4191-02U

SOCIAL SECURITY ADMINISTRATION

20 CFR Part 404

[Docket No. SSA-2011-0098]

RIN 0960-AH43

Revised Medical Criteria for Evaluating Cancer (Malignant Neoplastic Diseases)

AGENCY: Social Security Administration.

ACTION: Notice of proposed rulemaking.

SUMMARY: We propose to revise the criteria in parts A and B of the Listing of Impairments (listings) that we use to evaluate cases involving cancer (malignant neoplastic diseases) in adults and children under titles II and XVI of the Social Security Act (Act). These proposed revisions reflect our adjudicative experience, advances in medical knowledge, and recommendations from medical experts we consulted, as well as public comments we received on methods of evaluating cancer.

DATES: To ensure that your comments are considered, we must receive them no later than [insert date 60 days after date of publication in the FEDERAL REGISTER].

ADDRESSES: You may submit comments by one of three methods—Internet, fax, or mail. Do not submit the same comments multiple times or by more than one method. Regardless of which method you choose, please state that your comments refer to Docket No. SSA-2011-0098 so that we may associate your comments with the correct regulation.

CAUTION: You should be careful to include in your comments only information that you wish to make publicly available. We strongly urge you not to include in your comments any personal information, such as your Social Security number or medical information.

1. Internet: We recommend that you submit your comments via the Internet. Please visit the Federal eRulemaking portal at http://www.regulations.gov. Use the Search function to find docket number SSA-2011-0098. The system will issue a tracking number to confirm your submission. You will not be able to view your comment immediately because we must post each comment manually. It may take up to a week for your comment to be viewable.

2. Fax: Fax comments to (410) 966-2830.

3. Mail: Address your comments to the Office of Regulations and Reports Clearance, Social Security Administration, 107 Altmeyer Building, 6401 Security Boulevard, Baltimore, Maryland 21235-6401.

Comments are available for public viewing on the Federal eRulemaking portal at http://www.regulations.gov, or in person, during regular business hours, by arranging with the contact person identified below.

FOR FURTHER INFORMATION CONTACT: Cheryl A. Williams, Office of Medical Listings Improvement, 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:

What revisions are we proposing?

We propose to:

- Change the name of this body system;

- Add several new listings and revise some current ones;

- Revise the introductory text of these listings to provide more information about how we evaluate cancer and to reflect the new listings; and

- Make editorial changes throughout the rules to make the rules internally consistent.

Why are we proposing to make these changes?

We last issued final rules revising these listings on October 6, 2009, effective November 5, 2009.[1] We stated in the preamble of the final rules that we would continue to monitor these listings and revise them, if warranted, before their eight-year effective period ends in 2017. These proposed revisions reflect our adjudicative experience, advances in medical knowledge, and recommendations from medical experts we consulted. They also reflect public comments we received on a notice of proposed rulemaking (NPRM) that we published in 2008 before issuing the final rules in 2009.[2] We did not address these public comments at the time because they were outside the scope of the 2008 NPRM.

Why are we proposing to change the name of this body system?

We propose to change the name of this body system from "Malignant Neoplastic Diseases" to "Cancer" to improve clarity and ease of use of the listings. While both terms represent the same condition, "cancer" is a more commonly used term, and more recognized by the lay public and by health care professionals. The phrase "malignant neoplastic disease" is a term used almost exclusively, although infrequently, by health care professionals. We would also replace the term "malignant neoplastic diseases" with the term "cancer" in the introductory text and listings.

What changes are we proposing to make in the introductory text of the listings for

[1] 74 FR 51229.
[2] 73 FR 22871 (April 28, 2008). Public comments are available at http://www.regulations.gov/#!docketDetail;rpp=10;po=0;D=SSA-2007-0066.

evaluating cancer in adults?

The following is a detailed explanation of the significant changes we would make to the introductory text:

Proposed section 13.00E—When do we need longitudinal evidence?

We propose to restructure current section 13.00E3 for clarity. We would also add proposed 13.00E3c to clarify how we evaluate cancer treated with multimodal antineoplastic therapy under certain listings. We would explain that we need evidence under current listings 13.02E, 13.11D, and 13.14C to establish that the treating source has initiated multimodal therapy. We also explain that we may defer adjudication if the treating source plans multimodal therapy but has not yet initiated it.

Proposed section 13.00I—What do we mean by the following terms?

We propose several changes in section 13.00I:

- We would add the term "antineoplastic therapy" to the list of defined terms. We would move the definition of "antineoplastic therapy" from current section 13.00B3 to proposed section 13.00I1. This change will make it easier for our adjudicators to find the definition for "antineoplastic therapy." We would renumber the definitions in proposed section 13.00I that follow the definition for "antineoplastic therapy."

- We would revise and expand the definition of the term "persistent" in current section 13.00I4 (proposed section 13.00I5) to reflect how the meaning of this term relates to the outcome of initial antineoplastic therapy. Similarly, we would revise and expand the definition of the term "progressive" in current section 13.00I5 (proposed section 13.00I6) to reflect how its meaning relates to the outcome of therapy.

- We would revise and expand the definition of the term "unresectable" in current section 13.00I7 (proposed section 13.00I8) to explain situations in which positive surgical margins would not indicate unresectable cancer. We propose this change because the initial surgery may be followed by additional surgery that eliminates the positive surgical margins.

Proposed section 13.00K—How do we evaluate specific cancers?

We propose several changes to current section 13.00K:

- We would revise current section 13.00K2b to explain that we consider chronic myelogenous leukemia (CML) to be in the "accelerated" or "blast" phase when the proportion of blast (immature) cells in the peripheral blood or bone marrow is 10 percent or greater. We propose this change in response to questions we have received from our adjudicators.

- We would remove the word "ordinarily" from current section 13.00K2d to clarify that we do not consider an increase in a person's white blood cell count alone to be sufficient evidence to determine the severity of chronic leukemia. The word "ordinarily" may be misinterpreted to mean there are some situations in which an increase in the white blood cell count by itself may determine severity, and this interpretation would be contrary to our intent.

- We would revise and expand current section 13.00K3 to explain that we can evaluate macroglobulinemia or heavy chain disease under current listing 13.05A2. We would make this change to recognize that current medical practice may treat macroglobulinemia as an indolent non-Hodgkin lymphoma. We also explain that we may evaluate macroglobulinemia or heavy chain disease under the appropriate listings in the hematological body system (7.00). We would make a similar change in current section 13.00K2cii to explain that we may evaluate the complications and residual impairments from chronic lymphocytic leukemia under the appropriate listings in the hematological body system.

- We would make two changes to revise and expand current section 13.00K4. First, we would use the broader heading, "Primary breast cancer," rather than the current heading, "Bilateral primary breast cancer." Second, we would add guidance to explain how we evaluate secondary lymphedema resulting from breast cancer treatment under proposed listing 13.10E. We would continue to include guidance in the revised section to explain how we evaluate bilateral primary breast cancer under current listing 13.10A.

- We would reorganize and revise section 13.00K6 to explain why we evaluate specific central nervous system (CNS) cancers by diagnosis alone, unlike other CNS cancers that we evaluate based on a World Health Organization (WHO) grade. We also explain that we use the criteria in listing 13.13 to evaluate "primary central nervous system cancers," which means cancers that originate within the central nervous system, that is, brain and spinal cord cancers.

- We would add section 13.00K7 to explain that we can evaluate primary peritoneal carcinoma in women under current listing 13.23E for ovarian cancer. This change responds to a public comment on the 2008 NPRM that suggested we provide guidance for evaluating this type of cancer. We can evaluate primary peritoneal carcinoma in women under listing 13.23E because the disease course, treatment, and outcome are more similar to ovarian cancer than other cancers. We also explain that we can evaluate primary peritoneal carcinoma in men under current listing 13.15A for malignant mesothelioma because many of these cases in men are similar to malignant mesothelioma.

