SOCIAL SECURITY ADMINISTRATION

20 CFR Part 404

[Reg. No. 4]

RIN 0960–AD67

Revised Medical Criteria for Evaluating Hematological Disorders and Malignant Neoplastic Diseases

AGENCY: Social Security Administration.

ACTION: Proposed rules.

SUMMARY: We are proposing to revise the criteria in the Listing of Impairments (the listings) that we use to evaluate claims involving hematological disorders and malignant neoplastic diseases at the third step of our sequential evaluation processes for adults and children under title II and title XVI of the Social Security Act (the Act). The proposed revisions reflect advances in medical knowledge, treatment, and methods of evaluating hematological disorders and malignant neoplastic diseases.

DATES: To be sure your comments are considered, we must receive them by January 28, 2002.

ADDRESSES: Give us your comments using our Internet site facility (i.e., Social Security Online) at: *http://www.ssa.gov/regulations/*. If that facility is unavailable or not desired, you may send us your comments: by e-mail to regulations@ssa.gov; by telefax to (410) 966–2830; or, by letter to the Commissioner of Social Security, P.O. Box 17703, Baltimore, Maryland 21235–7703. You may also deliver them to the Office of Process and Innovation Management, Social Security Administration, L2109 West Low Rise Building, 6401 Security Boulevard, Baltimore, Maryland 21235–6401, between the 8:00 a.m. and 4:30 p.m. on regular business days. Comments are posted on our Internet site, or you may inspect them on regular business days by making arrangements with the contact person shown in this preamble.

Electronic Version: The electronic file of this document is available on the date of publication in the **Federal Register** on *http://www.access.gpo.gov/su_docs/aces/aces140.html*. It is also available on the Internet site for SSA (i.e., Social Security Online): *http://www.ssa.gov/regulations/*. Electronic copies of public comments may also be found on this site.

FOR FURTHER INFORMATION CONTACT: Suzanne DiMarino, Social Insurance Specialist, Office of Process and Innovation Management, Social Security Administration, L2109 West Low Rise, 6401 Security Boulevard, Baltimore, Maryland 21235–6401, (410) 965–1769 or TTY (410) 966–5609. For information on eligibility or filing for benefits, call our national toll-free number, 1–800–772–1213 or TTY 1–800–325–0778, or visit our Internet web site, *SSA Online,* at *www.ssa.gov*.

SUPPLEMENTARY INFORMATION:

What Programs Would Be Affected by These Proposed Regulations?

These proposed regulations would affect disability determinations and decisions we make for individuals under title II and title XVI of the Act. In addition, to the extent that Medicare and Medicaid eligibility are based on title II and title XVI eligibility, these proposed regulations also would 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 to three groups of individuals:

- Workers insured under the Act.
- Children of insured workers.
- Widows, widowers, and surviving divorced spouses of insured individuals.

Under title XVI of the Act, we provide for SSI payments on the basis of disability to adults and children who 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 can be expected to result in death or that has lasted or can be expected to last for a continuous period of at least 12 months. Our definition of disability is shown in the following table:

If you file a claim under * * *	And you are * * *	Disability means you have a medically determinable impairment(s) that meets the statutory duration requirement and results in * * *
title II	an adult or a child	the inability to do any substantial gainful activity (SGA)
title XVI	an adult	the inability to do any SGA
title XVI	a child	marked and severe functional limitations

What Are the Listings?

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. Although the listings are contained only in appendix 1 to subpart P of part 404, we incorporate them by reference in the SSI program by § 416.925 of our regulations.

How Do We Use the Listings?

We divide the listings into part A and part B. We apply the medical criteria in part A when we assess the claims of adults. We may also use the medical criteria in part A when we evaluate the claims of children, if the disease processes have a similar effect on adults and children. However, we first use the criteria in part B to evaluate claims by children. If the criteria in part B do not apply, we then use the criteria in part A. (See §§ 404.1525, 404.1526, 416.925 and 416.926.)

We use the criteria in the listings only to make favorable determinations or decisions regarding disability. We never deny a claim or find that an individual's disability has ceased because an impairment(s) does not meet or medically equal a listing. When an individual has a severe impairment(s) that does not meet or medically equal a listing, we may still find him or her disabled (or still disabled) based on other rules. For more information about our sequential evaluation processes for adults and children, see §§ 404.1520, 416.920, and 416.924 of our regulations regarding initial claims, and §§ 404.1594, 416.994, and 416.994a of our regulations regarding continuing disability reviews.

Why Are We Proposing To Revise the Listings for Hematological Disorders and Malignant Neoplastic Diseases?

We last published final rules revising the listings for the hemic and lymphatic system and the malignant neoplastic diseases system in the **Federal Register** on December 6, 1985 (50 FR 50068). In the preamble to those rules, we indicated that due to medical advances in disability evaluation and treatment and program experience we would periodically review and update the listings. The current listings for the

hemic and lymphatic system and malignant neoplastic diseases will no longer be effective on July 2, 2003. We are proposing to update the listings in part A, 7.00 and 13.00, and in part B, 107.00 and 113.00. We propose to make the rules effective for 5 years from their effective date, unless we extend them, or revise and issue them again.

We will continue to apply our current listings until we evaluate the public comments on these proposed rules and determine whether they should be issued as final rules. If we finalize these proposed rules, when any final rules become effective, we will apply them to new applications filed on or after the effective date of the final rules, and to cases that are pending in the administrative review process. In accordance with our usual practice, we would explain how we would apply any final rules in greater detail in the preamble to the final rules.

When we conduct reviews to determine whether your disability continues, we would not find that your disability has ended based only on any changes in the listings. Our regulations explain that we continue to use our prior listings when we review your case if you receive disability benefits or SSI payments based on our determination or decision that your impairment(s) met or equaled the listings. 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 impairment(s) still meets or equals the same listing section that we used to make our most recent favorable determination or decision, we will find the medical improvement is not related to the ability to work. If your condition has medically improved so that you no longer meet or 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 20 CFR 404.1594(c)(3)(i), 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. 20 CFR 416.994a(b)(2).

What Revisions Are We Proposing That Affect Both the Hematological Disorders and Malignant Neoplastic Diseases Listings?

To present the listing criteria in a more logical order, and make the listings easier to use, we propose to:

- Renumber the listings in part A and part B for the hematological disorders and malignant neoplastic diseases body systems. To the extent possible, we number the listings in part B to correspond with listings addressing the same impairments in part A.
- Reorganize these listings by grouping related impairments under broader medical diagnostic categories. For example, we would group chronic thrombocytopenia (current listings 7.06 and 107.06) and coagulation defects (current listings 7.08 and 107.08) under the category ''Disorders of hemostasis'' (proposed listings 7.03 and 107.03); and we would group sarcoma of skin (current listing 13.03) and malignant melanoma (current listing 13.05) under the category ''Skin'' (proposed listing 13.03).
- Further reorganize these listings to place all listings for malignant neoplastic diseases under that body system. To do this, we would move the criteria for acute leukemia, chronic leukemia, myeloma, and malignant brain tumors, current listings 7.11, 7.12, 7.16, 11.05, 107.11, and 111.05, to proposed listings 13.06, 13.07, 13.13, 113.06 and 113.13. We would also move the guidance for evaluating macroglobulinemia or heavy chain disease, current listing 7.14, to section 13.00K(3) of the proposed preface. The current listing for this disorder is a reference listing. In accordance with the discussion below, we propose to eliminate reference listings.
- Replace reference listings in these areas with guidance in the preface. Reference listings are listings that are met by satisfying the criteria of another listing. For example, current listing 7.16B, for myeloma with evidence of renal impairment, is a reference listing that requires evaluation under current listing 6.02, for impairment of renal function. Instead of using reference listings, we propose to provide general guidance in the preface to each of these body systems stating that resulting impairments should be evaluated under the criteria for the affected body system. Where appropriate, we would also provide references to specific listings. For example, in proposed section 13.00K(3) we indicate that macroglobulinemia or heavy chain disease should be evaluated under the criteria of proposed listings 7.03 or 7.04, or under the criteria of any other affected body system.

We also propose to use the phrase ''bone marrow or stem cell transplantation'' in proposed listings 7.06, 107.06, 13.28, and 113.28 instead of ''bone marrow transplantation'' as used in current listing 7.17. The purpose of bone marrow transplantation is to transplant stem cells, but stem cells from other sources, such as peripheral blood or cord blood, may also be used. Because of this, the phrase ''stem cell transplantation'' more accurately represents the type of transplantation addressed in the proposed listings. However, as ''bone marrow transplantation'' is still in common usage, we would also retain it in our listings in order to avoid confusion.

In several of the proposed listings, such as listings 7.03A2, 13.28, and 113.11D, we provide that we will consider the individual disabled for a specified period of time, such as for 12 months from the date of diagnosis. After that time, we will evaluate any residual impairment(s) under the criteria for the affected body system. In these situations, the beginning date specified is not related to the onset date; it is used only to calculate the period of time we would presume the impairment is disabling. We can establish an earlier onset date if the individual is not engaging in SGA and the evidence in file supports the earlier onset date.

We also propose to make nonsubstantive editorial changes to update the medical terminology in the listings and to make the language clearer.

How Are We Proposing To Change the Preface to the Listings for Evaluating Hematological Disorders in Adults?

7.00 Hematological Disorders

We propose to change the name of this body system from Hemic and Lymphatic System to Hematological Disorders because we are proposing to move the lymphatic impairments now contained in 7.00 to 13.00, Malignant Neoplastic Diseases.

