Medicines for COVID-19

Essential medicine status ✓

EMLc | ATC codes: Pending

Indication	COVID-19 ICD11 code: RA01
Medicine type	Chemical agent
List type	Core
Additional notes	WHO recommends that effective and safe therapeutics for prevention and treatment of COVID-19 should be considered as essential medicines in the context of the public health emergency. WHO recommendations are revised and updated regularly in WHO living guidelines for therapeutics for the treatment and prevention of COVID-19. Selection of essential therapeutics for COVID-19 at the national level should be informed by recommendations in these guidelines, and consideration of the latest evidence, epidemiology and national priorities. The latest WHO Therapeutics and COVID-19: living guideline is available online at: https://app.magicapp.org/#/guideline/nBkO1E The latest WHO Drugs to prevent COVID-19: living guideline is available online at: https://app.magicapp.org/#/guideline/L6RxYL
Formulations	Refer to WHO living guidelines
EML status history	First added in 2023 (TRS 1049)
Sex	All
Age	Also recommended for children
Therapeutic alternatives	The recommendation is for this specific medicine
Patent information	Read more about patents.
Wikipedia	Medicines for COVID-19

Expert Committee recommendation

The Expert Committee noted that the evidence presented in the applications for each medicine was the same as that considered by the WHO Guideline Development Group for COVID-19 therapeutics, which informed the following recommendations in WHO living guidelines for COVID-19 (2). • Baricitinib: strong recommendation for the use of baricitinib for patients with severe or critical COVID-19 • Molnupiravir: conditional recommendation for use of molnupiravir for treatment of patients with non-severe COVID-19 at highest risk of hospitalization • Nirmatrelvir and ritonavir: strong recommendation for the use of nirmatrelvir and ritonavir for treatment of patients with non-severe COVID-19 at highest risk of hospitalization • Remdesivir: conditional recommendation for the use of remdesivir for treatment of patients with non-severe COVID-19 at highest risk of hospitalization or with severe COVID-19 • Tocilizumab: strong recommendation for the use of IL-6 inhibitors (namely tocilizumab and sarilumab) for adults and children with severe or critical COVID-19 Given the global recognition of the need for effective therapeutics to prevent and treat COVID-19, as well as the need to ensure adequate and affordable access globally to these treatments, the Expert Committee recommended that effective and safe therapeutics for COVID-19 be considered as essential medicines and therefore be prioritized by countries for national selection and procurement. The Expert Committee acknowledged that new variants of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) have emerged, and continue to emerge, affecting the epidemiology, clinical characteristics and, most importantly, the response to treatment of the disease. The Committee considered that predicting how mutations carried by new virus variants modify the response to available treatments is difficult, if not impossible. Furthermore, the evolution of the pathogen combined with the evolving immunity in the population over time (through previous natural infection or vaccination) may influence the severity of the disease, thus potentially affecting the relative and absolute benefits associated with the use of COVID-19 therapeutics. Data on COVID-19 and hospitalization rates are fluctuating, with countries reporting surges, often in association of new variants or subvariants. However, the Committee noted that increases in COVID-19 cases do not always lead to increased severity of the disease or hospital admissions. COVID-19 data have shown lower hospitalization rates in more recent waves compared with previous ones (3). Nevertheless, new variants may further mutate and potentially cause more severe disease. With this in mind,

the Committee considered that the advantages of adding a medicine for the treatment of COVID-19 to the Model Lists must be evaluated against potential risks. The WHO Model Lists are updated every 2 years and national essential medicines lists are often updated less frequently. In the context of rapidly evolving public health emergencies, there is therefore a risk of including a medicine on the Model Lists that later has to be removed because it is no longer relevant for the reasons outlined above, a scenario that should be avoided. The Committee considered that WHO's timeline and process of selecting essential medicines is not ideally suited to rapidly evolving public health emergencies, where the prioritization of health care interventions needs to be adjusted according to the evolving evidence base. The Committee recognized the important role of WHO and national guidelines as tools for countries to orient prioritization of medicines during public health emergencies. The Committee also commended the role of adaptive trial platforms as a basis to guide clinical decision-making during a public health emergency. During the COVID-19 pandemic, adaptive platform trials were rapidly created at national (e.g. RECOVERY) and international (e.g. Solidarity) levels, which contributed to the generation of evidence on critically relevant outcomes, such as preventing deaths or hospitalizations. These adaptive trial platforms were characterized by high external and internal validity, prioritization of relevant research questions and use of robust methods. These elements contributed to the rapid implementation of their results in routine clinical care. The Committee encouraged the strengthening of national infrastructure to successfully conduct adaptive platform trials, noting that their use need not be limited to public health emergencies, but should also be extended to other priority health care questions. The Expert Committee therefore recommended that a new section be added to the EML and EMLc for COVID-19 therapeutics, but that individual medicines should not be specifically listed. Rather, the Committee recommended that this section of the Model Lists should serve to direct national decision-makers to the WHO living guidelines for COVID-19 therapeutics, which are being revised and updated regularly. Importantly, these living guidelines also include recommendations for the use of other medicines already included on the Model Lists (e.g. dexamethasone, oxygen), as well as recommendations against the use of medicines that are included on the Model Lists for other indications (e.g. hydroxychloroquine, lopinavir-ritonavir).

Background

The Expert Committee considered five applications for inclusion of medicines for COVID-19 on the Model Lists: baricitinib, molnupiravir, nirmatrelvir and ritonavir, remdesivir, and tocilizumab. The recommendations made by the Expert Committee are applicable to all proposed medicines and are presented below.

Public health relevance

Data from 11 January 2023 report that globally, cumulative cases of COVID-19 were more than 660 million, with almost 6.7 million deaths (1). Vaccination is having a substantial impact on hospitalizations and deaths in a number of high-income countries, but limitations in global access to COVID-19 vaccines mean that many populations remain vulnerable. More effective treatments for COVID-19 are still needed.

1. Coronavirus disease (COVID-19) pandemic [internet]. Geneva: World Health Organization; 2023 (https://www.who.int/emergencies/diseases/novel-coronavirus-2019, accessed 6 October 2023).
2. Therapeutics and COVID-19: living guideline, 13 January 2023. Geneva: World Health Organization; 2023 (https://apps.who.int/iris/handle/10665/365584, accessed 6 October 2023).
3. Coronavirus (COVID-19) hospitalizations [internet]. Our World in Data; 2023 (https://ourworldindata.org/covid-hospitalizations, accessed 6 October 2023).