- We would add section 13.00K8 to explain that current listing 13.24A for recurrent prostate cancer does not include "biochemical recurrence," as measured with the cancer biomarker prostate-specific antigen (PSA). Although the PSA biomarker may track the progression of the person's prostate cancer, we do not consider PSA useful in determining disability because its values do not necessarily correlate with a person's

degree of functional impairment.

- We would add section 13.00K9 to explain that we evaluate any malignant melanoma under proposed new listing 13.29. As we note in our detailed explanation of proposed 13.29 below, malignant melanoma may occur in places besides the skin, such as in the eyes and mucosal membranes. The proposed listing provides comprehensive criteria to reflect the full range of malignant melanomas. We would also explain that we evaluate benign melanoma under the listings in 8.00 or other affected body systems.

Proposed section 13.00L—How do we evaluate cancer treatment by bone marrow or stem cell transplantation, including transplantation using stem cells from umbilical cord blood?

We would revise current section 13.00L to further explain how we evaluate cancers treated with bone marrow or stem cell transplantation, including transplantation using stem cells from umbilical cord blood. We explain that the transplantation must occur before we will evaluate it under the listings. We also explain that we may establish an onset date of disability that is earlier than the date of the transplantation, or the date of first treatment in a treatment regimen that includes transplantation, if an earlier onset date is consistent with the evidence in the case record.

How do we propose to revise the criteria in the listings for evaluating cancer in adults?

We propose to add a criterion in several of the listings for evaluating small-cell (oat cell) carcinoma. We currently only have a listing for small-cell carcinoma in the lungs (listing 13.14). Small-cell carcinoma may originate in places in the body other than the lungs. We would add a criterion for small-cell carcinoma to the listings for these other places.[3] We propose this change in light of our adjudicative experience and the current medical literature establishing that in most instances small-cell carcinomas are of listing-level severity regardless of where they occur in the body.

Proposed listing 13.02—Soft tissue cancers of the head and neck (except salivary glands—13.08—and thyroid gland—13.09).

We propose to revise current listing 13.02 for soft tissue cancer of the head and neck by removing the requirement for persistent disease following initial multimodal antineoplastic therapy from current listing 13.02B. Based on our adjudicative experience and information from medical experts, we believe persistent cancer following a treatment plan using only a single mode of therapy (for example, solely radiation) is also an indication of head and neck cancer of listing-level severity. We would evaluate cancer that is either persistent or recurrent following initial antineoplastic therapy under proposed listing 13.02B. We would delete current listing 13.02C because we would also evaluate recurrent cancer under proposed listing 13.02B. We would also redesignate current listing 13.02D as listing 13.02C.

[3] The criterion for evaluating small-cell (oat cell) carcinoma would be added under these proposed listings: 13.02D for soft tissue cancers of the head and neck; 13.10D for cancer of the breast; 13.15C for cancer of the pleura and mediastinum; 13.16C for cancer of the esophagus or stomach; 13.17C for cancer of the small intestine; 13.18D for cancer of the large intestine; 13.22E for cancer of the urinary bladder; 13.23F for cancers of the female genital tract; and 13.24C for cancers of the prostate gland.

In proposed 13.02B, we also propose to exclude cancer in the true vocal cords that is persistent or recurrent following initial antineoplastic therapy. Physicians often treat cancer at this location with radiation therapy to preserve the larynx, but if the cancer persists or recurs, they are able to remove the cancer with surgery.

Proposed listing 13.03—Skin (except malignant melanoma—13.29).

We would revise current listing 13.03 by adding a criterion, proposed listing 13.03B, to evaluate skin cancer that invades deep extradermal structures, such as skeletal muscle, cartilage, or bone. Skin cancer with these findings is often unresectable. We propose to add this criterion to be consistent with the criteria for other cancers that are unresectable and to recognize the poor prognosis for this condition. We would evaluate malignant melanoma of the skin under proposed listing 13.29, which we explain in more detail below.

Proposed listing 13.05—Lymphoma (including mycosis fungoides, but excluding T-cell lymphoblastic lymphoma—13.06).

We would add proposed listing 13.05A3 for evaluating mantle cell lymphoma (MCL), a high-grade, non-Hodgkin lymphoma. Current medical practice is unable to achieve a long-lasting remission in MCL or significantly increase a person's life

expectancy. Similar to other cancers (for example, liver or gallbladder cancer) with a very poor prognosis, we would consider a person disabled on a confirmed diagnosis of MCL.

Proposed listing 13.10—Breast (except sarcoma—13.04).

Secondary lymphedema that results from breast cancer treatment (for example, radiation treatment) may advance to the point that the person needs surgery to treat the lymphedema and restore the functional use of an upper extremity. We propose to add listing 13.10E to find the person disabled for at least 12 months from the date of this surgery that treated the secondary lymphedema. After that, we would evaluate any residual impairment(s) under the criteria for the affected body system. We propose this new criterion to recognize the debilitating effects of advanced secondary lymphedema, as well as the time needed to recover from the surgery.

Proposed listing 13.12—Maxilla, orbit, or temporal fossa.

We propose to make a minor editorial change to current listing 13.12C by moving the term "base of the skull" to the end of the sentence. We do not intend for the word "base" in this term to apply to the "orbit," "meninges," or "sinuses." We believe the proposed editorial change will make the current sentence structure clearer.

Proposed listing 13.13—Nervous system.

We propose to reorganize and revise current 13.13A. We would list separately in proposed listings 13.13A1 and 13.13A2 highly malignant primary CNS cancers that we consider to be of listing-level severity by diagnosis alone. These CNS cancers include Grade III and Grade IV astrocytomas, and medulloblastoma and other primitive neuroectodermal tumors (PNETs). We would no longer require highly malignant PNETs to have documented metastases. Our adjudicative experience and the current medical literature establish that Grade III and Grade IV PNETs do not respond well to treatment and in most instances have a poor prognosis. We would evaluate all other primary CNS cancers, including low-grade PNETs, under proposed 13.13A3 or 13.13B.

Proposed listing 13.20—Pancreas.

We propose to make a minor editorial change to current listing 13.20B for islet cell cancer of the pancreas in response to questions from our adjudicators. We would reorganize the listing to clarify that the requirement of "physiologically active" cancer applies to tumors that are either inoperable or unresectable.

Proposed listing 13.23—Cancers of the female genital tract—carcinoma or sarcoma (including primary peritoneal carcinoma).

We propose to add listing 13.23B3 for cervical cancer that has spread to distant (for example, para-aortic or supraclavicular) lymph nodes. Current medical literature

establishes that cervical cancer with involvement of distant lymph nodes is associated with a poor prognosis and short-term survival, as well as a high recurrence rate.

We also propose to make a minor editorial change in current listing 13.23E1a for ovarian cancer to clarify that the spread of the cancer beyond the pelvis includes direct extension of the tumor. We currently find claimants who have direct tumor extension to the peritoneal, omental, or bowel surfaces to be disabled based on medical equivalence to the current listing.

Proposed listing 13.29—Malignant melanoma (including skin, ocular, or mucosal melanomas).

We propose to evaluate malignant melanoma separately from other cancers that involve the skin. We would move the criteria for evaluating malignant melanoma in skin from current listing 13.03B to proposed new listing 13.29. We would also evaluate malignant melanoma in the eye (ocular melanoma) and malignant melanoma in mucous membranes (mucosal melanoma) under the proposed listing. This change recognizes that malignant melanoma that originates in the eye or mucous membrane constitutes an impairment of listing-level severity. We also propose an identical listing for evaluating malignant melanoma in children (proposed listing 113.29). We currently find all such children disabled based on medical equivalence to listing 13.03B.

Other proposed changes

We would make nonsubstantive editorial revisions throughout these proposed rules to clarify the introductory text and listings. For example, we propose to change the term "tumor" to "cancer" in the sections of the introductory text where it is obvious that the rules apply to cancerous tumors. These editorial revisions would also include updating the medical terminology in the listings. For example, we would replace the term "Hodgkin's disease" with the term "Hodgkin lymphoma" to reflect how the medical community currently refers to this cancer.

