

HIV/AIDS

Drug treatment

if fresh vesicles are present and preferably within 72 hours of onset:

- aciclovir, oral, 800 mg five times daily for 7 days. Doctor-initiated.

if secondary infection is present:

- erythromycin, oral, 500 mg 6 hourly

pain relief:

- paracetamol/codeine, oral, 1 000 mg/20 mg 3 to 4 times a day when needed

for prolonged pain occurring after shingles has healed:

- amitriptyline, oral, 25 mg at night.
 - increase dose to 50 mg after two weeks
 - and to 75 mg after a further two weeks.

Referral

- involvement of the eye
- disseminated disease (many vesicles extending beyond the main area)
- features of meningitis (headache and neck stiffness)
- severe post-herpetic neuralgia not responding to amitriptyline

Candidiasis, oral

B20.4

See section 1.02

Eczema, seborrhoeic

L30.9

See section 6.04.2

Papular pruritic eruption

L30.9

Exclude scabies

- chlorpheniramine, oral, 4 mg 3 times daily

for itching:

- calamine lotion, applied on the skin
- hydrocortisone 1% cream, applied twice daily for 7 days
 - apply sparingly to the face
 - do not apply around the eyes

Candida oesophagitis

B20.4

Description

Infection of the oesophagus with candida, a fungus causing oral thrush. Almost all cases will be HIV infected. Occurs in patients with oral thrush who have pain or difficulty on swallowing. (See section 1.0.1)

Management objectives

- treat the infection

Non-drug treatment

- maintain hydration

Drug treatment

- fluconazole, oral, 200 mg daily for 14 days

Referral

- inability to swallow
- frequent relapses

Diarrhoea, HIV associated

A08.3

See section 2.06.3

Herpes simplex ulcers, chronic

B20.3

Description

Painful ulcers due to herpes simplex virus, involving the skin around the anogenital area or mouth in patients with advanced HIV infection. Ulcers persist for weeks and may be several centimeters in diameter.

HIV/AIDS

Ulcers in the anogenital area fail to respond to syndromic treatment for genital ulcers (see section 10.13)

Management objectives

- relieve pain
- treat ulcers

Non-drug treatment

Keep affected areas clean with soap and water or diluted antiseptic solution.

Drug treatment

- aciclovir, oral, 400 mg 8 hourly for 10 days

pain relief:

- paracetamol/codeine, oral 1 000 mg/20 mg 3 to 4 times a day when needed

Referral

- no response to therapy
- frequent relapses

Meningitis, cryptococcal

B45.1

Description

Fungal meningitis occurring in advanced HIV infection.

Presents with headache, lasting for weeks.

Neck stiffness is often absent.

Decreased level of consciousness and fever are common.

Management objectives

- relieve pain
- treat the infection

Non-drug treatment

Therapeutic lumbar puncture for severe headaches, removing 10-20 mL of cerebrospinal fluid or reduce CSF pressure to less than 18 cm of water, if facilities exist at PHC, otherwise refer.

Drug treatment

- amphotericin B initially for up to 2 weeks **in hospital**
- fluconazole, oral, 400 mg daily for 8 weeks

pain relief:

- paracetamol/codeine, oral 1 000 mg/ 20 mg 3 to 4 times a day when needed

secondary prophylaxis:

- fluconazole, oral, 200 mg daily

Referral

- all patients for initial management in hospital
- treatment unavailable at clinic level

Pneumonia, bacterial

J15.9

See section 15.07

Pneumonia, *Pneumocystis carinii*

B20.6

See section 15.07

Toxoplasmosis

B58.9

- trimethoprim/sulfamethoxazole, oral, 320/1 600 mg 12 hourly for 4 weeks, then 160/ 800 mg 12 hourly for 12 weeks, **in hospital**.

Secondary prophylaxis:

- trimethoprim/sulfamethoxazole, oral 160/ 800 mg daily.

Tuberculosis (TB)

B20.0

See section 15.08

TB chemoprophylaxis

Patients with HIV infection are more susceptible to TB infection than HIV-negative patients.

The indication for preventive therapy is a Mantoux 5 mm or larger or a recent TB contact. Initiate only once active disease is excluded.

- isoniazid, oral, 300 mg daily for 6 months
 - educate patients on the symptoms of hepatotoxicity and the need to be followed up monthly. Instruct patient to present early if these symptoms arise
- pyridoxine, oral, 25 mg once daily

Note

Only some primary care facilities are able to do Mantoux testing and exclude TB reliably. Consult with local TB Programme managers.

