4191-02U

SOCIAL SECURITY ADMINISTRATION

20 CFR Part 404

[Docket No. SSA-2007-0082]

RIN 0960-AG71

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

AGENCY: Social Security Administration.

ACTION: Final rule.

SUMMARY: We are revising the criteria in the Listing of Impairments (listings) that we use to evaluate claims involving human immunodeficiency virus (HIV) infection in adults and children under titles II and XVI of the Social Security Act (Act). We also are revising the introductory text of the listings that we use to evaluate functional limitations resulting from immune system disorders. The revisions reflect our program experience, advances in medical knowledge, our adjudicative experience, recommendations from a commissioned report, and comments from medical experts and the public.

DATES: These rules are effective January 17, 2017

FOR FURTHER INFORMATION CONTACT: Cheryl Williams, Office of Disability Policy, Social Security Administration, 6401 Security Boulevard, Baltimore, Maryland 21235-6401, (410) 965-1020. For information on eligibility or filing for benefits, call our

national toll-free number, 1-800-772-1213, or TTY 1-800-325-0778, or visit our Internet site, Social Security Online, at http://www.socialsecurity.gov.

SUPPLEMENTARY INFORMATION:

Background

We are revising and making final the rule for evaluating HIV infection we proposed in a Notice of Proposed Rulemaking (NPRM) published in the Federal Register on February 26, 2014 (79 FR 10730), and a correction to the proposed rule on March 25, 2014 (79 FR 16250). Even though this rule will not go into effect until January 17, 2017, for clarity, we refer to it in this preamble as the "final" rule. We are making several changes in this final rule from the NPRM based upon some of the public comments we received. We are also making minor editorial changes throughout this final rule. We explain these changes below in the "Summary of Public Comments on the NPRM" section of this preamble.

The preamble to the NPRM provided an explanation of the changes from the current rules and our reasons for proposing those changes. To the extent that we are adopting the proposed rule as published, we are not repeating that information here. You can view the NPRM by visiting http://www.regulations.gov and searching for document SSA-2007-0082.

Why are we revising the listings for evaluating HIV infection?

We are revising the listings for evaluating HIV infection to reflect our program experience and advances in medical knowledge since we last revised the listings related to HIV infection, recommendations from a commissioned report,[1] and a number of public comments. We received comments from medical experts and the public at an outreach policy conference, in response to an Advance Notice of Proposed Rulemaking (ANPRM),[2] and in response to the NPRM. Although we published final rules for immune system disorders on March 18, 2008, that included changes to listings 14.08 and 114.08,[3] the criteria in the current HIV infection listings are not substantively different from the criteria in the final rules we published on July 2, 1993.[4] We indicated in the preamble to those rules that we would carefully monitor these listings to ensure that they continue to meet program purposes, and that we would update them if warranted.

Other Information

In the NPRM, we proposed to remove listing 114.08H for evaluating growth disturbance with an involuntary weight loss (or failure to gain weight at an appropriate rate for age) that meets specified criteria. We proposed instead to evaluate this impairment under a growth impairment listing in 100.00 or a digestive system listing in

[1] Institute of Medicine. (2010). HIV and Disability: Updating the Social Security Listings. Washington, DC: The National Academies Press.
[2] 73 FR 14409
[3] 73 FR 14570
[4] 58 FR 36051

105.00. On April 13, 2015, we published a final rule for growth disorders and weight loss in children in 100.00 that retained a listing in 114.00 for growth failure due to HIV immune suppression.[5] We are repeating that listing here for clarity. We have redesignated the listing as 114.11I and the related introductory text as 114.00F7.

Summary of Public Comments on the NPRM

In the NPRM, we provided the public with a 60-day comment period, and we subsequently extended the comment period to May 27, 2014. We received 68 comments from 22 commenters. The commenters included advocacy groups, legal services organizations, State agencies, a national group representing disability examiners in State agencies that make disability determinations for us, medical organizations, and individual members of the public.

We carefully considered all of the comments relevant to this rulemaking. We have condensed and summarized the comments below. We present the commenters' concerns and suggestions, respond to all significant issues that are within the scope of this rule, and provide our reasons for adopting or not adopting the recommendations in our responses below.

We received several comments supporting our proposed changes. We appreciate those comments; however, we did not include them. Other comments were on subjects

[5] 80 FR 19522

not related to the proposed rule. Although we read and considered these comments, we did not summarize or respond to them below because they are outside the scope of this rulemaking.

Documentation

Comment: Several commenters disagreed with our proposal to remove guidance in the current introductory text that instructed our adjudicators how to consider documentation of HIV infection and manifestations of HIV infection that does not include the results of definitive laboratory testing. Two of these commenters urged us to retain language from the introductory text that explains that we will consider documentation of HIV infection and manifestations of HIV infection that is consistent with the prevailing state of medical knowledge and clinical practice. They also noted that one of the examples of a manifestation of HIV infection in 14.11I, lipodystrophy, is generally diagnosed by clinical observations instead of by a laboratory test. Another commenter requested clarification about making a disability determination when we cannot obtain definitive evidence or a persuasive report from a physician of a manifestation of an HIV infection.

Response: We agree with these comments and have retained the current language in the introductory text for non-definitive documentation of HIV infection and manifestations of HIV infection. This guidance is found in 14.00F1c(ii) and 114.00F1c(ii) for documentation of HIV infection, and 14.00F2c(ii) and 114.00F2c(ii) for

manifestations of HIV infection. We have also noted in 14.00F3 and 114.00F3 that, to establish a diagnosis of the disorders that we discuss in the section, we will accept other generally acceptable methods that are consistent with the prevailing state of medical knowledge and clinical practice. Retaining this language provides adjudicators with the information needed to make a disability determination when we cannot obtain either definitive evidence or a persuasive report from a physician of HIV infection or a manifestation of HIV infection.

We have removed the statement "we will not purchase laboratory testing to establish whether you have HIV infection" from listing sections 14.00F1b and 114.00F1b, because it implies that we will never pay for diagnostic laboratory HIV testing. Instead, we have clarified that while we will not pay for diagnostic laboratory HIV testing as standard practice because our rules do not require claimants to have definitive laboratory testing documenting the existence of HIV to qualify for disability, we will purchase laboratory HIV testing under limited circumstances.

Specifically, if the existing evidence is not sufficient for us to make a disability determination decision, and no other acceptable documentation exists, we will purchase the examinations or laboratory tests necessary to make a determination in your claim.. At times, a specific laboratory test may be necessary to make a determination in a claim, such as a CD4 count that helps to predict clinical outcomes for a person living with HIV.

Similarly, we removed the proposed language in 14.00F2b and 114.00F2b, and

that indicated we would not purchase laboratory testing for manifestations of HIV infection. These sections now clarify we will purchase such laboratory tests when they are a necessary part of the disability determination process.

Comment: One commenter asked whether we will use the degree of viremia (the presence of viruses in the blood) for the HIV p24 antigen (p24Ag) test to assess the severity of infection.

Response: We did not make any changes in response to this comment. We cannot use HIV p24Ag to assess the severity of HIV infections because it is an inadequate indicator of immune suppression. In this final rule, we include criteria based on CD4 levels, which is a better measurement of immune suppression. However, we may accept a positive finding on HIV p24Ag testing as documentation of an HIV infection.

Comment: One commenter was concerned that we are making assumptions about individuals and their levels of function based on blood tests and counts.

Response: We have not made any changes in response to this comment. We do not, and will not, require blood tests in order for an HIV-related impairment to satisfy a listing or to find a person with an HIV infection to be disabled. Only listings 14.11F, 14.11G, 114.11F, and 114.11I require a CD4 count to meet the listing. We have set these criteria based on recommendations from experts in the field of HIV infection who believe that it would be appropriate to find people whose CD4 counts meet the requirements are

disabled. However, these listings are not the only way that we may find a person with HIV infection to be disabled. If a person's impairment(s) does not meet or equal the severity of a listing, we may find that he or she is disabled at later steps of the sequential evaluation process.

Comment: One commenter noted that proposed listings 14.11A-E and 114.11A-E rely heavily on information located in the proposed introductory text for proper application and understanding. This commenter recommended we revise these listings to include this guidance. The commenter also provided language for these suggested revisions.

Response: We have adopted the commenter's suggested revisions. We have added the commenter's language to clarify that we only consider multicentric Castleman disease under 14.11A and 114.11A. In addition, we have also incorporated the commenter's suggestion to note that the values required by 14.11G do not have to be measured on the same date. We have also made appropriate conforming changes to the introductory text.

Comment: One commenter opined that our proposed revisions discriminate against the poor, as the criteria include medical tests, such as HIV nucleic acid tests by polymerase chain reaction and examination of cerebral spinal fluid, and hospitalizations that many individuals cannot afford and that we are not willing to purchase. The commenter notes that, "although some of the simpler tests may be available through public health departments and charity clinics, these organizations usually cannot afford to

provide any of the more expensive tests and charity clinics are not…available in many areas." The commenter also requests that we delete the hospitalization criterion from the proposed listings, as we will not pay for hospitalizations.

Response: We did not adopt this comment. The Social Security Act and our regulations require medical evidence to establish a medically determinable impairment. We use medical evidence generally accepted in the medical community and available in medical records to establish and evaluate an impairment. We look at all available evidence about all of the claimant's impairments, not just information about a particular allegation such as HIV infection. We may find a person disabled even if he or she does not have a medical diagnosis for his or her impairments when applying for benefits, as long as we are able to establish a medically determinable severe physical or mental impairment or combination of impairments that meets the duration requirement.

In response to public comments and as discussed above, we have retained the guidance in the introductory text that explains we will accept non-definitive evidence of HIV infection or manifestations of HIV infection. This will allow us to establish HIV infection and manifestations of HIV infection more easily without definitive tests. We will accept a persuasive report from a physician that a positive diagnosis of your HIV infection was confirmed by an appropriate laboratory test(s), such as those described in 14.00F1a. To be persuasive, this report must state that you had the appropriate definitive laboratory test(s) for diagnosing your HIV infection and provide the results. The report must also be consistent with the remaining evidence of record.

