Covering India's HIV-Positives

- Way Forward?

Dr Dhiraj Goud describes how the guidelines described in the recent Exposure Statement might affect life insurance coverage for PLHAs in the future. He also describes the history, epidemiology, and natural progression of HIV/AIDS in India, and current challenges for the insurers in providing coverage to PLHAs.

Providing Health insurance cover to those living with; and to those vulnerable to the Human Immunodeficiency Virus (HIV) and Acquired Immune Deficiency Syndrome (AIDS), such as health care professionals, is an ongoing challenge for insurers in India.

In February 2012, IRDA, acting on recommendations from various stakeholders including public bodies and Government authorities, has issued an Exposure Draft of proposed regulations for insurance coverage of HIV-infected individuals, whether or not the infection has progressed to AIDS.

The Exposure Draft, issued for comment to all life and non-life insurance companies, recommends the following:

- Insurers to develop and emplace underwriting guidelines for both HIV-infected individuals and Persons Living with HIV/AIDS (PLHA), indicating eligibility criteria for obtaining Health insurance cover.
- The guidelines should take into consideration, at minimum, the following criteria:
  - o Stage of HIV infection (Applicants with Stage 1 and Stage 2 infections should be considered for coverage);
  - o PLHA compliance with prescribed treatment schedules;
  - o P24 antigenemia status (the earliest diagnostic marker for HIV);
  - o CD4 (T-cell) counts and CD4 vs. CD8 cell percentages.
- Guidelines should indicate that depending upon the above criteria, additional premium may be applicable for PLHA and the amount of extra premium that would be applicable.
- Suitable proposal forms to be developed to elicit relevant information.
- Guidelines should also indicate that applicants for insurance who are HIV-negative at the time of application but become HIV-positive while covered under a policy cannot be denied any claim on such grounds, but upon policy renewal, suitable loading can be charged.

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The Exposure Draft also suggested type of products and coverages that could be offered to PLHAs:

- Critical illness products, with HIV/AIDS as one of the covered conditions.
- Riders to existing or newly-developed Health insurance or cash products that would provide a lump-sum benefit, also payable as an annuity for life, to individuals upon HIV diagnosis.
- Death due to AIDS would be a covered insurance event.
- Coverage of HIV/AIDS under group schemes for various segments of the population.

To understand these suggested guidelines, and their implications and challenges, it would benefit to understand the HIV/AIDs pandemic's epidemiology; i.e., how HIV is identified, how it progresses to AIDS, and the current nature of the disease's spread and prevalence throughout India.

HIV's PATH IN INDIA

In 1981, an unusual cluster of cases of opportunistic diseases such as

pneumocystis carinii pneumonia and Kaposi's sarcoma emerged. Since its first emergence in the 1980s, HIV has spread virtually to every country. As per the UNAIDS World AIDS Day report 2011, towards the end of 2010, an estimated 34 million people were living with HIV worldwide, up 17% from 2001. The number of people dying of AIDS-related causes fell to 1.8 million in 2010, down from a peak of 2.2 million in the mid-2000s[15].

India's population is over one billion, around half of whom are sexually active adults. The first AIDS case in this country was detected in 1986. HIV since then has been reported in every Indian state and union territory, and India now has the third largest number of people within its borders living with HIV/AIDS. The Annual Sentinel Surveillance for HIV Infection 2008-09 reported that an estimated 2.39 million people were then living with HIV/AIDS in India – an adult prevalence rate of 0.31% – with 39% of those infected female, and 3.5% children. In India, HIV is concentrated among high-risk groups such as female sex workers, injecting drug users, men who have sex with men (MSM) and transgender individuals. The rate of infection among these populations is about 20 times higher than the general population.

Over the past decade, according to the Surveillance Report, India has seen HIV incidence (new annual HIV infections) decline by more than 50% in the past decade – to 120,000 new infections in 2009 from 270,000 in 2000. Six states with historically high prevalence levels accounted for 39% of the cases, while seven lower-prevalence states accounted for 41%.

AIDS-related mortality in India has declined as well. In 2009, 172,000 people in India were reported to have died from AIDS-related causes[1]. This statistic should not be taken at face value, as many AIDS-related deaths go unreported in India, due to stigma still attached to the disease, and discrimination against those suffering from it. Indeed, HIV-infected patients frequently die without the disease ever having been diagnosed, and their deaths are attributed to one of HIV's many opportunistic infections.

