African Union

AFRICA CDC
Centres for Disease Control and Prevention
Safeguarding Africa's Health

COVID-19 Test to Treat Guidelines

Guidance to African Union Member States

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+251 11 551 7700 africacdc@africa-union.org www.africacdc.org africacdc @AfricaCDC

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Africa Centres for Disease Control and Prevention
(Africa CDC)
Roosevelt Street, Old Airport Area, W21 K19
P. O. Box 3243, Addis Ababa, Ethiopia
Tel: +251 11 551 7700
Email: africacdc@africa-union.org

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EXECUTIVE SUMMARY

In response to the outbreak, the Africa Centres for Disease Control and Prevention (Africa CDC) has been supporting African Union Member States in responding to the COVID-19 pandemic through a variety of interventions such as non-pharmaceutical interventions, quarantine, testing, isolation, contact tracing, and clinical management.

The Test to Treat guideline aims to increase continental testing efforts and reduce COVID-19 transmission in Africa and put-up response measures to control the impact of the virus, both to limit spread and to reduce substantially the risks of severe health outcomes related to COVID-19 infection. These countermeasures include highly effective vaccines and boosters, rapid testing options for monitoring exposure, and effective therapeutic options for both pre-exposure prevention and treatment of mild-to-moderate disease, oxygen therapy for moderate-severe disease, all of which can potentially be updated efficiently as new variants emerge that may affect the effectiveness of the available tools. The guideline is a living document and will continue being updated as the COVID-19 pandemic evolves.

As of early 2022, there are increasingly a broad array of therapeutics available to prevent the serious consequences of SARS-CoV-2 infections. Test to Treat is a concept of facilitating expedited access to treatment by allowing patients to easily receive both COVID-19 testing and rapid access to available treatments. This guideline recommends a one-stop-care for COVID-19 testing and treatment such as home-based care by community health workers, community test centres and local community pharmacies, working closely with community health centres and hospital facilities including outpatient and inpatient departments at health facilities..

This Test to Treat guideline is a key element of enabling COVID-19 containment on the African continent, both to save lives and livelihoods, and preventing further disruptions from new variants or surges. Africa CDC is cognizant of the rapidly evolving epidemiological nature of COVID-19 pandemic, and encourages establishment of Test to Treat sites, which will provide “one-stop” testing, medical evaluation, and, if appropriate, provide treatment for COVID-19. The Africa CDC looks forward to successful adoption and implementation of this guidance to augment Test to Treat initiatives to enhance access to testing and treatment on the African continent.

1.0 BACKGROUND

1.1 Natural history of COVID-19

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is a novel severe acute respiratory syndrome coronavirus. It was first isolated from three people with pneumonia connected to the cluster of acute respiratory illness cases in Wuhan, China, on 31 December 2019. On March 11, 2020, the coronavirus disease 2019 (COVID-19) was declared a pandemic by the World Health Organization (WHO). All structural features of the novel SARS-CoV-2 virus particle occur in related coronaviruses in nature. SARS-CoV-2 is postulated to have originated in a large animal and seafood market. The virus is spread by coughing, sneezing, singing, talking and so on. During activities that produce droplets, the virus is released into the air. If other people inhale those droplets, or get them into their mouth, nose, or eyes they may become infected with the virus.

The COVID-19 outbreak has caused severe disruptions to healthcare systems globally and the overall well-being of people. The COVID-19 pandemic is still rapidly and frequently evolving, as is the case with COVID-19 therapeutics. The first line of protection against severe COVID-19 outcomes is vaccination against the disease. Several COVID-19 outpatient therapeutic options are currently available. Treatments are available for eligible patients based on exposure status, symptoms and risk factors for severe disease progression. Ultimately, COVID-19 treatments play an important role in preventing severe illness and helping people recover from COVID-19, with the goal of saving lives, reducing hospitalizations, and relieving pressure on stressed hospital systems.