We may also document HIV infection by the medical history, clinical and laboratory

findings, and diagnoses indicated in the medical evidence, provided that this documentation is consistent with the rest of the medical evidence and the prevailing state of medical knowledge and clinical practice. For example, we will accept a diagnosis of HIV infection without definitive laboratory evidence of the HIV infection if you have an opportunistic disease that is predictive of a defect in cell-mediated immunity (for example, toxoplasmosis of the brain or Pneumocystis pneumonia (PCP)), and there is no other known cause of diminished resistance to that disease (for example, long-term steroid treatment or lymphoma). In such cases, we will make every reasonable effort to obtain full details of the history, medical findings, and results of testing. In the NPRM, we had proposed to accept only definitive tests as evidence of HIV infection or manifestations of HIV infection. Many of the tests that the commenter specifically named were these definitive tests. Allowing adjudicators to establish HIV infection or manifestations of HIV infection without the requirement of a definitive test result helps to allay concerns about the accessibility of tests that we had proposed to require.

Furthermore, the hospitalization criterion is just one of multiple ways adjudicators can find a person is disabled in the sequential evaluation process.[6] The hospitalization criterion is an advantage to a person who applies for disability benefits because it adds another way we may find him or her disabled at the third step of the sequential evaluation process, but it is not the only way we can find a person with HIV infection to be disabled. If a person with HIV infection meets our requirements for disability, but has not been

[6] See 20 CFR 404.1520 and 416.920 for the sequential evaluation process we use to determine disability for adults and 20 CFR 416.924 for the sequential evaluation process we use to determine disability for children.

hospitalized to the extent required by our listings, we can find that he or she is disabled based on a finding of medical equivalence, by meeting other listings, or at a later step in our adjudication process. These other mechanisms for finding a person is disabled help to account for the variation of claimants' access to medical treatment.

CD4 Counts

Comment: A number of commenters provided suggestions related to our use of CD4 counts versus CD4 percentages in the proposed listings. One commenter requested that we provide a CD4 percentage for 14.00F1 that would be equivalent to an absolute CD4 count of 50 cells/$mm^3$ or less. Two commenters requested that we make changes to proposed 114.11F in order to have greater consistency between the childhood and adult HIV listings. These commenters stated that in the proposed listings, children from birth to the attainment of age 5 may rely on a CD4 percentage of less than 15 percent to establish disability under 114.11F1 or 114.11F2, while children age 5 to the attainment of age 18 may rely only on an absolute CD4 count of 50 cells/$mm^3$ to meet the listing. The commenters stated that they believe that children ages 5 to 18 should be able to use CD4 percentage in order to be consistent with the adult listing.

Response: We will not add a CD4 percentage that is equivalent to an absolute CD4 count of 50 cells/$mm^3$ or less, because there is no precise correlation between the two measurements. With regard to the commenters' concerns about consistency between the adult and childhood listings involving CD4 measurements, we believe that the

commenter may have misread the proposed rule. We note that the criterion based on absolute CD4 measurement alone for adults, like that for children from age 5 to the attainment of age 18, does not include a CD4 percentage. The IOM indicated to us that CD4 levels in children correspond with adult levels by the age of 5 and that absolute CD4 count is generally the preferred metric for these age groups. Therefore, we believe that it is appropriate for the criterion for children in this older age group to mirror that for adults and require this type of measurement.

Furthermore, 14.11G for adults, which was the only current or proposed adult criterion that includes CD4 percentage, requires a CD4 measurement (either absolute count or percentage) in conjunction with either a BMI measurement of less than 18.5 or a hemoglobin measurement of less than 8.0 grams per deciliter. The final rule for evaluating growth disorders and weight loss in children, published April 13, 2015, made changes to the immune system listings, which were not in the NPRM.[7] Under current listing 114.08H for immune suppression and growth failure, we may find a child to be disabled based on a combination of CD4 measurement and growth failure (based on weight-for-length percentiles or body mass index (BMI), depending on age). For children age 5 to the attainment of age 18, the CD4 measurement may be an absolute count or a CD4 percentage. In this final rule, that listing will become 114.11I. Although 14.11G and 114.11I are not analogous (as we do not evaluate adults under listings related to growth impairments), we point this out to show the commenter that there are listings for both adults and children in which we consider CD4 percentages.

[7] 80 FR 19522

Comment: Two commenters disagreed with our proposal to require a single CD4 measurement under proposed listings 14.11F and 14.11G. One commenter remarked that this proposal is different from other listings in which we require two measurements at least 60 days apart and is inconsistent with our durational requirements. The other commenter noted that "[a]dvances achieved with the availability of highly active antiretroviral therapy (HAART) have dramatically changed the prognosis and functional impact of HIV infection." Two commenters expressed concerns about establishing a 12-month period of continuous disability based on one CD4 count alone, and one of the commenters suggested adding another CD4 count, hemoglobin level, or BMI assessment to the listing criteria.

One commenter also suggested that we provide specific guidance in relation to low CD4 counts for claimants who do not have access to medical care. The commenter noted that such claimants would be expected to have a more aggressive clinical course of infection. Three commenters stated that claimants may present for medical care with very low CD4 counts, at which point a diagnosis of HIV infection would be made and treatment initiated. With treatment, the claimant's CD4 count would be expected to rise due to the suppression of HIV infection.

Response: We have not adopted these comments. Anyone who meets the requirements in 14.11F or 14.11G occurring within the period that we are considering in

connection with his or her application or continuing disability review, has an impairment of listing-level severity that will satisfy our duration requirement, whether or not he or she is receiving medical care. Even though a person's absolute CD4 count or percentage, BMI, or hemoglobin may increase with treatment, the person's immune deficiency will continue with an increased risk of morbidity and mortality for a continuous period of at least 12 months, which satisfies our duration requirement.

Comment: One commenter recommended that we explain in the introductory text that adjudicators can use the lowest values within the entire rating period for CD4 count and BMI or hemoglobin levels to evaluate an impairment. The commenter was concerned that adjudicators might misinterpret the listings to mean these findings must occur simultaneously.

Response: We adopted the comment by making changes to 14.00F5 to explain that the CD4 count and claimant BMI or hemoglobin levels evaluated under 14.11G do not have to be measured on the same date.

Comment: One commenter noted that proposed listings 14.11F and 14.11G use the lowest absolute CD4 count or CD4 percent as the basis for allowance. This commenter requested that we clarify the guidance in the proposed introductory text that these measurements "must occur within the period we are considering in connection with [the claimant's] application or continuing disability review."

Response: We did not adopt this comment because it is already considered by our program rules. We are generally required to develop a complete medical history for at least 12 months preceding the month of the date of application. We will remind adjudicators about periods of consideration during our training on the HIV listings..

Comment: One commenter stated that "there are a number of HIV-infected individuals who have [a BMI of less than] 20 and are severely malnourished, but who fall short of the requirements under [proposed] 14.11G." This commenter asked that we "consider adding a listing for [claimants] who have a BMI [greater than] 18.5 and [less than] 19, with a history of a documented current opportunistic infection and an absolute CD4 count of [less than] 200 in the [adjudicative timeframe]."

Response: We did not adopt the comment. The criteria in proposed 14.11G are appropriate for establishing listing-level severity when considering CD4 and BMI or hemoglobin measurements, as these data are highly predictive of an impairment that we consider disabling. We do not believe the findings proposed by the commenter will generally indicate an impairment that is severe enough to prevent an individual from doing any gainful activity. Moreover, we believe that the impact of adopting this comment would be negligible. Nevertheless, we may find that an individual who meets the criteria suggested by the commenter is disabled at steps 4 or 5 of our sequential evaluation process.

Comment: One commenter pointed out that after the publication of our NPRM,

the Centers for Disease Control and Prevention (CDC) published a surveillance case definition that extended CD4 counts and percentages to children as well as adults and adolescents.[8] This updated case definition "determines the stage of HIV infection in children age 6-12 years in the same way as adults and adolescents." Additionally, the commenter stated that staging is primarily based on the CD4 count, which takes precedence over the CD4 percentages; the percentage is considered only if the count is missing. The commenter requested that we make conforming changes to all instances of the listings in which we refer to a CD4 count or percentage. The commenter also wished to note that the CD4 number is the most important measurement and that the CDC made changes for the percentage ranges for immunosuppression in all age groups.

Response: We did not adopt the comment. We use CD4 measurements for a different purpose than the CDC does in their surveillance case definition for HIV infection. The CDC provides surveillance case definitions only for public health surveillance purposes. We have provided CD4 counts in our listings to correspond to a specific level of impairment, which the CDC does not take into account in its surveillance case definitions. However, we have added CD4 counts in the final rule to HIV listings 114.11F1 for children from birth to attainment of age 1 and 114.11F2 for children from age 1 to attainment of age 5.

Comment: One commenter recommended that we "should not depend exclusively

[8] Selik, R.M., Mokotoff, E.D., Branson, B., Owen, S.M., Whitmore, S., & Hall, H.I. (2014). Revised Surveillance Case Definition for HIV Infection – United States, 2014. Morbidity and Mortality Weekly Report (MMWR), 63(RR03), 1-10.

on CD4 count or [our] list of fatal or severely disabling HIV-related conditions" when determining eligibility for benefits." The commenter noted that "some people that live with HIV/[acquired immunodeficiency syndrome] (AIDS) with CD4 counts above 50 are very ill and not able to seek gainful employment," and asked that our "adjudicators take into account all fatal or very debilitating conditions when determining…eligibility for benefits."

