Constrained benefits!

Issue 10 of 2014

Human Immunodeficiency Virus (HIV) is a PMB condition. All medical schemes are required by law to pay for the diagnosis, treatment and care costs of the condition in full. This includes HIV voluntary counselling and testing, Co-trimoxazole as preventative therapy, screening and preventative therapy for TB, diagnosis and treatment of sexually transmitted infections, pain management in palliative care, treatment of opportunistic infections, prevention of mother-to-child transmission of HIV\*, post-exposure prophylaxis following occupational exposure or sexual assault, medical management and medication, including the provision of anti-retroviral therapy, and ongoing monitoring for medicine effectiveness and safety, to the extent provided for in the national guidelines applicable in the public sector.

# **Background on HIV**

Council

for Medical Schemes

The total number of persons living with HIV in South Africa increased from an estimated 4 million in 2002 to over 5 million in 2013. This means that an estimated 10% of the total population was HIV positive in 2013. For adults (non-paediatrics), aged 15–49 years, approximately 15, 9% of this population is HIV positive.

Antiretroviral Therapy (ART) has, however, converted HIV infections from an almost universally fatal illness to a chronic manageable disease. South Africa currently has a National Strategic Plan aimed at zero new HIV and Tuberculosis (TB) infections; zero new infections due to vertical transmission; zero preventable deaths associated with HIV and TB and zero discrimination associated with HIV and TB.

# **Types of HIV**

There are two types of HIV. HIV 1 is most common in sub-Saharan Africa and throughout the world and HIV 2 is mainly often found in West Central Africa, parts of Europe and India. HIV2 causes a more slowly progressive disease than HIV 1.

# How is HIV Transmitted?

HIV is transmitted through unprotected sexual contact with an infected partner, exposure of broken skin or wound to infected blood or body fluids, transfusion with HIV-infected blood, injection with contaminated objects and mother to child during pregnancy, birth or breastfeeding.

# **Prevention**

- Abstinence is the only 100 % effective method of not acquiring HIV
- Keeping relationships monogamous by having only one sex partner
- Having protected sexual intercourse by using condoms (female or male) every time during sexual intercourse
- Using sterile needles

# Stages of HIV infection according to World Health Organisation

Stage 1 - Patients are asymptomatic or have persistent generalised swollen lymph nodes (lymphadenopathy for longer than 6 months).

Stage 2 - Patients may have mild symptoms, some may experience unexplained weight loss and recurrent respiratory tract infections such as sinusitis, bronchitis, middle ear infections and pharyngitis.

Stage 3 - As the disease progresses, additional clinical signs may appear such as unexplained diarrhoea, pulmonary (lung) tuberculosis, and severe bacterial infections such as pneumonia, meningitis, bone and joint infections. Stage 4 – This stage is characterised by opportunistic infections, opportunistic cancers, recurrent pneumonias, severe weight loss, meningitis, memory loss.

\*Please note that this Script does not cover Prevention of Mother to Child Transmission of HIV (PMTCT), HIV management in newborns and children

## How is HIV diagnosed?

Pre- and post-test counselling should be provided to patients before any testing can be done. HIV screening tests can be done in the providers' rooms using rapid test kit to diagnose HIV. Blood taken from a finger prick or oral mucous can be used for testing. Results are often available within 20 to 30 minutes. If the test results are positive, another rapid test may be done to confirm the diagnosis. When the initial and the confirmatory test are discordant, the provider needs to send blood to the laboratory for Enzyme Linked Immonosorbent Assay (Elisa).

Alternatively a blood test can be done at the laboratory. When the test is positive the laboratory will do an HIV confirmatory test. The most commonly used blood test is Elisa. Once the blood result is positive, a second test may be done to confirm the result.

# Benefits of knowing HIV status

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Knowing your status gives you the ability to plan properly for the future. Important decisions such as having children, protecting yourself and others by using condoms, accessing healthcare, and getting support for treatment to prevent opportunistic infections like (TB) makes knowing your status necessary.

Patients with a CD4 count above 350 not yet eligible for ART require referral to a wellness programme for regular follow up. This programme performs CD4 count testing twice a year, offers the patient advice on how to avoid HIV transmission to sexual partners and children, and undertakes counselling on nutrition and contraception. Furthermore, initiation of Isoniazid (INH) prophylaxis may be done if the patient is asymptomatic for TB, while an annual pap smear may be done in females.

