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 Voretigene Neparvovec

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. Annex XII shall be amended in alphabetical order to include the active ingredient voretigene neparvovec as follows:

Voretigene Neparvovec

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

Therapeutic indication (according to the marketing authorisation of 22 November 2018):

Luxturna is indicated for the treatment of adult and paediatric patients with vision loss due to inherited retinal dystrophy caused by confirmed biallelic *RPE65* mutations and who have sufficient viable retinal cells.

1. Extent and probability of the additional benefit of the medicinal product

Voretigene neparvovec is approved as a medicinal product for the treatment of rare diseases in accordance with Regulation (EC) No. 141/2000 of the European Parliament and the Council of 16 December 1999 on orphan drugs. According to Section 35a, paragraph 1, sentence 11, 1st half of the sentence German Social Code, Book Five (SGB V), the additional medical benefit is considered to be proven through the grant of the marketing authorisation.

The Federal Joint Committee (G-BA) determines the extent of the additional benefit for the number of patients and patient groups for which there is a therapeutically significant additional benefit in accordance with Chapter 5, Section 12, paragraph 1, number 1, sentence 2 of its Rules of Procedure (VerfO) in conjunction with Section 5, paragraph 8 AM-NutzenV, indicating the significance of the evidence. This quantification of the additional benefit is based on the criteria laid out in Chapter 5, Section 5, paragraph 7, numbers 1 to 4 of the Rules of Procedure (VerfO).

Adult and paediatric patients with vision loss due to inherited retinal dystrophy caused by confirmed biallelic *RPE65* mutations and who have sufficient viable retinal cells

Extent and probability of the additional benefit of voretigene neparvovec:

Hint for a considerable additional benefit

Study results according to endpoints:[1]

Study 301: randomised, controlled, open-label Phase III study: Voretigene neparvovec vs monitoring wait-and-see approach

Study 301 Endpoint category Endpoint	Voretigene neparvovec		Monitoring wait-and-see approach		Voretigene neparvovec vs monitoring wait-and-see approach
	N	Patients with event n (%)	N	Patients with event n (%)	RR [95% CI]; p value
Mortality					

[1] Data from the dossier evaluation by the G-BA (published on 15 July 2019) and from the amendment unless indicated otherwise.

Study 301 Endpoint category Endpoint	Voretigene neparvovec		Monitoring wait-and-see approach		Voretigene neparvovec vs monitoring wait-and-see approach
	N	Patients with event n (%)	N	Patients with event n (%)	RR [95% CI]; p value
no deaths[a]					

Study 301 Endpoint category Endpoint	Voretigene neparvovec				Monitoring wait-and-see approach				Voretigene neparvovec vs monitoring wait-and-see approach
	N[b] Baseline (N Year 1)	Score baseline MV (SD) *Median (min; max)*	Score Year 1T[c] MV (SD)	Changes from baseline MV (SD) *Median (min; max)*	N[b] Baseline (N Year 1)	Score baseline MV (SD) *Median (min; max)*	Score Year 1C[c] MV (SD)	Changes from baseline MV (SD) *Median (min; max)*	Change[d] [95% CI]; exact p value[e]
Morbidity (ITT population)									
Multi-luminance mobility test (MLMT)									
Change in MLMT score[f] for both eyes (bilateral)	21 (21)	3.1 (1.7) *No data available*	4.9 (2.0)	1.8 (1.1) *2 (0; 4)*	10 (10)	2.9 (1.6) *No data available*	3.2 (1.8)	0.2 (1.0) *0 (−1; 2)*	1.6 [0.7; 2.4]; 0.001[g] SMD[x] according to Hedges' g: 1.50 [0.66; 2.34]

