

Individual Patient Use Ncomeka Makalima


Individual Patient Use

PTCs may approve the use of medicines for 'Individual Patient Use' where a medicine needed is


- not on the formulary of the health establishment where receiving health care service
- patient is referred and requires medicines not on formulary of receiving health establishment
- on the formulary of the health establishment but require more control e.g. cost or possible irrational medicine use



Applications are submitted by clinicians



health
Department:
Health
REPUBLIC OF SOUTH AFRICA



Appendix 19: Individual Patient Access Application

Date

Reference

Annexure C details the sections of the application that must be completed for individual patient access scenarios

Section 1: Patient and Medicine Details					
Patient's Name:		Age:	Gender:		
Weight:		Height:			
Hospital or ID Number:		Patient Contact Number:			
Patient Category:	H0	H1	H2	PHP	
Medical Aid: Yes / No	Medical Aid Name:	Number:			
Diagnosis:					

Individual Patient Use

Applications for Individual Patient Use

- Applications may be submitted by the relevant **treating clinician** to the applicable PTC on an approved application form.
- Application must include a **motivation** providing reasons as to why the medicine is needed for the patient in question.
- If the application is for a **non-EML** medicine, the application must also include evidence of efficacy and safety in similar groups of patients, for a similar indication with cost-effectiveness and affordability also being taken into consideration.

Special Access

- Application for use of a **Special Access** medicine may only be initiated at the **tertiary/quaternary** level of care by an appropriate specialist for the indication or under the supervision of an appropriate specialist at a lower level of care.
- Applications should be for a course of therapy, with the period for authorisation being determined to suit the relevant condition or medicine.
- Patients who meet the predefined criteria as stated by **NEMLC** will be considered for eligibility on receipt of the required application and motivation.
- **Cost implication** to the National Tertiary Services Grant will also be taken into account.

Monitoring of Individual Patient Use and EML

Individual patient and EML must be monitored as follows:

1. **Register (database) must be maintained by PTC of all applications received, as well as approval granted and rejected per health establishment and district;**
2. Each health establishment must keep a record of patients receiving these medicines;
3. Records must be considered when the formulary of the province, district or health establishment is reviewed;
4. **PPTC must maintain oversight of all non-EML medicines used in the province and submit an annual report to NEMLC to assist in generating a signal that such medicine be reviewed**



Thank you

