

A.27	Nirmatrelvir and ritonavir – COVID-19 – EML and EMLc
Draft recommendation	<div> <input type="checkbox"/> Recommended <input checked="" type="checkbox"/> Not recommended </div> <p>Justification:</p> <ul style="list-style-type: none"> The Covid-19 pandemic had devastating effects on morbidity and mortality globally. Effective treatments have been essential in that context. However, emerging new variants of SARS-CoV-2 can impact the disease's epidemiology, clinical characteristics, and response to treatments. The 'essential' nature of listing COVID-19 treatments may not be long lasting, an argument against their listing on the EML. Currently expensive; no formal cost-effectiveness analysis
Does the proposed medicine address a relevant public health need?	<div> <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable </div> <p>Comments:</p>
Does adequate evidence exist for the efficacy/effectiveness of the medicine for the proposed indication? (this may be evidence included in the application, and/or additional evidence identified during the review process)	<div> <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable </div> <p>Comments:</p> <ul style="list-style-type: none"> reduction in hospitalization amongst patients at highest risk of 84 per 1000 (moderate certainty)
Does adequate evidence exist for the safety/harms associated with the proposed medicine? (this may be evidence included in the application, and/or additional evidence identified during the review process)	<div> <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable </div> <p>Comments:</p> <ul style="list-style-type: none"> reduction of discontinuation of study drug due to adverse events: no important difference (high-certainty evidence)
Are there any adverse effects of concern, or that may require special monitoring?	<div> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Not applicable </div> <p>Comments:</p>

24th WHO Expert Committee on Selection and Use of Essential Medicines
Expert review

<p>Are there any special requirements for the safe, effective and appropriate use of the medicines?</p> <p>(e.g. laboratory diagnostic and/or monitoring tests, specialized training for health providers, etc)</p>	<p><input checked="" type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Not applicable</p> <p>Comments:</p> <ul style="list-style-type: none"> • The appropriate use of rapid diagnostic tests such as antigen-detection assays can improve early diagnosis in the community and in primary health care settings. • multiple possible dangerous drug interactions to consider • contraindicated in the case of severe hepatic impairment or severe renal impairment
<p>Are there any issues regarding cost, cost-effectiveness, affordability and/or access for the medicine in different settings?</p>	<p><input checked="" type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Not applicable</p> <p>Comments:</p> <ul style="list-style-type: none"> • no formal cost-effectiveness analysis • cost for proprietary nirmatrelvir-ritonavir (Paxlovid) in the US is \$529
<p>Are there any issues regarding the registration of the medicine by national regulatory authorities?</p> <p>(e.g. accelerated approval, lack of regulatory approval, off-label indication)</p>	<p><input type="checkbox"/> Yes</p> <p><input checked="" type="checkbox"/> No</p> <p><input type="checkbox"/> Not applicable</p> <p>Comments:</p>
<p>Is the proposed medicine recommended for use in a current WHO guideline?</p> <p>(refer to: https://www.who.int/publications/who-guidelines)</p>	<p><input checked="" type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Not applicable</p> <p>Comments:</p> <p>WHO guidance makes a strong recommendation for the use of nirmatrelvir-ritonavir for patients with non-severe Covid-19 at highest risk of hospitalization.</p>