## Treatment

Standard antiretroviral (ARV) therapy consists of the use of at least three ARV drugs to maximally suppress HIV and stop the progression of the HIV disease.

Antiretroviral (ARV) Drugs commonly used are:

- Nucleoside Reverse Transcriptase (NRTI) inhibitors such as AZT (Zidovudine) and Lamivudine (3TC)
- Non-Nucleoside Transcriptase (NNRTI) inhibitors like Nevirapine (NVP) and Efavirenz (EFV)
- Protease Inhibitors (PI) such as Lopinavir/Ritonavir (LPV/r)

Eligible to Start ART	Require ART initiation within 7 days of being eligible
CD4 count <350 cells/mm3 irrespective of WHO clinical stage	HIV positive women who are pregnant or breast feeding
Irrespective of CD4 count o All types of TB (In patients with TB/HIV drug resistant or sensitive TB, including extra pulmonary TB) o HIV positive women who are pregnant or breast feeding Or Patients with Cryptococcus meningitis or TB meningitis (defer ART for 4-6 weeks)	Patients with low CD4 <200
WHO stage 3 or 4 irrespective of CD4 count	Patients with Stage 4, irrespective of CD4 count
	Patients with TB/HIV co morbidity with CD4 count < 50

# Standardised national eligibility criteria for starting ART regimens for adults and adolescents

	First Line							
All new patients needing treatment, including pregnant women	Tenofovir + Lamivudine /Emtricitibine + Nevirapine /Efavirenz	For TB co-infection Efavirenz is preferred. For pregnant women or women of child bearing age, not on						
		reliable contraception, NVP is preferred. Replace Efavirenz with Nevirapine in patients with significant psychiatric co-morbidity.						
Currently on Stavudine (d4T) -based	Stavudine + Lamivudine +	Remain on Stavudine if well						
regimen with no side-effects	Nevirapine/Efavirenz	tolerated. Switch to Tenofovir if at high risk of toxicity (high BMI, pregnant)						
Contraindication to	Zidovudine + Lamivudine +							
Tenofovir such as renal disease	Nevirapine/Efavirenz							
	Second Line							
Failing on a Stavudine or	Tenofovir + Lamivudine	Virological failure must be followed by						
Zidovudine based 1st line	/Emtricitibine + Lopinavir/ Ritonavir	intensive adherence management, as						
liegimen		reneat VL remains >1000 in 3 months						
		despite adherence intervention.						
		switch.						
Failing on a Tenofovir based	Zidovudine + Lamivudine +	Virological failure must be followed by						
1st line regimen	Lopinavir/ Ritonavir	intensive adherence management, as						
		re-suppression is often possible. If						
		repeat VL remains >1000 in 3 months						
		switch.						
Dyslinidaemia or diarrhoea	Switch Lopinavir/ Ritonavir to							
associated with Lopinavir/ Ritonavir	Atazanavir/Ritonavir							
Third line or Salvage Therapy								
Failing any 2nd line	Specialist referral	Virological failure on protease						
regimen		inhibitors is almost always due to						
		non-adherence. Intensively exploring						
		and addressing issues relating to						
		rauses of non-adherence will most often lead to						
		re-suppression. If VL remains high						
		refer where possible, but maintain on						
		failing regimen.						

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Patients that develop TB while using ART should continue taking their antiretrovirals together with the TB treatment. Those on Lopinavir/Ritonavir should have their dose doubled slowly over two weeks; other medications can be continued unchanged. Treatment changes with Lopinavir/ Ritonavir to be continued until two weeks after completion of TB treatment.

## **Cotrimoxazole Prophylaxis**

Patients with a CD4 count of 200 or those on stage 2, 3 or 4 HIV diseases (including TB) need Cotrimoxazole prophylaxis. Dapsone is given to patients who have had a reaction to Cotrimoxazole.

#### **Immunizations**

Influenza vaccine is recommended annually prior to the influenza season for all HIV patients.

## Substituting ART

There are times when treatment needs to be changed. This can happen when a patient experiences symptoms of drug toxicity due to immune recovery especially after initiation of ART. This however usually resolves spontaneously. Replacing the medicine causing side- effects may be all that is needed to clear the drug toxicity.

There are also instances when treatment needs to be switched due to virological failure. Virological failure is considered when the viral load is more than 1000 copies/ml on two occasions despite intensive adherence counselling. Virological failure is almost always related to poor adherence, often due to poor attention by the clinician to drug toxicity, or where social factors have not been addressed.

