



NATIONAL ESSENTIAL MEDICINES LIST COMMITTEE (NEMLC) BULLETIN FOR THE MEETING HELD ON 27 JUNE 2024: MEETING OUTCOMES FOR PUBLIC DISSEMINATION Accessible on the following platforms:

Knowledge Hub: <u>https://knowledgehub.health.gov.za/elibrary/national-essential-medicines-list-committee-nemlc-2021-2024</u> National Health Insurance (NHI) Website: <u>https://www.health.gov.za/nhi-edp-comm/</u>

ACCESS TO STANDARD TREATMENT GUIDELINES AND ESSENTIAL MEDICINES LIST

The following are the latest editions of the Standard Treatment Guidelines (STGs) and Essential Medicines List (EML):

- **Primary Healthcare:** STGs and EML 2020 Edition (plus updated chapters for the 2024 edition ratified by NEMLC)
- Adult Hospital Level: STGs and EML 2019 Edition (plus updated chapters for the 2024 edition ratified by NEMLC)
- Paediatric Hospital Level: STGs and EML 2023 Edition (plus individual chapters)
- Tertiary and Quaternary: EML June 2024 Edition

The following formats of the STGs and EML are accepted by the National Department of Health (NDoH):

• Knowledge Hub eLibrary on the link: <u>https://knowledgehub.health.gov.za/e-library</u>. Refer to Annexure A, for guidance on how to access STGs and EML and related technical documents on the Knowledge Hub.

Resource	Keywords to use in the Search bar	Notes: Folder contents continually updated
PrimaryHealthcare(PHC)Level, 2020 (plus)updated Chapters for the2020-4 edition ratified byNEMLC,MedicineReviews, Costing ReportsandImplementationSlides)	Primary Healthcare, PHC, Standard Treatment Guidelines, STGs, Essential Medicines List, EML	Contains complete PDF of 2020 edition, new chapters already reviewed and ratified for the 2024 edition (with supporting NEMLC reports) which will be replacing chapters from the 2020 edition and form part of the 2024 edition, medicine reviews, costing reports, implementation slides, therapeutic interchange database and EML based on 2020 edition of the STGs and EML
HospitalLevel–Paediatrics,2023 (plusupdatedChaptersratifiedbyNEMLC,Errata,Medicine Reviewsand Costing Reports)Hospital Level – Adults,2019	Hospital Level, Hospital, Paediatric, Standard Treatment Guidelines, STGs, Essential Medicines List, EML, Medicine Reviews, Costing Reports Hospital Level, Hospital, Adult, Standard Treatment	Complete PDF of the 2023 edition, updated chapters, individual chapters for the 2023 edition and errata Medicine reviews and costing reports in a separate folder Contains complete PDF of the 2019 edition, new chapters (with supporting NEMLC

Keywords:

(plus updated Chapters	Guidelines, STGs, Essential	reports) already reviewed and ratified for
for the 2020-4 edition	Medicines List, EML,	the 2024 edition replacing chapters from
ratified by NEMLC,	Medicine Reviews, Costing	the 2020 edition and form part of the 2024
Errata, Medicine Reviews	Reports	edition, notices of errata from the 2019
and Costing Reports)		edition, therapeutic interchange database
		and EML based on the 2019 edition of the
		STGs and EML
Tertiary and Quaternary	Hospital Level, Hospital,	2022 - 2024 medicine reviews, costing
Level, June 2024	Tertiary & Quaternary,	reports, latest Tertiary and Quaternary EML
	Tertiary, Quaternary,	2017 – 2021 medicine reviews and costing
	Medicine	documents in separate folders but same key
	Recommendations,	words
	Medicine Reviews, Costing	
	Reports	
Medicine Reviews and	Medicine reviews,	Different folders for Paediatrics, Adult and
Costing Reports	reviews, costing reports,	Tertiary/ Quaternary
•	costing	
		Contains all medicine reviews and costing
		reports per level of care, except PHC level
Notice for Comment	Notice for Comment,	Current notices for all levels of care – these
	Notice Comment, PHC,	notices are removed once comment period
	Adult, Paediatric, Hospital	is closed
	Level, STGs, EML	
National Essential	NEMLC, National Essential,	Member photos with short biographies,
Medicines List	Essential Medicines,	policies, NEMLC terms of reference, NEMLC
Committee (NEMLC)	Committee	bulletins
Affordable Medicines	Affordable Medicines	2022 - 2024 circulars
Circulars	Circulars, Affordable	
	Medicines, Circulars	
Health Technology	Health Technology	HTA Methods Guide, HTA Methods Guide
Assessment (HTA)	Assessment, Health	Templates
	Technology, HTA, Essential	
	Medicines List	
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- **EMGuidance mobile application:** To sign up, use the following link: <u>http://onelink.to/sy896k</u>. Please note there may be a lag time for any updated documents published on the Knowledge Hub to be transcribed onto the EMGuidance platform.
- NHI website (latest version of the STGs and EML): The STGs and EMLs can be accessed using the following link: <u>https://www.health.gov.za/nhi-edp-stgs-eml/</u>. Click on the relevant tab to access the STGs, EMLs and technical documents for each Level of Care.
- For webinar recordings aimed at strengthening implementation of the STGs and EML: <u>https://knowledgehub.health.gov.za/webinars</u>.
- COVID-19 rapid review reports are available on the **NDoH website** at: <u>http://www.health.gov.za/covid-19-rapid-reviews/</u>.
- Tecovirimat medicine summary is available on the NDoH website at: <u>https://www.health.gov.za/general-notices/</u>

ACCESS TO NATIONAL DEPARTMENT OF HEALTH, ESSENTIAL DRUGS PROGRAMME (EDP) CIRCULARS

Circulars that are developed by the Essential Drugs Programme (EDP) are disseminated to EDP stakeholders and uploaded on the Knowledge Hub eLibrary and the Affordable Medicines webpage on the NHI website. These circulars can be accessed on the following links:

Knowledge Hub eLibrary: <u>https://knowledgehub.health.gov.za/elibrary/affordable-medicines-circulars-2022-2024</u> NHI website: <u>https://www.health.gov.za/nhi-edp-comm/</u>

Please email SAEDP (**SAEDP@health.gov.za**) if you would like to be added to the mailing list for circulars and other EDP updates.

The following circulars/documents were disseminated for June - July 2024:

- <u>Notice</u>: Guidance on Insulin switching: Insulin pen sets to insulin vials and human insulin products to insulin analogue products 21 June 2024.
- <u>Notice</u>: Publication of the National Essential Medicines List (NEMLC) approved updates to the Primary Healthcare and Adult Hospital level chapters. The circular outlines updates to the following chapters in the PHC and Adult Hospital Level STGs and EML for the 2024 edition:
 - PHC Chapter 2: Gastro-intestinal conditions
 - PHC Chapter 21: Emergencies and injuries
 - AHL Chapter 1: Alimentary tract
 - AHL Chapter 5: Gynaecology
 - AHL Chapter 9: Systemic Healthcare Associated infections
 - AHL Chapter 20: Emergencies and Injuries
 - Adult Hospital EML: Appendix V- Asthma Monitoring

The circular outlines the availability of the following medicine reviews:

- Rapid scoping review: Burn dressings.
- Medicine review: Ketamine for analgosedation in trauma.
- Medicine review: Morphine for pulmonary oedema.
- Medicine review: Olanzapine for delirium.
- Evidence summary: Temperature control post-cardiac arrest.
- Erratum to the Paediatric Hospital Level Standard Treatment Guidelines and Essential Medicine List, 2023, <u>5th Edition</u> – 04 July 2024.
- <u>Notice:</u> Publication of the National Essential Medicines List (NEMLC) approved updates to the Primary Healthcare and Adult Hospital level Standard Treatment Guidelines and Essential Medicines List (EML) for the 2024 edition:

The circular outlines the availability of the PHC level implementation slide decks for the following chapters:

- Chapter 1: Dental and oral conditions
- Chapter 6: Obstetrics & Gynaecology
- Chapter 3: Nutrition and Anaemia
- Chapter 16: Mental Health Conditions
- Chapter 7: Family planning
- Chapter 10: Infections and Related Conditions

The circular outlines the availability of the following medicine reviews:

- Buprenorphine for Opiate Agonist Therapy
- Methadone for Opiate Agonist Therapy

HAEMOPHILIA STGS

- Haemophilia B Prophylaxis A rapid review for factor IX prophylaxis in patients with severe haemophilia
 B was presented to NEMLC, outlining the costing and underlying assumptions. Noting the limitations around ascertaining patient numbers and understanding the current practice on the ground, NEMLC ratified the rapid review on factor IX prophylaxis for patients with severe haemophilia B.
- Updated haemophilia STGs The STGs have been updated to include the haemophilia B prophylaxis, as well as to incorporate external comments received. The Chapters have been shared with stakeholders for final commenting prior to being finalised by NEMLC and the can be found on the Knowledge Hub eLibrary on the following link: https://knowledgehub.health.gov.za/elibrary/notice-comment-phc-adult-and-paediatric-hospital-level-stgs-and-eml. The comment period closes on 29 July 2024 and comments may be submitted via email to: Dr Jane Riddin at jane.riddin@health.gov.za.

PRIMARY HEALTHCARE AND ADULT HOSPITAL LEVEL STANDARD TREATMENT GUIDELINES AND ESSENTIAL MEDICINES LIST

- The following chapters have been reviewed and *ratified for publication*, with the respective NEMLC reports and relevant medicine review(s), following clinical editing as part of the 2024 edition of the STGs and EML:
- PHC Level
 - PHC Chapter 2: Gastrointestinal Conditions published
 - PHC Chapter 21: Emergencies and Injuries published
- AHL Level
 - AH Chapter 1: Alimentary published
 - AH Chapter 20: Emergencies and Injuries published
 - AH Appendix V: Asthma monitoring-published
- Medicine Reviews
 - o Buprenorphine for Opioid Agonist Therapy
 - Methadone for Opioid Agonist Therapy
- The following items were reviewed by NEMLC:
 - Aspirin dosing at bedtime for prevention of pre-eclampsia The initiation of aspirin at PHC level for reducing the risk of early onset pre-eclampsia for women with risk factors was accepted by NEMLC at the 16 May 2024 NEMLC meeting, however the Committee queried if aspirin should be dosed at bedtime to reduce gastric irritation. Bedtime dosing was accepted by NEMLC with a further suggestion for aspirin to be ingested preferably not on an empty stomach. These changes will be reflected in the updated PHC CH 6: Obstetrics & Gynaecology.
 - Use of antivirals in the third trimester of pregnancy in women who are HIV Negative and HBeAg positive At the 16 May 2024 NEMLC meeting, the committee ratified the review on the use of antivirals in the third trimester of pregnancy, in HIV negative women with chronic Hepatitis B infection who are HBeAG positive, to prevent vertical transmission of Hepatitis B. TDF prophylaxis was recommended from 28 weeks of pregnancy until birth to HIV Negative and HBeAg positive pregnant woman. Subsequent to the ratification of the review questions were raised regarding the antiviral recommendation in relation to HBsAG testing as well as the March 2024 update to the World Health Organization (WHO) Guidelines for the prevention, diagnosis, care and treatment for people with chronic hepatitis B infection and its impact on the antiviral review. An addendum to the review on the use of antivirals in the third trimester of pregnancy in women who are HIV Negative and HBeAg positive was ratified by NEMLC.

In summary the recommendation of TDF prophylaxis remains unchanged in this group of patients. However, in line with the updated WHO recommendation, TDF prophylaxis should be initiated from 28 weeks of pregnancy until birth to women with a high hepatitis viral load (≥200 000 IU/mL), or positive HBeAg, or positive HBsAG where HBeAg/viral load result is unavailable at 28 weeks.

