NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Appraisal

Remdesivir for treating COVID-19

Draft scope

Draft remit/appraisal objective

To appraise the clinical and cost effectiveness of remdesivir within its marketing authorisation for treating coronavirus disease 2019 (COVID-19) in people with pneumonia requiring supplemental oxygen.

Background

COVID-19 is predominantly an acute respiratory illness caused by infection with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). It varies widely in clinical severity. Symptoms can range from asymptomatic infection to severe pneumonia and respiratory failure with the need for mechanical ventilation. People who become critically ill may develop acute respiratory distress syndrome (ARDS), the leading cause of mortality among patients with COVID-19.

The COVID-19 pandemic is rapidly evolving globally, with countries facing different stages of the spread of disease. In England and Wales between 1 March and 30 June 2020 50,335 deaths occurred involving COVID-19, of these 46,736 had COVID-19 assigned as the underlying cause of death[1]. Initial data from the UK suggest that mortality in hospital due to COVID-19 was strongly associated with male gender[1], older age[1], pre-existing conditions[1], ethnic background[2], and deprivation[3]. Children and young people appear to be less affected by the virus, with low numbers of deaths and critical care admissions in this age group[4].

Treatment options for COVID-19 are limited and there are trials underway to assess the efficacy of available medicines to manage the disease. Currently people with severe disease may receive oxygen support, invasive mechanical ventilation, non-invasive ventilation, or organ support. NHS England's interim clinical commissioning policy recommends remdesivir as a treatment option for patients hospitalised with COVID-19. It also states that dexamethasone can be used with remdesivir.

The technology

Remdesivir (Veklury, Gilead) is a viral RNA polymerase inhibitor that interferes with the production of RNA, stopping the virus from multiplying inside cells. This can help the body to overcome the virus infection, it may help patients recover quicker. It is administered intravenously.

Remdesivir has a conditional marketing authorisation for treating coronavirus disease 2019 (COVID-19) in adults and adolescents (aged 12 years and older with body weight at least 40 kg) with pneumonia requiring supplemental oxygen.

Intervention(s)	Remdesivir with standard care
Population(s)	Adults and adolescents (aged 12 years and older with body weight at least 40 kg) with COVID-19 with pneumonia requiring supplemental oxygen.
Comparators	Established clinical management with or without dexamethasone
Outcomes	The outcome measures to be considered include: • time to recovery • length of illness • time to return to normal activities • virological outcomes (viral shedding and viral load) • mortality • adverse effects of treatment • health-related quality of life.
Economic analysis	The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year. The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared. Costs will be considered from an NHS and Personal Social Services perspective. The availability of any commercial arrangements for the intervention, comparator and subsequent treatment technologies will be taken into account. The availability of any managed access arrangement for the intervention will be taken into account.
Other considerations	Guidance will only be issued in accordance with the marketing authorisation. Where the wording of the therapeutic indication does not include specific treatment combinations, guidance will be issued only in the context of the evidence that has underpinned the marketing authorisation granted by the regulator.
Related NICE recommendations and NICE Pathways	Guideline COVID-19 rapid guideline: managing suspected or confirmed pneumonia in adults in the community (2020) NICE guideline 165

	Evidence summary COVID-19 rapid evidence summary: acute use of non-steroidal anti-inflammatory drugs (NSAIDs) for people with or at risk of COVID-19 (2020) NICE evidence summary 23 COVID-19 rapid evidence summary: angiotensin-converting enzyme inhibitors (ACEIs) or angiotensin receptor blockers (ARBs) in people with or at risk of COVID-19 (2020) NICE evidence summary 24 COVID-19 rapid evidence summary: Long-term use of non-steroidal anti-inflammatory drugs (NSAIDs) for people with or at risk of COVID-19 (2020) NICE evidence summary 25 COVID 19 rapid evidence summary: Anakinra for COVID-19 associated secondary haemophagocytic lymphohistiocytosis (2020) NICE evidence summary 26 COVID 19 rapid evidence summary: Remdesivir for treating hospitalised patients with suspected or confirmed COVID-19 (2020) NICE evidence summary 27 COVID-19 rapid evidence summary: vitamin D for COVID-19 (2020) NICE evidence summary 28 Medtech innovation briefing Cytokine adsorption devices for treating respiratory failure in people with COVID-19 (2020) NICE Medtech innovation briefing 217 Lifelight First for monitoring vital signs (2020) Medtech innovation briefing 213 myCOPD for self-management of chronic obstructive pulmonary disease (2020) Medtech innovation briefing 214
Related National Policy	NHS England (2020) COVID-19 Clinical/medical management NHS England (2020) Clinical management of persons admitted to hospital with suspected COVID-19 infection NHS England (2020) Interim Clinical Commissioning Policy: Remdesivir for patients hospitalised with COVID-19 (adults and children 12 years and older) NHS England (2020) Coronavirus guidance for clinicians and NHS managers NHS England (2020) Rapid Clinical Policy development: COVID-19 The NHS Long Term Plan, 2019. NHS Long Term Plan

	NHS England (2018/2019) NHS manual for prescribed specialist services (2018/2019) Department of Health and Social Care, NHS Outcomes Framework 2016-2017: Domains 1, 3. https://www.gov.uk/government/publications/nhs-outcomes-framework-2016-to-2017

Questions for consultation

Which treatments are considered to be established clinical practice in the NHS for the treatment of COVID-19 with pneumonia requiring supplemental oxygen?

Are the outcomes listed appropriate?

Are there any subgroups of people in whom remdesivir is expected to be more clinically effective and cost effective or other groups that should be examined separately?

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the proposed remit and scope may need changing in order to meet these aims. In particular, please tell us if the proposed remit and scope:

- could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which remdesivir is licensed;
- could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology;
- could have any adverse impact on people with a particular disability or disabilities.

Please tell us what evidence should be obtained to enable the Committee to identify and consider such impacts.

Do you consider remdesivir to be innovative in its potential to make a significant and substantial impact on health-related benefits and how it might improve the way that current need is met (is this a 'step-change' in the management of the condition)?

Do you consider that the use of remdesivir can result in any potential significant and substantial health-related benefits that are unlikely to be included in the QALY calculation?

Please identify the nature of the data which you understand to be available to enable the Appraisal Committee to take account of these benefits.

To help NICE prioritise topics for additional adoption support, do you consider that there will be any barriers to adoption of this technology into practice? If yes, please describe briefly.

NICE intends to appraise this technology through its Single Technology Appraisal (STA) Process. We welcome comments on the appropriateness of appraising this topic through this process. (Information on the Institute's Technology Appraisal processes is available at http://www.nice.org.uk/article/pmg19/chapter/1-Introduction).

References

1. Office for National Statistics (2020) Deaths involving COVID-19, England and Wales: deaths occurring in June 2020. Accessed August 2020.
2. Public Health England (2020) Beyond the data: Understanding the impact of COVID-19 on BAME groups. Accessed August 2020.
3. Office for National Statistics (2020) Deaths involving COVID-19 by local area and socioeconomic deprivation: deaths occurring between 1 March and 30 June 2020. Accessed August 2020.
4. Lu X, Zhang L, Du H et al. (2020) SARS-CoV-2 Infection in Children. The New England Journal of Medicine 382;17.