Remdesivir (COVID-19, without supplemental oxygen, increased risk of progressing to severe COVID-19, ≥ 4 weeks, 3 to < 40 kg)

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

EXTRACT

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[1] Translation of Sections I 1 to I 6 of the dossier assessment *Remdesivir (COVID-19, ohne zusätzliche Sauerstoffzufuhr, erhöhtes Risiko für schweren Verlauf, ≥ 4 Wochen, 3 kg bis < 40 kg) – 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.

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Remdesivir, COVID-19, Infant, Child – Preschool, Child, 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.

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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
BSC	best supportive care
COVID-19	coronavirus disease 2019
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 remdesivir. 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 3 July 2025.

Research question

The aim of this report is to assess the added benefit of remdesivir in comparison with best supportive care (BSC) as the appropriate comparator therapy (ACT) in children and adolescents (at least 4 weeks of age and weighing 3 kg to < 40 kg) with coronavirus disease 2019 (COVID-19) who do not require supplemental oxygen and who are at increased risk of progressing to severe COVID-19. The assessment of remdesivir in children and adolescents ≥ 40 kg and in adults who do not require supplemental oxygen and who are at increased risk of progressing to severe COVID-19, has already been conducted in this therapeutic indication (see dossier assessments A22-112 and A22-04, as well as the G-BA's resolutions).

The research question shown in Table 2 was defined in accordance with the ACT specified by the G-BA.

Table 2: Research question for the benefit assessment of remdesivir

Therapeutic indication	**ACT[a]**
Children and adolescents (at least 4 weeks of age and weighing 3 kg to < 40 kg) with COVID-19[b] who do not require supplemental oxygen and who are at increased risk of progressing to severe COVID-19	BSC[c, d]

a. Presented is the ACT specified by the G-BA.
b. In case of a positive rapid antigen test, the diagnosis of SARS-CoV-2 infection should be confirmed by a PCR test, especially if the results have therapeutic consequences. It is recommended that relevant SARS-CoV-2 mutation variants (e.g. so-called VOCs) are also taken into account when recording and interpreting the results on efficacy.
c. According to the G-BA, BSC refers to the therapy that provides the patient with the best possible, individually optimized, supportive treatment to alleviate symptoms and improve the quality of life. According to the G-BA, BSC in the treatment of non-hospitalized patients should primarily involve symptomatic drug therapies (e.g. analgesics, antipyretics, thrombosis prophylaxis), depending on the severity of the disease and where indicated. The marketing authorizations of the treatment options must be taken into account.
d. Remdesivir should be used in patients at a stage of infection with mild to moderately symptomatic COVID-19, i.e. without requiring supplemental oxygen. According to the G-BA, therapeutic measures that are used at a later (possibly more severe) stage of the disease are therefore not addressed in the specification of the ACT. However, according to the G-BA, it is assumed that patients in the studies will also receive appropriate treatment in the event of disease progression and hospitalization. It is recommended that the therapies used in the study and other supportive measures are documented and presented in the dossier.

BSC: best supportive care; COVID-19: coronavirus disease 2019; G-BA: Federal Joint Committee; PCR: polymerase chain reaction; SARS-CoV-2: severe acute respiratory syndrome coronavirus 2; VOC: variants of concern

The company deviated from the ACT defined by the G-BA by considering an individualized treatment of physician's choice as the ACT. However, the company pointed out that there are currently no approved and available antiviral therapies for the treatment of the patient population covered by the research question. According to the S3 guideline 'Recommendations for the treatment of patients with COVID-19', none of the approved monoclonal antibodies is rated as clinically sufficiently effective, and antiviral agents should only be used in children and adolescents as part of an individual treatment attempt. The company explained that the therapy depends on the severity of the disease, whereby supportive measures are of great importance in any course of COVID-19.

The company's deviation remained without consequence for this benefit assessment, as the company neither presented suitable data versus the G-BA's comparator therapy nor versus the company's comparator therapy.

Results

Consistent with the findings of the company, the search did not identify any randomized controlled trials (RCTs) that would allow a direct comparison, or an adjusted indirect comparison using a common comparator, of remdesivir versus the ACT. Hence, there were no data for the assessment of remdesivir in comparison with the ACT.

