# Remdesivir and tixagevimab plus cilgavimab for treating COVID-19

For public – contains no ACIC information

**Multiple Technology Appraisal – Fourth appraisal committee meeting**

**Technology appraisal committee C [05 March 2024]**

**Chair:** Stephen O'Brien

**External assessment group:** School of Health and Related Research (ScHARR), Sheffield

**Technical team:** Rachel Ramsden, Adam Brooke, Ross Dent

**Company:** Gilead Sciences

# Key issues

| Issue | Resolved? | ICER impact |
|---|---|---|
| Restrictive patient population | No – for discussion | N/A – issue relating to decision problem |
| Underlying mortality rate | No – for discussion | Large |
| Remdesivir relative efficacy on mortality | Partly – for discussion | Large |

Abbreviations: ICER, incremental cost effectiveness ratio; N/A, not applicable

# Remdesivir and tixagevimab plus cilgavimab for treating COVID-19

- ✓ **Recap**
- ❑ Draft guidance 2 consultation responses
- ❑ Modelling and cost effectiveness
- ❑ Summary

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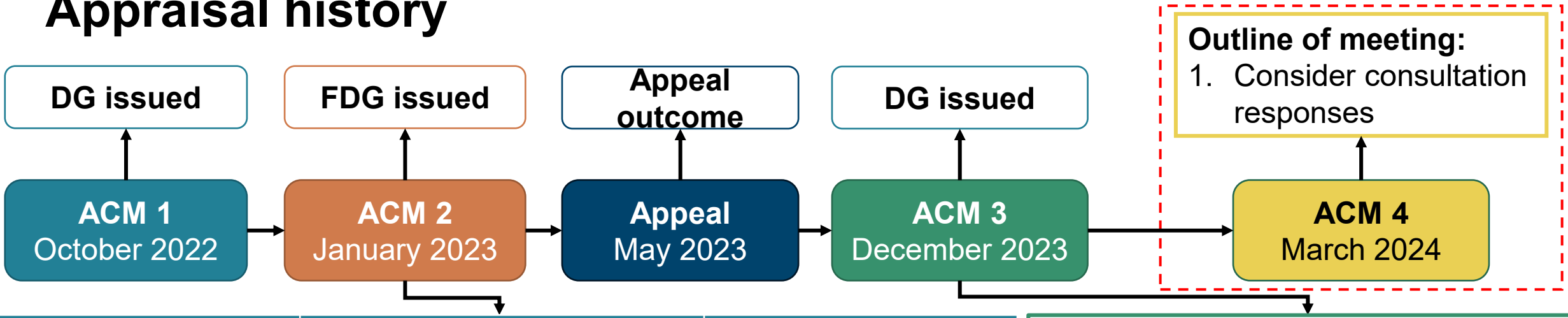
# Appraisal history




| Setting | Recommended | Not recommended |
|---|---|---|
| **Mild COVID-19** (high risk of progression, also hospital-onset COVID-19) | • nirmatrelvir plus ritonavir<br>• sotrovimab (only if nirmatrelvir plus ritonavir is contraindicated or unsuitable) | • casirivimab plus imdevimab<br>• molnupiravir<br>• remdesivir<br>• tixagevimab plus cilgavimab |
| **Severe COVID-19** (w/out supplemental oxygen) | • no technologies recommended | • casirivimab plus imdevimab |
| **Severe COVID-19** (with supplemental oxygen) | • tocilizumab | • casirivimab plus imdevimab<br>• remdesivir |

Remdesivir is recommended in:

- adults
  - in hospital with pneumonia, and
  - need LFO, and
  - have a high risk of serious illness (risk factors defined in McInnes report)
- babies, children and young people
  - aged 4 weeks to 17 years and weigh ≥3 kg, and
  - in hospital with pneumonia, and
  - need supplemental oxygen



Abbreviations: ACM, appraisal committee meeting; DG, draft guidance; FDG, final draft guidance; LFO low-flow supplemental oxygen