Study 301 Endpoint category Endpoint	Voretigene neparvovec				Monitoring wait-and-see approach				Voretigene neparvovec vs monitoring wait-and-see approach
	N baseline (N Year 1)	Score baseline MV (SE)	Score Year 1 MV (SE)	Changes from baseline MV (SE)	N baseline (N Year 1)	Score baseline MV (SE)	Score Year 1 MV (SE)	Changes from baseline MV (SE)	Mean change[h] [95% CI]; p value
Morbidity									
Full-field light sensitivity threshold test (FST)[i,j]									
White light (log10(cd*s/m²))[k] (ITT population)	20[j] (19)	−1.29 (0.09)	−3.36 (0.28)	−2.08 (0.29)	9[j] (9)	−1.65 (0.14)	−1.61 (0.42)	0.04 (0.44)	−2.11 [−3.19; −1.04]; < 0.001 SMD[l] according to Hedges' g: −1.52 [−2.41; −0.63]
Blue light (log10(cd*s/m²)) (mITT population)	20[m] (17[n])	−1.64 (0.11)	−3.61 (0.30)	−1.97 (0.34)	9[m] (9[n])	−1.99 (0.17)	−1.87 (0.44)	0.13 (0.49)	−2.10 [−3.32; −0.88]; 0.001
Red light (log10(cd*s/m²)) (mITT population)	20[m] (17[n])	−1.21 (0.11)	-2.51 (0.18)	−1.30 (0.17)	9[m] (9[n])	−1.69 (0.16)	−1.53 (0.26)	0.16 (0.24)	−1.46 [−2.06, −0.87]; < 0.001
Visual acuity[o] (logMAR) (ITT population)									
ETDRS/HOTV eye chart	21 (20)	1.18 (0.14)	1.03 (0.17)	−0.16 (0.07)	10 (9)	1.29 (0.21)	1.3 (0.25)	0.01 (0.10)	−0.16 [−0.41; 0.08][p]; Exact p value[q]: 0.170

Endpoint category Endpoint Study	Voretigene neparvovec		Monitoring wait-and-see approach		Voretigene neparvovec vs monitoring wait-and-see approach
	N	Patients with event n (%)	N	Patients with event n (%)	Relative risk difference [95% CI]; p value
Visual acuity (ITT population)					
Improvement of visual acuity (≥ 10 letters ETDRS)	18	6	8	0	0.33 [−0.05; 0.60]; 0.071

Study 301 **Endpoint category** **Endpoint**	**Voretigene neparvovec**				**Monitoring wait-and-see approach**				**Voretigene neparvovec vs monitoring wait-and-see approach**
	N Baseline **(N Year 1)**	**Score baseline** **MV (SD)** ***Median (min; max)***	**Score Year 1T[c]** **MV (SD)** ***Median (min; max)***	**Mean change from baseline**	**N Baseline** **(N Year 1)**	**Score baseline** **MV (SD)** ***Median (min; max)***	**Score Year 1T[c]** **MV (SD)** ***Median (min; max)***	**Mean change from baseline**	**Difference change[s] [95% CI][t]; p value**
Morbidity									
Visual field measurement using perimetry[r] (ITT population)									

Goldmann: III4e (sum score)[u]	20[v] (20)	332.9 (413.3) *153 (0; 1418)*	673.9 (423.7) *592.0 (0; 1405)*	302.1 (289.6)	10 (9)	427.1 (372.0) *372 (0;1042)*	397.8 (367.3) *349.0 (45; 1114)*	−76.7 (258.7)	378.7 [145.5; 612.0]; 0.006 SMD[w] according to Hedges' g: 1.27, 95% CI [0.41; 2.12]
Humphrey: Fovea sensitivity (dB)	20 (20)	22.4 (6.8) *24 (5; 32)*	25.8 (9.1) *30 (0; 37)*	2.4 (9.7)	10 (9)	17.6 (8.9) *17 (3; 28)*	21.5 (8.9) *26 (6; 31)*	2.3 (5.3)	0.04 [−7.1; 7.2]; 0.18
Humphrey: Average macular limit (dB)	20 (20)	16.1 (5.5) *15 (8;26)*	24.0 (8.0) *28 (2; 32)*	7.7 (6.2)	10 (9)	14.4 (8.0) *16 (0; 22)*	15.8 (7.4) *16 (2; 25)*	−0.2 (1.7)	7.9 [3.5; 12.2]; < 0.001 SMD[w,x] according to Hedges' g: 1.45, 95% CI [0.61; 2.29]

Study 301 **Endpoint category** **Endpoint**	**Voretigene neparvovec**		**Monitoring wait-and-see approach**		**Voretigene neparvovec vs monitoring wait-and-see approach**
	N	**Patients with event n (%)**	**N**	**Patients with event n (%)**	**RR [95% CI]; p value**
Health-related quality of life					
Visual function questionnaire					
No suitable data were submitted.					