What specific changes are we proposing to make in the introductory text of the listings for evaluating cancer in children?

We propose to make the following changes to the introductory text of the childhood listings that correspond with the changes we are proposing for the introductory text of the adult listings:

- Move the definition for "antineoplastic therapy" from current section 113.00B3 to proposed section 113.00I1.

- Revise the definition of "persistence" in proposed section 113.00I4 and revise the definition of "progressive" in proposed section 113.00I5.

- Revise current section 113.00K2b to explain that CML is in the accelerated or

blast phase if the proportion of blast cells in the peripheral blood or bone marrow is 10 percent or greater.

- Remove the word “ordinarily” in current section 113.00K2d.

- Revise current section 113.00K3 to provide more information about which solid tumor cancers we evaluate under listing 113.03 and which we evaluate under other listings in this body system.

- Revise current section 113.00K4 to explain that we evaluate primary CNS cancers under listing 113.13.We would also list primary CNS cancers that are highly malignant.

- Add guidance in current section 113.00L for evaluating cancers treated with bone marrow or stem cell transplantation, including transplantation using stem cells from umbilical cord blood.

- Make minor editorial changes to make the child introductory text consistent with the adult introductory text.

How do we propose to revise the criteria in the listings for evaluating cancer in children?

We would revise the headings of current listings 113.05 and 113.06 to indicate

that we evaluate all types of lymphoblastic lymphomas (not just the T-cell lymphomas) under 113.06. In making this change in the headings of the current listings, we would remove the specific reference to "T-cell lymphomas" in 113.05 and 113.06. We would also revise current listing 113.05 for evaluating non-Hodgkin lymphoma (NHL) and Hodgkin lymphoma to recognize that these cancers in children require treatment regimens that are very toxic and prolonged when they have spread to the bone marrow or to visceral organs, such as the brain, liver, or lung. With this level of cancer involvement, we would consider a child with NHL or Hodgkin lymphoma to be under a disability for 24 months from the date of diagnosis without regard to the effectiveness of treatment. After that, we would evaluate any residual impairment(s) under the criteria for the affected body system. We are not proposing similar revisions to current listings 13.05 and 13.06 for lymphomas and leukemias in adults. Pediatric lymphomas and leukemias behave differently, as they are more aggressive and more difficult to treat than most adult lymphomas and leukemias.

We would also add proposed listing 113.05D that is the same as the proposed adult listing for evaluating mantle cell lymphoma.

We would add proposed listing 113.13C to evaluate cancers of the CNS in children that are metastatic. We would also use proposed 113.13C to evaluate cancers of the CNS in children that are progressive or recurrent following initial antineoplastic therapy. We currently find disabled all children with the CNS cancer described in the proposed listing based on medical equivalence to current listing 13.13A2.

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.[4]

How long would these proposed rules be effective?

If we publish these proposed rules as final rules, they would remain in effect for 5 years after the date they become effective, unless we extend them, or revise and issue them again.

Clarity of These Proposed Rules

Executive Order 12866, as supplemented by Executive Order 13563, requires each agency to write all rules in plain language. In addition to your substantive comments on these proposed rules, we invite your comments on how to make them easier to understand.

For example:

- Would more, but shorter sections be better?
- Are the requirements in the rules clearly stated?

[4] Sections 205(a), 702(a)(5), and 1631(d)(1) of the Act.

- Have we organized the material to suit your needs?
- Could we improve clarity by adding tables, lists, or diagrams?
- What else could we do to make the rules easier to understand?
- Do the rules contain technical language or jargon that is not clear?
- Would a different format make the rules easier to understand, such as grouping and order of sections, use of headings, paragraphing?

When will we start to use these rules?

We will not use these rules until we evaluate public comments and publish final rules in the Federal Register. All final rules we issue include an effective date. We will continue to use our current rules until that date. If we publish final rules, we will include a summary of the relevant comments we received, along with responses, and an explanation of how we will apply the new rules.

Regulatory Procedures

Executive Order 12866, as supplemented by Executive Order 13563

We consulted with the Office of Management and Budget (OMB) and determined that these proposed rules meet the criteria for a significant regulatory action under Executive Order 12866, as supplemented by Executive Order 13563. Therefore, OMB reviewed them.

Regulatory Flexibility Act

We certify that these proposed rules would not have a significant economic impact on a substantial number of small entities because they affect individuals only. Therefore, the Regulatory Flexibility Act, as amended, does not require us to prepare a regulatory flexibility analysis.

Paperwork Reduction Act

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

References

We consulted the following references when we developed these proposed rules:

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Yii, N.W., et al., Mucosal malignant melanoma of the head and neck: The Marsden experience over half a century, Clinical Oncology, Jun;15(4), 199-204 (2003).

We included these references in the rulemaking record for these proposed rules and will make them available for inspection by interested individuals who make arrangements with the contact person above.

(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.

Dated: December 6, 2013

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Carolyn W. Colvin,
Acting Commissioner of Social Security.

For the reasons set out in the preamble, we propose to amend 20 CFR chapter III 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 as follows:

a. Revise item 14 of the introductory text before part A of appendix 1.

b. Amend part A by revising the body system name for section 13.00 in the table of contents.

c. Revise section 13.00 of part A of appendix 1.

d. Amend listing 13.02 of part A of appendix 1 by revising the heading, revising current listing 13.02B, deleting current listing 13.02C, redesignating current listing 13.02D as 13.02C, and adding new listings 13.02D and 13.02E.

e. Amend listing 13.03 of part A of appendix 1 by revising listing 13.03B.

f. Amend listing 13.05 of part A of appendix 1 by revising listing 13.05A2, adding listing 13.05A3 and replacing the word “disease” with the word “lymphoma” in listing 13.05B.

g. Amend listing 13.06 of part A of appendix 1 by adding a cross-reference in the first sentence of listing 13.06B1.

h. Amend listing 13.10 of part A of appendix 1 by revising 13.10A, adding the word “OR” after listing 13.10C, and adding listings 13.10D and 13.10E.

i. Amend listing 13.11 of part A of appendix 1 by replacing the word “tumor” in listing 13.11B with the word “cancer” and the word “tumors” in listing 13.11D with the word “cancers,” and adding a cross-reference to the first sentence of listing 13.11D.

j. Amend listing 13.12 of part A of appendix 1 by revising 13.12C.

k. Revise listing 13.13 of part A of appendix 1.

l. Amend listing 13.14 of part A of appendix 1 by adding a cross-reference in the first sentence of listing 13.14C.

m. Amend listing 13.15 of part A of appendix 1 by adding the word “OR” after listing 13.15B, and adding listing 13.15C.

n. Amend listing 13.16 of part A of appendix 1 by adding the word “OR” after listing 13.16B, and adding listing 13.16C.

o. Amend listing 13.17 of part A of appendix 1 by adding the word “OR” after listing 13.17B, and adding listing 13.17C.

p. Amend listing 13.18 of part A of appendix 1 by adding the word “OR” after listing 13.18C, and adding listing 13.18D.

q. Amend listing 13.19 of part A of appendix 1 by replacing the word “tumors” with the word “cancer.”

r. Amend listing 13.20 of part A of appendix 1 by revising listing 13.20B.

s. Amend listing 13.22 of part A of appendix 1 by adding the word “OR” after listing 13.22D, and adding listing 13.22E.

t. Amend listing 13.23 of part A of appendix 1 by revising listings 13.23B and 13.23E, adding the word “OR” after listing 13.23E, and adding listing 13.23F.

u. Amend listing 13.24 of part A of appendix 1 by revising listing 13.24A, adding the word “OR” after listing 13.24B, and adding listing 13.24C.

v. Amend listing 13.25 of part A of appendix 1 by replacing the word “tumor” with the word “cancer.”

w. Amend listing 13.28 of part A of appendix 1 by replacing the phrase “malignant neoplastic diseases” with the word “cancer.”

x. Add listing 13.29 after listing 13.28 of part A of appendix 1.

y. Revise section 113.00 of part B of appendix 1.

z. Amend listing 113.03 of part B of appendix 1 by changing the phrase “2 years” to the phrase “24 months” in listings 113.03A and 113.03B.

aa. Amend listing 113.05 of part B of appendix 1 by revising listings 113.05A and

113.05B, adding the word “OR” after listing 113.05C, and adding listing 113.05D.

bb. Amend listing 113.06 of part B of appendix 1 by revising the first sentence of listing 113.06A and adding a cross-reference to the first sentence of listing 113.06B1.

cc. Revise listing 113.13 of part B of appendix 1.

dd. Add listing 113.29 after listing 113.21 of part B of appendix 1.

