

## MULTICENTER AIDS COHORT STUDY GUIDELINES FOR COMPLETING OUTCOME FORM

The following guidelines are for reference when completing the MACS Outcome Form. When reporting information to CAMACS, please use the comments section on page 1 of the form if you feel that it will help to clarify the information being reported. In addition to the comments section, there is space available for your notes on the pages of NP diagnoses, Cardiovascular diagnoses and Other diagnoses. PLEASE PRINT LEGIBLY WHERE APPLICABLE. Place the participant's valid MACS identification number on each page where requested.

### **Section A. General Information**

1. Fill in valid 5 digit identification number of the MACS participant. If not sure person is MACS participant, contact center's coordinator/director.
2. Date the form is being completed using format MMDDYYYY where MM is the month, 01 = January, ..., 12 = December. DD is the day, from 01 = 1st day, ..., 31 = 31st day, and YYYY is the year.
3. Participant's date of birth using format MMDDYYYY where MM is the month, 01 = January, ..., 12 = December. DD is the day, from 01 = 1st day, ..., 31 = 31st day, and YYYY is the year.
4. Print the name of person completing the form.
5. Print the MACS center from which the form is originating.
6. Reason for status change:
  - (a) If this report is the participant's initial AIDS diagnosis, check here and complete Section B (*Source of Information*) and Section C (*AIDS Diagnoses*). An initial AIDS diagnosis is defined as the 1st report of a CDC-AIDS defining condition. **If the initial AIDS diagnosis is of a malignancy (Kaposi's sarcoma, brain lymphoma, non-Hodgkin's lymphoma, brain metastasis), also check (e) and complete Section F (*Cancer Diagnosis*).**
  - (b) If this report is a new AIDS condition (i.e. not first AIDS diagnosis, but first time diagnosed with KS) or an additional diagnosis (i.e. "another" or 2nd, 3rd episode of PCP), check here and complete Section B (*Source of Information*) and Section C (*AIDS Diagnoses*). **If the new AIDS condition is a malignancy (Kaposi's sarcoma, brain lymphoma, non-Hodgkin' lymphoma, brain metastasis), also check (e) and complete Section F (*Cancer Diagnosis*).**
  - (c) If this report is a correction to a previously reported AIDS diagnosis (i.e. date correction, method of dx change, etc.), check here and complete Section B (*Source of Information*) and

Section C (*AIDS Diagnoses*). If it is a correction to an AIDS-related malignancy diagnosis (Kaposi's sarcoma, brain lymphoma, non-Hodgkin's lymphoma, brain metastasis), also check (f) and complete Section F (*Cancer Diagnosis*).

- (d) If there is information on this report which pertains to a non-AIDS, non-malignancy diagnosis, check here and complete Section B (*Source of Information*) and Section D (*Other Conditions/Diseases*).
- (e) If there is information on this report which pertains to a new malignancy diagnosis (AIDS-related or non-AIDS-related), check here and complete Section B (*Source of Information*) and Section F (*Cancer Diagnosis*). If it is an AIDS-related malignancy, also check (a) or (b) as appropriate and complete Section C (*AIDS Diagnoses*).
- (f) If this report is a correction to a previously reported malignancy diagnosis, check here and complete Section B (*Source of Information*) and Section F (*Cancer Diagnosis*). If it is an AIDS-related malignancy, also check (c) and complete Section C (*AIDS Diagnoses*).
- (g) If there is mortality information on this report, check here and complete Section B (*Source of Information*) and Section E (*Information Relevant to Death*). Also, if the death is due to AIDS, complete Section C, Item 1 (*Individual AIDS Status*) in which "Definite" should be checked off.
- (h) If this report is a correction to a previously reported mortality, check here and complete Section B (*Source of Information*) and Section E (*Information Relevant to Death*). Also, if the death is due to AIDS, complete Section C, Item 1 (*Individual AIDS Status*) in which "Definite" should be checked off.
- (i) If this report does not fit into any of the categories described above, check here and complete Section B (*Source of Information*), describe the reason for the report in the "Comments" section, and fill out any other pertinent sections.

**NOTE:** Diagnoses based on death information: If an autopsy has been performed and gives information on conditions which have not previously been reported, then Section F (*Cancer Diagnoses*) should be completed as applicable. In this case the method of diagnosis would be "autopsy" in Section F. PLEASE NOTE THAT DIAGNOSES WHICH ARE BASED ON DEATH CERTIFICATE ALONE (I.E. NO AUTOPSY CONFIRMATION) SHOULD NOT BE REPORTED IN SECTION C (*AIDS Diagnoses*) OR SECTION D (*Other/NP/CV Diagnoses*). However, malignancies (AIDS-related or non-AIDS-related) which are noted on a death certificate only can be reported in Section F, where "death certificate" is a valid method of diagnosis.

## Section B. Source of Information

1. Place a check next to the appropriate category indicating whether medical records were obtained and/or reviewed.
2. Place a check next to the appropriate choice if the source of information was a telephone contact with a physician or another source, such as friend, parent, etc. Specify source, if other.