The Africa Centres for Disease Control and Prevention (Africa CDC) has been supporting African Union Member States to respond to the COVID-19 pandemic since 2020, through a series of interventions, including non-pharmaceutical interventions, quarantine, testing, isolation, contact tracing, and clinical management. Clinical care of patients with COVID-19 is changing with the unfolding of events and research into the SARS-CoV2 virus. Oral antiviral drugs and monoclonal antibodies are late arrivals to the continent; many people are not sure if they qualify to receive these treatments or when to begin treatment, and others do not have a healthcare provider to ask. Test to Treat aims to remove those barriers. To help increase continental testing efforts and reduce COVID-19 transmission in Africa, Africa CDC launched the Partnership to Accelerate COVID-19 Testing (PACT): Test, Trace to Treat. PACT mobilized experts, community workers, supplies and other resources to TEST, TRACE and TREAT COVID-19 cases in a timely manner to minimize the impact of the pandemic on the African continent. Provision of timely, effective and safe supportive therapies is the cornerstone of treatment for patients with severe COVID-19.

"Test to Treat" is a concept of facilitating expedited access to treatment as soon as someone tests positive for a disease. From decades of advancement in HIV/AIDS and sexually transmitted infections care, there are successive logistical steps from obtaining a test, to accessing a prescriber and accessing medication which lead to a drop-off in patients accessing treatment. Thus, we are applying similar principles to reinforce the importance of expediting treatment so that all those who test positive for COVID-19 are urgently taken care of. Importantly, "Test to Treat "as a concept generally applies to any efforts to ensure the key elements of (1) testing, (2) prescribing, and (3) giving medication occur simultaneously. The Test to Treat programme will provide access to COVID-19 testing and treatment in a single location. However, this programme is not a replacement for the relationship between patients and their usual provider. Patients may continue to be tested and treated by their own qualified healthcare providers, who can also prescribe these oral antiviral drugs. Ideally the test to treat is intended to eliminate any barriers to accessing testing and treatment in the early days of infection.

2.0 THE RATIONALE

The Test to Treat initiative is a partnership between healthcare providers on every level (multi-level) of the healthcare system, working together as a healthcare community to prevent, test, treat and care for people with COVID-19 or those with high risk for severe COVID-19 complications. The main purpose is to reduce a surge in healthcare facilities by task-shifting and sharing, triaging to home and community care in time to prevent unnecessary hospitalizations. This initiative embraces the following as "one-stop-care" for COVID-19 testing, treatment and care:

1. Home-based care by community health workers (CHW) using COVID-19 self-test and treat kits, telehealth modalities, and community health posts.
2. Community test centre and local community pharmacies working closely with community health centres.
3. Health facilities including outpatient (clinic) and inpatient (hospitalization) COVID-19 respiratory disease experts working closely with other specialties within the healthcare system, including public (government) and private hospitals, general hospitals at district level, teaching hospitals, healthcare institutes and national specialty care hospitals.

3.0 MANAGEMENT OF COVID-19 PATIENTS

There is strong scientific evidence that antiviral treatment of outpatients at risk for severe COVID-19 reduces their risk of hospitalization and death. The antiviral drugs **Paxlovid (ritonavir-boosted nirmatrelvir)** is the preferred treatment for eligible adult and paediatric patients with positive results of direct SARS-CoV-2 viral testing and who are at high risk for progression to severe COVID-19. Clinicians should consider COVID-19 treatment in non-hospitalized patients who meet all of the following:

- Test positive for SARS-CoV-2 (with PCR or antigen test, including self-test)
- Present with symptoms consistent with mild-to-moderate COVID-19. People with mild COVID-19 experience symptoms such as fever, sore throat, cough, or headache but do not have symptoms of respiratory distress (respiratory rate >20 or O_2 saturation of <94 or other signs of respiratory distress). People with moderate illness have symptoms that affect the lungs like shortness of breath or difficulty breathing.
- Are within 5 days of symptom onset for Paxlovid (ritonavir-boosted nirmatrelvir) or 7 days of symptom onset for Veklury (remdesivir).
- Have one or more risk factors for the development of severe COVID-19 which includes:
    - Age over 50 years, with risk increasing substantially at age ≥ 65 years
    - Being unvaccinated or not being up to date on COVID-19 vaccinations for specific medical conditions and behaviors.
    - Immuno-suppressed individuals
    - Specific medical conditions such as diabetes, pregnancy, chronic kidney disease, cardiovascular disease or hypertension, obesity etc. *(Annex –II)*