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These reductions are important evidence of the impact of India's 20-year-old National AIDS Control Programme (NACP) and its scaled-up prevention strategies over the years. Over the past two years, however, some low-prevalence states have shown a slight increase in the number of new HIV infections. This underscores the need for the NACP to focus more on these states with low prevalence but high vulnerability.

SYMPTOMS AND SIGNS

In 1983, the cytopathic retrovirus known as HIV was identified. A retrovirus, also known as an RNA virus, is one where the virus invades a host's genome, infects the host's DNA, and thereafter is replicated by the host's DNA. 'Cytopathic' refers to the virus's tendency to cause degeneration or disease in cells.

Many who become infected with HIV may not discover it for a very long time. A variety of reasons exist for this. First, many do not develop any symptoms upon infection. Some do develop a flu-like illness within days to weeks after exposure, with symptoms including fever, headache, tiredness, and enlarged lymph nodes in the neck. These symptoms, however, usually disappear without medical intervention within a few weeks.

Second, the disease's progression can vary widely. Its asymptomatic phase can last anywhere from a few months to more than 10 years. During this phase the virus multiplies actively and destroys CD4 cells, the primary infection fighters among white blood cells. This is a dangerous phase of the disease, as the individual, though asymptomatic, is contagious.

AIDS is the later stage of HIV infection, when the body loses its ability to fight infections. Once an individual's CD4 cell count falls below 200 cells/mm^3, an HIV-infected person is said to have AIDS. Diagnosis generally occurs when the individual begins to experience unusual, opportunistic infections or cancers that show the immune system is comprised.

Infections that occur with AIDS include (but are not limited to):

- Bacterial pneumonia, caused by the *Pneumocystis jirovecii* (formerly called *Pneumocystis carinii*) fungus, which causes coughing, fever, wheezing, and shortness of breath.
- Toxoplasmosis, a systemic infection caused by the parasite *Toxoplasmosis gondii*. In individuals with weakened immune systems, the most common expression has been toxoplasmic encephalitis, with symptoms that can include confusion, fever, headache, blurred vision due to inflammation of the retina, and seizures. (source: http://hivinsite.ucsf.edu/InSite?page=kb-05-04-03#S1X)
- Widespread systemic infection from MAC (mycobacterium avium complex). This can cause fevers, stomach cramps, tiredness, diarrhea, nausea and vomiting, and weight loss. If MAC spreads beyond the intestines, it can also cause bone, brain and skin infections as well as joint pain.
- Yeast infection of the esophagus, which causes pain with swallowing.
- Fungal diseases such as histoplasmosis, which can turn

systemic and cause fever, cough, anemia and other problems, and can be fatal if left untreated.

AIDS can also lead to lymphoma of the brain, which can cause fever and difficulty in thinking; and the soft tissue cancer Kaposi's sarcoma, which causes brown, reddish, or purple spots to develop on the skin or in the mouth.

DIAGNOSIS AND TESTING

HIV is considered today to have two strains, HIV-1 and HIV-2. Worldwide and in India, HIV-1, the more virulent strain, predominates; and is generally the strain people are referring to when they mention HIV. Both HIV-1 and HIV-2 are transmitted among humans through exposure to blood, semen, and vaginal secretions (especially during menstrual cycle, when levels can rise). HIV can also be transmitted via breast milk, with the risk there primarily to infants. (HIV has been found in human tears as well, but at levels too low for transmission.)

HIV-2 infections are primarily concentrated in West Africa, but have been detected (albeit infrequently) in India as well (source: http://en.wikipedia.org/wiki/Subtypes_of_HIV). The possibility of HIV-2 infection is usually suspected in the following persons[14]:

- those from HIV 2-endemic areas (areas where the pandemic has taken hold in a population without external inputs) who are present with AIDS-like illnesses;
- HIV-seropositive patients with no detectable HIV RNA who are experiencing declining immunity despite antiretroviral therapy;
- untreated HIV seropositive patients with low or non-detectable viral loads. (HIV-2 tends to remain asymptomatic, on average, for longer than HIV-1, so virual loads are lower).