**NOTE:** Blank lines are provided for any additional comments you may have. If submitting only a subset of the form (less than 7 pages), state here which pages are being sent.

## Section C. AIDS Diagnoses

**NOTE:** Multiple episodes of the same AIDS condition are not reportable to CAMACS - except for PCP. PCP is reportable more than once as long as the episodes occurred at least 3 months apart. Multiple, different sites of CMV are reportable to CAMACS (ex: CMV encephalitis and CMV adrenalitis).

1. Individual AIDS Status - Place a check next to the category that best delineates the person's status.
  - (1) Definite - If person has been diagnosed with a CDC-defined AIDS condition, or has died from AIDS.
  - (2) Presumptive - If person did not have an AIDS condition definitively diagnosed, nor has died from AIDS, but rather had an AIDS condition clinically diagnosed (using CDC-defined guidelines).
  - (3) Probable - If all AIDS diagnoses are not yet confirmed by medical records (i.e. participant self-report).

**NOTE:** If a participant has at least one "Definite" AIDS diagnosis, or if AIDS was a cause of death, then his status on file will be "Definite", regardless of subsequent "Presumptive" or "Probable" diagnoses.

2. Self-reported CD4<sup>+</sup> T-lymphocyte levels indicative of AIDS

For men reporting that they have AIDS based on enumeration of CD4<sup>+</sup> T-lymphocytes, complete section C.2. For this section, a depressed immune state is defined as either number of CD4<sup>+</sup> T-lymphocytes less than 200 cells/ $\mu$ l or that CD4<sup>+</sup> T-lymphocytes are less than 14% of all T-lymphocytes.

- (1) Enter the date participant was informed of a depressed immune state using the format MMDDYYYY where MM is the month, 01 = January, ..., 12 = December. DD is the day, from 01 = 1st day, ..., 31 = 31st day, and YYYY is the year. **If the exact day is unknown, use a "15" (representing mid-month). If only the year is known, use "06" for the month and "30" for the day (representing mid-year).**
- (2) Enter the code representing the location of the laboratory. If the laboratory was one of the MACS laboratories, write 2 in the space provided. If the depressed immune state was diagnosed based on measurements determined at a laboratory other than in MACS, write 1 in the space provided.

### 3. Diseases Indicative of Cellular Immunodeficiency and AIDS

- Column a: Enter the date of diagnosis here using format MMDDYYYY where MM is the month, 01 = January, ..., 12 = December. DD is the day, from 01 = 1st day, ..., 31 = 31st day, and YYYY is the year. **If the exact day is unknown, use a "15" (representing mid-month). If only the year is known, use "06" for the month and "30" for the day (representing mid-year).** For those diagnosed with recurrent pneumonia (code=51), the date of diagnosis is the date of the 2nd episode of pneumonia occurring within 1 year of a previous episode.
- Column b: Print the AIDS diagnosis on this line.
- Column c: Enter the corresponding disease code here. These codes can be found on pages 1-2 of the MACS coding list under "CDC-Defined AIDS Diagnoses". They range from 01 to 29 and 50-51.
- Column d: Enter the method(s) of diagnosis here. Up to 3 different methods may be coded. Note that "Necropsy" can only be a method for a diagnosis made from an autopsy report and should be used as a confirmation of at least one other method of diagnosis. **Diagnoses which are based on death alone should not be reported in this section.** However, AIDS-related malignancies (Kaposi's sarcoma, brain lymphoma, non-Hodgkin's lymphoma, brain metastasis), are reportable in Section F (*Cancer Diagnosis*), even if based on death alone. If bronchoscopy was used to diagnose PCP without further differentiation to cytology or biopsy, code as if cytology was performed.
- Column e: Enter the diagnosis status here: *definite*, *presumptive*, or *probable*. Please see Appendix A for acceptable methods of diagnosis for each AIDS illness. **NOTE:** AIDS illnesses not yet confirmed by medical records should always have a diagnosis status of *probable*.

## Section D. Other Conditions/Diseases

**NOTE:** This section is for diagnoses that are not AIDS-defining or malignancies. **Multiple episodes of the same condition are not reportable to CAMACS - except pneumonia. If pneumonia is reported twice in one year, and the participant is seropositive, please fill out Section C (AIDS Diagnoses) for recurrent pneumonia (code=51).**

Please refer to the **ICD-9-CM manual** for lists of codes. **DO NOT USE the ICD-10.**

**Any edition of the ICD-9-CM manual may be used. ICD-9-CM codes could also be obtained through the following CDC website. Please do not use any other 3rd party website to code the diagnoses.**

**The following link allows you to order the ICD-9 CD-ROMS:**  
[http://www.cdc.gov/nchs/products/elec\\_prods/subject/icd96ed.htm](http://www.cdc.gov/nchs/products/elec_prods/subject/icd96ed.htm)

**This link allows you to download a Rich Text File (RTF) of each edition of the ICD-9-CM:**  
<http://www.cdc.gov/nchs/icd9.htm>

### 1. Neurological Diseases/Conditions Other Than CDC-Defined AIDS

Column a: Enter the date of diagnosis here using format MMDDYYYY where MM is the month, 01 = January, ..., 12 = December. DD is the day, from 01 = 1st day, ..., 31 = 31st day, and YYYY is the year. **If the exact day is unknown, use a "15" (representing mid-month). If only the year is known, use "06" for the month and "30" for the day (representing mid-year).**

Column b: Print the neurological diagnosis on this line.