3.1 COVID-19 OUTPATIENT TEST AND TREAT

3.1.1 Outpatient Antiviral Treatment of COVID-19

While vaccination continues to provide the best protection against COVID-19, therapies are now available to help treat eligible people who tested positive for COVID-19. There is strong scientific evidence that antiviral treatment of outpatients at risk for severe COVID-19 reduces their risk of hospitalization and death when taken soon after symptom onset, but there is need for additional evidence for vaccinated persons. Clinicians should consider COVID-19 treatment in non-

hospitalized patients who meet all of the following (*Annex -III*):

- Test positive for SARS-CoV-2 (with PCR or antigen test, including at-home tests)
- Have symptoms consistent with mild to moderate COVID-19
- Are within 5 days of symptom onset, to be eligible for Paxlovid (ritonavir-boosted nirmatrelvir) and Molnupiravir use or 7 days of symptom onset for Veklury (remdesivir) use
- Have one or more risk factors for severe COVID-19, (see *Annex-III*):

Qualifying criteria for treatment with Paxlovid (ritonavir-boosted nirmatrelvir): is the preferred treatment for eligible adult and pediatric patients with positive results of SARS-CoV-2 viral testing and who are at high risk for progression to severe COVID-19. This drug can be used in patients with:

- Mild to moderate COVID infection defined as mild-moderate symptoms AND
- Positive test for SARS-CoV-2 and symptom onset **within 5 days.** It should be initiated as soon as possible following COVID-19 diagnosis
- At high risk for progression to severe disease (see *Annex-III*)
- Without contraindications to paxlovid treatment (e.g., on one or more contraindicated home medication, underlying severe renal (eGFR <30 mL/min or hepatic dysfunction)
- At least 12 years old, weighing at least 40 kg and clinically stable for outpatient treatment (no new O_2 requirement).

Paxlovid dosing:

- GFR ≥ 60 mL/min:
  - Nirmatrelvir 300 mg orally twice daily for 5 days
  - Ritonavir 100 mg orally twice daily for 5 days
- GFR 30 to <60 mL/min:
  - Nirmatrelvir 150 mg orally twice daily for 5 days
  - Ritonavir 100 mg orally twice daily for 5 days

Qualifying criteria for treatment with Lagevrio (molnupiravir): is the alternate preferred treatment for eligible adult patients with positive results of SARS-CoV-2 viral testing and who are at high risk for progression to severe COVID-19. Lagevrio is contraindicated in patients aged ≤18 years and pregnant women due to bone and cartilage toxicity.

Lagevrio dosing:

Symptom onset ≤5 days.

- Patient is 18 or older and not pregnant (females)
- Positive test for SARS-CoV-2 and symptom onset within 5 days
- At high risk for progression to severe COVID-19 (see above)
- People of childbearing potential should use reliable contraception for the duration of molnupiravir treatment and for 4 days after it is stopped.
- Men, if sexually active, should use a reliable method of contraception during molnupiravir treatment and for 3 months after molnupiravir is stopped.

Dosing: Molnupiravir 800 mg (four 200 mg capsules) orally twice daily for 5 days.

Veklury (remdesivir):

Symptom onset ≤ 7 days*:*

Dosing for patients over 12 years or over 40 kg: 200 mg IV on day 1, 100 mg IV on days 2 and 3.
Dosing for patients under 12 years and less than 40 kg but more than 3 kg: 5 mg/kg IV on day 1 followed by 2.5 mg/kg IV once daily from day 2 to day 3.

When giving products under Emergency Use Authorization, providers must:

Give the patient the "Fact sheet for patients"
Inform patients of alternatives to treatment
Inform patients that this is an unapproved drug.

3.1.2 Patient Prioritization Strategies for Treatment

When there are logistical or supply constraints, clinicians should prioritize treatment for patients at highest risk of clinical progression to severe COVID-19 based on 4 keys elements: unvaccinated individuals presenting with moderate-severe COVID-19 symptoms**, age, vaccination status, immune status** and **clinical risk factors.** The group are listed by tier in descending order of priority: *(Annex-IV)*

Tier 1:

- Immunocompromised individuals, regardless of vaccination status
- Unvaccinated individuals at the highest risk of severe disease (anyone aged ≥ 75 years or anyone aged ≥ 65 years with additional risk factors)

Tier 2: unvaccinated individuals not included in Tier 1 who are at risk of severe disease (anyone aged ≥ 65 years or anyone aged < 65 years with clinical risk factors)

