

Operational Processing Instruction 2002-004
MEDICAL ASSESSMENT OF HIV POSITIVE APPLICANTS

Background:

Applicants may be divided into two groups:

1. those who are Excessive Demand exempt (EDE), according to section 38(2) of the *Immigration and Refugee Protection Act* (IRPA); and
2. those who are non-Excessive Demand exempt (non-EDE).

EDE applicants who are HIV positive:

- should only be assessed according to public health and public safety health grounds for inadmissibility (IRPA sections 38(1)(a) & (b)).
- should NOT be assessed for excessive demands. Thus, examining physicians or medical officers should NOT request further tests to determine excessive demands, such as CD4 or pVL tests.
- are medically admissible if they meet health admissibility criteria of public health and public safety.

Non-EDE applicants who are HIV positive:

- should be assessed according to public health, public safety, AND excessive demands health grounds for inadmissibility (IRPA sections 38(1)(a)(b) & (c)).

When appropriate, examining physicians or medical officers should request further tests, such as CD4 or pVL tests, to help determine whether an applicant represents excessive demands.

HIV Positive Non-EDE Applicants - Information Relating to Excessive Demands:

Non-EDE applicants identified as being HIV positive should be asked to undergo CD4 testing by the examining physician. If an applicant's CD4 count is less than 350 cells/mm³, antiretroviral therapy (ARV) is required in a Canadian setting and applicant will represent excessive demands. - see Annex A which includes the consultant report "HIV Infection in Applicants for Immigration to Canada". If an applicant has a CD4 count above 500 cells/mm³, he/she should then be asked to undergo pVL testing. [Note: the consultant report refers to pVL testing for applicants with 500 cells/mm³, but this does not take into account what to do for

CD4 counts 350-500.] Those applicants with pVL results over 55,000 copies/mL are not medically admissible, because they meet the current Canadian criteria for ARV treatment. If pVL testing is not available, then a second CD4 test should be obtained approximately two (2) months after the first CD4 test was taken – see #6 below.

Non-EDE applicants who are HIV positive are assessed on an individual basis in order to determine their demand on health and social services if granted entry to Canada. These services are assessed over a five year period unless significant costs are anticipated in the five to ten year period following the immigration medical examination.

Antiretroviral therapy (ARV) costs average \$1000 per month. CD4 counts and viral loads cost \$150 each and are routinely done every three months. Assuming a conservative estimate of four (4) visits annually to a physician, the cost per quarterly visit plus blood work in **stable** patients is approximately \$360 (assuming \$30 MD fee and \$30 lab fee for other tests). The annual cost for ARV treated patients is thus approximately \$13,440 (\$1,120 per month of treatment). This figure does not include any hospitalizations which may occur. See **Annex A** for the paper prepared by the consultant, which includes information on HIV costs. It should be noted that the consultant does not separate HIV positive applicants into EDE and non-EDE cases. Thus, although the paper refers to ALL applicants, the information pertains solely to non-EDE applicants.

1. All non-EDE applicants should be requested to provide a current (and any previously available) CD4 lymphocyte count. Failure to provide this information is sufficient grounds to assess the applicant as medically inadmissible since the vast majority of newly diagnosed HIV individuals will require ARVs within the ten year assessment period.
2. The natural history of untreated HIV infection is characterized by progressive CD4 cell depletion. The rate of CD4 cell decline is determined principally by the pVL.
3. ARVs are initiated in Canada if the CD4 lymphocyte count is below 350 cells/mm³ or if plasma HIV-RNA concentration, commonly known as the plasma viral load or pVL, exceeds 55,000 copies/mL.
4. Any non-EDE applicant currently receiving ARV is inadmissible based on excessive demand on health care services.
5. Most HIV positive non-EDE applicants who have CD4 counts between 350 and 500 cells/mm³ will experience a fall in their CD4 count to below 350 cells/mm³ within the five year or ten year time frames placing an excessive demand on health services.

6. Non-EDE applicants identified as being HIV positive should be asked to undergo CD4 testing by the examining physician. If an applicant's CD4 count is less than 350 cells/mm³, antiretroviral therapy (ARV) is required in a Canadian setting and applicant will represent excessive demands - see Annex A which includes the consultant report "HIV Infection in Applicants for Immigration to Canada". If an applicant has a CD4 count above 500 cells/mm³, he/she should then be asked to undergo pVL testing. [Note: the consultant report refers to pVL testing for applicants with 500 cells/mm³, but this does not take into account what to do for CD4 counts 350-500.] Those applicants with pVL results over 55,000 copies/mL are not medically admissible, because they meet the current Canadian criteria for ARV treatment. If pVL testing is not available, then a second CD4 test should be obtained approximately two (2) months after the first CD4 test was taken.
7. Non-EDE applicants with CD4 counts above 500 cells/mm³ and pVLs below 55,000 copies/mL will be few in number, and will generally be admissible if all other health factors are unremarkable.