Column c: Enter the corresponding disease code here. These codes can be found on pages 3-5 of the MACS coding list under "Diseases/ Conditions Other Than CDC-Defined AIDS - Neurological". The prefix 1, 3 or 9 on each code indicates whether the condition is Not HIV-Related (1) or HIV-Related, but not AIDS (3) or unknown (9).

Column d: Enter the method(s) of diagnosis here. Up to 3 methods may be coded. Note that "Necropsy" can only be a method for a diagnosis made from an autopsy report and should be used as a confirmation of at least one other method of diagnosis. **Diagnoses which are based on death alone should not be reported in this section.**

Column e: Code whether or not this diagnosis has been reviewed by an NP Neurologist in the MACS. The codes are:

1 = No, this diagnosis was not reviewed by MACS NP neurologist or neuropsychologist

- 2 = Yes, diagnosis was reviewed by MACS NP committee
- 3 = Yes, diagnosis was reviewed by a local neurologist only
- 9 = It is unknown whether the diagnosis was reviewed.

**NOTE:** Blank lines are provided for any comments you may have concerning the NP diagnoses.

## 2. Cardiovascular conditions not diagnostic of AIDS

Column a: Enter the date of diagnosis here using format MMDDYYYY where MM is the month, 01 = January, ..., 12 = December. DD is the day, from 01 = 1st day, ..., 31 = 31st day, and YYYY is the year. **If the exact day is unknown, use a "15" (representing mid-month). If only the year is known, use "06" for the month and "30" for the day (representing mid-year).**

Column b: Print the diagnosis or condition on this line.

Column c: Enter the corresponding disease code here. **Diagnoses reported in this section should have corresponding codes found in the International Classification of Diseases, 9th Revision.** Pages 6-7 of the MACS coding list ("Diseases/Conditions Other Than CDC-Defined AIDS") contain a list of example infections and chronic diseases categories and directs you to the location of the codes in the ICD-9 book by the first 3 digits of the codes. The list contains the categories "Infections", "Infections By Site But No Agent" and "Other Conditions".

Column d: Enter the method(s) of diagnosis here. Up to 3 methods may be coded. Note that "Necropsy" can only be a method for a diagnosis made from an autopsy report and should be used as a confirmation of at least one other method of diagnosis. Diagnoses which are based on death alone should not be reported in this section.

Column e: Leave column e blank. Cardiovascular diagnoses no longer require adjudication.

**NOTE:** Blank lines are provided for any comments you may have concerning the Cardiovascular diagnoses.

## 3. Other Diagnoses/Conditions Not Diagnostic of AIDS

Column a: Enter the date of diagnosis here using format MMDDYYYY where MM is the month, 01 = January, ..., 12 = December. DD is the day, from 01 = 1st day, ..., 31 = 31st day, and YYYY is the year. **If the exact day is unknown, use a "15" (representing mid-month). If only the year is known, use "06" for the month and "30" for the day (representing mid-year).**

- Column b: Print the diagnosis or condition on this line.
- Column c: Enter the corresponding disease code here. Diagnoses reported in this section should have corresponding codes found in the International Classification of Diseases, 9th Revision, 3rd Edition (ICD-9). The MACS Common ICD-9 codes document lists codes and descriptions for common outcomes. Please note the code for Anal Dysplasia (AIN I, II or III): 209.0, which will be used until the ICD determines a specific code for this outcome.
- Column d: Enter the method(s) of diagnosis here. Up to 3 methods may be coded. Note that "Necropsy" can only be a method for a diagnosis made from an autopsy report and should be used as a confirmation of at least one other method of diagnosis. Diagnoses which are based on death alone should not be reported in this section.