Response: Although we agree that we should not depend exclusively on CD4 count in order to determine eligibility for benefits, we did not make any changes to our listings and note that our regulations include criteria reaching beyond the stated value. At step 3 of our five-step disability determination process, we consider whether the claimant's impairment(s) meets (or medically equals) any of the listings. Many listing criteria do not require a specific diagnosis or laboratory level. For example, the criteria in 14.11I allow us to consider all manifestations of HIV infection that result in significant, documented signs and symptoms and marked limitation in function. If we do not find that a claimant is disabled at step 3, we must still consider whether he or she is disabled at steps 4 or 5 of our sequential evaluation process.[9] We always consider all of a person's impairments when determining whether he or she is disabled, not just the impairments that are in our listings.

Complications and Manifestations

[9] We evaluate disability differently for children under the age of 18. If we do not find that the child's impairment(s) meet or medically equal a medical listing at step 3, we will consider whether the impairment(s) functionally equal the listings. Steps 4 and 5 do not apply. 20 CFR 416.924, 416.926a.

Comment: Two commenters recommended that we clarify the difference between complications of HIV infection in proposed listing 14.11H, which is based on multiple hospitalizations, and manifestations of HIV infection in proposed listing 14.11I, which is based on functional limitations. We provide examples of complications of HIV infection in the introductory text at 14.00F6 and examples of manifestations of HIV infection in listing 14.11I itself. These commenters noted that some of the conditions given as examples of complications in 14.00F6 are not provided as examples of manifestations in 14.11I, and considered this to be confusing. One of the commenters believed that "any 'complication' severe enough to result in hospitalization could also be severe enough to cause functional limitations and thus, should be referenced in the list of manifestations in 14.11I."

Response: We agree with the commenters and have revised listing 14.11I so that the list of manifestations includes all examples of complications given in 14.00F6.

Comment: Three commenters suggested that we consider signs or symptoms of HIV infection and adverse effects of HIV treatment instead of solely considering repeated manifestations of HIV infection when considering an impairment under proposed listing 14.11I. One commenter provided specific text for a suggested edit to this proposed listing that reflected consideration of signs and symptoms of HIV infection as well as the adverse effects of HIV treatment. Another commenter noted that, in particular, symptoms of HIV infection that are not the direct result of a manifestation of HIV infection, such as

fatigue, malaise, and pain, would not be considered under 14.11I.

Response: We did not adopt the comments. We require both repeated manifestations of HIV infection as well as a functional impairment in order to satisfy the criteria under 14.11I because both are necessary to reflect a level of impairment that indicates listing-level severity. If we find that a person's impairment does not meet listing 14.11I (or any of our listings), we will continue to apply the remaining steps in our sequential evaluation process to determine whether the person is disabled. In current 14.00G, which we did not propose to change and therefore did not include in the NPRM, we provide instructions on how we consider the effects of treatment, including adverse effects, in evaluating autoimmune disorders, immune deficiency disorders, or HIV infection. In current 14.00J, which we also did not propose to change and therefore did not include in the NPRM, we provide instructions on how we evaluate immune system disorders (including HIV infection) when it does not meet one of the listings. We apply these instructions when a person manifests signs or symptoms of HIV infection that are not specifically named in the HIV listings.

Comment: One commenter was critical of the proposed listings, stating they discriminate in favor of those with only severe manifestations of HIV. The commenter stated that "HIV infection can have a wide variety of manifestations such as diarrhea, fever, headache, thrush, skin rashes, weakness, weight loss, and dementia," and "these problems can be compounded by the coexistence of a wide variety of heart, lung, orthopedic, mental and other disorders." The commenter noted the proposed listings do

not include most of these possible combinations, and felt the proposed listings discriminate against those with combinations of manifestations of HIV infection and other disorders.

Response: We did not make any changes in our final listings in response to these comments because we consider all of a claimant's impairments, related or unrelated to HIV infection, when determining whether a person is disabled.[10] We explain in section 14.00I3 that adjudicators may consider multiple types of manifestations of HIV infection when determining whether a person's impairment meets listing 14.11I. While we do not consider impairments other than manifestations of HIV infection when evaluating whether a claimant's impairment meets listing 14.11I, the listings are only step 3 of our five step disability determination process. The purpose of these listings is to quickly identify impairments that we consider severe enough to prevent a person from doing any gainful activity, without the need to evaluate vocational factors. We may still find a person disabled later in our sequential evaluation process even if we find that his or her impairments do not meet or medically equal a listing.

Comment: One commenter requested that we add language to note that proposed listing 14.11I "does not contain an exhaustive list of conditions that may qualify under step 3 of the sequential evaluation process."

[10] We evaluate disability claims for children from birth to the attainment of age 18 differently. Steps 4 and 5 of the adult sequential evaluation process do not apply. After we consider whether the child's impairment(s) meets or medically equals a listing, we consider whether the child's impairment(s) functionally equal a listing.

Response: We adopted the comment and have added wording to clarify that the examples given in 14.11I are not an exhaustive list.

Comment: A number of commenters noted that HIV infection may also accelerate or interact with impairments in other body systems. One of these commenters stated that our proposed rule "does not account for those individuals whose HIV disease effectively accelerates the onset of conditions such as diabetes, heart disease, or kidney disease." Two commenters asked that we include cardiovascular conditions in the list of manifestations of HIV infection in proposed 14.11I. These commenters cited the report on HIV and disability that we commissioned from the Institute of Medicine (IOM), which states "an increased risk for cardiovascular disease in HIV-infected populations as compared with HIV-negative populations has been well documented."[11] These commenters noted that the IOM report states, "[cardiovascular disease] is also a leading cause of death in those infected with HIV, with an analysis of the Data Collection on Adverse Events of Anti-HIV Drugs Study finding that 11 percent of HIV-positive people die of a cardiovascular condition."[12]

Two other commenters recommended that we include a cross-reference to the cardiovascular listings to ensure that adjudicators "consider the impact and interplay of HIV infection and associated cardiovascular conditions." These commenters also suggested that we should cross-reference hepatitis in the HIV listings.

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[11] Institute of Medicine. (2010). HIV and Disability: Updating the Social Security Listings. Washington, DC: The National Academies Press.
[12] Id.

Response: We agree with the comments and have added language to final 14.00J2 and 114.00J2 to note that HIV infection may affect the onset or course of, or treatment for, conditions in other body systems, such as cardiovascular disease and hepatitis. We have also revised 14.11I to provide examples of cardiovascular manifestations of HIV infection.

Comment: One commenter requested that we either eliminate our proposed criteria in 14.11H regarding duration and intervals between hospitalizations or add language that instructs adjudicators to defer to the treating physician with regard to the medical severity of the claimant's condition instead of relying on the hospitalization criteria for the listing. The commenter believes that we are incentivizing claimants to opt for longer hospital stays or abstain from treatment to prove the severity of their conditions and meet the listing criteria.

Response: We did not adopt the comment. In our experience, individuals do not opt for unwarranted hospital stays or forgo treatment in order to possibly qualify for disability benefits. The benefit of having a listing that captures more disabled individuals at step 3 of our sequential evaluation process outweighs the concern that particular claimants may attempt to lengthen hospital stays or abstain from treatment to meet the listing. We believe that a complication(s) of HIV infection that warrants three hospitalizations of 48 hours or longer, 30 days or more apart, within a 12 month period that we are considering in connection with an application or continuing disability review

will prevent a person from engaging in any gainful activity and, therefore, represents listing-level severity. Moreover, we are able to evaluate complications of HIV infection resulting in fewer than three hospitalizations in a consecutive 12-month period using medical equivalence, the other listing criteria for adults, the functional equivalence rules for children, or at other steps in our sequential evaluation process. For example, the criteria in listing 14.11I evaluate the functional impact of the person's impairment in the broad areas of activities of daily living, social functioning, and concentration, persistence, or pace, including the functional impact of treatment such as repeated outpatient visits for complications.

Our medical equivalence rules permit us to find that a disorder is medically equivalent to a listing at step 3 if there are other findings related to the disorder that are at least of equal medical significance to the listing criteria (see §§ 404.1526 and 416.926). Although some of our listings include criteria for repeated hospitalizations (14.11H and 114.11G), our medical equivalence policy accommodates recent trends in clinical care that emphasize quality of, rather than quantity of, medical treatment.

The medical equivalence policy also accommodates claimants' varying level of access to medical care, the preference of some medical providers to reduce the use of emergency department and hospital-level medical interventions, and recent trends in clinical care that emphasize quality of, rather than quantity of, medical treatment. This accommodation accounts for differences in medical care people with similar disorders receive depending on the medical resources available to them. The medical equivalence

policy provides some flexibility in determining whether a claimant is disabled at step 3 of the sequential evaluation process by allowing us to consider whether the claimant's impairment meets the listed criteria exactly or is at least equal in severity and duration to the criteria of any listed impairment.

If we are not able to find that a person's impairment due to HIV infection is disabling using our listings, we may still find the person disabled at the final steps of the sequential evaluation process.

Finally, the commenter's suggestion that we defer to the treating physician with regard to the medical severity of a person's condition in lieu of hospitalization frequency and duration in this listing means that we would be permitting the physician to determine whether the person is disabled. Under our rules, the finding of disability is an issue reserved to the Commissioner of Social Security.[13]

Comment: One commenter requested that we train adjudicators to evaluate repeated manifestations of HIV infection correctly. The commenter states that, under the current listings, they "rarely see adjudicators willing to approve claims of individuals with HIV based on repeated manifestations of [HIV infection]."

Response: We did not make any changes in our final listings as a result of this comment. We will provide training on the new listings, as we do for all listing updates.

[13] See 20 CFR 404.1527(c) and (d) and 416.927(c) and (d).

We will also conduct a study on the use of the listings after they have been in use for a year, as we do for all listing updates, and issue further training or policy guidance if needed.

Comment: One commenter recommended that the introductory text be improved by adding a more significant definition of multicentric Castleman disease (MCD), particularly how it is very similar to a lymphoma, although it is not actually a cancer.