The revisions and additions read as follows:

Appendix 1 to Subpart P of Part 404—Listing of Impairments

* * * * *

14. Cancer (Malignant Neoplastic Diseases) (13.00 and 113.00): [DATE 5 YEARS AFTER EFFECTIVE DATE OF THE FINAL RULE].

* * * * *

Part A

* * * * *

13.00 Cancer (Malignant Neoplastic Diseases)

* * * * *

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. If you have HIV infection, we use the criteria in 14.08E to evaluate carcinoma of the cervix, Kaposi sarcoma, lymphoma, and squamous cell carcinoma of the anal canal and anal margin.

B. What do we consider when we evaluate cancer under these listings? We will consider factors including:

1. Origin of the cancer.

2. Extent of involvement.

3. Duration, frequency, and response to antineoplastic therapy.

4. Effects of any post-therapeutic residuals.

C. How do we apply these listings? We apply the criteria in a specific listing to a cancer originating from that specific site.

D. What evidence do we need?

1. We need medical evidence that specifies the type, extent, and site of the primary, recurrent, or metastatic lesion. When the primary site cannot be identified, we will use evidence documenting the site(s) of metastasis to evaluate the impairment under 13.27.

2. For operative procedures, including a biopsy or a needle aspiration, we generally need a copy of both the:

a. Operative note, and

b. Pathology report.

3. When we cannot get these documents, we will accept the summary of hospitalization(s) or other medical reports. This evidence should include details of the findings at surgery and, whenever appropriate, the pathological findings.

4. In some situations, we may also need evidence about recurrence, persistence, or

progression of the cancer, the response to therapy, and any significant residuals. (See 13.00G.)

E. When do we need longitudinal evidence?

1. Cancer with distant metastases. We generally do not need longitudinal evidence for cancer that has metastasized beyond the regional lymph nodes because this cancer usually meets the requirements of a listing. Exceptions are for cancer with distant metastases that we expect to respond to antineoplastic therapy. For these exceptions, we usually need a longitudinal record of 3 months after therapy starts to determine whether the therapy achieved its intended effect, and whether this effect is likely to persist.

2. Other cancers. When there are no distant metastases, many of the listings require that we consider your response to initial antineoplastic therapy; that is, the initial planned treatment regimen. This therapy may consist of a single modality or a combination of modalities; that is, multimodal therapy. (See 13.00I4.)

3. Types of treatment.

a. Whenever the initial planned therapy is a single modality, enough time must pass to allow a determination about whether the therapy will achieve its intended effect. If the treatment fails, the failure often happens within 6 months after treatment starts, and there will often be a change in the treatment regimen.

b. Whenever the initial planned therapy is multimodal, we usually cannot make a determination about the effectiveness of the therapy until we can determine the effects of all the planned modalities. In some cases, we may need to defer adjudication until we can assess the effectiveness of therapy. However, we do not need to defer adjudication to determine whether the therapy will achieve its intended effect if we can make a fully favorable determination or decision based on the length and effects of therapy, or the residuals of the cancer or therapy (see 13.00G).

c. We need evidence under 13.02E, 13.11D, and 13.14C to establish that your treating source initiated multimodal antineoplastic therapy. We do not need to make a determination about the length or effectiveness of your therapy. Multimodal therapy has been initiated, and satisfies the requirements in 13.02E, 13.11D, and 13.14C, when your treating source starts the first modality. We may defer adjudication if your treating source plans multimodal therapy and has not yet initiated it.

F. How do we evaluate impairments that do not meet one of the cancer listings?

1. These listings are only examples of cancer that we consider severe enough to prevent you from doing any gainful activity. If your severe impairment(s) does not meet the criteria of any of these listings, we must also consider whether you have an impairment(s) that meets the criteria of a listing in another body system.

2. If you have a severe medically determinable impairment(s) that does not meet a listing, we will determine whether your impairment(s) medically equals a listing. (See §§404.1526 and 416.926 of this chapter.) If your impairment(s) does not meet or medically equal a listing, you may or may not have the residual functional capacity to engage in substantial gainful activity. In that situation, we proceed to the fourth, and, if necessary, the fifth steps of the sequential evaluation process in §§404.1520 and 416.920 of this chapter. We use the rules in §§404.1594 and 416.994 of this chapter, as appropriate, when we decide whether you continue to be disabled.

G. How do we consider the effects of antineoplastic therapy?

1. How we consider the effects of antineoplastic therapy under the listings. In many cases, cancers meet listing criteria only if the therapy is not effective and the cancer persists, progresses, or recurs. However, as explained in the following paragraphs, we will not delay adjudication if we can make a fully favorable determination or decision based on the evidence in the case record.

2. Effects can vary widely.

a. We consider each case on an individual basis because the therapy and its toxicity may vary widely. We will request a specific description of the therapy, including these items:

i. Drugs given.

ii. Dosage.

iii. Frequency of drug administration.

iv. Plans for continued drug administration.

v. Extent of surgery.

vi. Schedule and fields of radiation therapy.

b. We will also request a description of the complications or adverse effects of therapy, such as the following:

i. Continuing gastrointestinal symptoms.

ii. Persistent weakness.

iii. Neurological complications.

iv. Cardiovascular complications.

v. Reactive mental disorders.

3. Effects of therapy may change. The severity of the adverse effects of antineoplastic therapy may change during treatment; therefore, enough time must pass to allow us to evaluate the therapy's effect. The residual effects of treatment are temporary in most instances; however, on occasion, the effects may be disabling for a consecutive period of at least 12 months.

4. When the initial antineoplastic therapy is effective. We evaluate any post-therapeutic residual impairment(s) not included in these listings under the criteria for the affected body system. We must consider any complications of therapy. When the residual impairment(s) does not meet or medically equal a listing, we must consider its effect on your ability to do substantial gainful activity.

H. How long do we consider your impairment to be disabling?

1. In some listings, we specify that we consider your impairment to be disabling until a particular point in time (for example, at least 12 months from the date of diagnosis). We may consider your impairment to be disabling beyond this point when the medical and other evidence justifies it.

2. When a listing does not contain such a specification, we will consider an impairment(s) that meets or medically equals a listing in this body system to be disabling

until at least 3 years after onset of complete remission. When the impairment(s) has been in complete remission for at least 3 years, that is, the original tumor or a recurrence (or relapse) and any metastases have not been evident for at least 3 years, the impairment(s) will no longer meet or medically equal the criteria of a listing in this body system.

3. Following the appropriate period, we will consider any residuals, including residuals of the cancer or therapy (see 13.00G), in determining whether you are disabled. If you have a recurrence or relapse of your cancer, your impairment may meet or medically equal one of the listings in this body system again.

I. What do we mean by the following terms?

1. Antineoplastic therapy means surgery, radiation, chemotherapy, hormones, immunotherapy, or bone marrow or stem cell transplantation. When we refer to surgery as an antineoplastic treatment, we mean surgical excision for treatment, not for diagnostic purposes.