Because we are proposing to move the criteria for evaluating leukemia to proposed listing 13.06, we propose to move the guidance contained in current 7.00E, ''Acute leukemia,'' to proposed 13.00K(2)(a). We discuss our revisions to that guidance in the explanation of proposed 13.00K(2)(a).

We also propose to expand and reorganize the introductory material in 7.00 to provide additional guidance and reflect the new listings. The following is a detailed explanation of the proposed material.

Proposed 7.00A—What Do We Consider When We Evaluate Hematological Disorders Under These Listings?

In this new section, we list the factors we consider.

Proposed 7.00B—What Documentation Do We Need?

To clarify the first sentence of current 7.00B, ''Chronicity,'' we explain that we

generally need a longitudinal clinical record covering a period of at least 3 months of observations and treatment unless we can make a fully favorable determination or decision without it.

We expand the second sentence of current 7.00B to provide examples of the types of laboratory findings that should be in the longitudinal clinical record.

We also clarify, in 7.00B(2) and 7.00B(3), what additional information the longitudinal clinical record should contain.

Proposed 7.00C—How Do We Evaluate Impairments That Do Not Meet One of the Hematological Disorders Listings?

In this new section, we state our basic adjudicative principle that if the individual's impairment(s) does not meet or medically equal the requirements of a listing, we will continue the sequential evaluation process to determine whether or not the individual is disabled.

Proposed 7.00D—How Do We Assess the Effectiveness of Treatment?

In this new section, we set forth our policy on considering the response to, effectiveness of, and adverse consequences of treatment.

Proposed 7.00E—How Do We Evaluate Episodic Hematological Disorders?

In this new section, we propose to revise the requirement in our current listings that events for episodic hematological impairments occur within the 5-month or 12-month period prior to adjudication. Instead of using the date of adjudication, as we do under the current criteria, we propose to require that the events occur within the period we consider in connection with the application or continuing disability review; that is, the period for which we will develop medical evidence through the date we make our determination or decision. Sections 404.1512(d)(2), 404.1593(b), 416.912(d)(2), and 416.993(b) of our regulations discuss the period for which we will develop medical evidence. This period generally begins 12 months prior to either the date of the application or the date the individual signed a report about his or her continuing disability status. This proposed approach is consistent with the way we evaluate episodic impairments in other body systems.

We also indicate that in every listing in which we require more than one event, there must be at least 1 month between the events. We propose this requirement to ensure that we are evaluating separate episodes.

Proposed 7.00F—What Do These Terms in the Listings Mean?

We propose to define the terms ''persistent'' and ''repeated'' or ''repeatedly'' in the hematological disorders listings.

Proposed 7.00G—How Do We Evaluate Specific Hematological Disorders?

We propose to incorporate and clarify current 7.00A, ''Impairment caused by anemia,'' 7.00C, ''Sickle cell disease,'' and 7.00D, ''Coagulation defects,'' and add guidance for evaluating additional hematological disorders. The following is a discussion of the information provided for the disorders in this section.

Proposed 7.00G(1)—Anemia

This paragraph corresponds to current 7.00A, ''Impairment caused by anemia'' and would also replace current listing 7.02B. Current listing 7.02B provides that the effects of chronic anemia should be evaluated under the criteria for the affected body system. In addition to causing residual impairments, chronic anemia can be a marker of severity for an underlying disorder, such as myelofibrosis. Thus, we propose to expand our guidance on chronic anemia to provide that this impairment can be evaluated under the criteria for the underlying disorder or for the affected body system.

Proposed 7.00G(2)—Sickle Cell Disease or One of Its Variants

This paragraph corresponds to the first two paragraphs of current 7.00C. We propose to clarify the policy regarding hematological evidence by adding that, in lieu of a copy of the actual laboratory report, we will accept medical evidence that is persuasive that a positive diagnosis has been confirmed by appropriate laboratory testing at some time prior to evaluation.

We propose to delete the third paragraph of current 7.00C, which defines ''major visceral episodes,'' because the term does not appear in the listings. The term ''major visceral complication'' does appear in the current childhood listing for sickle cell disease, listing 107.05B. Instead of extending the criterion to adults, we propose to delete it from the childhood listing. We explain our reasons for doing so in the discussion of proposed listing 107.02A (the proposed listing that corresponds to current listing 107.05).

Proposed 7.00G(3)—Disorders of Hemostasis

This section corresponds to current 7.00D ''Coagulation defects.'' We are using a more comprehensive term to reflect the criteria in proposed listing 7.03, ''Disorders of hemostasis.'' We would continue to include coagulation defects in the revised section, but as an example rather than as the only disorder covered by the listing.

We would also revise our guidance on how to document these disorders to address all the disorders covered by the proposed listing and to update the medical terminology. We are also adding guidance on how to consider complications of these disorders.

Proposed 7.00G(4)—Hematological Malignancies

The current criteria for evaluating hematological malignancies, such as lymphoma, leukemia, macroglobulinemia or heavy chain disease, and myeloma, are in 7.00. As we indicated above, we propose to move these disorders to 13.00, Malignant Neoplastic Diseases. We are adding this section to reflect that move. We are also adding a reminder that there is a separate listing for lymphoma associated with HIV infection, listing 14.08E.

Proposed 7.00G(5)—Chronic Iron Overload

The medical community is increasingly recognizing complications from this disorder. We propose to add this section to provide guidance on evaluating these complications under the listings.

Proposed 7.00H—How Do We Evaluate non-malignant Hematological Disorders Treated by Allogeneic Bone Marrow or Stem Cell Transplantation?

We provide that non-malignant hematological disorders treated by allogeneic bone marrow or stem cell transplantation must be evaluated under the criteria in proposed listing 7.06, regardless of whether there is another listing that addresses that impairment. We discuss the criteria in proposed listing 7.06. We also discuss some of the factors we consider when we evaluate any residual impairment(s) that results from transplantation.

How Are We Proposing to Change the Criteria in the Listings for Evaluating Hematological Disorders in Adults?

7.01 Category of Impairments, Hematological Disorders

In addition to proposing to move listings 7.11, 7.12, 7.13, 7.14, and 7.16, we propose to delete current listings 7.02, ''Chronic anemia (hematocrit persisting at 30 percent or less due to any cause),'' and 7.07, ''Hereditary telangiectasia.''

Current listing 7.02A requires one or more blood transfusions on an average of at least once every 2 months. The average frequency of blood transfusions is not an accurate measure of severity or duration of the impairment. If an individual had several transfusions performed close together in the past and none thereafter, the average might still satisfy the frequency criterion for the current listing, even though the underlying impairment may not have persisted at this level. Also, some individuals with anemia may be treated with scheduled red cell transfusions in order to maintain the oxygen-carrying capacity of the blood.

As we explained above, we propose to retain the criterion in current listing 7.02B, evaluation of the resulting impairment under the criteria for the affected body system, in proposed 7.00C.

We propose to delete current listing 7.07 because listing-level hereditary telangiectasia is rare and can be evaluated under other criteria, for example, those for other hematological disorders or for the affected body system, such as digestive.

The provisions of proposed 7.00E apply to proposed listings 7.02A, 7.02B, 7.03A2, 7.03B, 7.03C, 7.04B, and 7.05. Because we have already discussed the provisions in proposed 7.00E, they are not included in the following explanation of the proposed listing criteria.

Proposed Listing 7.02—Sickle Cell Disease or One of its Variants

This proposed listing has three separate evaluation criteria. Proposed listing 7.02A, documented painful (vaso-occlusive) crises, corresponds to current listing 7.05A. We propose to include a requirement that the crises require parenteral medication, to clarify the level of severity intended by the listing.

We also propose to lengthen the period of time during which the pain crises must occur from 5 months to 6 months. We believe that pain crises of the type described in proposed listing 7.02A that occur at least 3 times in a 6-month period are indicative of listing-level severity.

Proposed listing 7.02B, hospitalization (for 24 hours or more), is similar to current listing 7.05B. We propose to replace the current requirement of ''beyond emergency care'' with ''for 24 hours or more'' to more clearly define our intent.

Proposed listing 7.02C, chronic anemia, corresponds to current listing 7.05C. We propose to revise the criterion to provide a more accurate measure of severity. The current criterion is a persistent hematocrit of 26 percent or less. A hematocrit at this level does not necessarily correlate to an inability to perform any gainful activity. The hemoglobin level required in the proposed listing is indicative of an impairment that we believe would preclude any gainful activity in individuals with sickle cell disease. Throughout these proposed listings, we are using hemoglobin levels instead of hematocrit values as used in the current listings. Hemoglobin levels are measured directly; hematocrit values must be derived.

We also propose to delete the word ''severe,'' which is used in current listing 7.05C. The use of the word ''severe'' in current listing 7.05C is not intended to be the same as the definition of ''severe'' in §§ 404.1521 and 416.921 of our regulations. We believe the proposed revision is sufficiently clear that we do not need the word. Therefore, we propose to delete it to avoid confusion.

As part of our effort to eliminate reference listings, we propose to delete the criterion in current listing 7.05D, which provides for evaluation of the resulting impairment under the criteria for the affected body system. We have incorporated this criterion in proposed 7.00C(1).

Proposed Listing 7.03—Disorders of Hemostasis

As already noted, we propose to incorporate current listings 7.06, ''Chronic thrombocytopenia,'' and 7.08, ''Coagulation defects,'' under this heading and provide criteria for evaluating hypercoagulable states. The following is a discussion of the criteria in the proposed listing.

