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**Revised Medical Criteria for Evaluating
Hematological Disorders and Malignant
Neoplastic Diseases; Final Rule and
Proposed Rule**

SOCIAL SECURITY ADMINISTRATION

20 CFR Part 404

[Regulations No. 4]

RIN 0960-AD67

Revised Medical Criteria for Evaluating Malignant Neoplastic Diseases

AGENCY: Social Security Administration.

ACTION: Final rules.

SUMMARY: We are revising the criteria in the Listing of Impairments (the listings) that we use to evaluate claims involving malignant neoplastic diseases. We apply these criteria when you claim benefits based on disability under title II and title XVI of the Social Security Act (the Act). The revisions reflect advances in medical knowledge, treatment, and methods of evaluating malignant neoplastic diseases.

DATES: These rules are effective December 15, 2004.

Electronic Version

The electronic file of this document is available on the date of publication in the **Federal Register** at <http://www.gpoaccess.gov/fr/index.html>. It is also available on the Internet site for SSA (i.e., Social Security Online): <http://policy.ssa.gov/pnpublic.nsf/LawsRegs>.

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772-1213 or TTY 1-800-325-0778, or visit our Internet Web site, Social Security Online, at <http://www.socialsecurity.gov/>.

SUPPLEMENTARY INFORMATION: We are revising and making final the rules we proposed for evaluating malignant neoplastic diseases in the Notice of Proposed Rulemaking (NPRM) published in the **Federal Register** on November 27, 2001 (66 FR 59306). In that NPRM, we proposed revisions to both the listings for hematological disorders and the listings for malignant neoplastic diseases. We proposed to make revisions to the listings for these two body systems in order to update their medical criteria and to provide more information about how we evaluate disorders in these body systems. We initially provided a 60-day comment period that ended on January 28, 2002. Subsequently, on April 18, 2002, we reopened the comment period for an additional 60 days, until June 17, 2002 (67 FR 19138). For the reasons explained below, we have decided to publish only revisions to the malignant neoplastic diseases body system in this final rule. We are publishing separately, in today's edition of the **Federal Register**, a notice withdrawing the proposed rules that would have revised the hematological disorders listings. We plan to publish a new NPRM for the hematological disorders listings at a later date.

We provide a summary of the provisions of the final rules below, with an explanation of the changes we have made from the text in the NPRM. We then provide summaries of the public comments and our reasons for adopting or not adopting the recommendations in

those comments in the section "Public Comments." The final rule language follows the public comments section.

What Programs Do These Final Regulations Affect?

These final regulations affect disability determinations and decisions that we make under title II and title XVI of the Act. In addition, to the extent that Medicare entitlement and Medicaid eligibility are based on whether you qualify for disability benefits under title II and title XVI, these final regulations also affect the Medicare and Medicaid programs.

Who Can Get Disability Benefits?

Under title II of the Act, we provide for the payment of disability benefits if you are disabled and belong to one of the following three groups:

- Workers insured under the Act.
- Children of insured workers.
- Widows, widowers, and surviving divorced spouses (see § 404.336) of insured workers.

Under title XVI of the Act, we provide for Supplemental Security Income (SSI) payments on the basis of disability if you are disabled and have limited income and resources.

How Do We Define Disability?

Under both the title II and title XVI programs, disability must be the result of any medically determinable physical or mental impairment or combination of impairments that is expected to result in death or which has lasted or can be expected to last for a continuous period of at least 12 months. Our definitions of disability are shown in the following table:

If you file a claim under * * *	And you are * * *	Disability means you have a medically determinable impairment(s) as described above and that results in * * *
title II	an adult or a child	the inability to do any substantial gainful activity (SGA).
title XVI	an individual age 18 or older	the inability to do any SGA.
title XVI	an individual under age 18	marked and severe functional limitations.

How Do We Decide Whether You Are Disabled?

If you are seeking benefits under title II of the Act, or if you are an adult seeking benefits under title XVI of the Act, we use a five-step "sequential evaluation process" to decide whether you are disabled. We describe this five-step process in our regulations at §§ 404.1520 and 416.920. We follow the five steps in order and stop as soon as we can make a determination or decision. The steps are:

1. Are you working and is the work you are doing substantial gainful

activity? If you are working and the work you are doing is substantial gainful activity, we will find that you are not disabled, regardless of your medical condition or your age, education, and work experience. If you are not, we will go on to step 2.

2. Do you have a "severe" impairment? If you do not have an impairment or combination of impairments that significantly limits your physical or mental ability to do basic work activities, we will find that you are not disabled. If you do, we will go on to step 3.

3. Do you have an impairment(s) that meets or medically equals the severity of an impairment in the listings? If you do, and the impairment(s) meets the duration requirement, we will find that you are disabled. If you do not, we will go on to step 4.

4. Do you have the residual functional capacity to do your past relevant work? If you do, we will find that you are not disabled. If you do not, we will go on to step 5.

5. Does your impairment(s) prevent you from doing any other work that exists in significant numbers in the

national economy, considering your residual functional capacity, age, education, and work experience? If it does, and it meets the duration requirement, we will find that you are disabled. If it does not, we will find that you are not disabled.

We use a different sequential evaluation process for children who apply for payments based on disability under title XVI of the Act. We describe that sequential evaluation process in § 416.924 of our regulations. If you are already receiving benefits, we also use a different sequential evaluation process when we decide whether your disability continues. See §§ 404.1594, 416.924, 416.994, and 416.994a of our regulations. However, all of these processes include steps at which we consider whether your impairment meets or medically equals one of our listings.

What Are the Listings?

The listings are examples of impairments that we consider severe enough to prevent you as an adult from doing any gainful activity. If you are a child seeking SSI benefits based on disability, the listings describe impairments that we consider severe enough to result in marked and severe functional limitations. Although the listings are contained only in appendix 1 to subpart P of part 404 of our regulations we incorporate them by reference in the SSI program in § 416.925 of our regulations, and apply them to claims under both title II and title XVI of the Act.

How Do We Use the Listings?

The listings are in two parts. There are listings for adults (part A) and for children (part B). If you are an individual age 18 or over, we apply the listings in part A when we assess your claim, and we do not use the listings in part B.

If you are an individual under age 18, we first use the criteria in part B of the listings. If the listings in part B do not apply, and the specific disease process(es) has a similar effect on adults and children, we then use the criteria in part A. (See §§ 404.1525 and 416.925.)

If your impairment(s) does not meet any listing, we will also consider whether it medically equals any listing; that is, whether it is as medically severe as an impairment in the listings. (See §§ 404.1526 and 416.926.)

What if You Do Not Have an Impairment(s) That Meets or Medically Equals a Listing?

We use the listings only to decide that individuals are disabled or that they are

still disabled. We will not deny your claim because your impairment(s) does not meet or medically equal a listing. If you are not doing work that is substantial gainful activity, and you have a severe impairment(s) that does not meet or medically equal any listing, we may still find you disabled based on other rules in the "sequential evaluation process" described above. Likewise, we will not decide that your disability has ended only because your impairment(s) does not meet or medically equal a listing.

Also, when we conduct reviews to determine whether your disability continues, we will not find that your disability has ended because we have changed a listing. Our regulations explain that, when we change our listings, we continue to use our prior listings when we review your case, if you had qualified for disability benefits or SSI payments based on our determination or decision that your impairment(s) met or medically equaled a listing. In these cases, we determine whether you have experienced medical improvement, and if so, whether the medical improvement is related to the ability to work. If your condition(s) has medically improved so that you no longer meet or medically equal the prior listing, we evaluate your case further to determine whether you are currently disabled. We may find that you are currently disabled, depending on the full circumstances of your case. See §§ 404.1594(c)(3)(i) and 416.994(b)(2)(iv)(A). If you are a child who is eligible for SSI payments, we follow a similar rule when we decide whether you have experienced medical improvement in your condition(s). See § 416.994a(b)(2).

Why Are We Revising the Listings for Malignant Neoplastic Diseases?

We are revising these listings to update our medical criteria for evaluating malignant neoplastic diseases and to provide more information about how we evaluate such diseases. On April 24, 2002, we published final rules in the **Federal Register** (67 FR 20018) that included technical revisions to some of the listings for malignant neoplastic diseases. Prior to this, we last published final rules making comprehensive revisions to the listings for malignant neoplastic diseases in the **Federal Register** on December 6, 1985 (50 FR 50068). Because we have not comprehensively revised the listings for this body system since 1985, we believe that we need to update the rules.

What Do We Mean by "Final Rules" and "Prior Rules"?

Even though these rules will not go into effect until 30 days after publication of this notice, for clarity, we refer to the changes we are making here as the "final rules" and to the rules that will be changed by these final rules as the "prior rules."

When Will We Start To Use These Final Rules?

We will start to use these final rules on their effective date. We will continue to use our prior rules until the effective date of these final rules. When the final rules become effective, we will apply them to new applications filed on or after the effective date of these rules and to claims pending before us, as we describe below.

As is our usual practice when we make changes to our regulations, we will apply these final rules on or after their effective date when we make a determination or decision, including those claims in which we make a determination or decision after remand to us from a Federal court. With respect to claims in which we have made a final decision, and that are pending judicial review in Federal court, we expect that the court's review of the Commissioner's final decision would be made in accordance with the rules in effect at the time of the administrative law judge's (ALJ) decision, if the ALJ's decision is the final decision of the Commissioner. If the court determines that the Commissioner's final decision is not supported by substantial evidence, or contains an error of law, we would expect that the court would reverse the final decision, and remand the case for further administrative proceedings pursuant to the fourth sentence of section 205(g) of the Act, except in those few instances in which the court determines that it is appropriate to reverse the final decision and award benefits without remanding the case for further administrative proceedings. In those cases decided by a court after the effective date of the rules, where the court reverses the Commissioner's final decision and remands the case for further administrative proceedings, on remand, we will apply the provisions of these final rules to the entire period at issue in the claim.

How Long Will These Final Rules Be Effective?

These rules will no longer be effective 5 years after the date on which they become effective, unless we extend them or revise and issue them again.

Why Are We Not Publishing Final Rules for Evaluating Hematological Disorders in This Notice?

The public comments we received on the NPRM raised significant issues about the proposed listings for some of the hematological disorders, and we have not finished resolving these issues. The public comments did not raise similar issues with respect to the listings for malignant neoplastic diseases. Therefore, we are issuing these final regulations to implement changes to the listings for malignant neoplastic diseases, and we summarize and respond here only to the significant public comments that we received about the proposed changes regarding those diseases.

As noted above, we are publishing separately in today's edition of the **Federal Register** a notice withdrawing the proposed rules for the hematological disorders listings. We plan to issue a new NPRM for the hematological disorders listings at a later date.

What General Changes Are We Making That Affect Both the Adult and Childhood Listings for Malignant Neoplastic Diseases?

To present the listings in a more logical order, and make them easier to use, we are:

- Redesignating the listings in part A and part B. To the extent possible, the listings in part B correspond with listings addressing the same or similar impairments in part A.
- Placing all listings for malignant neoplastic diseases in this body system, with the exception of certain ones associated with human immunodeficiency virus (HIV) infection. To do this, we are moving the criteria for acute leukemia, chronic leukemia, myeloma, and malignant brain tumors, prior listings 7.11, 7.12, 7.16, 11.05, 107.11, and 111.05, to final listings 13.06, 13.07, 13.13, 113.06 and 113.13, respectively. We are also moving the guidance for evaluating macroglobulinemia or heavy chain disease, prior listing 7.14, to 13.00K3 of the introductory text because the prior listing for this disorder was a reference listing. As noted below, we are eliminating reference listings and providing guidance in the introductory text.
- Removing reference listings from this body system. Reference listings are listings that are met by satisfying the criteria of another listing. For example, prior listing 7.16B, for myeloma with evidence of renal impairment, was a reference listing that requires evaluation under listing 6.02, for impairment of

renal function. Instead of using reference listings, we are providing guidance in the introductory text stating that these impairments should be evaluated under the criteria for the affected body system. Where appropriate, we also provide references to specific listings. For example, in 13.00K3 we indicate that macroglobulinemia or heavy chain disease should be evaluated under the criteria of 7.02, 7.06, or 7.08, or under the criteria of any other affected body system.

How Are We Changing the Introductory Text to the Listings for Evaluating Malignant Neoplastic Diseases in Adults?

13.00 Malignant Neoplastic Diseases

We are expanding and reorganizing the introductory text to these listings to provide additional guidance and reflect the new listings. The following is a detailed explanation of this material.

13.00A—What Impairments Do These Listings Cover?

In this section, we explain that we use these listings to evaluate all malignant neoplasms, except certain neoplasms associated with human immunodeficiency virus (HIV) infection. We use the criteria in listing 14.08E to evaluate carcinoma of the cervix, Kaposi's sarcoma, lymphoma, and squamous cell carcinoma of the anus if you also have HIV infection.

13.00B—What Do We Consider When We Evaluate Malignant Neoplastic Diseases Under These Listings?

