Tislelizumab
(small cell lung cancer, extensive stage)

Benefit assessment according to §35a SGB V[1]

EXTRACT

Project: A25-118 Version: 1.0 Status: 17 Dec 2025 DOI: 10.60584/A25-118_en

[1] Translation of Sections I 1 to I 6 of the dossier assessment *Tislelizumab (kleinzelliges Lungenkarzinom, fortgeschritten) – Nutzenbewertung gemäß § 35a SGB V*. Please note: This translation is provided as a service by IQWiG to English-language readers. However, solely the German original text is absolutely authoritative and legally binding.

Publishing details

Publisher

Institute for Quality and Efficiency in Health Care

Topic

Tislelizumab (small cell lung cancer, extensive stage) – Benefit assessment according to §35a SGB V

Commissioning agency

Federal Joint Committee

Commission awarded on

18 September 2025

Internal Project No.

A25-118

DOI-URL

https://doi.org/10.60584/A25-118_en

Address of publisher

Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen
Siegburger Str. 237
50679 Köln
Germany

Phone:+49 221 35685-0
Fax: +49 221 35685-1
E-mail: berichte@iqwig.de
Internet: www.iqwig.de

Recommended citation

Institute for Quality and Efficiency in Health Care. Tislelizumab (small cell lung cancer, extensive stage); Benefit assessment according to §35a SGB V; Extract [online]. 2025 [Accessed: DD.MM.YYYY]. URL: https://doi.org/10.60584/A25-118_en.

Keywords

Tislelizumab, Small Cell Lung Carcinoma, Benefit Assessment

Medical and scientific advice

No advisor on medical and scientific questions was involved in the present dossier assessment.

Patient and family involvement

No patients or families were involved in the present dossier assessment.

IQWiG employees involved in the dossier assessment

- Ulrike Mikulić
- Simon Bogner
- Katharina Hirsch
- Thomas Jakubeit
- Maximilian Kind
- Christopher Kunigkeit
- Torben Lütkehermölle
- Katrin Nink
- Sabine Ostlender

Part I: Benefit assessment

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[2] Table numbers start with “2” as numbering follows that of the full dossier assessment.

I List of abbreviations

Abbreviation	Meaning
ACT	appropriate comparator therapy
ES-SCLC	extensive-stage small cell lung cancer
G-BA	Gemeinsamer Bundesausschuss (Federal Joint Committee)
IQWiG	Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (Institute for Quality and Efficiency in Health Care)
RCT	randomized controlled trial
SGB	Sozialgesetzbuch (Social Code Book)

I 1 Executive summary of the benefit assessment

Background

In accordance with §35a Social Code Book V, the Federal Joint Committee (G-BA) commissioned the Institute for Quality and Efficiency in Health Care (IQWiG) to assess the benefit of the drug tislelizumab. The assessment is based on a dossier compiled by the pharmaceutical company (hereinafter referred to as the 'company'). The dossier was sent to IQWiG on 18 September 2025.

Research question

The aim of this report is to assess the added benefit of tislelizumab, in combination with etoposide and platinum chemotherapy, in comparison with the appropriate comparator therapy (ACT) for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC).

The research question shown in Table 2 was defined in accordance with the ACT specified by the Federal Joint Committee (G-BA).

Table 2: Research questions for the benefit assessment of tislelizumab in combination with etoposide and platinum chemotherapy

Therapeutic indication	**ACT**[a]
Adult patients with ES-SCLC in combination with etoposide and platinum-based chemotherapy for first-line treatment[b]	▪ atezolizumab in combination with carboplatin and etoposide or ▪ durvalumab in combination with carboplatin and etoposide or ▪ durvalumab in combination with cisplatin and etoposide
a. Presented is the ACT specified by the G-BA. b. It is assumed that intensive antineoplastic combination therapy is suitable for the patients. ACT: appropriate comparator therapy; ES-SCLC: extensive-stage small cell lung cancer; G-BA: Federal Joint Committee	

The company followed the G-BA's specification of the ACT.

The assessment was conducted by means of patient-relevant outcomes on the basis of the data provided by the company in the dossier. Randomized controlled trials (RCTs) were used to derive the added benefit.

Results

A review of the information retrieval identified no relevant studies for assessing the added benefit of tislelizumab in combination with etoposide and platinum chemotherapy.

Results on added benefit

Since no relevant study was available for the benefit assessment, there is no hint of an added benefit of tislelizumab, in combination with etoposide and platinum chemotherapy, in comparison with the ACT; an added benefit is not proven.

Probability and extent of added benefit, patient groups with therapeutically important added benefit[3]

Table 3 shows a summary of the probability and extent of the added benefit of tislelizumab, in combination with etoposide and platinum chemotherapy.

Table 3: Tislelizumab in combination with etoposide and platinum chemotherapy – probability and extent of added benefit

Therapeutic indication	ACT[a]	Probability and extent of added benefit
Adult patients with ES-SCLC in combination with etoposide and platinum-based chemotherapy for first-line treatment[b]	▪ atezolizumab in combination with carboplatin and etoposide or ▪ durvalumab in combination with carboplatin and etoposide or ▪ durvalumab in combination with cisplatin and etoposide	Added benefit not proven
a. Presented is the ACT specified by the G-BA. b. It is assumed that intensive antineoplastic combination therapy is suitable for the patients. ACT: appropriate comparator therapy; ES-SCLC: extensive-stage small cell lung cancer; G-BA: Federal Joint Committee		

The G-BA decides on the added benefit.