Proposed Listing 7.03A—Chronic Thrombocytopenia (Due to Any Cause)

This listing corresponds to current listing 7.06. We propose the following changes:

- In proposed listing 7.03A1, we indicate that chronic thrombocytopenia with platelet counts repeatedly below 10,000/mm^3 despite prescribed therapy is, by itself, an impairment that would preclude an individual from performing any gainful activity.
- In proposed listing 7.03A2, we require platelet counts repeatedly below 20,000/mm^3 instead of the current criterion of 40,000/mm^3. We propose this change because the incidence of spontaneous bleeding episodes increases significantly when the platelet count is below 20,000/mm^3. Some individuals whose platelet counts are 20,000/mm^3 or higher may still be limited or restricted, but many of these individuals will not be precluded from engaging in any gainful activity. Therefore, we will evaluate these individuals on a case-by-case basis.
- In proposed listing 7.03A2, we also propose to clarify the reference to transfusion and change the frequency requirements in current listing 7.06A. We clarify the reference to transfusion by specifying red cell or platelet transfusion. We propose this revision to reflect common medical practice. We also propose to change the frequency requirement from one episode of bleeding within the 5 months prior to adjudication to at least three episodes of bleeding in a consecutive 12-month period. We propose this revision because one episode of bleeding in 5 months is not sufficient to establish that the impairment has lasted or can be expected to last for at least 12 months.
- We propose to replace the criterion in current listing 7.06B, intracranial bleeding within 12 months prior to adjudication, with guidance in 7.00G(3)(c) indicating that intracranial bleeding should be evaluated under listing 11.04. We are proposing this change to be consistent with the criteria in other listings that evaluate intracranial bleeding (for example, listing 4.10D) and to recognize that improved diagnostic techniques can detect very minor bleeds that have no functional impact. We are placing this guidance in the preface, rather than retaining it as a listing criterion, as part of our effort to eliminate reference listings.

Proposed Listing 7.03B—Hemophilia

This listing and proposed listing 7.03C correspond to current listing 7.08, ''Coagulation defects (hemophilia or a similar disorder).'' We propose to separate hemophilia from other hypocoagulable disorders because, unlike those other disorders, current treatment for most individuals with hemophilia includes the use of prophylactic factor replacement. Consistent with this treatment, we propose to replace the requirement for transfusions with a criterion indicating that the bleeding occurs despite prophylactic factor replacement. We would also revise the frequency of bleeding episodes to be consistent with the changes in proposed listing 7.03A2.

Proposed Listing 7.03C—Other Hypocoagulable States (Such as von Willebrand's Disease, or Thrombasthenia)

In this listing, we propose criteria for evaluating hypocoagulable states other than hemophilia. We would change the

frequency of bleeding episodes to be consistent with other proposed listings. We would require hospitalization instead of transfusions to recognize that bleeding in these disorders may often be managed with other forms of treatment. Hospitalization is usually required when the bleeding cannot be easily controlled.

Proposed Listing 7.03D—Hypercoagulable States (Deficiency of Anti-coagulant Proteins Such as C, Protein S, And Anti-thrombin, or the Presence of Abnormal Proteins Such as Factor V Leiden)

We propose to add this listing to recognize that, for individuals with this disorder, thrombotic episodes are comparable to bleeding episodes in individuals who are hypocoagulable.

Proposed Listing 7.04—Aplastic Anemia, Myeloproliferative Disorders (Such as Polycythemia Vera or Myelofibrosis), or Myelodysplastic Syndrome

We propose to combine these disorders because, despite differing etiologies, the functional consequences are similar. This proposed listing incorporates current listings 7.09, ''Polycythemia vera,'' and 7.10, ''Myelofibrosis.''

In proposed listing 7.04A, we would revise the anemia criterion in current listing 7.10A and extend it to the other disorders in the listing. Current listing 7.10A contains a cross-reference to current listing 7.02A which, for the reasons explained above, we are proposing to delete. The proposed anemia criterion is ''repeated hemoglobin of 7.0 gm/dl or less despite prescribed therapy.''

In proposed listing 7.04B, we would revise the infection criterion in current listing 7.10B and extend it to the other disorders in this listing. We propose to require documentation of treatment with parenteral antimicrobial medication, the treatment given for systemic infections, to more clearly define a systemic infection. By using this type of treatment, which is also used to treat other types of systemic infections, such as viral or fungal infections, we are broadening the criterion to acknowledge that other types of systemic infections have the same impact as bacterial infections. We would also revise the frequency of treatment requirement to be consistent with other proposed listings.

As part of our efforts to eliminate reference listings, we propose to delete the criterion in current listing 7.09 that provides for the evaluation of the resulting impairment under the criteria for the affected body system. Instead, we provide general guidance to this effect in 7.00C(1). We also propose to delete the criterion in current listing 7.10C of intractable bone pain with radiologic evidence of osteosclerosis. This complication is very rare, and can be evaluated under the listings 1.00 ff., Musculoskeletal System.

Proposed Listing 7.05—Chronic Granulocytopenia (Due to Any Cause)

This listing corresponds to current listing 7.15. We propose three revisions to the criteria:

- Changing the required neutrophil counts from repeatedly below 1000/mm^3 to repeatedly below 500/mm^3. We propose this change because the incidence of infection increases significantly when the neutrophil count is below 500/mm^3. Some individuals whose neutrophil counts are 500/mm^3 or higher may still be limited or restricted, but many of these individuals will not be precluded from engaging in any gainful activity. Therefore, we will evaluate these individuals on a case-by-case basis.
- Changing the infection criterion in listing 7.05B to be consistent with proposed listing 7.04B.
- Changing the required frequency of treatment in listing 7.05B to be consistent with proposed listing 7.04B.

Proposed Listing 7.06—Non-Malignant Hematological Diseases Treated by Allogeneic Bone Marrow or Stem Cell Transplantation (see 7.00H)

We propose to revise the rule in current listing 7.17, ''Aplastic anemias or hematological malignancies (excluding acute leukemia),'' to recognize the increasing number of diseases treated by allogeneic bone marrow or stem cell transplantation. While the current rule does not specify allogeneic transplantation, it is the type of transplantation that is performed for the disorders evaluated under this body system. We are identifying the type of transplantation in the proposed rule for clarity.

Under this proposed listing, we would consider an individual disabled until at least 12 months from the date of transplantation. As with other proposed listings that use the phrase ''at least,'' there is leeway to establish a longer period when it is justified by the medical evidence. The proposed rule acknowledges the early uncertainty of the outcome, but recognizes that 12 months after the transplant an individual may have improved significantly.

How Are We Proposing to Change the Preface in the Listings for Evaluating Malignant Neoplastic Diseases in Adults?

13.00 Malignant Neoplastic Diseases

We propose to expand and reorganize the preface to these listings to provide additional guidance and reflect the new listings. The following is a detailed explanation of this proposed material.

Proposed 13.00A—What Impairments Do These Listings Cover?

In this new section, we explain that we use these listings to evaluate all malignant neoplasms except carcinoma of the cervix, Kaposi's sarcoma, lymphoma, and squamous cell carcinoma of the anus in individuals with HIV infection. We would continue to evaluate these impairments under listing 14.08E.

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

This section corresponds to current 13.00A, ''Introduction.'' For clarity, we propose to use ''origin of the malignancy'' instead of the current prefatory language, ''the site of the lesion, the histogenesis of the tumor.'' We also propose to change the phrase ''apparent adequacy and response to therapy'' in the current 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 claimant's treating source. We are adding the word ''antineoplastic'' to be consistent with the language in the listing criteria. We also are specifically identifying the types of antineoplastic therapy referred to in the listings.

Proposed 13.00C—How Do We Apply The Listings?

In this new section, we explain that, except for metastatic carcinoma to the brain or spinal cord (proposed listing 13.13C), we apply the listing criteria to a malignant neoplastic disease originating from the site addressed by the particular listing.

Proposed 13.00D—What Evidence Do We Need?

We propose to expand the guidance in current 13.00B, ''Documentation,'' by:

- Explaining that when the primary site cannot be identified, we will use

documentation of the site(s) of metastasis to evaluate the impairment under proposed 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 are making 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.

Proposed 13.00E—When Do We Need Longitudinal Evidence?

We propose to incorporate and expand the guidance in the fourth paragraph of current 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.

Proposed 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 current 13.00D, ''Effects of Therapy.'' We state our basic adjudicative principle that if the individual's impairment(s) does not meet or medically equal the requirements of a listing, we will continue the sequential evaluation process to determine whether or not the individual is disabled.

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

We propose to reorganize the guidance in current 13.00D, ''Effects of Therapy.'' We also propose to clarify 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.

Proposed 13.00H—How Long Do We Consider the Individual Disabled?

We propose to incorporate and expand the guidance contained in the third paragraph of current 7.00E, ''Acute leukemia,'' and the fifth paragraph of current 13.00C, ''Evaluation.'' In some of the proposed listings, we specify that the impairment is considered disabling until a particular point in time. If an individual has 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 that individual to be under a disability until at least 3 years after onset of complete remission. We also explain what we do when the appropriate time period has passed.

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

We propose to replace the first two paragraphs and the first sentence of the third paragraph of current 13.00C, ''Evaluation,'' and provide additional definitions. The current section contains 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 proposed listings is consistent with current clinical practice.

In the proposed listings, we also differentiate between the terms ''inoperable'' and ''unresectable.'' With the proposed changes in the listing criteria, we would no longer need to define an unresectable tumor in terms of the nature of the surgery performed.