PAEDIATRIC HOSPITAL LEVEL STANDARD TREATMENT GUIDELINES AND ESSENTIAL MEDICINES LIST

- The updated complete Paediatric Hospital Level STGs and EML, 2023 edition, updated July 2024 (plus individual chapters updated and ratified by NEMLC) is available for download on the Knowledge Hub and NHI webpage on the following link: https://www.health.gov.za/wp-content/uploads/2024/07/Paediatric-STGs-and-EML-2023-Edition_Updated-July-2024.pdf
 - An errata circular to the Paediatric STGs and EML 2023 edition has been published: <u>https://www.health.gov.za/wp-content/uploads/2024/07/Paed_STG-EML-errata-July2024.pdf</u>
 - Presentations from the Paediatric Hospital Level STGs and EML 2023 edition launch webinar series (held in September 2023) can be found on the Knowledge Hub Webinars tab or on the following link: <u>https://knowledgehub.health.gov.za/webinars</u>.

TERTIARY AND QUATERNARY HOSPITAL LEVEL ESSENTIAL MEDICINES LIST

- The following items were reviewed by NEMLC:
 - PDE5-inhibitors in PPHN The phosphodiesterase-5 (PDE5) inhibitors for persistent pulmonary hypertension in neonates (PPHN) review was presented to NEMLC, highlighting that PPHN is associated with high mortality and that in a number of settings nitric oxide may not be available for management of this condition. Additionally nitric oxide is expensive and requires specialised equipment to administer. NEMLC recommended that PDE5-inhibitors be available for the management PPHN in all settings where neonates are being ventilated.
 - Itraconazole, histoplasmosis Itraconazole for HIV-positive patients with disseminated histoplasmosis was reviewed in 2008, however it was not recommended by NEMLC. Review indicators at the time were set as new evidence of efficacy compared to amphotericin B, increase in incidence and significant price changes. Following an updated review, NEMLC approved the recommendation to include itraconazole for disseminated histoplasmosis.
 - Transdermal fentanyl A review on transdermal fentanyl for severe stable pain in patients who are unable to take oral medication and do not have access to subcutaneous opioids *via* a syringe driver; together with a clinical guide for use were presented to NEMLC. The Committee approved the use of transdermal fentanyl at the tertiary level of care for the specific population as outlined above, while noting that further consideration will be required as to how this access can be extended to all that may require this agent, across levels of care.

Final reviews and supporting technical documents are published on the following links: Knowledge Hub's eLibrary: <u>https://knowledgehub.health.gov.za/elibrary/hospital-level-tertiary-quaternary-medicine-recommendations-medicine-reviews-</u> <u>and-costing</u> and the NHI website: <u>https://www.health.gov.za/nhi-edp-stgs-eml/</u>

THE STGS AND EML AND NATIONAL PROGRAMME GUIDELINES

 Opioid Agonist Therapy (OAT) progress on implementation – NEMLC previously recommended that Opioid Agonist Therapy (OAT) not be recommended for inclusion to the national EML but may be made available for pilot sites selected and monitored by the NDoH Mental Health and Substance Use Programme. The NDoH Mental Health and Substance Use programme provided a progress updated on the NDoH OAT implementation research project. The medicine reviews on methadone and buprenorphine for OAT have been published on the Knowledge Hub and NDoH websites. Both methadone and buprenorphine remain non-EML items. Data from the selected sites will inform further decisions regarding inclusion of OAT on the national EML for universal access

TECOVIRIMAT: MPOX REVIEW

The NDoH Communicable Disease Programme in collaboration with the National institute for Communicable Diseases (NICD) are in the process of developing guidelines for the clinical recognition, diagnosis and management of mpox in South Africa. In parallel the NEMLC has provided an evidence-based review/summary for tecovirimat. Tecovirimat, is currently being undertaken via a Section 21 approval on a per-patient basis, funded through a limited donation program through the World Health Organisation (WHO). In summary given the absence of randomised controlled trial data of safety and efficacy and the lack of South African Health Products Regulatory Authority (SAHPRA) registration of tecovirimat for the treatment of mpox in South Africa, the NEMLC cannot make a recommendation at this time for the inclusion of tecovirimat on the South African EML. However, given the public health concern around the current outbreak of mpox, NEMLC has proposed, with conditions, that the NDOH program should subscribe to the international recommendations and support access to tecovirimat, oral, on a compassionate basis for adult and paediatric patients *via* the limited WHO donation programme and Section 21 approval, for mpox. The summary on tecovirimat has been published on the NDOH website.