This section corresponds to prior 13.00A, "Introduction." For clarity, we are using the phrase "origin of the malignancy" instead of the prior language, "the site of the lesion, the histogenesis of the tumor" to describe one of the factors we consider when we evaluate malignant neoplastic diseases. We also changed the phrase "apparent adequacy and response to therapy" in the prior section to "[r]esponse to antineoplastic therapy" to eliminate any misunderstanding concerning who can make judgments about the appropriateness of the treatment regimen. "Apparent adequacy" was intended to mean effectiveness of the therapy. Judgments about its appropriateness must be left entirely to the treating source. We added the word "antineoplastic" to be consistent with the language in the listing criteria. We also specifically identify the types of antineoplastic therapy referred to in the listings.

13.00C—How Do We Apply the Listings?

In this section, we explain that we apply the criteria in a specific listing to a malignancy originating from that specific site.

In this section of the NPRM (66 FR at 59321), we stated that metastatic carcinoma to the brain or spinal cord was an exception to the guidance above. We received a public comment questioning this exception. In response to this comment, we determined that this exception was unnecessary and have removed it. We will evaluate metastatic carcinoma to the brain or spinal cord under the site of origin for the primary tumor or, if this is unknown, under final listing 13.27.

13.00D—What Evidence Do We Need?

We are expanding the guidance in prior 13.00B, "Documentation," by:

- Explaining that when the primary site cannot be identified, we will use evidence documenting the site(s) of metastasis to evaluate the impairment under listing 13.27.
- Clarifying that we consider biopsies and needle aspirations to be "operative procedures."
- Using the more general term "pathology report" instead of "the report of the gross and microscopic examination of the surgical specimen." We made this change to recognize that a report of the gross examination is not always required and to recognize that a microscopic examination of appropriate body fluids may be used as an alternative to the gross and microscopic examination of the surgical specimen.

13.00E—When Do We Need Longitudinal Evidence?

We are incorporating and expanding the guidance in the fourth paragraph of prior 13.00C, "Evaluation." We explain when we need longitudinal evidence, and the time period such evidence should cover. We also explain when we may need to defer adjudication.

13.00F—How Do We Evaluate Impairments That Do Not Meet One of the Malignant Neoplastic Diseases Listings?

This paragraph corresponds to the first sentence in the second paragraph of prior 13.00D, "Effects of Therapy." We state our basic adjudicative principle that, if your impairment(s) does not meet or medically equal the requirements of a listing, we will continue the sequential evaluation process to determine whether you are disabled.

13.00G—How Do We Consider the Effects of Therapy?

We are reorganizing the guidance in prior 13.00D, “Effects of Therapy.” In final 13.00G2a, we are adding “extent of surgery” and “schedule and fields of radiation therapy” to the list of the elements of therapy for which we will request a description noted in the second paragraph of prior 13.00D. In final 13.00G2b, we are adding “neurological complications” and “cardiovascular complications” to the list of examples of complications or adverse effects for which we will request a description. We are also clarifying that we will not delay adjudication to determine whether the therapy has achieved its intended effect if we can make a fully favorable determination or decision based on the evidence in the case record.

13.00H—How Long Do We Consider Your Impairment To Be Disabling?

We are incorporating and expanding the guidance contained in the third paragraph of prior 7.00E, “Acute leukemia,” and the fifth paragraph of prior 13.00C, “Evaluation.” In some of the listings, we specify that we consider an impairment to be disabling until a particular point in time; for example, at least 18 months from the date of diagnosis. If you have an impairment(s) that meets or equals a listing in this body system that does not contain such a specification, we provide that we will consider the impairment(s) to be disabling until at least 3 years after onset of complete remission. We also explain what we do when the appropriate time period has passed.

For those listings in which we specify that the impairment is considered disabling until a particular point in time, such as listing 13.28, the beginning date specified is not related to the onset date. We can establish an earlier onset date if the evidence in your case record supports the earlier onset date, as we explain in final 13.00J.

13.00I—What Do These Terms in the Listings Mean?

We are revising the first two paragraphs and the first sentence of the third paragraph of prior 13.00C, “Evaluation,” and providing additional definitions. The prior section contained an adjudicative definition of “distant metastases” and “metastases beyond the regional lymph nodes.” We are not retaining this definition because our use of these terms in the final listings is consistent with current clinical practice. We are also adding definitions in order

to differentiate between the terms “inoperable” and “unresectable.”

13.00J—Can We Establish the Existence of a Disabling Impairment Prior to the Date of the Evidence That Shows the Malignancy Satisfies the Criteria of a Listing?

This section corresponds to prior 13.00E, “Onset.” We are making no substantive changes.

13.00K—How Do We Evaluate Specific Malignant Neoplastic Diseases?

We are incorporating and clarifying prior 7.00E, “Acute leukemia,” and the last sentence of the third paragraph in prior 13.00C, “Evaluation,” and providing guidance for evaluating additional malignant neoplastic disorders. The following is a detailed discussion of the information provided.

13.00K1—Lymphoma

In paragraphs K1a and K1b of this section, we discuss the evaluation of low grade or indolent (non-aggressive) lymphomas. We explain that we may defer adjudication of these cases for an appropriate period after the initiation of therapy to determine whether the therapy will achieve its intended effect. We do not specify a particular time for this deferral because it will vary from case to case. We also explain that changes in therapy based solely on patient or physician preference are not indicative of a failure to stabilize the disease. We also explain how the disease should be evaluated when stability has been achieved.

Final paragraphs 13.00K1a and 13.00K1b reflect nonsubstantive editorial corrections made to the corresponding proposed paragraphs in the NPRM (66 FR at 59322). Proposed paragraph K1a referred to indolent lymphoma. We added a reference to low grade lymphoma to final paragraph K1a to be consistent with the listing language. We also added a reference to low grade or indolent lymphoma in final paragraph K1b for clarity.

We have not retained the last sentence of the third paragraph of prior 13.00C, “Evaluation.” This sentence stated, “In the evaluation of lymphomas, the tissue type and site of involvement are not necessarily indicators of the degree of impairment.” We do not believe this guidance provided useful information for applying the criteria in final listing 13.05.

In paragraph K1c, we provide that Hodgkin’s disease that recurs more than 12 months after completing initial antineoplastic therapy will be evaluated as a new disease rather than as a recurrence.

13.00K2—Leukemia

In paragraph K2a, we expand the guidance in the first paragraph of prior 7.00E, “Acute leukemia,” to indicate sources of additional diagnostic information. We clarify that recurrent disease must be documented by peripheral blood, bone marrow, or cerebrospinal fluid examination. We also clarify that the initial and follow-up pathology reports should be included.

In paragraph K2b, we provide guidance on documenting chronic myelogenous leukemia (CML). We have not included in this paragraph the guidance in the second paragraph of prior 7.00E, which provided that the acute phase of CML should be considered under the requirements for acute leukemia. Instead, we have provided a separate listing for the acute phase (more appropriately called the accelerated or blast phase) of CML, final listing 13.06B1, that uses the same criteria as the listing for acute leukemia (final listing 13.06A).

In paragraph K2c, we provide guidance for documenting and evaluating chronic lymphocytic leukemia (CLL). Consistent with our effort to eliminate reference listings, this guidance incorporates the cross-references from prior listing 7.12 that are appropriate for evaluating CLL.

In paragraph K2d, we explain that, in cases of chronic leukemia (either myelogenous or lymphocytic), an elevated white cell count, in itself, is not ordinarily a factor in determining the severity of the impairment.

13.00K3—Macroglobulinemia or Heavy Chain Disease

This section replaces prior listing 7.14, which was a reference listing. We are making no substantive changes in how we evaluate these disorders.

13.00K4—Bilateral Primary Breast Cancer

We are clarifying the statement in prior listing 13.09D, “bilateral breast carcinoma, synchronous or metachronous is *usually* primary in each breast” (emphasis added) by removing the suggestion that there are exceptions to this rule. See the discussion of final listing 13.10B, below.

13.00K5—Carcinoma-in-situ

In this section, we explain that this type of carcinoma usually responds to treatment and is not included when we use the term “carcinoma” in these listings.

13.00K6—Brain Tumors

In this section, we explain that malignant tumors are evaluated under final listing 13.13, while benign tumors continue to be evaluated under listing 11.05. We also explain that we evaluate any complications of malignant brain tumors, such as resultant neurological or psychological impairments, under the criteria for the affected body system.

13.00L—How Do We Evaluate Malignant Neoplastic Diseases Treated by Bone Marrow or Stem Cell Transplantation?

In paragraphs L1 and L2, we discuss how long we consider you disabled if you have leukemia, lymphoma, or multiple myeloma and you undergo bone marrow or stem cell transplantation.

In paragraph L3, we provide that any other malignant neoplastic diseases treated with bone marrow or stem cell transplantation must be evaluated under final listing 13.28, regardless of whether there is another listing that addresses that impairment. We explain that under final listing 13.28, the length of time we will consider you disabled will depend on whether you undergo allogeneic or autologous transplantation. We also define “allogeneic” and “autologous” in paragraphs L3a and L3b.

In paragraph L4, we discuss some of the factors we consider when we evaluate any residual impairment(s) that results from transplantation.

How Are We Changing the Listings for Evaluating Malignant Neoplastic Diseases in Adults?*13.01—Category of Impairments, Malignant Neoplastic Diseases*

We are removing prior listing 13.15, “Abdomen,” because disorders covered by this listing can be evaluated under other final listings. Prior listings 13.15A, “Generalized carcinomatosis,” and 13.15C, “Ascites with demonstrated malignant cells,” represent malignancies that have spread to the abdomen from another site. We will evaluate these conditions under final listing 13.27, “Primary site unknown after appropriate search for primary.” We will evaluate “Retroperitoneal cellular sarcoma not controlled by prescribed therapy,” the impairment in prior listing 13.15B, under final listing 13.04, “Soft tissue sarcoma.”

In the final listings, we:

- Take into account medical advances in the detection, treatment, control, and cure of malignant neoplastic diseases.
- Recognize that in some situations the effects of therapy for these disorders can be disabling.

- Provide for the evaluation of residual impairments.

The following is a detailed explanation of the final listings.

Listing 13.02—Soft Tissue Tumors of the Head and Neck (Except Salivary Glands—13.06—and Thyroid Gland—13.07)

This listing corresponds to prior listing 13.02, “Head and neck.” We are revising the listing heading to ensure that only tumors of the soft tissue of the head and neck are considered under this listing. This change allows us to delete the last two exceptions in the prior heading (orbit or temporal fossa), as these are not soft tissue tumors. In response to a comment, we are also removing prior listing 13.02E, “Epidermoid carcinoma occurring in the pyriform sinus or posterior third of the tongue,” as these conditions can be evaluated under other sections of the final listing. We had proposed to evaluate epidermoid carcinoma occurring in the pyriform sinus under proposed listing 13.02E. We explain our reasons for this change in more detail in the public comments section of this preamble.

Final listing 13.02A is substantively the same as prior listing 13.02A. We are updating the terminology to reflect the definitions used in the final listings.

In final listing 13.02B, which corresponds to prior listing 13.02B, we are replacing “[n]ot controlled by prescribed therapy” with “[p]ersistent disease following initial multimodal antineoplastic therapy” to clarify our intent.

Final listing 13.02C corresponds to prior listing 13.02C. We are replacing “after radical surgery or irradiation” with “following initial antineoplastic therapy” to recognize that other therapeutic modalities may be used. We are also excluding local vocal cord recurrences, because these recurrences have a good response to therapy.

Final listing 13.02D corresponds to prior listing 13.02D. We are making no substantive change.

Final listing 13.02E corresponds to proposed listing 13.02F in the NPRM. As we have already noted, we removed prior and proposed listing 13.02E in response to a comment. Therefore, we are redesignating proposed listing 13.02F as final listing 13.02E. It recognizes the length and debilitating effects of multimodal treatment for soft tissue tumors of the head and neck.

Listing 13.03—Skin

We are combining prior listing 13.03, “Sarcoma of skin,” and prior listing 13.05, “Malignant melanoma,” so that

all malignancies originating in the skin are evaluated under this listing. Accordingly, we are revising the heading by removing the reference to sarcoma.

Final listing 13.03A corresponds to prior listing 13.03A, “Angiosarcoma with metastases to regional lymph nodes or beyond.” We are expanding the provision to include all skin sarcomas and carcinomas because other skin malignancies of the severity described would also be disabling.

Final listing 13.03B corresponds to prior listing 13.05. We clarify that an additional primary melanoma at a different site is not considered recurrent disease. We are also adding a criterion for palpable nodal metastases. Prior listing 13.05B addressed only metastases to the regional lymph nodes or beyond, and not palpable nodal metastases.

We are moving prior listing 13.03B, “Mycosis fungoides” (a type of lymphoma), to final listing 13.05, “Lymphoma,” so that all lymphomas will be evaluated under the same listing.

