Gemeinsamer Bundesausschuss

# Resolution

of the Federal Joint Committee on an Amendment of the Pharmaceuticals Directive:
Annex XII – Benefit Assessment of Medicinal Products with New Active Ingredients according to Section 35a SGB V

Repotrectinib (solid tumours, NTRK gene fusion, ≥ 12 years)

of 16 October 2025

At their session on 16 October 2025, the Federal Joint Committee (G-BA) resolved to amend the 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 by the publication of the resolution of D 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 Repotrectinib as follows:**

**Repotrectinib**

Resolution of: 16 October 2025
Entry into force on: 16 October 2025
Federal Gazette, BAnz AT DD. MM YYYY Bx

**Therapeutic indication (according to the marketing authorisation of 13 January 2025):**

AUGTYRO as monotherapy is indicated for the treatment of adult and paediatric patients 12 years of age and older with advanced solid tumours expressing a NTRK gene fusion, and

- who have received a prior NTRK inhibitor, or
- have not received a prior NTRK inhibitor and treatment options not targeting NTRK provide limited clinical benefit, or have been exhausted

**Therapeutic indication of the resolution (resolution of 16 October 2025):**

See therapeutic indication according to marketing authorisation.

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

a) Adults and adolescents 12 years of age and older with advanced solid tumours expressing a neurotrophic tyrosine receptor kinase (NTRK) gene fusion, and who have not received a prior NTRK inhibitor and treatment options not targeting NTRK provide limited clinical benefit, or have been exhausted

**Appropriate comparator therapy:**

Individualised therapy with selection of

- Larotrectinib
- Entrectinib
- Best supportive care

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

An additional benefit is not proven.

b) Adults and adolescents 12 years of age and older with advanced solid tumours expressing a neurotrophic tyrosine receptor kinase (NTRK) gene fusion, and who have received a prior NTRK inhibitor

**Appropriate comparator therapy:**

- Best supportive care

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

An additional benefit is not proven.

**Study results according to endpoints:**[1]

a) Adults and adolescents 12 years of age and older with advanced solid tumours expressing a neurotrophic tyrosine receptor kinase (NTRK) gene fusion, and who have not received a prior NTRK inhibitor and treatment options not targeting NTRK provide limited clinical benefit, or have been exhausted

There are no assessable data.

**Summary of results for relevant clinical endpoints**

| Endpoint category | Direction of effect/ risk of bias | Summary |
|---|---|---|
| Mortality | n.a. | There are no assessable data. |
| Morbidity | n.a. | There are no assessable data. |
| Health-related quality of life | n.a. | There are no assessable data. |
| Side effects | n.a. | There are no assessable data. |
| Explanations:<br>↑: statistically significant and relevant positive effect with low/unclear reliability of data<br>↓: statistically significant and relevant negative effect with low/unclear reliability of data<br>↑↑: statistically significant and relevant positive effect with high reliability of data<br>↓↓: statistically significant and relevant negative effect with high reliability of data<br>↔: no statistically significant or relevant difference<br>∅: No data available.<br>n.a.: not assessable | | |

b) Adults and adolescents 12 years of age and older with advanced solid tumours expressing a neurotrophic tyrosine receptor kinase (NTRK) gene fusion, and who have received a prior NTRK inhibitor

There are no assessable data.

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A25-58) unless otherwise indicated.

**Summary of results for relevant clinical endpoints**

| Endpoint category | Direction of effect/ risk of bias | Summary |
|---|---|---|
| Mortality | n.a. | There are no assessable data. |
| Morbidity | n.a. | There are no assessable data. |
| Health-related quality of life | n.a. | There are no assessable data. |
| Side effects | n.a. | There are no assessable data. |
| Explanations:<br>↑: statistically significant and relevant positive effect with low/unclear reliability of data<br>↓: statistically significant and relevant negative effect with low/unclear reliability of data<br>↑↑: statistically significant and relevant positive effect with high reliability of data<br>↓↓: statistically significant and relevant negative effect with high reliability of data<br>↔: no statistically significant or relevant difference<br>∅: No data available.<br>n.a.: not assessable | | |

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

a) Adults and adolescents 12 years of age and older with advanced solid tumours expressing a neurotrophic tyrosine receptor kinase (NTRK) gene fusion, and who have not received a prior NTRK inhibitor and treatment options not targeting NTRK provide limited clinical benefit, or have been exhausted

Approx. 330 – 560 patients

b) Adults and adolescents 12 years of age and older with advanced solid tumours expressing a neurotrophic tyrosine receptor kinase (NTRK) gene fusion, and who have received a prior NTRK inhibitor

Approx. 60 – 210 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 Augtyro (active ingredient: repotrectinib) at the following publicly accessible link (last access: 7 October 2025):

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

Treatment with repotrectinib should only be initiated and monitored by specialists experienced in the treatment of adult and paediatric patients with solid tumours, specifically in the treatment of the respective tumour entity, and other doctors from other specialist groups participating in the Oncology Agreement.