Tier 3: Vaccinated individuals at high risk of severe disease (anyone aged ≥ 75 years or anyone aged ≥ 65 years with clinical risk factors)

Tier 4: Vaccinated individuals at risk of severe disease (anyone aged ≥65 years or anyone aged <65 years with clinical risk factors)
Risk factors: *hypertension, diabetes, cardiac disease, chronic lung disease, cerebrovascular disease, dementia, mental disorders, chronic kidney disease, immunosuppression (including HIV), obesity, cancer and unvaccinated against COVID-19. Risk factors in pregnant or recently pregnant women: advanced maternal age (>=35 years), obesity, chronic medical conditions, and pregnancy specific disorders (e.g. gestational diabetes and pre-eclampsia/ eclampsia).*

4.0 CASE DETECTION AND REFERRAL FOR TEST AND TREAT

Common indications for COVID-19 testing:

- Presence of COVID-19 symptoms (e.g., fever or chills, cough, sore throat, shortness of breath or difficulty breathing, fatigue, headache, muscle aches, etc.)
- At least 5 days after known or suspected close contact with COVID-19
- Symptoms in an area with high COVID-19 prevalence or high community transmission.
- Only WHO Emergency Use Listed test kits should be used for COVID-19 testing. The antigen detection rapid diagnostic test (Ag-RDT) is a useful diagnostic tool for the detection and management of COVID-19 spread; however, it may miss the first day of symptom onset depending on the variant of SARS-CoV-2.

This guideline is intended to get eligible symptomatic COVID-19 patients with positive test results treated as soon as possible. If the patient has symptoms but tests negative, consider re-testing at a later point. For individuals where Test to Treat is not indicated, preventive measures for transmission to others should be followed including quarantining, use of face masks or coverings and proper hand washing to minimize the risk of transmission. Countries carefully consider the national referral guide for testing and treatment. Individuals should follow national guidelines on physical or social distancing.

5.0 MANAGEMENT STRATEGIES FOR DRUG AND DRUG INTERACTIONS

Drug and drug interactions may lead to:

- Clinically significant adverse reactions, potentially leading to severe, life-threatening, or fatal events from greater exposures of concomitant medications.
- Clinically significant adverse reactions from greater exposures to PAXLOVID.
- Loss of therapeutic effect of PAXLOVID and possible development of viral resistance.

Potential management strategies for patients who are to receive **Paxlovid** (ritonavir-boosted nirmatrelvir) include:

- Temporarily withholding the concomitant medication,
- Increasing monitoring for potential adverse reactions to the concomitant medication,
- Adjusting the dose of the concomitant medication,
- Using an alternative to the concomitant medication, *or*
- Using alternative COVID-19 therapies.
  Check for drug interactions: https://www.med.umich.edu/asp/pdf/outpatient_guidelines/Paxlovid-DDI.pdf
  https://www.fda.gov/media/158165/download

Use the chosen strategy for the 5-day duration of Paxlovid (ritonavir-boosted nirmatrelvir) treatment and for at least 2 to 3 days after treatment completion. This strategy may need to continue for a longer duration if Paxlovid (ritonavir-boosted nirmatrelvir) is initiated in an elderly patient or if the interacting medication has a long half-life.

Patient counselling information:

- Advise the patient to discontinue the drug and to inform their healthcare provider at the first sign of skin rash, hives or other skin reactions, difficulty in swallowing or breathing, any swelling suggesting angio-oedema (e.g., swelling of lips, tongue, face, tightness of the throat, hoarseness) or other symptoms of allergic reaction
- Inform the patient that Paxlovid may interact with some drugs and is contraindicated for use with some drugs, so the patient should be advised to report to their healthcare provider the use of any prescription, non-prescription medication, or herbal products
- Provide patients with clear administration instructions.

