

PMB definition guideline: COVID-19 v2 05 May 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 <u>National Institute for Communicable Diseases</u> (NICD) and the National <u>Department of Health</u> (NDoH) websites.

Major Changes in this version

- · Inclusion of statement that "The test should be funded from the risk benefit irrespective of the RT-PCR result."
- Testing of asymptomatic patients as per scheme rules
- · Outlining what is not included in PMB level of care
- Inclusion of a repeat RT-PCR test to be funded at discretion of the scheme based on the scheme rules
- CT scan recommended on motivation
- Inclusion of some applicable codes for COVID-19 claims
- Appendix of prioritisation for providers of testing for symptomatic and asymptomatic patients

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 (NDoH), 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 COVID-19 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 to form part of the 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	Persons with acute respiratory illness with sudden onset of at least one of the following: cough, sore
investigation	throat, shortness of breath or fever [≥ 38°C (measured) or history of fever (subjective)] irrespective
(PUI)	of admission status.
i.e. A person to be	
tested for COVID-19	
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 <u>www.nicd.ac.za</u>)

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 4 May 2020, there were 3,660,476 confirmed cases globally with 252,682 deaths and 1,204,025 recoveries.
- 3.5. Data from the 4th of May showed that South Africa had conducted 257 541 tests, 7 220 confirmed as positive, 2 746 people had recovered, and 138 deaths were reported.
- 3.6. Additionally, the mortality rate in South Africa was currently at 1,91%, lower than the global mortality of 6,90%.
- 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:
 - o ≥80 years: 14.8%
 - o 70–79 years: 8.0%
 - o 60–69 years: 3.6%
 - o 50–59 years: 1.3%
 - o 40–49 years: 0.4%
 - o <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
 - o Cardiovascular disease
 - o Diabetes mellitus
 - o Hypertension

- o 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
- o 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 have 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 is questionnaire based and may be part of virtual or face to face consultation. The consultation for screening by a healthcare worker (nurses or doctors) for COVID-19 is recommended as PMB level of care. Some of the questions that can be asked by the healthcare worker during screening include:
 - § Recent travel to a high-risk country (in the last 14 days)
 - § Any contact with anyone with confirmed COVID-19 (in the last 14 days)
 - § Any history of visiting live animal markets
 - § Any history of attending or working at a facility where COVID-19 patients were being treated
 - § Any symptoms such as fever, sore throat, cough and difficulty in breathing
 - § Any underlying condition (including high blood pressure, diabetes, asthma, respiratory illnesses, systemic illnesses)
 - § Any medications being taken (including immunosuppressive therapy)
- 7.1.3. Testing for COVID-19 is PMB level of care upon referral from a health care worker (doctor or nurse) who has screened a patient. Patients to be tested include individuals who meet the criteria for a person under investigation and those classified as high risk. The criteria for a person under investigation and high risk was provided earlier in 2.5 and 2.6.
- 7.1.4. The test should be funded from the risk benefit irrespective of the RT-PCR result.
- 7.1.5. Testing of asymptomatic patients will be funded according to scheme rules.
- 7.1.6. 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 <u>"Notice to amend clause (b) & (c) of the guidance on the application of telemedicine guidelines during the COVID-19 pandemic."</u>
- 7.1.7. 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."
- 7.1.8. 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."
- 7.1.9. In the out of hospital setting, no prior authorisation is required for telehealth consultations with a general practitioner, specialist consultations may require pre-authorisation.
- 7.1.10. Schemes can develop screening pre-risk assessment tools and use designated service providers (DSPs.)
- 7.1.11. 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. The NICD guidelines recommends the use of molecular testing for diagnosis of SARS-CoV-2 virus.
- 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 is recommended as PMB level of care for patients with confirmed COVID-19.
- 7.3.3 CT scan is recommended as PMB level of care on motivation.
- 8. Management of suspected and confirmed cases with mild to moderate disease
 - 8.1. The clinical management of a suspected or a confirmed COVID-19 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 COVID-19 is supportive and there is no cure or recommended vaccination for COVID-19.
 - 8.4. There is no specific antiviral treatment available, however, various antivirals are being tested in clinical trials globally. Remdesivir has recently received an Emergency Use Authorisation (EUA) from the Food and Drug Association (FDA) for the treatment of severe hospitalised COVID-19 patients.
 - 8.5. 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.
 - 8.6. Although antibiotics do not treat viral infections, empiric treatment for secondary bacterial and fungal infections might be required.
 - 8.7. 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.
 - 8.8. 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.

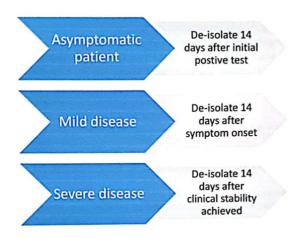
10. Off label medication

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 discretionary funding of offlabel use of medications that show clinical benefit. The NDoH acknowledges that investigational 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. A repeat RT-PCR test will be funded at discretion of the scheme based on the scheme rules.



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

12. What is not PMB level of care

The following is not recommended as PMB level of care:

- Follow-up treatment and care for any person (symptomatic) who tests negative for COVID-19 (RT-PCR test).
- Follow-up care for any person (asymptomatic) who tests negative for COVID-19 (RT-PCR test).

- Routine RT-PCR testing of asymptomatic, unscreened and unreferred patients which turns out negative is based on scheme rules.
- Routine preadmission RT-PCR testing for asymptomatic patients which turns out negative is based on scheme rules.