# Appeal panel conclusion

## Appeal panel suggested actions and considerations for committee based on Gilead's 4 upheld appeal points

| | |
|---|---|
| **Committee asked to:** | • Address the unfairness resulting from deviation from NICE's processes for MTA, specifically, the challenges to stakeholder engagement<br>• Consider how best to ensure that that all relevant evidence, including Real World Evidence, is identified, evaluated, and critically appraised<br>• Provide a clear explanation of why the cohort of patients with severe COVID-19 who require low-flow oxygen was not considered suitable for sub-group analysis, and reconsider whether an analysis of this subgroup would be informative<br>• Reconsider whether their decision not to recommend any therapy for children with severe COVID-19 is a proportionate means to achieve NICE's legitimate aims |
| **Consider rewording FDG to:** | • Provide further explanation why a probabilistic sensitivity analysis was not performed<br>• Clarify what "other differences specific to pandemic setting" (FDG 3.12) means |



Abbreviations: FDG, final draft guidance; MTA, multiple technology appraisal

# Clinical rationale for population sub-groups considered at ACM3

## Sub-groups in which Gilead consider remdesivir to be most effective

**Table** Definition of population sub-groups identified by Gilead

| | |
|---|---|
| **Low-flow oxygen** | Patients requiring oxygen delivered by a simple face mask or nasal canula at a flow rate usually up to 15 litres/min as per the NICE COVID-19 rapid guidelines |
| **Children** | Paediatric population as per the marketing authorisation indication (previous slide) |
| **Immunocompromised patients** | Patients who have a weakened immune system due to a particular health condition or patients who are on medication or treatment that suppresses their immune system |

**Table** EAG summary of the clinical rationale for the selected sub-groups provided by Gilead

| | |
|---|---|
| **Low-flow oxygen** | • Subgroup considered as distinct and readily defined population<br>• ESCMID Guidelines conditionally recommend remdesivir for use in hospitalised patients requiring no or LFO but not in patients requiring high-flow oxygen |
| **Children** | • Remdesivir is the only available licensed treatment option<br>• Inequity of access to comprehensive clinical care for this group |
| **Immunocompromised patients** | • Considered to experience worse clinical outcomes than others; make up less than 1% of people but account for large proportion of COVID-19 hospitalisations/deaths<br>• Nirmatrelvir and ritonavir is the only recommended antiviral and is not appropriate for all immunocompromised patients |

Abbreviations: ESCMID, European Society of Clinical Microbiology and Infectious Diseases; LFO, low-flow oxygen.

# Summary of recommendations at ACM3

**Table** Recap of rationale for committee recommendations for remdesivir

| | | |
|---|---|---|
| ACM3 | **Adults in hospital with pneumonia who need LFO** | ICERs >£20,000 per QALY gained for underlying mortality rates <14%. Mortality rate considered to be <14% for all people requiring LFO, so remdesivir would not be cost-effective. Further investigation needed to give a more accurate estimate of mortality in this population |
| | **Adults in hospital with pneumonia who need LFO and who are immunocompromised** | ICERs <£30,000 per QALY gained when a 14% underlying mortality rate used. Mortality rate likely >14% for immunocompromised people, so cost-effective in this group.<br>Immunocompromised defined using McInnes criteria |
| | **Babies, children and young people in hospital with pneumonia who need supplemental oxygen** | Limited clinical evidence comparing remdesivir with standard care, so cost-effectiveness estimates highly uncertain. But limited treatment options licensed for this group and the number who would have remdesivir is very small |

Abbreviations: ACM, appraisal committee meeting; ICERs, incremental cost-effectiveness ratio; LFO, low-flow oxygen; QALY, quality adjusted life year