ANNEXES

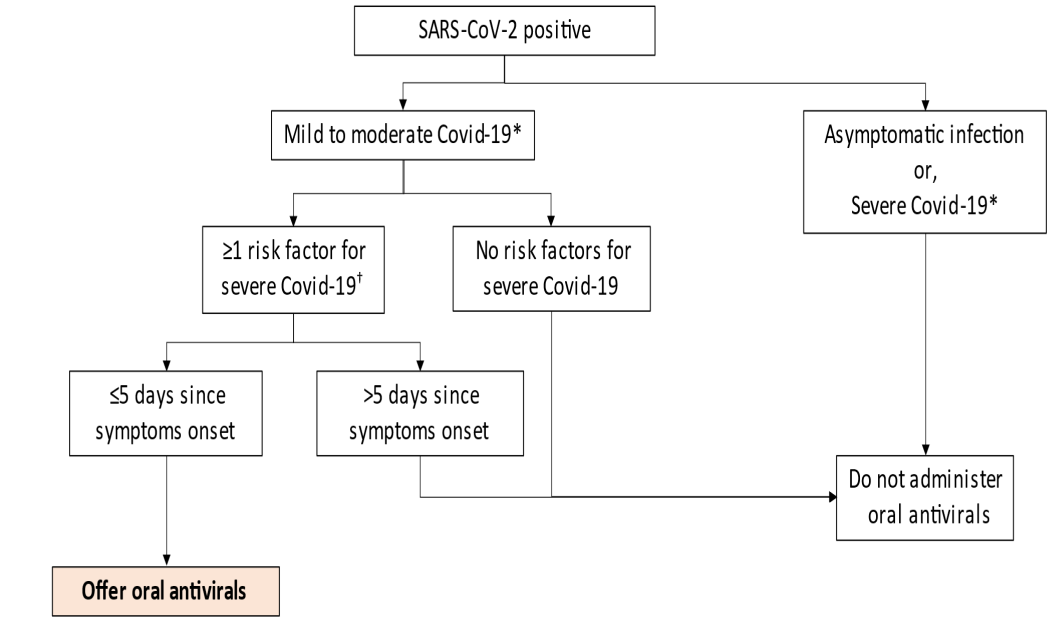
Annex I: List of Abbreviations and Acronyms

Africa CDC	Africa Centres for Disease Control and Prevention
Ag-RDTs	Antigen rapid diagnostic tests
AIDS	Acquired immunodeficiency syndrome
ART	Antiretroviral therapy
AU	Africa Union
CFR	Case Fatality Rate
CHWs	Community health workers
COVID-19	Coronavirus disease 2019
HIV	Human Immunodeficiency Virus
OPD	Out-patient department
PACT	Partnership to Accelerate COVID-19 Testing
PLHIV	People living with HIV&AIDS
SARS-COV-2	Severe acute respiratory syndrome coronavirus 2
TB	Tuberculosis
TWGs	Technical working groups
VoC	Variant of concern
WHO	World Health Organization

Annex II: Risk factors for severe COVID-19

Risk factors for severe COVID-19		
Included here are some medical conditions that may place patients at a higher risk for progression to severe COVID-19:		
▪ Age 65 years and older ▪ BMI of more than 25 kg/m^2 ▪ Pregnancy ▪ Chronic kidney disease ▪ Diabetes mellitus	▪Immunosuppressing medications ▪ Cardiovascular disease or hypertension ▪ Chronic lung disease ▪ Sickle cell disease	• Neurodevelopmental disorders or conditions that confer medical complexity • Medical technological dependence, e.g., tracheostomy

Annex III: Treatment algorithm for oral antiviral drugs for SARS-CoV-2



* Severe Covid-19 is defined as: Shortness of breath/dyspnoea on exertion/difficulty breathing, Oxygen requirement (SpO2 <90% of room air), or tachypnoea (i.e., ≥30 breaths per minute)
† For patients 50-64 years old who are vaccinated, the overall risk of progression to severe disease is low enough that the absolute benefit of treatment may not outweigh any potential risk of harm (eg, medication adverse effects, risk of "rebound COVID-19" requiring extension of the isolation period). For unvaccinated individuals 50-64 years old, the clinical benefit likely outweighs risks

Annex IV: Patient Prioritization for Treatment

Patient Prioritization for Treatment	
Tier	**Risk Group**
1.	Immunocompromised individuals not expected to mount an adequate immune response to COVID-19 vaccination or SARS-CoV-2 infection due to their underlying conditions, regardless of vaccine status (see Immunocompromising Conditions below); or Unvaccinated individuals at the highest risk of severe disease (anyone aged ≥75 years or anyone aged ≥65 years with additional risk factors).
2.	Unvaccinated individuals not included in Tier 1 who are at risk of severe disease (anyone aged ≥65 years or anyone aged)
3.	Vaccinated individuals at high risk of severe disease (anyone aged ≥75 years or anyone aged ≥65 years with clinical risk factors) **Note:** Vaccinated individuals who have not received a COVID-19 vaccine booster dose are likely at higher risk for severe disease; patients within this tier in this situation should be prioritized for treatment.
4.	Vaccinated individuals at risk of severe disease (anyone aged ≥65 years or anyone aged < 65 years with clinical risk factors. **Note:** Vaccinated individuals who have not received a COVID-19 vaccine booster dose are likely at higher risk for severe disease; patients within this tier in this situation should be prioritized for treatment.