Proposed 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 current 13.00E, ''Onset.'' We propose no substantive changes.

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

We incorporate and clarify current 7.00E, ''Acute leukemia,'' the last sentence of the third paragraph in current 13.00C, ''Evaluation,'' and provide guidance for evaluating additional malignant neoplastic disorders. The following is a detailed discussion of the information provided for the disorders in this section.

Proposed 13.00K(1)—Lymphoma

In the first two paragraphs of this new section, we discuss the evaluation of indolent (non-aggressive) lymphomas. We explain that we will defer adjudication 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 provide a caution 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.

We have not retained the last sentence of the third paragraph of current 13.00C, ''Evaluation.'' This sentence states, ''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 provides useful information for applying the criteria in proposed listing 13.05.

In the third paragraph we state 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.

Proposed 13.00K(2)—Leukemia

In paragraph (a), we expand the guidance in the first paragraph of current 7.00E, ''Acute leukemia,'' to indicate sources of additional diagnostic information. We also clarify the evidence needed to document recurrent disease by requiring one of the three laboratory findings named.

In paragraph (b), we provide guidance on documenting chronic myelogenous leukemia (CML). We have not included in this paragraph the guidance in the second paragraph of current 7.00E, which provides that the acute phase of CML should be considered under the requirements for acute leukemia. Instead, we have incorporated this guidance in proposed listing 13.06B1.

In paragraph (c), 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 in current listing 7.12 that are appropriate for evaluating CLL.

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

Proposed 13.00K(3)—Macroglobulinemia or Heavy Chain Disease

This section replaces current listing 7.14, which is a reference listing. We propose no substantive changes in how we evaluate these disorders.

Proposed 13.00K(4)—Bilateral Primary Breast Cancer

We are clarifying the statement in current listing 13.09D, ''bilateral breast carcinoma, synchronous or metachronous is usually primary in each breast'' by removing the suggestion that there are exceptions to this rule.

Proposed 13.00K(5)—Carcinoma-in-situ

In this new section, we explain why this type of carcinoma is not included when ''carcinoma'' is used in these listings.

Proposed 13.00K(6)—Brain Tumors

In this new section, we explain that malignant tumors are evaluated under proposed listing 13.13 and benign tumors are evaluated under proposed listing 11.05. We also explain that we evaluate any complications of malignant brain tumors under the criteria for the affected body system.

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

In paragraphs (1) and (2) of this new section, we discuss how long we consider an individual disabled when that individual has leukemia, lymphoma, or multiple myeloma and undergoes bone marrow or stem cell transplantation.

In paragraph (3), we provide that all other malignant neoplastic diseases treated with bone marrow or stem cell transplantation must be evaluated under proposed listing 13.28, regardless of whether there is another listing that addresses that impairment. We explain that under proposed listing 13.28, how long we will consider the individual disabled depends on whether the individual has allogeneic or autologous transplantation. We define ''allogeneic'' and ''autologous,'' and discuss the criteria in proposed listing 13.28.

In paragraph (4), we discuss some of the factors we consider when we evaluate any residual impairment(s) that results from transplantation.

How Are We Proposing to Change the Criteria in the Listings for Evaluating Malignant Neoplastic Diseases in Adults?

13.01 Category of Impairments, Malignant Neoplastic Diseases

We propose to delete current listing 13.15, ''Abdomen,'' because this disorder can be evaluated under other proposed listings. Current 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 would evaluate these conditions under proposed listing 13.27, ''Primary site unknown after appropriate search for primary.'' Current listing 13.15B, ''Retroperitoneal cellular sarcoma not controlled by prescribed therapy,'' would be evaluated under proposed listing 13.04, ''Soft tissue sarcoma.''

In the following proposed 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 proposed listing criteria.

Proposed 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 current listing 13.02, ''Head and neck.'' We propose to change the listing heading to ensure that only tumors of the soft tissue of the head and neck are considered under this listing. This change would allow us to delete the last two exceptions in the current heading (orbit or temporal fossa), as these are not soft tissue tumors.

Proposed listing 13.02A is substantively the same as current listing 13.02A. We propose to update the terminology to reflect the definitions used in the proposed listings.

In proposed listing 13.02B, which corresponds to current listing 13.02B, we propose to replace ''not controlled by prescribed therapy'' with ''[p]ersistent disease following initial multimodal antineoplastic therapy'' to clarify our intent.

Proposed listing 13.02C corresponds to current listing 13.02C. We propose to replace ''after radical surgery or irradiation'' with ''following initial antineoplastic therapy'' to recognize that other therapeutic modalities may be used. We also propose to exclude local vocal cord recurrences, because these recurrences have a good response to therapy.

Proposed listing 13.02D corresponds to current listing 13.02D. We propose no substantive change.

In proposed listing 13.02E, which corresponds to current listing 13.02E, we propose to delete the current criterion for epidermoid carcinoma in the posterior third of the tongue. Early-stage disease may be successfully treated. Later-stage disease can be assessed under the other criteria in this listing.

We propose to add the criterion in listing 13.02F to recognize the length and debilitating effects of multimodal treatment for head and neck tumors.

Proposed Listing 13.03—Skin

We propose to combine current listing 13.03, ''Sarcoma of skin,'' and current listing 13.05, ''Malignant melanoma,'' so that all malignancies originating in the skin are evaluated under this listing. Accordingly, we propose to revise the heading by removing the reference to sarcoma.

Proposed listing 13.03A corresponds to current listing 13.03A, ''Angiosarcoma with metastases to regional lymph nodes or beyond.'' We propose to expand the provision to include all skin sarcomas and carcinomas because other skin malignancies of the severity described would also be disabling.

Proposed listing 13.03B corresponds to current listing 13.05. We propose to clarify that an additional primary malignancy at a different site is not considered recurrent disease. We are also adding a criterion for palpable nodal metastases.

We propose to move current listing 13.03B, ''Mycosis fungoides'' (a type of lymphoma), to proposed listing 13.05, ''Lymphoma,'' so that all lymphomas will be evaluated under the same listing.

Proposed Listing 13.04—Soft Tissue Sarcoma

This listing proposes to update the heading of current listing 13.04, ''Sarcoma of soft parts,'' to recognize that ''soft tissue'' is a more common term than ''soft parts.'' We propose to add a criterion for regional or distant metastases, proposed listing 13.04A, to be consistent with the criteria for other malignant neoplastic diseases and to recognize the grave prognosis for these conditions. In proposed listing 13.04B, we define the current criterion ''not controlled by prescribed therapy'' similar to the way we defined it in other listings, such as proposed listing 13.02B.

Proposed Listing 13.05—Lymphoma (Including Mycosis Fungoides, but Excluding T-Cell Lymphoblastic Lymphoma—13.06)

This listing corresponds to current listing 13.06. We propose to change the heading from ''Lymph nodes'' to ''Lymphoma'' to more accurately reflect the disease. We provide that we will evaluate T-cell lymphoblastic lymphoma under the listing for acute leukemia. This is because the course, treatment, and outcome of this lymphoma are more similar to acute leukemia than to other lymphomas. We also provide a cross-reference to the explanatory paragraphs in proposed 13.00K(1).

We evaluate both Hodgkin's disease and non-Hodgkin's lymphoma under current listing 13.06A. We propose to separate and clarify the criteria for each of these diseases. Proposed listing 13.05A would provide criteria for evaluating non-Hodgkin's lymphoma; proposed listing 13.05B would provide criteria for Hodgkin's disease. For each of these disorders, we would also clarify the current criteria by replacing the phrase ''progressive disease not controlled by prescribed therapy'' in the current listing with clearer language.

In proposed listing 13.05C, we would 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 propose to delete current 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 propose to evaluate this impairment under proposed listing 13.27, ''Primary site unknown after appropriate search for primary.'' We also propose to delete current listing 13.06C. We would evaluate epidermoid carcinoma in a lymph node in the neck under proposed listing 13.02, ''Soft tissue tumors of the head and neck.''

Proposed Listing 13.06—Leukemia

We propose to revise current listing 7.11, ''Acute leukemia,'' and current listing 7.12, ''Chronic leukemia.''

In proposed listing 13.06A, we provide that an individual with acute leukemia (including T-cell lymphoblastic lymphoma) will be considered 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. After the appropriate period, we will evaluate any residual impairment(s) under the criteria for the affected body system.

Under the current listing, we find an individual with acute leukemia disabled for 2½ years from the time of the initial diagnosis. We are proposing to shorten this period to 2 years because of improvement in the treatment of this disorder. However, as with other proposed listings, we provide that we would permit a longer period when the facts warrant it. We would also recognize that a relapse of acute leukemia is as significant as the initial diagnosis.

The criterion we propose for bone marrow or stem cell transplantation in cases of acute leukemia is similar to the proposed transplantation criteria for other diseases. Unlike those diseases, however, we would not reevaluate an individual with acute leukemia who undergoes bone marrow or stem cell transplantation 12 months after transplant 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 in individuals with acute leukemia who undergo bone marrow or stem cell transplantation.

Proposed listing 13.06B, ''Chronic myelogenous leukemia,'' would replace current listing 7.12. The current listing is a reference listing. Rather than replace the entire listing with guidance in the preface, we propose to provide separate evaluation criteria for CML. Consistent with our guidance in the second paragraph of current 7.00E, the proposed criteria for the accelerated or blast phase of CML are the same as proposed listing 13.06A.

We propose to retain those references that are appropriate for evaluating chronic lymphocytic leukemia in 13.00K(2)(c).