20.02 Human immunodeficiency virus infection in children

B33.3

Description

HIV enters lymphocytes and replicates, leading to progressive destruction of the immune system, until the infected person becomes unable to fight infection and develops the syndrome of **A**cquired **I**mmune **D**eficiency **S**yndrome (AIDS).

Infants infected with HIV during pregnancy, birth or breast-feeding may be initially well and later follow one of three patterns:

- in a quarter of them, the virus replicates rapidly and the child present with signs of infection in the first year of life
- many children present with symptoms between the first and fifth year of life
- approximately 5–10% remain asymptomatic until 8 years of age

When an older child acquires HIV, the infection begins with an acute non-specific flu-like illness followed by several years of good health. However, during this period immune cells are progressively being destroyed. Later, opportunistic or common infections and some malignancies occur and may be life threatening.

WHO staging system for HIV infection and disease children**Clinical stage I**

- asymptomatic
- generalised lymphadenopathy

Clinical stage II

- unexplained chronic diarrhoea
- persistent or recurrent candidiasis
- weight loss or failure to thrive
- persistent fever
- recurrent severe bacterial infections

Clinical stage III

- AIDS defining opportunistic infections
- severe failure to thrive
- progressive encephalopathy
- malignancy
- recurrent septicaemia

Risk factors

HIV infection should be suspected in the following situations:

- exposure to infection from infected mothers
- sexual abuse

Diagnosis

Adequate pre- and post-test counselling must be provided.

Ensure patient confidentiality.

Antibody tests, e.g. HIV antibody rapid test and HIV ELISA test will determine the response of the body to the virus and not directly the presence of virus.

- **A positive antibody test in an infant less than 15 months of age:**
 - may reflect maternal antibody rather than infection in the child. If the child has features of symptomatic HIV infection, it is very likely that the child is HIV infected. The test should be repeated when the child is 15–18 months old to confirm if HIV infection is present or absent, especially in a child without signs suggestive of HIV infection.
- **A positive antibody test in a child over the age of 15 months:**
 - two HIV antibody tests are performed. This can either be two rapid tests (using kits from different manufacturers) or with a laboratory test (usually ELISA).

HIV/AIDS

- **A negative antibody test:**
 - means that the infant is not HIV infected, provided, that the infant has not received breast milk in the previous 6 months.
 - If the infant has received any breast milk in the previous 6 months and the mother is HIV infected, the test should be repeated 6 months after stopping breastfeeding to confirm that the child is truly HIV negative.
 - In the period between becoming infected and the development of antibodies, the antibody test may be negative, “the window period”.

Management Objectives

- provide guidance on how to prevent HIV infection (See section 7.05.4 Prevention of Mother To Child Transmission of HIV)
- counsel and test for HIV in parents and children
- prevent the transmission of HIV from mother to child
- prevent opportunistic and common infections
- provide psychological, family and social support
- provide nutritional support
- maintain immunisation schedule and prophylactic treatment

Knowledge about HIV/AIDS is constantly being updated. Practices may require changes based on the latest information.

Non-drug treatment

- ensure that a well-balanced diet is maintained
- support all members of the family
- psychosocial support
- community support

Drug treatment

- multivitamin syrup, oral, daily

less than 6 months	2.5 mL
6 months – 5 years	5 mL
over 5 years	10 mL
- vitamin A, oral, according to the national protocol

at 6 weeks non-breastfed infants	50 000 IU
at 6 months	100 000 IU
at 1 year and 6 monthly thereafter	
until the age of 5 years	200 000 IU

in areas with high prevalence of intestinal worms or if signs of worms or malnutrition:

- albendazole, oral, 400 mg single dose every six months after the first year of life

20.02.1 Opportunistic infections, prophylaxis in children

Immunisation

Z26.9

Normal schedule should be followed. Siblings should also be fully immunised. BCG should not be given to children with symptomatic HIV.

(See section 11 Immunisation)

Pneumonia, *Pneumocystis carinii*

B20.6

See section 15.06 Pneumonia

When can prophylaxis be stopped?

For infants less than 12 months of age, prophylaxis should continue until HIV infection has been ruled out.

When should prophylaxis be continued?

