

PMB definition guideline: COVID-19 v8

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Disclaimer:

This document may change as guidance from the National Institute of Communicable Diseases (NICD), World Health Organisation (WHO) and Department of Health (NDOH) evolves. 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> (DOH) websites.

Major changes in this version:

- Updated ICD10 codes
- Updated the section of SARS-CoV-2 variants

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 approved a submission from the Council for Medical Schemes (CMS) for the inclusion of COVID-19 as a Prescribed Minimum Benefit (PMB). As such, on 7 May 2020, the Minister of Health in terms of section 67 of the Medical Schemes Act, 1998 (Act No. 131 of 1998), published an amendment to the Medical Schemes Act Regulations in Notice 515 in Government Gazette 43295.

The amendment required the inclusion of COVID-19 as PMB in the Diagnosis and Treatment Pair (DTP) of the "Respiratory System". The treatment component includes screening, clinically appropriate diagnostic tests, medication, medical management including hospitalisation and treatment of complications, and Rehabilitation of COVID-19. The Regulations came into effect on 7 May 2020.

On 24 December 2020, the Minister of Health approved the inclusion of COVID-19 vaccine under the treatment component of the COVID-19 DTP.

For this reason, this guideline seeks to clarify PMB entitlements of medical scheme beneficiaries within the context of the pandemic, ensuring that there is uniform interpretation amongst all stakeholders. It sets out recommendations for the vaccination, screening, diagnosis, treatment, and care of individuals with suspected, and confirmed COVID-19 as per WHO case definitions.

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. A new DTP has been assigned to ICD-10 codes to ensure the correct PMB classification of COVID-19.
- 2.3. The surveillance for COVID-19 is essential to permit early recognition of suspected cases, early diagnosis, containment, and prevention of onward transmission.
- 2.4. It is also important to note that COVID-19 is a Category 1 Notifiable Medical Condition that requires immediate reporting by the most rapid means available upon diagnosis followed by a written or electronic notification to the Department of Health within 24 hours of diagnosis by health care providers, private or public health laboratories.
- 2.5. Medical schemes are also required to notify and submit COVID-19 related information to the CMS, consistent with <u>Circular 29 of 2020.</u>

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

PMB code	Diagnosis	Treatment	ICD10 code	ICD10 description		
177D	COVID-19	Prevention and treatment:	U07.0	Vaping related disorder		
	clinically appropriate vaccination, screening, diagnostic tests, medical	U07.1	COVID-19, virus identified			
		vaccination, screening,	ccination, screening, U07.2 COVID-19, virus not identified			
		U08.9	Personal history of COVID-19, unspecified			
		management including	U09.9	Post COVID-19 condition, unspecified		
	hospitalisation and treatment of complications; and	U10.9	Multisystem inflammatory syndrome associated with COVID-19, unspecified			
		Rehabilitation	U11.9	Need for immunization against COVD-19, unspecified		
			U12.9	COVID-19 vaccines causing adverse effects in therapeutic use, unspecified		

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

- 2.6. The ICD-10 code U07.2 includes the following:
 - Clinically-epidemiologically diagnosed COVID-19.
 - Probable COVID-19
 - Suspected COVID-19
- 2.7. At the time of publishing this guideline, the NICD guidelines for "case-finding, diagnosis, management and public health response" were in the process of being updated and hence not available on NICD website.
- 2.8. Given the antigen testing national guidelines published on 11 December 2020, and the updated WHO case definitions, the CMS has adjusted the current case definition to be aligned with both guidelines. Upon publishing of national guidelines by the NICD, the CMS will also ensure that the PMB definition guidelines are aligned with these guidelines.
- 2.9. The table below summarises the case definition for COVID-19.

