PMB definition guideline: COVID-19 v1 14.04.2020

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Disclaimer:

The document may change as the guidance changes. The contents are up to date as at the time of publishing. Please always check for updates on the National Institute for Communicable Diseases *(NICD) and the National* *Department of Health* *(NDoH) websites.*

1. Introduction

The World Health Organization (WHO) was alerted of a cluster of pneumonia of unknown aetiology in patients in Wuhan City, Hubei Province of China on 31 December 2019.

The respiratory tract infection was identified as being caused by a coronavirus, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and the illness was named coronavirus disease 2019 (COVID-19) on 11 February 2020. The following month, the WHO declared the outbreak as a pandemic and on 15 March 2020, a National State of Disaster was declared in South Africa.

The National Department of Health, in collaboration with the National Institute for Communicable Diseases (NICD), has been providing the nation with guidance in respect of the management of the COVID 19 pandemic within the Republic of South Africa. The Minister of health has approved a submission from the Council for Medical Schemes (CMS) for the inclusion of COVID19 as a Prescribed Minimum Benefit (PMB). The CMS has lodged a draft amendment to the PMB regulations with the minister of health for the promulgation of COVID 19 into the PMB regulations in terms of section 67 (3) (b) to enable COVID 19 form part of the Prescribed Minimum Benefit (PMB) package. As this in the interest of the public, it is being done on an urgent basis.

As such, this document seeks to clarify the PMB entitlements of beneficiaries within the context of the pandemic and to ensure that there is uniform interpretation amongst all stakeholders. The document is a recommendation for the screening, diagnosis, treatment and care of individuals with suspected and confirmed COVID-19 as per WHO case definitions. Identification of suspected cases is provided for later in the document.

2. Scope and purpose

2.1. The WHO has published ICD-10 codes to be used for the COVID -19 and CMS recommends that correct coding be used to enable correct identification and reporting thereof.

2.2. The surveillance for COVID-19 is essential to permit early recognition of suspected cases, early diagnosis, containment and prevention of onward transmission.

2.3. It is also important to note that COVID-19 is a notifiable medical condition and persons under investigation and confirmed cases must be reported by medical schemes.

Table 1: Possible ICD-10 codes for identifying COVID-19

ICD-10 code	WHO description
U07.1	COVID-19, virus identified
U07.2	COVID-19, virus not identified

Source: WHO list of official ICD-10 updates: https://www.who.int/classifications/icd/icd10updates/en/

2.4. The ICD-10 code U07.2 includes the following:

- Clinically-epidemiologically diagnosed COVID-19
- Probable COVID-19
- Suspected COVID-19

2.5. There are similarities between the WHO case definition and the NICD case definition. Below is the NICD case definitions.

Confirmed cases	A confirmed case is a person with laboratory confirmation (RT – PCR assay) of infection with the COVID-19 virus, irrespective of clinical signs and symptoms. Symptomatic cases are considered infectious from 2 days before symptom onset to 14 days after symptom onset.
Person under investigation (PUI) *i.e. A person to be tested for COVID-19*	Persons with acute respiratory illness with sudden onset of at least one of the following: cough, sore throat, shortness of breath or fever [≥ 38°C (measured) or history of fever (subjective)] irrespective of admission status.
Probable case	A probable case is a person under investigation (PUI) for whom the report from laboratory testing for the COVID-19 virus is inconclusive or who tested positive on an approved pan-coronavirus assay.

2.6. The NICD continues to define the characteristics of a high-risk persons and this is defined as:

Persons at a highest risk are those who have an acute respiratory illness and who, in the 14 days prior to onset of symptoms, met at least one of the following epidemiological criteria:

- Were in close contact with a confirmed or probable case of SARS-CoV-2 infection

OR

- Had a history of travel to areas with local transmission of SARS-CoV-2; (NB Affected countries will change with time, consult NICD website for current updates www.nicd.ac.za)

OR

- Worked in or attended a health care facility where patients with SARS-CoV-2 infections were being treated.

OR

- Admitted with severe pneumonia of unknown aetiology.

3. Epidemiology

3.1. Coronaviruses are a large family of viruses that are common in many different species of animals, including camels, cattle, cats, and bats. These viruses cause illness ranging from the common cold to more severe diseases such as bronchitis, pneumonia and respiratory and multi-organ failure. Coronaviruses are also responsible for previous epidemics including severe acute respiratory syndrome (SARS) and middle east respiratory syndrome (MERS).

