مركز أبوظبي للصحة العامة
ABU DHABI PUBLIC HEALTH CENTRE

دائـــرة الـصـحـــة
DEPARTMENT OF HEALTH

Circular No(2022 / 265) تعميـم رقم

Date: 08/12/2022

التاريخ: 2022/12/08

To:
All Healthcare Facilities in the Emirate of Abu Dhabi

إلى :
جميع المنشآت الصحية في إمارة أبوظبي

Subject:Updates on Guidelines for Management of Covid-19 Cases

الموضوع: تحديث دليل إجراءات التعامل مع حالات كوفيد-19

Greetings,

تحية طيبة وبعد ،،،

We would like to extend you our greetings wishing you all the best and success.

بدايةً، يسرنا أن نتقدم لكم بخالص التحية والتقدير متمنين لكم دوام التوفيق والسداد.

In the light of easing restrictions and measures related to Covid-19 and enhancing the recovery from the pandemic, and providing the highest standards of care, Covid-19 Guidelines for Healthcare Professionals has been updated (attached).

في ظل تخفيف القيود والتدابير الخاصة بكوفيد-19 وتعزيز التعافي من الجائحة، وتوفير أعلى معايير الخدمات الصحية المقدمة، فقد تم تحديث دليل الإرشادات الخاصة بكوفيد-19 للمهنيين الصحيين (مرفق).

The guidelines include the updates on the following therapeutic and prophylactic medications:

يشمل الدليل تحديث العقارات العلاجية والوقائية التالية:

- Update of pre-exposure prophylaxis for Evusheld.
- Adding Evusheld as treatment for cases at high risk for severe or critical disease.
- Adding indications for use of Paxlovid antiviral medication in treatment plan.
- Remove Sotrovimab from treatment plan.

- تحديث الجرعة الوقائية لما قبل الإصابة لعقار إيفوشيلد.
- إضافة إيفوشيلد كعقار علاجي للحالات المعرضة للإصابة الشديدة والحرجة.
- إضافة دواعي استخدام المضاد الفيروسي Paxlovid ضمن الخطة العلاجية.
- إزالة عقار سترووفيماب من الخطة العلاجية.

For further enquiries, kindly contact Communicable Diseases Department /ADPHC via email: responseCDD@adphc.gov.ae

لمزيد من الاستفسارات، يرجى التواصل مع إدارة الأمراض السارية بمركز أبوظبي للصحة العامة عبر البريد الإلكتروني: responseCDD@adphc.gov.ae

We hope that all will adhere to the above, for the best interest of work.

آملين من الجميع الالتزام بما ورد أعلاه، لما فيه مصلحة العمل.

Thanking you for your kind cooperation,,,

شاكرين لكم حسن تعاونكم معنا،،،

دائرة الصحة US 02 DEPARTMENT OF HEALTH

د. جمال محمد الكعبي
وكيل دائرة الصحة

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COVID-19 Guideline for Healthcare Professionals

Updated November 2022

Version 4

Summary of Updates – November 2022:

- Evusheld therapeutic indications added
- Evusheld dose for Pre-exposure Prophylaxis updated
- Sotrovimab removed from treatment plan
- Paxlovid indications added in treatment plan
- Isolation and contact tracing protocols updated
- Routine PCR indications added

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Contents

Introduction

- This guidance has been produced to ensure safe admission and discharge of COVID-19 related illness patients through various healthcare facilities and isolation modalities.
- Consequently, if the COVID-19 diagnosis is an incidental finding in a patient with an unrelated primary diagnosis requiring hospitalization then it is the primary diagnosis that should drive disposition decisions.

- Admission decision: This guidance has been produced to aid physicians to risk stratify patients according to three categories; Comorbidities, Clinical, and Radiological criteria to aid the admission decision destination.

  - Every patient should have all three criteria assessed and taken into consideration before a decision been made to dispose of the patient.

  - The most severe of each category (comorbidities, clinical and radiological) should drive decision making. For example; patient has comorbidity and clinical criteria suitable for home isolation but radiological criteria that qualify them for tertiary hospital care, then the patient should be admitted to tertiary hospital.

- Discharge decision: The discharge decision criteria have been detailed below to ensure safe stepdown of care from healthcare facilities.
  It is important to remember that when the patient fulfil criteria to discharge from tertiary/field hospital to isolation facility/home isolation, there is no need to wait for a negative PCR result/s.

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Case Definition

Suspected case

- Any person meeting the clinical criteria.

Probable case:

- Any person meeting the clinical criteria with an epidemiological link **OR**
- A suspect case for whom testing result for the COVID-19 is reported as "Inconclusive" by the laboratory.

Confirmed case:

- Any person meeting the clinical criteria and/or epidemiological criteria with laboratory criteria.
- Any person meeting the laboratory criteria.