Clinical Criteria		Epidemiological Criteria:
Acute onset of fever AND cough		- Residing or working in an area with high risk
OR		of transmission of virus: closed residential
Acute onset of ANY THREE OR MORE		settings, humanitarian settings such as camp and camp-like settings for displaced persons;
of the following signs or symptoms:		anytime within the 14 days prior to symptom onset
Fever	AND	Unset
Cough	A	
General weakness/fatigue*		OR
Headache		- Residing or travel to an area with community
Myalgia		transmission anytime within the 14 days prior
Sore throat		to symptom onset
Coryza		
Dyspnoea		OR
Anorexia/nausea/vomiting*	1	

Table 2: Case definition of SARS-CoV-2 infection

	Diarrhoea - Working in any health care setting, including within health facilities or within the community; any time within the 14 days prior of symptom onset. *Signs separated with slash (/) are to be counted as one sign - Working in any health care setting, including within health facilities or within the 14 days prior of symptom onset.			
	 A patient with severe acute respiratory illness: (SARI: acute respiratory infection with history of fever or measured fever of ≥ 38 C°; and cough; with onset within the last 10 days; and requires hospitalisation). 			
Probable case	1. Apatient who meets clinical criteria above AND is a contact of a probable or confirmed case or linked to a COVID-19 cluster.			
	2. A suspect case with chest imaging showing findings suggestive of COVID-19 disease. A person with recent onset of anosmia (loss of smell) or ageusia (loss of taste) in the absence of any other identified cause.			
	3. Death, not otherwise explained, in an adult with respiratory distress preceding death AND was a contact of a probable or confirmed case or linked to a COVID-19 cluster.			
Confirmed	1. A person with a positive RT-PCR test			
cases	 Aperson with a positive SARS-CoV-2 Antigen-RDT AND meeting either the probable case definition or suspect criteria 1 OR 2 			
	 An asymptomatic person with a positive SARS-CoV-2 Antigen-RDT who is a contact of a probable or confirmed case. 			

- 2.10. A person having had face-to-face contact (≤1 metre) or having been in a closed space with a confirmed COVID-19 case for at least 15 minutes. This includes, amongst others:
 - All persons living in the same household as a COVID-19 case, and people working closely in the same environment as a case.
 - Healthcare workers or other people providing direct care for a COVID-19 case while not wearing recommended personal protective equipment (PPE) (e.g., gowns, gloves, N95 respirator, eye protection).
 - A contact in an any mode of transportation where passenger details are captured sitting within two seats (in any direction) of the case, travel companions or persons providing care, and crew members serving in the section where the case was seated.
 - NICD had previously defined high-risk persons separately to the suspected case definition. CMS has noted that high-risk persons are now included in the new definition with the exception of people who are admitted with pneumonia.
- 2.11. The purpose of the document is to provide detailed clarification in respect of benefit and entitlements to members and beneficiaries of medical schemes. Subject to the managed care protocols, PMB level of care benefits must be paid in full of the risk benefit irrespective of member's plan type or benefit option

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. Most countries have experienced or are currently experiencing a third wave of COVID-19 infections. Several new variants of SARS-CoV-2 have been identified from September 2020 and these have been classified by the CDC as variants of interest, variants of concern and variants of high consequence. These variants have now been renamed using letters of the Greek alphabet by the WHO. According to the new naming system the variants of concern identified are:
 - Alpha B.1.1.7 first identified in the United Kingdom.
 - Beta B.1.351 first discovered in South Africa.
 - Gamma P1 first identified in Japan/Brazil
 - Delta B.1.617.2 first discovered in India
 - Epsilon B.1.427, B.1.429 first identified in United States (California)
- 3.5. These variants of concern are being monitored due to the possibilities of increased transmissibility and immune evasion.
- 3.6. Based on the recently updated publication by CDC, there are no variants of high consequence; meaning that there is no clear evidence that the current prevention or medical measures have reduced efficacy when compared to the previous circulating variants.

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. 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. South Africa has developed a COVID-19 exposure notification application called COVID Alert SA to help South Africans know when they have been in close contact with someone who has tested positive for COVID-19. Additional information on the app can be found <u>here</u>.

- 4.3. The World Health Organization (WHO) has acknowledged that there is "evidence emerging" of the airborne spread of the novel coronavirus, after a group of scientists urged for an update to its guidance on how the respiratory disease passes between people especially in closed, poorly ventilated spaces.
- 4.4. A PHIRST-C study is being conducted in South Africa to gain a better understanding of the transmission dynamics of SARS-CoV-2, asymptomatic infection prevalence, and the extent of transmission from asymptomatic infection.
- 4.5. According to the WHO, the reproductive number (R) for the virus is approximately 2.2 (meaning that on average each person spreads the infection to two others).
- 4.6. In South Africa, the reproductive number was 1.33 at the start of the pandemic and rose to its highest in April 2020, to 1.5. The NICD reported an R of 1.1. on 26 August 2020, indicating a decline in the number of new cases and the slowing down of COVID-19 transmissions. The average R was 0.99 between 21 September and 27 October 2020. There is currently no data for the reproductive rate during the second wave, however given the rate of transmission prior to the current lockdown, it can be assumed that there has been an increase in the average R rate.