Listing 13.04—Soft Tissue Sarcoma

We are updating the heading of prior listing 13.04, “Sarcoma of soft parts,” to recognize that “soft tissue” is a more common term than “soft parts.” We are adding a criterion for regional or distant metastases, final listing 13.04A, to be consistent with the criteria for other malignant neoplastic diseases and to recognize the grave prognosis for these conditions. In final listing 13.04B, we define the prior criterion “not controlled by prescribed therapy” similarly to the way we defined it in other listings, such as final listing 13.02B.

Listing 13.05—Lymphoma (Including Mycosis Fungoides, But Excluding T-cell Lymphoblastic Lymphoma—13.06)

This listing corresponds to prior listing 13.06. We are changing the heading from “Lymph nodes” to “Lymphoma” to more accurately reflect the disease. We also provide a cross-reference to the explanatory paragraphs in 13.00K1 and 13.00K2c. This listing also replaces prior listing 7.13, “Lymphomas.”

We evaluated both Hodgkin’s disease and non-Hodgkin’s lymphoma under prior listing 13.06A. We are separating and clarifying the criteria for each of these diseases. Final listing 13.05A provides criteria for evaluating non-Hodgkin’s lymphoma; final listing 13.05B provides criteria for Hodgkin’s disease. For each of these disorders, we clarify the prior criteria by replacing the phrase “progressive disease not

controlled by prescribed therapy” in the prior listing with clearer language.

In the final rules, we are making a minor editorial revision to proposed listing 13.05A2 for clarity. We amended the proposed listing by adding the words “at least” between “from” and “the” in the last sentence to clarify that the individual can be found disabled prior to the date specified in the listing.

In final listing 13.05C, we provide that a lymphoma treated by bone marrow or stem cell transplantation is considered disabling until at least 12 months from the date of transplantation. After this period, we will evaluate any residual impairment(s) under the criteria for the affected body system.

We are removing prior listing 13.06B, “Metastatic carcinoma in a lymph node (except for epidermoid carcinoma in a lymph node in the neck) where the primary site is not determined after adequate search.” We will evaluate this impairment under final listing 13.27, “Primary site unknown after appropriate search for primary.” We are also removing prior listing 13.06C. We will evaluate epidermoid carcinoma in a lymph node in the neck under final listing 13.02, “Soft tissue tumors of the head and neck.”

Listing 13.06—Leukemia

This final listing replaces prior listing 7.11, “Acute leukemia,” and prior listing 7.12, “Chronic leukemia.”

Final listing 13.06A replaces prior listing 7.11. We provide that acute leukemia (including T-cell lymphoblastic lymphoma) will be considered disabling until at least 24 months from the date of diagnosis or relapse, or at least 12 months from the date of bone marrow or stem cell transplantation, whichever is later. After the appropriate period, we will evaluate any residual impairment(s) under the criteria for the affected body system.

Under the prior listing, we considered acute leukemia disabling for 2½ years from the time of the initial diagnosis. We are shortening this period to 2 years because of improvement in the treatment of this disorder. However, as with other final listings, and unlike the prior listing, we permit a longer period when the facts warrant it. We also recognize that a relapse of acute leukemia is as significant as the initial diagnosis.

The criterion for bone marrow or stem cell transplantation in cases of acute leukemia is similar to the transplantation criteria for other diseases. Unlike those diseases, however, we will not reevaluate cases of acute leukemia 12 months after transplantation if that date is earlier

than 24 months after onset or relapse. We provide this option for this disease because of the disease course and the high rate of infection and other complications that occur when this disease is treated with bone marrow or stem cell transplantation.

Final listing 13.06B, “Chronic myelogenous leukemia,” replaces prior listing 7.12. The prior listing was a reference listing. Rather than replace the entire listing with guidance in the preface, we are providing separate evaluation criteria for CML. Consistent with our guidance in the second paragraph of prior 7.00E, the listing for the accelerated or blast phase of CML is the same as final listing 13.06A.

We are retaining references to the listings that are appropriate for evaluating chronic lymphocytic leukemia in 13.00K2c.

Listing 13.07—Multiple Myeloma (Confirmed by Appropriate Serum or Urine Protein Electrophoresis and Bone Marrow Findings)

This listing replaces prior listing 7.16. In this listing, we remove the specific findings in prior listings 7.16A–D and substitute the criterion “[f]ailure to respond or progressive disease following initial antineoplastic therapy.” Our intent is to clarify that this listing includes all listing-level manifestations of this disease. We also clarify that we consider multiple myeloma treated with bone marrow or stem cell transplantation to be disabling until at least 12 months from the date of transplantation. After that time, we will evaluate any residual impairment(s) under the criteria for the affected body system.

Listing 13.08—Salivary Glands

This listing redesignates prior listing 13.07. There are no substantive changes.

Listing 13.09—Thyroid Gland

In the NPRM, we proposed to amend current listing 13.08, for malignancies of the thyroid gland, by:

- Redesignating the current listing as proposed listing 13.09.
- Adding a separate criterion for anaplastic (undifferentiated) carcinoma in proposed listing 13.09A.
- Redesignating the criterion in current listing 13.08, “carcinoma with metastases beyond the regional lymph nodes, not controlled by prescribed therapy,” as proposed listing 13.09B.
- Replacing the term “not controlled by prescribed therapy” used in current listing 13.08 with “progressive despite radioactive iodine therapy” to clarify our intent.

On April 24, 2002, we published final rules in the **Federal Register** (67 FR 20018, 20026) that made technical revisions to the listings. Those rules added the criterion for anaplastic (undifferentiated) carcinoma and redesignated the criterion in prior listing 13.08 as final listing 13.08B.

In these final rules, we are redesignating prior listing 13.08 as final listing 13.09, and are clarifying the language as indicated in the fourth bullet above.

Listing 13.10—Breast

This listing corresponds to prior listing 13.09. In final listing 13.10A, we are amending the criterion in prior listing 13.09B, “Inflammatory carcinoma,” by adding other types of locally advanced carcinoma.

In final listing 13.10B, “Carcinoma with distant metastases,” we are revising prior listing 13.09D by removing the parenthetical statement “bilateral breast carcinoma, synchronous or metachronous, is usually primary in each breast.” Instead, we provide guidance about evaluating bilateral breast cancer in final 13.00K4. As indicated in our discussion of that section, we are clarifying this guidance by removing the suggestion that there are exceptions to this rule.

In final listing 13.10C, which replaces prior listing 13.09C, we are replacing the term “controlled by prescribed therapy” used in the prior listing with “that remits with antineoplastic therapy” to clarify our intent.

We are removing prior listing 13.09A, “inoperable carcinoma,” to avoid confusion about what this term means for this malignancy. We can evaluate cases in which breast cancer is inoperable under other criteria in final listing 13.10. We are also removing prior listing 13.09E, “Sarcoma with metastases anywhere.” We will evaluate this impairment under final listing 13.04, “Soft tissue sarcoma.”

Listing 13.11—Skeletal System

This listing replaces prior listing 13.10. We are expanding the listing to include tumors of the mandible that were evaluated under prior listing 13.11. In final listings 13.11A, 13.11B, and 13.11C, we revise prior listing 13.10A to clarify when these tumors are of listing-level severity. In final listing 13.11D, we provide that we consider all other malignant tumors originating in bone with multimodal antineoplastic therapy to be disabling for 12 months from the date of diagnosis. Consistent with the changes we have made for other listings, any residual impairment(s) will be evaluated under

the criteria for the affected body system after that period. With this criterion, we recognize the length and debilitating effects of multimodal treatment for these tumors.

Listing 13.12—Maxilla, Orbit, or Temporal Fossa

This listing corresponds to prior listing 13.11. As noted above, we evaluate tumors of the mandible under final listing 13.11. Final listings 13.12A and 13.12B reorganize the criteria in prior listings 13.11A and 13.11B by moving the criterion for carcinoma with regional or distant metastases (part of prior listing 13.11B) to final listing 13.12A. We did this so that all tumors of the maxilla, orbit, or temporal fossa with regional or distant metastases would be covered in the same listing. The final listings do not make any substantive changes.

In the NPRM, we inadvertently changed the word “temporal” in the heading of current listing 13.11 to “infratemporal” in the heading of proposed listing 13.12 (66 FR at 59323). We are correcting the heading in these final rules. Additionally, although we moved the criterion for carcinoma with regional or distant metastases to proposed listing 13.12A, we failed to remove the criterion from proposed listing 13.12B. We are removing the criterion from final listing 13.12B in response to a public comment indicating that retaining the criterion in listing 13.12B was redundant.

In final listing 13.12C, we consolidate the disease sites in prior listings 13.11C, 13.11D, 13.11E, and 13.11F.

Listing 13.13—Nervous System

This listing incorporates the criteria for malignant brain tumors from listing 11.05, “Brain tumors,” in the neurological body system, and replaces prior listing 13.12, “Brain or spinal cord.” We are expanding the listings to include tumors of the spinal cord, spinal nerve roots, and the peripheral nervous system. We are also including tumors of the central nervous system that are not specifically named.

Under final listing 13.13A, we evaluate central nervous system malignant neoplasms; that is, those affecting the brain or spinal cord. In final listing 13.13A1, we list and revise the criteria for the impairments named in prior listing 11.05A. We are revising the reference to medulloblastoma to include other primitive neuroectodermal tumors (PNETs) and to require documented metastases for this type of tumor. Advances in treatment have significantly improved the overall prognosis of this disease, so that, in the

absence of metastases, many individuals do well. We can evaluate medulloblastomas or other PNETs that have not metastasized, as well as the malignant brain tumors listed in prior listing 11.05B, under final listing 13.13A2.

We are also adding diffuse intrinsic brain stem gliomas in final listing 13.13A1. We are requiring that the impairment be “diffuse” and “intrinsic” because progress in medical diagnostic tools has now allowed for effective treatment of individuals with localized brain stem tumors.

In the NPRM, the criteria in proposed listing 13.13A were preceded by the phrase, “Central nervous system neoplasms (brain and spinal cord), including * * *.” In final listing 13.13A, we are changing the word “including” to the phrase “as described in 1 or 2” to be consistent with other listings.

In final listing 13.13B, we provide criteria for evaluating malignant tumors of peripheral nerves and spinal roots.

In the NPRM, we had proposed a listing, listing 13.13C, to correspond to prior listing 13.12A for metastatic carcinoma to brain or spinal cord. In response to a public comment, we have determined that this listing is unnecessary. These malignancies will be evaluated under the criteria for the site of origin, or under listing 13.27 if the primary site is unknown. Therefore, we are removing prior listing 13.12A and proposed listing 13.13C. We are also removing prior listing 13.12B, which was a reference listing.

Listing 13.14—Lungs

This listing corresponds to prior listing 13.13. In final listing 13.14A, we consolidate prior listings 13.13A, 13.13B, 13.13D, and 13.13E. This change is consistent with current medical terminology, which no longer distinguishes between the types of non-small-cell carcinoma.

In the NPRM, proposed listing 13.14A covered metastatic disease to or beyond the mediastinal or subcarinal lymph nodes. A public comment pointed out that this criterion would exclude cases of non-small-cell carcinomas with metastases to the hilar lymph nodes that had been included under prior listing 13.13E. The comment also indicated that, even when the involved hilar nodes are excised, the prognosis for this disease is unfavorable. In response to this comment, we have revised final listing 13.14A to include metastases to the hilar nodes.

We are redesignating prior listing 13.13C as final listing 13.14B. We are making no substantive changes.

Listing 13.15—Pleura or Mediastinum

This listing corresponds to prior listing 13.14. Final listing 13.15A is the same as prior listing 13.14A. In final listing 13.15B, which corresponds to prior listing 13.14C, we provide new language that clarifies the phrase “not controlled by prescribed therapy” used in the prior listing.

In the NPRM, the criterion in proposed listing 13.15B1 was “Metastatic.” In final listing 13.15B1, we revise this criterion to “With metastases to or beyond the regional lymph nodes” to be consistent with the other listings in these rules.

We are removing prior listing 13.14B, “Malignant tumors, metastatic to pleura.” We will evaluate this malignancy under final listing 13.27, “Primary site unknown.”

Listing 13.16—Esophagus or Stomach

This listing corresponds to prior listing 13.16. Final listing 13.16A is the same as prior listing 13.16A. In final listing 13.16B, we consolidate prior listings 13.16B through 13.16E to clarify that all of those criteria relate to carcinoma or sarcoma of the stomach. We also provide new language to clarify the phrase “not controlled by prescribed therapy” used in prior listing 13.16C.

Listing 13.17—Small Intestine

This listing corresponds to prior listing 13.17. In final listing 13.17A, we expand the criterion in prior listing 13.17B, for recurrent malignancies, to indicate that inoperable and unresectable malignancies are also of listing-level severity. We also provide new language to clarify the phrase “not controlled by prescribed therapy” used in prior listing 13.17C. Final listing 13.17B corresponds to prior listing 13.17A, and is substantively unchanged.

