Sent by e-mail only: xxxxxxxxxxxxxxxxxxxxxxx

FAO xxxxxxxxxxxxxx, Executive Director

Gilead Sciences Ltd

280 High Holborn, London WC1V 7EE

4 April 2023

Dear xxxxxxxxxxxxx

**Re: Final Draft Guidance — Therapeutics for people with COVID-19 [ID4038] [now** [**ID6261**](https://www.nice.org.uk/guidance/indevelopment/gid-ta11297)**]**

Thank you for your letter of 28 March 2023 responding to my initial scrutiny views. This is my final decision on initial scrutiny.

I consider the ground 1(a) points followed by the ground 1(b) point and then the ground 2 points.

***Ground 1(a): In making the assessment that preceded the recommendation, NICE has failed to act fairly***

**Appeal point 1(a).3 Cost-effectiveness estimates were not informed by a probabilistic sensitivity analysis without adequate justification and so the Committee failed to sufficiently explore parameter uncertainty**

Having considered the additional arguments made in your letter of 27 March 2023, I agree that this is a valid appeal point.

**Appeal point 1(a).4 The Committee did not consider the cost-effectiveness for remdesivir for severe COVID-19 and so denied Gilead the opportunity to discuss commercial agreements that would mitigate or resolve the uncertainty around the ICERs**

Thank you for confirming that while Gilead do not agree with my initial view regarding appeal point 1(a).4, you do not propose to challenge this. I confirm my initial view.

**Appeal point 1(a).5 The Committee did not conduct a thorough assessment of treatments for children with severe COVID-19 and the resulting failure to recommend any treatment for children with severe COVID-19 is unfair and discriminatory**

Having considered the additional arguments made in your letter of 27 March 2023, I agree that this is a valid appeal point under ground 1(b).

**Appeal point 1(a).7 Gilead was not given a fair hearing because it was not given the opportunity to discuss key issues at the appraisal committee meetings**

Thank you for confirming that while Gilead do not agree with my initial view regarding appeal point 1(a).7, you do not propose to challenge this. I confirm my initial view.

**Appeal point 1(a).9 The Committee has not given adequate reasons why differences in standard care give rise to significant concerns about the generalisability of SOLIDARITY data**

Thank you for confirming that while Gilead do not agree with my initial view regarding appeal point 1(a).9 you do not propose to challenge this. I confirm my initial view.

**Appeal point 1(a).10 The Committee’s exclusion of treatment effects for hospital time to discharge data for remdesivir is unfair because these treatment effects were reflected in the base-case ICER results for tocilizumab**

Having considered the additional arguments made in your letter of 27 March 2023, I agree that this is a valid appeal point.

I understand your position to be that the committee treated remdesivir differently to other treatments and in doing so this was procedurally unfair. You have provided evidence in support of the position that remdesivir has been treated differently which you allege impacted on the cost-effectiveness analysis for remdesivir. You also argue that the committee has failed to provide adequate reasoning to distinguish the different approaches taken for each treatment. On this basis I agree that there is an arguable point as to whether the committee have treated remdesivir differently and if so whether sufficient reasoning has been provided.

***Ground 2:******the recommendation is unreasonable in the light of the evidence submitted to NICE***

**Appeal point 2.2 The Committee’s recommendations are unreasonable because, ignoring clinical need and practice, they fail to recommend any antiviral treatment for patients with severe COVID-19**

Thank you for confirming that while Gilead do not agree with my initial view regarding appeal point 2.2, you do not propose to challenge this. I confirm my initial view.

Conclusion

Therefore the valid appeal points are:

* 1(a).1 For lack of time and resource allocated to this MTA, companies were not given the opportunity to make a full evidence submission and NICE refused Gilead’s request to submit an economic model, resulting in important evidence not being considered by the Committee;
* 1(a).2 For lack of time, the EAG relied on pre-existing living systematic reviews and network meta-analyses which were not originally designed to address the decision problem and were not sufficiently validated, resulting in significant flaws in the information considered by the Committee;
* 1(a).3 Cost-effectiveness estimates were not informed by a probabilistic sensitivity analysis without adequate justification, and so the Committee failed to sufficiently explore parameter uncertainty;
* 1(a).6: The Committee has not given adequate reasons for why the population requiring “low-flow oxygen” was not considered as a potential subgroup;
* 1(a).8: NICE treated Gilead unfairly compared to another stakeholder company by refusing to consider new data that could potentially change the Committee’s final conclusions;
* 1(a).10: The Committee’s exclusion of treatment effects for hospital time to discharge data for remdesivir is unfair because these treatment effects were reflected in the base-case ICER results for tocilizumab;
* 1(b).1 (originally 1(a).5): The Committee did not conduct a thorough assessment of treatments for children with severe COVID-19 and the resulting failure to recommend any treatment for children with severe COVID-19 is unfair and discriminatory
* 2.1 The Committee’s conclusion that significant uncertainty remains in terms of generalisability of the trial evidence for remdesivir in severe COVID-19 is unreasonable because it ignores clinical practice and in-vitro data that has not been countered

NICE shares the valid appeal grounds of each appellant with the other appellants to assist with preparation for the hearing. These will be included in the appeal papers when they are circulated.

NICE will be in contact with you regarding the administration of the appeal, which will be held orally.

Yours sincerely

Dr Mark Chakravarty

Lead Non-Executive Director for Appeals & Vice Chairman

National Institute for Health and Care Excellence