Summary:

EDE applicants who are HIV positive:

- should be assessed only for public health and public safety, NOT excessive demands.
- are medically admissible if they meet admissibility criteria for public health and public safety.

Non-EDE applicants who are HIV positive:

- should be assessed according to public health, public safety, AND excessive demands health grounds for inadmissibility (IRPA sections 38(1)(a)(b) & (c)).

Table 1 below includes information useful in determining whether a non-EDE applicant who is HIV positive is likely to represent an excessive demand on health or social services.

Table 1

HIV Positive Non-EDE Applicants	
Medically Admissible (assuming public health and public safety criteria are met)	Medically Inadmissible (based on Excessive Demand for health and/or social services)
<ul style="list-style-type: none"> • Non-EDE applicants with CD4 counts above 500 cells/mm³ and pVLs below 55,000 copies/mL will generally be medically admissible if all other health factors are unremarkable. 	<ul style="list-style-type: none"> • A non-EDE applicant who does not provide CD4 lymphocyte count information. <p>Failure to provide this information is sufficient grounds to assess a non-EDE applicant as medically inadmissible since the vast majority of newly diagnosed HIV individuals will require antiretroviral therapy (ARV) within the ten year assessment period.</p>
	<ul style="list-style-type: none"> • Any non-EDE applicant currently receiving ARV.
	<ul style="list-style-type: none"> • Any non-EDE applicant with a CD4 lymphocyte count below 350 cells/mm³, as meets in Canada standard for receiving ARV.
	<ul style="list-style-type: none"> • Any non-EDE applicant with pVL exceeding 55,000 copies/mL, as meets in Canada standard for receiving ARV.
	<ul style="list-style-type: none"> • Most non-EDE HIV-infected persons with CD4 counts between 350 and 500 cells/mm³ will experience a fall in their CD4 count to below 350 cells/mm³ within the five year or ten year time frames placing an excessive demand on health services.

Note: The consultant in the report below does not separate HIV positive applicants into EDE and non-EDE cases. Thus, although the paper refers to ALL applicants, the information pertains solely to non-EDE applicants.

HIV Infection in Applicants for Immigration to Canada

Background

1. CIC has implemented mandatory HIV serologic testing effective January 15, 2002 for all individuals aged 15 years and older applying to immigrate to Canada.
2. Prospective immigrants to Canada can be excluded on medical grounds for 3 reasons: risk to public health, risk to public safety, or excess demand on Canadian healthcare services. Presently, “excess demand” is usually defined as exceeding \$15,000 of publicly funded health care costs over the next 5 years, but the assessment time can be extended to 10 years (and costs to \$30,000), if relevant to the medical condition.
3. HIV infection is not considered a reason for non-admittance on grounds of risk to public health, because its transmission requires specific voluntary behaviours, principally sexual activity and sharing of injection drug using materials.
4. HIV infection could only be considered a risk to public safety under the unusual circumstance in which an HIV-infected person were a sexual offender.
5. HIV infection will frequently meet the CIC definition of excess demand, due principally to the high cost of drug therapy (see below). The costs of antiviral therapy are borne entirely by some provinces and territories, and in some provinces and territories, the patient pays a small proportion thereof.

Management and Costs of HIV Infection in Canada

HIV-infected persons typically require quarterly medical appointments when they are doing well medically, with more frequent visits (and occasional hospitalizations) when they are experiencing problems.

At these quarterly visits, bloodwork is required, including both CD4 lymphocyte and plasma HIV-RNA (viral load) quantifications, usually with additional blood biochemistry. The CD4 and plasma HIV-RNA quantifications each cost about \$150. Hence, the cost per quarterly visit plus blood work in **stable** patients is approximately \$360 (assuming \$30 MD fee and \$30 lab fee for other tests). These costs are all borne by the provinces/territories. This does NOT include x-rays and serologic tests for potential co-infections, such as hepatitis B and C, which are routinely done, or the additional medical costs borne by those co-infected with either of those hepatitis viruses.