Listing 13.18—Large Intestine (From Ileocecal Valve to and Including Anal Canal)

This listing corresponds to prior listing 13.18. We are removing the phrase “carcinoma or sarcoma” from the heading of this listing because sarcomas of the large intestine are extremely rare. In final listing 13.18A, we consolidate prior listings 13.18A and 13.18C and clarify that these criteria apply to adenocarcinoma. In final listing 13.18B, we provide that squamous cell carcinoma of the anus will not be found to meet the listing unless it is recurrent after surgery. Advances in treatment have made chemotherapy and radiation the treatment of choice for this disorder. However, good results can be achieved through surgery if the preferred treatment is not effective. Final listing

13.18C is the same as prior listing 13.18B.

Listing 13.19—Liver or Gallbladder

This listing corresponds to prior listing 13.19. We are clarifying that the listing applies only to malignancies that originate in the liver, gallbladder, or bile ducts. We evaluate metastases to the liver from other sites under the criteria for the site of origin, or under the criteria of final listing 13.27 when the primary site is unknown.

Listing 13.20—Pancreas

This listing corresponds to prior listing 13.20. We are not making any substantive changes, other than adding “inoperable” conditions to the second listing criterion. We are making this change to reflect the revised definitions used in these listings.

Listing 13.21—Kidneys, Adrenal Glands, or Ureters

This listing corresponds to prior listing 13.21. In final listing 13.21A, we expand the criteria of unresectable tumors in prior listing 13.21A to include inoperable and recurrent tumors. Final listing 13.21B consolidates prior listings 13.21B and 13.21C. We are eliminating the modifier “hematogenous” used in prior listing 13.21B because metastases by lymphatic spread or by direct extension carry the same poor prognosis.

Listing 13.22—Urinary Bladder

This listing corresponds to prior listing 13.22. We are removing prior listing 13.22E, which provided for the evaluation of renal impairment following total cystectomy under the criteria in listing 6.02, because it was a reference listing.

Listing 13.23—Cancers of the Female Genital Tract

In this listing, we incorporate and revise prior listings 13.25, “Uterus,” 13.26, “Ovaries,” 13.28, “Uterine (Fallopian) tubes,” and 13.30, “Vulva.” In final listings 13.23A, “Uterus (corpus),” and 13.23B “Uterine cervix,” we replace the prior criteria in listings 13.25B, “Recurrent after total hysterectomy,” and 13.25C, “Total pelvic exenteration,” with “Persistent or recurrent following initial antineoplastic therapy.” With this revision, we recognize changes in treatment for these disorders. In final listing 13.23C, “Vulva,” we provide criteria in addition to the criteria for distant metastases used in the prior listing.

We are making several changes in final listing 13.23D, “Fallopian tubes.”

In final listing 13.23D1, “Extending to the serosa or beyond,” we replace the criteria in prior listings 13.28A, “Unresectable,” and 13.28B, “Metastases to regional lymph nodes.” Tumors extending to the serosa are considered to be unresectable for the purposes of this listing; tumors extending beyond the serosa equate to tumors that have metastasized to the regional lymph nodes. In final listing 13.23D2, we are also adding criteria to evaluate fallopian tube tumors when the initial antineoplastic therapy has not achieved the desired effect.

In final listing 13.23E, “Ovaries,” we separate germ-cell and non-germ-cell tumors. In final listing 13.23E1, which provides the criteria for evaluating non-germ-cell tumors, we expand the criteria in prior listing 13.26 to reflect advances in diagnostic techniques and treatment. We provide criteria for evaluating germ-cell tumors in final listing 13.23E2.

Listing 13.24—Prostate Gland

In this listing, which corresponds to prior listing 13.23, we provide new language to clarify the phrase “not controlled by prescribed therapy” used in the prior listing.

Listing 13.25—Testicles

This listing corresponds to prior listing 13.24. We are removing prior listing 13.24A, for choriocarcinoma because the literature we consulted does not separate choriocarcinoma from other forms of nonseminomatous germ-cell tumors with regard to staging or treatment. (See 67 FR 19138 for a list of the literature we consulted.)

Listing 13.26—Penis

This listing corresponds to prior listing 13.29. We have clarified the listing to explicitly include metastases to or beyond the regional lymph nodes.

Listing 13.27—Primary Site Unknown After Appropriate Search for Primary

We are providing a listing for the occasional case in which metastases have been appropriately verified but the site of the primary malignancy cannot be determined. The final listing specifically excludes solitary squamous cell carcinoma in the neck, as this type of metastasis is often amenable to treatment.

Listing 13.28—Malignant Neoplastic Diseases Treated by Bone Marrow or Stem Cell Transplantation

As we have already noted in our discussion of final 13.00L above, final listing 13.28 is a listing for bone marrow or stem cell transplantation in any malignant neoplastic disease other than

acute leukemia, CML, lymphoma, or multiple myeloma, which we evaluate under final listings 13.05, 13.06 and 13.07. In final listing 13.28A, we provide that allogeneic transplantation is disabling until at least 12 months from the date of transplantation. In final listing 13.28B, we provide that autologous transplantation is disabling until at least 12 months from the date of the first treatment under the treatment plan that includes transplantation. We use an earlier date to begin the 12-month period for autologous transplantation because the recovery period after this type of transplantation is generally shorter than for allogeneic transplantation. In both cases, we will evaluate any residual impairment(s) after the applicable period under the criteria for the affected body system.

How Are We Changing the Introductory Text to the Listings for Evaluating Malignant Neoplastic Diseases in Children?

113.00 Malignant Neoplastic Diseases

Except for minor changes to refer to children, we are repeating much of the introductory text in 13.00 in the introductory text in 113.00. This is because the same basic rules for establishing and evaluating the existence and severity of malignant neoplastic diseases in adults also apply to children. Because we have already described these provisions under the explanation of 13.00, the following discussions describe only those provisions that are unique to the childhood rules or that require further explanation.

113.00B—What Do We Consider When We Evaluate Malignant Neoplastic Diseases Under These Listings?

In this section, which is the same as final 13.00B, we replace the guidance in prior 113.00A1.

113.00D—What Evidence Do We Need?

In this section, we replace and expand prior 113.00B. This section is substantively the same as final 13.00D. We are not including a childhood listing to correspond to final listing 13.27, primary site unknown after appropriate search for primary, because the inability to determine the primary site is an extremely rare occurrence in childhood malignancies. Instead, we indicate that, in these rare situations, we will use final listing 13.27.

113.00E—When Do We Need Longitudinal Evidence?

This section is similar to final 13.00E. We are adding a general description of most malignant childhood tumors.

113.00F—How Do We Evaluate Impairments That Do Not Meet One of the Malignant Neoplastic Diseases Listings?

In this section, we repeat the guidance in final 13.00F, but use the definition of disability for children who claim SSI payments.

113.00G—How Do We Consider the Effects of Therapy?

This section replaces prior 113.00A2 and the last paragraph of prior 113.00A. We repeat the guidance in final 13.00G but use the definition of disability for children who claim SSI payments.

113.00H—How Long Do We Consider Your Impairment To Be Disabling?

This section corresponds to final 13.00H. It also replaces prior 113.00D, “Duration of disability,” which referred to the specific time periods that we included in prior listings 113.02 and 113.03. Although we do not cite specific listings, we indicate that some listings specify that the impairment should be considered disabling until a particular point in time. In final 113.00H2, we state that, when the listing does not contain such a specification, we will consider an impairment that meets or medically equals the listings in this body system to be disabling until at least 3 years after onset of complete remission. We added this section to ensure consistency between the adult and childhood rules.

113.00I—What Do These Terms in the Listings Mean?

This section corresponds to final 13.00I. As we explain below, we are retaining our listings for malignant solid tumors. Because of this, there are no listings in part B of these final rules that include the terms “inoperable” and “unresectable.” Therefore, in these final rules, we revised proposed 113.00I to remove the definitions of those terms.

113.00K—How Do We Evaluate Specific Malignant Neoplastic Diseases?

In this section, we incorporate the discussion in prior 107.00C, “Acute leukemia,” and provide guidance for other childhood malignancies. Except for minor changes to refer to children, final 113.00K4, “Brain Tumors,” is the same as final 13.00K6. The following is a discussion of the other malignant neoplastic diseases addressed in this section.

113.00K1—Lymphoma

In this section, we indicate that final listing 113.05 should not be used for evaluating low grade or indolent lymphomas because they are rare in children. We will evaluate these lymphomas under final listing 13.05. We also indicate that many children with lymphoma are treated according to a long-term protocol that can result in significant adverse medical, social, and emotional consequences. We provide a reference to final 113.00G to evaluate those consequences.

113.00K2—Leukemia

In final 113.00K2c, we provide a description of juvenile CML (JCML) and explain that we will evaluate it under final listing 113.06A.

Final 113.00K2d is similar to final 13.00K2d. We did not include a discussion about chronic lymphocytic leukemia, as in final 13.00K2c, because the disorder is extremely rare in children.

113.00K3—Malignant Solid Tumors

In this section, we incorporate the guidance in prior 113.00C, “Malignant solid tumors.” We have revised the reference to the listing for brain tumors because that listing is now in this body system. As we have added a listing for the thyroid gland, we no longer need guidance in the introductory text explaining how thyroid tumors should be evaluated.

113.00K5—Retinoblastoma

In this section, we state that treatment for bilateral retinoblastoma usually results in a visual impairment and that we will evaluate any resulting visual impairment under listing 102.02.

113.00L—How Do We Evaluate Malignant Neoplastic Diseases Treated by Bone Marrow or Stem Cell Transplantation?

In this section, we provide the same guidance as in final 13.00L1, 13.00L2, and 13.00L4. We have added JCML to the heading of 13.00L1 to reflect that JCML is included in final listing 113.06A. We do not refer to multiple myeloma in final 113.00L2 because this impairment is not included in the final childhood listings. Multiple myeloma is extremely rare in children.

In the NPRM, we had also proposed a section in part B, similar to final 13.00L3, that contained guidance on how to evaluate bone marrow or stem cell transplantation for other disorders in children. That section, proposed 113.00L3, indicated that malignant neoplastic diseases treated with bone marrow or stem cell transplantation

should be evaluated under proposed listing 113.28. Proposed listing 113.28 was one of several listings that we proposed as a replacement for prior listing 113.03, “Malignant solid tumors.” As we explain in the public comments section of this preamble, we have decided not to change our prior criteria for malignant solid tumors in these final rules. Therefore, we do not need the guidance we included in proposed section 113.00L3, and we are not including it in these final rules. As we indicate in response to a public comment on bone marrow or stem cell transplantation in children, final listing 13.28 can be used in those few cases in which the end of the 2-year period provided by final listing 113.03 is earlier than the end of the period that the impairment would be considered disabling based on the bone marrow or stem cell transplantation.

How Are We Changing the Listings for Evaluating Malignant Neoplastic Diseases in Children?*113.01 Category of Impairments, Malignant Neoplastic Diseases*

We are redesignating the childhood listings to maintain consistency with the adult rules for those malignancies that are addressed in both the adult and childhood rules. Because of this, the numbers of the final childhood listings are not consecutive.

Listing 113.03—Malignant Solid Tumors

This listing corresponds to prior listing 113.03, “Malignant Solid Tumors.” We are making minor editorial changes to make the language consistent with that used in other listings and to indicate that, after the appropriate time period has passed, any residual impairment should be evaluated under criteria for the affected body system.

In the NPRM, we proposed removing prior listing 113.03 and providing separate listings for specific types of malignant solid tumors and a listing for malignant neoplastic diseases treated by bone marrow or stem cell transplantation. In response to a comment, we have decided to retain prior listing 113.03 as we further consider how to include solid tumors in children in our listings. Because we are retaining prior listing 113.03 in these final rules, we are not incorporating the proposed listings that would have replaced it: Proposed listing 113.04, “Soft Tissue Sarcoma (including Ewing’s Sarcoma, Primitive Neuroectodermal Tumors (PNETs));” proposed listing 113.11, “Osteogenic Sarcoma”; proposed listing 113.13A2,

for any central nervous system neoplasm progressive or recurrent following initial antineoplastic therapy; proposed listing 113.13B, for peripheral nerve or spinal root neoplasm; proposed listing 113.21B, for Wilms' tumor persistent or recurrent following initial Antineoplastic therapy; proposed listing 113.25, "Testicles—Tumor With Metastatic Disease Progressive of Recurrent Following Initial Chemotherapy"; proposed listing 113.26, "Germ Cell Tumors—Gonadal or Extragonadal"; and proposed listing 113.28, "Malignant Neoplastic Diseases Treated by Bone Marrow or Stem Cell Transplantation."

Listing 113.05—Lymphoma (Excluding T-cell Lymphoblastic Lymphoma—113.06)

This listing corresponds to prior listing 113.02, "Lymphoreticular malignant neoplasms." We are revising the listing to make it more consistent with final listing 13.05.

Final listing 113.05A replaces the criteria for non-Hodgkin's lymphoma in prior listing 113.02B. Currently, there are several treatment regimens for this disease, and they vary in the amount of time needed to complete them. Many are of sufficiently short duration that the impairment may be disabling for less than 12 months. Due to these advances in treatment, it is no longer appropriate to assume that the impairment will meet the statutory duration requirement. Instead, we will find the impairment disabling under this listing when it is persistent or recurrent following initial antineoplastic therapy. We also clarify that non-Hodgkins lymphoma includes Burkitt's and anaplastic large cell.