Prophylaxis should be continued for life if HIV infected child has:

- an episode of PCP pneumonia
- symptomatic HIV disease
- had three pneumonia episodes

TB Chemoprophylaxis

B20.0

See section 15.08

Bacterial infections, recurrent

B20.1

- trimethoprim/sulfamethoxazole, oral, 1.25 mL/kg daily 5 days a week, e.g. Monday to Friday

20.02.2 Opportunistic infections, treatment in children

Candidiasis, oral (thrush), recurrent

B20.4

- nystatin suspension, oral, 100 000 IU/mL, 0.5 mL after each feed. Keep nystatin in contact with affected areas for as long as possible.

or

- gentian violet, 0.5%, aqueous solution, applied to the inside of the mouth three times daily. Continue for 48 hours after cure.

Candidiasis, oesophageal

B20.4

- fluconazole, oral, 3–6 mg/kg per day as a single daily dose for 21 days

Skin conditions

B20.7

These are common and include scabies, seborrhoeic eczema and others. See section 6.

If no response to simple care as in skin conditions section, refer.

Measles and chickenpox

B20.7

Children who have contracted or are exposed to measles and chickenpox should be referred.

Diarrhoea

B23.8

See section 2.06

Tuberculosis (TB)

B20.0

TB should be considered earlier in non-resolving pneumonias.

Tuberculin tests are often not reliable and a negative test does not exclude TB.

If TB is suspected but cannot be proven, refer for diagnosis.

Manage children with TB according to the national TB guidelines (See section 15.07)

Lower respiratory tract infection, acute

B23.8

See section 15 Respiratory conditions

20.02.3 Developmental delay or deterioration

B23.8

Refer for assessment

20.02.4 Anaemia

B23.8

See section 4.01

20.03 Palliation

Respite care in hospital or hospice or help in the home by volunteers, etc. can provide relief from the burden of nursing a dying family member and providing care at the same time.

Counseling, listening, caring and loving can provide relief from grief and bereavement.

Pain relief:

See section 18.09.1 Chronic pain control

fever relief:

- tepid sponging

and/or

- paracetamol, oral, 4–6 hourly, when needed to a maximum of four doses daily

Weight kg	Dose mg	Syrup 120 mg/5 mL	Tab 500 mg	Approx Age years
6–10 kg	60	2.5 mL	—	3–12 months
10–18 kg	120	5 mL	—	1–5 years
18–25 kg	240	10 mL	1/2 tab	5–8 years
25–50 kg	500	—	1 tab	8–14 years
over 50 kg and adults	1000	—	2 tabs	14 years and older

GUIDELINE ON EDL REVIEW PROCESS & SUBMISSION FOR AMENDMENTS

The National Essential Drugs selection process is based upon a well-developed network of provincial, district and institutional Pharmacy and Therapeutics committees.

Motivations for inclusion in the list will only be considered if:

- The prescribed form has been fully completed.
- The motivators' contact details are complete.
- The drug name has been stated
- The submission has been evaluated and approved by the provincial Pharmacy and Therapeutics Committee (PTC).
- The indication has been clearly stated.
- All relevant comparator drug/s have been listed.
- There is sufficient evidence to support the proposed amendment.

Motivations may address major or minor amendments.

Major amendments include:

- new indications
- new therapeutic entities
- new therapeutic classes

All major amendments must be supported by evidence reflecting safety, efficacy and cost of the medicine compared to an already listed drug for the same indication.

A major amendment may also include motivations for drugs not listed and for conditions not addressed in the EDL. In such cases submissions must be supported by demographic data.

Minor amendments include:

- new formulations
- combination therapies of existing essential drugs

For minor amendments the supporting evidence should be relevant to the nature of amendment.

Screening

Motivations are screened by the Rational Selection Group (RSG) at the National Department of Health to ensure that:

- the submission has been approved by the provincial PTC
- the motivators' contact details are included
- the drug can be identified in terms of the INN
- an indication has been included
- relevant comparator drug/s have been identified with their corresponding dosing regimens
- there are supporting references to substantiate the request

Guidelines on EDL review process & submission for amendments

RSG will compile a review of the prevailing cost of therapy.

Submissions that have been accepted by RSG are tabled at the relevant technical subcommittee for allocation to a suitably qualified reviewer who compiles a technical report. This technical report summarizes a review of the submitted data in terms of the following:

- relative safety
- relative efficacy
- practice environment – the focus here being efficacy relative to current EDL drugs
- pharmacoeconomic evaluation

The report is then presented to the technical subcommittee. The committee may request further information from the applicant through the province or commission a literature search and review.

The technical subcommittee will make recommendations to the National Essential Drug List Committee (NEDLC) for approval or rejection. Where the NEDLC is of the opinion that further review is required the decision will be sent back to the technical subcommittee for further review.