- **Clinical criteria**

Any person with at least one of the following symptoms *

- Cough
- Fever
- Shortness of breath
- Sudden onset of anosmia, ageusia or dysgeusia

* *Additional less specific symptoms may include headache, chills, muscle pain, fatigue, vomiting and/or diarrhea*

- **Diagnostic imaging criteria**

Radiological evidence showing lesions compatible with COVID-19
Laboratory criteria

Detection of SARS-CoV-2 nucleic acid in a clinical specimen

- **Epidemiological criteria**

- Close contact with a confirmed COVID-19 case in the 14 days prior to onset of symptoms.

Note: Clinicians should be alert to the possibility of atypical presentations in patients who are immunocompromised.

Isolation Protocol for COVID-19 cases

- High risk patients and/or age above 50 years or having symptoms, should visit designated assessment centers within 24 hours for medical assessment and isolation measures
- Patients below 50 years old should repeat the PCR test in any testing center/healthcare facility. If second result is positive, self-isolate at home until virtual assessment team contacts them.
- Patient should discontinue the isolation after 5 days of positive PCR or two consecutive negative PCR test (24 hours gap).

Contact Tracing

- Close contacts should self- monitor for symptoms and get tested immediately if they develop any symptoms.
- Home quarantine is not required for contacts.
- High-risk contacts (above 50, chronic diseases or people of determination) are recommended to test and monitor symptoms for 7 days. Those who develop symptoms should seek medical care for clinical assessment and management plan.

Routine Tests (PCR)

- Health care workers (HCW): no routine test is required. All HCW should comply with wearing mask in the facilities

- Visitors: no routine test is required. All visitors should comply with wearing mask in the facilities. When visiting high risk units, facility must screen visitors for respiratory symptoms prior to entering

- Pre-operative screening:

    - All patients must be screened for Covid-19 using PCR prior to the procedure. For positive cases, **elective** procedures must be postponed for at least 7 weeks. The medical team can decide to do the procedure earlier as deemed necessary for the quality of care for patient

Adults COVID-19 Management Guidelines

Comorbidities Categories

a) Category One
b) Category Two

Clinical Spectrum of illness

a) Asymptomatic
b) Mild Illness
c) Moderate Illness
d) Severe Illness
e) Critical Illness

Radiological Spectrum of illness

a. No radiological features of COVID pneumonia
b. Mild severity COVID Pneumonia
c. Moderate severity COVID
d. Severe COVID

1. Comorbidities Categories

I. **Category One:**

a) Age more than 65 with no comorbidities
b) Diabetes Mellitus: well controlled
c) Hypertension: Well controlled on management plan
d) Stable chronic kidney disease including End Stage Renal disease on Hemodialysis
e) Stable Chronic Liver disease (No history of decompensation)
f) Stable chronic heart disease, including Ischemic heart disease
g) Immunocompromised state, Malignancy; stable disease on chemotherapy/radiotherapy or transplant patients and those on current use of biological medications (e.g., TNF inhibitors, interleukin inhibitors, anti-B cell agents).
h) Stable other medical conditions required no hospitalization for the last 6 months.
i) BMI more than 35.

II. **CategoryTwo** *(Note that the main reason of tertiary hospital admission can be related to underlying co morbidities for subspecialty care and not ONLY covid-19 management).*

a. Unstable or severe chronic clinical condition
b. Cardiovascular diseases
   i. Recent history (less than one month) of myocardial infarction/cardiac intervention.
   ii. Unstable or severe cardiovascular diseases
   iii. Heart failure class 4
c. Severe Chronic lung disease:
   i. Patient on home oxygen/Nebulizer
   ii. Limited mobility due to SOB, not able to care for him/herself. (unless the patient has a career who met the criteria as an escort)
d. Severe unstable Chronic Kidney disease
e. Decompensated liver disease
f. Patient with labile or unstable INR on warfarin

g. Patient eligible for monoclonal antibody but refused treatment (requires medical evaluation by tertiary hospital).

h. Patients from Long term care facility

i. Active/Unstable psychiatric conditions requiring inpatient care.

j. Unstable symptomatic pregnancy at any trimester.

k. Any condition from category one or two perceived by the physician to possess an overall clinical concern for risk in outpatient or hospital field settings.

2. Clinical Spectrum of illness

a) Asymptomatic

- Individuals who have no symptoms that are consistent with COVID-19.

b) Mild Illness:

- Individuals who have any of the various signs and symptoms of COVID-19 (e.g., fever, cough, sore throat, malaise, headache, muscle pain, nausea, vomiting, diarrhoea, loss of taste and smell) but who do not have shortness of breath, dyspnoea, respiratory rate <20 at rest, oxygen saturation (SpO2) ≥94% on room air.

c) Moderate Illness:

- Individuals who has new onset dyspnoea or those with evidence of lower respiratory disease during clinical assessment and who have respiratory rate < 24 at rest, an oxygen saturation (SpO2) ≥94% on room air at sea level.

d) Severe Illness:

- Individuals who have SpO2 <94% on room air at sea level, a ratio of arterial partial pressure of oxygen to fraction of inspired oxygen (PaO2/FiO2) <300 mm Hg, a respiratory rate >30 breaths/min.

e) Critical Illness:

- Individuals who have respiratory failure, septic shock, and/or multiple organ dysfunction.