5. Risk factors

- 5.1. 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.
- 5.2. Risk factors for severe disease once infected include:
 - Individuals 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%
 - o 70–79 years: 8.0%
 - 60–69 years: 3.6%
 - o 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.
 - o Cardiovascular disease
 - o 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
- 5.3. 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.
- 6.4. In addition to the above symptoms, it has been observed that children between the ages of 2 15 years are at risk of developing Paediatric Inflammatory Multisystem Syndrome (PIMS) associated with COVID-19, which may include some of the following symptoms:
 - abdominal pain
 - skin rash
 - red, cracked lips.
 - red eyes
 - swelling of the hands or feet
 - reddish, swollen toes ('COVID toes')
 - swollen glands on one or both sides of the neck
 - vision problems
 - paleness

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 spread.
- 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 PMB level of care. The healthcare worker will establish the clinical, epidemiological criteria, and any other criteria that may warrant subsequent laboratory investigation.
- 7.1.3. To further reduce the person to person risk of transmission and reduce the number of patients at doctors rooms, telehealth delivered through online platforms must be reimbursed as PMB level of care in line with the latest Health Professions Council of South Africa (HPCSA) communication as published on their website.
- 7.1.4. 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."

- 7.1.5. 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."
- 7.1.6. In the out of hospital setting, no prior authorisation is required for telehealth consultations with a general practitioner, however, specialist consultations may require pre-authorisation.
- 7.1.7. Schemes may use designated service providers (DSPs), and managed care protocols may apply.

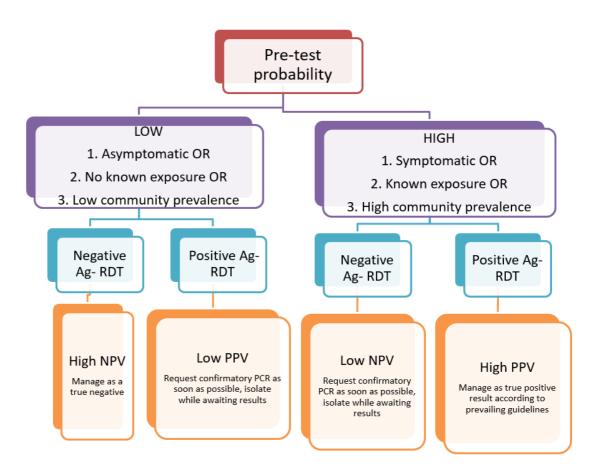
7.2 Laboratory workup

- 7.2.1 South African Health Products Regulatory Authority (SAHPRA) has approved three different types of in-vitro tests for COVID-19 namely molecular tests, and serological tests, and antigen 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/or 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 Antigen tests directly detect SARSCoV-2 proteins produced by replicating virus in respiratory secretions and have been developed as both laboratory-based tests and point of care tests which are referred to as rapid diagnostic tests (RDTs). RDTs provide diagnostic information faster than molecular tests and hence clinical decision making can be quicker when compared to molecular testing.
- 7.2.5 On 11 December 2020, the NDoH published a guideline on the role of the rapid antigen testing as an alternative for the diagnosis of SARS-COV-2. The accuracy and interpretation of the rapid antigen tests is dependent on symptoms, prevalence and exposure to the SARS-COV-2 virus. Understanding the application of these variables is important in avoiding inaccurate conclusions due to false positive or false negative results.
- 7.2.6 SAHPRA has provided a list of serological, molecular and antigen tests that are registered in South Africa and this is available on their <u>website</u>.