Response: We adopted the comment and have provided expanded definitions for MCD in 14.00F3a and 114.00F3a.

Function

Comment: One commenter requested that we provide language to clarify that the examples in the introductory text of complications of HIV infection that may result in hospitalization are "not an all-inclusive or inflexible list."

Response: We adopted this comment and have provided text in 14.00F6b and 114.00F5b to indicate that the examples in 14.00F6a and 114.00F5a are not an exhaustive list.

Comment: One commenter agreed with our revisions to section 14.00I5 of the introductory text to clarify our explanation of the term "marked," but suggested that we

construct "this change in a manner that facilitates a better process for determining the 'severity' of the disability."

Response: We did not adopt this comment. We provide guidance in current sections 14.00I5 through 14.00I8 that explains how we take into consideration a "marked" level of limitation in functioning to determine the severity of a person's impairment. This guidance is sufficient to allow adjudicators to evaluate the functional limitations resulting from HIV infection and other immune system disorders.

Comment: Two commenters asked that we "recognize the validity of an HIV treating physician's objective evaluation of a patient's HIV-related functional limitations." They remarked, "HIV affects individuals differently according to physiological and biological factors unique to the individual," and that "responses to treatment, including side effects, vary greatly according to sex, age and co-occurring conditions." These commenters provided specific text that they wanted us to add to proposed listing 14.11I. The proposed text would instruct adjudicators to give special consideration to the opinion(s) of a claimant's primary care provider, in particular, an experienced HIV medical provider.

Response: We did not adopt the comment. When we evaluate medical opinions, such as those described by the commenters, we consider several factors. Those factors include the treating relationship between the opining medical source and the claimant, how much the medical source's treatment records support the medical opinion, and the

consistency of the medical opinion with the other evidence throughout the record as a whole, including a claimant's self-reporting.[14] This is true for all impairments across all body systems, not just in cases involving HIV infection.

Additionally, the finding about whether a claimant is or is not disabled is an issue reserved to the Commissioner. We do not give any special significance to the source of a statement on an issue reserved to the Commissioner, even if that source is a medical source who has treated the claimant.[15]

Comment: One commenter suggested that we expand the role of evidence of a claimant's functional limitations, as required under 14.11I, from sources other than those that we consider acceptable medical sources. The commenter urged us to "immediately adopt the IOM recommendation to expand acceptable medical sources to a wide array of licensed professionals and broaden the acceptable medical sources rule and guidance."

Response: We did not adopt the comment because it is outside the scope of this rulemaking. However, under our rules, we may use evidence from sources other than acceptable medical sources in order to show the severity of a person's impairment and how that impairment affects the individual's ability to function.[16] For example, we might request evidence from a social worker or another medical or professional source who has been treating a claimant, because this evidence can provide information about the

[14] See 20 CFR 404.1527(c) and 416.927(c).
[15] See 20 CFR 404.1527(d) and 416.927(d).
[16] See 20 CFR 404.1513(d) and 20.CFR 416.913(d).

claimant's functional capabilities. Other sources of evidence that we may consider include counselors, family members, caregivers, or neighbors.

Comment: One commenter disagreed with our proposal to remove diarrhea as a standalone listing (current listing 14.08I). The commenter stated that "diarrhea is a 'manifestation' of HIV infection that does not result in a corresponding 'sign or symptom', and, at [a] certain degree of severity, automatically results in a marked functional limitation." The commenter suggested that we retain and revise the current standalone listing for diarrhea, and provided specific language for the revision.

Response: We did not adopt this comment. While we agree that diarrhea is a manifestation of HIV infection that may result in a marked functional limitation, we do not believe it is best evaluated under a standalone listing. We agree with the recommendation of the IOM that diarrhea should be evaluated using functional impairment criteria.[17] We have specifically listed diarrhea as an example of a manifestation of HIV infection that may be evaluated under 14.11I.

Comment: Two commenters requested that we revise proposed listing 14.11I for clarity, to include "neurocognitive or other mental limitations (including dementia, anxiety, depression, or other mental impairments not meeting the criteria in 12.02, 12.03, 12.04, or 12.06)."

[17] Institute of Medicine. (2010). HIV and Disability: Updating the Social Security Listings. Washington, DC: The National Academies Press.

Response:

We did not add references to the specific mental disorders listings requested by the commenters, because doing so would appear to restrict the mental disorders we would consider under 14.11I to those specific conditions. Instead, we added language to 14.11I to clarify that we may consider any neurocognitive or other mental limitations not meeting the criteria in 12.00.

Comment: One commenter asked how we would implement the evaluation of a neurocognitive limitation under proposed 14.11I and whether its presence in a claim would necessitate review of the case by a psychological consultant.

Response: We did not make any changes in the final rule based on this comment. The need for a psychological consultant review depends on the facts in the individual case. The neurocognitive limitations provided as an example under listing 14.11I are considered a manifestation of HIV infection. We evaluate medical evidence based on the underlying disorder. If the level of limitation is such that we consider the neurocognitive limitation to be a mental impairment on its own, then a psychological consultant (or a medical consultant who is a psychiatrist) would review the case.

Specific Groups with HIV Infection

Comment: Numerous commenters disagreed with our proposal to remove the text in current section 14.00F4 about manifestations of HIV infection that are specific to

women and requested that we restore this language in the final rule. The commenters were concerned that adjudicators who are unfamiliar with HIV infection may not immediately recognize that certain signs and symptoms are related to HIV infection in women. They believed that retaining the current language would help to instruct adjudicators to acknowledge and take these signs and symptoms into account as manifestations of HIV infection in women when making disability determinations.

Response: We adopted these comments and have placed this guidance in section 14.00F7 of the final rule. Additionally, we have added language to 14.11I specifically noting that certain gynecologic conditions may be manifestations of HIV infection.

Comment: One commenter recommended that we consider including the adolescent population more specifically in the listings. The commenter stated that youth ages 13 to 25 years "constitute the fastest growing and largest group of new HIV infections in the United States." The commenter feels the listings "should take into account adolescents who are transitioning from the Part B listings for children to the Part A listings for adults so that HIV-infected youth are not lost to care."

Response: We did not adopt this comment. The Part A and Part B listings for adults and children are very similar and closely parallel one another. In addition, under our rules, we may use the criteria in Part A when those criteria give appropriate consideration to the effects of the impairment(s) in children.[18]

[18] See 20 CFR 404.1525(b)(2) and 20 CFR 416.925(b)(2)(i).

Other Body Systems

Comment: One commenter suggested that we remove the information in the proposed revisions to 5.00D4 of the introductory text about how comorbid disorders, such as HIV infection, may affect chronic viral hepatitis infections. The commenter stated that the language "does not provide meaningful guidance for the listings themselves."

Response: We did not adopt the comment. We have based our final revisions on recommendations in the IOM report.[19] These revisions also align with the requests of a number of commenters. In the introductory text, we include information that will be useful to our adjudicators when they evaluate impairments in a particular body system. Comorbid disorders, such as HIV infection, do have an impact on chronic viral hepatitis infections, and their presence can affect how we evaluate an impairment under the digestive body system.

General Comments

Comment: Two commenters made suggestions regarding setting diaries for continuing disability review (CDR) under the HIV/AIDS listings. One commenter recommended that "individuals with HIV/AIDS associated malignancies have markedly

[19] Institute of Medicine. (2010). HIV and Disability: Updating the Social Security Listings. Washington, DC: The National Academies Press.

improved survival rates," and suggested that "these impairments should be assessed with the same three-year review diary as outlined for primary malignancies in the [cancer (malignant neoplastic)] listings." The other commenter suggested that all HIV/AIDS listings should have a three-year review diary, with the decision to continue or cease benefits defined by the medical improvement review standard (the legal standard for determining whether disability continues in a CDR). The commenter noted "the specter and presence of an indicator disease no longer portends a poor prognosis," and stated that "improvements in medical care, HAART, and improved survival rates support the need for [a CDR]."

Response: We did not adopt these comments. We do not specify a particular period of disability in the medical listings unless we can uniformly expect medical improvement for an impairment in a specific listing such that a person would no longer be disabled (for example, listing 6.04 for chronic kidney disease with kidney transplant). This is not the case for the impairments in the listings for HIV infection. We will address any new considerations for diary length and CDRs related to HIV infection in our internal policy guidance, as we normally do.

Comment: One commenter expressed concern that we do not provide quantitative data to show the validity of any of our proposed listings. The commenter stated that "hundreds of thousands of individuals engage in substantial gainful activity while meeting requirements of [other] listings," such as hearing loss not treated with cochlear implantation. The commenter requested that we state the information and methods that

we used to develop the listing criteria, and questioned whether it is "possible to evaluate a person's ability to engage in gainful activities using…the listings."

Response: We did not make any changes in the final rule based on this comment. In the NPRM, we provided a list of specific references that we used to inform the changes that we proposed.[20] In this final rule, we are making changes to the proposed rule based on comments that we received in response to the NPRM. The listings in this final rule represent impairments that we consider severe enough to prevent a person from engaging in any gainful activity.

Comment: One commenter noted that medications for HIV infection affect people in different ways and may cause a person's other psychological and physical issues to worsen.

Response: We did not make any changes in the final rule based on this comment. We take the effects of treatment, including medications for HIV infection, into account when evaluating a case. This guidance is provided in section 14.00G of the introductory text, which was not shown in the NPRM because we did not propose to change it. Specifically, in 14.00G5, we explain how we evaluate the effects of treatment of HIV infection, including the effects of antiretroviral drugs, on the ability to function.

Comment: One commenter believed that the language in proposed listing 14.11I

[20] 79 FR 10730

is unclear and discussed concerns with how we would apply the rule. The commenter requested that we clarify the listing by adding additional text noting that we consider more than repeated manifestations of HIV (for example, "significant, documented manifestations, symptoms, or signs") under 14.11I and asks that we provide training to our adjudicators to properly consider these criteria.