3. Radiological Spectrum of illness

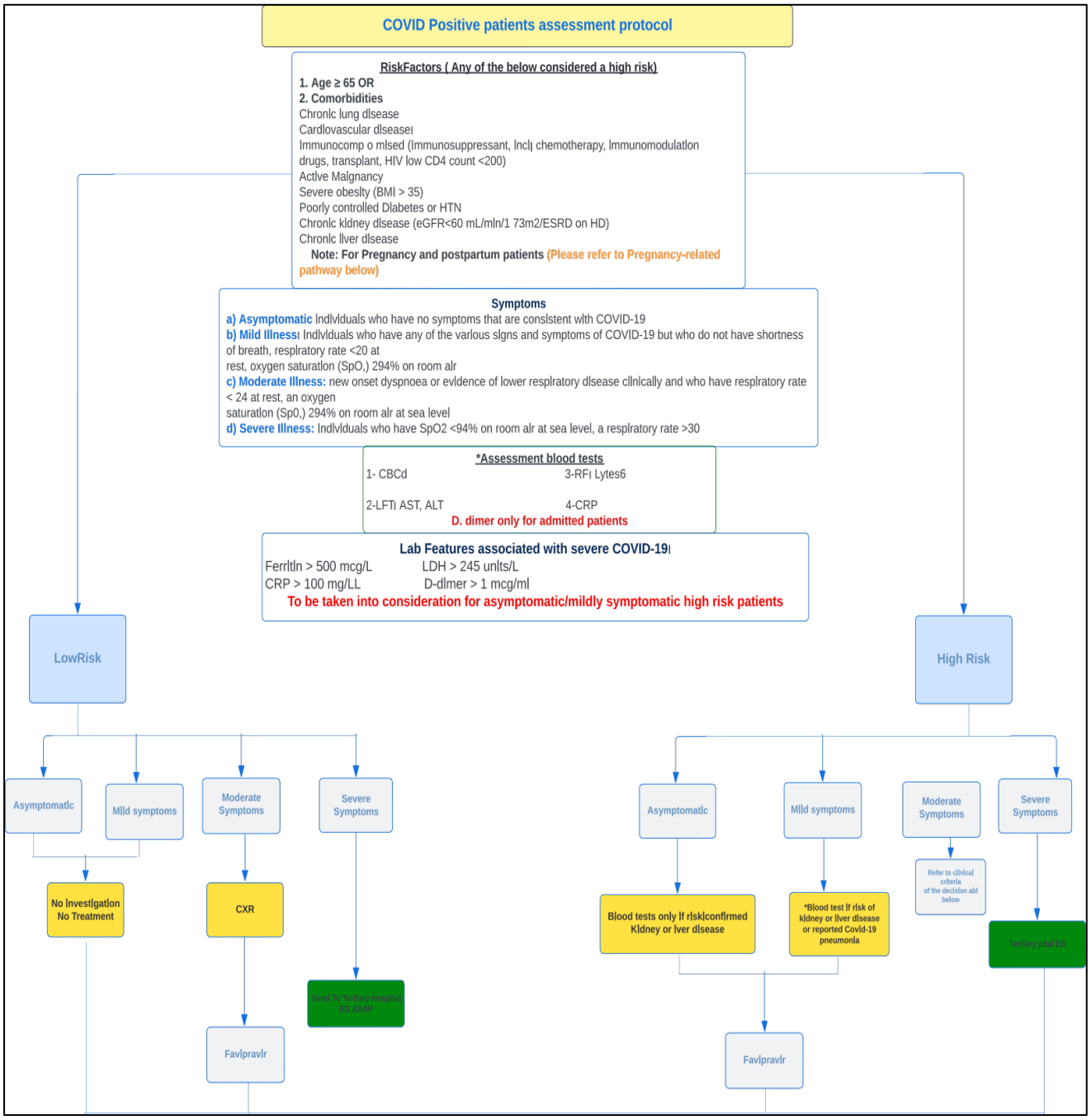
a) **No radiological features of COVID pneumonia**

b) **Mild severity COVID Pneumonia**

c) **Moderate severity COVID**

d) **Severe COVID**

4. Criteria for disposition of COVID-19 infected patients from assessment centers



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5. Criteria for transfer from field hospital to nearest tertiary hospital

i. Persistent deterioration from baseline vitals or clinical condition not responding to initial treatment, or

ii. Patient is unable to maintain target oxygen saturation on 6 Liter/min Oxygen therapy, or

iii. MEWS of 4 or a single score of 2 or more for SBP, HR and AVPU or more than 2 for RR.