Role and funding of antigen testing for SARS-COV-2

- 7.2.7. The guidance on the use of antigen testing has been specified in the NDoH guideline and antigen tests which meet the minimum performance requirements of more than 97% specificity and more than 80% sensitivity may be used for diagnosing infection with SARS-CoV-2, where no RT-PCR is available or have prolonged turnaround times.
- 7.2.8. Based on the algorithm provided by the NDoH, the CMS recommends antigen testing to be funded as PMB level of care for those individuals where the pre-test probability of COVID-19 disease (the likelihood that the patient has COVID-19 before their results are known, based on epidemiologic and clinical factors) is relatively high, and positive test results have a high positive predictive value.
- 7.2.9. The figure below is adapted from the NDoH guidelines, and the CMS recommends antigen testing only within five days of symptom onset for cases where there is a high probability of a high positive predictive value (PPV) and a low negative predictive value (NPV). It is only under these conditions that high accuracy of the antigen test can be predicted.

Figure 1: Antigen testing recommendation: Adapted from the NDoH guidelines.



Funding of antigen test within the high pre-test probability population

- 7.2.10. The probability of a true positive test is high in a population with high community prevalence or symptomatic individuals or individuals with known exposure. The sensitivity of the test is higher within the first 5 days of symptom onset; hence the timing of the test is also important.
- 7.2.11. If an antigen test is positive in the high pre-test probability population, the antigen result is considered a true positive result and hence there is no role of a confirmatory RT-PCR test. The antigen test is PMB level of care in these individuals.
- 7.2.12. If an antigen test is negative in the high pre-test probability population, a confirmatory RT-PCR test is required and if the PCR test is positive, both the antigen and the PCR test constitute PMB level of care.
- 7.2.13. If an antigen test is negative in the high pre-test probability population, a confirmatory RT-PCR test is required and if the PCR test is negative, both the antigen and the PCR test constitute PMB level of care.

Funding of antigen test within the low pre-test probability population

- 7.2.14. If the patient is asymptomatic or no known exposure or there is low community prevalence, there is a low probability of getting a true positive result and hence the use of an antigen test in this population is not recommended.
- 7.2.15. A negative antigen test is not PMB level of care.
- 7.2.16. If the patient in 7.2.14 then proceeds to have an RT-PCR test and the RT-PCR is positive, then both the RT-PCR and the positive antigen test will be PMB level of care.
- 7.2.17. If the patient in 7.2.14 then proceeds to have an RT-PCR test and the RT-PCR is negative, then both the RT- PCR and the positive antigen test will not constitute PMB level of care.

7.2.18. The CMS will ensure that the antigen testing criteria, including any documented thresholds for prevalence, is always aligned with the NDoH recommendations.

Funding of RT-PCR test

- 7.2.19. RT-PCR 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 are individuals who meet the criteria for a suspected case definition and the RT-PCR test must be funded from the risk benefit irrespective of the RT-PCR result.
- 7.2.20. RT-PCR test after a positive antigen result for patients who have a high pre-test probability is not PMB level of care. This is because a positive antigen result in that population is already considered a true positive and there is no need for a confirmatory RT-PCR test.
- 7.2.21. Routine RT-PCR testing of asymptomatic, unscreened and unreferred patients which turns out positive is PMB level of care.
- 7.2.22. Routine RT-PCR testing of asymptomatic, unscreened and unreferred patients which turns out negative is funded at the discretion of the scheme, based on scheme rules.
- 7.2.23. A single positive RT-PCR test is sufficient proof of COVID-19 infection, and there is no role of repeat confirmatory test. A repeat confirmatory RT-PCR test is not PMB level of care.
- 7.2.24. An RT-PCR test can however be falsely negative due to factors such as sampling technique or timing of the test. If alternative diagnosis has been explored and there is still clinical suspicion of COVID-19, a motivation should be submitted to the scheme for a repeat test.
- 7.2.25. According to the WHO, as of 24 April 2020, no study has evaluated whether the presence of antibodies to SARS-CoV-2 confers immunity to subsequent infection by this virus in humans. There is currently no evidence that people who have recovered from COVID-19, and have antibodies are protected from reinfection. As such the number of RT-PCR tests per member should not be capped for a member who presents with COVID-19 symptoms and meets the case definition.
- 7.2.26. The table below summarises the role and PMB recommendations of the different molecular, antibody, and antigen tests for diagnosis of SARS-CoV-2.