**NOTE:** Blank lines are provided for any comments you may have concerning the "Other" diagnoses.

## Section E. Information Relevant to Death

**NOTE:** If a participant dies, all items in Section E should be completed.

### 1. Date of Death

- (1) If AIDS was a cause of the participant's death, and if the participant was diagnosed with a clinical AIDS condition prior to his death, check here and enter the date of death using format MMDDYYYY where MM is the month, 01 = January ... 12 = December. DD is the day, from 01 = 1st day, ..., 31 = 31st day, and YYYY is the year. If the exact day is unknown, use a "15" (representing mid-month). If only the year is known, use "06" for the month and "30" for the day (representing mid-year). The midyear should not be used if prior to a known diagnosis or visit. Code as the last day of the year. If the entire date is unknown code 09/09/9999. A report of the prior AIDS diagnosis should have been sent to CAMACS.
- (2) If AIDS was a cause of the participant's death, but he was not diagnosed with a clinical AIDS condition prior to his death, check here, and enter the date of death using format MMDDYYYY where MM is the month, 01 = January, ..., 12 = December. DD is the day, from 01 = 1st day, ..., 31 = 31st day, and YYYY is the year. If the exact day is unknown, use a "15" (representing mid-month). If only the year is known, use "06" for the month and "30" for the day (representing mid-year). The midyear should not be used if prior to a known diagnosis or visit. Code as the last day of the year. If the entire date is unknown code 09/09/9999.
- (3) If AIDS was NOT a cause of the participant's death, check here, and enter the date of death using format MMDDYYYY where MM is the month, 01 = January, ..., 12 = December. DD is the day, from 01 = 1st day, ..., 31 = 31st day, and YYYY is the year. If the exact day is unknown, use a "15" (representing mid-month). If only the year is known, use "06" for the

month and "30" for the day (representing mid-year). The midyear should not be used if prior to a known diagnosis or visit. Code as the last day of the year. If the entire date is unknown code 09/09/9999.

- (4) If it is unknown whether or not the participant died of AIDS, check here, and enter the date of death using format MMDDYYYY where MM is the month, 01 = January, ..., 12 = December. DD is the day, from 01 = 1st day, ..., 31 = 31st day, and YYYY is the year. If the exact day is unknown, use a "15" (representing mid-month). If only the year is known, use "06" for the month and "30" for the day (representing mid-year). The midyear should not be used if prior to a known diagnosis or visit. Code as the last day of the year. If the entire date is unknown code 09/09/9999.

**NOTE:** The type of death (1,2,3,4) can change based on new information. For example, if a center learns that one of its participants has died of AIDS, but has no previous AIDS diagnosis on file for this participant, it would be reported as an "AIDS death with no prior report" (2). After obtaining medical records, the center may learn that the participant was diagnosed with PCP some months before he died. When this diagnosis is reported to CAMACS, it would indicate moving his type of death from "AIDS death with no prior report" (2) to "AIDS death with a prior report" (1).

2. Causes of Death: Enter the causes of death with their corresponding ICD-9 codes. If specific cause is unknown, then write unknown and code as 799.9 (unknown and/or unspecified cause).

Character prefix for external causes: The spaces preceding those for the numeric ICD-9 codes are for characters which are used in ICD-9 for "external" causes (i.e. Gunshot wound NOS=E922.90). If the code for a participant's cause of death does not require a character prefix, then leave this space blank.

3. Source of Information for Cause of Death

Check "Death Certificate (1)," "Autopsy (2)," "Personal Report (3)," "SSDI (5)," "NDI (6)," "Cancer Registry (7)," or "Other (4)" corresponding to the source that was used to obtain information on cause of death.

The Social Security Death Index (SSDI) website is: <http://ssdi.rootsweb.com/>

The National Death Index (NDI) website is: <http://www.cdc.gov/nchs.ndi.htm>

**NOTE:** The causes and source of information (1, 2, 3, 4, 5, 6, 7) for death can change based on new information. For example, if a cause of death previously based on a "personal report" (3) was changed due to receipt of the death certificate, the cause of death would change and the source of information would change to "death certificate" (1).

4. Place a check next to the appropriate category indicating whether or not an autopsy was performed.
5. If an autopsy was performed, place a check next to the appropriate category indicating whether or not autopsy tissue was obtained by the MACS Center. If no autopsy was performed, check

"NA".

6. Indicate here whether or not the medical records of the deceased were reviewed by a MACS neurologist or outcome specialist.
7. Indicate here whether or not the participant had indications of encephalopathy. A diagnosis of probable dementia prior to death will automatically become "yes" in Q.E.7. (*Refer to Appendix A for definition criteria of HIV dementia.*)

**No:** Person had a medical examination within three months of death, but did not have clinical indications consistent with encephalopathy at this examination. Death certificates are not adequate for either diagnosing or eliminating dementia.

**Yes:** Indications of encephalopathy at any point in person's medical history as reviewed by the MACS neurologist. Death certificates are not adequate for either diagnosing or eliminating dementia.

**Other Confounding Condition:** MACS neurologist has reviewed the medical records and concluded that the person has another diagnosis related to their cognitive function.

**Don't Know Because Records are Inadequate:** "Adequate records" require sufficient neurological information (exam/laboratory results/ documented clinical interaction) within 3 months of death to either diagnose or eliminate dementia.

## Section F. Cancer Diagnosis

Notes about reporting cancer diagnoses:

For skin cancers, only melanomas, Kaposi's sarcoma cases and squamous cells are to be followed up with medical records and reported on the Outcome Form. **Do not report basal-cell skin carcinomas.**

**Kaposi's sarcoma should only be reported once per participant; however, all sites of involvement should be reported.** For example, a participant is diagnosed with Kaposi's sarcoma of the soft palate on 2/11/87. Check (e) in Section A, Item 6, and complete Sections B, C and F. On 9/2/89 the same participant develops a Kaposi's sarcoma lesion on the skin of his thigh. Submit a new Outcome Form with (f) checked in Section A, Item 6, and update the record by adding the new site in Section F, Item 5.