The most severe of each category (comorbidities, clinical and radiological) should drive decision making

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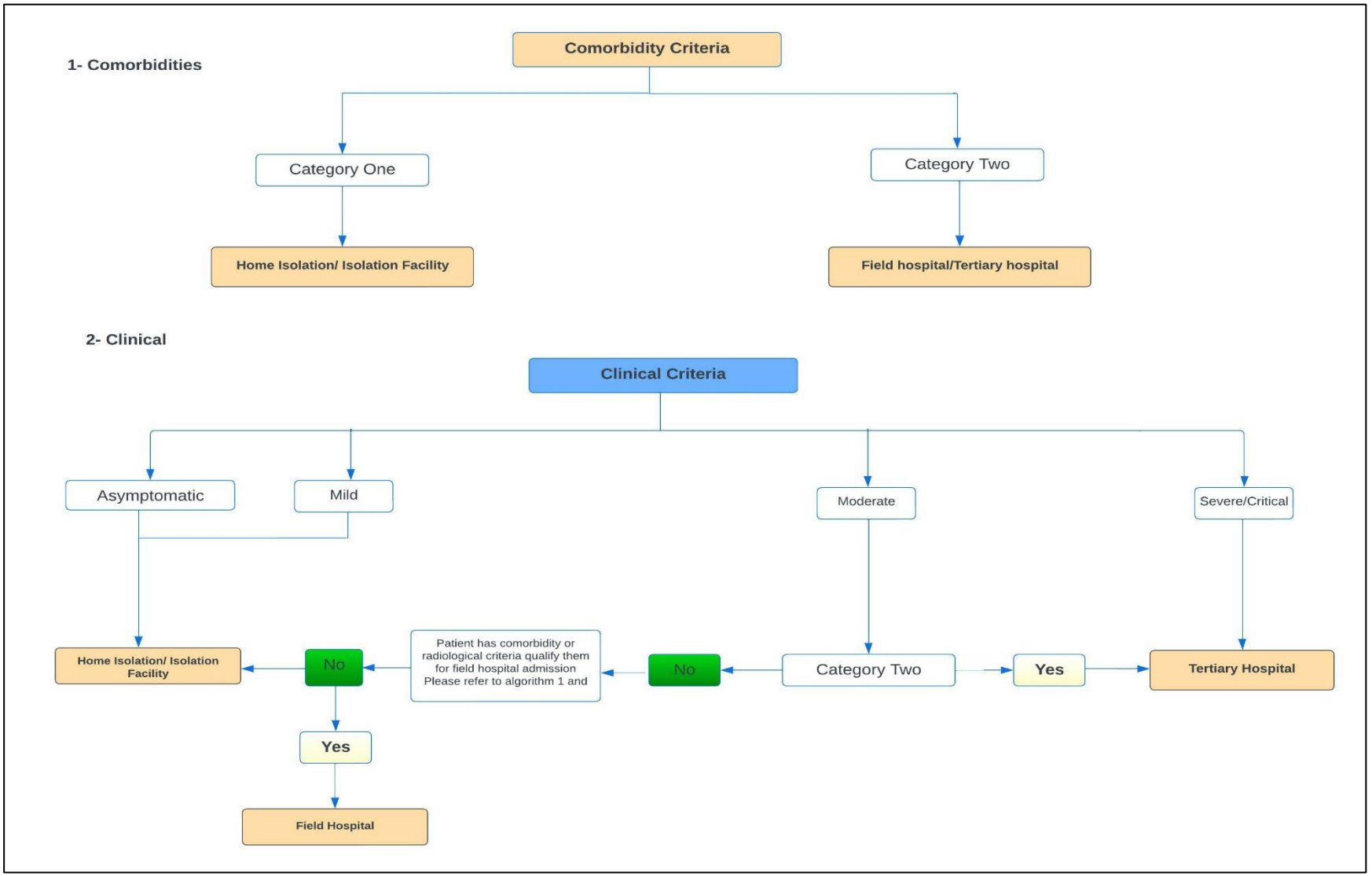
1- Comorbidities
Comorbidity Criteria
Category One
Category Two
Home Isolation/ Isolation Facility
Field hospital/Tertiary hospital
2- Clinical
Clinical Criteria
Asymptomatic
Mild
Moderate
Severe/Critical
Home Isolation/ Isolation Facility
No
Patient has comorbidity or radiological criteria qualify them for field hospital admission Please refer to algorithm 1 and
No
Category Two
Yes
Tertiary Hospital
Yes
Field Hospital