Annex V: Types of COVID-19 Testing Methods

Test Name	Type of Test	Early Detection of COVID-19 (First 1-5 Days)	Sensitivity/ Specificity	Authorized by WHO or US FDA or Other?	Comment (Why is this diagnostic tool good for Test-to-Treat?)	Websites
Xpert Xpress SARS-CoV-2	Molecular point of care	N/A	97.8% / 95.6%	WHO EUL, US FDA	EUL listed; listed as POC by FIND and US FDA	Cepheid | Xpert Xpress SARS-CoV-2 (EUA)
VitaPCR™ SARS-CoV-2 Gen 2 Assay	Molecular point of care	N/A	N/A	CE-IVD (submitted to US FDA for approval)	20 min TAT; listed as POC by FIND	VitaPCR™ SARS-CoV-2 Gen 2 Assay (FDA EUA) - Credo Diagnostics Biomedical Pte. Ltd (credodxbiomed.com)
Wondfo 2019-nCoV Antigen Test (Lateral Flow Method)-Self-test	Antigen	N/A	91.63%/ 99.84%	WHO EUL	20 min TAT; EUL listed; listed as POC by FIND	Wondfo Biotech – Leading POCT Company Specialize in the IVD Industry
LumiraDx SARS-CoV-2 Ag Test	Antigen	Within 12 days of symptom onset	97.6%/ 96.6%	WHO EUL, US FDA	EUL listed; listed as POC by FIND	https://www.lumiradx.com/
Flowflex SARS-CoV-2 Antigen Rapid Test (Nasal/ Saliva)	Antigen	Within 7 days of symptom onset	93%/100%	WHO EUL/ US FDA	EUL listed; listed as POC by FIND	COVID-19 Antigen Home Test - Instructions for Use for Healthcare Providers (fda.gov)
OnSite COVID-19 Ag Rapid Test	Antigen	Within 7 days of symptom onset	94.7%/ 100%	WHO EUL	15 min TAT; EUL listed (and listed as at-home test); listed as POC by FIND	https://www.ctkbiotech.com
Sure status COVID-19 antigen Card Test	Antigen	N/A	94.16%/ 100%	WHO EUL	15-20 mins TAT; EUL listed; listed as POC by FIND	https://www.premiermedcorp.com 21 06 04 EUL 0590-010-00 Sure Status COVID-19 Card Test _PR_v_1.0.pdf (who.int)
Panbio COVID-19 Ag Rapid Test Device (Nasopharyngeal)	Antigen	Within 7 days of symptom onset	91.4%/ 99.8%	WHO EUL	EUL listed; listed as POC by FIND	https://www.abbott.com/
Panbio COVID-19 Ag Rapid Test Device (Nasal)	Antigen	Within 7 days of symptom onset	98.1%/ 99.8%	WHO EUL	EUL listed; listed as POC by FIND	https://www.abbott.com/
SD Biosensor STANDARD Q COVID-19 Ag Test	Antigen	N/A	84.97/ 98.4	WHO EUL	15-20 mins TAT; EUL listed; listed as POC by FIND	https://www.sdbiosensor.com SD BIOSENSOR | PRODUCTS

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Disclaimer: *This resource is intended to serve as a guide to available COVID-19 antiviral treatment options.* ***It is not intended to endorse or otherwise promote a specific clinical recommendation or course of action.*** *Additionally, it does not include other forms of guidance that may be available for specific subsets of populations. Finally, the guidelines referenced here may not consider local allocation and availability of scarce resources.*

Africa Centres for Disease Control and Prevention (Africa CDC),
African Union Commission
Roosevelt Street W21 K19, Addis Ababa, Ethiopia

+251 11 551 7700 africacdc@africa-union.org www.africacdc.org africacdc @AfricaCDC