2. Inoperable means surgery is thought to be of no therapeutic value or the surgery cannot be performed; for example, when you cannot tolerate anesthesia or surgery because of another impairment(s), or you have a cancer that is too large or that has invaded crucial structures. This term does not include situations in which your cancer could have been surgically removed but another method of treatment was chosen; for example, an attempt at organ preservation. Your physician may determine whether the

cancer is inoperable before or after you receive neoadjuvant therapy. Neoadjuvant therapy is antineoplastic therapy, such as chemotherapy or radiation, given before surgery in order to reduce the size of the cancer.

3. Metastases means the spread of cancer cells by blood, lymph, or other body fluid. This term does not include the spread of cancer cells by direct extension of the cancer to other tissues or organs.

4. Multimodal therapy means antineoplastic therapy that is given as a combination of at least two types of treatment given in close proximity as a unified whole and usually planned before any treatment has begun. There are three types of treatment modalities: surgery, radiation, and systemic drug therapy (chemotherapy, hormone therapy, and immunotherapy or biological modifier therapy). Examples of multimodal therapy include:

a. Surgery followed by chemotherapy or radiation.

b. Chemotherapy followed by surgery.

c. Chemotherapy and concurrent radiation.

5. Persistent means the planned initial antineoplastic therapy failed to achieve a complete remission of your cancer; that is, your cancer is evident, even if smaller, after

the therapy has ended.

6. Progressive means the cancer becomes more extensive after treatment; that is, there is evidence that your cancer is growing after you have completed at least half of your planned initial antineoplastic therapy.

7. Recurrent or relapse means the cancer that was in complete remission or entirely removed by surgery has returned.

8. Unresectable means surgery or surgeries did not completely remove the cancer. This term includes situations in which your cancer is incompletely resected or the surgical margins are positive. It does not include situations in which there is a finding of a positive margin(s) if additional surgery obtains a margin(s) that is clear. It also does not include situations in which the cancer is completely resected but you are receiving adjuvant therapy. Adjuvant therapy is antineoplastic therapy, such as chemotherapy or radiation, given after surgery in order to eliminate any remaining cancer cells or lessen the chance of recurrence.

J. Can we establish the existence of a disabling impairment prior to the date of the evidence that shows the cancer satisfies the criteria of a listing? Yes. We will consider factors such as:

1. The type of cancer and its location.

2. The extent of involvement when the cancer was first demonstrated.

3. Your symptoms.

K. How do we evaluate specific cancers?

1. Lymphoma.

a. Many indolent (non-aggressive) lymphomas are controlled by well-tolerated treatment modalities, although the lymphomas may produce intermittent symptoms and signs. We may defer adjudicating these cases for an appropriate period after therapy is initiated to determine whether the therapy will achieve its intended effect, which is usually to stabilize the disease process. (See 13.00E3.) Once your disease stabilizes, we will assess severity based on the extent of involvement of other organ systems and residuals from therapy.

b. A change in therapy for indolent lymphomas is usually an indicator that the therapy is not achieving its intended effect. However, your impairment will not meet the requirements of 13.05A2 if your therapy is changed solely because you or your physician chooses to change it and not because of a failure to achieve stability.

c. We consider Hodgkin lymphoma that recurs more than 12 months after

completing initial antineoplastic therapy to be a new disease rather than a recurrence.

2. Leukemia.

a. Acute leukemia. The initial diagnosis of acute leukemia, including the accelerated or blast phase of chronic myelogenous (granulocytic) leukemia, is based on definitive bone marrow examination. Additional diagnostic information is based on chromosomal analysis, cytochemical and surface marker studies on the abnormal cells, or other methods consistent with the prevailing state of medical knowledge and clinical practice. Recurrent disease must be documented by peripheral blood, bone marrow, or cerebrospinal fluid examination, or by testicular biopsy. The initial and follow-up pathology reports should be included.

b. Chronic myelogenous leukemia (CML). We need a diagnosis of CML based on documented granulocytosis, including immature forms such as differentiated or undifferentiated myelocytes and myeloblasts, and a chromosomal analysis that demonstrates the Philadelphia chromosome. In the absence of a chromosomal analysis, or if the Philadelphia chromosome is not present, the diagnosis may be made by other methods consistent with the prevailing state of medical knowledge and clinical practice. The requirement for CML in the accelerated or blast phase is met in 13.06B if laboratory findings show the proportion of blast (immature) cells in the peripheral blood or bone marrow is 10 percent or greater.

c. Chronic lymphocytic leukemia.

i. We require the diagnosis of chronic lymphocytic leukemia (CLL) to be documented by evidence of a chronic lymphocytosis of at least 10,000 cells/mm^3 for 3 months or longer, or other acceptable diagnostic techniques consistent with the prevailing state of medical knowledge and clinical practice.

ii. We evaluate the complications and residual impairment(s) from CLL under the appropriate listings, such as 13.05A2 or the hematological listings (7.00).

d. Elevated white cell count. In cases of chronic leukemia (either myelogenous or lymphocytic), an elevated white cell count, in itself, is not a factor in determining the severity of the impairment.

3. Macroglobulinemia or heavy chain disease. We require the diagnosis of these diseases to be confirmed by protein electrophoresis or immunoelectrophoresis. We evaluate the resulting impairment(s) under the appropriate listings, such as 13.05A2 or the hematological listings (7.00).

4. Primary breast cancer.

a. We evaluate bilateral primary breast cancer (synchronous or metachronous) under 13.10A, which covers local primary disease, and not as a primary disease that has

metastasized.

b. We evaluate secondary lymphedema that results from antineoplastic therapy for breast cancer under 13.10E if the lymphedema is treated by surgery to salvage or restore the functioning of an upper extremity. Secondary lymphedema is edema that results from obstruction or destruction of normal lymphatic channels. We may not restrict our determination of the onset of disability to the date of the surgery; we may establish an earlier onset date of disability if the evidence in your case record supports such a finding.

5. Carcinoma-in-situ. Carcinoma-in-situ, or preinvasive carcinoma, usually responds to treatment. When we use the term "carcinoma" in these listings, it does not include carcinoma-in-situ.

6. Primary central nervous system (CNS) cancers. We use the criteria in 13.13 to evaluate cancers that originate within the CNS (that is, brain and spinal cord cancers).

a. The CNS cancers listed in 13.13A1 are highly malignant and respond poorly to treatment, and therefore we do not require additional criteria to evaluate them.

b. We consider a CNS tumor to be malignant if it is classified as Grade II, Grade III, or Grade IV under the World Health Organization (WHO) classification of tumors of the CNS (WHO Classification of Tumours of the Central Nervous System, 2007).

c. We evaluate benign (Grade I) CNS tumors under 11.05. We evaluate metastasized CNS cancers from non-CNS sites under the primary cancers (see 13.00C). We evaluate any complications of CNS cancers, such as resultant neurological or psychological impairments, under the criteria for the affected body system.

7. Primary peritoneal carcinoma. We use the criteria in 13.23E to evaluate primary peritoneal carcinoma in women because this cancer is often indistinguishable from ovarian cancer and is generally treated the same way as ovarian cancer. We use the criteria in 13.15A to evaluate primary peritoneal carcinoma in men because many of these cases are similar to malignant mesothelioma.

8. Prostate cancer. We exclude "biochemical recurrence" in 13.24A, which is defined as an increase in the serum prostate-specific antigen (PSA) level following the completion of antineoplastic therapy. We need corroborating evidence to document recurrence, such as radiological studies or findings on physical examination.

9. Melanoma. We evaluate malignant melanoma that affects the skin (cutaneous melanoma), eye (ocular melanoma), or mucosal membranes (mucosal melanoma) under 13.29. We evaluate melanoma that is not malignant that affects the skin (benign melanocytic tumor) under the listings in 8.00 or other affected body systems.

L. How do we evaluate cancer treated by bone marrow or stem cell transplantation, including transplantation using stem cells from umbilical cord blood?

