Drug assessment at a glance: A25-160[1]

Nipocalimab (generalized myasthenia gravis)

20 July 2026

[1] This is a courtesy translation of the summary provided as a service by IQWiG. For further information on the subject matter and the result of the assessment, please refer to the dossier assessment for Project A25-160. The G-BA decides on the added benefit.

Research question 1 of the benefit assessment

Population	Adults with anti-AChR antibody-positive generalized myasthenia gravis for whom add-on therapy to standard treatment is an option
Intervention	nipocalimab
Comparator	eculizumab (for refractory patients) or efgartigimod alfa or ravulizumab or rozanolixizumab or zilucoplan
Outcomes	At least one patient-relevant outcome

Overview of positive and negative effects – research question 1

	Size of the effects	Informative value of the effects
Mortality	∅	–
Morbidity	∅	–
Symptoms	∅	–
Health-related quality of life	∅	–
Side effects	∅	–
	∅ No (suitable) data ↔ No advantage or disadvantage ↑ / ↓ Small advantage/disadvantage ↑↑ / ↓↓ Moderate advantage/disadvantage ↑↑↑ / ↓↓↓ Large advantage/disadvantage	– Not applicable ★ Low ★★ Moderate ★★★ High

Overall: No advantage or disadvantage (no data)

Evidence base and noteworthy aspects – research question 1

- No relevant study was identified.

Research question 2 of the benefit assessment

Population	Adults with anti-MuSK antibody-positive generalized myasthenia gravis for whom add-on therapy to standard treatment is an option
Intervention	nipocalimab
Comparator	rozanolixizumab
Outcomes	At least one patient-relevant outcome

Overview of positive and negative effects – research question 2

	Size of the effects	Informative value of the effects
Mortality	∅	–
Morbidity	∅	–
Symptoms	∅	–
Health-related quality of life	∅	–
Side effects	∅	–
	∅ No (suitable) data ↔ No advantage or disadvantage ↑ / ↓ Small advantage/disadvantage ↑↑ / ↓↓ Moderate advantage/disadvantage ↑↑↑ / ↓↓↓ Large advantage/disadvantage	– Not applicable ★ Low ★★ Moderate ★★★ High

Overall: No advantage or disadvantage (no data)

Evidence base and noteworthy aspects – research question 2

- No relevant study was identified.

Research question 3 of the benefit assessment

Population	Adolescents (12 to 17 years) with anti-AChR antibody-positive refractory generalized myasthenia gravis for whom add-on therapy to standard treatment is an option
Intervention	nipocalimab
Comparator	eculizumab
Outcomes	At least one patient-relevant outcome

Overview of positive and negative effects – research question 3

	Size of the effects	Informative value of the effects
Mortality	∅	–
Morbidity	∅	–
Symptoms	∅	–
Health-related quality of life	∅	–
Side effects	∅	–
	∅ No (suitable) data ↔ No advantage or disadvantage ↑ / ↓ Small advantage/disadvantage ↑↑ / ↓↓ Moderate advantage/disadvantage ↑↑↑ / ↓↓↓ Large advantage/disadvantage	– Not applicable ★ Low ★★ Moderate ★★★ High

Overall: No advantage or disadvantage (no data)

Evidence base and noteworthy aspects – research question 3

- No relevant study was identified.

Research question 4 of the benefit assessment

Population	Adolescents (12 to 17 years) with anti-AChR antibody-positive nonrefractory generalized myasthenia gravis or with anti-MuSK antibody-positive generalized myasthenia gravis for whom add-on therapy to standard treatment is an option
Intervention	nipocalimab
Comparator	BSC
Outcomes	At least one patient-relevant outcome

Overview of positive and negative effects – research question 4

	Size of the effects	Informative value of the effects
Mortality	∅	–
Morbidity	∅	–
Symptoms	∅	–
Health-related quality of life	∅	–
Side effects	∅	–
	∅ No (suitable) data ↔ No advantage or disadvantage ↑ / ↓ Small advantage/disadvantage ↑↑ / ↓↓ Moderate advantage/disadvantage ↑↑↑ / ↓↓↓ Large advantage/disadvantage	– Not applicable ★ Low ★★ Moderate ★★★ High

Overall: No advantage or disadvantage (no suitable data)

Evidence base and noteworthy aspects – research question 4

- No suitable data were available.
- There is a randomized controlled trial, VIVACITY-MG3, comparing nipocalimab versus placebo – in each case as an add-on to current stable treatment – in adults. In addition, there is the single-arm VIBRANCE-MG study on nipocalimab in children and adolescents. Neither study was suitable for drawing conclusions regarding the added benefit of nipocalimab versus BSC in adolescents, as set out in research question 4.

References

Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen. Nipocalimab (generalisierte Myasthenia gravis); Nutzenbewertung gemäß § 35a SGB V; Dossierbewertung [online]. 2026 [Accessed: 22.06.2026]. URL: https://doi.org/10.60584/A25-160.

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English translations for this project are published at https://www.iqwig.de/en/projects/a25-160.html and https://www.iqwig.de/en/projects/a26-51.html.

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