Reporting requirements	Role in SARS-CoV-2 and corresponding PMB		
	recommendation		
All confirmed tests must be reported to the NHLS.	Modality for clinical diagnosis - PMB level of care		
All results must be recorded and reported to the National Health Laboratory Service (NHLS)	No role in clinical diagnosis of acute COVID-19 due to low sensitivity – Not PMB level of care		
Must be administered by suitably qualified and trained health professionals only.	Retrospective diagnosis for those who have recovered from COVID-19 compatible illness and tested negative by RT- PCR - Not PMB level of care.		
	All confirmed tests must be reported to the NHLS. All results must be recorded and reported to the National Health Laboratory Service (NHLS) Must be administered by suitably qualified and trained health		

Table 3: Role and PMB recommendations of the different molecular, antibody, and antigen tests for diagnosis of SARS-CoV-2.

Laboratory	All results must be recorded and	Diagnosis of COVID-19 in patients who are admitted with
based	reported to the NHLS.	suspected SARS-CoV2 infection and test negative for RT-PCR,
serological test	Should be conducted in ISO15189 accredited facilities only.	including children with suspected multi system inflammatory syndrome. –PMB level of care on motivation.
		Seroprevalence surveys - Not PMB level of care
		Scientific research and clinical trials including assessing antibody reactivity for prognosis, identification of SARS-CoV-2 vaccine responses – Not PMB level of care
Antigen testing	Notification of positive cases to NMC is mandatory. All results (positive and negative) must be submitted to NHLS and NICD (private sector) as per current RT-PCR results submission.	Symptomatic OR known exposure OR high prevalence – PMB level of care irrespective of the result.

- 7.2.27. In addition to a RT- PCR and/ or antigen testing, and where clinically indicated, the following laboratory investigations are also 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 may require motivation e.g. liver function tests, renal function tests, CRP, glucose, D-dimer levels, prothrombin, blood gas, and urine for lipoarabinomannan (LAM) test if HIV positive.

7.3 Imaging radiology

- 7.3.1 Imaging modalities are not PMB level of care for screening or diagnosis of COVID 19, as the definitive test for SARS-CoV-2 is the RT-PCR or the antigen test.
- 7.3.2 Chest X-ray is PMB level of care for patients with confirmed COVID-19.
- 7.3.3 CT scan is PMB level of care in patients presenting with features indicating worsening respiratory function. CT scan is also recommended in COVID-19 patients with functional impairment and/or hypoxemia after recovery from 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-19 case depends on the severity and the presenting symptoms and not the risk of deterioration. High risks patients who present with mild symptoms should therefore be managed based on their symptoms.
- 8.2. Suspected and confirmed cases who are medically well, or who have mild disease may be managed at home, based on the treating provider's guidance.

- 8.3. Although antibiotics do not treat viral infections, empiric treatment for secondary bacterial and fungal infections might be required. Where evidence suggests bacterial or fungal infections this should be paid for as PMB level of care
- 8.4. Pre-existing PMB chronic conditions such as diabetes mellitus, HIV, asthma etc, should be managed as per the corresponding Diagnostic Treatment Pair (DTP) and/ or Chronic Disease List (CDL), and are deemed PMB level of care.
- 8.5. Treatment and care for the management of mild to moderate disease is PMB level of care.
- 8.6. Given that the scheme is notified of all positive cases of COVID-19, irrespective of the severity, medication prescribed by the doctor for managing COVID-19 symptoms must be funded as PMB level of care. The provider should include the correct ICD 10 code (U07.1) on the prescription. To reduce the administrative burden, and given that this is not a chronic condition, no prior authorisation is required. Generic substitution is permissible, unless the provider instructs otherwise.

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. Funding of oxygen therapy for COVID-19 is based on the oxygen saturation results. Given the pandemic and limited health resources, blood gases are not a pre-requisite for oxygen funding. Hence the only criterion is for a patient to meet the oxygen saturation required.
- 9.5. Ambulatory oxygen and pulse oximeter are PMB level of care subject to provider motivation and oxygen saturation results.
- 9.6. Patients with severe disease are generally hospitalised and the cost of their management must be funded according to the PMB Regulations.
- 9.7. Patients might be admitted to the intensive care unit (ICU) and the use of mechanical ventilators where indicated is PMB level of care.
- 9.8. If clinical setting is appropriate and there is provider preference, non- invasive ventilation is PMB level of care in line with the NICD guidelines. In the absence of an indication for endotracheal intubation, a trial of high-flow nasal oxygen (HFNO), continuous positive airway pressure (CPAP), synchronised inspiratory positive airway pressure (SiPEP) or other non-invasive ventilation (NIV) technique may be considered for adults with COVID-19, and acute hypoxaemic respiratory failure failing standard oxygen therapy.

