NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Technology Appraisal

ID6262: Nirmatrelvir plus ritonavir for treating COVID-19 (Partial Rapid Review of TA878)

All relevant health bodies must comply with technology appraisal recommendations and make a health technology available for patients within 3 months of publication of final guidance. When it considers it to be appropriate, NICE can specify a longer period of compliance.

Please see the National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013, (the 'Regulations'), for more information.

This template document should be used by commissioners to submit a formal request that NICE consider a longer period of compliance. The questions and prompts are there to guide you. You do not have to answer every question. Please provide short, focused answers, giving a commissioning perspective on the issues you think NICE needs to consider.

1. Name of organisation:	NHS England
2. Your name:	John Stewart
3. Job title or position:	National Director of Specialised Commissioning, NHS England.
4. Please state the reason for applying to vary the funding period (please tick all that apply):	☒ The technology exceeds the Budget Impact Test (BIT) level of £20million in any of the first 3 years following implementation The health technology cannot be appropriately administered until: ☒ Training is put in place ☒ Certain health service infrastructure requirements including goods, materials or other facilities are put in place ☒ Other appropriate health services resources, including staff, are put in place
Additional rationale to support the funding variation request	
5. What is the duration of, and the justification for, the proposed variation? *[Include information on* *- how the request is in proportion to the size of the*	Access to nirmatrelvir plus ritonavir is already in place for around 3.9 million people who have an increased risk of progression to severe COVID-19 (as described in TA878). ID6262: Nirmatrelvir plus ritonavir for treating COVID-19 (Partial Rapid Review of TA878) recommends an expansion of the cohort beyond the high-risk group to people • aged 70 years and over • with a body mass index (BMI) of 35 kg/m2 or more

budget impact (where appropriate) *- how the request takes account of the severity and acuity of the condition to which the guidance relates]*	• with diabetes • with heart failure This expansion will more than triple the number of people eligible from 3.9 million to an estimated 15.0 million people. This equates to almost a quarter of the England population. ICBs will need time beyond the usual 90-day implementation period to put in place the necessary treatment pathways and ensure the necessary capacity, knowledge and expertise is in place to support equitable access for the expanded population. Existing ICB commissioned services will not immediately have capacity to manage the additional demand from the expanded cohort, particularly at a time when primary care is already under significant and sustained pressure to recover routine access to services. Access to COVID treatments has been transitioning from COVID medicine delivery units (CMDUs) that were established in 2021 as part of the pandemic response to more routine access and assessment arrangements. These new arrangements include GP federations operating at scale and community providers. This process is not yet complete and we expect it to continue into 2024. As Paxlovid is a complex drug with several contraindications, ICBs will have put in place additional services which provide the triage, assessment and check for drug interactions that is needed to ensure appropriate and safe prescribing. Currently, these services are scaled to meet the needs of the highest risk population only. Based on activity from 2022/23, expanding access as recommended by NICE could result in 1-2 million more people coming forward to primary care services. People with diabetes and heart failure are likely to be on several medicines, which will mean greater requirements for assessment of drug interactions to ensure safe prescribing. For example, nirmatrelvir plus ritonavir can increase bleeding risk for patients on Direct Oral Anticoagulants (DOACs) and greater caution will be required for patients on antiarrhythmic drugs. Given the significant staffing, infrastructure and resource required to scale up to provide access to all the groups in this recommendation, ICBs will need more time to determine and implement the most efficient, safe and equitable arrangements for their local populations. Therefore, NHS England is requesting, on behalf of the NHS, a one-year funding variation period. During the period of the variation, the NHS will rollout equitable access to treatment as follows: • Patients aged 85 years and above who test positive for COVID in the community. This equates to ~1.1 million more people and recognises the clinical evidence on the additional risk of severe COVID associated with ageing[1].

[1] TCRP modelling group findings: risk of severe COVID-19 outcomes – GOV.UK (www.gov.uk)

	• All eligible patients covered by the NICE recommendation who are resident in a care home (~300,000) and test positive for COVID. • All eligible patients who are covered by the NICE recommendation who are already hospitalised and who test positive for COVID. Because a positive test is a requirement for treatment with nirmatrelvir plus ritonavir, NHS England will put in place arrangements that ensure patients in the above groups can access free COVID tests. As with the current arrangements, patients in these groups will also be able to access treatment using a self-funded test. However, during the funding variation access to treatment for the full cohort of patients recommended by NICE will not be available, even if they provide their own self-funded test. This approach is fully consistent with the fundamental NHS principle that access to treatment is not based on the ability to pay. Treatment on the NHS must go hand in hand with the ability for patients to access the companion diagnostic free of charge. In the short to medium term, the only feasible approach to testing will be to extend the arrangements already in place for the highest risk cohort. Testing is currently provided by UK Health Security Agency's (UKHSA) home channel, which makes available lateral flow device (LFD) testing for the existing cohort of highest risk patients. NHS England is working with UKHSA and DHSC to agree a transfer in responsibility and funding for this testing to the NHS. From November 2023, NHS England is planning to implement a new community-based testing model. It is highly unlikely that the existing UKHSA arrangements or the new community pharmacy model would result in the cost-effective usage of Paxlovid across the entire eligible cohort when testing costs are fully factored in. The licence for Paxlovid stipulates a patient must be COVID positive and treatment must be provided in a 5-day window. In practice, this requirement means that people would need a test whenever they have flu-like symptoms, which may be many times through the year. For planning purposes, we have assumed on average that each eligible person required a box of 5 tests per year, which would mean the additional testing costs for the full expanded population could be c£150 million. However, there is uncertainty about how many people would come forward for free tests or what the ratio of tests to treatment uptake will be, which will have implications for both the financial impact and the cost-effectiveness. The take up of testing and treatment is likely to fluctuate over time depending on factors such as prevalence of both COVID and flu and severity of disease. Therefore, during the funding variation period, NHS England working in partnership with UKHSA will also consider how to put