Study 301 Endpoint category Endpoint	Voretigene neparvovec[y]		Monitoring wait-and-see approach[y]		Voretigene neparvovec vs monitoring wait-and-see approach
	N	Patients with event n (%)	N	Patients with event n (%)	RR [95% CI][z]; p value[aa]
Side effects (at year 1 after baseline) (safety population)					
AE	20	20 (100)	9	9 (100)	-
AE ≥ grade 3[ab]	20	11 (55.0)	9	2 (22.2)	2.48 [0.80; 24.37]; 0.130
Severe AE[ac]	20	3 (15.0)	9	0 (0.0)	no data available[ab,ad]
SAE	20	2 (10.0)	9	0 (0.0)	no data available[ad]; 1,000
AE leading to termination of study	20	0 (0.0)	9	0 (0.0)	n.c.
AE leading to death[ae]	20	0 (0.0)	9	0 (0.0)	n.c.

a: The survey was carried out within the framework of safety.
b: Missing values for year 1 for persons who were eliminated before application of the test medication were imputed with 0.
c: Primary endpoint.
d: The difference between the mean changes observed and the baseline was calculated. The pharmaceutical company uses a mixed model to calculate the 95% CI; this includes terms for treatment and study rounds (or according to external SAP, time and treatment). Specific information on the statistical model (e.g. on the covariance structure) could not be identified.
e: A Wilcoxon rank sum test with exact bilateral p value was used to investigate the change at Year 1 compared with baseline between treatment groups.
f: A higher value in the mobility score means an improvement in the MLMT.
g: A p value of 0.002 is given in the dossier.
h: The mean change and p value were computed with an MMRM with the terms treatment, study round, and treatment*study round.
i: For both treatment groups, the average was averaged over both eyes.
j: The more negative the value, the better the light sensitivity.
k: Secondary endpoint
l: SMD according to Hedges' g was calculated for the endpoint FST with white light *post hoc* for Module 4.
m: In accordance with the pharmaceutical company, the analysis should be based on the ITT population. It remains unclear why data are missing for one person in each treatment group.
n: It was not possible to identify why results for Year 1 were reported by only 17 persons in the intervention group and 9 persons in the control group.
o: For both treatment groups, the average was averaged over both eyes.
p: The mean change and p value were computed with an MMRM with the terms treatment, study round, and treatment*study round.
q: A p value of 0.175 is given in the dossier.
r: For both treatment groups, the average was averaged over both eyes.
s: The difference between the mean changes observed and the baseline was calculated. A mixed model was used to calculate the 95% CI; this includes terms for treatment and study rounds.
t: The two-sided p value was calculated *post hoc* using the Wilcoxon rank sum test. No imputations were performed for missing values.
u: Size of stimulus III4e: Size: 4 mm^2, brightness: 315 cd/m^2
v: For one person in the intervention group, no reliable test results could be obtained for baseline for both perimetry tests.
w: The SMD and Hedges' g were calculated post-hoc for the dossier
x: The SMD was presented only in the written statements. An output file of the statistics program used was not submitted for verification.
y: Different start of the survey period between the two groups: In the intervention group, the survey began from the first injection; in the control group, it began from the baseline examination.
z: Effect estimator calculated *post hoc* by the pharmaceutical company using a four-field table. The CI was calculated with an exact method (tail method).
aa: The p value was value calculated *post hoc* using the exact Fischer test.
ab: A summary of the AE ≥ grade 3 is given in the dossier. Further information on the specific AE could not be identified.
ac: Only severe but not mild or moderate AE were presented.
ad: No effect estimators were calculated by the pharmaceutical company.
ae: Because deaths were recorded as AEs and were not defined as a separate endpoint, they are presented under safety.