3.2. These viruses were originally transmitted between animals and people. In the case of SARS, viruses were transmitted from civet cats to humans while in MERS, the infection travelled to humans from a type of camel.

3.3. In the case of COVID-19, scientists have pointed to infected animal species, including pangolins and bats as the original source of the virus. While it is suspected that the initial COVID-19 epidemic started through animal-to-human transmission, the current epidemic is being fuelled by human-to-human transmission and the virus has spread to more than 208 countries and territories, including South Africa.

3.4. As of 14 April 2020, there were 1,934,557 confirmed cases globally with 120,248 deaths and 456,737 recoveries.

3.5. Data from the 14th of April showed that South Africa had conducted 83,663 tests, 2,272 confirmed as positive, 410 people had recovered, and 27 deaths were reported.

3.6. Additionally, the mortality rate in South Africa was currently at 1,19%, lower than the global mortality of 6,22%.

4. Route of transmission from COVID-19 patients

4.1. New evidence on the transmission has been evolving and there is evidence on the following modes of transmission

- Symptomatic: Data from published epidemiology and virologic studies provides evidence that COVID-19 is primarily transmitted from symptomatic people to others who are in close contact through respiratory droplets, by direct contact with infected persons, or by contact with contaminated objects and surfaces.
- Pre- symptomatic: The incubation period for COVID-19, which is the time between exposure to the virus (becoming infected) and symptom onset, is on average 5-6 days, however, this period can take up to 14

days. During this period, also known as the “pre-symptomatic” period, some infected persons can be contagious. Therefore, transmission from a pre-symptomatic case can occur before symptom onset.

- Asymptomatic: There are few reports of laboratory-confirmed cases who are truly asymptomatic, and to date, there has been no documented asymptomatic transmission. This does not exclude the possibility that it may occur. Asymptomatic cases have been reported as part of contact tracing efforts in some countries. The proportion of asymptomatic carriers is currently unknown.

4.2. According to the WHO, the reproductive number for the virus is approximately 2.2 (meaning that on average each person spreads the infection to two others).

4.3. The latest update from the WHO, published on 29 March 2020, included an analysis of some scientific evidence which suggested the possibility of airborne transmission. Ultimately, the WHO concluded that the evidence to date was not yet conclusive.

5. Risk factors

Risk factors for acquiring the infection include:

- Individuals with a recent travel history to high-risk countries
- History of exposure to individuals infected with COVID-19

Risk factors for severe disease once infected include:

- Individual 60 years and older: Among more than 44,000 confirmed cases of COVID-19 in China, the case fatality rate was highest among older persons:
  - ≥80 years: 14.8%
  - 70–79 years: 8.0%
  - 60–69 years: 3.6%
  - 50–59 years: 1.3%
  - 40–49 years: 0.4%
  - <40 years: 0.2%.
- Individuals who live in a nursing home or long-term care facility
- People with severe obesity (body mass index [BMI] of 40 or higher)
- Individuals at any age with underlying comorbidities, particularly if not well controlled. Patients with no reported underlying medical conditions have had an overall case fatality of 0.9%, but case fatality was higher for patients with comorbidities
  - Cardiovascular disease
  - Diabetes mellitus
  - Hypertension

- Chronic respiratory disease
- Immunosuppression: this could be due to cancer treatment, smoking, bone marrow or organ transplantation, immune deficiencies, poorly controlled HIV or AIDS, and prolonged use of corticosteroids and other immune weakening medications
- People with chronic kidney disease undergoing dialysis
- People with liver disease

Disease in children appears to be relatively rare and mild with approximately 2.4% of the total reported cases reported amongst individuals aged under 19 years. A very small proportion, that is 2.5% of those aged under 19 years have developed severe disease while only 0.2% became critical.

6. Signs and symptoms

6.1. Eighty percent of symptomatic patients develop mild disease, an estimated 15% develop severe disease (with hypoxaemia, dyspnoea and tachypnoea) while 5% become critically ill (with respiratory failure, septic shock and/or multiorgan dysfunction).