[3] On the basis of the scientific data analysed, IQWiG draws conclusions on the (added) benefit or harm of an intervention for each patient-relevant outcome. Depending on the number of studies analysed, the certainty of their results, and the direction and statistical significance of treatment effects, conclusions on the probability of (added) benefit or harm are graded into 4 categories: (1) “proof”, (2) “indication”, (3) “hint”, or (4) none of the first 3 categories applies (i.e., no data available or conclusions 1 to 3 cannot be drawn from the available data). The extent of added benefit or harm is graded into 3 categories: (1) major, (2) considerable, (3) minor (in addition, 3 further categories may apply: non-quantifiable extent of added benefit, added benefit not proven, or less benefit). For further details see [1,2].

I 2 Research question

The aim of this report is to assess the added benefit of tislelizumab, in combination with etoposide and platinum chemotherapy, in comparison with the appropriate comparator therapy (ACT) for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC).

The research question shown in Table 4 was defined in accordance with the ACT specified by the G-BA.

Table 4: Research questions for the benefit assessment of tislelizumab in combination with etoposide and platinum chemotherapy

Therapeutic indication	**ACT**[a]
Adult patients with ES-SCLC in combination with etoposide and platinum-based chemotherapy for first-line treatment[b]	▪ atezolizumab in combination with carboplatin and etoposide or ▪ durvalumab in combination with carboplatin and etoposide or ▪ durvalumab in combination with cisplatin and etoposide
a. Presented is the ACT specified by the G-BA. b. It is assumed that intensive antineoplastic combination therapy is suitable for the patients. ACT: appropriate comparator therapy; ES-SCLC: extensive-stage small cell lung cancer; G-BA: Federal Joint Committee	

The company followed the G-BA's specification of the ACT.

The assessment was conducted by means of patient-relevant outcomes on the basis of the data provided by the company in the dossier. Randomized controlled trials (RCTs) were used to derive the added benefit. This concurred with the company's inclusion criteria.

I 3 Information retrieval and study pool

The study pool for the assessment was compiled on the basis of the following information:

Sources used by the company in the dossier:

- Study list on tislelizumab (status: 20 August 2025)
- Bibliographical literature search on tislelizumab (last search on 20 August 2025)
- Search of trial registries / trial results databases for studies on tislelizumab (last search on 12 August 2025)
- Search on the G-BA website for tislelizumab (last search on 11 August 2025)

To check the completeness of the study pool:

- Search of trial registries for studies on tislelizumab (last search on 8 October 2025); for search strategies, see I Appendix A of the full dossier assessment

Concurring with the company, this review did not identify any relevant studies.

In Module 4 A, the company presented the pivotal study RATIONALE 312 [3] without using it for the derivation of the added benefit. The RATIONALE 312 study is a double-blind RCT comparing tislelizumab versus placebo, each in combination with etoposide and a platinum derivative (cisplatin or carboplatin). Adult patients with ES-SCLC who had not yet received prior systemic treatment for ES-SCLC were included.

The therapy used in the comparator arm of the RATIONALE 312 study was a pure cytostatic chemotherapy without an immunotherapeutic component and thus did not correspond to the G-BA's ACT.

There were no suitable data for the comparison of tislelizumab in combination with etoposide and platinum chemotherapy versus the comparator therapy specified by the G-BA.

I 4 Results on added benefit

No suitable data were available to assess the added benefit of tislelizumab in combination with etoposide and platinum chemotherapy in comparison with the ACT for the first-line treatment of adult patients with ES-SCLC. There is no hint of an added benefit of tislelizumab in comparison with the ACT; an added benefit is therefore not proven.

I 5 Probability and extent of added benefit

Table 5 summarizes the result of the assessment of added benefit of tislelizumab in combination with etoposide and platinum chemotherapy in comparison with the ACT.

Table 5: Tislelizumab in combination with etoposide and platinum chemotherapy – probability and extent of added benefit

Therapeutic indication	**ACT**[a]	**Probability and extent of added benefit**
Adult patients with ES-SCLC in combination with etoposide and platinum-based chemotherapy for first-line treatment[b]	▪ atezolizumab in combination with carboplatin and etoposide or ▪ durvalumab in combination with carboplatin and etoposide or ▪ durvalumab in combination with cisplatin and etoposide	Added benefit not proven
a. Presented is the ACT specified by the G-BA. b. It is assumed that intensive antineoplastic combination therapy is suitable for the patients. ACT: appropriate comparator therapy; ES-SCLC: extensive-stage small cell lung cancer; G-BA: Federal Joint Committee		

The company also did not derive an added benefit.

The G-BA decides on the added benefit.

I 6 References for English extract

Please see full dossier assessment for full reference list.

1. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen. Allgemeine Methoden; Version 7.0 [online]. 2023 [Accessed: 02.09.2025]. URL: https://www.iqwig.de/methoden/allgemeine-methoden_version-7-0.pdf.

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The full report (German version) is published under https://www.iqwig.de/en/projects/a25-118.html.