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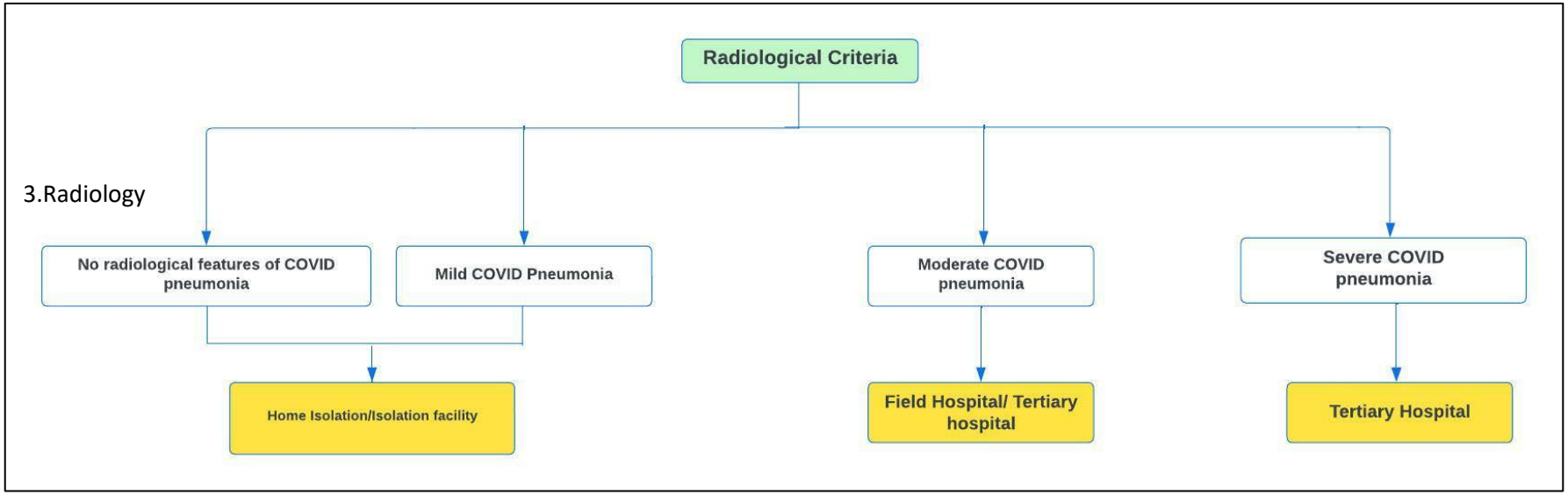
3.Radiology



6. Criteria for discontinuing Isolation of Patients with COVID-19

- Mild/moderate COVID-19 / Not severely immunocompromised
    a) Resolution of fever, if present, for at least 24 hours, and
    b) Clinical improvement of symptoms other than fever and
    c) Two consecutive negative SARS-CoV-2 RADT or RT-PCR tests from respiratory specimens with a minimum 24-hour interval.

    OR

    d) 5 days after the first positive PCR test.
- Severe COVID-19/ Not severely immunocompromised
    a) Resolution of fever for at least 24 hours and clinical improvement of symptoms other than fever, **and**
    b) Two consecutive negative SARS-CoV-2 RADT or RT-PCR tests from respiratory specimens with a minimum 24-hour interval

    OR

    c) minimum 14 and up to 20 days after the first positive PCR test.

- Immunocompromised patient
    a) Resolution of fever, if present, for at least 24 hours and
    b) clinical improvement of symptoms other than fever and
    c) Two consecutive negative SARS-CoV-2 RADT or RT-PCR tests from respiratory specimens with a minimum 24-hour interval

    OR

    d) **20 days** after the first positive PCR test.

7- Monoclonal Antibodies (MAB) for Covid-19

i- Pre-Exposure Prophylaxis:

Evusheld is approved under emergency use authorization for pre-exposure prophylaxis among non-infected individuals and who are not a contact of COVID-19 case. Eligible groups include adults and children above 12 who weigh at least 40 kg and:

- unvaccinated individuals due to severe adverse reaction to the available vaccines. Or,
- Those with immunocompromised conditions or taking immunosuppressant medications who may not mount sufficient immune response.

Dosage and Administration:

Evusheld is given as two separate consecutive intramuscular injections (IM)

- Dosing for individuals who did not receive Evusheld previously:

Initial dose: 300 mg of tixagevimab and 300 mg of cilgavimab administered as two separate consecutive intramuscular injections.

- Dosing for Individuals Who Initially Received 150 mg of Tixagevimab and 150 mg Cilgavimab
  - if Initial dose ≤3 months prior: 150 mg tixagevimab and 150 mg cilgavimab.
  - Initial dose >3 months prior: 300 mg tixagevimab and 300 mg cilgavimab.

- Repeat dose:

300 mg of tixagevimab and 300 mg of cilgavimab every 6 months. Repeat dosing should be timed from the date of the most recent EVUSHELD dose, and based on the assessed epidemiological situation of Covid-19 and continued risk of exposure.

Warnings and Precautions:

- Hypersensitivity Including Anaphylaxis: observe for clinical signs and symptoms of anaphylactic reaction. In case of occurrence provide supportive medical management.
- Clinically significant bleeding disorder: Evusheld must be administered with caution in presence of thrombocytopenia or coagulation disorders.
- Cardiovascular Event: although no causal relationship established between Evusheld and cardiovascular events, precautions and close monitoring must be considered prior to administration. Discuss risk and benefits among individuals with cardiovascular risk factors or history. Individuals must seek medical attention if they develop signs and symptoms of cardiovascular event.

Contraindications:

Evusheld is contraindicated among individuals with history of anaphylactic reaction to the treatment or any of its components.

Post administration monitoring:

We emphasize importance of post administration observation for one hour, particularly for people with coagulation abnormality or cardiovascular risk factors. Follow-up shall continue through teleconsultation, once weekly for 1 month after administration.

ii- Treatment:

Evusheld is approved under emergency use authorization in EU for treatment of mild to moderate Covid-19 among adults and children above 12 who weigh at least 40 kg, and are at high risk of developing severe disease or death, and who do not require supplemental oxygen.