Response: We did not make any changes in the final rule based on this comment. Our proposed language is clear and captures the intent of the listing. The changes that the commenter suggests would alter the meaning of the listing, not clarify it. We will address the concerns with the application of the rule in training for our adjudicators.

Comment: One commenter requested that we provide our disability examiners with more training in evaluating a claim involving HIV infection and applying the HIV infection listings.

Response: We did not make any changes in the final rule based on this comment. As we do with all updates to the listings, we will provide our disability examiners with training on the final rule for evaluating HIV infection.

Other Changes

In the NPRM, we proposed to remove listing 114.08L for evaluating functional limitations resulting from HIV infection in children. We explained that we were not

including similar criteria in proposed listing 114.11 for HIV infection in children because of proposed changes in the mental disorders listings and because we may find children disabled under the Supplemental Security Income program based on functional equivalence to the listings.[21] However, we did not propose to revise 114.00I, which notes the childhood listings that we use to evaluate functional limitations under the immune body system, to reflect the removal of 114.08L. After we published the NPRM, we published a final rule for evaluating mental disorders, which removed 114.08L as well as other childhood listing criteria that considered functional limitations under the immune disorders body system. In this final rule, we revised paragraph 114.00I to address how we will consider the impact of immune system disorders, including HIV, on a child's functioning.

In order to provide consistent guidance, we are also making conforming changes to the listings for hematological disorders in 7.00A2 and 107.00A2 to explain that we will evaluate primary central nervous system lymphoma and primary effusion lymphoma associated with HIV infection under 14.11B, 14.11C, 114.11B, and 114.11C, respectively.

When will we begin to use this final rule?

We will begin to use this final rule on its effective date. We will continue to use the current listings until the date this final rule becomes effective. We will apply the final

[21] See 20 CFR 416.924(d).

rule to new applications filed on or after the effective date of this final rule and to claims that are pending on or after the effective date.[22]

How long will this final rule be in effect?

This final rule will remain in effect for 3 years after the date it becomes effective, unless we extend the expiration date. We will continue to monitor the rule and may revise it, as needed, before the end of the 3-year period.

What is our authority to make rules and set procedures for determining whether a person is disabled under the statutory definition?

Under the Act, we have full power and authority to make rules and regulations and to establish necessary and appropriate procedures to carry out such provisions. Sections 205(a), 702(a)(5), and 1631(d)(1).

## REGULATORY PROCEDURES

### Executive Order 12866, as Supplemented by Executive Order 13563

[22] This means that we will use this final rule on and after their effective date, in any case in which we make a determination or decision. We expect that Federal courts will review our final decisions using the rules that were in effect at the time we issued the decisions. If a court reverses our final decision and remands a case for further administrative proceedings after the effective date of this final rule, we will apply this final rule to the entire period at issue in the decision we make after the court's remand.

We consulted with the Office of Management and Budget (OMB) and determined that this final rule meets the criteria for a significant regulatory action under Executive Order 12866, as supplemented by Executive Order 13563. Therefore, OMB reviewed it.

Regulatory Flexibility Act

We certify that this final rule will not have a significant economic impact on a substantial number of small entities because it affects individuals only. Therefore, the Regulatory Flexibility Act, as amended, does not require us to prepare a regulatory flexibility analysis.

Paperwork Reduction Act

These Final Rules do not create any new or affect any existing collections, and therefore, do not require OMB approval under the Paperwork Reduction Act.

(Catalog of Federal Domestic Assistance Program Nos. 96.001, Social Security--Disability Insurance; 96.002, Social Security--Retirement Insurance; 96.004, Social Security--Survivors Insurance; and 96.006, Supplemental Security Income).

List of Subjects in 20 CFR Part 404

Administrative practice and procedure, Blind, Disability benefits, Old-age, Survivors, and Disability Insurance, Reporting and recordkeeping requirements, Social Security.

_____

Carolyn W. Colvin,
Acting Commissioner of Social Security.

For the reasons set out in the preamble, we are amending 20 CFR part 404 subpart P as set forth below:

PART 404--FEDERAL OLD-AGE, SURVIVORS AND DISABILITY INSURANCE (1950- )

Subpart P—Determining Disability and Blindness

1. The authority citation for subpart P of part 404 continues to read as follows:

Authority: Secs. 202, 205(a)-(b) and (d)-(h), 216(i), 221(a), (i), and (j), 222(c), 223, 225, and 702(a)(5) of the Social Security Act (42 U.S.C. 402, 405(a)-(b) and (d)-(h), 416(i), 421(a), (i), and (j), 422(c), 423, 425, and 902(a)(5)); sec. 211(b), Pub. L. 104-193, 110 Stat. 2105, 2189; sec. 202, Pub. L. 108-203, 118 Stat. 509 (42 U.S.C. 902 note).

2. Amend appendix 1 to subpart P of part 404 by:

a. Revising item 15 of the introductory text before part A;

b. Revising the last sentence of paragraph 5.00D4a(i) of part A;

c. Revising paragraph 5.00D4b of part A;

d. Revising paragraph 7.00A2 of part A;

e. Revising the last sentence of paragraph 8.00D3 of part A;

f. Revising paragraph 13.00A of part A;

g. Revising paragraphs 14.00A4, 14.00F, and 14.00I1 of part A;

h. Revising the first two sentences of paragraph 14.00I5 of part A;

i. Removing the first three sentences of paragraph 14.00J2 of part A and adding two sentences in their place;

j. Removing and reserving listing 14.08 of part A;

k. Adding listing 14.11 to part A;

l. Revising the last sentence of paragraph 105.00D4a(i) of part B;

m. Revising paragraph 105.00D4b of part B;

n. Revising paragraph 107.00A2 of part B;

o. Revising the last sentence of paragraph 108.00D3 of part B;

p. Revising paragraph 113.00A of part B;

q. Revising paragraphs 114.00A4, 114.00F, and 114.00I of part B;

r. Removing the first two sentences of 114.00J2 of part B and adding three sentences in their place;

s. Removing and reserving listing 114.08 of part B; and

t. Adding listing 114.11 to part B.

The revisions and additions read as follows:

APPENDIX 1 TO SUBPART P OF PART 404--LISTING OF IMPAIRMENTS

* * * * *

15. Immune System Disorders (14.00 and 114.00): January 17, 2020.

* * * * *

Part A

* * * * *

5.00 DIGESTIVE SYSTEM

* * * * *

D. * * *

4. * * *

a. * * *

(i) * * * Comorbid disorders, such as HIV infection, may accelerate the clinical course of viral hepatitis infection(s) or may result in a poorer response to medical treatment.

* * * * *

b. Chronic hepatitis B virus (HBV) infection.

(i) Chronic HBV infection can be diagnosed by the detection of hepatitis B

surface antigen (HBsAg) or hepatitis B virus DNA (HBV DNA) in the blood for at least 6 months. In addition, detection of the hepatitis B e antigen (HBeAg) suggests an increased likelihood of progression to cirrhosis, ESLD, and hepatocellular carcinoma. (HBeAg may also be referred to as "hepatitis B early antigen" or "hepatitis B envelope antigen.")

(ii) The therapeutic goal of treatment is to suppress HBV replication and thereby prevent progression to cirrhosis, ESLD, and hepatocellular carcinoma. Treatment usually includes interferon injections, oral antiviral agents, or a combination of both. Common adverse effects of treatment are the same as noted in 5.00D4c(ii) for HCV, and generally end within a few days after treatment is discontinued.

* * * * *

7.00 HEMATOLOGICAL DISORDERS

A. * * *

2. We evaluate malignant (cancerous) hematological disorders, such as lymphoma, leukemia, and multiple myeloma, under the appropriate listings in 13.00, except for two lymphomas associated with human immunodeficiency virus (HIV) infection. We evaluate primary central nervous system lymphoma associated with HIV infection under 14.11B, and primary effusion lymphoma associated with HIV infection under 14.11C.

* * * * *

8.00 SKIN DISORDERS

* * * * *

D. * * *

3. * * * We evaluate SLE under 14.02, scleroderma under 14.04, Sjögren's syndrome under 14.10, and HIV infection under 14.11.

* * * * *

13.00 CANCER (MALIGNANT NEOPLASTIC DISEASES)

A. What impairments do these listings cover? We use these listings to evaluate all cancers (malignant neoplastic diseases) except certain cancers associated with human immunodeficiency virus (HIV) infection. We use the criteria in 14.11B to evaluate primary central nervous system lymphoma, 14.11C to evaluate primary effusion lymphoma, and 14.11E to evaluate pulmonary Kaposi sarcoma if you also have HIV infection. We evaluate all other cancers associated with HIV infection, for example,

Hodgkin lymphoma or non-pulmonary Kaposi sarcoma, under this body system or under 14.11F-I in the immune system disorders body system.

* * * * *

14.00 IMMUNE SYSTEM DISORDERS

A. * * *

4. Human immunodeficiency virus (HIV) infection (14.00F). HIV infection may be characterized by increased susceptibility to common infections as well as opportunistic infections, cancers, or other conditions listed in 14.11.

* * * * *

F. How do we document and evaluate HIV infection? Any individual with HIV infection, including one with a diagnosis of acquired immune deficiency syndrome (AIDS), may be found disabled under 14.11 if his or her impairment meets the criteria in that listing or is medically equivalent to the criteria in that listing.

1. Documentation of HIV infection.

a. Definitive documentation of HIV infection. We may document a diagnosis of

HIV infection by positive findings on one or more of the following definitive laboratory tests:

(i) HIV antibody screening test (for example, enzyme immunoassay, or EIA), confirmed by a supplemental HIV antibody test such as the Western blot (immunoblot), an immunofluorescence assay, or an HIV-1/HIV-2 antibody differentiation immunoassay.

(ii) HIV nucleic acid (DNA or RNA) detection test (for example, polymerase chain reaction, or PCR).