#### Issues which impact adherence to treatment

Personal, and/or environmental issues may hamper adherence to treatment. Personal issues can be internalised stigma, external discrimination, denial of diagnosis, unresolved grief reaction, lack of disclosure, guilt, alcohol and other substance abuse/addiction, mental illness and dementia.

Environmental issues relate to pill burden and side-effects of medication, income and food insecurity – underlying starvation, negative staff attitudes, lack of training of staff; perceived lack of caring by health facility and staff, shift work; time off work to attend appointments.

## Ways to promote adherence

Patients need support from their medical team to adhere at all points of intervention including discussing a treatment plan that the patient can understand and commit to. Information needs to be given to patients about undesirable drug-drug interactions than can be caused by the use of herbs and other medications including over the counter preparations. These drug-drug interactions may lead to kidney and liver toxicity, and may even weaken the effect of antiretroviral drugs.

Additionally, missed appointments for medicine collection are a powerful predictor of poor adherence, and should trigger immediate questions about issues that may affect attendance and adherence.

Attendance and participation in a support group and having a treatment buddy can be beneficial. Regarding employment, patients should be encouraged to return to the job market as soon as it is possible, or to seek support. Employer support is also crucial for medical check-ups and monthly medication pick-ups.

## **Nutrition**



#### Follow-up blood tests

Blood tests such as CD4 count and Viral Load will be monitored once treatment is started. Other blood tests such as Full Blood Count (FBC) or Haemoglobin, Creatinine and Alanine transaminase (ALT) may need monitoring depending on the treatment the patient takes.

#### Resistance testing

Resistance testing is recommended for all patients failing first-line NNRTI-based ARV regimens, with failure described as two VL measurements >1 000 RNA copies/ ml. with adherence and other issues addressed.

Resistance tests help to provide a fully sensitive pattern that may mean that the patient is not adhering to treatment; and also show the presence of resistance mutations so that the clinician, if possible together with an expert, can decide on the most appropriate second-line regimen. Resistance testing is also suggested for all patients failing second line PI-based ARV regimen.

# 1. genotype

Genotype tests look to see how the structure of a sample of your HIV may have changed.



# 2. phenotype

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Phenotyp	)e				
tests see					
whether					
HIV drugs	s				
still work	to	1			
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type of H	IV.		de la compañía de la	dava	
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		niv		10 cest	

# Post-exposure prophylaxis

PEP is treatment used to prevent HIV infection after exposure to blood or bodily fluids such as semen and vaginal fluids. Exposure may be due to needle stick injuries, sexual assault or rape and unprotected sexual intercourse. Preand post-test counselling should be offered to all exposed persons at any testing facility.

PEP should be administered as soon as possible, that is within 72 hours of the incident. All PEP ARV medication must be administered for a full 28 days. Condom usage for 6 months to protect the partner is very important until the ELISA test is negative. Triple ARV therapy is also used for PEP.

# What is covered by the Prescribed Minimum Benefits (PMBs)?

HIV is a PMB condition. All medical schemes are required by law to pay for the diagnosis, treatment and care costs of the condition in full. The following should therefore be paid according to the PMB regulation:

HIV voluntary counselling and testing, Co-trimoxazole as preventative therapy, Screening and preventative therapy for TB, Diagnosis and treatment of sexually transmitted infections, Pain management in palliative care, Treatment of opportunistic infections, Prevention of mother-to-child transmission of HIV, Post-exposure prophylaxis following occupational exposure or sexual assault, Medical management and medication, including the provision of anti-retroviral therapy, and ongoing monitoring for medicine effectiveness and safety, to the extent provided for in the national guidelines applicable in the public sector.

If you have been exposed to HIV or diagnosed with the condition, it is important to confirm with your medical scheme about the type of tests, consultations and medication covered for the diagnosis. This is important because Medical schemes are allowed to limit the number and types of tests, and consultations that will be covered in a calendar year. The medical scheme is also allowed to have a formulary (list of medications) covered for HIV according to the PMB regulation.

However, should the doctor see the need for additional tests, consultations or medications which your medical

scheme does not normally fund, the doctor will have to write a clinical motivation to your scheme and your scheme must then pay for the requested services.

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The Communications Unit would like to to thank Kate Kgasi for assisting with this edition of CMScript information@medicalschemes.com Hotline: 0861 123 267 Fax: 012 430 7644

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