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

In this proposed listing, we delete the specific findings in current listing 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 propose that an individual with multiple myeloma who undergoes bone marrow or stem cell transplantation will be considered disabled 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.

Proposed Listing 13.08—Salivary Glands

This listing corresponds to current listing 13.07. We propose no substantive changes.

Proposed Listing 13.09—Thyroid Gland

We propose to expand current listing 13.08 to include anaplastic (undifferentiated) carcinoma. This type of carcinoma has a very poor prognosis. We also propose to replace the term ''not controlled by prescribed therapy'' used in the current listing with ''progressive despite radioactive iodine therapy'' to clarify our intent.

Proposed Listing 13.10—Breast

This listing corresponds to current listing 13.09. In listing 13.10A, we propose to revise the criterion in current listing 13.09B, ''Inflammatory carcinoma,'' to include other types of locally advanced carcinoma.

In listing 13.10B, ''Carcinoma with distant metastases,'' we propose to revise current listing 13.09D by deleting the parenthetical statement ''bilateral breast carcinoma, synchronous or metachronous, is usually primary in each breast.'' Instead, we propose to provide guidance about evaluating bilateral breast cancer in proposed 13.00K(4). 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 proposed listing 13.10C, which would replace current listing 13.09C, we propose to replace the term ''controlled by prescribed therapy'' used in the current listing with ''that remits with antineoplastic therapy'' to clarify our intent.

We propose to delete current 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 the proposed listing. We also propose to delete current listing 13.09E, ''Sarcoma with metastases anywhere.'' We would evaluate this impairment under proposed listing 13.04, ''Soft tissue sarcoma.''

Proposed Listing 13.11—Skeletal System

This listing would replace current listing 13.10. We propose to expand the listing to include tumors of the mandible that are currently evaluated under listing 13.11. In proposed listings 13.11A, 13.11B, and 13.11C, we would revise current listing 13.10A to clarify when these tumors are of listing-level severity. In listing 13.11D, we propose to provide that we will consider all other malignant tumors originating in bone with multimodal antineoplastic therapy disabling until 12 months from the date of diagnosis. Consistent with the changes we have proposed for other listings, after that period, any residual impairment(s) would be evaluated under the criteria for the affected body system. With this criterion, we recognize the length and debilitating effects of multimodal treatment for these tumors.

Proposed Listing 13.12 Maxilla, Orbit, or Infratemporal Fossa

This listing corresponds to current listing 13.11. As noted above, we propose to evaluate tumors of the mandible under proposed listing 13.11. Proposed listings 13.12A and 13.12B correspond to current listings 13.11A and 13.11B and are substantively unchanged.

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

Proposed Listing 13.13—Nervous System

This listing incorporates the criteria for malignant brain tumors in current listing 11.05, ''Brain tumors,'' in the neurological body system, and replaces current listing 13.12, ''Brain or spinal cord.'' We propose to expand the listings to include tumors of the spinal cord, spinal nerve roots, and the peripheral nervous system. We also propose to include tumors of the central nervous system that are not specifically named.

Under listing 13.13A, we propose to evaluate central nervous system malignant neoplasms; that is, those affecting the brain or spinal cord. In proposed listing 13.13A1, we list and revise the criteria for the impairments named in current listing 11.05A. We propose to revise 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 current listing 11.05B, under proposed listing 13.13A2.

We also propose to add diffuse intrinsic brain stem gliomas in proposed listing 13.13A1. We are proposing to require 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 proposed listing 13.13B, we provide criteria for evaluating malignant tumors of peripheral nerves and spinal roots.

Proposed listing 13.13C, for metastatic carcinoma to the brain or spinal cord, is substantively the same as current listing 13.12A. We propose to clarify that this listing includes ''epidural metastases.''

We propose to delete current listing 13.12B, which provides cross-references to listings 11.05 and 11.08, as we have incorporated this guidance in the other sections of this proposed listing and 13.00K(6).

Proposed Listing 13.14—Lungs

This listing corresponds to current listing 13.13. In proposed listing 13.14A, we consolidate current 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. We also propose to remove metastases to the hilar nodes from the listing criteria as metastases to the hilum can often be surgically excised.

We are redesignating current listing 13.13C as proposed listing 13.14B. We propose no substantive changes.

Proposed Listing 13.15—Pleura or Mediastinum

This listing corresponds to current listing 13.14. Proposed listing 13.15A is the same as current listing 13.14A. In proposed listing 13.15B, which corresponds to current listing 13.14C, we provide new language that would clarify the phrase ''not controlled by prescribed therapy'' used in the current listing.

We propose to delete current listing 13.14B, ''Malignant tumors, metastatic to pleura.'' This malignancy would be evaluated under proposed listing 13.27, ''Primary site unknown.''

Proposed Listing 13.16—Esophagus or Stomach

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

Proposed Listing 13.17—Small Intestine

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

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

This listing corresponds to current listing 13.18. We propose to delete the phrase ''carcinoma or sarcoma'' from the heading of this listing because sarcomas of the large intestine are extremely rare. In proposed listing 13.18A, we consolidate current listings 13.18A and 13.18C and clarify that these criteria apply to adenocarcinoma. In proposed 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. Proposed listing 13.18C is the same as current listing 13.18B.

Proposed Listing 13.19—Liver or Gallbladder

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

Proposed Listing 13.20—Pancreas

This listing corresponds to current listing 13.20. We are not proposing any changes, other than adding ''inoperable'' conditions to the second listing criterion. We would make this change to reflect the revised definitions used in these listings.

Proposed Listing 13.21—Kidneys, Adrenal Glands, or Ureters

This listing corresponds to current listing 13.21. In proposed listing 13.21A, we would expand the criteria to include inoperable and recurrent tumors. Proposed listing 13.21B consolidates current listings 13.21B and 13.21C. We propose to eliminate the modifier ''hematogenous'' used in current listing 13.21B because metastases by lymphatic spread or by direct extension carry the same poor prognosis.

Proposed Listing 13.22—Urinary Bladder

This listing corresponds to current listing 13.22. We propose to delete current listing 13.22E, which provides

for the evaluation of renal impairment following total cystectomy under the criteria in listing 6.02, because it is a reference listing.

Proposed Listing 13.23—Cancers of the Female Genital Tract

In this listing, we propose to incorporate and revise current listings 13.25, ''Uterus,'' 13.26, ''Ovaries,'' 13.28, ''Uterine (Fallopian) tubes, and 13.30, ''Vulva.''

In proposed listings 13.23A, ''Uterus (corpus),'' and 13.23B ''Uterine cervix,'' we would replace the current 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 proposed 13.23C, ''Vulva,'' we provide criteria in addition to the criteria for distant metastases used in the current listing.

In proposed 13.23D1, '' Extending to the serosa or beyond,'' we replace the criteria in current 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. We also propose adding criteria to evaluate fallopian tube tumors when the initial antineoplastic therapy has not achieved the desired effect.

In proposed 13.23E, ''Ovaries,'' we propose to separate germ cell and non-germ cell tumors. In proposed 13.23E1, which provides the criteria for evaluating non-germ cell tumors, we would expand the criteria in current listing 13.26 to reflect advances in diagnostic techniques and treatment. We provide criteria for evaluating germ cell tumors in proposed listing 13.23E2.

Proposed Listing 13.24—Prostate Gland

In this listing, which corresponds to current listing 13.23, we propose to provide new language to clarify the phrase ''not controlled by prescribed therapy'' used in the current listing.

Proposed Listing 13.25—Testicles

This listing corresponds to current listing 13.24. We propose to delete current listing 13.24A, for choriocarcinoma, in recognition of advances in the treatment of this disease.

Proposed Listing 13.26—Penis

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

Proposed Listing 13.27—Primary Site Unknown After Appropriate Search for Primary

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

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

In this listing, we propose to indicate how long we consider individuals who undergo bone marrow or stem cell transplantation disabled. The criterion for allogeneic transplantation, proposed listing 13.28A, is consistent with the criterion in proposed listing 7.06. This criterion states that we consider the individual disabled until at least 12 months from the date of transplantation. For autologous transplantation, we would consider the individual to be under a disability 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 Proposing to Change the Preface in the Listings for Evaluating Hematological Disorders in Children?

107.00 Hematological Disorders

As in proposed 7.00 in the adult rules, we propose to change the name of this body system to ''Hematological Disorders'' and to move the guidance contained in current 107.00C, ''Acute leukemia,'' to proposed 113.00K(2)(a).

Except for minor changes to refer to children, we have repeated much of the preface of proposed 7.00 in the preface to proposed 107.00. This is because the same basic rules for establishing and evaluating the existence and severity of hematological impairments in adults also apply to children. Because we have already described these provisions under the explanation of proposed 7.00, the following discussions describe only those provisions that are unique to the childhood rules or that require further explanation.

Proposed 107.00C—How Do We Evaluate Impairments That Do Not Meet One of the Hematological Disorders Listings?

In this section, we use the definition of disability for children who claim SSI payments.

Proposed 107.00G—How Do We Evaluate Specific Hematological Disorders?

In this section, we incorporate and revise the guidance in current 107.00A, ''Sickle cell disease,'' and 107.00B, ''Coagulation defects,'' and provide guidance for evaluating additional hematological disorders in children. Proposed 107.00G(1), ''Anemia,'' 107.00G(3), ''Disorders of hemostasis,'' and 107.00G(4), ''Hematological malignancies,'' contain the same information as the adult sections that address these disorders.