(iii) HIV p24 antigen (p24Ag) test.

(iv) Isolation of HIV in viral culture.

(v) Other tests that are highly specific for detection of HIV and that are consistent with the prevailing state of medical knowledge.

b. We will make every reasonable effort to obtain the results of your laboratory testing. Pursuant to §§ 404.1519f and 416.919f of this chapter, we will purchase examinations or tests necessary to make a determination in your claim if no other acceptable documentation exists.

c. Other acceptable documentation of HIV infection. We may also document HIV

infection without definitive laboratory evidence.

(i) We will accept a persuasive report from a physician that a positive diagnosis of your HIV infection was confirmed by an appropriate laboratory test(s), such as those described in 14.00F1a. To be persuasive, this report must state that you had the appropriate definitive laboratory test(s) for diagnosing your HIV infection and provide the results. The report must also be consistent with the remaining evidence of record.

(ii) We may also document HIV infection by the medical history, clinical and laboratory findings, and diagnosis(es) indicated in the medical evidence, provided that such documentation is consistent with the prevailing state of medical knowledge and clinical practice and is consistent with the other evidence in your case record. For example, we will accept a diagnosis of HIV infection without definitive laboratory evidence of the HIV infection if you have an opportunistic disease that is predictive of a defect in cell-mediated immunity (for example, toxoplasmosis of the brain or Pneumocystis pneumonia (PCP)), and there is no other known cause of diminished resistance to that disease (for example, long-term steroid treatment or lymphoma). In such cases, we will make every reasonable effort to obtain full details of the history, medical findings, and results of testing.

2. Documentation of the manifestations of HIV infection.

a. Definitive documentation of manifestations of HIV infection. We may

document manifestations of HIV infection by positive findings on definitive laboratory tests, such as culture, microscopic examination of biopsied tissue or other material (for example, bronchial washings), serologic tests, or on other generally acceptable definitive tests consistent with the prevailing state of medical knowledge and clinical practice.

b. We will make every reasonable effort to obtain the results of your laboratory testing. Pursuant to §§ 404.1519f and 416.919f of this chapter, we will purchase examinations or tests necessary to make a determination of your claim if no other acceptable documentation exists.

c. Other acceptable documentation of manifestations of HIV infection. We may also document manifestations of HIV infection without definitive laboratory evidence.

(i) We will accept a persuasive report from a physician that a positive diagnosis of your manifestation of HIV infection was confirmed by an appropriate laboratory test(s). To be persuasive, this report must state that you had the appropriate definitive laboratory test(s) for diagnosing your manifestation of HIV infection and provide the results. The report must also be consistent with the remaining evidence of record.

(ii) We may also document manifestations of HIV infection without the definitive laboratory evidence described in 14.00F2a, provided that such documentation is consistent with the prevailing state of medical knowledge and clinical practice and is consistent with the other evidence in your case record. For example, many conditions are

now commonly diagnosed based on some or all of the following: Medical history, clinical manifestations, laboratory findings (including appropriate medically acceptable imaging), and treatment responses. In such cases, we will make every reasonable effort to obtain full details of the history, medical findings, and results of testing.

3. Disorders associated with HIV infection (14.11A-E).

a. Multicentric Castleman disease (MCD, 14.11A) affects multiple groups of lymph nodes and organs containing lymphoid tissue. This widespread involvement distinguishes MCD from localized (or unicentric) Castleman disease, which affects only a single set of lymph nodes. While not a cancer, MCD is known as a lymphoproliferative disorder. Its clinical presentation and progression is similar to that of lymphoma, and its treatment may include radiation or chemotherapy. We require characteristic findings on microscopic examination of the biopsied lymph nodes or other generally acceptable methods consistent with the prevailing state of medical knowledge and clinical practice to establish the diagnosis. Localized (or unicentric) Castleman disease does not meet or medically equal the criterion in 14.11A, but we may evaluate it under the criteria in 14.11H or 14.11I.

b. Primary central nervous system lymphoma (PCNSL, 14.11B) originates in the brain, spinal cord, meninges, or eye. Imaging tests (for example, MRI) of the brain, while not diagnostic, may show a single lesion or multiple lesions in the white matter of the brain. We require characteristic findings on microscopic examination of the cerebral

spinal fluid or of the biopsied brain tissue, or other generally acceptable methods consistent with the prevailing state of medical knowledge and clinical practice to establish the diagnosis.

c. Primary effusion lymphoma (PEL, 14.11C) is also known as body cavity lymphoma. We require characteristic findings on microscopic examination of the effusion fluid or of the biopsied tissue from the affected internal organ, or other generally acceptable methods consistent with the prevailing state of medical knowledge and clinical practice to establish the diagnosis.

d. Progressive multifocal leukoencephalopathy (PML, 14.11D) is a progressive neurological degenerative syndrome caused by the John Cunningham (JC) virus in immunosuppressed individuals. Clinical findings of PML include clumsiness, progressive weakness, and visual and speech changes. Personality and cognitive changes may also occur. We require appropriate clinical findings, characteristic white matter lesions on MRI, and a positive PCR test for the JC virus in the cerebrospinal fluid to establish the diagnosis. We also accept a positive brain biopsy for JC virus or other generally acceptable methods consistent with the prevailing state of medical knowledge and clinical practice to establish the diagnosis.

e. Pulmonary Kaposi sarcoma (Kaposi sarcoma in the lung, 14.11E) is the most serious form of Kaposi sarcoma (KS). Other internal KS tumors (for example, tumors of the gastrointestinal tract) have a more variable prognosis. We require characteristic

findings on microscopic examination of the induced sputum, bronchoalveolar lavage washings, or of the biopsied transbronchial tissue, or by other generally acceptable methods consistent with the prevailing state of medical knowledge and clinical practice to establish the diagnosis.

4. CD4 measurement (14.11F). To evaluate your HIV infection under 14.11F, we require one measurement of your absolute CD4 count (also known as CD4 count or CD4+ T-helper lymphocyte count). This measurement must occur within the period we are considering in connection with your application or continuing disability review. If you have more than one measurement of your absolute CD4 count within this period, we will use your lowest absolute CD4 count.

5. Measurement of CD4 and either body mass index or hemoglobin (14.11G). To evaluate your HIV infection under 14.11G, we require one measurement of your absolute CD4 count or your CD4 percentage, and either a measurement of your body mass index (BMI) or your hemoglobin. These measurements must occur within the period we are considering in connection with your application or continuing disability review. If you have more than one measurement of your CD4 (absolute count or percentage), BMI, or hemoglobin within this period, we will use the lowest of your CD4 (absolute count or percentage), BMI, or hemoglobin. The date of your lowest CD4 (absolute count or percentage) measurement may be different from the date of your lowest BMI or hemoglobin measurement. We calculate your BMI using the formulas in 5.00G2.

6. Complications of HIV infection requiring hospitalization (14.11H).

a. Complications of HIV infection may include infections (common or opportunistic), cancers, and other conditions. Examples of complications that may result in hospitalization include: Depression; diarrhea; immune reconstitution inflammatory syndrome; malnutrition; and PCP and other severe infections.

b. Under 14.11H, we require three hospitalizations within a 12-month period that are at least 30 days apart and that result from a complication(s) of HIV infection. The hospitalizations may be for the same complication or different complications of HIV infection and are not limited to the examples of complications that may result in hospitalization listed in 14.00F6a. All three hospitalizations must occur within the period we are considering in connection with your application or continuing disability review. Each hospitalization must last at least 48 hours, including hours in a hospital emergency department immediately before the hospitalization.

c. We will use the rules on medical equivalence in §§ 404.1526 and 416.926 of this chapter to evaluate your HIV infection if you have fewer, but longer, hospitalizations, or more frequent, but shorter, hospitalizations, or if you receive nursing, rehabilitation, or other care in alternative settings.

7. HIV infection manifestations specific to women.

a. General. Most women with severe immunosuppression secondary to HIV infection exhibit the typical opportunistic infections and other conditions, such as PCP, Candida esophagitis, wasting syndrome, cryptococcosis, and toxoplasmosis. However, HIV infection may have different manifestations in women than in men. Adjudicators must carefully scrutinize the medical evidence and be alert to the variety of medical conditions specific to, or common in, women with HIV infection that may affect their ability to function in the workplace.

b. Additional considerations for evaluating HIV infection in women. Many of these manifestations (for example, vulvovaginal candidiasis or pelvic inflammatory disease) occur in women with or without HIV infection, but can be more severe or resistant to treatment, or occur more frequently in a woman whose immune system is suppressed. Therefore, when evaluating the claim of a woman with HIV infection, it is important to consider gynecologic and other problems specific to women, including any associated symptoms (for example, pelvic pain), in assessing the severity of the impairment and resulting functional limitations. We may evaluate manifestations of HIV infection in women under 14.11H-I, or under the criteria for the appropriate body system (for example, cervical cancer under 13.23).

8. HIV-associated dementia (HAD). HAD is an advanced neurocognitive disorder, characterized by a significant decline in cognitive functioning. We evaluate HAD under 14.11I. Other names associated with neurocognitive disorders due to HIV infection include: AIDS dementia complex, HIV dementia, HIV encephalopathy, and

major neurocognitive disorder due to HIV infection.

* * * * *

I. How do we use the functional criteria in these listings?

1. The following listings in this body system include standards for evaluating the functional limitations resulting from immune system disorders: 14.02B, for systemic lupus erythematosus; 14.03B, for systemic vasculitis; 14.04D, for systemic sclerosis (scleroderma); 14.05E, for polymyositis and dermatomyositis; 14.06B, for undifferentiated and mixed connective tissue disease; 14.07C, for immune deficiency disorders, excluding HIV infection; 14.09D, for inflammatory arthritis; 14.10B, for Sjögren's syndrome; and 14.11I, for HIV infection.