Results on added benefit

No data were available to assess the added benefit of remdesivir in comparison with the ACT in children and adolescents (at least 4 weeks of age and weighing 3 kg to < 40 kg) with COVID-19 who do not require supplemental oxygen and who are at increased risk of progressing to severe COVID-19. There is no hint of an added benefit of remdesivir in comparison with the ACT; an added benefit is therefore not proven.

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

Table 3 shows a summary of probability and extent of the added benefit of remdesivir.

[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].

Table 3: Remdesivir – probability and extent of added benefit

Therapeutic indication	**ACT[a]**	**Probability and extent of added benefit**
Children and adolescents (at least 4 weeks of age and weighing 3 kg to < 40 kg) with COVID-19[b] who do not require supplemental oxygen and who are at increased risk of progressing to severe COVID-19	▪ BSC[c, d]	Added benefit not proven

a. Presented is the ACT specified by the G-BA.
b. In case of a positive rapid antigen test, the diagnosis of SARS-CoV-2 infection should be confirmed by a PCR test, especially if the results have therapeutic consequences. It is recommended that relevant SARS-CoV-2 mutation variants (e.g. so-called VOCs) are also taken into account when recording and interpreting the results on efficacy.
c. According to the G-BA, BSC refers to the therapy that provides the patient with the best possible, individually optimized, supportive treatment to alleviate symptoms and improve the quality of life. According to the G-BA, BSC in the treatment of non-hospitalized patients should primarily involve symptomatic drug therapies (e.g. analgesics, antipyretics, thrombosis prophylaxis), depending on the severity of the disease and where indicated. The marketing authorizations of the treatment options must be taken into account.
d. Remdesivir should be used in patients at a stage of infection with mild to moderately symptomatic COVID-19, i.e. without requiring supplemental oxygen. According to the G-BA, therapeutic measures that are used at a later (possibly more severe) stage of the disease are therefore not addressed in the specification of the ACT. However, according to the G-BA, it is assumed that patients in the studies will also receive appropriate treatment in the event of disease progression and hospitalization. It is recommended that the therapies used in the study and other supportive measures are documented and presented in the dossier.

BSC: best supportive care; COVID-19: coronavirus disease 2019; G-BA: Federal Joint Committee; PCR: polymerase chain reaction; SARS-CoV-2: severe acute respiratory syndrome coronavirus 2; VOC: variants of concern

The G-BA decides on the added benefit.

I 2 Research question

The aim of this report is to assess the added benefit of remdesivir in comparison with best supportive care (BSC) as the appropriate comparator therapy (ACT) in children and adolescents (at least 4 weeks of age and weighing 3 kg to < 40 kg) with coronavirus disease 2019 (COVID-19) who do not require supplemental oxygen and who are at increased risk of progressing to severe COVID-19. The assessment of remdesivir in children and adolescents ≥ 40 kg and in adults who do not require supplemental oxygen and who are at increased risk of progressing to severe COVID-19, has already been conducted in this therapeutic indication (see dossier assessments A22-112 [3] and A22-04 [4], as well as the G-BA's resolutions [5,6] and justifications [7,8]).

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

Table 4: Research question for the benefit assessment of remdesivir

Therapeutic indication	**ACT**[a]
Children and adolescents (at least 4 weeks of age and weighing 3 kg to < 40 kg) with COVID-19[b] who do not require supplemental oxygen and who are at increased risk of progressing to severe COVID-19	▪ BSC[c, d]

a. Presented is the ACT specified by the G-BA.
b. In case of a positive rapid antigen test, the diagnosis of SARS-CoV-2 infection should be confirmed by a PCR test, especially if the results have therapeutic consequences. It is recommended that relevant SARS-CoV-2 mutation variants (e.g. so-called VOCs) are also taken into account when recording and interpreting the results on efficacy.
c. According to the G-BA, BSC refers to the therapy that provides the patient with the best possible, individually optimized, supportive treatment to alleviate symptoms and improve the quality of life. According to the G-BA, BSC in the treatment of non-hospitalized patients should primarily involve symptomatic drug therapies (e.g. analgesics, antipyretics, thrombosis prophylaxis), depending on the severity of the disease and where indicated. The marketing authorizations of the treatment options must be taken into account.
d. Remdesivir should be used in patients at a stage of infection with mild to moderately symptomatic COVID-19, i.e. without requiring supplemental oxygen. According to the G-BA, therapeutic measures that are used at a later (possibly more severe) stage of the disease are therefore not addressed in the specification of the ACT. However, according to the G-BA, it is assumed that patients in the studies will also receive appropriate treatment in the event of disease progression and hospitalization. It is recommended that the therapies used in the study and other supportive measures are documented and presented in the dossier.