Final listing 113.05B replaces the criteria for Hodgkin's disease in prior listing 113.02A. With the final criterion, we clarify what we meant by "progressive disease not controlled by prescribed therapy" in the prior listing.

In final listing 113.05C, we add a criterion for bone marrow or stem cell transplantation.

Listing 113.06—Leukemia

This listing replaces prior listing 107.11, "Acute leukemia." In final listing 113.06A, for "acute leukemia," we also include T-cell lymphoblastic lymphoma and JCML. JCML is an aggressive leukemia that responds poorly to therapy and is, therefore, more appropriately evaluated like an acute leukemia. The criteria in this listing are the same as in final listing 13.06A, and are explained in the discussion of that listing.

In final listing 113.06B, which is the same as final listing 13.06B, we added

criteria for evaluating CML other than JCML.

Listing 113.09—Thyroid Gland

This listing is the same as final listing 13.09 and incorporates the guidance contained in prior 113.00C. The listing criteria define when the malignancy is not controlled by prescribed therapy.

Listing 113.12—Retinoblastoma

This final listing revises prior listing 113.05. We are removing prior listing 113.05A, for bilateral involvement, because with advances in treatment this malignancy is often treated successfully. As we indicate in final 113.00K4, we will evaluate the resulting visual impairment under listing 102.02. If treatment is not successful, we will evaluate the impairment under the other criteria in the final listing.

Final listing 113.12A corresponds to prior listing 113.05C. We are making no substantive changes.

Final listing 113.12B corresponds to prior listing 113.05D. We are revising the criteria to recognize that persistence after treatment, as well as recurrence, indicates a poor prognosis.

Final listing 113.12C corresponds to prior listing 113.05B. We are revising the description to make it clear that any metastatic disease is included under the listing.

Listing 113.13—Brain Tumors

This listing revises the criteria for malignant brain tumors in prior listing 111.05, "Brain tumors." We use the same criteria for evaluating brain tumors in children as in final listing 13.13A1.

In the NPRM, we proposed to expand the criteria in this listing to address other tumors of the nervous system. As explained above, we have decided to retain our prior criteria for evaluating malignant solid tumors, and these additional criteria are not needed. Because we are not including the additional criteria, we have revised the heading of this listing to reflect the types of tumors evaluated under it.

Listing 113.21—Neuroblastoma

Final listing 113.21A corresponds to prior listing 113.04, "Neuroblastoma." We have made minor editorial revisions to be consistent with other listings.

In the NPRM, we proposed changing the criteria for neuroblastoma. As explained above, we have decided to retain our prior criteria for malignant solid tumors as we further consider how to include solid tumors in children in our listings. Similarly, we have decided to retain our prior criteria for neuroblastoma.

We also proposed to expand the criteria in this listing to address Wilms' tumors. Because we are retaining our prior criteria for malignant solid tumors, this additional criterion is not needed. Therefore, we have revised the heading of this listing to reflect the types of tumors evaluated under it.

What Other Revisions Are We Making?

Consistent with the changes explained above, we are also:

- Changing the name of 7.00 and 107.00 from Hemic and Lymphatic System to Hematological Disorders. We are making this change because we are moving the lymphatic impairments now contained in these body systems to 13.00 and 113.00.

- Revising the heading of listing 7.17 to remove the reference to hematologic malignancies. We are making this change because we are moving the listings for hematological malignancies to 13.00 and 113.00.

- Revising 11.00B to indicate that malignant brain tumors should be evaluated under the criteria in listing 13.13.

- Adding 111.00E to provide the same guidance as final 11.00B.

- Revising prior listings 11.05 and 111.05 by removing the criteria for malignant brain tumors. In the NPRM, proposed listing 11.05 indicated that benign brain tumors would be evaluated under 11.02, 11.03, 11.04A or B, or 12.02. Proposed listing 111.05 indicated that these tumors would be evaluated under the criteria for the resulting neurological impairment. As we reviewed these criteria, we realized that these listings should be the same. We also realized that they should allow for the evaluation of all complications of benign brain tumors. Therefore, we have replaced the reference to 12.02 with "the criteria of the affected body system" and revised final listing 111.05 for consistency between the adult and childhood listings.

- Making nonsubstantive editorial changes throughout these rules to reflect the technical changes that were implemented by the final regulation we published in the **Federal Register** on April 24, 2002, (67 FR 20018), to correct typographical errors and omissions, to make the language clearer, and to be consistent with other rules.

Public Comments

In the NPRM we published in the **Federal Register** on November 27, 2001 (66 FR 59306), we provided the public with a 60-day comment period that ended on January 28, 2002. Due to some significant issues raised by commenters, we provided an additional 60-day

public comment period by publishing a notice in the **Federal Register** on April 18, 2002 (67 FR 19138). The additional comment period ended on June 17, 2002.

In response to the two notices, we received comments from 61 commenters, 16 of whom addressed the proposed criteria for malignant neoplastic diseases. These 16 commenters included medical organizations, legal services organizations, State agencies that make disability determinations for us, and individuals. Many of the commenters raised more than one issue. We carefully considered all of the comments.

A number of the comments were quite long and detailed, requiring us to condense, summarize, or paraphrase them. We have tried to accurately present all views of the commenters and have tried to respond to all of the significant issues raised by the commenters. We provide our reasons for adopting or not adopting the comments in our responses below.

General Comments

Extend the Comment Period and Provide the Medical and Scientific Justification for the Proposed Listings.

Comment: During the initial comment period, several commenters asked us to extend the 60-day comment period due to the length and complexity of the proposed rules. Commenters also asked us to provide the medical and scientific justification for these changes.

Response: As we reviewed the initial comments, we realized that significant issues were being raised, and we determined that it would be appropriate to reopen the comment period in order to get additional input on those and other issues. Therefore, on April 18, 2002, we published a notice in the **Federal Register** (67 FR 19138) reopening the comment period and providing an additional 60-day period within which to comment. The additional comment period ended on June 17, 2002. The notice that reopened the comment period included references to the medical and scientific sources we consulted when developing the NPRM, and invited comment on those references as well.

The Proposed Listings are More Restrictive Than the Prior Listings

Comment: Some commenters believed that these criteria reflect a trend toward an increased level of severity in the listings. One commenter noted that, although good arguments may be made for these changes, the criteria in the childhood listings for non-Hodgkin's

lymphoma, chronic granulocytic leukemia, thyroid carcinoma, medulloblastoma, Wilms' tumor, testicular cancer, and germ-cell tumors were more restrictive.

Response: As we reviewed our proposed listings to respond to the public comments, we realized that we need to consider further how to address childhood malignant solid tumors in our listings. In the interim, we are retaining our prior criteria that provide that malignant solid tumors, other than brain tumors or thyroid tumors, are disabling for 2 years from the date of initial diagnosis or from the date of recurrence of active disease. We are also retaining our prior criteria for neuroblastoma.

Impact of the Changes

Comment: Two commenters stated that the proposed rules would result in a considerable reduction in the number of individuals eligible for disability benefits and requested that we provide an estimate of the impact of these changes.

Response: Based on our assessment of these rules, we do not believe that a considerable number of individuals will be adversely affected by the changes we are making in these final rules. We believe that these final rules appropriately reflect advances in medical knowledge, treatment, and methods for evaluating malignant neoplastic diseases.

Comment: One commenter expressed concern that these rules would result in fewer claims being allowed at step 3 of the sequential evaluation process, and that a functional assessment would be required in more cases.

Response: Based on our assessment of these rules, we do not believe that fewer claims will be allowed at step 3 of the sequential evaluation process.

The Proposed Listings May Result in Delays

Comment: Several commenters expressed concern that it will take longer to evaluate some malignancies because the proposed listings for these malignancies require that the treatment has not been effective. Some of these commenters believed that evaluation of these malignancies would need to be delayed until treatment was completed. One commenter thought that we would not evaluate cases at other steps in the sequential evaluation process while we were waiting to determine the effectiveness of the treatment. One commenter thought that deferring adjudication in these cases would result in more informed decisions and prevent us from denying some cases in error.

Response: While we agree that these final rules may delay the adjudication of some cases, we do not believe the number of affected cases will be significantly more than under the prior rules. The prior listings for most of these malignancies also included a requirement that the impairments not be controlled by prescribed therapy. To make this determination under the prior rules, we also had to allow sufficient time to determine whether the impairments would be controlled.

When we can determine whether treatment will be effective before the treatment regimen is completed, we will make the decision about whether the malignancy is of listing-level severity at that point. Additionally, as we state in final 13.00E3 and 113.00E3, we will not 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 malignancy or therapy.

Focus on the Individual's Particular Situation

Comment: One commenter stressed the importance of focusing on an individual's particular situation, especially when he or she has significant limitations past the listed disability time period. The commenter stated that cancer patients typically incur short-term impairments resulting from toxicities associated with chemotherapy and other treatment, and from the disease itself. The commenter also noted that impairments from treatment, such as cardiotoxicity and infertility, can manifest several years later, and that a tumor may cause disability to a patient for a period of time far surpassing that which has been allocated by the proposed regulations for certain malignant neoplastic diseases. The commenter believed that it is essential that the new regulations maintain sufficient flexibility to adequately adjust disability time periods based on the individualized nature of cancer and patient responses to treatment of the disease.

Another commenter believed that the proposed rules did not adequately address problems with fatigue, energy levels and ability to sustain work for normal periods of time. The commenter also requested that we consider the lack of immunity to infection from which many individuals with cancer suffer.

Response: We believe these final regulations do allow sufficient flexibility to adjust the period of time the individual is considered disabled and stress the importance of considering residual impairment(s) or symptoms

caused by the disease or the treatment. However, the severity of any residual impairment(s) or symptom can vary greatly, and must be evaluated on an individualized, case-by-case basis. If a severe residual impairment(s) does not meet or medically equal any listing, we will evaluate the impact of the impairment(s), as well as the impact of any symptoms caused by the disease or the treatment, at later steps in the sequential evaluation process.

The Listings Need Timely Review

Comment: Two commenters stated that these listings will need timely review in the future to keep up with advances in treatment and to ensure that they reflect current medical knowledge.

Response: We agree that the listings should continue to reflect the latest medical knowledge and advances in treatment. We intend to monitor these listings and to update the criteria for any impairment contained in these listings as the need arises. For this reason, we are indicating that these rules will be in effect for 5 years after they become effective, unless we extend them or revise and issue them again.

Comments on the Introductory Text

Provide Additional Definitions

Comment: Two commenters asked us to include definitions of “regional lymph nodes” and “distant metastases” in the introductory text.

Response: As we indicated in our explanation of 13.00I, our intent is to use these terms as they are used in current clinical practice. In clinical practice, these terms are defined in relation to the site of the primary malignancy. To define these terms in our listings, we would need a separate definition for each primary site specified in the listings. Our adjudicative experience has shown that the medical evidence usually indicates whether the malignancy has spread to the regional lymph nodes or beyond. Therefore, we do not believe it is practicable or necessary to add these definitions to the introductory text. Instead, we will rely on the description of the malignancy contained in the medical records.

Documenting Complete Remission

Comment: One commenter requested that we add a discussion of the documentation required to establish a “complete remission.”

Response: We partially adopted this comment by revising final 13.00H2 and 113.00H2 to clarify that “complete remission” occurs when the original tumor and any metastases are no longer

evident. However, we did not add a discussion about the documentation we require to establish a complete remission. The treating source will determine the methods of evaluating complete remission for the particular malignancy for each individual patient. We will usually rely on the documentation provided by the treating source.

13.00 K2c—Chronic Lymphocytic Leukemia

Comment: One commenter noted that chronic lymphocytic leukemia (CLL) is mentioned only in the introductory text and believed that this is a potential source of confusion. The commenter requested that CLL be added to the heading of proposed listing 13.05, Lymphoma, and included in the criteria in proposed listings 13.05A1 and 13.05A2, which address non-Hodgkin’s lymphoma.

Response: We partially adopted the comment. The complications of CLL are diverse and, because of this, it is not always appropriate to evaluate CLL using the criteria for lymphoma. By maintaining the references in the introductory text, we provide the flexibility needed to evaluate this disorder. We have, however, included a reference to 13.00K2c in the heading of final listing 13.05 as a reminder that CLL may be evaluated under this listing when appropriate.

Evaluation of Hodgkin’s Disease That Recurs More Than 1 Year After Completion of Therapy

Comment: One commenter disagreed with our proposed rule in 13.00K1c to consider Hodgkin’s disease that recurs more than 12 months after the completion of initial antineoplastic therapy as new disease under the listings, rather than a recurrence. The commenter indicated that oncologists would consider such patients as having relapsed, rather than as having developed a new disease.