* * * * *

5. Marked limitation means that the signs and symptoms of your immune system disorder interfere seriously with your ability to function. Although we do not require the use of such a scale, "marked" would be the fourth point on a five-point scale consisting of no limitation, mild limitation, moderate limitation, marked limitation, and extreme limitation. * * *

* * * * *

J. * * *

2. Individuals with immune system disorders, including HIV infection, may manifest signs or symptoms of a mental impairment or of another physical impairment. For example, HIV infection may accelerate the onset of conditions such as diabetes or affect the course of or treatment options for diseases such as cardiovascular disease or hepatitis. We may evaluate these impairments under the affected body system. * * *

* * * * *

14.08 [Reserved]

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14.11 Human immunodeficiency virus (HIV) infection. With documentation as described in 14.00F1 and one of the following:

A. Multicentric (not localized or unicentric) Castleman disease affecting multiple groups of lymph nodes or organs containing lymphoid tissue (see 14.00F3a).

OR

B. Primary central nervous system lymphoma (see 14.00F3b).

OR

C. Primary effusion lymphoma (see 14.00F3c).

OR

D. Progressive multifocal leukoencephalopathy (see 14.00F3d).

OR

E. Pulmonary Kaposi sarcoma (see 14.00F3e).

OR

F. Absolute CD4 count of 50 cells/$mm^3$ or less (see 14.00F4).

OR

G. Absolute CD4 count of less than 200 cells/$mm^3$ or CD4 percentage of less than 14 percent, and one of the following (values do not have to be measured on the same date) (see 14.00F5):

1. BMI measurement of less than 18.5; or

2. Hemoglobin measurement of less than 8.0 grams per deciliter (g/dL).

OR

H. Complication(s) of HIV infection requiring at least three hospitalizations within a 12-month period and at least 30 days apart (see 14.00F6). Each hospitalization must last at least 48 hours, including hours in a hospital emergency department immediately before the hospitalization.

OR

I. Repeated (as defined in 14.00I3) manifestations of HIV infection, including those listed in 14.11A-H, but without the requisite findings for those listings (for example, Kaposi sarcoma not meeting the criteria in 14.11E), or other manifestations (including, but not limited to, cardiovascular disease (including myocarditis, pericardial effusion, pericarditis, endocarditis, or pulmonary arteritis), diarrhea, distal sensory polyneuropathy, glucose intolerance, gynecologic conditions (including cervical cancer or pelvic inflammatory disease, see 14.00F7), hepatitis, HIV-associated dementia, immune reconstitution inflammatory syndrome (IRIS), infections (bacterial, fungal, parasitic, or viral), lipodystrophy (lipoatrophy or lipohypertrophy), malnutrition, muscle weakness, myositis, neurocognitive or other mental limitations not meeting the criteria in

12.00, oral hairy leukoplakia, osteoporosis, pancreatitis, peripheral neuropathy) resulting in significant, documented symptoms or signs (for example, but not limited to, fever, headaches, insomnia, involuntary weight loss, malaise, nausea, night sweats, pain, severe fatigue, or vomiting) and one of the following at the marked level:

1. Limitation of activities of daily living.

2. Limitation in maintaining social functioning.

3. Limitation in completing tasks in a timely manner due to deficiencies in concentration, persistence, or pace.

* * * * *

Part B

* * * * *

105.00 DIGESTIVE SYSTEM

* * * * *

D. * * *

4. * * *

a. * * *

(i) * * * Comorbid disorders, such as HIV infection, may accelerate the clinical course of viral hepatitis infection(s) or may result in a poorer response to medical treatment.

* * * * *

b. Chronic hepatitis B virus (HBV) infection.

(i) Chronic HBV infection can be diagnosed by the detection of hepatitis B surface antigen (HBsAg) or hepatitis B virus DNA (HBV DNA) in the blood for at least 6 months. In addition, detection of the hepatitis B e antigen (HBeAg) suggests an increased likelihood of progression to cirrhosis, ESLD, and hepatocellular carcinoma. (HBeAg may also be referred to as "hepatitis B early antigen" or "hepatitis B envelope antigen.")

(ii) The therapeutic goal of treatment is to suppress HBV replication and thereby prevent progression to cirrhosis, ESLD, and hepatocellular carcinoma. Treatment usually includes interferon injections, oral antiviral agents, or a combination of both. Common adverse effects of treatment are the same as noted in 105.00D4c(ii) for HCV, and

generally end within a few days after treatment is discontinued.

* * * * *

107.00 HEMATOLOGICAL DISORDERS

A. * * *

2. We evaluate malignant (cancerous) hematological disorders, such as lymphoma, leukemia, and multiple myeloma, under the appropriate listings in 113.00, except for two lymphomas associated with human immunodeficiency virus (HIV) infection. We evaluate primary central nervous system lymphoma associated with HIV infection under 114.11B, and primary effusion lymphoma associated with HIV infection under 114.11C.

* * * * *

108.00 SKIN DISORDERS

* * * * *

D. * * *

3. * * * We evaluate SLE under 114.02, scleroderma under 114.04, Sjögren's syndrome under 114.10, and HIV infection under 114.11.

* * * * *

113.00 CANCER (MALIGNANT NEOPLASTIC DISEASES)

A. What impairments do these listings cover? We use these listings to evaluate all cancers (malignant neoplastic diseases) except certain cancers associated with human immunodeficiency virus (HIV) infection. We use the criteria in 114.11B to evaluate primary central nervous system lymphoma, 114.11C to evaluate primary effusion lymphoma, and 114.11E to evaluate pulmonary Kaposi sarcoma if you also have HIV infection. We evaluate all other cancers associated with HIV infection, for example, Hodgkin lymphoma or non-pulmonary Kaposi sarcoma, under this body system or under 114.11F-I in the immune system disorders body system.

* * * * *

114.00 IMMUNE SYSTEM DISORDERS

A. * * *

4. Human immunodeficiency virus (HIV) infection (114.00F). HIV infection may

be characterized by increased susceptibility to common infections as well as opportunistic infections, cancers, or other conditions listed in 114.11.

* * * * *

F. How do we document and evaluate HIV infection? Any child with HIV infection, including one with a diagnosis of acquired immune deficiency syndrome (AIDS), may be found disabled under 114.11 if his or her impairment meets the criteria in that listing or is medically equivalent to the criteria in that listing.

1. Documentation of HIV infection.

a. Definitive documentation of HIV infection. We may document a diagnosis of HIV infection by positive findings on one or more of the following definitive laboratory tests:

(i) HIV antibody screening test (for example, enzyme immunoassay, or EIA), confirmed by a supplemental HIV antibody test such as the Western blot (immunoblot) or immunofluorescence assay, for any child age 18 months or older.

(ii) HIV nucleic acid (DNA or RNA) detection test (for example, polymerase chain reaction, or PCR).

(iii) HIV p24 antigen (p24Ag) test, for any child age 1 month or older.

(iv) Isolation of HIV in viral culture.

(v) Other tests that are highly specific for detection of HIV and that are consistent with the prevailing state of medical knowledge.

b. We will make every reasonable effort to obtain the results of your laboratory testing. Pursuant to § 416.919f of this chapter, we will purchase examinations or tests necessary to make a determination in your claim if no other acceptable documentation exists.

c. Other acceptable documentation of HIV infection. We may also document HIV infection without definitive laboratory evidence.

(i) We will accept a persuasive report from a physician that a positive diagnosis of your HIV infection was confirmed by an appropriate laboratory test(s), such as those described in 114.00F1a. To be persuasive, this report must state that you had the appropriate definitive laboratory test(s) for diagnosing your HIV infection and provide the results. The report must also be consistent with the remaining evidence of record.

(ii) We may also document HIV infection by the medical history, clinical and laboratory findings, and diagnosis(es) indicated in the medical evidence, provided that

such documentation is consistent with the prevailing state of medical knowledge and clinical practice and is consistent with the other evidence in your case record. For example, we will accept a diagnosis of HIV infection without definitive laboratory evidence of the HIV infection if you have an opportunistic disease that is predictive of a defect in cell-mediated immunity (for example, toxoplasmosis of the brain or Pneumocystis pneumonia (PCP)), and there is no other known cause of diminished resistance to that disease (for example, long-term steroid treatment or lymphoma). In such cases, we will make every reasonable effort to obtain full details of the history, medical findings, and results of testing.

2. Documentation of the manifestations of HIV infection.

a. Definitive documentation of manifestations of HIV infection. We may document manifestations of HIV infection by positive findings on definitive laboratory tests, such as culture, microscopic examination of biopsied tissue or other material (for example, bronchial washings), serologic tests, or on other generally acceptable definitive tests consistent with the prevailing state of medical knowledge and clinical practice.

b. We will make every reasonable effort to obtain the results of your laboratory testing. Pursuant to § 416.919f of this chapter, we will purchase examinations or tests necessary to make a determination of your claim if no other acceptable documentation exists.

c. Other acceptable documentation of manifestations of HIV infection. We may also document manifestations of HIV infection without definitive laboratory evidence.

(i) We will accept a persuasive report from a physician that a positive diagnosis of your manifestation of HIV infection was confirmed by an appropriate laboratory test(s). To be persuasive, this report must state that you had the appropriate definitive laboratory test(s) for diagnosing your manifestation of HIV infection and provide the results. The report must also be consistent with the remaining evidence of record.

(ii) We may also document manifestations of HIV infection without the definitive laboratory evidence described in 114.00F2a, provided that such documentation is consistent with the prevailing state of medical knowledge and clinical practice and is consistent with the other evidence in your case record. For example, many conditions are now commonly diagnosed based on some or all of the following: Medical history, clinical manifestations, laboratory findings (including appropriate medically acceptable imaging), and treatment responses. In such cases, we will make every reasonable effort to obtain full details of the history, medical findings, and results of testing.