Indications:

To be used for in adults who are currently infected with SARS-CoV-2 and symptom onset less than 5 days with risk factors.

• For paediatric population (12 years of age and older weighing at least 40 kg), to consult paediatric ID

Dosage and Administration:

300 mg of tixagevimab and 300 mg of cilgavimab administered as two separate consecutive intramuscular injections.

Evusheld is available in the following facilities:

SEHA & AHS Facilities
SSMC
Cleveland Clinic Abu Dhabi
VPS group Hospitals

Annex

Annex 1: Adult Modified Early Warning Score

APPENDIX D: Adult Modified Early Warning Score Tool

This tool may not identify all patients at risk of deterioration, therefore if you have any clinical concerns that the patient is becoming un well contact the physician.

PARAMETER	SCORE						
	3	2	1	0	1	2	3
Temperature - ° C		35 or less	35.1- 36	36.1 - 37.9	38-38.9	39 or more	
Systolic Blood Pressure -SBP	70 or less	71-80	81-100	101-179		180-199	200 or more
Heart rate/minute -HR	40 or less		41-50	51-100	101-110	111-129	130 or more
Respiration/minute -RR	8 or less			9-18	19-25	26-29	30 or more
Oxygen Saturation - SpO2	89% or less	90 -93%	94 - 96%	Greater than 96%			
AVPU*				Alert	New confusion or agitation	Voice	Pain or Unresponsive

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Annex2: Phlebotomy Service Requirements at Isolation Camp

Ref No.	Requirement	Specification	Guidelines
BC001	Facility, Furniture, Safety and Security	Furniture shall Include: Blood Collection Reclining chair that allows 12" height above the heart for the foot piece	The nurse should be able to adjust the chair to recline it in case if the patient faint.
BC002	Blood collection Policies and SOPs	There shall be a properly indexed Blood collection file with:	all the policies and procedures should be available and accessible by the phlebotomists
BC003	Blood collection Policies and SOPs	1.Blood collection Policies (Patient ID, Samples handling and preservation, and transportation)	check preanalytical requirements as listed in PP.4
BC004	Blood collection Policies and SOPs	2. Standard Operating Procedure (SOP) for Venous and capillary blood collection.	according to the scope of practice and procedures list, check written policies and procedures that are developed to provide specimen collection protocols for each type of specimen submitted to the laboratory. This is also applicable for areas outside of the blood collection area where health care professionals other than lab staff collect specimens, i.e. nurses in wards,
BC005	Blood collection Policies and SOPs	3. SOP for the collection of any special blood samples (e.g., blood culture, GTT, ..., etc).	locate SOP in each are that practice specimen collection (electronic or hard copies)
BC006	Blood collection Policies and SOPs	4. If applicable, SOP for the proper collection of all collected nonblood samples (Urine, Culture Swaps, …, etc	locate SOP in each are that practice specimen collection (electronic or hard copies
BC007	Staff and Staff Competency	1. Copies of evidence of Job description, Orientation, On-going training and competency (Last two) on using the Vacutainer, Syringe, Butterfly and Capillary blood collection, for the authorized staff to perform the blood collection in the phlebotomy room. (including their names in a list)	The list should be available including the name of the staff who are trained and authorized to perform in the phlebotomy room (only names). Competency and other requirements should be available in the personal file of the staff.
BC008	Blood Collection Log/Sheets/Books/IT	1. Soft and/or hard copies of records shall be maintained and retained for patients that had their blood collected. And it should be secured 24/7.	it should be secured and accessible only by the staff

BC009	Blood Collection Log/Sheets/Books/IT	2. The record shall have the date. Sequence number, patient's full name. Patient's unique identifier (file number), gender, ordering doctor, fasting status, type and number of collected tubes, comments section, and the timed signature of the phlebotomist who collected the blood.	if it is hard copy, it should be written in a fixed style without leaving gaps or empty spaces Corrector should not be applied to remove errors from the book, only cross and signature of the one who make the correction.
Ref No.	**Requirement**	**Specification**	**Guidelines**
BC011	Blood Collection Materials and Expiration Date Monitoring	2. There shall be a noted evidence (dated signature with comment/s) that these records are monitored by the designated Center/clinic/lab staff.	Auditor requested form
BC012	Specimens labelling (patient and Phlebotomist)	1. Proper label must have, but not limited to, Patients full name, Unique ID number, Location (OPD/ER/room number) Phlebotomist signature/date and time of collection	Time of collection should be written by the phlebotomist, not only electronically. Because there is a time gap between printing the sticker and the actual time of collecting the blood.
BC013	Specimens labelling (patient and Phlebotomist)	2. If a sticker is used, the phlebotomist shall initial across the sticker after posting in the blood collection logbook/computer.	To prevent any misuse or alteration the actual information, in other words to prevent any one to put another sticker with another patient information on the actual sticker. So, to apply the sticker then initial cross between the sticker the page of the logbook.
BC014	Blood Collection Errors/incidents Monitoring Records (hematoma/>2 Sticks)	Monitoring log sheets shall be developed for phlebotomists to record the occurrences associated with Material Defects (Tubes without Vacuum, Defective syringes, Non-polished needles, …, etc); Patient's discomfort [multiple sticks (>1) Fainting]; and patient injuries (Needle stick and tripping)	The form should be available or the way of reporting incidents (which be included in the policy). In addition, the action taken after the incidents should be available as well.
BC015	Specimens Rejection: monitoring Records	1. There shall be a mechanism (Policy, SOP, Protocol) with a recording system for the systematic monitoring of the different types of samples rejection.	REVIEW REJECTION LOGS FOR SAMPLE REJECTION, TRACE SOURCES, FREQUENCY, CORRECTION PLANS
BC016	Commissioning, Calibration and PPM Reports (Centrifuge and Refrigerator/s):	Calibration report	review historical file for each instrument
BC017	Commissioning, Calibration and PPM Reports (Centrifuge and Refrigerator/s):	Electrical Safety Test report and Printout	review historical file for each instrument
BC018	Refrigerator Temperature monitoring and Temperature Stability test (using Grade-A Internal Thermometer)	Temperature stability at all shelves is performed (once per year)	REVIEW HISTORICAL FILE AND DOCUMENTATION
BC019	Refrigerator Temperature monitoring and Temperature Stability test (using Grade-A Internal Thermometer)	24/7 Temperature monitoring records (Temp. Chart or tracer)	REVIEW HISTORICAL FILE AND DOCUMENTATION