Response: We agree that, for treatment purposes, Hodgkin’s disease that recurs more than 12 months after the completion of therapy should not be considered as new disease. However, Hodgkin’s disease frequently remits within 12 months of the initiation of treatment, and the period of remission is often longer than 12 months. In these instances, the impairment would not satisfy the statutory duration requirement. If the disease then recurs, we have to consider it as a new disease for purposes of determining whether the duration requirement will be met. Additionally, secondary treatment for a

recurrence after 12 months can result in complete remission or cure.

Comments on the Listing Criteria

Add Additional Criteria

Comment: Several commenters suggested that we add specific additional malignancies to the listings. One commenter expressed concern that malignancies that are not contained in the listings because they are rare or because they are often amenable to treatment will not be properly evaluated. The commenter indicated that there are no instructions as to how to adjudicate the cases of individuals who do not respond well to treatment, and believed that there was no guidance for evaluating any cases on a case-by-case basis. The commenter also believed it is not acceptable to rely on the sequential evaluation process, since that process is often difficult to enforce and apply uniformly to people of all age groups. The commenter said this is especially true for children. The commenter suggested that these regulations include a full listing of any malignancy that is of listing-level severity.

Response: We have not added the specific malignancies suggested by the commenters. In some instances, we believe the malignancies are already included in the final rules. For example, one commenter suggested we add nasopharyngeal cancer. This malignancy will be evaluated under final listing 13.02, for soft tissue tumors of the head and neck. Another commenter suggested we add an adult listing for germ-cell tumors. These malignancies will be evaluated under the criteria in listing 13.15B or listing 13.23E2, depending on the site of the malignancy.

In other instances, such as prostate cancer with bone metastases or earlier stages of multiple myeloma, we believe that there are effective therapies that, even considering their length and effects, generally do not result in an impairment of listing-level severity. In these situations, we believe that the impairment should not be considered to be of listing-level severity until it is demonstrated that therapy is not effective.

We did not add the other suggested additions, such as granulocytic sarcoma, because these malignancies are rare. As noted in sections 13.00F and 113.00F of these rules, the listings contain examples of impairments that we consider severe enough to prevent an adult from doing any gainful activity, or that cause marked and severe functional limitations in a child. The listings are

not intended to be all-inclusive. The purpose of the listings—to allow us to readily identify individuals with common impairments of listing-level severity—would be defeated if we tried to identify every malignancy that could be of listing-level severity.

However, we believe that our regulations do provide adequate guidance about how to evaluate malignancies that do not respond to treatment or that are unlisted. Many of these final listings address situations in which treatment is not successful. For example, final listing 13.02B addresses the situation in which the malignancy is persistent following initial multimodal antineoplastic treatment and final listing 13.09B addresses the situation in which the malignancy is progressive despite radioactive iodine therapy. We also have other rules that discuss how to evaluate impairments that are not listed. These other rules are not included in this notice, as we are not making any changes to them. We believe that malignancies that are not listed can be properly and uniformly evaluated under these other rules.

Also, and as we have already noted, as we reviewed our proposed listings to respond to the last comment, we realized that we need to consider further how to include childhood malignant solid tumors in our listings. In the interim, we have decided to retain our prior criteria for these impairments.

Comment: One commenter recommended that all cases of lymphoma should be determined to be of listing-level severity and that cases not covered by the proposed rules should be allowed with a short reexamination diary.

Response: We have not included criteria for additional lymphoma cases. It would not be appropriate to include lymphomas that do not satisfy the criteria in these final rules because we cannot presume that these impairments will meet the statutory duration requirement. Other lymphomas may respond more readily to therapy.

Use Staging Systems

Comment: Two commenters suggested we incorporate accepted classifications and staging in the listings. One indicated we should use clinical classifications and stagings that are tied to ongoing tumor registries that are matched with survival rates.

Response: As in the NPRM, these final rules incorporate staging criteria where appropriate. In these instances, we list the criteria for the stage rather than refer to the stage number. For example, the criteria in final listing 13.10A, for

locally advanced breast carcinoma, correspond to stage IIIB.

We decided not to include staging numbers for two reasons. The first is that there are different staging classifications and these different classifications are not necessarily consistent. The second is that staging classifications change. If we used the staging number as the criterion, these rules may no longer be appropriate if a change in staging classifications is made.

Listings With Time Limits

Comment: Several commenters noted that several of the proposed listings included language about time limits after which the adjudicator was advised to evaluate any residual impairment(s) under the relevant body system, but that these listings did not refer to the medical improvement review standard in §§ 404.1594, 416.994, and 416.994a. They believed that failure to apply the medical improvement review standard at the end of the specified period would be contrary to the statute. One of these commenters believed that a time limit should, at most, result in a date for reviewing the individual's continuing eligibility for disability benefits.

Response: As in the prior listings and in a number of listings in other body systems, some of the listings in these final rules contain time limits in their criteria to explain the period for which we will presume that the individuals are disabled based on the nature of their impairments, the duration and effects of therapy, and the expected course of the impairments. After the therapy is completed and the relevant time period has passed, we can no longer presume that these individuals are disabled. When we review these claims to determine if these individuals continue to be disabled, we will apply the appropriate medical improvement review standard set forth in our regulations in §§ 404.1594, 416.994, or 416.994a.

Final Listing 13.02

Comment: One commenter noted that we replaced the phrase “not controlled by prescribed therapy” in prior listing 13.02B with “[p]ersistent disease following initial multimodal antineoplastic therapy” in proposed listing 13.02B. The commenter expressed concern that this criterion would exclude patients who are treated with radiation alone (uni-modal therapy), have persistent disease, and who cannot undergo surgery because of the medical condition or because the tumor remains unresectable. The commenter indicated the prognosis for

these individuals seems to fit the intent of the listing. The commenter recommended we use the phrase “therapy for curative intent” instead of “initial multimodal antineoplastic therapy.”

Response: We did not adopt the comment because individuals described in the comment have impairments that meet final listing 13.02A. That listing describes individuals who have tumors that are inoperable or unresectable. The definitions of the terms “inoperable” and “unresectable” in final 13.00I1 and 13.00I2 include the individuals described by the commenter.

Comment: One commenter noted the criterion for epidermoid carcinoma occurring in the pyriform sinus in proposed listing 13.02E and questioned why this site was singled out. The commenter indicated this impairment would be covered under the criteria for soft tissue tumors with multimodal therapy in proposed listing 13.02F.

Response: We agree with the commenter and have deleted the criterion for epidermoid carcinoma occurring in the pyriform sinus in final listing 13.02. Due to this deletion, we redesignated proposed listing 13.02F, for soft tissue tumors of the head and neck treated with multimodal therapy, as final listing 13.02E.

Final Listing 13.05

Comment: One commenter believed that the language in proposed listing 13.05A2, for low-grade or indolent lymphoma requiring initiation of more than 1 antineoplastic treatment regimen within a consecutive 12-month period, was confusing. The commenter indicated that we should specify that concurrent treatments would not apply and that the treatments must occur on separate occasions.

Response: The listing refers to a treatment regimen that may consist of more than one modality of treatment. The modalities used in the treatment regimen may be administered concurrently or sequentially, depending on the regimen. Regardless of the way the modalities are administered, they are still considered to be one treatment regimen. Therefore, we have not adopted the commenter's suggested changes.

However, in reviewing the proposed listing in response to this comment, we realized that some clarification of the introductory text to the listings was needed. The heading of final listing 13.05 cross-refers to 13.00K1 in the introductory text. However, proposed 13.00K1a discussed only “indolent” lymphoma, and did not refer to “low grade” lymphoma even though the

listing refers to both. This was an oversight. To be consistent with the listing criteria, we have amended final 13.00K1a to refer to both low grade and indolent lymphomas.

Final Listing 13.10

Comment: One commenter noted the criterion for breast cancer in proposed listing 13.10C, for recurrent carcinoma, except local recurrence that remits with antineoplastic therapy. The commenter believed that this criterion should be interpreted to mean a recurrence that remits with therapy subsequent to initial treatment and that adjudicators would therefore be looking at two separate events. The commenter asked whether this interpretation was correct.

Response: The commenter's interpretation is correct. Breast carcinoma that had previously remitted with initial antineoplastic treatment, that has now recurred locally, and that remits with the antineoplastic therapy given for the recurrence does not represent an impairment of listing-level severity. An example is breast cancer that initially remits following a lumpectomy and radiation, but later recurs at the site of the incision, and is successfully treated with mastectomy.

Final Listing 13.12

Comment: One commenter noted that the phrase "or with regional or distant metastases" in proposed listing 13.12B was unnecessary as regional and distant metastases are covered in proposed listing 13.12A.

Response: We agree with the commenter and have removed the phrase from final listing 13.12B.

Final Listing 13.13

Comment: One commenter questioned why we retained the listing for metastatic carcinoma to the brain (proposed listings 13.13C and 13.13C) when all other listings refer to the site of origin of the tumor. The commenter asked if these listings apply to cases of testicular cancer with brain metastases.

Response: In response to this comment, we did not incorporate proposed listings 13.13C and 13.13C, for metastatic carcinoma to brain or spinal cord, in the final rules so that the final listings will refer to the site of origin of the tumor. We also revised the introductory text (13.00C and 13.00C) to reflect this change.

Final Listing 13.14

Comment: One commenter disagreed with the proposed deletion of the listing for non-squamous non-small-cell carcinoma with metastases to the hilar lymph nodes (prior listing 13.13E). The

commenter indicated that there have not been significant treatment advances for this malignancy, nor has there been a significant improvement in prognosis. The commenter stated that excising the involved hilar nodes has not altered the unfavorable prognosis for this malignancy.

Response: We agree with the commenter and have revised listing 13.14A to include the hilar nodes.

Final Listing 13.25

Comment: One commenter objected to the deletion of prior listing 13.24A, for choriocarcinoma. The commenter indicated that choriocarcinoma is a particularly aggressive testicular cancer with frequent distant metastases and should not be evaluated in the same manner as other forms of testicular cancer.

Response: The literature we consulted did not separate choriocarcinoma from other forms of testicular nonseminomatous germ-cell tumors with regard to staging or treatment. Therefore, we did not adopt the comment.

Final Listing 113.10

Comment: One commenter questioned the proposed deletion of the criterion for bilateral retinoblastoma (prior listing 113.05A). The commenter indicated that most children with this disease are blind in one eye and have decreased vision in the other eye, resulting in significant visual impairments.

Response: We recognize that the current treatment of this disease results in significant visual impairments. While we have not retained this criterion in final listing 113.10, we have added guidance to the introductory text, final 113.00K5, providing that we will evaluate any resulting visual impairment(s) under the criteria in listing 102.02.

Final Listing 113.21

Comment: One commenter noted that prior listing 113.04, for neuroblastoma, included a criterion for recurrent disease which was not included in proposed listing 113.21A. The commenter asked if we intended to delete this criterion, as the deletion was not addressed in the explanation of the proposed listing.

Response: We did not intend to delete this criterion, and it is included in these rules as final listing 113.21C.

Final Listings 113.25 and 113.26

Comment: Two commenters noted that testicular germ-cell tumors could be evaluated under either proposed listing 113.25, for testicular malignancies, or

proposed listing 113.26, for germ-cell tumors. The commenters suggested that we evaluate testicular germ-cell tumors under the listing for testicular malignancies and exclude them from the listing for germ-cell tumors.

Response: We did not adopt the comments because we decided to retain our prior criteria for malignant solid tumors in children. Under these final rules, malignant neoplasms that would have been evaluated under the proposed listings 113.25 and 113.26 will be considered to be disabling for 2 years from the date of initial diagnosis or the date of recurrence of active disease.

Final Listing 113.28

Comment: One commenter believed that a 12-month listing criterion is too short for children who have malignant neoplastic diseases treated by allogeneic bone marrow or stem cell transplantation. The commenter believed we should consider the increased risk of acute or chronic graft vs. host disease and infection in pediatric patients.

Response: As already noted, we decided to retain our prior criteria for malignant solid tumors in children. Therefore, we are not including the proposed listing that was the subject of this comment in these final rules.

Under these final rules, criteria for evaluating bone marrow or stem cell transplants in cases of leukemia or lymphoma are included in the listings for those disorders, final listings 113.05 and 113.06. Under final listing 113.03, malignant solid tumors in children will be considered disabling for 2 years from the date of initial diagnosis or the date of recurrence of active disease regardless of whether a bone marrow or stem cell transplant has been performed. The adult listing for bone marrow or stem cell transplantation, final listing 13.28, can be used to evaluate those few cases in which the end of the 2-year period is earlier than the end of the period that the impairment would be considered disabling based on the bone marrow or stem cell transplantation. Final listing 13.28A, for malignant neoplastic diseases treated by allogeneic bone marrow or stem cell transplantation, provides that the individual will be considered to be under a disability until "at least" 12 months from the date of transplantation. Use of the phrase "at least" provides us with the flexibility to set a longer time frame when appropriate.

Regulatory Procedures

Executive Order 12866

We have consulted with the Office of Management and Budget (OMB) and determined that these final rules meet the criteria for a significant regulatory action under Executive Order 12866, as amended by Executive Order 13258. Thus, they were subject to OMB review.