6.2. The most common presenting symptoms has been:

- Fever (~90%, but only present in 44% on admission).
- Dry cough (68%)
- Anosmia and ageusia (30%)
- Fatigue (38%),
- Sputum production (34%)
- Shortness of breath (19%),
- Myalgia or arthralgia (15%),
- Sore throat (14%),
- Headache (13.6%)
- Chills (12%)

6.3. Gastrointestinal symptoms such as nausea or vomiting (5.0%) and diarrhoea (3.8%) appear to be uncommon.

7. Diagnostic workup

7.1. Consultations

7.1.1. Given the modes of transmission discussed earlier, surveillance for COVID-19 is essential to permit early recognition of suspected cases, early diagnosis, containment and prevention of further cases.

7.1.2. Screening for COVID 19 is considered PMB level of care if the individual meets the criteria for a person under investigation and for those classified as high risk. The criteria for a person under investigation and high risk was provided earlier in 2.5 and 2.6.

7.1.3. As with the NICD recommendations, testing of patients who do not present with any symptoms is not PMB level of care.

7.1.4. To further reduce the person to person risk of transmission and reduce the number of patients at doctors rooms, the CMS also recommends that telehealth delivered through online platforms be reimbursed as PMB level of care in line with the latest Health Professions Council of South Africa (HPCSA) communication *"Notice to amend clause (b) & (c) of the guidance on the application of telemedicine guidelines during the COVID-19 pandemic."*

7.1.5. In accordance with the HPCSA recommendations, "*Telehealth should preferably be practiced in circumstances where there is an already established practitioner-patient relationship. Where such a relationship does not exist, practitioners may still consult using Telehealth provided such consultations are done in the best clinical interest of patients."*

7.1.6. In addition, HPCSA, emphasise that "*Although practitioners may charge fees for consultations undertaken through Telehealth platforms, the Council [HPCSA] strongly cautions against practices that may amount to over-servicing, perverse incentives and supersession."*

7.1.7. In the out of hospital setting, no prior authorisation is required for telehealth consultations with a general practitioner, specialist consultations may require pre-authorisation.

7.1.8. Schemes can develop screening pre-risk assessment tools and use designated service providers (DSPs.)

7.1.9. The CMS cannot stipulate the frequency of consults for a COVID-19 case as this may vary between individuals and on the "case definition".

7.2. Laboratory workup

7.2.1. From the South African Health Products Regulatory Authority (SAHPRA) report, two different types of in-vitro tests are possible, molecular tests and serological tests.

7.2.2. Molecular tests detect the presence of the SARS-CoV-2 virus' genetic material (nucleic acid) and are performed on material obtained by means of nasopharyngeal and oropharyngeal swabs. Such tests are good at detecting the virus early in the infection and can detect the virus in a person before they become symptomatic.

7.2.3. Serological tests are tests that detect antibodies to the SARS-CoV-2 virus and are conducted on samples likely to have antibodies, such as finger-pick blood samples. Serological tests are conducted at the point-

of-care and detect the presence of immunoglobulin M (IgM) and/or immunoglobulin G (IgG) antibodies to SARS-CoV-2.

7.2.4. According to the latest guidance by SAHPRA, diagnosis of SARS-CoV-2 virus is ONLY confirmed by the reverse transcriptase polymerase chain reaction (RT-PCR) test and not the serological tests as the period between acute infection and detection of antibodies is unknown at this time.

7.2.5. In addition, the WHO also states that "the role of rapid disposable tests for antigen detection for COVID-19 needs to be evaluated and is not currently recommended for clinical diagnosis pending more evidence on test performance and operational utility."

7.2.6. The RT-PCR test is therefore recommended as PMB level of care for the investigation and/or diagnosis of COVID-19.

7.2.7. SAHPRA has provided a list of tests that are registered in South Africa and this is available on their website.

7.2.8. In addition to a RT- PCR, and where clinically indicated, the following laboratory investigations are also recommended as PMB level of care for confirmed cases depending on the severity of symptoms:

- Full blood count including differential count
- Nasopharyngeal swabs or aspirates and oropharyngeal swabs for detection of viral and atypical pathogens
- Sputum for MCS and Mycobacterium tuberculosis detection (GeneXpert MTB/RIF Ultra)
- Other adjunct investigations that may be clinically appropriate or indicated will require motivation e.g. liver function tests, lactate dehydrogenase, D-dimer levels and urine for lipoarabinomannan (LAM) test if HIV positive.