3. Disorders associated with HIV infection (114.11A-E).

a. Multicentric Castleman disease (MCD, 114.11A) affects multiple groups of lymph nodes and organs containing lymphoid tissue. This widespread involvement distinguishes MCD from localized (or unicentric) Castleman disease, which affects only a

single set of lymph nodes. While not a cancer, MCD is known as a lymphoproliferative disorder. Its clinical presentation and progression is similar to that of lymphoma, and its treatment may include radiation or chemotherapy. We require characteristic findings on microscopic examination of the biopsied lymph nodes or other generally acceptable methods consistent with the prevailing state of medical knowledge and clinical practice to establish the diagnosis. Localized (or unicentric) Castleman disease does not meet or medically equal the criterion in 114.11A, but we may evaluate it under the criteria in 114.11G or 14.11I in part A.

b. Primary central nervous system lymphoma (PCNSL, 114.11B) originates in the brain, spinal cord, meninges, or eye. Imaging tests (for example, MRI) of the brain, while not diagnostic, may show a single lesion or multiple lesions in the white matter of the brain. We require characteristic findings on microscopic examination of the cerebral spinal fluid or of the biopsied brain tissue, or other generally acceptable methods consistent with the prevailing state of medical knowledge and clinical practice to establish the diagnosis.

c. Primary effusion lymphoma (PEL, 114.11C) is also known as body cavity lymphoma. We require characteristic findings on microscopic examination of the effusion fluid or of the biopsied tissue from the affected internal organ, or other generally acceptable methods consistent with the prevailing state of medical knowledge and clinical practice to establish the diagnosis.

d. Progressive multifocal leukoencephalopathy (PML, 114.11D) is a progressive neurological degenerative syndrome caused by the John Cunningham (JC) virus in immunosuppressed children. Clinical findings of PML include clumsiness, progressive weakness, and visual and speech changes. Personality and cognitive changes may also occur. We require appropriate clinical findings, characteristic white matter lesions on MRI, and a positive PCR test for the JC virus in the cerebrospinal fluid to establish the diagnosis. We also accept a positive brain biopsy for JC virus or other generally acceptable methods consistent with the prevailing state of medical knowledge and clinical practice to establish the diagnosis.

e. Pulmonary Kaposi sarcoma (Kaposi sarcoma in the lung, 114.11E) is the most serious form of Kaposi sarcoma (KS). Other internal KS tumors (for example, tumors of the gastrointestinal tract) have a more variable prognosis. We require characteristic findings on microscopic examination of the induced sputum, bronchoalveolar lavage washings, or of the biopsied transbronchial tissue, or other generally acceptable methods consistent with the prevailing state of medical knowledge and clinical practice to establish the diagnosis.

4. CD4 measurement (114.11F). To evaluate your HIV infection under 114.11F, we require one measurement of your absolute CD4 count (also known as CD4 count or CD4+ T-helper lymphocyte count) or CD4 percentage for children from birth to attainment of age 5, or one measurement of your absolute CD4 count for children from age 5 to attainment of age 18. These measurements (absolute CD4 count or CD4

percentage) must occur within the period we are considering in connection with your application or continuing disability review. If you have more than one CD4 measurement within this period, we will use your lowest absolute CD4 count or your lowest CD4 percentage.

5. Complications of HIV infection requiring hospitalization (114.11G).

a. Complications of HIV infection may include infections (common or opportunistic), cancers, and other conditions. Examples of complications that may result in hospitalization include: Depression; diarrhea; immune reconstitution inflammatory syndrome; malnutrition; and PCP and other severe infections.

b. Under 114.11G, we require three hospitalizations within a 12-month period that are at least 30 days apart and that result from a complication(s) of HIV infection. The hospitalizations may be for the same complication or different complications of HIV infection and are not limited to the examples of complications that may result in hospitalization listed in 114.00F5a. All three hospitalizations must occur within the period we are considering in connection with your application or continuing disability review. Each hospitalization must last at least 48 hours, including hours in a hospital emergency department immediately before the hospitalization.

c. We will use the rules on medical equivalence in § 416.926 of this chapter to evaluate your HIV infection if you have fewer, but longer, hospitalizations, or more

frequent, but shorter, hospitalizations, or if you receive nursing, rehabilitation, or other care in alternative settings.

6. Neurological manifestations specific to children (114.11H). The methods of identifying and evaluating neurological manifestations may vary depending on a child's age. For example, in an infant, impaired brain growth can be documented by a decrease in the growth rate of the head. In an older child, impaired brain growth may be documented by brain atrophy on a CT scan or MRI. Neurological manifestations may present in the loss of acquired developmental milestones (developmental regression) in infants and young children or, in the loss of acquired intellectual abilities in school-age children and adolescents. A child may demonstrate loss of intellectual abilities by a decrease in IQ scores, by forgetting information previously learned, by inability to learn new information, or by a sudden onset of a new learning disability. When infants and young children present with serious developmental delays (without regression), we evaluate the child's impairment(s) under 112.00.

7. Growth failure due to HIV immune suppression (114.11I).

a. To evaluate growth failure due to HIV immune suppression, we require documentation of the laboratory values described in 114.11I1 and the growth measurements in 114.11I2 or 114.11I3 within the same consecutive 12-month period. The dates of laboratory findings may be different from the dates of growth measurements.

b. Under 114.11I2 and 114.11I3, we use the appropriate table under 105.08B in the digestive system to determine whether a child's growth is less than the third percentile.

(i) For children from birth to attainment of age 2, we use the weight-for-length table corresponding to the child's gender (Table I or Table II).

(ii) For children from age 2 to attainment of age 18, we use the body mass index (BMI)-for-age corresponding to the child's gender (Table III or Table IV).

(iii) BMI is the ratio of a child's weight to the square of his or her height. We calculate BMI using the formulas in 105.00G2c.

* * * * *

I. How do we consider the impact of your immune system disorder on your functioning?

1. We will consider all relevant information in your case record to determine the full impact of your immune system disorder, including HIV infection, on your ability to function. Functional limitation may result from the impact of the disease process itself on your mental functioning, physical functioning, or both your mental and physical functioning. This could result from persistent or intermittent symptoms, such as

depression, diarrhea, severe fatigue, or pain, resulting in a limitation of your ability to acquire information, to concentrate, to persevere at a task, to interact with others, to move about, or to cope with stress. You may also have limitations because of your treatment and its side effects (see 114.00G).

2. Important factors we will consider when we evaluate your functioning include, but are not limited to: Your symptoms (see 114.00H), the frequency and duration of manifestations of your immune system disorder, periods of exacerbation and remission, and the functional impact of your treatment, including the side effects of your medication (see 114.00G). See §§416.924a and 416.926a of this chapter for additional guidance on the factors we consider when we evaluate your functioning.

3. We will use the rules in §§ 416.924a and 416.926a of this chapter to evaluate your functional limitations and determine whether your impairment functionally equals the listings.

J. * * *

2. Children with immune system disorders, including HIV infection, may manifest signs or symptoms of a mental impairment or of another physical impairment. For example, HIV infection may accelerate the onset of conditions such as diabetes or affect the course of or treatment options for diseases such as cardiovascular disease or hepatitis. We may evaluate these impairments under the affected body system. * * *

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114.08 [Reserved]

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114.11 Human immunodeficiency virus (HIV) infection. With documentation as described in 114.00F1 and one of the following:

A. Multicentric (not localized or unicentric) Castleman disease affecting multiple groups of lymph nodes or organs containing lymphoid tissue (see 114.00F3a).

OR

B. Primary central nervous system lymphoma (see 114.00F3b).

OR

C. Primary effusion lymphoma (see 114.00F3c).

OR

D. Progressive multifocal leukoencephalopathy (see 114.00F3d).

OR

E. Pulmonary Kaposi sarcoma (see 114.00F3e).

OR

F. Absolute CD4 count or CD4 percentage (see 114.00F4):

1. For children from birth to attainment of age 1, absolute CD4 count of 500 cells/$mm^3$ or less, or CD4 percentage of less than 15 percent; or

2. For children from age 1 to attainment of age 5, absolute CD4 count of 200 cells/$mm^3$ or less, or CD4 percentage of less than 15 percent; or

3. For children from age 5 to attainment of age 18, absolute CD4 count of 50 cells/$mm^3$ or less.

OR

G. Complication(s) of HIV infection requiring at least three hospitalizations within a 12-month period and at least 30 days apart (see 114.00F5). Each hospitalization

must last at least 48 hours, including hours in a hospital emergency department immediately before the hospitalization.

OR

H. A neurological manifestation of HIV infection (for example, HIV encephalopathy or peripheral neuropathy) (see 114.00F6) resulting in one of the following:

1. Loss of previously acquired developmental milestones or intellectual ability (including the sudden onset of a new learning disability), documented on two examinations at least 60 days apart; or

2. Progressive motor dysfunction affecting gait and station or fine and gross motor skills, documented on two examinations at least 60 days apart; or

3. Microcephaly with head circumference that is less than the third percentile for age, documented on two examinations at least 60 days apart; or

4. Brain atrophy, documented by appropriate medically acceptable imaging.

OR

I. Immune suppression and growth failure (see 114.00F7) documented by 1 and 2, or by 1 and 3:

1. CD4 measurement:

a. For children from birth to attainment of age 5, CD4 percentage of less than 20 percent; or

b. For children from age 5 to attainment of age 18, absolute CD4 count of less than 200 cells/mm3 or CD4 percentage of less than 14 percent; and

2. For children from birth to attainment of age 2, three weight-for-length measurements that are:

a. Within a consecutive 12-month period; and

b. At least 60 days apart; and

c. Less than the third percentile on the appropriate weight-for-length table under 105.08B1; or

3. For children from age 2 to attainment of age 18, three BMI-for-age measurements that are:

a. Within a consecutive 12-month period; and

b. At least 60 days apart; and

c. Less than the third percentile on the appropriate BMI-for-age table under 105.08B2.

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