WEBINAR SERIES FOR THE IMPLEMENTATION OF THE STGS AND EML

- Take note of the advertisements for the series of webinars to be held showcasing the Health Technology Assessment process applied to the review of the STGs and EML and the updated chapters and reviews that have been published as part of the 2024 editions of the Primary Healthcare and Adult Hospital Level STGs and EML. The recordings and presentations for the conducted webinars can be accessed on the following:

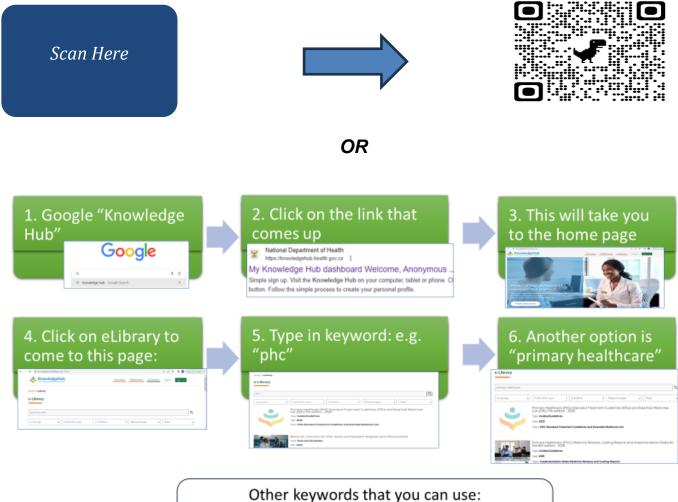
Session 1: Health Technology Assessment - held on 25 June 2024 (<u>https://knowledgehub.health.gov.za/webinar/national-department-health-standard-treatment-guidelines-essential-medicines-list-session-1</u>)

Session 2: Mental Health – Update to the STGs & EML held on 16 July 2024 (https://knowledgehub.health.gov.za/webinar/mental-health-updates-ndoh-standard-treatment-guidelinesand-essential-medicine-list)

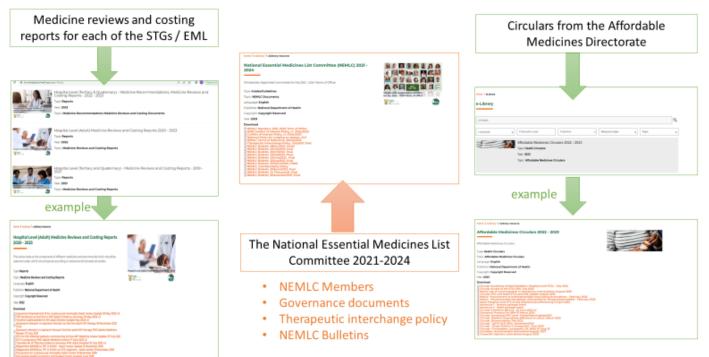
- The webinars planned for July and August 2024 are as follows:
 - o 30 July 2024: Obstetrics & Gynaecology, Family Planning Update to the STGs & EML (Invitation attached)
 - 13 August 2024: Adult Critical Care, Morphine Reformulation Update to the STGs & EML
 - o 27 August 2024: Infections and Antimicrobial Resistance Update to the STGs & EML

Annexure A

Guide on how to access the Standard Treatment Guidelines and Essential Medicines List and related technical documents on Knowledge Hub



Other keywords that you can use: 'hospital level'; 'paediatric'; 'adult'; 'tertiary'; 'notice for comment'



What else is available on KnowledgeHub?

How the STGs/EML are presented on KnowledgeHub