Once advanced immunosuppression has occurred in HIV-infected individuals (i.e., their CD4 cell counts fall below 200 cells/mm^3), presentation symptoms for both viral strains are similar, as both are at risk for opportunistic infections.

Diagnosis of HIV occurs in of the four following ways[8]:

- detection of HIV antibodies in blood serum;
- detection of the viral p24 antigen;
- detection of viral nucleic acid (NAT);
- ability to culture HIV from various bodily fluids.

A variety of diagnostic assays are available for HIV infection, which vary in terms of turnaround time, sensitivity and specificity, and specimen handling.

Standard HIV-1 antibody test

Since 1985, the standard screening assay for detecting antibodies to HIV is the enzyme immunoassay (EIA), or ELISA (Enzyme-Linked Immunosorbent Assay) blood test. This test, which detects HIV-specific IgG (immunoglobulin G) antibodies in serum within 6-12 weeks after infection in the majority of patients, typically requires two medical visits: one to provide the blood sample, and the second to receive results. Counseling and referrals are usually provided on the second visit if the test result is positive.

Test results are reported as positive, negative, or indeterminate. A confirmatory Western blot test is performed if the screening test is positive to exclude a false positive test. False positive HIV antibody tests are very rare, and usually represent labeling errors. False negatives are more common, with the most frequent cause in high-risk patients stemming from the assay being conducted during the 'window period' of acute HIV infection prior to seroconversion.

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If the result is indeterminate, the most important step in its evaluation is assessing the patient's risk factors. Low-risk patients should be reassured that HIV infection is unlikely; repeat serologic testing and HIV RNA quantification can provide absolute assurance. In contrast, high-risk patients may be in the process of seroconversion and an HIV RNA test should be performed. Patients with acute HIV infection often have high-level viremia and should be counseled regarding the risk of HIV transmission. Repeat serologic testing and tests to determine the presence of HIV RNA should be done within one month.

Rapid HIV Test (HIV-1 and HIV-2)

The Rapid HIV Test produces high-accuracy results within 5 to 30 minutes, enabling testing, counseling and referrals at the point of care. The test can be performed on venous blood, plasma, or oral fluids, and is the only approved antibody test that can differentiate HIV-1 and HIV-2 infections.

This test is particularly useful for occupational or non-occupational HIV exposures, women in labor who have not been tested for HIV previously, and patients unlikely to return for results.

Positive results from this test must be confirmed with supplemental standard EIA (ELISA) antibody and Western blot tests. If the results are negative, however, there is no need for further immediate testing unless there is clinical suspicion of acute HIV infection. In this case, HIV RNA testing should be performed.

Patients with indeterminate results should be tested again in one to two

months with either rapid or standard serologies.

Combination antibody-antigen testing

Fourth-generation tests simultaneously detect both antibodies and p24 antigens, and perform with high sensitivity and specificity. The advantage of these tests is their ability to detect HIV p24 antigens (the earliest HIV marker) during the window period of acute HIV infection.

Viral detection assays

Other methods to establish HIV infection include viral isolation or qualitative or quantitative detection of HIV antigens alone through polymerase chain reaction techniques, branched-chain DNA testing, or nucleic acid sequence-based amplification. The major limitations of these assays include cost, the requirement for venipuncture, and time interval between sample collection and test results.

Viral detection testing may be useful in specific situations, such as the diagnosis of neonatal HIV infection, in patients with indeterminate serologic tests, or in those who may be in the 'window period' of HIV seroconversion.

CLASSIFICATION

It is useful to understand the natural progression of HIV infection without antiretroviral therapy, and review the classification of disease.

Classification of HIV/AIDS is complex. The classification system for adolescents and adults in use since 1993, developed by the Centers for Disease Control in the U.S., categorizes all HIV-infected individuals, whether HIV-1 or HIV-2, according to CD4 counts and clinical categories of HIV infection.

In this system, AIDS is defined as including all HIV-infected persons with CD4+ cell counts less than 200 cells/mm^3, and as any individual who has ever suffered from an AIDS-indicator condition.

An alternative classification system was developed in 2005 by the World Health Organization (WHO) in collaboration with the Centers for Disease Control (CDC). The system uses four clinical stages, segmented by signs and symptoms. The emphasis is on clinical symptoms to make a presumptive diagnosis if definitive diagnostic testing resources for CD4 counts are not available.