# Summary of committee conclusions at ACM3

**Committee preferences**

- Remove treatment effects on clinical improvement or time to discharge (DG 3.28)
- Use mortality hazard ratios for remdesivir from Amstutz et al. (2023) with SOLIDARITY (DG 3.23)
- Consider mean–low and low efficacy scenarios for remdesivir's relative treatment effects on mortality (DG 3.23)

**Key areas of uncertainty**

- Underlying mortality rate for all people requiring low-flow oxygen (DG 3.29)



Abbreviations: ACM, appraisal committee meeting; DG, draft guidance

# Remdesivir (Veklury, Gilead Sciences)

**Table** Recap of details of the technology

| | |
|---|---|
| **Marketing authorisation** | Remdesivir is indicated for the treatment of COVID-19 in:<br>• adults and paediatric patients (at least 4 weeks of age and weighing at least 3 kg) with pneumonia requiring supplemental oxygen (low- or high-flow oxygen)<br>• adults and paediatric patients (weighing at least 40 kg) who do not require supplemental oxygen and are at increased risk of progressing to severe COVID-19 |
| **Mechanism** | Remdesivir is an adenosine nucleotide prodrug which inhibits RNA polymerase |
| **Administration** | Day 1: IV infusion of 200 mg or 5 mg/kg for paediatric patients less than 40 kg<br>Day 2+: IV infusion of 100mg or 2.5 mg/kg for paediatric patients less than 40 kg<br>Duration: daily for at least 5 days, not more than 10 |
| **Price** | £340.00 for one vial 100 mg powder for concentrate for solution for infusion<br>£2,040 for a treatment duration of 5 days<br>A simple patient access scheme discount is available |



Abbreviations: RNA, ribonucleic acid

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# Consultation responses

Comments from 2 professional groups and 3 public (web) submissions, including AstraZeneca UK

| Theme | |
|---|---|
| Immunocompromised people hospitalised but not requiring supplemental oxygen | • Immunocompromised people with no oxygen requirement or high flow oxygen requirements were not considered<br>• NHS interim clinical commissioning policy on remdesivir (2022) includes the caveat: "For significantly immunocompromised patients hospitalised for COVID-19 symptoms: ...the criterion on the need for supplemental oxygen requirement does not apply".<br>• Excluding this caveat from this NICE TA may exclude/delay access |
| Underlying mortality rate | • AstraZeneca considers the best estimate of mortality rate for the immunocompromised population in the LFO group to be 10.39% based on the INFORM study (2022 data) |

Abbreviations: LFO, low-flow oxygen

# Consultation responses

## Comments from the company, not addressed in key issues

| Theme | |
|---|---|
| Committee's preferred assumptions do not reflect the available evidence for remdesivir | • Committee failed to acknowledge the benefit remdesivir has on clinical improvement<br>• Committee chose an inappropriate subset of the Amstutz et al. meta-analysis which is not aligned with the patient population which Gilead is seeking reimbursement for<br>• Given depth of available evidence for remdesivir in the LFO population, mean efficacy levels should apply to remdesivir, as was applied for tocilizumab |
| Cost effectiveness threshold | • Committee has suggested an ICER >£20,000 in LFO population would not be cost-effective, without explanation for this threshold in context of section 6 of the Manual<br>• Uncaptured benefits for remdesivir have not been properly accounted for in the current draft guidance. For example:<br>  • Caffrey et al. (>20,000 patients) showed remdesivir significantly lowered 30-day post discharge readmission compared to non-remdesivir group<br>  • Boglione et al. demonstrated that remdesivir reduces the likelihood of long COVID-19 syndrome |

Abbreviations: ICER, incremental cost effectiveness ratio; LFO, low-flow oxygen

# Key issues: Restrictive patient population

**Background**

- Appeal panel asked the committee to reconsider whether an analysis of the subgroup of people with severe COVID-19 who require LFO would be informative
- In DG2, the committee recommended remdesivir in adults in hospital with pneumonia, and need LFO, and have a high risk of serious illness (risk factors defined in McInnes report)

**Company**

- Restricting remdesivir to people already on LFO negates benefit of access earlier in disease course
- Meeting both McInnes criteria and LFO requirements will restrict access for people most likely to benefit
- Unnecessary to additionally impose McInnes criteria, which aimed to identify individuals at high risk of progressing to severe COVID-19, to people in hospital with COVID-19 on LFO

**EAG comments**

- EAG has run analyses for adults immunocompromised population, not requiring LFO

Is remdesivir cost-effective for immunocompromised people in hospital for COVID-19, but not on LFO?