Prior to initiation of treatment with repotrectinib, the presence of an NTRK gene fusion in a tumour sample must be confirmed by a validated test.

This medicinal product received a conditional marketing authorisation. This means that further evidence of the benefit of the medicinal product is anticipated. The European Medicines Agency will evaluate new information on this medicinal product at a minimum once per year and update the product information where necessary.

## 4. Treatment costs

**Annual treatment costs:**

The costs for the first year of treatment are shown for the cost representation in the resolution.

a) Adults and adolescents 12 years of age and older with advanced solid tumours expressing a neurotrophic tyrosine receptor kinase (NTRK) gene fusion, and who have not received a prior NTRK inhibitor and treatment options not targeting NTRK provide limited clinical benefit, or have been exhausted

| Designation of the therapy | Annual treatment costs/ patient |
|---|---|
| Medicinal product to be assessed: | |
| Repotrectinib | € 115,083.04 |
| Appropriate comparator therapy: | |
| Entrectinib | € 42,346.25 – € 63,519.37 |
| Larotrectinib | € 66,642.09 |
| Best supportive care[2] | Different from patient to patient |

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 August 2025)

Costs for additionally required SHI services: not applicable

b) Adults and adolescents 12 years of age and older with advanced solid tumours expressing a neurotrophic tyrosine receptor kinase (NTRK) gene fusion, and who have received a prior NTRK inhibitor

| Designation of the therapy | Annual treatment costs/ patient |
|---|---|
| Medicinal product to be assessed: | |
| Repotrectinib | € 115,083.04 |
| Best supportive care | Different from patient to patient |
| Appropriate comparator therapy: | |

[2] When comparing repotrectinib versus best supportive care, the costs of best supportive care must also be additionally considered for the medicinal product to be assessed.

| Designation of the therapy | Annual treatment costs/ patient |
|---|---|
| Best supportive care | Different from patient to patient |

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 August 2025)

Costs for additionally required SHI services: not applicable

## 5. Designation of medicinal products with new active ingredients according to Section 35a, paragraph 3, sentence 4 SGB V that can be used in a combination therapy with the assessed medicinal product

In the context of the designation of medicinal products with new active ingredients pursuant to Section 35a, paragraph 3, sentence 4 SGB V, the following findings are made:

a) Adults and adolescents 12 years of age and older with advanced solid tumours expressing a neurotrophic tyrosine receptor kinase (NTRK) gene fusion, and who have not received a prior NTRK inhibitor and treatment options not targeting NTRK provide limited clinical benefit, or have been exhausted

   – No designation of medicinal products with new active ingredients that can be used in combination therapy pursuant to Section 35a, paragraph 3, sentence 4 SGB V, as the active ingredient to be assessed is an active ingredient authorised in monotherapy.

b) Adults and adolescents 12 years of age and older with advanced solid tumours expressing a neurotrophic tyrosine receptor kinase (NTRK) gene fusion, and who have received a prior NTRK inhibitor

   – No designation of medicinal products with new active ingredients that can be used in combination therapy pursuant to Section 35a, paragraph 3, sentence 4 SGB V, as the active ingredient to be assessed is an active ingredient authorised in monotherapy.

The designation of combinations exclusively serves the implementation of the combination discount according to Section 130e SGB V between health insurance funds and pharmaceutical companies. The findings made neither restrict the scope of treatment required to fulfil the medical treatment mandate, nor do they make statements about expediency or economic feasibility.

## 6. Percentage of study participants at study sites within the scope of SGB V in accordance with Section 35a, paragraph 3, sentence 5 SGB V

The medicinal product repotrectinib (Augtyro) is a medicinal product placed on the market from 1 January 2025.

No information was provided on the number of study participants involved in the clinical studies of the medicinal product in the therapeutic indication under assessment, which were conducted or commissioned by the pharmaceutical company at study sites within the scope of SGB V and/or on the total number of study participants.

Due to the absence of information, it is therefore not possible to determine that the percentage of study participants reached or exceeded the relevance threshold of at least 5 per cent.

The clinical studies of the medicinal product in the therapeutic indication to be assessed were therefore not conducted to a relevant extent within the scope of SGB V.

**II. The resolution will enter into force on the day of its publication on the website of the G-BA on 16 October 2025.**

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

Berlin, 16 October 2025

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

Prof. Hecken