Regulatory Flexibility Act

We certify that these final rules do not have a significant economic impact on a substantial number of small entities because they affect only individuals. Thus, a regulatory flexibility analysis as provided in the Regulatory Flexibility Act, as amended, is not required.

Paperwork Reduction Act

These final rules contain reporting requirements at 13.00B, 13.00D, 13.00E, 13.00G, 13.00K, 113.00B, 113.00D, 113.00E, 113.00G, and 113.00K of the final rules. An Information Collection Request has been submitted to OMB. While these rules will be effective 30 days from publication, these burdens will not be effective until approved by OMB. We will publish a notice in the **Federal Register** upon OMB's approval of the information collection requirements.

List of Subjects in 20 CFR Part 404

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

(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)

Dated: July 19, 2004.

Jo Anne B. Barnhart,

Commissioner of Social Security.

■ For the reasons set forth in the preamble, subpart P of part 404 of chapter III of title 20 of the Code of Federal Regulations is amended as set forth below:

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

■ 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) and (i), 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) and (i), 422(c), 423, 425, and

902(a)(5)); sec. 211(b), Pub. L. 104–193, 110 Stat. 2105, 2189.

Appendix 1 to Subpart P of Part 404— [Amended]

- 2. Appendix 1 to subpart P of part 404 is amended as follows:
 - a. Item 8 of the introductory text before part A of appendix 1 is amended by revising the body system name.
 - b. Item 14 of the introductory text before part A of appendix 1 is amended by revising the body system name and expiration date.
 - c. The Table of Contents for part A of appendix 1 is amended by revising the body system names for sections 7.00 and 13.00.
 - d. The body system name of section 7.00 of part A of appendix 1 is revised and paragraph E of the introductory text of section 7.00, Hematological Disorders, is removed.
 - e. Listings 7.11, 7.12, 7.13, 7.14, and 7.16 of part A of appendix 1 are removed.
 - f. Listing 7.17 of part A of appendix 1 is revised.
 - g. Paragraph B of the introductory text of section 11.00, Neurological, of part A of appendix 1 is revised.
 - h. Listing 11.05 of part A of appendix 1 is revised.
 - i. Section 13.00 of part A of appendix 1 is revised.
 - j. The Table of Contents for part B of appendix 1 is amended by revising the body system names for sections 107.00 and 113.00.
 - k. The body system name of section 107.00 of part B of appendix 1 is revised and paragraph C of the introductory text of section 107.00, Hematological Disorders, is removed.
 - l. Listing 107.11 of part B of appendix 1 is removed.
 - m. Paragraph E is added to the introductory text of section 111.00, Neurological, of part B of appendix 1.
 - n. Listing 111.05 of part B of appendix 1 is revised.
 - o. Section 113.00 of part B of appendix 1 is revised.

The revised text is set forth as follows:

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

*	*	*	*	*
8. Hematological Disorders (7.00 and 107.00): July 1, 2005.				
*	*	*	*	*
14. Malignant Neoplastic Diseases (13.00 and 113.00): December 15, 2009.				
*	*	*	*	*

Part A

*	*	*	*	*
7.00	Hematological Disorders			
*	*	*	*	*
13.00	Malignant Neoplastic Diseases			
*	*	*	*	*

7.00 HEMATOLOGICAL DISORDERS

*	*	*	*	*
E. [removed]				
*	*	*	*	*
7.11	[removed]			
7.12	[removed]			
7.13	[removed]			
7.14	[removed]			
*	*	*	*	*
7.16	[removed]			
7.17	<i>Aplastic anemias</i> with bone marrow or stem cell transplantation. Consider under a disability for 12 months following transplantation; thereafter, evaluate according to the primary characteristics of the residual impairment.			
*	*	*	*	*
11.00	NEUROLOGICAL			
*	*	*	*	*
B. <i>Brain tumors.</i> We evaluate malignant brain tumors under the criteria in 13.13. For benign brain tumors, we determine the severity and duration of the impairment on the basis of symptoms, signs, and laboratory findings (11.05).				
*	*	*	*	*
11.05	<i>Benign brain tumors.</i> Evaluate under 11.02, 11.03, 11.04, or the criteria of the affected body system.			
*	*	*	*	*

13.00 MALIGNANT NEOPLASTIC DISEASES

A. *What impairments do these listings cover?* We use these listings to evaluate all malignant neoplasms except certain neoplasms associated with human immunodeficiency virus (HIV) infection. We use the criteria in 14.08E to evaluate carcinoma of the cervix, Kaposi's sarcoma, lymphoma, and squamous cell carcinoma of the anus if you also have HIV infection.

B. *What do we consider when we evaluate malignant neoplastic diseases under these listings?* We consider factors such as the:

1. Origin of the malignancy.
2. Extent of involvement.
3. Duration, frequency, and response to antineoplastic therapy. Antineoplastic therapy means surgery, irradiation, 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.
4. Effects of any post-therapeutic residuals.

C. *How do we apply these listings?* We apply the criteria in a specific listing to a malignancy 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.
 - 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 malignancy, the response to therapy, and any significant residuals. (See 13.00G.)

E. When do we need longitudinal evidence?

1. *Tumors with distant metastases.* We generally do not need longitudinal evidence for tumors that have metastasized beyond the regional lymph nodes because these tumors usually meet the requirements of a listing. Exceptions are for tumors with distant metastases that are 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 intended effect of therapy has been achieved and is likely to persist.

2. *Other malignancies.* 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 (multimodal) given in close proximity as a unified whole, and is usually planned before any treatment(s) is initiated. Examples of multimodal therapy include:

- a. Surgery followed by chemotherapy or radiation.
- b. Chemotherapy followed by surgery.
- c. Chemotherapy and concurrent radiation.

3. *Types of treatment.* 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 will often happen within 6 months after the treatment starts, and there will often be a change in the treatment regimen. Whenever the initial planned therapy is multimodal, a determination about the effectiveness of the therapy usually cannot be made until the effects of all the planned modalities can be determined. In some cases, we may need to defer adjudication until the effectiveness of therapy can be assessed. 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 malignancy or therapy (see 13.00G).

F. How do we evaluate impairments that do not meet one of the malignant neoplastic diseases listings?

1. These listings are only examples of malignant neoplastic diseases 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.) 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. If you are an adult, we use the rules in §§ 404.1594 and 416.994, as appropriate, when we decide whether you continue to be disabled.

G. How do we consider the effects of therapy?

1. *How we consider the effects of therapy under the listings.* In many cases, malignancies meet listing criteria only if the therapy does not achieve the intended effect: the malignancy persists, progresses, or recurs despite treatment. 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. Because the therapy and its toxicity may vary widely, we consider each case on an individual basis. 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.* Because the severity of the adverse effects of antineoplastic therapy may change during treatment, enough time must pass to allow us to evaluate the therapy's effect. The residual effects of treatment are temporary in most instances. But 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 will consider your impairment to be disabling until a particular point in time (for example, at least 18 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 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 malignancy or therapy (see 13.00G), in determining whether you are disabled.

I. What do these terms in the listings mean?

1. *Inoperable:* Surgery is thought to be of no therapeutic value or the surgery cannot be performed. Examples of when surgery cannot be performed include a tumor that is too large or that invades crucial structures, or an intolerance of anesthesia or surgery due to other medical conditions. This term does not include situations in which the tumor could have been surgically removed but another method of treatment was chosen; for example, an attempt at organ preservation. The determination whether a tumor is inoperable usually occurs before attempts to shrink the tumor with chemotherapy or radiation.

2. *Unresectable:* The operation was performed, but the malignant tumor was not removed. This term includes situations in which a tumor is incompletely resected or the surgical margins are positive.

3. *Persistent:* Failure to achieve a complete remission.

4. *Progressive:* The malignancy became more extensive after treatment.

5. *Recurrent, relapse:* A malignancy that had been 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 malignancy satisfies the criteria of a listing? Yes. We will consider factors such as:

1. The type of malignancy and its location.
2. The extent of involvement when the malignancy was first demonstrated.
3. Your symptoms.

K. How do we evaluate specific malignant neoplastic diseases?

1. *Lymphoma.*

a. Many low grade or indolent (non-aggressive) lymphomas are controlled by well-tolerated treatment modalities, although they may produce intermittent symptoms and signs. Therefore, we may defer adjudication of these cases for an appropriate period after initiation of therapy to determine whether the therapy will achieve its intended effect. (See 13.00E3.) For a low grade or indolent lymphoma, the intended effect of therapy is usually stability of the disease process. When stability has been achieved, we will assess severity on the basis of the extent of involvement of other organ systems and residuals from therapy.

b. A change in therapy for low grade or indolent lymphomas is usually an indicator that the therapy is not achieving its intended effect. However, it does not indicate this if the change is based on your (or your physician's) choice rather than a failure to achieve stability. If the therapy is changed

due solely to choice, the requirements of listing 13.05A2a are not met.

c. We consider Hodgkin's disease 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 upon 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. The initial and follow-up pathology reports should be included.

b. *Chronic myelogenous leukemia (CML).* The diagnosis of CML should be based upon 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.

c. Chronic lymphocytic leukemia.

i. The diagnosis of chronic lymphocytic leukemia (CLL) must be documented by evidence of a chronic lymphocytosis of at least 10,000/mm³ 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, 7.02, and 7.15.

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

3. *Macroglobulinemia or heavy chain disease.* The diagnosis of these diseases must be confirmed by protein electrophoresis or immunoelectrophoresis. We evaluate the resulting impairment(s) under the criteria of 7.02, 7.06, 7.08, or any other affected body system.

4. *Bilateral primary breast cancer.* 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.

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. *Brain tumors.* We use the criteria in 13.13 to evaluate malignant brain tumors. We will evaluate any complications of malignant brain tumors, such as resultant neurological or psychological impairments, under the criteria for the affected body system. We evaluate benign brain tumors under 11.05.

L. *How do we evaluate malignant neoplastic diseases treated by bone marrow or stem cell transplantation?* Bone marrow or stem cell transplantation is performed for a variety of malignant neoplastic diseases.

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 malignancies.* We will evaluate any other malignant neoplastic disease 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:

- Graft-versus-host (GVH) disease.
- Immunosuppressant therapy, such as frequent infections.
- Significant deterioration of other organ systems.

13.01 Category of Impairments, Malignant Neoplastic Diseases

13.02 *Soft tissue tumors of the head and neck (except salivary glands—13.06—and thyroid gland—13.07).*

A. Inoperable or unresectable.

OR

B. Persistent disease following initial multimodal antineoplastic therapy.

OR

C. Recurrent disease following initial antineoplastic therapy, except local vocal cord recurrence.

OR

D. With metastases beyond the regional lymph nodes.

OR

E. Soft tissue tumors of the head and neck not addressed in A-D, with multimodal antineoplastic therapy. 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.

A. Sarcoma or carcinoma with metastases to or beyond the regional lymph nodes.

OR

B. Melanoma, with either 1 or 2:

1. Recurrent after wide excision (except an additional primary melanoma at a different site, which is not considered to be recurrent disease).

2. Palpable nodal metastases or metastases to adjacent skin (satellite lesions) or elsewhere.

13.04 Soft tissue sarcoma.

A. With regional or distant metastases.

OR

B. Persistent or recurrent following initial antineoplastic therapy.

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

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

1. Intermediate or high-grade lymphoma persistent or recurrent following initial antineoplastic therapy.

2. Low-grade or indolent lymphoma requiring initiation of more than one antineoplastic treatment regimen within a consecutive 12-month period. Consider under a disability from at least the date of initiation of the treatment regimen that failed within 12 months.

OR

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

OR

C. With bone marrow or stem cell transplantation. Consider under a disability until at least 12 months from the date of transplantation. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

13.06 Leukemia. (See 13.00K2.)

A. Acute leukemia (including T-cell lymphoblastic lymphoma). Consider under a disability until at least 24 months from the date of diagnosis or relapse, or at least 12 months from the date of bone marrow or stem cell transplantation, whichever is later. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

OR

B. Chronic myelogenous leukemia, as described in 1 or 2:

1. Accelerated or blast phase. Consider under a disability until at least 24 months from the date of diagnosis or relapse, or at least 12 months from the date of bone marrow or stem cell transplantation, whichever is later. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

2. Chronic phase, as described in a or b:

a. Consider under a disability until at least 12 months from the date of bone marrow or stem cell transplantation. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

b. Progressive disease following initial antineoplastic therapy.

13.07 *Multiple myeloma (confirmed by appropriate serum or urine protein electrophoresis and bone marrow findings).*

A. Failure to respond or progressive disease following initial antineoplastic therapy.

OR

B. With bone marrow or stem cell transplantation. Consider under a disability until at least 12 months from the date of transplantation. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

13.08 *Salivary glands*—carcinoma or sarcoma with metastases beyond the regional lymph nodes.

13.09 *Thyroid gland.*

A. Anaplastic (undifferentiated) carcinoma.

OR

B. Carcinoma with metastases beyond the regional lymph nodes progressive despite radioactive iodine therapy.

13.10 *Breast (except sarcoma—13.04).* (See 13.00K4.)