Bone marrow or stem cell transplantation is performed for a variety of cancers. We require the transplantation occur before we evaluate it under these listings. We do not need to restrict our determination of the onset of disability to the date of the transplantation (13.05, 13.06, or 13.07) or the date of first treatment under the treatment plan that includes transplantation (13.28). We may be able to establish an earlier onset date of disability due to your transplantation if the evidence in your case record supports such a finding.

1. Acute leukemia (including T-cell lymphoblastic lymphoma) or accelerated or blast phase of CML. If you undergo bone marrow or stem cell transplantation for any of these disorders, we will consider you to be disabled until at least 24 months from the date of diagnosis or relapse, or at least 12 months from the date of transplantation, whichever is later.

2. Lymphoma, multiple myeloma, or chronic phase of CML. If you undergo bone marrow or stem cell transplantation for any of these disorders, we will consider you to be disabled until at least 12 months from the date of transplantation.

3. Other cancers. We will evaluate any other cancer treated with bone marrow or stem cell transplantation under 13.28, regardless of whether there is another listing that addresses that impairment. The length of time we will consider you to be disabled depends on whether you undergo allogeneic or autologous transplantation.

a. Allogeneic bone marrow or stem cell transplantation. If you undergo allogeneic transplantation (transplantation from an unrelated donor or a related donor other than an identical twin), we will consider you to be disabled until at least 12 months from the date of transplantation.

b. Autologous bone marrow or stem cell transplantation. If you undergo autologous transplantation (transplantation of your own cells or cells from your identical twin (syngeneic transplantation)), we will consider you to be disabled until at least 12 months from the date of the first treatment under the treatment plan that includes transplantation. The first treatment usually refers to the initial therapy given to prepare you for transplantation.

4. Evaluating disability after the appropriate time period has elapsed. We consider any residual impairment(s), such as complications arising from:

a. Graft-versus-host (GVH) disease.

b. Immunosuppressant therapy, such as frequent infections.

c. Significant deterioration of other organ systems.

13.01 Category of Impairments, Cancer (Malignant Neoplastic Diseases)

13.02 Soft tissue cancers of the head and neck (except salivary glands--13.08--and thyroid gland--13.09).

* * * * *

B. Persistent or recurrent disease following initial antineoplastic therapy, except persistence or recurrence in the true vocal cord.

OR

C. With metastases beyond the regional lymph nodes.

OR

D. Small-cell (oat cell) carcinoma.

OR

E. Soft tissue cancers originating in the head and neck treated with multimodal antineoplastic therapy (see 13.00E3c). Consider under a disability until at least 18 months from the date of diagnosis. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

13.03 Skin (except malignant melanoma--13.29).

* * * * *

B. Carcinoma invading deep extradermal structures (for example, skeletal muscle, cartilage, or bone).

* * * * *

13.05 Lymphoma (including mycosis fungoides, but excluding T-cell lymphoblastic lymphoma--13.06). (See 13.00K1 and 13.00K2c.)

A. Non-Hodgkin lymphoma, as described in 1, 2, or 3:

* * * * *

2. Indolent lymphoma (including mycosis fungoides and follicular small cleaved cell) requiring initiation of more than one (single mode or multimodal) antineoplastic treatment regimen within a period of 12 consecutive months. Consider under a disability from at least the date of initiation of the treatment regimen that failed within 12 months.

3. Mantle cell lymphoma.

OR

B. Hodgkin lymphoma with failure to achieve clinically complete remission, or recurrent disease within 12 months of completing initial antineoplastic therapy.

* * * * *

13.06 Leukemia. (See 13.00K2.)

* * * * *

B. * * *

1. Accelerated or blast phase (see 13.00K2b).

* * * * *

13.10 Breast (except sarcoma--13.04). (See 13.00K4.)

A. Locally advanced cancer (inflammatory carcinoma, cancer of any size with direct extension to the chest wall or skin, or cancer of any size with metastases to the ipsilateral internal mammary nodes).

* * * * *

C. * * *

OR

D. Small-cell (oat cell) carcinoma.

OR

E. With secondary lymphedema that is caused by antineoplastic therapy and treated by surgery to salvage or restore the functioning of an upper extremity. (See 13.00K4b.) Consider under a disability until at least 12 months from the date of the surgery that treated the secondary lymphedema. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

13.11 Skeletal system--sarcoma.

* * * * *

B. Recurrent cancer (except local recurrence) after initial antineoplastic therapy.

* * * * *

D. All other cancers originating in bone with multimodal antineoplastic therapy (see 13.00E3c). Consider under a disability for 12 months from the date of diagnosis. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

13.12 Maxilla, orbit, or temporal fossa.

* * * * *

C. Cancer with extension to the orbit, meninges, sinuses, or base of the skull.

13.13 Nervous system. (See 13.00K6.)

A. Primary central nervous system (CNS; that is, brain and spinal cord) cancers, as described in 1, 2, or 3:

1. Glioblastoma multiforme, ependymoblastoma, and diffuse intrinsic brain stem gliomas (see 13.00K6a).

2. Any Grade III or Grade IV CNS cancer (see 13.00K6b), including astrocytomas, sarcomas, and medulloblastoma and other primitive neuroectodermal tumors (PNETs).

3. Any primary CNS cancer, as described in a or b:

a. Metastatic.

b. Progressive or recurrent following initial antineoplastic therapy.

OR

B. Primary peripheral nerve or spinal root cancers, as described in 1 or 2:

1. Metastatic.

2. Progressive or recurrent following initial antineoplastic therapy.

13.14 Lungs.

* * * * *

C. Carcinoma of the superior sulcus (including Pancoast tumors) with multimodal antineoplastic therapy (see 13.00E3c). Consider under a disability until at least 18 months from the date of diagnosis. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

13.15 Pleura or mediastinum.

* * * * *

B. * * *

OR

C. Small-cell (oat cell) carcinoma.

13.16 Esophagus or stomach.

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B. * * *

OR

C. Small-cell (oat cell) carcinoma.

13.17 Small intestine--carcinoma, sarcoma, or carcinoid.

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B. * * *

OR

C. Small-cell (oat cell) carcinoma.

13.18 Large intestine (from ileocecal valve to and including anal canal).

* * * * *

C. * * *

OR

D. Small-cell (oat cell) carcinoma.

13.19 Liver or gallbladder--cancer of the liver, gallbladder, or bile ducts.

13.20 Pancreas.

* * * * *

B. Islet cell carcinoma that is physiologically active and is either inoperable or unresectable.

* * * * *

13.22 Urinary bladder—carcinoma.

* * * * *

D. * * *

OR

E. Small-cell (oat cell) carcinoma.

13.23 Cancers of the female genital tract--carcinoma or sarcoma (including primary peritoneal carcinoma).

* * * * *

B. Uterine cervix, as described in 1, 2, or 3:

1. Extending to the pelvic wall, lower portion of the vagina, or adjacent or distant organs.

2. Persistent or recurrent following initial antineoplastic therapy.

3. With metastases to distant (for example, para-aortic or supraclavicular) lymph nodes.

* * * * *

E. Ovaries, as described in 1 or 2:

1. All cancers except germ-cell cancers, with at least one of the following:

a. Extension beyond the pelvis; for example, implants on, or direct extension to, peritoneal, omental, or bowel surfaces.

b. Metastases to or beyond the regional lymph nodes.

c. Recurrent following initial antineoplastic therapy.