Proposed 107.00G(2)—Hemolytic Anemias

Proposed 107.00G(2)(a)—Sickle Cell Disease or One of Its Variants

In proposed 107.00G(2)(a)(i), which is the same as proposed 7.00G(2), we incorporate and expand the guidance from the first two paragraphs of current 107.00A.

In proposed 107.00G(2)(a)(iv), we explain that, to meet the criterion in proposed listing 107.02A2, hospitalizations must be due to complications of sickle cell disease and that the most common complications requiring hospitalization are shown in the listing. However, we also provide that hospitalizations for complications other than the ones listed can be determined to be of equal clinical significance and thus be medically equal to the ones listed.

We propose to delete the guidance in the third and fourth paragraphs of current 107.00A. The third paragraph summarizes the listing criteria but provides no additional information on how to evaluate the disorder. The fourth paragraph lists examples of major visceral episodes, a criterion of current listing 107.05B, the current childhood listing for sickle cell disease. We propose to delete this criterion. We explain the reasons for this proposed deletion under the explanation of proposed listing 107.02A, the listing that corresponds to current listing 107.05B.

Proposed 107.00G(2)(b)—Thalassemia

In this new section, we propose to provide guidance on how to document this disorder. We discuss some of the residual impairments that result from this disorder and indicate that we evaluate these, or any other, residual impairments resulting from this disorder under the criteria for the affected body system.

Proposed 107.00G(2)(c)—Prophylactic Transfusion Programs

In this new section, we propose to explain why, for children on prophylactic transfusion programs, we will not use pre-transfusion hemoglobin values to determine if the child's sickle cell disease or thalessmia major meet the requirements of proposed listings 107.02A or 107.02B.

Proposed 107.00G(2)(d)—Chronic Iron Overload

In this section, which is similar to proposed 7.00G(5), we propose to provide that residuals from chronic iron overload due to chronic transfusion programs will be evaluated under the criteria for the affected body system. In proposed 7.00G(5), we include guidance on evaluating residuals from chronic iron overload due to hereditary hemochromatosis as well as chronic transfusion programs. We have not repeated the guidance on hereditary hemochromatosis in the childhood rules because residuals from this disorder are very rare in children. As the proposed childhood guidance addresses only residuals from chronic iron overload due to chronic transfusion programs, we believe it is appropriate to place this guidance in the same section as the guidance on prophlylactic transfusion programs, rather than in a separate section.

How Are We Proposing To Change the Criteria in the Listings for Evaluating Hematological Disorders in Children?

107.01 Category of Impairments, Hematological Disorders

We propose to move current listing 107.11, ''Acute leukemia,'' to the malignant neoplastic diseases body system (proposed listing 113.06). We also propose to add new listings 107.05, ''Chronic granulocytopenia (due to any cause),'' and 107.06, ''Non-malignant hematological diseases treated by allogeneic bone marrow or stem cell transplantation,'' because they are applicable to children as well as adults. We are not explaining these new listings here as they are identical to, and explained in, the corresponding adult listings. We also propose to renumber these listings to be consistent with the adult listings. Because of this, the numbers of the proposed childhood listings are not consecutive.

Proposed Listing 107.02—Anemia

In proposed listings 107.02A and 107.02B, we incorporate current listings 107.05, ''Sickle cell disease,'' and 107.03, ''Hemolytic anemia (due to any cause).'' In proposed listing 107.02C, we add criteria to evaluate aplastic anemia. We discuss the provisions of proposed listing 107.02 below.

Proposed Listing 107.02A—Sickle Cell Disease or One of Its Variants

Proposed listing 107.02A1, for documented painful vaso-occlusive crises, would replace current listing 107.05A. The proposed criteria provide more specificity and clarity than the criterion ''Recent, recurrent, severe'' used in the current listing. We also propose to delete the parenthetical list of examples of vaso-occlusive crises to avoid any confusion about the types of crises that can be considered.

Proposed listing 107.02A2 would replace current listing 107.05C and partially replace current listing 107.05B. Many children with sickle cell disease are hospitalized on a precautionary basis. To ensure that the hospitalizations considered under the listing are due to complications of the disease, and are not precautionary, we list the most common complications that result in hospitalizations. We provide, in proposed 107.00G(2)(a)(iv), that hospitalizations for other complications can be used to determine whether a complication medically equals the listings.

We propose to delete the criterion for a ''major visceral complication'' from current listing 107.05B and, as indicated above, to delete the fourth paragraph of current 107.00A which provides examples of ''major visceral episodes.'' If a major visceral episode results in hospitalization, we will consider it under proposed listing 107.02A2. If an episode results in another impairment(s), we will evaluate the residual impairment(s) under the criteria for the affected body system(s). However, the kinds of complications described in the fourth paragraph of current 107.00A, as well as those in current listing 107.05C, may be acute and resolve completely with treatment. The fact that a child has had one episode is not sufficient to establish that the child has been, or will be, disabled for a continuous period of at least 12 months.

Proposed listing 107.02A3, requiring chronic anemia, would revise the criterion in current listing 107.05D to reflect a more accurate measure of severity. The current criterion is a persistent hematocrit of 26 percent or less. A hematocrit at this level does not necessarily correlate with an impairment of listing-level severity.

Consistent with our changes in the adult rules, we would not retain the word ''severe'' used in current listing 107.05D in our proposed criterion for sickle cell disease with chronic anemia. We explain our reasons for deleting this word in our discussion of proposed listing 7.02.

Proposed Listing 107.02B—Other Hemolytic Anemias

In this listing, we propose to revise the criteria in current listing 107.03 to provide a more accurate measure of severity. Children whose hematocrit persists at 26 percent or less despite prescribed therapy will not necessarily have marked and severe functional limitations. Additionally, we propose to delete the requirement for reticulocyte counts since a reticulocyte count is not needed to determine whether the impairment is of listing-level severity and such counts may not be included in the laboratory findings.

Proposed Listing 107.02C—Aplastic Anemia

This listing contains the same criteria as proposed listing 7.04.

Proposed listing 107.03—Disorders of Hemostasis

For this listing, we use the same criteria as proposed listing 7.03. The following is a discussion of how these proposed criteria relate to the current criteria.

Proposed listing 107.03A, ''Chronic thrombocytopenia (due to any cause),'' replaces current listing 107.06, ''Chronic idiopathic thrombocytopenic purpura of childhood.'' The proposed criteria are more accurate measures of severity. The current criterion requires platelet counts of 40,000/mm^3 or less despite therapy or recurrent upon withdrawal of treatment, but platelet counts at this level will not necessarily result in marked and severe functional limitations. We would also delete the specification of thrombocytopenic purpura, broadening the listing to address chronic thrombocytopenia due to any cause.

Proposed listings 107.03B, ''Hemophilia,'' and 107.03C, ''Other hypocoagulable states (such as von Willebrand's disease or thrombasthenia),'' would replace current listing 107.08, ''Inherited coagulation disorder.'' The proposed criteria provide more specificity and

clarity than the criterion in current listing 107.08A, ''repeated spontaneous or inappropriate bleeding.'' We propose to move the criterion in current listing 107.08B, for hemarthrosis with joint deformity, to proposed 107.00G(3)(c). The current listing does not specify the level of joint deformity required. We propose to make it clear that only serious joint deformity resulting in listing-level functional deficit will constitute an impairment of listing-level severity. To do this, we propose that this complication be evaluated under current listing 101.02. Because this guidance would result in a reference listing, we are placing it in the preface.

How Are We Proposing To Change the Preface in the Listings for Evaluating Malignant Neoplastic Diseases in Children?

113.00 Malignant Neoplastic Diseases

We propose to delete the discussion in current 113.00C, ''Malignant solid tumors,'' for the following reasons:

- We are proposing to delete current listing 113.03, the general listing for malignant solid tumors. We provide the reason for this deletion in the discussion of 113.01.
- We are proposing to incorporate the guidance about the evaluation of thyroid tumors in the second sentence of current 113.00C in proposed listing 113.09.
- We are proposing to move the criteria for evaluating malignant brain tumors to this body system. Therefore, we would no longer need the reference to current listing 111.05.

As we explained in the discussion of 107.00, we have, with the exception of minor changes to refer to children, repeated much of the preface of proposed 13.00 in the preface to proposed 113.00. Because we have already described these provisions under the explanation of proposed 13.00, the following discussions describe only those provisions that are unique to the childhood rules or that require further explanation.

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

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

Proposed 113.00D—What Evidence Do We Need?

In this section, we replace and expand current 113.00B. This section is the same as proposed 13.00D, except that we have deleted the guidance about what we need when the primary site cannot be identified. We are not proposing a childhood listing to correspond to proposed listing 13.27, primary site unknown, because the inability to determine the primary site is an extremely rare occurrence in childhood malignancies. In these rare situations, we would use proposed listing 13.27.

Proposed 113.00E—When Do We Need Longitudinal Evidence?

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

Proposed 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 proposed 13.00F but use the definition of disability for children who claim SSI payments.

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

This section would replace current 113.00A2 and the last paragraph of 113.00A. We repeat the guidance in proposed 13.00G but use the definition of disability for children who claim SSI payments.

Proposed 113.00H—How Long Do We Consider the Child Disabled?

This section would replace current 113.00D, ''Duration of disability,'' which refers to the periods of disability included in current listings 113.02 and 113.03. Although we do not cite specific listings in the proposed rule, we indicate that some listings specify that the impairment should be considered disabling until a particular point in time. In proposed 113.00H(2) we also state that when the listing does not contain such a specification, we will find a child whose impairment meets or medically equals the listings in this body system to be under a disability until at least 3 years after onset of complete remission. We propose this to ensure consistency between the adult and childhood rules.