Abbreviations: DG, draft guidance; LFO, low-flow oxygen

# Key issues: Underlying mortality rates

## Background

- After appeal, underlying mortality rate changed to account for positioning for LFO population
- DG 3.35: ICERs < £30k per QALY gained for a 14% mortality rate
  - For immunocompromised people on LFO, mortality rate likely >14%, so remdesivir is a cost-effective use of NHS resources in this group
- Committee considered further investigation needed to give a more accurate estimate of underlying mortality for all people requiring LFO, due to sensitivity of cost-effectiveness estimates to this parameter

## Company

- Committee failed to acknowledge the mortality risk for LFO population (experts advised critically unwell)
- Any reliance on a figure of 7% (discussed with NICE in a phone call following ACM3) lacks transparency
- A more plausible range for the mortality rate is ~9 to [redacted] in LFO population
- Values provided align with the 14% estimate used previously in MTA process for decision making

## EAG comments

- Company did not provide a full critique of strengths and limitations of the evidence sources
- Mozaffari et al. and Isath et al. note limitations of the potential for residual confounding and misclassification of COVID-19 diagnosis, and data on vaccinations were not available
- Real-world data may be confounded, and not be generalisable to the current conditions in the UK

What underlying mortality rate should be used in the model for the LFO group?



Abbreviations: ACM, appraisal committee meeting; DG, draft guidance; LFO, low-flow oxygen; MTA, multiple technology appraisal

# Underlying mortality rates: LFO

**Company**: data does not distinguish between oxygenation status or treatment received, so likely to represent lower threshold for mortality rate in LFO population

**Company**: likely to represent an upper estimate of the mortality rate

**EAG**: scant details on the dataset and cannot rule out confounding factors when generalising to UK*

| Underlying mortality rate | Population | Source |
|---|---|---|
| 10% at 15 days | People requiring LFO | Suggested by company based on 14% mortality in SOLIDARITY |
| 14% at 28 days | People who needed oxygen but without ventilation, who did not receive remdesivir | Amstutz et al. |
| 12% | People needing oxygen and care from a respiratory consultant | Clinical expert opinion at ACM3 |
| 6% | People with COVID-19 in critical care | Clinical expert opinion at ACM3 |
| 2% | Overall population hospitalised with COVID-19 | Clinical expert opinion at ACM3 |
| 9% | People with COVID-19 | UKHSA (2023 dataset) |
| [redacted] | [redacted] | [redacted] |
| 12.3% at 28 days | People requiring LFO, who did not receive remdesivir | Mozaffari et al. |
| 13.2% | Adults hospitalised with COVID-19 in United States | Isath et al. |
| 9.8% at 28 days | People requiring LFO, receiving standard of care (dexamethasone monotherapy) | 2024 CROI conference (data generated December 2021 to April 2023) |

*Gilead supplied additional materials on the dataset, received after the EAG's final critique of Gilead's response to consultation

Abbreviations: ACM, appraisal committee meeting; LFO, low-flow oxygen

# Underlying mortality rates: recent statistics for all people hospitalised with COVID-19

**OpenSAFELY-TPP database (based on NHS electronic health records from GP surgeries in England that use TPP software)**

- Study population: all people hospitalised with COVID-19 as a diagnosis in any position between 1st January 2023 and 31st December 2023

| Population | N | Events | 28-day mortality rate |
|---|---|---|---|
| All | 60,460 | 1,095 | 1.81% |
| Hospitalised (no ICU admission) | 57,930 | 990 | 1.71% |
| Hospitalised (ICU admission) | 2,530 | 105 | 4.15% |
| Admitted January-June 2023 | 37,760 | 750 | 1.99% |
| Admitted July-December 2023 | 22,700 | 345 | 1.52% |
| COVID-19 primary reason for admission | 17,395 | 230 | 1.32% |
| COVID-19 not primary reason for admission | 43,065 | 865 | 2.01% |