Malignancy diagnoses based on death (certificate, autopsy, personal report, etc.) alone (no autopsy confirmation) are reportable in Section F. However, if the malignancy is AIDS-related (Kaposi's sarcoma, brain lymphoma, non-Hodgkin's lymphoma, brain metastasis), it should not be reported in Section C (*AIDS Diagnoses*) if it is based on death alone.

**In Section F, the date of diagnosis for a malignancy (AIDS-related or non-AIDS-related) should**

always be the date of biopsy or autopsy when it is available. However, in Section C (*AIDS Diagnoses*), an AIDS-related malignancy should always have the initial date of diagnosis, whether it was clinical or histologic.

Please use the ICD-O-3 to code the cancer topography and morphology on the outcome form. The following link can be used to order the ICD-O-3 book: <http://bookorders.who.int/bookorders/anglais/detart1.jsp?sesslan=1&codlan=1&codcol=15&codch=3350#>

You can also access the following link for an online listing of ICD-O-3 codes: <http://seer.cancer.gov/icd-o-3/>. Please click on '**sitetype.d06212004.pdf**' for codes.

### 1. Site of Primary Cancer

Record the site of the malignancy, in words, in the space provided. Be as specific as possible. If the site is unknown, write "unknown" and use the code 80.9.

If the participant presents with multiple sites, but the primary site is unknown, write "multiple", use the code 80.9, and list all the sites in Item 5.

**Use ICD-0-3 topography codes for primary site of cancer.** Do not enter the ICD-9 code.

### 2. Type of Primary Cancer

In the space provided, enter the name of the type of tumor as specifically as possible.

**Use ICD-0-3 morphology codes for type of primary cancer.** Do not enter the ICD-9 code.

### 3. Date of Diagnosis

Enter the date of diagnosis here using format MMDDYYYY where MM is the month, 01 = January, ..., 12 = December. DD is the day, from 01 = 1st day, ..., 31 = 31st day, and YYYY is the year. **If the exact day is unknown, use a "15" (representing mid-month). If only the year is known, use "06" for the month and "30" for the day (representing mid-year).**

Use the date of histologic (biopsy or autopsy) diagnosis whenever available. If a biopsy/autopsy was not performed, the biopsy was non-diagnostic, or the date of the biopsy is not known, enter the date of diagnosis as can best be determined from the available data. **If the biopsy date becomes available after the initial malignancy report has been submitted, update the date of diagnosis using the date of biopsy. Do this only for Section F.** The date of an AIDS-related malignancy in Section C should be the initial date of diagnosis, whether it was clinical or histologic. If a diagnosis is made at autopsy, use the date of death as the date of diagnosis, even if the autopsy was performed the day after death.

#### 4. Methods of Diagnosis

Indicate how the cancer diagnosis was made by completing "a" through "e" for each malignancy. **Only complete "f" if evidence of the malignancy is obtained through a source other than "a" through "e".** Use "c"=Clinical evidence only for clinical diagnoses; use "f"=other if the available records contain only historical reference (i.e. a secondhand report) of a malignancy.

In the first column (Was the procedure performed/available?), code "2"=Yes for each method that was used in making the diagnosis. Code "1"=No for methods which were not used for making the diagnosis, and code "9" if it is unknown whether or not the method was used. Code "2"=Yes next to Clinical evidence (c) if a clinical diagnosis was made.

In the second column (Did the data support the diagnosis?), indicate whether the data from procedures which were performed (column 1 = "2") support the malignancy diagnosis. For biopsy (a), code "2" if the biopsy is "diagnostic of" or "consistent with" the malignancy. Code "9" if the biopsy is not definitive (i.e. language such as "suggestive of" or "suspicious for" is used).

In the third column (Has copy of report been obtained?), indicate whether reports for procedures performed/available (column 1 = "2") have been obtained by circling the appropriate code.

**If the diagnostic method was not performed or it is not known (column 1 = "1" or "9"), then columns 2 and 3 should be left blank.**

#### 5. Progression of Cancer

- a. Indicate whether the cancer has spread to sites in addition to the primary site listed in Item 1 by circling the appropriate code.
- b. If the answer to "a" is yes ("2"), list all sites to which the cancer has progressed. Do not list the primary site which was entered in Item 1. If the participant presents with multiple sites, or if it is impossible to determine the primary site based on the available data, enter all sites here. Use the ICD-0-3 topography codes. Do not enter the ICD-9 codes.