Ref No.	Requirement	Specification	Guidelines
BC020	Refrigerator Temperature monitoring and Temperature Stability test (using Grade-A Internal Thermometer)	Evidence of monitoring all Temperature and Centrifuge records (dated signatures and comments)	REVIEW HISTORICAL FILE AND DOCUMENTATION
BC021	Centrifuge Daily care/Calibration/ PPM Reports:	Daily care (cleaning inside (Balance buckets) and outside)	Log sheet should be available and checked daily by the responsible staff.
BC022	Specimens Transport Sheet:	Includes, Full name Unique ID, Total and type of tubes (Red, Lavender) and sample (Serum Plasma), tubes position should be vertical and contact with frozen or Cold Back, Seal Number or Keylock, tech and driver's timed names and signatures. Temperature should be written and approved at each station; departure, with the driver once received by him and the final destination once received in the lab.	Should be available and clear step by step as mentioned in the point (concern on the left). The staff (phlebotomists) should be aware of the full journey of transporting the specimens.
BC023	Specimens preparation for Transport: (temperature monitoring, isolation from Cold Pack, and Security Lo)	Completed Sample Transport sheet and locked (secure) container	REVIEW TRANSPORT SHEET
BC024	Specimens Transport Sheet is available and completed by Sending and Receiving Facilities:	Copy of send out sheet are available and retained as per policy.	The copy should be available at the phlebotomy location soft or hard copy, to protect the specimens and the staff. Everyone is responsible.

Annex 3: Antiviral therapy protocol

Clinical Presentation	Suggested Medications
Clinical Presentation	**Dosing & frequency mentioned is for normal Renal & Hepatic Functions** For Moderate to severe Hepatic Impairment & or severe Renal impairment, Drug interaction etc. (Consult individual drug monograph for additional monitoring or dose adjustment)
Confirmed COVID19 Asymptomatic	**No treatment**, **If high risk: (**Age above 60 years old, Cardiovascular disease, hypertension, Diabetics, Pre- existing lung disease, or Immunocompromised / cancer patients, (Obesity (BMI>35) or, if height not available, weight >100kg) **Favipiravir** 1600 mg PO BID X 2 doses then 600 mg PO BID (total 5 days).
Confirmed COVID19 URTI without Pneumonia	**Favipiravir** 1600 mg PO BID X 2 doses then 600 mg PO BID (total 5 days) Addition of **Camostat** 200 mg PO TID X 5 days optional on case by case basis as per treating physician choice (if available).
Confirmed COVID19 With Pneumonia	**If radiological evidence of Mild pneumonia give Favipiravir** 1600 mg PO BID X 2 doses then 600 mg PO BID (total 7 days). Addition of **Camostat** 200 mg PO TID X 5 days optional on case by case basis as per treating physician choice (if available). **If radiological evidence of Moderate-Severe pneumonia to follow pneumonia recommendation and admit patient to designated hospital.**

Favipiravir in child bearing age and breast feeding women
• **Rule out pregnancy before starting treatment** • **Child-bearing women patient:** Explain fully the risks and instruct thoroughly to use most effective contraceptive methods during and for 7 days after the end of the treatment. If pregnancy is suspected during the treatment, instruct to discontinue the treatment immediately and to consult a doctor. • **Breastfeeding /Lactation:** When administering Favipiravir to lactating women, instruct to stop lactating as hydroxylated form was found to be distributed in breast milk.) • **Male patient:** should be explained fully the risks and instruct thoroughly to use most effective contraceptive methods in sexual intercourse during and for 7 days after the end of the treatment (men must wear a condom). In addition, instruct not to have sexual intercourse with pregnant women during & for 7 days after the end of the treatment as the medication major metabolite can be distributed in sperms.