CDC Classification System for HIV Infection and AIDS

Cd4 Cell Count	A Asymptomatic, Acute HIV or PGL (Persistent Generalized Lympha-denopathy)	B Symptomatic (No A or conditions)	C AIDS-Indicator Conditions
>500 cells/mm^3	A1	B1	C1
200-499 cells/mm^3	A2	B2	C2
<200 cells/mml^3	A3	B3	C3

Source: Centers for Disease Control (CDC)

Clinical Categories of HIV Infection

Category	Clinical Criteria - examples include, but are not limited to, the following:
A	Asymptomatic Acute HIV infection Persistent generalized lymphadenopathy (PGL)
B	Candidiasis (oropharyngeal or vaginal) Cervical dysplasia / carcinoma in situ Fever or diarrhea (>1 month) Hairy leukoplakia (oral) Herpes zoster Idiopathic thrombocytopenic purpura Peripheral neuropathy
C	Candidiasis (respiratory or esophageal) Cervical cancer Encephalopathy (HIV-related) Kaposi's sarcoma Lymphoma (Burkitt's or Brain) Pneumocystis carinii pneumonia Toxoplasmosis of brain Tuberculosis Wasting syndrome due to HIV

Source: Centers for Disease Control (CDC)

WHO/CDC Clinical Staging of HIV/AIDS for Adults and Adolescents

Primary HIV Infection
- Asymptomatic
- Acute retroviral syndrome

Clinical Stage 1
- Asymptomatic
- Persistent generalized lymphadenopathy

Clinical Stage 2
- Moderate unexplained weight loss (<10% of presumed or measured body weight)
- Recurrent respiratory infections (sinusitis, tonsillitis, otitis media, and pharyngitis)
- Herpes zoster
- Angular cheilitis
- Recurrent oral ulceration
- Papular pruritic eruptions
- Seborrheic dermatitis
- Fungal nail infections

Clinical Stage 3
- Unexplained severe weight loss (>10% of presumed or measured body weight)
- Unexplained chronic diarrhea for >1 month
- Unexplained persistent fever for >1

month (>37.6°C, intermittent or constant)
Persistent oral candidiasis (thrush)
Oral hairy leukoplakia
Pulmonary tuberculosis (current)
Severe presumed bacterial infections (e.g., pneumonia, empyema, pyomyositis, bone or joint infection, meningitis, bacteremia)
Acute necrotizing ulcerative stomatitis, gingivitis, or periodontitis
Unexplained anemia (hemoglobin <8 g/dL)
Neutropenia (neutrophils <500 cells/μL)
Chronic thrombocytopenia (platelets <50,000 cells/μL)

Clinical Stage 4

HIV wasting syndrome (as defined by the CDC)
Pneumocystis pneumonia
Recurrent severe bacterial pneumonia
Chronic herpes simplex infection (orolabial, genital, or anorectal site for >1 month or visceral herpes at any site)
Esophageal candidiasis (or candidiasis of trachea, bronchi, or lungs)
Extrapulmonary tuberculosis
Kaposi's sarcoma
Cytomegalovirus infection (retinitis or infection of other organs)
Central nervous system toxoplasmosis
HIV encephalopathy
Cryptococcosis, extrapulmonary (including meningitis)
Disseminated nontuberculosis mycobacteria infection
Progressive multifocal leukoencephalopathy
Candida of the trachea, bronchi, or lungs
Chronic cryptosporidiosis (with diarrhea)
Chronic isosporiasis
Disseminated mycosis (e.g., histoplasmosis, coccidioidomycosis, penicilliosis)
Recurrent nontyphoidal Salmonella bacteremia
Lymphoma (cerebral or B-cell non-Hodgkin)
Invasive cervical carcinoma
Atypical disseminated leishmaniasis
Symptomatic HIV-associated nephropathy
Symptomatic HIV-associated cardiomyopathy
Reactivation of American trypanosomiasis (meningoencephalitis or myocarditis)

Sources: World Health Organization (WHO), Centers for Disease Control (CDC)

TRANSMISSION

Analysis of information from approximately 300,000 persons testing HIV-positive at various counselling and testing centres throughout India found that the main mode of HIV transmission has been unprotected heterosexual intercourse. In 2009-10, this transmission mode accounted for 87.4% of all reported HIV cases. Most of the rest of the reported cases (5.4%) were due to transmission from a pregnant infected mother to her fetus. Homosexual sex accounted for 1.3% of cases, injecting drug use (IDU) for 1.6%, and infected blood and blood products for 1.0%.