BSC: best supportive care; COVID-19: coronavirus disease 2019; G-BA: Federal Joint Committee; PCR: polymerase chain reaction; SARS-CoV-2: severe acute respiratory syndrome coronavirus 2; VOC: variants of concern

The company deviated from the ACT defined by the G-BA by considering an individualized treatment of physician's choice as the ACT. However, the company pointed out that there are currently no approved and available antiviral therapies for the treatment of the patient population covered by the research question. According to the S3 guideline 'Recommendations for the treatment of patients with COVID-19' [9], none of the approved

monoclonal antibodies is rated as clinically sufficiently effective, and antiviral agents should only be used in children and adolescents as part of an individual treatment attempt [10]. The company explained that the therapy depends on the severity of the disease, whereby supportive measures are of great importance in any course of COVID-19.

The company's deviation remained without consequence for this benefit assessment, as the company neither presented suitable data versus the G-BA's comparator therapy nor versus the company's comparator therapy.

The present assessment was carried out in comparison with the G-BA's current ACT. The assessment was conducted by means of patient-relevant outcomes on the basis of the data provided by the company in the dossier.

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 remdesivir (status: 8 May 2025)
- Bibliographical literature search on remdesivir (last search on 8 May 2025)
- Search of trial registries / trial results databases for studies on remdesivir (last search on 8 May 2025)

To check the completeness of the study pool:

- Search of trial registries for studies on remdesivir (last search on 22 July 2025); for search strategies, see I Appendix A of the full dossier assessment

Consistent with the findings of the company, the search did not identify any randomized controlled trials (RCTs) that would allow a direct comparison, or an adjusted indirect comparison using a common comparator, of remdesivir versus the ACT.

This means that overall no suitable data were available for the comparison of remdesivir with the G-BA's ACT.

I 4 Results on added benefit

No data were available to assess the added benefit of remdesivir in comparison with the ACT in children and adolescents (at least 4 weeks of age and weighing 3 kg to < 40 kg) with COVID-19 who do not require supplemental oxygen and who are at increased risk of progressing to severe COVID-19. There is no hint of an added benefit of remdesivir 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 the added benefit of remdesivir in comparison with the ACT.

Table 5: Remdesivir – probability and extent of added benefit

Therapeutic indication	**ACT[a]**	**Probability and extent of added benefit**
Children and adolescents (at least 4 weeks of age and weighing 3 kg to < 40 kg) with COVID-19[b] who do not require supplemental oxygen and who are at increased risk of progressing to severe COVID-19	▪ BSC[c, d]	Added benefit not proven

a. Presented is the ACT specified by the G-BA.
b. In case of a positive rapid antigen test, the diagnosis of SARS-CoV-2 infection should be confirmed by a PCR test, especially if the results have therapeutic consequences. It is recommended that relevant SARS-CoV-2 mutation variants (e.g. so-called VOCs) are also taken into account when recording and interpreting the results on efficacy.
c. According to the G-BA, BSC refers to the therapy that provides the patient with the best possible, individually optimized, supportive treatment to alleviate symptoms and improve the quality of life. According to the G-BA, BSC in the treatment of non-hospitalized patients should primarily involve symptomatic drug therapies (e.g. analgesics, antipyretics, thrombosis prophylaxis), depending on the severity of the disease and where indicated. The marketing authorizations of the treatment options must be taken into account.
d. Remdesivir should be used in patients at a stage of infection with mild to moderately symptomatic COVID-19, i.e. without requiring supplemental oxygen. According to the G-BA, therapeutic measures that are used at a later (possibly more severe) stage of the disease are therefore not addressed in the specification of the ACT. However, according to the G-BA, it is assumed that patients in the studies will also receive appropriate treatment in the event of disease progression and hospitalization. It is recommended that the therapies used in the study and other supportive measures are documented and presented in the dossier.

BSC: best supportive care; COVID-19: coronavirus disease 2019; G-BA: Federal Joint Committee; PCR: polymerase chain reaction; SARS-CoV-2: severe acute respiratory syndrome coronavirus 2; VOC: variants of concern

The assessment described above concurs with the company’s assessment.

The G-BA decides on the added benefit.

I 6 References for English extract

Please see full dossier assessment for full reference list.

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