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

In this section, we incorporate the discussion in current 107.00C, ''Acute leukemia,'' and provide guidance for other childhood malignancies. Except for minor changes to refer to children, proposed 113.00K(3), ''Brain Tumors,'' is the same as the proposed 13.00K(6). The following discussions of lymphoma and leukemia reflect criteria we are proposing specifically for the evaluation of these malignancies in children.

Proposed 113.00K(1)—Lymphoma

In this section we indicate that proposed listing 113.05 should not be used for evaluating low grade or indolent lymphomas because they are rare in children. We would evaluate these lymphomas under proposed listing 13.05. We also provide a reminder to consider the duration and effects of long-term protocols used to treat lymphoma.

Proposed 113.00K(2)—Leukemia

Proposed 113.00K(2)(a), ''Acute leukemia,'' is the same as proposed 13.00K(2)(a).

Proposed 113.00K(2)(b), ''Chronic myelogenous leukemia (CML),'' is the same as proposed 13.00K(2)(b).

In proposed 113.00K(2)(c), we provide a description of juvenile CML (JCML).

Proposed 113.00K(2)(d) is similar to proposed 13.00K(2)(d). We did not repeat the reference to chronic lymphocytic leukemia in proposed 13.00K(2)(c) because the disorder is extremely rare in children.

Proposed 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 proposed 13.00L, but we do not refer to multiple myeloma because this impairment is not included in the proposed childhood listings.

How Are We Proposing To Change the Criteria in the Listings for Evaluating Malignant Neoplastic Diseases in Children?

113.01 Category of Impairments, Malignant Neoplastic Diseases

We propose to delete current listing 113.03, ''Malignant solid tumors.'' Instead, we propose to provide separate listings for specific types of malignant solid tumors, such as soft tissue sarcoma (proposed listing 113.04), osteogenic sarcoma (proposed listing 113.11), and Wilms' tumor (proposed listing 113.21B). Due to advances in treatment, all malignant solid tumors in children do not necessarily result in listing-level severity. We would evaluate any malignant solid tumor not listed in these proposed rules on a case-by-case basis.

We propose to renumber 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

proposed childhood listings are not consecutive.

Proposed Listing 113.04—Soft Tissue Sarcoma (Including Ewing's Sarcoma, Primitive Neuroectodermal Tumor (PNET)

In proposed listing 113.04A, we provide for a finding of disability for at least 12 months from the date of diagnosis for any localized tumor with or without metastases. With this provision, we would recognize the duration and debilitating effects of the treatment for this malignancy in children. In proposed listing 113.04B, we provide for a finding of disability when treatment has not been effective.

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

This listing corresponds to current listing 113.02, ''Lymphoreticular malignant neoplasms.'' We propose to revise the listing to make it more consistent with proposed listing 13.05. In the discussion of the proposed adult listing above, we explain why we evaluate T-cell lymphocytic lymphoma under the criteria for leukemia.

Proposed listing 113.05A would replace the criteria for Non-Hodgkin's lymphoma in current 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 period of time the child has an impairment of listing-level severity is usually less than 12 months. Due to these advances in treatment, it is no longer appropriate to presume that the impairment will meet the statutory duration requirement. Instead, we propose to find a child disabled when treatment has not been effective.

Proposed listing 113.05B would replace the criteria for Hodgkin's disease in current listing 113.02A. With the proposed criterion, we clarify what we mean by ''progressive disease not controlled by prescribed therapy'' in the current listing.

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

Proposed 113.06—Leukemia

This listing would replace current listing 107.11, ''Acute leukemia.'' In proposed listing 113.06A, ''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 proposed listing 13.06A, and are explained in the discussion of that listing.

In proposed listing 113.06B, which is the same as proposed listing 13.06B, we would add criteria for evaluating CML, other than JCML.

Proposed Listing 113.09—Thyroid Gland

This listing is the same as proposed adult listing 13.09 and would incorporate the guidance contained in current 113.00C. The listing criteria define when the malignancy is not controlled by prescribed therapy.

Proposed Listing 113.10—Retinoblastoma

This proposed listing would revise current listing 113.05. We propose to delete current listing 113.05A, for bilateral involvement, because with advances in treatment this condition is often treated successfully. If treatment is not successful, we will evaluate the impairment under the other criteria in the proposed listing.

Proposed listing 113.10A corresponds to current listing 113.05C. We propose no substantive changes.

Proposed listing 113.10B corresponds to current listing 113.10D. We propose to revise the criteria to recognize that persistence after treatment, as well as recurrence, indicates a poor prognosis.

Proposed listing 113.10C corresponds to current listing 113.05B. We propose to revise the description to make it clear that any metastatic disease is included under the listing.

Proposed 113.11—Osteogenic Sarcoma

This listing is the same as proposed listing 13.11 except that we propose to limit the listing to ''osteogenic sarcoma'' instead of the broader category used in proposed listing 13.11 because other bone tumors are extremely rare in children.

Proposed 113.13—Nervous System

This listing would revise the criteria for malignant brain tumors in current listing 111.05, ''Brain tumors.'' We propose to use the same criteria as proposed listing 13.13.

Proposed Listing 113.21—Kidneys and Adrenal Glands

Proposed listing 113.21A would revise current listing 113.04, ''Neuroblastoma,'' to reflect the present evaluation and treatment of this condition.

Proposed listing 113.21B adds criteria for evaluating Wilms' tumor.

Proposed Listing 113.25—Testicles

This listing is the same as proposed listing 13.25.

Proposed Listing 113.26—Germ Cell Tumors

In this listing, we provide criteria for evaluating these malignancies.

Proposed Listing 113.28—Malignant Neoplastic Diseases Treated by Bone Marrow or Stem Cell Transplantation

This listing is the same as proposed listing 13.28.

What Other Revisions Are We Proposing?

Consistent with the proposed changes explained above, we also propose to:

- Revise current 11.00B to indicate that malignant brain tumors should be evaluated under the criteria in listing 13.13.
- Add 111.00E to provide the same guidance as proposed 11.00B.
- Revise current listings 11.05 and 111.05 by removing the criteria for malignant brain tumors.
- Revise the cross-references in current listings 14.08G and 114.08G to reflect the numbers in the proposed hematological disorders listings.

Clarity of These Proposed Rules

Executive Order 12866 and the President's memorandum of June 1, 1998 (63 FR 31885) require each agency to write all rules in plain language. In addition to your substantive comments on these proposed rules, we invite your comments on how to make these proposed rules easier to understand.

For example:

- Have we organized the material to suit your needs?
- Are the requirements in the rules clearly stated?
- Do the rules contain technical language or jargon that isn't clear?
- Would a different format (grouping and order of sections, use of headings, paragraphing) make the rules easier to understand?
- Would more (but shorter) sections be better?
- Could we improve clarity by adding tables, lists, or diagrams?
- What else could we do to make the rules easier to understand?

Regulatory Procedures

Executive Order 12866

The Office of Management and Budget (OMB) has reviewed these proposed rules in accordance with Executive Order 12866.

Regulatory Flexibility Act

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

Paperwork Reduction Act

These proposed rules contain reporting requirements at 7.00A, 7.00B, 7.00D, 7.00E, 7.00G, 7.02, 7.03, 7.04, 7.05, 13.00B, 13.00D, 13.00E, 13.00G, 13.00K, 107.00A, 107.00B, 107.00D, 107.00E, 107.00G, 107.02, 107.03, 107.05, 113.00B, 113.00D, 113.00E, 113.00G, and 113.00K. The public reporting burden is accounted for in the Information Collection Requests for the various forms that the public uses to submit the information to SSA. Consequently, a 1-hour placeholder burden is being assigned to the specific reporting requirement(s) contained in these rules. We are seeking clearance of the burdens referenced in these rules because they were not considered during the clearance of the forms. An Information Collection Request has been submitted to OMB. We are soliciting comments on the burden estimate; the need for the information; its practical utility; ways to enhance its quality, utility and clarity; and on ways to minimize the burden on respondents, including the use of automated collection techniques or other forms of information technology. Comments should be submitted to the Social Security Administration at the following address:

Social Security Administration, Attn: SSA Reports Clearance Officer, Rm. 1–A–20, Operations Building, 6401 Security Boulevard, Baltimore, MD 21235–6401

Comments can be received for between 30 and 60 days after publication of this notice and will be most useful if received by SSA within 30 days of publication.

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

List of Subjects in 20 CFR Part 404

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

Dated: November 8, 2001.

Larry G. Massanari,

Acting Commissioner of Social Security.

For the reasons set forth in the preamble, we propose to amend chapter III of title 20 of the Code of Federal Regulations 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. Items 8 and 14 of the introductory text before part A are revised.

b. The Table of Contents for part A is amended by revising the body system names for sections 7.00 and 13.00.

c. Section 7.00 of part A is revised.

d. Paragraph B of the introductory text of section 11.00, Neurological, of part A is revised.

e. Listing 11.05 of part A is revised.

f. Section 13.00 of part A is revised.

g. Listing 14.08G of part A is revised.

h. The Table of Contents for part B is amended by revising the body system names for sections 107.00 and 113.00.

i. Section 107.00 of part B is revised.

j. Section 111.00E is added to part B.

k. Listing 111.05 of part B is revised.

l. Section 113.00 of part B is revised.

m. Listing 114.08G of part B 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): (*insert date 5 years from the effective date of the final rules*).