10. Pharmacological management

- 10.1. All pharmacological management recommendations are based on the guidance issued in the NDoH/ NICD version 5 guidance on the clinical management of suspected or confirmed COVID-19 cases and the NEMLC subcommittee medicine reviews which are available <u>here</u>.
- 10.2. The use of a short duration of low-dose systemic corticosteroids in hospitalised severe COVID-19 patients receiving respiratory support (as either invasive mechanical ventilation or non-invasive oxygen supplementation) and for COVID-19 patients with septic shock is PMB level of care.
- 10.3. Hospitalised patients not on respiratory support should not routinely be administered systemic corticosteroids, unless indicated for another reason such as an acute exacerbation of asthma or chronic obstructive pulmonary disease.

- 10.4. Prophylactic doses of either unfractionated or low molecular weight heparin is PMB level of care for all hospitalised patients. In line with the NEMLC recommendations, there is insufficient evidence for the use of therapeutic doses of either unfractionated or low molecular weight heparin as thromboprophylaxis for patients with severe COVID-19. Therapeutic doses are PMB level of care for patients with a hypercoagulable state as clinically indicated.
- 10.5. Low molecular weight heparin is PMB level of care at discharge subject to motivation by treating provider.
- 10.6. Routine use of oseltamivir for all patients with influenza is not PMB level of care. Oseltamivir is PMB level of care for severely ill patients when administered within 72 hours of symptom onset when prevalence of influenza is moderate to high.
- 10.7. Off label medication and investigational medicine is not PMB level of care. In line with the NEMLC recommendations, the following are not currently PMB level of care for the treatment of COVID-19 and the funding is based on scheme rules:
 - Convalescent plasma
 - Interferon beta
 - Intravenous immunoglobulin
 - Tocilizumab
 - Azithromycin
 - Convalescent plasma
 - Favipiravir
 - Ivermectin
 - Remdesivir
 - Hydroxychloroquine/chloroquine
 - Lopinavir/ritonavir
 - Colchicine
 - Bromhexine

11. Palliative care for COVID-19

- 11.1. Palliative care is a multifaceted, integrated approach to improving the quality of life of adults and paediatric patients, and their families facing the problems associated with life-threatening illness such as COVID-19. CMS is cognisant of the WHO definition of palliative care. However, palliative care for confirmed COVID-19 cases is PMB level of care.
- 11.2. Palliative care includes but not limited to:
 - complex symptom management
 - advance care planning or goals of care conversations
 - complex discussions with patient, and more often with family:
 - diagnoses and current/future care plans,
 - when a patient's condition deteriorates, or withdrawal of treatment decisions needs to be made.
 - family's own (mental)health
 - integration of psychosocial support especially for families on the outside:
 - isolation causing mayor distress and mental health issues with patients and families.
 - primary physicians do not have capacity to always keep loved ones updated or discuss when difficult decisions need to be made quickly.
 - bereavement support to families
- 11.3. Palliative care includes a multi-disciplinary team approach. The team may consist of doctors (GPs and specialists), psychologists, social workers, palliative care home nurses. Palliative care can be provided in different settings including:

- in the home (even if severe and patient so wishes e.g. frail elderly or people with dementia),
- long term care facilities,
- hospices,
- and in hospital including general ward, ICU and high care.
- 11.4. CMS recommends the funding of palliative care. Where a multi-disciplinary team is involved in the treatment and care of COVID-19 patients, the primary provider must submit an initial treatment plan to the scheme for pre-authorisation and weekly updates to allow the scheme to make informed continued funding decisions.

12. Management of COVID-19 in special populations – children, new-borns, pregnant and breastfeeding women and people living with HIV.

12.1. Management of children

- 12.1.1. Although the understanding of COVID-19 related symptoms continues to evolve, the current guidance from NICD states that the clinical presentation and case definition of adults and children are the same.
- 12.1.2. All suspected children with an acute respiratory infection should be tested for COVID-19.