7.3. Imaging radiology

7.3.1. Imaging modalities are not recommended as PMB level of care for screening or diagnosis of COVID – 19, as the definitive test for SARS-CoV-2 is the RT-PCR.

7.3.2. Chest X-ray and chest CT scan are recommended as PMB level of care for patients with confirmed COVID-19.

8. Management of suspected and confirmed cases with mild to moderate disease

8.1. The clinical management of a suspected or a confirmed COVID case depends on the severity and the presenting symptoms.

8.2. Suspected and confirmed cases who are medically well, or who have mild disease may be managed at home.

8.3. It is important to note that, at the time of publishing this document, treatment for COVID19 is supportive and there is no cure or recommended vaccination for COVID 19.

8.4. There is no specific antiviral treatment available. Given that in South Africa, it is almost flu season, a neuraminidase inhibitor (e.g. oseltamivir) may be considered for patients with influenza or at high risk for severe disease.

8.5. Although antibiotics do not treat viral infections, empiric treatment for secondary bacterial and fungal infections might be required.

8.6. All underlying pre-existing comorbid chronic conditions such as diabetes, HIV, asthma etc, should be managed as per the corresponding Diagnostic Treatment Pair (DTP) and/ or Chronic Disease List (CDL) are deemed PMB level of care.

8.7. Treatment and care for the management of mild to moderate disease is PMB level of care.

9. Management of severe cases

9.1. Patients with severe disease are closely monitored and any signs of clinical deterioration (e.g. respiratory failure and sepsis) are managed appropriately.

9.2. Based on clinical diagnosis, treatment of co-infections with empiric antibiotics is recommended and this may include treatment of pneumocystis pneumonia (PCP), influenza and atypical bacterial pathogens.

9.3. Supportive treatment includes oxygen therapy in patients who are short of breath. The target oxygen saturation (SpO2) rates are ≥90% in non-pregnant adults and SpO2 ≥92-95 % in pregnant patients.

9.4. As with patients with suspected or mild disease, a neuraminidase inhibitor (e.g. oseltamivir) may be considered.

9.5. Patients with severe disease are generally hospitalised and the cost of their management must be funded according to the PMB Regulations.

9.6. Patients might be admitted to the intensive care unit (ICU) and the use of mechanical ventilators where indicated is PMB level of care.

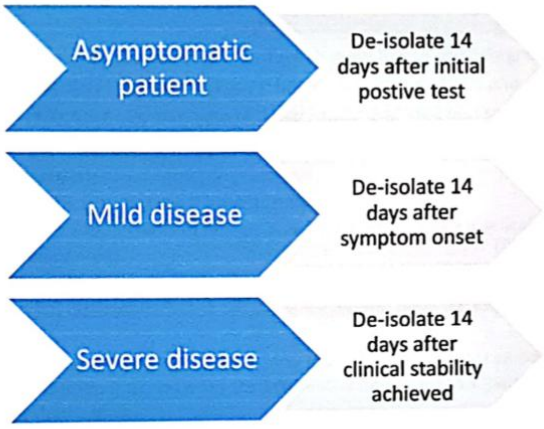
10. Off label medication

There is consensus in literature as reported by the WHO and SAHPRA, that currently there are no pharmaceutical products that have shown to be safe and effective for the treatment of COVID-19. CMS recommends funding for investigational drugs or therapies (e.g. chloroquine) only for patients who are hospitalised. The NDoH acknowledges that such medicines should be used in the realm of a clinical trial, but given the nature of the pandemic, a pragmatic approach might be required, and such medicines should be used under the Monitored Emergency Use of Unregistered Interventions (MEURI) framework.

Any medicines, including vaccines that become available for COVID-19 and listed on the national essential medicines list are recommended as PMB level of care.

11. Follow up care

Patients may continue to be PCR positive after clinical resolution, although for how long such virus is viable (and thus infectious) remains to be determined. A patient can de-isolate after the recommended period without further testing. The NICD recommends de-isolation for 14 days, however there are differences depending on the severity of the disease as shown in the figure below.