Consultation	Diagnosis Related information		Treatment	
codes	Laboratory	Imaging	Procedure Codes	ATC codes
Codes 0130 0132 0133 0145 0146 0147 0149 0190 0191 0192 0197 0198 0199 0201	Laboratory U07.1 U07.2 Z11.5 3755 - Full blood count including differential count 3891 / 3892 / 3893 / 3894 / 3895 / 3896 / 3897 - Blood cultures	1241 - Chest X-ray 6443 - CT chest uncontrasted 6444 - CT chest with contrast 6445 - CT chest pre AND post contrast	Evidence of payment for COVID related Procedures	Evidence of payment for COVID related medicines
Inpatient Codes 0109 1204	3867 / 3895 - Sputum for MCS			
1205				
1206	3915 / 3919 / 3920 /			
1207	4655 / 4656 / 4657 -			
1208	Mycobacterium			
1209	tuberculosis detection			
1210				
1211	4434 / 3930			
1212	(GeneXpert MTB/RIF			
1213	Ultra)			
1214				
	4130 / 4131 - Liver			
	function tests			

Applicable codes in relation to COVID-19 funding

4137 - La	ctate	
dehydrog	enase	
3856 - D-	dimer levels	

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 1: Prioritisation of testing by providers

The prioritisation has no implications on funding, as all screened patients are funded as PMB level of care. This has included in the document as the providers may follow the approach below in prioritising the cases that require testing for COVID-19.

Prioritisation of testing

Priority 1:

- Hospitalised patients (including admissions for elective surgery)
- Healthcare facility workers with symptoms

Priority 2:

- Patients in long term care facilities with symptoms
- Patients aged 65 years and above with symptoms
- Patients with underlying conditions with symptoms
- First responders (e.g. paramedics) with symptoms
- Those that have been identified as contacts through contact tracing systems

Priority 3

- Critical infrastructure with symptoms
- Individuals who do not meet above criteria with symptoms
- Healthcare facility workers and first responders
- Individuals with mild symptoms in communities experiencing a high number of COVID-19 hospitalisations

Priority 4

- No symptoms

Prioritising of asymptomatic beneficiaries

Asymptomatic beneficiaries will still need to be listed for discretionary testing. The providers may consider a phased approach, commencing with essential frontline workers and people in congregate settings who are in high-risk environments.

Stage 1: Essential frontline workers in medical, retail, security and agricultural industries

Stage 2: Residents and workers at long-term care / group-living facilities, including care homes and prisons

Stage 3: Employees providing services in industries where social distancing may not be possible, including fisheries, manufacturing, clothing and textiles.

Stage 4: Underserved populations, including schools, tertiary organizations and informal townships (where applicable)

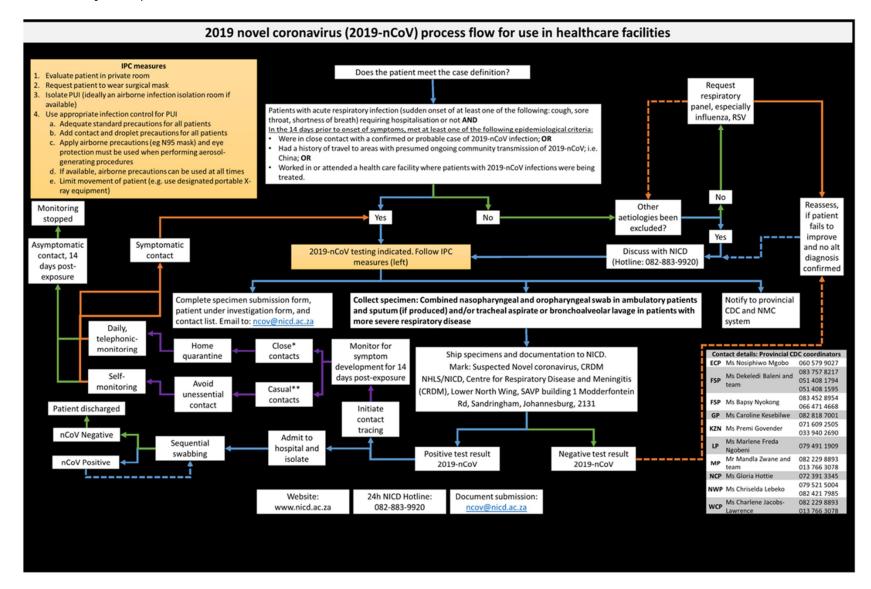
Frequency of testing for asymptomatic patients

The frequency of testing asymptomatic patients will be determined by disease prevalence in geographic area where individual spends >75% of their time, as well as level of exposure to potential COVID-19 cases.

Prevalence <20% - every 6 months	Level 1 (infrequent exposure <1 per month) - every 6 months
Prevalence 21% – 49% – every 3 months	Level 2 (frequent exposure >1 per month) – every 3 months
Prevalence 50% – 79% – every 6 weeks	Level 3 (very frequent exposure >1 per week) – every 6 weeks
Prevalence >80% - every 4 weeks	Level 4 (Imminent exposure >1 per day) - every 4 weeks

*where there is a discrepancy between prevalence & level of exposure, it is advised that level of exposure take precedence.

Appendix 2: Summary of the process flow for the 2019 novel coronavirus in healthcare facilities



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