The risk of HIV transmission is dependent on the following factors5:

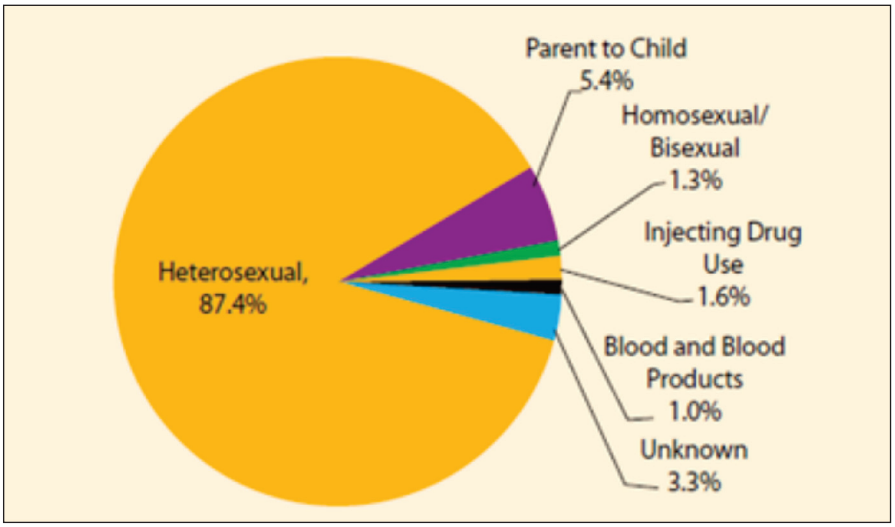
- The amount of HIV virus in the blood.
- Presence of sexually transmitted diseases.
- History of risky sexual practices; e.g. multiple sexual partners of unknown HIV serostatus; unprotected receptive anal sex with a partner (or partners) with unknown HIV serostatus; and/or past or current use of nitrite inhalants.
- Lack of circumcision.

TREATMENT

The introduction of antiretroviral drugs in 1987, and then, in 1996, of Highly Active Anti-Retroviral Therapy (HAART), a treatment characterized by a combination of drugs to fight HIV and its associated opportunistic infections and diseases, has substantially changed the outlook and survival rates for infected individuals.

The long-term EuroSIDA study on HIV/AIDS compared the early HAART treatment period to pre-HAART and later HAART (1998 to 2002) periods, and found a sustained decrease in mortality and of progression to AIDS with ongoing HAART[6]. Although a cure is still to be found, HAART radically changed HIV/AIDS' natural history[7].

Routes of HIV transmission in India (2009-10)



Source: National AIDS Control Organisation (NACO), 2009-10

The critical goals of HAART therapy[9] are:

- Durable suppression of HIV viral load to less than 50 copies/mL
- Restoration of immune function (as indicated by the CD4 cell count)
- Prevention of HIV transmission
- Prevention of drug resistance
- Improvement in quality of life

The typical HAART regimen will have at least three antiretroviral drugs recommended, to boost the immune system and keep the virus from replicating[9].

Antiretroviral viral drugs stop viral replication and delay the development of AIDS and prevent cancers from occurring as well[11]. However, they also have side effects that can be severe, such as decreased red blood cell counts or abnormal lipids[12]. These drugs may also affect the pancreas, liver, kidneys, gastrointestinal tract or even the peripheral nerves[12]. For maximum effectiveness, HAART, once started, must continue as prescribed. Patients must be continuously monitored for the development of any adverse side effects from the drugs.

HAART can also be used during pregnancy and involves two separate but related goals: reduction of perinatal transmission treatment and treatment of maternal HIV disease. However, the HAART drugs could be very harmful to the fetus, so are used with great caution in pregnant women.[13]

Individuals infected with HIV should either be under the care of a physician or enrolled with a medical facility experienced in HIV treatment and patient follow-up. HIV-infected individuals should also be counseled about how to avoid spreading the disease to their partners and/or family members. Infected individuals should also educate themselves about the disease process, and how medical care can help them improve the quality of their life.