2. Germ-cell cancers--progressive or recurrent following initial antineoplastic therapy.

OR

F. Small-cell (oat cell) carcinoma.

13.24 Prostate gland--carcinoma.

A. Progressive or recurrent (not including biochemical recurrence) despite initial hormonal intervention. (See 13.00K8.)

OR

B. * * *

OR

C. Small-cell (oat cell) carcinoma.

13.25 Testicles--cancer with metastatic disease progressive or recurrent following initial chemotherapy.

* * * * *

13.28 Cancer treated by bone marrow or stem cell transplantation. (See 13.00L.)

* * * * *

13.29 Malignant melanoma (including skin, ocular, or mucosal melanomas), as described in either A or B:

A. Recurrent (except an additional primary melanoma at a different site, which is not considered to be recurrent disease) following either 1, 2, or 3:

1. Wide excision (skin melanoma).

2. Enucleation of the eye (ocular melanoma).

3. Complete surgical excision (mucosal melanoma).

OR

B. With metastases as described in 1, 2, or 3:

1. Metastases to one or more clinically apparent nodes; that is, nodes that are detected by imaging studies (excluding lymphoscintigraphy) or by clinical evaluation (palpable).

2. If the nodes are not clinically apparent, with metastases to four or more nodes.

3. Metastases to adjacent skin (satellite lesions) or distant sites.

* * * * *

Part B

* * * * *

113.00 Cancer (Malignant Neoplastic Diseases)

* * * * *

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. If you have HIV infection, we use the criteria in 114.08E to evaluate carcinoma of the cervix, Kaposi sarcoma, lymphoma, and squamous cell carcinoma of the anal canal and anal margin.

B. What do we consider when we evaluate cancer under these listings? We will consider factors including:

1. Origin of the cancer.

2. Extent of involvement.

3. Duration, frequency, and response to antineoplastic therapy.

4. Effects of any post-therapeutic residuals.

C. How do we apply these listings? We apply the criteria in a specific listing to a cancer originating from that specific site.

D. What evidence do we need?

1. We need medical evidence that specifies the type, extent, and site of the primary, recurrent, or metastatic lesion. In the rare situation in which the primary site cannot be identified, we will use evidence documenting the site(s) of metastasis to evaluate the impairment under 13.27 in part A.

2. For operative procedures, including a biopsy or a needle aspiration, we generally need a copy of both the:

a. Operative note, and

b. Pathology report.

3. When we cannot get these documents, we will accept the summary of hospitalization(s) or other medical reports. This evidence should include details of the findings at surgery and, when appropriate, the pathological findings.

4. In some situations, we may also need evidence about recurrence, persistence, or progression of the cancer, the response to therapy, and any significant residuals. (See 113.00G.)

E. When do we need longitudinal evidence?

1. Cancer with distant metastases. Most cancer of childhood consists of a local lesion with metastases to regional lymph nodes and, less often, distant metastases. We generally do not need longitudinal evidence for cancer that has metastasized beyond the regional lymph nodes because this cancer usually meets the requirements of a listing. Exceptions are for cancer with distant metastases that is expected to respond to antineoplastic therapy. For these exceptions, we usually need a longitudinal record of 3 months after therapy starts to determine whether the therapy achieved its intended effect, and whether this effect is likely to persist.

2. Other cancers. When there are no distant metastases, many of the listings require that we consider your response to initial antineoplastic therapy; that is, the initial planned treatment regimen. This therapy may consist of a single modality or a combination of modalities; that is, multimodal therapy (see 113.00I3).

3. Types of treatment.

a. Whenever the initial planned therapy is a single modality, enough time must pass to allow a determination about whether the therapy will achieve its intended effect. If the treatment fails, the failure often happens within 6 months after treatment starts, and there will often be a change in the treatment regimen.

b. Whenever the initial planned therapy is multimodal, we usually cannot make a determination about the effectiveness of the therapy until we can determine the effects of all the planned modalities. In some cases, we may need to defer adjudication until we can assess the effectiveness of therapy. However, we do not need to defer adjudication to determine whether the therapy will achieve its intended effect if we can make a fully favorable determination or decision based on the length and effects of therapy, or the residuals of the cancer or therapy (see 113.00G).

F. How do we evaluate impairments that do not meet one of the cancer listings?

1. These listings are only examples of cancers that we consider severe enough to result in marked and severe functional limitations. If your severe impairment(s) does not meet the criteria of any of these listings, we must also consider whether you have an impairment(s) that meets the criteria of a listing in another body system.

2. If you have a severe medically determinable impairment(s) that does not meet a listing, we will determine whether your impairment(s) medically equals a listing. (See §§404.1526 and 416.926 of this chapter.) If it does not, we will also consider whether you have an impairment(s) that functionally equals the listings. (See §416.926a of this chapter.) We use the rules in §416.994a of this chapter when we decide whether you continue to be disabled.

G. How do we consider the effects of antineoplastic therapy?

1. How we consider the effects of therapy under the listings. In many cases, cancers meet listing criteria only if the therapy is not effective and the cancer persists, progresses, or recurs. However, as explained in the following paragraphs, we will not delay adjudication if we can make a fully favorable determination or decision based on the evidence in the case record.

2. Effects can vary widely.

a. We consider each case on an individual basis because the therapy and its toxicity may vary widely. We will request a specific description of the therapy, including these items:

i. Drugs given.

ii. Dosage.

iii. Frequency of drug administration.

iv. Plans for continued drug administration.

v. Extent of surgery.

vi. Schedule and fields of radiation therapy.

b. We will also request a description of the complications or adverse effects of therapy, such as the following:

i. Continuing gastrointestinal symptoms.

ii. Persistent weakness.

iii. Neurological complications.

iv. Cardiovascular complications.

v. Reactive mental disorders.

3. Effects of therapy may change. The severity of the adverse effects of antineoplastic therapy may change during treatment; therefore, enough time must pass to allow us to evaluate the therapy's effect. The residual effects of treatment are temporary in most instances; however, on occasion, the effects may be disabling for a consecutive period of at least 12 months.

4. When the initial antineoplastic therapy is effective. We evaluate any post-therapeutic residual impairment(s) not included in these listings under the criteria for the affected body system. We must consider any complications of therapy. When the residual impairment(s) does not meet a listing, we must consider whether it medically equals a listing, or, as appropriate, functionally equals the listings.

H. How long do we consider your impairment to be disabling?

1. In some listings, we specify that we will consider your impairment to be disabling until a particular point in time (for example, at least 12 months from the date of diagnosis). We may consider your impairment to be disabling beyond this point when the

medical and other evidence justifies it.

2. When a listing does not contain such a specification, we will consider an impairment(s) that meets or medically equals a listing in this body system to be disabling until at least 3 years after onset of complete remission. When the impairment(s) has been in complete remission for at least 3 years, that is, the original tumor or a recurrence (or relapse) and any metastases have not been evident for at least 3 years, the impairment(s) will no longer meet or medically equal the criteria of a listing in this body system.

3. Following the appropriate period, we will consider any residuals, including residuals of the cancer or therapy (see 113.00G), in determining whether you are disabled. If you have a recurrence or relapse of your cancer, your impairment may meet or medically equal one of the listings in this body system again.

I. What do we mean by the following terms?

1. Antineoplastic therapy means surgery, radiation, chemotherapy, hormones, immunotherapy, or bone marrow or stem cell transplantation. When we refer to surgery as an antineoplastic treatment, we mean surgical excision for treatment, not for diagnostic purposes.

2. Metastases means the spread of cancer cells by blood, lymph, or other body fluid. This term does not include the spread of cancer cells by direct extension of the

cancer to other tissues or organs.

3. Multimodal therapy means antineoplastic therapy that is given as a combination of at least two types of treatment given in close proximity as a unified whole and usually planned before any treatment has begun. There are three types of treatment modalities: surgery, radiation, and systemic drug therapy (chemotherapy, hormone therapy, and immunotherapy or biological modifier therapy). Examples of multimodal therapy include:

a. Surgery followed by chemotherapy or radiation.

b. Chemotherapy followed by surgery.

c. Chemotherapy and concurrent radiation.

4. Persistent means the planned initial antineoplastic therapy failed to achieve a complete remission of your cancer; that is, your cancer is evident, even if smaller, after the therapy has ended.

5. Progressive means the cancer becomes more extensive after treatment; that is, there is evidence that your cancer is growing after you have completed at least half of your planned initial antineoplastic therapy.