12.2. Management of new-borns

- 12.2.1. The case definition is the same as adults and children, although atypical presentation is expected in neonates.
- 12.2.2. COVID-19 should be included in differential diagnosis of any neonate presenting with acute respiratory symptoms and such neonates should be tested for COVID-19.
- 12.2.3. Babies in good health, who are born from a COVID-19 infected mother do not need a COVID-19 test, and such testing is therefore not PMB level of care.
- 12.2.4. Unwell or symptomatic babies should have a COVID-19 test on day 3 of life if the case definition is met, or at another time if clinically indicated.
- 12.2.5. According to the NICD guidelines, tests done before 72 hours may give a false negative result and should be repeated on day 5 of life if the first test is negative.

12.3. Management of pregnant and breastfeeding

- 12.3.1. According to the NICD guidelines, there is currently no indication that pregnant women are at higher risk of either contracting COVID-19 or of worse maternal outcomes with COVID-19.
- 12.3.2. Pregnant women with COVID-19 can have a vaginal delivery. COVID-19 is not an indication of caesarean section.

13. Funding of COVID-19 vaccine

- 13.1. On the 24 December 2020, the Minister of Health approved the inclusion of COVID-19 vaccine as a PMB level of care.
- 13.2. Medical Schemes must ensure that the identification and prioritisation of the scheme members and beneficiaries to be vaccinated must be aligned with the NDoH guidelines.
- 13.3. All SAHPRA approved vaccinations for COVID-19 must be funded for beneficiaries identified and prioritised as guided by the NDoH.
- 13.4. All COVID-19 vaccinations which are administered outside South Africa, will be funded at the discretion of the scheme, based on scheme rules.
- 13.5. The management of all side effects and complications which may result from administration of the COVID-19 vaccine must be reimbursed by the medical scheme when claimed with the relevant ICD-10 coding.
- 13.6. All appropriate and related vaccine inoculation costs must be reimbursed.

- 13.7. Given the national reporting requirements, schemes and providers must ensure that relevant information related to the administration of the COVID-19 vaccine, including adverse events, is collected and shared with the relevant authorities.
- 13.8. As of 28 June 2021, approximately 2.68 million doses had been administered to South Africans, with 480 000 fully vaccinated, equating to 0.8% of the population being fully vaccinated.

14. Funding of PPE

The department of Labour has issued <u>guidance</u> on workplace preparedness for COVID-19 and all employers (public or private sectors) are obligated to provide their workers with personal protective equipment (PPE) needed to keep them safe while performing their duties. The types of PPE required during a COVID-19 outbreak will be based on the risk of being infected with SARS-CoV-2 while working and tasks that may lead to exposure. PPE for non-healthcare workers is currently not PMB level of care irrespective of the level of risk and these costs cannot be transferred to members or schemes.

PPE for health workers who are treating and managing suspected and confirmed COVID-19 patients is PMB level of care. Claims should be backdated to 7 May 2020, when the PMB regulations for COVID-19 were promulgated.

15. Off label medication

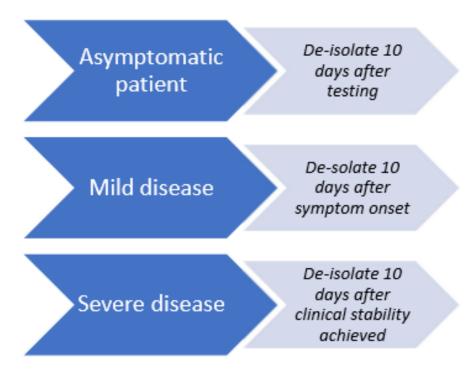
There is consensus in literature as reported by the WHO and SAHPRA, that currently there are no pharmaceutical products that have shown to be safe and effective for the treatment of COVID-19. CMS recommends discretionary funding of offlabel use of medications that show clinical benefit. The NDoH acknowledges 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 PMB level of care.

16. 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 repeat RT-PCR test to ensure that the patient is no longer positive will be funded at the discretion of the scheme based on the scheme rules.

A patient can de-isolate after the recommended period without further testing. Health Minister Dr Zweli Mkhize, announced on 17 July 2020 that the isolation period had been reduced to 10 days from 14 days on condition that the patient does not have a fever and the symptoms are improving.



On referral by the treating provider, chest physiotherapy and other rehabilitative modalities such as psychotherapy are also PMB level of care for confirmed COVID-19 cases.

