ml	3,000 IU	13,924.75 – 27,849.50 IU
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¹⁴ Metformin is named as an example of an additional anti-diabetic medication.

Costs:

Cost of pharmaceutical:

Description of therapy	Cost (pharmacy retail price)	Cost after legally mandated rebates
Pharmaceutical evaluated (albiglutide as a combination therapy with insulin (with or without an oral anti-diabetic medication)) ¹⁴		
Albiglutide 30 mg or 50 mg	€356.14	€335.26 [€1.77 ⁶ ; €19.11 ⁷]
Human insulin (NPH insulin) ⁸	€89.64	€81.65 [€1.77 ⁶ ; €6.22 ⁷]
Metformin ⁸	€18.78	€16.39 [€1.77 ⁶ ; €0.62 ⁷]
Appropriate comparator (human insulin with metformin; therapy only with human insulin if metformin is insufficiently effective or not tolerated)		
Human insulin (NPH insulin) ⁸	€89.64	€81.65 [€1.77 ⁶ ; €6.22 ⁷]
Metformin ⁸	€18.78	€16.39 [€1.77 ⁶ ; €0.62 ⁷]
Therapy only with human insulin if metformin is insufficiently effective or not tolerated		
Conventional insulin therapy (combination insulin) ⁸	€89.64	€81.65 [€1.77 ⁶ ; €6.22 ⁷]

"Lauer-Taxe", effective: 1 March 2015

Costs for additional, necessary SHI benefits: none

Annual treatment costs:

Description of therapy	Annual treatment costs per patient
Pharmaceutical evaluated (albiglutide as a combination therapy with insulin (with or without an oral anti-diabetic medication)) ¹⁴	
Albiglutide + human insulin (NPH insulin) or albiglutide + human insulin (NPH insulin) + metformin	€1,831.70 – 2,210.76 €1,865.01 – 2,310.47
Appropriate comparator (human insulin with metformin; therapy only with human insulin if metformin is insufficiently effective or not tolerated)	
Human insulin (NPH insulin) + metformin	€412.22 – €857.68
Therapy only with human insulin if metformin is insufficiently effective or not tolerated	
Conventional insulin therapy (combination insulin)	€378.99 – 757.97

II.

This resolution takes effect on the day of its publication in the internet on the website of the Federal Joint Committee on 19 March 2015.

The justification for this resolution will be published on the websites of the Federal Joint Committee at www.g-ba.de.

Berlin, 19 March 2015

The Federal Joint Committee in
accordance with SGB V,
section 91

The Chair
Prof. Hecken

Resolution
by the Federal Joint Committee
on an amendment to the Pharmaceutical Directive (AM-RL):
Appendix XII – Resolutions on the benefit assessment of pharmaceuticals
with new active ingredients, in accordance with the German Social Code,
Book Five (SGB V), section 35a
Albiglutide

From 16 July 2015

In its session on 16 July 2015, the Federal Joint Committee resolved to amend the Pharmaceutical Directive (AM-RL), version published 18 December 2008/22 January 2009 (Federal Gazette, number 49a of 31 March 2009), last amended on 18 June 2015 (Federal Gazette, AT 01.09.2015 B3), as follows:

I.

In appendix XII, the information on the benefit assessment of the active ingredient albiglutide shall be amended in point "2. Number of patients and criteria for defining patients groups eligible for treatment" as follows:

1. In subsection a, the information on the number of patients shall be replaced by the following:
approx. 522,500 patients
2. In subsection b1, the information on the number of patients shall be replaced by the following:
approx. 634,500 patients
3. In subsection c, the information on the number of patients shall be replaced by the following:
approx. 62,500 patients

II.

This resolution takes effect on the day of its publication in the internet on the website of the Federal Joint Committee on 16 July 2015.

The justification for this resolution will be published on the website of the Federal Joint Committee at www.g-ba.de.

Berlin, 16 July 2015

The Federal Joint Committee in
accordance with SGB V,
section 91

The Chair
Prof. Hecken