Abbreviations: GP, general practice; ICU, intensive care unit

# Underlying mortality rates: immunocompromised

| Underlying mortality rate | Population | Source |
|---|---|---|
| 24.98% | Immunocompromised (includes deaths following hospitalisation) | Evans at al. (INFORM study) |
| 10.39% | Hospitalised immunocompromised (greatest level of care is admission to the general ward) | Unpublished data on file for the INFORM study - AstraZeneca consultation response |
| 19.2% | Hospitalised immunocompromised | 2024 CROI conference (data generated during Omicron era) |

**Company**: remdesivir showed significantly lower mortality risk compared to non-remdesivir overall (adjusted HR [95% CI]: 0.75 [0.68-0.83]) in people with

- no supplemental oxygen requirements (0.72 [0.61-0.85]) at 28 days
- any supplemental oxygen requirement (0.77[0.68-0.87]) at 28 days

Abbreviations: CI confidence interval; CROI; Conference on Retroviruses and Opportunistic Infections; HR, hazard ratio

# Key issues: Remdesivir relative efficacy: mortality

**Background**

- Company preferred mortality data from Huang et al., EAG used Amstutz et al. (including SOLIDARITY)
- Committee preferred Amstutz et al. (including SOLIDARITY)
- DG 3.23: "The AG noted that a sensitivity analysis by Amstutz et al. did not show a significant difference in relative benefit between the no oxygen and the low-flow oxygen groups."

**Company:**

- LFO (without SOLIDARITY) dataset should be used for decision making
- LFO (with SOLIDARITY) dataset not representative of LFO population Gilead is seeking reimbursement for
- Amstutz et al. described the relative benefit between the no oxygen group and the LFO group as "similar" but results for LFO (with SOLIDARITY) and LFO (without SOLIDARITY) are very different

| Dataset | Mortality at day 28, aOR (95%CI) | |
|---|---|---|
| | No oxygen | LFO |
| With additional WHO SOLIDARITY data | 0.86 (0.53–1.39) | 0.79 (0.68–0.92) |
| Without additional WHO SOLIDARITY data | 0.77 (0.34–1.74) | 0.59 (0.43–0.82) |

**EAG comments**

- None of the relevant comparisons in Amstutz et al. are statistically significantly different
- EAG ran analyses with and without SOLIDARITY but maintains its preference for including SOLIDARITY (acknowledges this may be unfavourable to remdesivir due to inclusion of some people receiving HFO)

Has the committee seen any new evidence to change its preference for including SOLIDARITY data?

Abbreviations: AG, Assessment Group; aOR, adjusted odds ratio; CI, confidence interval; HFO, high-flow oxygen; LFO, low-flow oxygen

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# Amendments to the EAG's model (1/2)

The EAG's efficacy scenarios consider differences in the 1) source of underlying mortality, 2) source of relative efficacy of remdesivir, 3) use of mean, low or mean-low relative efficacy estimates for remdesivir, and 4) use of pooled data for no oxygen and LFO requirements

**1) Source of underlying mortality**

| Modelled population | Underlying mortality rate | Source |
|---|---|---|
| LFO, not immunocompromised | 7% | **Company:** preferred by the Committee, as discussed with NICE |
| | 9.8% | For presentation at the 2024 CROI conference (provided by the company) |
| | 14% | Amstutz et al. (used by the EAG in its previous report) |
| Immunocompromised, no supplemental oxygen | 10.39% | Unpublished estimate from INFORM (provided by AstraZeneca) |
| | 14% | Assumed to be a likely lower estimate by the Committee at ACM3 |
| | 19.2% | For presentation at the 2024 CROI conference (provided by the company) |