**Note that for Kaposi's sarcoma, "skin" is considered a single site, even if the participant has multiple skin lesions on different parts of his body.** For example, a participant initially develops a Kaposi's sarcoma lesion on the skin of his forehead. A year later, several lesions are found on the skin of his legs and arms. **An update indicating progression of the cancer to the legs and arms should not be submitted; the cancer is limited to one organ, namely the skin, which has already been reported.**

#### 6. Tumor Tissue Availability

Complete "a" through "d" for each malignancy. **Only complete "e" if tissue specimens of a type other than those in "a" through "d" were prepared.** Accessibility is defined as procedure was performed and location of materials is known and may be obtained for review. This includes

materials that are on loan or kept offsite. "Obtained" includes materials kept in local pathology and MACS repositories. If the procedure was not performed, code "1" under the appropriate column.

**Appendix A: MACS Criteria for Clinical Diagnoses**

**NOTE: AIDS illnesses not yet confirmed by medical records should always have a diagnosis status of *probable*.**

CONDITION	DISEASE CODE	DEFINITIVE	PRESUMPTIVE
<b>CMV RADICULOMYELOPATHY</b>	27	<ol style="list-style-type: none"> <li>1. A clinical syndrome such as: decreased lower extremity strength and reflexes.</li> <li>2. Evidence of CMV in the CSF by polymerase chain reaction.</li> </ol> <p align="center"><b>AND</b></p> <ol style="list-style-type: none"> <li>3. Absence of other pathogens.</li> </ol>	<ol style="list-style-type: none"> <li>1. Clinical syndrome such as: decreased lower extremity strength and reflexes.</li> <li>2. Polymorphonuclear pleocytosis.</li> <li>3. Absence of other pathogens.</li> </ol> <p align="center"><b>AND</b></p> <ol style="list-style-type: none"> <li>4. Evidence of CMV viremia by PCR.</li> </ol>
<b>CMV (OTHER)</b>	07	<ol style="list-style-type: none"> <li>1. Microscopy (histology or cytology), culture, or detection of antigen in a specimen obtained directly from the tissues affected or a fluid from those tissues.</li> </ol>	
<b>CMV ENCEPHALITIS</b>	07	<ol style="list-style-type: none"> <li>1. Histological evidence of CMV in brain tissue in the setting of a clinical syndrome with altered sensorium with progressive obtundation presenting acutely or subacutely in the absence of CT/MRI showing findings consistent with toxoplasmosis or lymphoma.</li> </ol>	<ol style="list-style-type: none"> <li>1. Clinical syndrome with altered sensorium with progressive obtundation presenting acutely or subacutely in the absence of CT/MRI showing findings consistent with toxoplasmosis or lymphoma.</li> </ol> <p align="center"><b>AND</b></p> <ol style="list-style-type: none"> <li>2a. CSF positive for CMV by PCR.</li> </ol> <p align="center"><b>AND</b></p> <ol style="list-style-type: none"> <li>2b. CSF culture positive for CMV.</li> </ol> <p align="center"><b>AND</b></p> <ol style="list-style-type: none"> <li>3. No other pathogen to explain syndrome.</li> </ol>

CONDITION	DISEASE CODE	DEFINITIVE	PRESUMPTIVE
<b>CMV ESOPHAGITIS, GASTROENTERITIS, COLITIS, PROCTITIS</b>	07	<ol style="list-style-type: none"> <li>1. At least one symptom:  <b>Esophagitis:</b> retrosternal pain or pain on swallowing, dysphagia.  <b>Gastroenteritis:</b> abdominal pain.  <b>Colitis:</b> abdominal pain and diarrhea (typically small volume associated with mucus and blood).  <b>Proctitis:</b> rectal pain, often associated with tenesmus, mucus and blood.  <b>AND</b> </li> <li>2. Tissue cytology or histopathology showing typical CMV cytopathology or identification of CMV antigen.</li> </ol>	<ol style="list-style-type: none"> <li>1. Endoscopy, colonoscopy or sigmoidoscopy reveals mucosal erythema, erosion or ulceration (or lesion is directly visualized as an oral or perianal ulcer).  <b>AND</b> </li> <li>2. Positive CMV culture from the lesion in the absence of other pathogens or the persistence of symptoms following appropriate treatment for other pathogens.</li> </ol>
<b>CMV PNEUMONITIS</b>	07	<ol style="list-style-type: none"> <li>1. Typical CMV inclusions seen on biopsy or bronchoalveolar lavage specimens, or autopsy.  <b>AND</b> </li> <li>2. Compatible clinical syndrome which must include: hypoxemia and abnormal chest X-ray.</li> </ol>	

