



FR Doc No: SSA-2007-0082; Notice Feb 28, 2014

Social Security Administration

**Revised Medical Criteria for Evaluating Human Immunodeficiency Virus
(HIV) Infection and for Evaluating Functional Limitations in
Immune System Disorders
Public Comment**



March 24, 2014

Office of Regulations and Reports Clearance
Social Security Administration
107 Altmeyer Building
6401 Security Boulevard
Baltimore, MD 21235-6401
(301) 443-1984

Dear Social Security Administration,

The Community Access National Network (CANN) and the ADAP Advocacy Association (aaa+®) are pleased to submit the following joint statement in response to the solicitation for public comment in the Register Volume 79, Number 38 [FR Doc No: SSA-2007-0082] on the "Revised Medical Criteria for Evaluating HIV Infection and for Evaluating Functional Limitations in Immune System Disorders." Our two organizations work closely with the medical community, patients, pharmaceutical companies, and government.

CANN is a national 501c3 nonprofit organization working to improve access to comprehensive medical services for people living with HIV and Hepatitis C. aaa+® is a national 501c3 nonprofit organization dedicated to promoting and enhancing the AIDS Drug Assistance Programs (ADAPs) and improving access to care for persons living with HIV/AIDS.

To that end, both organizations are committed to focusing on the stability of ADAPs we strive to improve access to timely care and treatment by ensuring that there are adequate resources nationwide to eliminate or prevent waiting lists for services, as well as preventing other cost containment strategies that ultimately result in restricting access to healthcare, services and treatment. A commonality between our organizations is to better engage people living with HIV/AIDS (PLWHA) by providing a platform whereby they can offer their personal experiences, challenges, knowledge, insight and solutions to solving this perpetual problem.

Whereas both of our organizations support the proposed changes, we caution that these changes will need to be monitored moving forward, considering the regional unevenness in the States expanding their Medicaid program under the Affordable Care Act. Ensuring that PLWHA have unrestricted access to supports and services, even those with previously covered AIDS-defining illnesses must remain paramount during the disability qualification process. It is our understanding that the proposed changes are only for the purpose of diagnosing HIV-infection, and not determining disability or severity of disability.

This background informs our response in support of the following changes:



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- Revise and expand the introductory text for evaluating HIV infection for both adults (section 14.00) and children (section 114.00)
- Revise the introductory text for evaluating functional limitations resulting from immune system disorders for adults (section 14.00)
- Remove current HIV infection listing sections 14.08A-J for adults
- Add HIV infection listing sections 14.11A-H for adults
- Re-designate and revise current HIV infection listing section 14.08K for adults as proposed listing section 14.11
- Remove current HIV infection listing section 114.08A-K for children
- Add HIV infection listing section 114.11A-H for children.

Revise and expand the introductory text for evaluating HIV infection for both adults (section 14.00) and children (section 114.00)

Adults

We agree with the proposed changes for this section to change the introductory text to explain that, *"...people with HIV infection have an increased susceptibility to 'common infections' as well as to the conditions that we describe in our HIV infection listings."* Further, we fully accept the revisions in this section to reflect the current medical knowledge and clinical practices for a definitive positive laboratory test in order to classify a patient as HIV positive. We also support the revisions of sections 14.003b (i) - 14.003e, which provides information and clarifies acceptable documentation of various illnesses associated with HIV infection.

We agree with the proposed revision to *"...remove the guidance on HIV infection manifestations specific to women in current section 14.00F4."* We believe that the agency is correct in its reasons to do so as the criteria for HIV infection manifestation is not gender specific. In addition, we agree with the addition of information in section 1400.F4 explaining that there would be a need for *"...one measurement of the absolute CD4 count to evaluate HIV infection under the proposed listing."*

The revision to section 14.00F6, with regard to evaluating the need for hospitalization, is also supported. We feel that these amendments will eliminate redundancy, add valuable information for the medical community and adjudicators, and streamline the text. Additionally, with the advent of new medical



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technologies, there are now more accurate ways to evaluate the disease state (i.e., viral load levels). We also believe that it is worth monitoring how this proposed change could impact individuals co-infected with HIV and Hepatitis C (HCV), especially considering the potential challenges that could arise from trying to treat both of these diseases.

Children

We agree that the same basic rules apply to adults and children with regard to the changes proposed for the introductory text for evaluating HIV infection. Therefore, we support the proposed revisions to section 114.00 just as we do for section 14.00.

Revise the introductory text for evaluating functional limitations resulting from immune system disorders for adults (section 14.00)

We support the revisions to section 14.00I. Specifically we agree that there should be clarification with regard to where the word “marked” fell on a scale use by adjudicators. This would eliminate redundancy in the text. This change needs to be constructed in a manner that facilitates a better process to determine the “severity” of the disability.

Remove current HIV infection listing sections 14.08A-J for adults

CANN and the AAP Advocacy Association also support removing the current HIV infection listings from section 14.08A-J. We agree with the findings and recommendations from the IOM report. These being, that some of the current listings of HIV infection (14.08A, B, C, D, F, and J) be removed as recent advances in HIV treatment have shown them to no longer fit the criteria of listing-level impairment.