Abbreviations:
dB: decibel; FST: full-field stimulus testing; ITT: intention to treat; Year 1T: Year 1 after treatment of the second eye in the intervention group; Year 1C: Year 1 after baseline in the control group; CI: confidence interval; MLMT: Multi-luminance mobility test; MMRM: Model for Repeated Measures; n.c.: not calculable; RR: relative risk; SAP: statistical analysis plan; SD: standard deviation; SE: standard error; SMD: standardised mean difference, (S)AE: (serious) adverse events

Study 301 **MedDRA System Organ Class** Preferred Term	**Voretigene neparvovec[y]**		**Monitoring wait-and-see approach[y]**		**Voretigene neparvovec vs monitoring wait-and-see approach**
	N	**Patients with event n (%)**	**N**	**Patients with event n (%)**	**RR [95% CI][z]; p value[aa]**
AE with an incidence ≥ 10% in one of the study arms and > 1 event within one year after baseline (safety population)					
Blood and lymphatic system disorders	20	9 (45.0)	9	0 (0.0)	No data available[ad]
Leukocytosis	20	9 (45.0)	9	0 (0.0)	

Study 301 MedDRA System Organ Class Preferred Term	Voretigene neparvovec[y]		Monitoring wait-and-see approach[y]		Voretigene neparvovec vs monitoring wait-and-see approach
	N	Patients with event n (%)	N	Patients with event n (%)	RR [95% CI][z]; p value[aa]
Eye disorders	20	10 (50.0)	9	1 (11.1)	4.50 [0.95; 124.40]; 0.096
Cataracts	20	3 (15.0)	9	0 (0.0)	
Eye inflammations	20	2 (10.0)	9	0 (0.0)	
Retinal tear	20	2 (10.0)	9	0 (0.0)	
Gastrointestinal disorders	20	12 (60.0)	9	3 (33.0)	1.80 [0.76; 9.21] 0.245
Upper abdominal pain	20	2 (10.0)	9	0 (0.0)	
Diarrhoea	20	2 (10.0)	9	1 (11.1)	
Nausea	20	6 (30.0)	9	1 (11.1)	
Vomiting	20	8 (40.0)	9	2 (22.2)	
General disorders and administration site conditions	20	10 (50.0)	9	1 (11.1)	4.50 [0.95; 124.40] 0.096
Reactions to the test medication	20	2 (10.0)	9	0 (0.0)	
Fever	20	7 (35.0)	9	1 (11.1)	
Infections and infestations	20	11 (55.0)	9	4 (44.4)	1.24 [0.57; 6.56] 0.700
Ear infection	20	1 (5.0)	9	1 (11.1)	
Nasopharyngitis	20	7 (35.0)	9	2 (22.2)	
Upper respiratory tract infections	20	2 (10.0)	9	3 (33.3)	
Injury, poisoning, and procedural complications	20	5 (25.0)	9	2 (22.2)	1.13 [0.26; 7.34] 1.000
Animal bite	20	2 (10.0)	9	0 (0.0)	
Investigations	20	7 (35.0)	9	1 (11.0)	3.15 [0.60; 82.84] 0.3715
Increased intraocular pressure	20	4 (20.0)	9	0 (0.0)	
Musculoskeletal and connective tissue disorders	20	1 (5.0)	9	1 (11.1)	0.45 [0.01; 14.86] 0.532

Study 301 MedDRA System Organ Class Preferred Term	Voretigene neparvovec[y]		Monitoring wait-and-see approach[y]		Voretigene neparvovec vs monitoring wait-and-see approach
	N	Patients with event n (%)	N	Patients with event n (%)	RR [95% CI][z]; p value[aa]
Nervous system disorders	20	10 (50.0)	9	3 (33.3)	1.50 [0.60; 6.61] 0.453
Headaches	20	7 (35.0)	9	2 (22.2)	
Psychiatric disorders	20	2 (10.0)	9	1 (11.1)	0.90 [0.08; 24.37] 1.000
Renal and urinary disorders	20	3 (15.0)	9	1 (11.1)	1.35 [0.15; 34.78] 1.000
Haematuria	20	3 (15.0)	9	1 (11.1)	
Reproductive system and breast disorders	20	3 (15.0)	9	0 (0.0)	no data available
Respiratory, thoracic and mediastinal disorders	20	10 (50.0)	9	5 (55.6)	0.90 [0.43; 2.49] 1.000
Coughing	20	6 (30.0)	9	1 (11.0)	
Nosebleeds	20	2 (10.0)	9	0 (0.0)	
Congested nose	20	2 (10.0)	9	0 (0.0)	
Oropharyngeal pain	20	6 (30.0)	9	4 (44.0)	
Skin and subcutaneous tissue disorders	20	2 (10.0)	9	1 (11.1)	0.90 [0.08; 24.37] 1.000
Vascular disorders	20	1 (5.0)	9	1 (11.1)	0.45 [0.01; 14.86] 0.532
High blood pressure	20	1 (5.0)	9	1 (11.1)	