CONDITION	DISEASE CODE	DEFINITIVE	PRESUMPTIVE
<b>CMV RETINITIS</b>	08, 28, 29	1. Positive diagnosis by ophthalmologist with findings of white areas with or without hemorrhages and/or gray-white areas of retinal necrosis with or without hemorrhages.	1. Included as likely or probable in differential by ophthalmologist. <b>OR</b> 2a. Diagnosed by non-ophthalmologist. <b>AND</b> 2b. Symptoms stabilized with anti-CMV meds. <b>AND</b> 2c. Evidence of CMV viremia by PCR.
<b>COCCIDIOIDOMYCOSIS (DISSEMINATED, EXTRAPULMONARY DISEASE)</b>	24	<b>EITHER</b> 1. Positive culture for <i>Coccidioides immitis</i> from nonpulmonary site. <b>OR BOTH</b> 2a. Positive serology (either complement fixation [CF] or counter immunoelectrophoresis [CIE]). <b>AND</b> 2b. Compatible clinical syndrome for disseminated disease (extrapulmonary: skin, bone, CNS, etc.).	
<b>CRYPTOCOCCUS - DISSEMINATED</b>	19, 21, 22	1. Identification of Cryptococcus in culture or biopsy from a non-pulmonary source (includes blood, urine, CSF; excludes sputa).	1a. Compatible clinical syndrome (extrapulmonary disease such as renal infection). <b>AND</b> 1b. Positive serum cryptococcal antigen (> 1:8).

CONDITION	DISEASE CODE	DEFINITIVE	PRESUMPTIVE
<b>CRYPTOCOCCUS - MENINGITIS</b>	20	<ol style="list-style-type: none"> <li>1. Positive CSF culture for <i>C. neoformans</i>.</li> <li><b>OR</b></li> <li>2. Positive CSF cryptococcal antigen test.</li> <li><b>OR</b></li> <li>3. Positive meningeal or brain tissue culture or histology for <i>C. neoformans</i>.</li> </ol>	<ol style="list-style-type: none"> <li>1. Compatible clinical syndrome (meningitis – headache, stiff neck, mental status abnormalities, fever, CSF white blood cells, elevated protein or reduced glucose) and positive CSF India ink stain preparation.</li> </ol>
<b>CRYPTOSPORIDIOSIS</b>	04	<ol style="list-style-type: none"> <li>1. Microscopic evidence of cryptosporidium present in either stool, body fluid or tissue specimen.</li> <li><b>AND</b></li> <li>2. Diarrhea.</li> </ol>	
<b>DEMENTIA/ ENCEPHALOPATHY</b>	13	<ol style="list-style-type: none"> <li>1a. Acquired abnormalities in cognitive or motor abilities that interfere with work or activities of daily living that are documented in the medical record.</li> <li><b>OR</b></li> <li>1b. A neuropsych testing report with findings consistent with dementia.</li> <li><b>AND</b></li> <li>2. No etiology determined by laboratory evaluation of CSF (no positive culture or PCR or antigen test from CSF other than HIV).</li> <li>3. No other etiology such as depression or medication side effect noted.</li> <li><b>AND ONE OF THE FOLLOWING</b></li> <li>4a. No etiology detected on CT or MRI imaging of the brain (for example, no masses or stroke).</li> </ol>	<ol style="list-style-type: none"> <li>1. Acquired abnormalities in cognitive abilities (which interfere with work or activities of daily living).</li> <li>2. No other etiology documented (including clinical depression).</li> </ol>

CONDITION	DISEASE CODE	DEFINITIVE	PRESUMPTIVE
		4b. <b>OR</b> No etiology detected at autopsy.	
<b>ESOPHAGEAL CANDIDIASIS</b>	14	1. Endoscopy findings consistent with esophageal candidiasis (+/- culture or histology).	<b>EITHER</b> 1a. Documentation of recent onset of retrosternal pain on swallowing or dysphagia. <b>OR</b> 1b. Reported result of barium swallow consistent with esophageal candidiasis. <b>AND EITHER</b> 2a. Oral candidiasis. <b>OR</b> 2b. Response to specific antifungal therapy.
<b>HISTOPLASMOSIS (DISSEMINATED)</b>	06	1. Positive culture from non-pulmonary source (not lung, sputum, cervical or hilar lymph node). <b>OR</b> 2. Positive histopathology for histoplasma in tissue (not lungs, hilar or cervical lymph node).	1a. Compatible clinical syndrome of disseminated infection (extrapulmonary). <b>AND</b> 1b. Detection of histoplasma antigen in tissue or fluid.
<b>HSV ESOPHAGITIS/ PNEUMONITIS</b>	23	1. Lesion consistent with HSV. <b>AND</b> 2. + HSV culture from lesion. <b>OR</b> 3. HSV antigen detection by immunoassay or DFA antibody stain.	<b>EITHER BOTH</b> 1a. Lesion c/w HSV. 1b. + Tzanck prep from lesion. <b>OR BOTH</b> 2a. Persistent dysphagia, non-responsive to anti-fungal meds. 2b. Persistent signs and symptoms,