17. What is not PMB level of care for COVID-19

The following is not PMB level of care:

- Follow-up treatment and care for any person who tests negative for COVID-19 (RT-PCR test).
- A repeat RT-PCR test to ensure that the patient is no longer positive will be funded at the discretion of the scheme based on the scheme rules.
- Routine RT-PCR testing of asymptomatic, unscreened and unreferred patients which turns out negative is based on scheme rules. This includes people returning to work, school or those intending to travel.
- Routine preadmission (including elective admissions) RT-PCR testing for asymptomatic patients which turns out negative is based on scheme rules.
- Routine antigen testing of patients who are unscreened, asymptomatic, no known exposure or if there is low community prevalence is not PMB level of care irrespective of the result. This is based on the high possibility of a false positive result in this population as shown on figure 1 and stated earlier (section 7.2.14).
- Serum antibody testing is not currently PMB level of care. Only exception is the diagnosis of COVID-19 in patients
 who are admitted with suspected SARS-CoV2 infection and test negative for RT-PCR including children with
 suspected multi system inflammatory syndrome.
- Off label medication and investigational medicine is not PMB level of care
- PPE for non-healthcare workers is not PMB level of care.

Consultation	Diagnosis Related information		Treatment	
codes	Laboratory Imaging		Procedure Codes	ATC codes
0130	U07.1	30100 X-ray of the chest,	Evidence of	Evidence of
0132	U07.2	single view	payment for	payment for COVID
0133	Z11.5		COVID related	related medicines
0145		30110 X-ray of the chest two	Procedures	
0146	3755 - Full blood	views, PA and lateral		
0147	count including			
0149	differential count	30120 X-ray of the chest		
0190		complete with additional views		
0191	3891 / 3892 / 3893 /			
0192	3894 / 3895 / 3896 /	30130 X-ray of the chest		
0197	3897 - Blood cultures	complete including fluoroscopy		
0198		,		
0199	3867 / 3895 - Sputum	30300 CT of the chest,		
0201	for MCS	limited study		
0201				
Inpatient Codes	3915 / 3919 / 3920 /	30310 CT of the chest		
0109	4655 / 4656 / 4657 -	uncontrasted		
1204	Mycobacterium			
1205	tuberculosis detection	30320 CT of the chest		
1206		contrasted.		
1200	4434 / 3930			
1208	(GeneXpert MTB/RIF	30330 CT of the chest, pre		
1209	Ultra)	and post contrast		
1210	Olitaj			
1210	4130 / 4131 - Liver	30340 CT of the chest,		
1211	function tests	limited high resolution study.		
1213		innited high resolution study.		
1213	4137 - Lactate	30350 CT of the chest,		
1214				
	dehydrogenase	complete high-resolution study		
	3856 - D-dimer levels	30355 CT of the chest,		
	5050 - D-uimer ieveis			
	2074 Delamente e	complete high-resolution study		
	3974 – Polymerase	with additional prone and		
	chain reaction	expiratory studies		
	4514 - Antigen	30360 CT of the chest for		
	specific IgE	pulmonary embolism		
	2000 Anti			
	3882 - Antigen	30370 CT of the chest for		
	detection with	pulmonary embolism with CT		
	monoclonal	venography of abdomen,		
	antibodies	pelvis and lower limbs		

Table 4: Applicable codes in relation to COVID-19 funding

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
Medicine rapid reviews	http://www.health.gov.za/index.php/national-essential-medicine-list-committee- nemlc/category/633-covid-19-rapid-reviews

COVID Alert SA app

Join the COVID Alert SA app community and help South Africa to curb the spread of COVID-19.

What is COVID Alert SA?

COVID Alert SA is South Africa's free exposure notification app. It lets people know when they have been in close contact with someone who has tested positive for COVID-19.

Who can use it?

Everyone in South Africa who has a Bluetooth-enabled smartphone can access this app. You can make a difference by adding your phone to the fight.

Is my privacy protected?

COVID Alert SA is entirely anonymous. The app protects your privacy and security at all times. It does not need or store any of your personal information.

Download the COVID Alert SA app today

By downloading and using the COVID Alert SA app, you become a part of a powerful digital network of app users who choose to work together for the benefit of everyone in the app community while all enjoying complete privacy and anonymity. App users understand their exposure to COVID-19 and help others to do the same. We can all work together to curb the spread of COVID-19 and, ultimately, to save lives.

The app is available for <u>Android</u> and <u>iOS</u>.

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