Abbreviations: ACM, appraisal committee meeting; CROI, Conference on Retroviruses and Opportunistic Infections; EAG, external assessment group; LFO, low-flow oxygen

# Amendments to the EAG's model (2/2)

**2) Source of relative efficacy of remdesivir:**

- Amstutz et al. including SOLIDARITY data
- Amstutz et al. excluding SOLIDARITY data
- Embargoed data provided by the company, for presentation at the 2024 CROI conference

**3) Use of mean, low or mean-low relative efficacy estimates for remdesivir** - See recap slide

**4) Use of pooled data for no oxygen and LFO requirements:**

| Analysis | Modelled population | |
|---|---|---|
| | LFO, not immunocompromised | Immunocompromised, no supplemental oxygen |
| Group specific (non-pooled) | LFO data only | No supplemental oxygen data only |
| Pooled | No supplemental oxygen and LFO data | |

**EAG comments:** pooled data may give more precise estimate of efficacy but differs from values used previously in patients requiring LFO

The model was also amended to use a starting ordinal scale of ordinal stage 4 for the immunocompromised, no supplemental oxygen population, and ordinal stage 5 for the LFO, not immunocompromised population

Abbreviations: CROI, Conference on Retroviruses and Opportunistic Infections; EAG, external assessment group; LFO, low flow oxygen

# EAG scenarios: LFO, not immunocompromised

ICER (including PAS for remdesivir)
- >30k
- Within 20-30k
- Below 20k

Committee preference at ACM3

| Study used for remdesivir | Pooled data | Population | Efficacy scenario | HR for time to death (assumes an impact on overall survival only) Underlying mortality rate 7% | Underlying mortality rate 9.8% | Underlying mortality rate 14% |
|---|---|---|---|---|---|---|
| **Amstutz *et al*** (including SOLIDARITY) | Yes | No oxygen, LFO, HFO | Mean | **1)** 0.814 | **1)** 0.814 | **1)** 0.814 |
| | | | Low | **2)** 0.935 | **2)** 0.935 | **2)** 0.935 |
| | | | Mean-Low | **3)** 0.875 | **3)** 0.875 | **3)** 0.875 |
| | No | LFO, HFO | Mean | **4)** 0.817 | **4)** 0.817 | **4)** 0.817 |
| | | | Low | **5)** 0.930 | **5)** 0.930 | **5)** 0.930 |
| | | | Mean-Low | **6)** 0.865 | **6)** 0.865 | **6)** 0.865 |
| **Amstutz *et al*** (excluding SOLIDARITY) | Yes | No oxygen, LFO | Mean | **7)** 0.636 | **7)** 0.636 | **7)** 0.636 |
| | | | Low | **8)** 0.850 | **8)** 0.850 | **8)** 0.850 |
| | | | Mean-Low | **9)** 0.744 | **9)** 0.744 | **9)** 0.744 |
| | No | LFO | Mean | **10)** 0.635 | **10)** 0.635 | **10)** 0.635 |
| | | | Low | **11)** 0.839 | **11)** 0.839 | **11)** 0.839 |
| | | | Mean-Low | **12)** 0.723 | **12)** 0.723 | **12)** 0.723 |
| **Company's embargoed data** | No | LFO | Mean | **13)** 0.741 | **13)** 0.741 | **13)** 0.741 |
| | | | Low | **14)** 0.800 | **14)** 0.800 | **14)** 0.800 |
| | | | Mean-Low | **15)** 0.770 | **15)** 0.770 | **15)** 0.770 |

Abbreviations: EAG, external assessment group; HFO, high-flow oxygen; HR, hazard ratio; ICER, incremental cost effectiveness ratio; LFO, low flow oxygen; PAS, patient access scheme