We also agree with the IOM report that to “...*evaluate malignant neoplastic diseases associated with HIV infection, other than primary central nervous system lymphoma, primary effusion lymphoma, and pulmonary Kaposi sarcoma, under the malignant neoplastic diseases listings in 13.00.*” It is for this reason that we believe section 14.08E be removed.

We support the agency’s decision to evaluate HIV encephalopathy under section 12.02 and eliminate it from section 14.08G. Further, we agree with the IOM report’s finding that, “...*it is uncommon that these manifestations (wasting syndrome and diarrhea) alone are predictive of disability, but they may be persistent and result in a marked level of limitation(s) in activities of daily living, maintaining social functioning, or completing tasks in a timely manner due to deficiencies in concentration, persistence, or pace.*” It is for this reason that we support removing them from sections 14.08H and 14.08I as they are already covered under the criteria in section 14.08K.



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Add HIV infection listing sections 14.11A-H for adults

We support the additions of HIV infection listings for sections 14.11A-E: A) Multicentric Castleman disease B) Primary central nervous system lymphoma C) Primary effusion lymphoma D) Progressive multifocal leukoencephalopathy E) Pulmonary Kaposi sarcoma. These are disorders often associated with HIV infection and we agree with the agency's findings that they are aggressive enough in nature to be classified as listing-level impairment.

We support the proposed addition of listing 14.11F for "*Absolute CD4 Count of 50 cells/mm³ or Less.*" CD4 count is a predictor of HIV progression, morbidity, and mortality, which meets the criteria for a listing-level impairment.

We further support the addition of listing 14.11G, "*Absolute CD4 Count of Less Than 200 Cells/mm³, or CD4 Percentage of Less Than 14 Percent.*" Either of these combinations of values is symptomatic of a loss of function that is severe enough to meet the criteria for a listing-level of impairment.

We also support the agency's proposal to add the listing 14.11H, "*Complication(s) of HIV Infection Requiring at Least Three Hospitalizations.*" We agree with the agency's findings that this is indicative of a condition serious enough to qualify as a listing-level impairment.

Re-designate and revise current HIV infection listing section 14.08K for adults as proposed listing section 14.11

We support the agency's proposal to re-designate and revise section 14.08K as 14.11. This will reflect the changes made in 14.08A with respect to Multicentric Castleman disease and expand the criteria for evaluations of manifestations of that listing. Further, we agree that the agency should revise "*cognitive or other mental limitation*" used in current listing 14.08K to "*neurocognitive limitation (including dementia not meeting the criteria in 12.02).*" We concur with the agency's findings that this revision is necessary as it "*is a better description of the limitation associated with HIV infection.*"

Remove current HIV infection listing section 114.08A-K for children

We support the proposal to remove listings 114.08A-K for children as their removal is based on the same criteria as the decision to remove 14.08A-J for adults. This proposal is based on recommendations by the IOM report and we agree with these findings with respect to children and adults. We further agree that the re-designation and revision of section 114.08K be made for children for the same reasons that 14.08K is made for adults. It is because "*the same basic rules for evaluating immune system disorders in adults also apply to children,*" that we support this change.



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Specifically, we agree with the findings by the IOM report that there should be a reclassification of listing 114.08H, with it now being evaluated under listing 100.00 or 105.0. We also agree with the re-designation and revision of section 114.08G, reclassifying it under section 114.11H. Also, we agree with the reclassification of section 114.08G3 to section 114.11H2 and section 114.08G2 to section 114.11H3. We believe that these revisions will eliminate redundancy in the text as well as provide clarification and greater information for adjudicators.

Add HIV infection listing section 114.11A-H for children

For the same reasons we support the removal of sections 114.08A-K, we also support the addition of sections 114.11A-H. The same criteria are used for evaluating adults and children.

Specifically, we support the addition of listing 114.11F, "*Absolute CD4 Count or CD4 Percentage.*" Although CD4 counts are similar in adults and children, we agree with the agency's findings that this listing be added to specifically address the fluctuation in CD4 counts in children younger than age 5. Further, we support the addition of section 114.11H, "*A Neurological Manifestation of HIV Infection.*" The added language of "documentation" and "developmental milestones" will help clarify and inform adjudicators.

We appreciate the thorough review by the Social Security Administration in this matter. Specifically, we applaud the holistic approach of including feedback from the public, the medical community, and the other stakeholders involved in this debate. Further, we are pleased that the Social Security Administration has made a commitment to continue to review these rules for evaluative criteria as we make medical advances in HIV.

Thank you for consideration of these comments above,

Respectfully,

William E. Arnold
President & CEO
Community Access National Network
1724 Florida Avenue, NW
Washington, DC 20009

Brandon M. Macsata
CEO
ADAP Advocacy Association
PO Box 15275
Washington, DC 20003