Nirmatrelvir-Ritonavir (Paxlovid)

Paxlovid is a combination of Nirmatrelvir, a SARS-CoV-2 main protease (Mpro: also referred to as 3CLpro or nsp5 protease) inhibitor, and ritonavir an HIV-1 protease inhibitor and CYP3A inhibitor.
It has FDA and MOHAP emergency use authorization for the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in outpatient adults and paediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death.

- *Limitations of Authorized Use*
  - PAXLOVID is not authorized for initiation of treatment in patients requiring hospitalization due to severe or critical COVID-19
  - PAXLOVID is not authorized for pre-exposure or post-exposure prophylaxis for prevention of COVID-19.
  - PAXLOVID is not authorized for use longer than 5 consecutive days.

- *Contraindications*

  - History of clinically significant hypersensitivity reactions to the active ingredients (nirmatrelvir or ritonavir) or any other components.
  - Co-administration with drugs highly dependent on CYP3A for clearance and for which elevated concentrations are associated with serious and/or life-threatening reactions.
  - Co-administration with potent CYP3A inducers where significantly reduced nirmatrelvir or ritonavir plasma concentrations may be associated with the potential for loss of virologic response and possible resistance.

- *Warnings and Precautions*

The concomitant use of PAXLOVID and certain other drugs may result in potentially significant drug interactions.
Hepatotoxicity: Hepatic transaminase elevations, clinical hepatitis, and jaundice have occurred in patients receiving ritonavir.
HIV-1 Drug Resistance: PAXLOVID use may lead to a risk of HIV-1 developing resistance to HIV protease inhibitors in individuals with uncontrolled or undiagnosed HIV-1 infection.

- *Adverse Reactions*

Adverse events (incidence ≥1% and ≥5 subject difference) were dysgeusia, diarrhoea, hypertension, and myalgia

- *Drug Interactions*
  - Co-administration of PAXLOVID can alter the plasma concentrations of other drugs and other drugs may alter the plasma concentrations of PAXLOVID.
  - Consider the potential for drug interactions prior to and during PAXLOVID therapy and review concomitant medications during PAXLOVID therapy.

- *Dosage and Administration*

PAXLOVID is nirmatrelvir tablets co-packaged with ritonavir tablets.
Nirmatrelvir must be co-administered with ritonavir.
Initiate PAXLOVID treatment as soon as possible after diagnosis of COVID-19 and within 5 days of symptom onset.
Administer orally with or without food.

Dosage: 300 mg nirmatrelvir (two 150 mg tablets) with 100 mg ritonavir (one 100 mg tablet), with all three tablets taken together twice daily for 5 days.
Missed dose: If <8 hours since dose was due, the missed dose should be administered as soon as possible, and normal dosing schedule should resume. If ≥8 hours since dose was due, the dose should be skipped, and dosing should resume at the next scheduled administration time. Do not double the dose to make up for a missed dose.
Dose reduction for moderate renal impairment (eGFR ≥30 to <60ml/min) to PAXLOVID is 150 mg nirmatrelvir and 100 mg ritonavir twice daily for 5 days

PAXLOVID is not recommended in patients with severe renal impairment (eGFR <30ml/min)
No dosage adjustment is needed in patients with mild (Child-Pugh Class A) or moderate (Child-Pugh Class B) hepatic impairment.
PAXLOVID is not recommended for use in patients with severe hepatic impairment

- *Pregnancy and lactation Considerations:*

Adverse events were observed following exposure to Nirmatrelvir in some embryo-fetal developmental toxicity studies, ritonavir has a low level of transfer across the human placenta and is the preferred pharmacologic booster in pregnancy, therefore, if pregnant patients have mild to moderate symptoms, especially patients with one or more additional risk factors (eg, BMI >25, cardiovascular disease, chronic kidney disease, diabetes mellitus)

Paxlovid should not be withheld when the potential benefits outweigh the possible risks.
Ritonavir is present in breast milk; excretion of nirmatrelvir is unknown, the decision to breastfeed during therapy should consider the risk of infant exposure, the benefits of breastfeeding to the infant, and the benefits of treatment to the mother

Annex 4: Required Antiviral Initial Blood Investigations

Initial investigations for newly in-patient cases:

1. CBC
2. Renal Profile
3. Uric acid
4. CRP, procalcitonin
5. D-Dimer
6. Hepatic Profile
7. BhCG; in child bearing female age group
8. Consider for severe cases LDH, ferritin and Interlukin-6.

Note: *any other required investigations for severe and critical cases are done upon medical decision case by case.*

Antiviral related blood results review:

Note: Any patient with any of the following readings would require hospital admission upon tertiary hospital consultation:

- D-Dimmer above 2 mcg/mL (transfer the case to the hospital for prophylaxis/possible therapeutic anticoagulation).
- Renal function: eGFR below 30mL/min/1.73m^2
- Liver function test (AST, ALT) x5 normal value
- CBC: Mainly neutropenia