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

OR

B. Carcinoma with distant metastases.

OR

C. Recurrent carcinoma, except local recurrence that remits with antineoplastic therapy.

13.11 *Skeletal system*—carcinoma or sarcoma.

A. Inoperable or unresectable.

OR

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

OR

C. With distant metastases.

OR

D. All other tumors originating in bone with multimodal antineoplastic therapy. 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.*

A. Sarcoma or carcinoma of any type with regional or distant metastases.

OR

B. Carcinoma of the antrum with extension into the orbit or ethmoid or sphenoid sinus.

OR

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

13.13 *Nervous system.* (See 13.00K6.)

A. Central nervous system neoplasms (brain and spinal cord), as described in 1 or 2:

1. Highly malignant tumors, such as Grades III and IV astrocytomas, glioblastoma

multiforme, ependyoblastoma, medulloblastoma or other primitive neuroectodermal tumors (PNETs) with documented metastases, diffuse intrinsic brain stem gliomas, or primary sarcomas.

2. Any central nervous system neoplasm progressive or recurrent following initial antineoplastic therapy.

OR

B. Peripheral nerve or spinal root neoplasm, as described in 1 or 2:

1. Metastatic.

2. Progressive or recurrent following initial antineoplastic therapy.

13.14 *Lungs.*

A. Non-small-cell carcinoma—inoperable, unresectable, recurrent, or metastatic disease to or beyond the hilar nodes.

OR

B. Small-cell (oat cell) carcinoma.

13.15 *Pleura or mediastinum.*

A. Malignant mesothelioma of pleura.

OR

B. Tumors of the mediastinum, as described in 1 or 2:

1. With metastases to or beyond the regional lymph nodes.

2. Persistent or recurrent following initial antineoplastic therapy.

13.16 *Esophagus or stomach.*

A. Carcinoma or sarcoma of the esophagus.

OR

B. Carcinoma or sarcoma of the stomach, as described in 1 or 2:

1. Inoperable, unresectable, extending to surrounding structures, or recurrent.

2. With metastases to or beyond the regional lymph nodes.

13.17 *Small intestine*—carcinoma, sarcoma, or carcinoid.

A. Inoperable, unresectable, or recurrent.

OR

B. With metastases beyond the regional lymph nodes.

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

A. Adenocarcinoma that is inoperable, unresectable, or recurrent.

OR

B. Squamous cell carcinoma of the anus, recurrent after surgery.

OR

C. With metastases beyond the regional lymph nodes.

13.19 *Liver or gallbladder*—tumors of the liver, gallbladder, or bile ducts.

13.20 *Pancreas.*

A. Carcinoma (except islet cell carcinoma).

OR

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

13.21 *Kidneys, adrenal glands, or ureters*—carcinoma.

A. Inoperable, unresectable, or recurrent.

OR

B. With metastases to or beyond the regional lymph nodes.

13.22 *Urinary bladder*—carcinoma.

A. With infiltration beyond the bladder wall.

OR

B. Recurrent after total cystectomy.

OR

C. Inoperable or unresectable.

OR

D. With metastases to or beyond the regional lymph nodes.

13.23 *Cancers of the female genital tract*—carcinoma or sarcoma.

A. Uterus (corpus), as described in 1, 2, or 3:

1. Invading adjoining organs.

2. With metastases to or beyond the regional lymph nodes.

3. Persistent or recurrent following initial antineoplastic therapy.

OR

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

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

2. Persistent or recurrent following initial antineoplastic therapy.

OR

C. Vulva, as described in 1, 2, or 3:

1. Invading adjoining organs.

2. With metastases to or beyond the regional lymph nodes.

3. Persistent or recurrent following initial antineoplastic therapy.

OR

D. Fallopian tubes, as described in 1 or 2:

1. Extending to the serosa or beyond.

2. Persistent or recurrent following initial antineoplastic therapy.

OR

E. Ovaries, as described in 1 or 2:

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

a. Tumor extension beyond the pelvis; for example, tumor implants on peritoneal, omental, or bowel surfaces.

b. Metastases to or beyond the regional lymph nodes.

c. Ruptured ovarian capsule, tumor on the serosal surface of the ovary, ascites with malignant cells, or positive peritoneal washings.

d. Recurrent following initial antineoplastic therapy.

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

13.24 *Prostate gland*—carcinoma.

A. Progressive or recurrent despite initial hormonal intervention.

OR

B. With visceral metastases.

13.25 *Testicles*—tumor with metastatic disease progressive or recurrent following initial chemotherapy.

13.26 *Penis*—carcinoma with metastases to or beyond the regional lymph nodes.

13.27 *Primary site unknown after appropriate search for primary*—metastatic carcinoma or sarcoma, except for solitary squamous cell carcinoma in the neck.

13.28 *Malignant neoplastic diseases treated by bone marrow or stem cell transplantation.* (See 13.00L.)

A. Allogeneic transplantation. Consider under a disability until at least 12 months from the date of transplantation. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

OR

B. Autologous transplantation. Consider under a disability until at least 12 months from the date of the first treatment under the treatment plan that includes transplantation. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

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Part B

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107.00 Hematological Disorders

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113.00 Malignant Neoplastic Diseases

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107.00 HEMATOLOGICAL DISORDERS

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C. [removed]

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107.11 [removed]

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111.00 NEUROLOGICAL

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E. *Brain tumors.* We evaluate malignant brain tumors under the criteria in 113.13. For benign brain tumors, we determine the severity and duration of the impairment on the basis of symptoms, signs, and laboratory findings (111.05).

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111.05 *Benign brain tumors.* Evaluate under 111.02, 111.03, 111.06, 111.09 or the criteria of the affected body system.

* * * * *

113.00 MALIGNANT NEOPLASTIC DISEASES

A. *What impairments do these listings cover?* We use these listings to evaluate all malignant neoplasms except certain neoplasms associated with human immunodeficiency virus (HIV) infection. We use the criteria in 114.08E to evaluate carcinoma of the cervix, Kaposi's sarcoma, lymphoma, and squamous cell carcinoma of the anus if you also have HIV infection.

B. *What do we consider when we evaluate malignant neoplastic diseases under these listings?* We consider factors such as the:

1. Origin of the malignancy.
2. Extent of involvement.
3. Duration, frequency, and response to antineoplastic therapy.

Antineoplastic therapy means surgery, irradiation, 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.

4. Effects of any post-therapeutic residuals.

C. *How do we apply these listings?* We apply the criteria in a specific listing to a malignancy 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.
- 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 malignancy, the response to therapy, and any significant residuals. (See 113.00G.)

E. *When do we need longitudinal evidence?*

1. *Tumors with distant metastases.* Most malignant tumors of childhood consist of a local lesion with metastases to regional lymph nodes and, less often, distant metastases. We generally do not need longitudinal evidence for tumors that have metastasized beyond the regional lymph nodes because these tumors usually meet the requirements of a listing. Exceptions are for tumors with distant metastases that are 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 intended effect of therapy has been achieved and is likely to persist.

2. *Other malignancies.* 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 (multimodal) given in close proximity as a unified whole, and is usually planned before any treatment(s) is initiated. Examples of multimodal therapy include:

- a. Surgery followed by chemotherapy or radiation.
- b. Chemotherapy followed by surgery.
- c. Chemotherapy and concurrent radiation.

3. *Types of treatment.* 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 will often happen within 6 months after treatment starts, and there will often be a change in the treatment regimen. Whenever the initial planned therapy is multimodal, a determination about the effectiveness of the therapy usually cannot be made until the effects of all the planned modalities can be determined. In some cases, we may need to defer adjudication until the effectiveness of therapy can be assessed. 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 malignancy or therapy (see 113.00G).

F. *How do we evaluate impairments that do not meet one of the malignant neoplastic diseases listings?*

1. These listings are only examples of malignant neoplastic diseases that we consider severe enough to result in marked and severe functional limitations. If your

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.) If it does not, we will also consider whether you have an impairment(s) that functionally equals the listings. (See § 416.926a.) We use the rules in § 416.994a when we decide whether you continue to be disabled.

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

1. *How we consider the effects of therapy under the listings.* In many cases, malignancies meet listing criteria only if the therapy does not achieve the intended effect: the malignancy persists, progresses, or recurs despite treatment. 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. Because the therapy and its toxicity may vary widely, we consider each case on an individual basis. 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.* Because the severity of the adverse effects of antineoplastic therapy may change during treatment, enough time must pass to allow us to evaluate the therapy's effect. The residual effects of treatment are temporary in most instances. But 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 listed impairment, 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 and any metastases have not been evident for at least 3 years, the impairment(s) will no longer meet or equal the criteria of a listing in this body system.

3. Following the appropriate period, we will consider any residuals, including residuals of the malignancy or therapy (see 113.00G), in determining whether you are disabled.

I. *What do these terms in the listings mean?*

1. *Persistent:* Failure to achieve a complete remission.

2. *Progressive:* The malignancy became more extensive after treatment.

3. *Recurrent, relapse:* A malignancy that had been 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 malignancy satisfies the criteria of a listing?* Yes. We will consider factors such as:

1. The type of malignancy and its location.

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

3. Your symptoms.

K. *How do we evaluate specific malignant neoplastic diseases?*

1. *Lymphoma.*

a. Listing 113.05 provides criteria for evaluating intermediate or high grade lymphomas that have not responded to antineoplastic therapy. Low grade or indolent lymphomas are rare in children. We will evaluate low grade or indolent lymphomas under 13.05 in part A.

b. We consider Hodgkin's disease that recurs more than 12 months after completing initial antineoplastic therapy to be a new disease rather than a recurrence.

c. Many children with lymphoma are treated according to a long-term protocol that can result in significant adverse medical, social, and emotional consequences. (See 113.00G.)

2. *Leukemia.*

a. *Acute leukemia.* The initial diagnosis of acute leukemia, including the accelerated or blast phase of chronic myelogenous (granulocytic) leukemia, is based upon 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. The initial and follow-up pathology reports should be included.

b. *Chronic myelogenous leukemia (CML).* The diagnosis of CML should be based upon 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.

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 ordinarily 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. Therefore, we will not evaluate brain tumors (see 113.13) or thyroid tumors (see 113.09) under this listing.

4. *Brain tumors.* We use the criteria in 113.13 to evaluate malignant brain tumors. We will evaluate any complications of malignant brain tumors, such as resultant neurological or psychological impairments, under the criteria for the affected body system. We evaluate benign brain tumors under 111.05.

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

L. *How do we evaluate malignant neoplastic diseases treated by bone marrow or stem cell transplantation?* Bone marrow or stem cell transplantation is performed for a variety of malignant neoplastic diseases.

1. *Acute leukemia (including T-cell 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, Malignant Neoplastic Diseases

113.03 *Malignant solid tumors.* Consider under a disability:

A. For 2 years from the date of initial diagnosis. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

OR

B. For 2 years 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 T-cell lymphoblastic lymphoma—113.06).* (See 113.00K1.)

A. Non-Hodgkins lymphoma, including Burkitt's and anaplastic large cell. Persistent or recurrent following initial antineoplastic therapy.

OR

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

OR

C. With bone marrow or stem cell transplantation. Consider under a disability until at least 12 months from the date of transplantation. Thereafter, evaluate any residual impairment(s) under the criteria of the affected body system.

113.06 *Leukemia.* (See 113.00K2.)

A. Acute leukemia (including T-cell lymphoblastic lymphoma and juvenile chronic myelogenous leukemia (JCML)). Consider under a disability until at least 24 months from the date of diagnosis or relapse, or at least 12 months from the date of bone marrow or stem cell transplantation, whichever is later. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

OR

B. Chronic myelogenous leukemia (except JCML), as described in 1 or 2:

1. Accelerated or blast phase. Consider under a disability until at least 24 months from the date of diagnosis or relapse, or at least 12 months from the date of bone marrow or stem cell transplantation, whichever is later. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

2. Chronic phase, as described in a or b:

a. Consider under a disability until at least 12 months from the date of bone marrow or stem cell transplantation. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

b. Progressive disease following initial antineoplastic therapy.

113.09 *Thyroid gland.*

A. Anaplastic (undifferentiated) carcinoma.

OR

B. Carcinoma with metastases beyond the regional lymph nodes progressive despite radioactive iodine therapy.

113.12 *Retinoblastoma.*

A. With extension beyond the orbit.

OR

B. Persistent or recurrent following initial antineoplastic therapy.

OR

C. With regional or distant metastases.

113.13 *Brain tumors.* (See 113.00K4.) Highly malignant tumors, such as Grades III and IV astrocytomas, glioblastoma multiforme, ependymoblastoma, medulloblastoma or other primitive neuroectodermal tumors (PNETs) with documented metastases, diffuse intrinsic brain stem gliomas, or primary sarcomas.

113.21 *Neuroblastoma.*

A. With extension across the midline.

OR
B. With distant metastases.
OR

C. Recurrent.
OR

D. With onset at age 1 year or older.
* * * * *

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