With proper treatment and careful adherence to medication regimens,

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average life expectancies for HIV-infected individuals are now in the decades. Medications have been developed that can help a compromised immune system fight infections and recover from them, and prevent cancers from occurring as well. Eventually, however, the virus may become resistant to the available drugs.

ADHERENCE TO ART IN INDIA

As per 'Covering Treatment for HIV and AIDS in India: A Feasibility Study', issued by the United Nations Development Programme (UNDP) in 2006, prices of anti-retroviral drugs (ARVs) has reduced significantly from the time they were first introduced[16]. But considering the fact the therapy is a lifelong multi-drug therapy, cost is always going to be a factor for adherence.

On April 1, 2004, India's government began to provide, free of charge, anti-retroviral therapy (ART) for eligible persons living with HIV who have not yet developed AIDS. The programme was launched in eight government hospitals located in six of India's high-prevalence states. Since then, the programme has scaled up, both in terms of facilities for treatment and number of beneficiaries seeking ART.

NACO is working to establish linkages with other departments and strengthen the public-private partnership by involving the corporate sector and NGOs.

The overall infrastructure scale-up has resulted in reduction in number of Lost to Follow-up (LFU) cases. According to the National AIDS Control Programme (NACP), the cumulative LFU for PLHA on ART in 2009 was just under 7%, and by 2011, had dropped to 6%[1].

To receive free ART, the patient must be registered with one of these government centres. However, given privacy concerns, especially in light of the taboo still associated with HIV/AIDS, a cohort of patients may not be willing to register with these centres, preferring instead to access treatment at their own cost or via other financing schemes, such as NGOs and other institutional or workplace health care facilities. For those wishing alternatives due to privacy concerns, can and will insurance companies preserve the confidentiality of infected applicants, or policyholders who later become infected with HIV? And, will insurance companies be able to monitor the adherence to the treatment which is a crucial component of any HIV insurance?

INTERNATIONAL PERSPECTIVE

In some other countries, insurance cover is available to HIV-positive individuals, but with many caveats. In Australia, New Zealand, Hong Kong, the United States, and certain European countries, for example, critical illness policies may be offered to individuals who have medically or occupationally acquired HIV. These individuals may also be offered non-renewable, limited term life products which are based on strict underwriting and adherence guidelines.

In South Africa, which has high HIV prevalence rates for both adults and children, HIV is a policy exclusion. All of the major South African insurance companies with fully underwritten products (90% of the market) require every applicant for individual risk cover to test for HIV. Applicants who test positive will not be offered any mainstream products. Many insurers, however, will provide cover for HIV acquired due to medical or occupational hazards, with stringent requirements to access such benefits.

The HIV market has also been targeted by smaller South African insurance companies, which sell products designed for HIV-positive individuals that cover life, disability, critical illness, funeral, and hospital cash. Medical reimbursement coverage is rarely offered in South Africa to HIV-positive individuals. Certain simplified-underwritten products in South Africa that target low-income individuals and are distributed through direct channels such as telesales do not require an HIV test and are priced accordingly. These products tend to be more expensive, but do provide cover for HIV-infected individuals.

A key requirement in South African policies for HIV-positive applicants is the commitment to adherence. So providing coverage for accidental HIV to the insurance company's satisfaction is another issue that needs to be managed.

Most insurers' 'Adherence Statements' require the insured, depending on his/her status of antiretroviral therapy (ART), to commit to taking various blood tests, such as CD4+ test and RNA Viral load test, every few months. If test results are found to be abnormal, then corrective measures are recommended which would have to be implemented within a specified period of time.

Failure to take appropriate action will result in the insured being designated non-adherent. In addition, if no blood test is conducted within the stipulated period, then the insured again can be deemed to be non-adherent. If the insured is designated as non-adherent, payout benefits will be automatically reduced to a certain percentage of the initial sum assured.

An example of an adherence requirement for a South African insurer follows below:

Definition of Adherence

For clients not enrolled on antiretroviral therapy (ART), the life insured must commit to taking a CD4+ blood test at least once every few months as defined by the insurance company which is usually six months, and to provide a copy of these results. Should the insured register a CD4+ count of below 200 cells/mm^3 in any CD4+ test, they further commit to start appropriate ART within 60 days and to follow this treatment as prescribed.