CONDITION	DISEASE CODE	DEFINITIVE	PRESUMPTIVE
			responsive to acyclovir therapy.
<b>ISOSPORIASIS</b>	05	1. Microscopic evidence of Isospora present in either stool, body fluid or tissue specimen. <b>AND</b> 2. Diarrhea.	
<b>KAPOSI'S SARCOMA</b>	01	1. Biopsy from any site ever + for KS.	1. Clinical diagnosis by dermatologist, oncologist or HIV clinician.
<b>LYMPHOMA</b>	10, 11	1. Biopsy proven.	
<b>LYMPHOMA, CNS</b>	09	1. Histologic evidence (tissue biopsy, aspirate, or at autopsy). <b>OR</b> 2. Cytologic evidence obtained from CSF.	1. Presence of CNS lesions on imaging scan (CT, SPECT or PET) consistent with lymphoma. <b>AND EITHER</b> 2a. Unresponsive to empiric toxoplasmosis treatment or Toxo IgG Ab negative. <b>OR</b> 2b. Positive Epstein Barr Virus (EBV) PCR.
<b>MAI (other than tuberculosis – Includes MAC, <i>M. Kansasii</i> and others)</b>	15, 17	1. Organism isolated (cultured) from extrapulmonary site: blood, bone marrow, liver, cerebrospinal fluid, or other normally sterile site excluding lung, hilar lymph node and cervical lymph node (other lymph nodes meet definition).	1. Symptomatology/Clinical Syndrome consistent with MAC in a person with a CD4 cell count <50 and response to empiric MAC treatment

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<b>MYCOBACTERIUM KANSASII</b>	17	1. <i>M. kansasii</i> cultured from blood, bone marrow, lymph node, liver, cerebrospinal fluid, or any other normally sterile body fluid, tissue or organ. <b>OR</b> 2. <i>M. kansasii</i> cultured from bronchopulmonary, gastrointestinal, urine, skin, or other non-sterile mucosal sites (as the only pathogen coupled with histopathologic confirmation of AFB/ <i>M. kansasii</i> in tissue specimens from which the culture was derived.	
<b>PCP</b>	02	1. Sputum, BAL, or biopsy specimen + for pneumocystis. <b>AND EITHER</b> 2a. New infiltrate on CXR. <b>OR</b> 2b. New symptoms (cough, SOB).	1. No evidence for definitive bacterial pneumonia. 2. Non-productive cough or dyspnea on exertion with documented onset in past 3 months. <b>AND 1 OF THE FOLLOWING</b> 3a. CXR showing diffuse bilateral interstitial infiltrates 3b. Gallium scan showing diffuse pulmonary disease. <b>AND</b> 4. Evidence of hypoxemia
<b>PROGRESSIVE MULTIFOCAL LEUKOENCEPHALOPATHY (PML)</b>	12	<b>EITHER</b> 1. Biopsy or autopsy positive for PML. <b>OR BOTH</b> 2a. Characteristic lesions on brain imaging. <b>AND</b> 2b. CSF positive for JCV PCR.	1. Consistent neurologic changes. <b>AND EITHER</b> 2. PCR positive for JCV PCR. <b>OR BOTH</b> 3a. Characteristic lesions on initial brain imaging.

CONDITION	DISEASE CODE	DEFINITIVE	PRESUMPTIVE
			3b. Clinical course c/w PML.
<b>PULMONARY CANDIDIASIS</b>	14	1. Histopathology consistent with invasive candidiasis consistent with trachea, bronchi, or lung.	
<b>RECURRENT PNEUMONIA (OTHER THAN PCP OR TB)</b>  <b>More than one episode in a 1-year period</b>	51	1. New or progressive infiltrate on CXR. <b>AND</b> 2a. + Sputum culture for pneumococcus, H. flu, Klebsiella, Staph. Aureus, Pseudomonas, Enterobacter or Legionella or other bacterial pathogens. <b>OR</b> 2b. + Serologic tests for mycoplasma (and no bacterial pathogen found). <b>OR</b> 2c. + Blood or pleural fluid culture (and no other identified source). <b>AND</b> 3. No other non-bacterial cause identified. <b>AND EITHER</b> 4a. Cough or shortness of breath. <b>OR</b> 4b. Respiratory rate >20.	1. No evidence for definitive PCP. 2. Acute onset cough, or dyspnea on exertion or shortness of breath or respiratory rate >20. <b>AND BOTH</b> 3a. New or progressive infiltrates on CXR 3b. Response to antibacterial medications.
<b>SALMONELLOSIS SEPTICEMIA (NON-TYPHOIDAL)</b>	25	1. Non-typhi Salmonella species isolated from blood.	

CONDITION	DISEASE CODE	DEFINITIVE	PRESUMPTIVE
<b>TOXOPLASMOSIS</b>	03	1. Biopsy + for <i>T. gondii</i> .	1. CT or MRI of brain showing 1 or more mass lesions (enhanced by contrast injection, if given). <b>AND</b> 2. Clinical response to anti-toxoplasma medications. <b>AND</b> 3. Serology Toxo IgG antibodies.
<b>TUBERCULOSIS</b>	50	1. Isolation of <i>M. tuberculosis</i> from fluid or tissue.	
<b>WASTING</b>	26	1. Documented weight loss >10% of baseline. <b>AND</b> 2. No concurrent depression, illness, or other condition associated with weight loss.	