Study 301 **MedDRA System Organ Class** Preferred Term	**Voretigene neparvovec[y]**		**Monitoring wait-and-see approach[y]**		**Voretigene neparvovec vs monitoring wait-and-see approach**
	N	**Patients with event n (%)**	**N**	**Patients with event n (%)**	**RR [95% CI][z]; p value[aa]**
SAE with an incidence ≥ 5% in one of the study arms and > 1 event within one year after baseline (safety population)					
Gastrointestinal disorders	20	2 (10.0)	9	0 (0.0)	No data available
Nausea	20	2 (10.0)	9	0 (0.0)	
Vomiting	20	2 (10.0)	9	0 (0.0)	
General disorders and administration site conditions	20	2 (10.0)	9	0 (0.0)	No data available
Reaction to the medicinal product	20	2 (10.0)	9	0 (0.0)	

Study 301 **MedDRA System Organ Class** Preferred Term	**Voretigene neparvovec[y]**		**Monitoring wait-and-see approach[y]**		**Voretigene neparvovec vs monitoring wait-and-see approach**
	N	**Patients with event n (%)**	**N**	**Patients with event n (%)**	**RR [95% CI][z]; p value[aa]**
SAE with an incidence ≥ 5% in one of the study arms and > 1 event within one year after baseline (safety population)					
General disorders and administration site conditions	20	2 (10.0)	9	0 (0.0)	No data available
Reaction to the medicinal product	20	2 (10.0)	9	0 (0.0)	

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

Adult and paediatric patients with vision loss due to inherited retinal dystrophy caused by confirmed biallelic *RPE65* mutations and who have sufficient viable retinal cells

Approx. 100–530 patients

3. Requirements for a quality-assured application

A. Regulatory requirements for marketing authorisation

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 Luxturna® (active ingredient: voretigene neparvovec) at the following publicly accessible link (last access: 8 October 2019):
https://www.ema.europa.eu/documents/product-information/luxturna-epar-product-information_de.pdf

Treatment with voretigene neparvovec must be performed by retinal surgeons experienced in performing macular surgery.

In accordance with the specifications of the European Medicines Agency (EMA) regarding additional measures for risk minimisation, the pharmaceutical company must provide training material for medical professionals (e.g. retinal surgeons and pharmacists) and a patient ID card. The training material contains, in particular, instructions for the preparation and implementation of the intraocular, subretinal application of voretigene neparvovec in an operating field under anaesthesia.
The Risk Management Plan (RMP) stipulates that the training material for healthcare professionals should contain relevant information on the preparation, storage, and use of voretigene neparvovec, including a description of the materials and subretinal administration.

Qualification and availability of medical and non-medical staff

In order to minimise the safety risks associated with treatment with voretigene neparvovec, it should be ensured that treatment facilities preparing and administering the voretigene neparvovec treatment meet the criteria approved by the EMA, which is to be implemented in accordance with the risk management plan. The staff involved in the administration (i.e. vitreoretinal surgeons and pharmacists) have participated in a compulsory training programme on the use of voretigene neparvovec to ensure the correct use of voretigene neparvovec and thus minimise the risks (increased intraocular pressure, retinal tear, macular diseases, cataract, intraocular inflammation and/or infection associated with the procedure and retinal detachment, transmission through third parties) associated with its administration and/or the administration procedure.

The criteria for treatment centres should include the following:

- Presence of a specialist ophthalmologist with expertise in the care and treatment of patients with hereditary retinal dystrophy.
- Presence or affiliation with a retinal surgeon experienced in subretinal surgery and qualified to administer voretigene neparvovec.
- An anti-inflammatory medication should be prescribed in accordance with the product information.
- The interval for treatment of the second eye should be planned according to the product information.