For clients enrolled on antiretroviral therapy (ART), or for clients who enroll on ART subsequent to inception of their policy, the life insured commits to taking both a CD4+ count and RNA Viral Load tests at least once every 6 months, and to provide a copy of these results to the Company.

Where an individual enrolled on ART registers two consecutive blood tests showing a reduction in CD4+ count, or a Viral Load above 1000 copies/ml in any single test, the Company will issue an adherence warning to the client, and request that the life insured takes the necessary steps to remain adherent.

Policyholders must commit to take scheduled CD4+ blood tests (as defined by the company) and to initiate antiretroviral therapy as prescribed by their healthcare practitioner and/or managed healthcare company immediately on registering a CD4+ result of below 200 cells/mm3.

Once on ART, adherence means taking the ART drugs daily as per the prescribed regimen. The blood test results need to confirm that the insured is taking the drugs as per the prescribed schedule. Once enrolled on ART, adverse test results may indicate that treatment is not working. This may be due to non-compliance with the prescribed regime, or because the insured has become resistant to the prescribed ART regime. If the insured is not taking the medication correctly then he or she will need to take appropriate steps to rectify the situation, or he/she may be classified as non-adherent. Should he/she become resistant to the prescribed ART regime he/she may need to change the ART regimen within 6 months. Failure to take appropriate action will result in the insured being designated non-adherent.

In addition, if no blood test is conducted within the stipulated period (every 6 months), then the insured again can be deemed to be non-adherent. If the insured is designated as non-adherent then payout benefits will be automatically reduced to a certain percentage of the initial sum assured.

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COVERAGE ISSUES TO CONSIDER

A key decision to be made when designing insurance coverage for PLHAs, or those vulnerable to HIV/AIDS is deciding what types of coverage to offer. Should only ART and tests also be covered, or should expenses for opportunistic infections be included or even other primary healthcare services? On one hand, the more general the scheme, the greater its ability to cater to a larger segment of the population. On the other hand, making the scheme too broad may make it operationally difficult for insurers, and insufficient in meeting the demands of those who need this cover the most.

If a product specific for HIV-positive individuals is to be offered, with conditions of adherence of treatment and monitoring similar to those in South Africa, the question remains whether it will be possible to implement these in India. Can the applicants be monitored for adherence? Will enough individuals qualify for these products to make them viable? Should coverage be offered only to individuals who contract HIV by accident, and how should companies ascertain,

beyond reasonable doubt, that infection was contracted accidentally?

A range of critical coverage issues for PLHAs and those vulnerable to HIV/AIDS will have to be addressed, such as:

- Should policies be designed only for HIV-positive individuals or for the population as a whole, with the ability to cover anyone who later becomes HIV-positive?
- Should there be one general scheme or two schemes: one for individuals who are not HIV-positive at inception and one for those who are already HIV-positive?
- Should existing health plans be amended to incorporate cover for PLHAs and related treatments or should new schemes be devised?
- If a covered individual contracts HIV, should he/she be allowed to continue on the same policy, or should he/she be asked to move to a different product designed specifically for HIV-positives? In such an occurrence, would portability guidelines be applicable?

The Exposure Draft states that insurers shall not reject or deny a claim for a person who was HIV-negative at the outset of the policy but subsequently becomes HIV-positive. The majority of Health insurance products currently available in India exclude coverage for hospitalisations in presence of AIDS and illnesses relating to or caused by HIV. Indirectly, this means that all such exclusions will need to be removed from the existing products. However, this could mean payment of many more claims, which could make the product far more expensive for the general public.

Whether HIV is to be excluded, or if two set of products are to be offered by an insurer, how should the issue of non-disclosure be dealt with? Screening all health cover applicants for HIV status, might increase acquisition cost and time, even for small covers.

Finally, what should be the term of a product covering HIV/AIDS? The Exposure Draft suggests cover be offered to those at certain stages of HIV, or to those with certain CD4 counts or viral load. It is not clear whether cover should still continue if the infected individual develops full-blown AIDS. These are some of the issues which must be resolved before developing any coverage scheme for PLHAs.

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