If the HIV-infected person requires antiretroviral (ARV) therapy, the costs of care increase markedly. Modern ARV therapy requires 3 drugs in most patients, and more than 3 in certain patients, particularly those who have failed to respond to prior ARV therapy. The cost for 3 drug containing ARV regimens ranges from a low of \$698.40 per month for the combination of stavudine 40 mg BID plus (non-enteric coated) didanosine 400 mg QD plus delavirdine 400 mg TID to a high of \$1560.60 per month for abacavir 300 mg BID plus lamivudine 150 mg BID plus amprenavir 1200 mg BID. Neither of those regimens are prescribed frequently. The most commonly prescribed 3 drug ARV regimens range from \$849 to \$1116 per month. The costs for ARV regimens used in “salvage therapy” for those who have failed other therapies is even higher. Thus, assuming a cost of \$1000 per month per ARV-treated patient is likely an underestimate of the mean cost per treated patient. When added to the lab and MD visit costs noted above for stable patients (again an underestimate for the “mean” patient), the annual cost for ARV treated patients is \$13,340 or \$1112 per month. An additional plasma viral load test is required about one month after starting a new ARV regimen, but these costs have not been included.

Using the above costs and the usual 5 year window, an HIV-infected person requiring ARV for 8 months will incur \$8896 (8 x \$1112) costs while on ARV and \$6120 while off ARV (17 quarterly visits over 4yr 4mo at \$360 per visit) for a total of \$15,016. Consequently, any HIV-infected adult expected to require a minimum of 8 months of ARV therapy over the ensuing 5 years is ineligible for admission due to the criterion of excess demand.

Using a 10 year time window, an HIV-infected person who is followed off ARV for 8.5 years and treated with ARV therapy for 1.5 years will incur costs of \$12,240 (\$360 x 34 assessments) while off ARV therapy plus \$18,000 (\$1000 x 18) while on ARV therapy for a total cost of \$30,240. Consequently, any HIV-infected adult expected to require a minimum of 18 months of ARV therapy over the ensuing 10 years is ineligible for admission due to the criterion of excess demand.

Recommendations for CIC Medical Officers

It should be noted that a large majority of HIV-infected applicants will meet the criteria of excess demand, but there will be a small proportion which will qualify

for admittance. Any applicant currently receiving ARV is inadmissible based on excess demand.

All other HIV-infected applicants should be requested to provide a current (and any previously available) CD4 lymphocyte count. Failure to provide this information should be sufficient grounds for non-admittance.

The current guidelines for ARV therapy (MMWR May 17,2002; Vol. 51; No.RR-7; www.cdc.gov/mmwr/PDF/rr/rr5107.pdf) indicate that ARVs should be initiated if the CD4 lymphocyte count is below 350 cells/mm³ or if plasma HIV-RNA concentration, commonly known as the viral load or pVL exceeds 55,000 copies/mL. Hence, persons with a CD4 count below 350 cells/mm³ are clearly excluded, as they qualify for immediate ARV therapy. (In the Northern Alberta HIV Program, the median CD4 count of newly recognized HIV-infected patients runs between 300 and 400 cells/mm³).

The natural history of untreated HIV infection is characterized by progressive CD4 cell depletion. The rate of CD4 cell decline is determined principally by the pVL. A significant percentage of HIV-infected persons with CD4 counts over 350 cells/mm³ will experience a decline in CD4 cells to below 350 cells/mm³ within 4years plus 4months, meeting the 5 year criterion for excess demand, and more still will develop a CD4 count below 350 cells/mm³ after 8.5 years, meeting the 10 year criterion for excess demand.

It is reasonable to assume that most HIV-infected persons with CD4 counts between 350 and 500 cells/mm³ will experience a fall in their CD4 count to below 350 cells/mm³ within the 4.33 year or 8.5 year time frames noted above, meeting the criterion of excess demand. Therefore, HIV-infected persons with CD4 lymphocyte counts below 500 cells/mm³ are considered inadmissible due to excess demand.

Applicants with CD4 counts above 500 cells/mm³ should be requested to provide a current (and any previous) pVL result. Those with pVL results over 55,000 copies/mL are not admissible, because they meet the current criteria for ARV treatment.

Applicants with CD4 counts above 500 cells/mm³ **and** pVLs below 55,000 copies/mL will be few in number, and will generally be admissible, although it is suggested that cases in which the applicants have CD4 and pVL values very close to these thresholds be referred for an opinion by IMAB, or a Canadian HIV treatment expert.

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