<u>B. Further requirements for the quality-assured application of voretigene neparvovec in qualified treatment facilities</u>

According to the current state of medical knowledge, the following requirements for the implementation of treatment should be considered in addition to the requirements in the product information and of the European Medicines Agency (EMA) with regard to additional risk minimisation measures:

Indication before the therapy is carried out

All of the following conditions should be met prior to therapy with voretigene neparvovec:

- The diagnosis of retinal dystrophy is clinically proven.
- Sequence variants homozygous or compound heterozygous biallelic in the gene *RPE65* are verified as the cause of disease. Ideally, proof should be provided by segregation analysis of the parents.
- It is ensured that sufficient target cells are available to ensure therapeutic benefit.
- The patient and, if necessary, the legal guardians were individually informed about the natural course of the disease, the prognosis of the planned therapy, and the risk profile of the therapy as well as about any other therapies.

Implementation of the therapy

All of the following clinical conditions should be met when conducting therapy with voretigene neparvovec:

- In particular, the doctor should have experience with vitrectomies in the respective age group of the patients. For the treatment of children, the doctor should have experience in paediatric ophthalmology.
- The doctor should also have experience in subretinal surgery in patients with advanced retinal dystrophy or other degenerative diseases of the retina.
- An accumulation of Luxturna™ in the vitreous cavity and thus the risk of lower bioavailability in the target tissue and/or higher systemic biodistribution should be avoided.
- If children are treated, an anaesthetist experienced in paediatric anaesthesia should be available.

All of the following technical conditions should be met when conducting therapy with voretigene neparvovec:

- The formal training for the preparation and surgical application of voretigene neparvovec by the manufacturer has been completed.
- The equipment for regular storage and preparation of the injection solution is available.
- The active ingredient is stored at temperatures below −60°C until application, and the cold chain is guaranteed.
- Voretigene neparvovec is prepared for use under aseptic conditions and in a sterile manner by trained staff using dual control.
- The entire surgical team is trained in handling substances of biological protection level 1.
- The application corresponds to the specifications of the manufacturer or the company selling the product.
- The disposal of the virus solution and the surface disinfection of the operating theatre is carried out according to the local regulations as well as the current recommendations of the Robert Koch Institute.
- Availability of a pharmacy capable of processing and manufacturing AAV vector-based gene therapy products.

After-care

All of the following conditions should be met in the after-care of patients after treatment with voretigene neparvovec:

- All side effects are recorded in a registry study.
- The treatment of complications is carried out by the initial treating physician or with his/her involvement.
- The clinical examination and testing of visual functions are performed under standardised conditions.
- In order to assess the success of the therapy, at least the best corrected visual acuity and global retinal sensitivity (FST) as well as OCT and FAF scans should be performed pre-operatively and post-operatively.

The regulations according to Section 136a SGB V remain unaffected by this.

4. Treatment costs

Annual treatment costs:

Adult and paediatric patients with vision loss due to inherited retinal dystrophy caused by confirmed biallelic *RPE65* mutations and who have sufficient viable retinal cells

Designation of the therapy	Annual treatment costs/patient (for both eyes)
Voretigene neparvovec	€ 821,100
Vitrectomy, including subretinal injection	approx. € 5,700[2]
Pre- and postoperative immunomodulatory treatment with prednisone	€ 18.05
Additionally required SHI services	Non-quantifiable[3]

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 October 2019

II. Entry into force

1. 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.

2. The period of validity of the resolution is limited to 31 December 2021.

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

[2] The costs for an inpatient procedure are shown as follows.

[3] At the time of the decision, part of the pre- and postoperative controls (e.g. optical coherence tomography (OCT)) cannot be calculated using the uniform rating scale (EBM). The resulting costs are thus non-quantifiable. Because of the individual determination of the intervals for control examinations by the treating physician, the costs incurred for all therapy options cannot be quantified. The sub-retinal application of voretigene neparvovec is also currently not quantifiable.

Berlin, 17 October 2019

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

Prof Hecken