New data submitted by company

# EAG's scenarios: No supplemental oxygen, immunocompromised

ICER (including PAS for remdesivir): >30k | Within 20-30k | Below 20k

Equivalent to Committee's preferences at ACM3

| Study used for remdesivir | Pooled data | Population | Efficacy scenario | HR for time to death (assumes an impact on overall survival only) Underlying mortality rate 10.39% | Underlying mortality rate 14% | Underlying mortality rate 19.2% |
|---|---|---|---|---|---|---|
| **Amstutz *et al*** (including SOLIDARITY) | Yes | No oxygen, LFO, HFO | Mean | **1)** 0.814 | **1)** 0.814 | **1)** 0.814 |
| | | | Low | **2)** 0.935 | **2)** 0.935 | **2)** 0.935 |
| | | | Mean-Low | **3)** 0.875 | **3)** 0.875 | **3)** 0.875 |
| | No | No oxygen | Mean | **4)** 0.894 | **4)** 0.894 | **4)** 0.894 |
| | | | Low | **5)** unity | **5)** unity | **5)** unity |
| | | | Mean-Low | **6)** unity | **6)** unity | **6)** unity |
| **Amstutz *et al*** (excluding SOLIDARITY) | Yes | No oxygen, LFO | Mean | **7)** 0.636 | **7)** 0.636 | **7)** 0.636 |
| | | | Low | **8)** 0.850 | **8)** 0.850 | **8)** 0.850 |
| | | | Mean-Low | **9)** 0.744 | **9)** 0.744 | **9)** 0.744 |
| | No | No oxygen | Mean | **10)** 0.850 | **10)** 0.850 | **10)** 0.850 |
| | | | Low | **11)** unity | **11)** unity | **11)** unity |
| | | | Mean-Low | **12)** unity | **12)** unity | **12)** unity |
| **Company's embargoed data** | Yes | No oxygen, LFO | Mean | **13)** 0.751 | **13)** 0.751 | **13)** 0.751 |
| | | | Low | **14)** 0.830 | **14)** 0.830 | **14)** 0.830 |
| | | | Mean-Low | **15)** 0.790 | **15)** 0.790 | **15)** 0.790 |
| | No | No oxygen | Mean | **16)** 0.723 | **16)** 0.723 | **16)** 0.723 |
| | | | Low | **17)** 0.850 | **17)** 0.850 | **17)** 0.850 |
| | | | Mean-Low | **18)** 0.786 | **18)** 0.786 | **18)** 0.786 |

Abbreviations: EAG, external assessment group; HFO, high-flow oxygen; HR, hazard ratio; ICER, incremental cost effectiveness ratio; LFO, low flow oxygen; PAS, patient access scheme

New data submitted by company

# Cost-effectiveness results

All results for remdesivir are reported in PART 2 slides because they include confidential PAS discounts

**Summary**

- Wide range of ICERs in both adults requiring LFO and in adults who are immunocompromised but do not require supplemental oxygen
  - ICERs are lower for higher underlying mortality rates
  - Source of efficacy data for remdesivir had a large impact on the ICER
  - When efficacy is from Amstutz et al., use of pooled data for no oxygen and LFO requirements has a large impact on the ICER in adults who are immunocompromised but do not require supplemental oxygen
    - This is because the efficacy estimates for remdesivir reported in Amstutz et al. for patients not requiring supplemental oxygen have wide confidence intervals that cross unity, implying that remdesivir may be harmful to people in this population
    - The impact of using pooled data on the ICER is small in adults requiring LFO



Abbreviations: ICER, incremental cost effectiveness ratio; LFO, low flow oxygen

# Key issues

| Key issue | ICER impact | Slide |
|---|---|---|
| Restrictive patient population | N/A | 13 |
| Underlying mortality rate | Large | 14 |
| Remdesivir relative efficacy on mortality | Large | 17 |

Abbreviations: N/A, not applicable

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# Thank you.