6. Recurrent or relapse means a cancer that was in complete remission or entirely removed by surgery has returned.

J. Can we establish the existence of a disabling impairment prior to the date of the evidence that shows the cancer satisfies the criteria of a listing? Yes. We will consider factors such as:

1. The type of cancer and its location.

2. The extent of involvement when the cancer was first demonstrated.

3. Your symptoms.

K. How do we evaluate specific cancers?

1. Lymphoma.

a. We provide criteria for evaluating lymphomas that are disseminated or have not responded to antineoplastic therapy in 113.05.

b. Lymphoblastic lymphoma is treated with leukemia-based protocols, so we evaluate this type of cancer under 113.06.

2. Leukemia.

a. Acute leukemia. The initial diagnosis of acute leukemia, including the accelerated or blast phase of chronic myelogenous (granulocytic) leukemia, is based on definitive bone marrow examination. Additional diagnostic information is based on chromosomal analysis, cytochemical and surface marker studies on the abnormal cells, or other methods consistent with the prevailing state of medical knowledge and clinical practice. Recurrent disease must be documented by peripheral blood, bone marrow, or cerebrospinal fluid examination, or by testicular biopsy. The initial and follow-up pathology reports should be included.

b. Chronic myelogenous leukemia (CML). We need a diagnosis of CML based on documented granulocytosis, including immature forms such as differentiated or undifferentiated myelocytes and myeloblasts, and a chromosomal analysis that demonstrates the Philadelphia chromosome. In the absence of a chromosomal analysis, or if the Philadelphia chromosome is not present, the diagnosis may be made by other methods consistent with the prevailing state of medical knowledge and clinical practice. The requirement for CML in the accelerated or blast phase is met in 113.06B if laboratory findings show the proportion of blast (immature) cells in the peripheral blood or bone marrow is 10 percent or greater.

c. Juvenile chronic myelogenous leukemia (JCML). JCML is a rare, Philadelphia-chromosome-negative childhood leukemia that is aggressive and clinically similar to

acute myelogenous leukemia. We evaluate JCML under 113.06A.

d. Elevated white cell count. In cases of chronic leukemia, an elevated white cell count, in itself, is not a factor in determining the severity of the impairment.

3. Malignant solid tumors. The tumors we consider under 113.03 include the histiocytosis syndromes except for solitary eosinophilic granuloma. We do not evaluate thyroid cancer (see 113.09), retinoblastomas (see 113.12), primary central nervous system (CNS) cancers (see 113.13), or neuroblastomas (see 113.21) under this listing.

4. Primary central nervous system (CNS) cancers. We use the criteria in 113.13 to evaluate cancers that originate within the CNS (that is, brain and spinal cord cancers).

a. The CNS cancers listed in 113.13A are highly malignant and respond poorly to treatment, and therefore we do not require additional criteria to evaluate them.

b. We consider a CNS tumor to be malignant if it is classified as Grade II, Grade III, or Grade IV under the World Health Organization (WHO) classification of tumors of the CNS (WHO Classification of Tumours of the Central Nervous System, 2007).

c. We evaluate benign (Grade I) CNS tumors under 111.05. We evaluate metastasized CNS cancers from non-CNS sites under the primary cancers (see 113.00C). We evaluate any complications of CNS cancers, such as resultant neurological or

psychological impairments, under the criteria for the affected body system.

5. Retinoblastoma. The treatment for bilateral retinoblastoma usually results in a visual impairment. We will evaluate any resulting visual impairment under 102.02.

6. Melanoma. We evaluate malignant melanoma that affects the skin (cutaneous melanoma), eye (ocular melanoma), or mucosal membranes (mucosal melanoma) under 113.29. We evaluate melanoma that is not malignant that affects the skin (benign melanocytic tumor) under the listings in 108.00 or other affected body systems.

L. How do we evaluate cancer treated by bone marrow or stem cell transplantation, including transplantation using stem cells from umbilical cord blood? Bone marrow or stem cell transplantation is performed for a variety of cancers. We require the transplantation occur before we evaluate it under these listings. We do not need to restrict our determination of the onset of disability to the date of transplantation (113.05 or 113.06). We may be able to establish an earlier onset date of disability due to your transplantation if the evidence in your case record supports such a finding.

1. Acute leukemia (including all types of lymphoblastic lymphomas lymphoblastic lymphoma and JCML) or accelerated or blast phase of CML. If you undergo bone marrow or stem cell transplantation for any of these disorders, we will consider you to be disabled until at least 24 months from the date of diagnosis or relapse, or at least 12 months from the date of transplantation, whichever is later.

2. Lymphoma or chronic phase of CML. If you undergo bone marrow or stem cell transplantation for any of these disorders, we will consider you to be disabled until at least 12 months from the date of transplantation.

3. Evaluating disability after the appropriate time period has elapsed. We consider any residual impairment(s), such as complications arising from:

a. Graft-versus-host (GVH) disease.

b. Immunosuppressant therapy, such as frequent infections.

c. Significant deterioration of other organ systems.

113.01 Category of Impairments, Cancer (Malignant Neoplastic Diseases)

113.03 Malignant solid tumors. Consider under a disability:

A. For 24 months from the date of initial diagnosis. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

OR

B. For 24 months from the date of recurrence of active disease. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

113.05 Lymphoma (excluding all types of lymphoblastic lymphomas--113.06). (See 113.00K1.)

A. Non-Hodgkin lymphoma (including Burkitt and anaplastic large cell), with either 1 or 2:

1. Bone marrow, brain, spinal cord, liver, or lung involvement at initial diagnosis. Consider under a disability for 24 months from the date of diagnosis. Thereafter, evaluate under 113.05A2, or any residual impairments(s) under the criteria for the affected body system.

2. Persistent or recurrent following initial antineoplastic therapy.

OR

B. Hodgkin lymphoma, with either 1 or 2:

1. Bone marrow, brain, spinal cord, liver, or lung involvement at initial diagnosis. Consider under a disability for 24 months from the date of diagnosis. Thereafter, evaluate under 113.05B2, or any residual impairment(s) under the criteria for the affected body

system.

2. Persistent or recurrent following initial antineoplastic therapy.

OR

C. * * *

OR

D. Mantle cell lymphoma.

113.06 Leukemia. (See 113.00K2.)

A. Acute leukemia (including all types of lymphoblastic lymphomas and juvenile chronic myelogenous leukemia (JCML)).

OR

B. * * *

1. Accelerated or blast phase (see 113.00K2b).

* * * * *

113.13 Nervous system. (See 113.00K4.) Primary central nervous system (CNS; that is, brain and spinal cord) cancers, as described in A, B, or C:

A. Glioblastoma multiforme, ependymoblastoma, and diffuse intrinsic brain stem gliomas (see 113.00K4a).

B. Any Grade III or Grade IV CNS cancer (see 113.00K4b), including astrocytomas, sarcomas, and medulloblastoma and other primitive neuroectodermal tumors (PNETs).

C. Any primary CNS cancer, as described in 1 or 2:

1. Metastatic.

2. Progressive or recurrent following initial antineoplastic therapy.

* * * * *

113.29 Malignant melanoma (including skin, ocular, or mucosal melanomas), as described in either A or B:

A. Recurrent (except an additional primary melanoma at a different site, which is not considered to be recurrent disease) following either 1, 2, or 3:

1. Wide excision (skin melanoma).

2. Enucleation of the eye (ocular melanoma).

3. Complete surgical excision (mucosal melanoma).

OR

B. With metastases as described in 1, 2, or 3:

1. Metastases to one or more clinically apparent nodes; that is, nodes that are detected by imaging studies (excluding lymphoscintigraphy) or by clinical evaluation (palpable).

2. If the nodes are not clinically apparent, with metastases to four or more nodes.

3. Metastases to adjacent skin (satellite lesions) or distant sites.

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