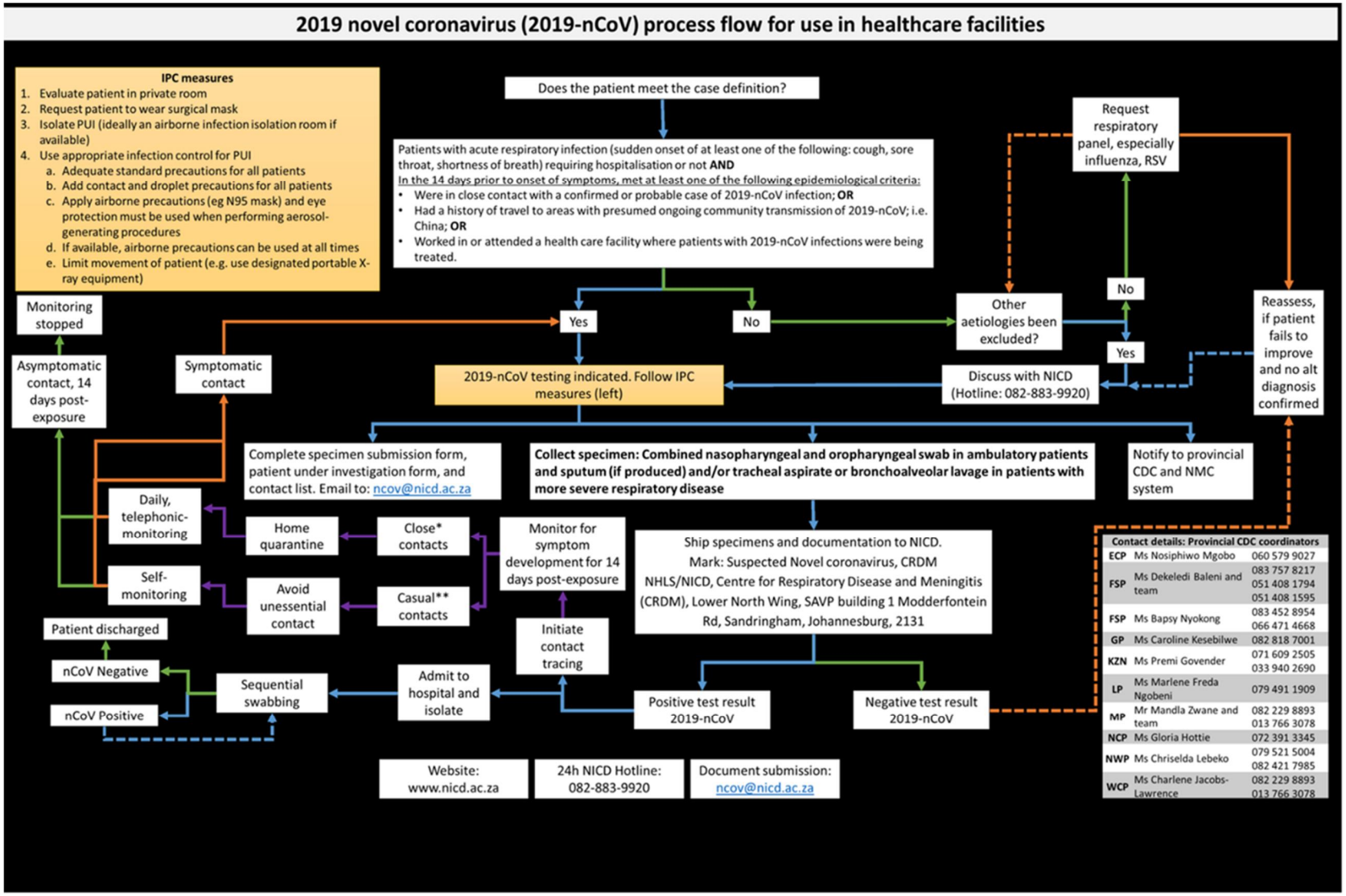


On referral and motivation by the treating provider, chest physiotherapy and other rehabilitative modalities such as psychotherapy are also PMB level of care.

Additional resources

NICD website on COVID-19:	http://www.nicd.ac.za/diseases-a-z-index/covid-19/
National Department of Health:	https://www.gov.za/; https://www.gov.za/coronavirus/guidelines; https://www.sacoronavirus.co.za/
The WHO website:	www.who.int/emergencies/diseases/novel-coronavirus

Appendix: Summary of the process flow for the 2019 novel coronavirus in healthcare facilities



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