	in place a cost-effective testing strategy that can be applied fairly and equitably to the entire eligible cohort. This will include, for example: • Exploring opportunities to reduce the acquisition costs of lateral flow device tests. • Examining alternative models for accessing tests which could improve access for patients and reduce costs. • Looking at potential trigger points for stepping up and down access to testing and treatment e.g. severity of disease, hospitalisation. These triggers might, for example, draw on the arrangements for access to antivirals for flu. • Consideration of the pipeline for new testing technologies and options e.g. multiplex testing. • Analysis of data collected on uptake of testing and treatment during the funding variation period. NHS England will also keep incidence and severity of disease under review to inform decisions about whether any further expansion of treatment and free testing should be introduced during the funding variation period. In addition, the NHS will continue to promote recruitment into the Paxlovid arm of the Panoramic clinical trial to validate the efficacy in the broader vaccinated population for the current circulating pathogens.
6. Describe any relevant provisions of any commercial arrangement reached with the company. *[Only complete where relevant.* *Include information on the amount of engagement between your organisation and the company and relevant conclusions for NICE to consider whether all reasonable opportunities for reaching a commercial agreement have been pursued]*	NHS England has engaged with the company as part of the MTA process and in relation to this Funding Variation. The updated list price for nirmatrelvir plus ritonavir is confidential until released by the company.
7. Describe the amount and phasing of funding that will be made available and how it is intended that this should be applied to patients eligible for treatment.	NHS England estimates that the costs of expanding access to people over 85 years old, people in care homes and hospitalised patients to be in the region of £20 million per annum, including both the increased administration costs and the costs of testing. These costs exclude drug costs. Based on information on prescribing from 2022/23, we estimate that 2.5% of the total population might receive treatment i.e. around 30,000 more patients, with over 100,000 coming forward for assessment. The costs of expansion include an administration cost of around £4.8 million. This cost is based on £150-200 per treatment, to

	account for the triage of patients and the additional time needed to check for any drug interactions. This cost may fall in future, but over the next 6-12 months, most system have put in place additional capacity, in part also to ensure timely access for patients. The cost of expansion also includes the costs of testing, which for 1.1 million people is estimated to be £14.4m, based on one box of tests for each eligible patient. Subject to the funding variation being accepted, further work will be needed to: - Understand with local systems how to best implement access for an expanded population. - Understand the features of an equitable, clinically and cost-effective testing strategy. This will include observed costs of testing provided and assessment of the operation of credible alternative approaches.
8. Provide detail of an assessment of the impact on patients, eligible for treatment under the guidance, but whose treatments will be delayed because of the funding variation, taking into account NHS England's and NICE's responsibilities under equalities legislation.	As set out in the Final Draft Guidance (FDG) documentation, equality issues in relation to COVID-19 antiviral treatment are complex and multifaceted. Under the variation request, access to free companion diagnostic testing will continue to be routinely provided to the highest risk cohort covered by the original recommendation in TA878, as well as hospitalised patients, people aged over 85 and those in care homes, ensuring people at highest risk of severe COVID have equitable access to testing and treatment. As with current arrangements for highest risk patients, people in these groups proposed in this variation, could potentially access assessment and treatment using a self-funded test. However, access on the basis of self-funded tests alone would not be consistent with the NHS Constitution where access to treatment is based on clinical need and not the ability to pay. NHS England also believes a testing strategy based on patients self-funding their tests would not be consistent with duties under equalities legislation. The NHS Act 2006 section 13G relates to the duty to reduce inequalities and requires that: The Board must, in the exercise of its functions, have regard to the need to— (a) reduce inequalities between patients with respect to their ability to access health services, and (b) reduce inequalities between patients with respect to the outcomes achieved for them by the provision of health services.
9. Provide detail of the interim commissioning policy that would be applied to phase in funding and to manage access to the technology during the	As outlined above, during the funding variation period NHS England will set out the necessary information and policy position on access as it relates to • the highest-risk cohort and people • people aged 85 and over • hospitalised patients with COVID

extended funding variation period.	• people in care homes Our aim is to extend the testing arrangements in place for the highest risk group to the groups outlined above within 90 days of the publication of Final Guidance. Primary care services will need this time to operationally prepare the service for the phased roll out of this recommendation.

Thank you for your time. Please log in to your NICE Docs account to upload your completed submission.