The data elements of the submission form

The motivation form is divided into 5 sections.

Section 1: Proposal

The proposal consists of:

- a) The International Nonproprietary Name (INN) of the medicine – this identifies a pharmaceutical substance or active pharmaceutical ingredient by a unique name that is globally recognized and is public property. A nonproprietary name is also known as a generic name.
- b) Level of Care - indicate whether the proposed medicine should be listed for use at primary care (PHC) or hospital level (Note drugs at PHC level are automatically included at the hospital level).
- c) Prescriber level - indicate the level of competency required to prescribe the drug.

Section 2: Motivators' Details

The NEDLC will acknowledge all submissions and communicate decisions with supporting arguments where appropriate. This section therefore forms a vital link between the motivator and the decision making process.

Guidelines on EDL review process & submission for amendments

Section 3: Proposed Indications

a) Indication

Points to consider:

- The EDL targets those conditions that are the most prevalent in South Africa. Where the motivator suggests an indication not currently reflected in the EDL, a brief motivation based upon South African epidemiological data must be included as an annexure.
- The indication allows for the identification of the appropriate comparator in the current EDL.
- Many drugs have multiple indications. However, not all are equally cost effective.

b) Proposed Regimen

This data will be used for cost comparison and is very important for pharmacoeconomic evaluation.

c) Cost assessment

The information is necessary for the determination of affordability. It is expected that the provincial PTC will deliberate about the affordability during their review prior to submission to NEDLC. For this reason, this data is considered mandatory at the national level.

Section 4: Drugs on the current EDL for the same indication

As a principle, the addition of an EDL item should replace an existing item. This is of particular importance when safety and economic implications are taken into account.

Evidence

Evidence is a vital component of the submission and review process. Evidence does not constitute a drug decision and merely informs the strength of the argument. It forms the basis upon which the decision is made and allows for transparent scrutiny of the decision as well as facilitating the review.

Evidence is required in support of:

- relative efficacy
- relative safety
- pharmacoeconomic benefits

Note

Evidence needs to be relevant to the South African context. Multinational or foreign studies must be supported by a motivation of the relevance of both the outcome measures as well as socio-economic facets to the South African context.

Guidelines on EDL review process & submission for amendments

The inclusion of at least one relevant reference is mandatory. A copy of the full journal article should be included in order to expedite the review process.

Section 5: For use at national level only

This section is intended to ensure that the submissions have followed the proper process.



Motivation Form for the Inclusion of a Drug on the National Essential Drugs List

Please complete Sections 1 to 4 in full

SECTION 1

NB - Only use INN (International Nonproprietary Name/Generic names) on this form

Proposed Drug

For Inclusion on the Essential Drug List for

PHC

Hospital

Check all appropriate blocks

Prescriber Level

Primary Health Care - 1

Medical Officer -2

Specialist -3

Designated Specialist - 4

Submission
Date

PTC Title

SECTION 3

Proposed Indication

See reverse side for the level of evidence schedule

	Indication	Proposed Regimen		
		Dose	Route	Inter
1				
2				
3				

Level Of Evidence

Ia Meta-analysis

Ib Randomized Controlled Trial

IV Expert committee

V Clinical experience

SECTION 4

Drugs on the Current EDL for the Same Indication

	Drug	Indication <i>as per list above</i>	Current	
			Dose	Route
1				
2				
3				

SECTION 5

FOR NATIONAL USE ONLY

Correspondence

Date received

 / /

Acknowledged

 /

Evidence

No of articles submitted:

For National Evaluation

Yes

No

Further evidence

Motivation

New C

Decision

Accepted

 /

Rejected

 /

SECTION 2

Motivator's Details

Title		Name			
Tel No	Code		Number		
Fax No	Code		Number		
Postal Address					
				code	
E Mail					

Cost assessment					Level of Evidence
Interval	Duration	Cost/Unit	Cost per Day	Cost per Course / Month	
hourly	Days	R /	R	R	
hourly	Days	R /	R	R	
hourly	Days	R /	R	R	

I Controlled study with no randomization III Comparative, correlation or case control study

NB The literature review on the reverse side must support this

Current regimen		Cost Assessment			Can Be Replaced by Proposed Drug
Interval	Duration	Cost/Unit	Cost per Day	Cost Per course /month	
hourly	Days	R /	R	R	Yes / No
hourly	Days	R /	R	R	Yes / No
hourly	Days	R /	R	R	Yes / No

/ Request for more evidence / /

Drug Standard Therapeutic Guideline New/Change Prescriber level