* * * * *

14. Malignant Neoplastic Diseases (13.00 and 113.00): (*insert date 5 years from the effective date of the final rules*).

* * * * *

Part A

* * * * *

7.00 Hematological Disorders

* * * * *

13.00 Malignant Neoplastic Diseases

* * * * *

7.00 Hematological Disorders

A. What do we Consider when we Evaluate Hematological Disorders Under These Listings?

We consider factors such as the:

(1) Type of disorder.

(2) Response to therapy.

(3) Side effects of therapy.

(4) Effects of any post-therapeutic residuals.

(5) Degree of limitation the disorder imposes on the individual.

(6) Expected duration.

B. What Documentation do we Need?

(1) We generally need a longitudinal clinical record covering a period of at least 3 months of observations and treatment, unless we can make a fully favorable determination or decision without it. The record should include laboratory findings, such as hemoglobin values or platelet counts, obtained on more than one examination over the 3-month period.

(2) Any longitudinal clinical record should also include a description of the therapy prescribed by the treating source and the individual's response to treatment, because medical management may improve functional status. The longitudinal record should provide information regarding functional recovery, if any.

(3) Even when an individual does not receive ongoing treatment or have an ongoing relationship with a medical source, it is important to obtain evidence from relevant sources over a sufficient period. Such evidence may provide information about the:

(a) Ongoing medical severity of the impairment.

(b) Frequency, severity, and duration of symptoms.

(c) Level of the individual's functioning.

C. How Do We Evaluate Impairments That Do Not Meet one of the Hematological Disorders Listings?

(1) These listings are only examples of common hematological disorders that we consider severe enough to prevent an individual from doing any gainful activity. If the individual's impairment(s) does not meet the criteria of any of these listings, we must also consider whether the individual has an impairment(s) that satisfies the criteria of a listing in another body system.

(2) If an individual has a medically determinable impairment(s) that does not meet a listing, we will determine whether the impairment(s) medically equals the listings. (See §§ 404.1526 and 416.926.) An individual who has an impairment(s) that does not meet or medically equal the listings may or may not have the residual functional capacity to engage in substantial gainful activity. For such an individual, we proceed to the fourth, and if necessary, the fifth steps of the sequential evaluation process in §§ 404.1520 and 416.920. When we decide whether an adult continues to be disabled, we use the rules in §§ 404.1594 and 416.994.

D. How Do We Assess the Effectiveness of Treatment?

(1) We assess the effectiveness of treatment by seeing if there is improvement in the

signs, symptoms, and laboratory findings of the disorder, and if there are side effects that may result in functional limitations in the individual. Because the response to treatment and adverse consequences of treatment may vary widely, we consider each case on an individual basis.

(2) We will request a specific description of the:

(a) Drugs or treatment given.

(b) Dosage, method, and frequency of administration.

(3) We will also request a description of the complications or adverse effects of treatment, such as the following:

(a) Continuing gastrointestinal symptoms.

(b) Persistent weakness.

(c) Neurological complications.

(d) Cardiovascular complications.

(e) Reactive mental disorders.

(4) Because the effects of treatment may be temporary, enough time must pass to allow us to evaluate the impact of treatment.

E. How Do We Evaluate Episodic Hematological Disorders?

Some hematological disorders listings are met when a specified number of events have occurred within a specified time period, such as 3 events within a consecutive 12-month period. Events include pain crises, hospitalizations, treatment with parenteral antimicrobial medication, bleeding episodes, and thromboses. When we use such criteria, the period specified in the listing (either 6 months or 12 months) must occur within the period we are considering in connection with an application or continuing disability review. In every listing in which we require more than one event, there must be at least 1 month between the events, in order to ensure that we are evaluating separate episodes.

F. What Do These Terms in the Listings Mean?

(1) *Persistent:* The longitudinal clinical record shows that, with few exceptions, the hemoglobin level has been at or below, or is expected to be at or below, the level specified in the listing for a continuous period of at least 12 months.

(2) *Repeated, repeatedly:* The longitudinal clinical record shows that the platelet count, neutrophil count, or hemoglobin level, as appropriate, satisfies the criteria in the listing most of the time, and that pattern has lasted or is expected to last for a continuous period of at least 12 months.

G. How Do We Evaluate Specific Hematological Disorders?

(1) *Anemia.* Anemia refers to decreased oxygen-carrying capacity of the blood and is usually measured as a decrease in hemoglobin concentration. A gradual reduction in hemoglobin, even to very low levels, is often well tolerated in individuals with normal cardiovascular and pulmonary systems. We generally evaluate the effects of chronic anemia under the criteria for the underlying disorder or for the affected body system. However, we include listings for sickle cell disease or one of its variants and aplastic anemia because of their specific manifestations.

(2) *Sickle cell disease or one of its variants.* (a) Sickle cell disease is a chronic hemolytic anemia in which the abnormal sickle cell hemoglobin may be either homozygous or in combination with thalassemia or with another abnormal hemoglobin. The diagnosis of sickle cell disease or one of its variants should be based on appropriate hematological evidence, such as hemoglobin electrophoresis. We accept medical evidence that is persuasive that a positive diagnosis of sickle cell disease or one of its variants has been confirmed by appropriate laboratory testing at some time prior to evaluation in lieu of a copy of the actual laboratory report.

(b) We will document the intensity, frequency, duration, and response to treatment of vaso-occlusive or aplastic episodes.

(c) Parenteral medication as required under 7.02A does not include hydration.

(3) *Disorders of hemostasis.* (a) ''Disorders of hemostasis'' refers to abnormalities in the ability of the blood to clot. These disorders must be documented by appropriate laboratory evidence, including platelet counts and evaluation of plasma clotting factors such as Factor VIII or Factor V Leiden.

(b) We will document the frequency, severity, and treatment of bleeding episodes or thromboses. Prophylactic therapy, such as factor concentrates or antithrombotic agents, does not, by itself, indicate any specific degree of severity.

(c) We must consider complications such as development of inhibitors against clotting factors, intrusiveness of treatment, and limitation of function. We must also consider effects on other body systems. For example, we will evaluate hemarthrosis with joint deformity under 1.02, and intracranial bleeding under 11.04.

(4) *Hematological malignancies.* With the exception of lymphoma associated with human immunodeficiency virus (HIV) infection, we use the guidance in 13.00K(3) (Macroglobulinemia or heavy chain disease) or the criteria in 13.05 (Lymphoma), 13.06 (Leukemia), 13.07 (Multiple myeloma), or 13.28 (Malignant neoplastic diseases treated by bone marrow or stem cell transplantation) to evaluate hematological malignancies. We evaluate lymphoma associated with HIV infection under the criteria in 14.08E.

(5) *Chronic iron overload.* Chronic iron overload resulting from hereditary hemochromatosis, a genetic disorder of excessive absorption of dietary iron, is usually treated by iron removal through repeated phlebotomy. Chronic iron overload resulting from repeated red blood cell transfusion (transfusion hemosiderosis) is generally treated with iron chelation therapy. We evaluate residuals of this impairment under the criteria for the affected body system, such as cardiovascular or digestive.

H. How Do We Evaluate Non-Malignant Hematological Disorders Treated by Allogeneic Bone Marrow or Stem Cell Transplantation?

Allogeneic bone marrow or stem cell transplantation (transplantation from an unrelated donor or a related donor other than an identical twin) is performed for a variety of non-malignant hematological diseases, such as sickle cell disease and aplastic anemia. We will evaluate any non-malignant hematological disorder that is treated with allogeneic bone marrow or stem cell transplantation under 7.06, regardless of whether there is another listing that addresses that impairment. Under 7.06, we consider an individual disabled until at least 12 months from the date of transplantation. Thereafter, for purposes of evaluating disability, we consider any residual impairment(s), such as complications arising from:

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

(2) Immunosuppressive therapy, such as frequent infections.

(3) Significant deterioration of other organ systems.

7.01 Category of Impairments, Hematological Disorders

7.02 *Sickle cell disease or one of its variants,* with one of the following:

A. Documented painful (vaso-occlusive) crises requiring parenteral medication, occurring at least 3 times in a consecutive 6-month period (see 7.00E).

OR

B. Hospitalization (for 24 hours or more) for sickle cell related diseases, occurring at least 3 times in a consecutive 12-month period (see 7.00E).

OR

C. Chronic anemia manifested by persistent hemoglobin of 7.0 gm/dl or less despite prescribed therapy (see 7.00F).

7.03 *Disorders of hemostasis.*

A. Chronic thrombocytopenia (due to any cause), with either 1 or 2:

1. Platelet counts repeatedly below 10,000/mm3 despite prescribed therapy (see 7.00F).

2. Platelet counts repeatedly below 20,000/mm3 and spontaneous bleeding despite prescribed therapy, requiring red cell or platelet transfusion at least 3 times in a consecutive 12-month period (see 7.00E, 7.00F). Consider under a disability for 12 months from the date of the last transfusion. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

OR

B. Hemophilia with spontaneous bleeding despite prophylactic factor replacement, occurring at least 3 times in a consecutive 12-month period (see 7.00E).

OR

C. Other hypocoagulable states (such as von Willebrand's disease or thrombasthenia) with spontaneous bleeding requiring hospitalization (for 24 hours or more), occurring at least 3 times in a consecutive 12-month period (see 7.00E).

OR

D. Hypercoagulable states (deficiency of anti-coagulant proteins such as protein C, protein S, and antithrombin, or the presence of abnormal proteins such as Factor V Leiden) with documented thromboses occurring at least 3 times in a consecutive 12-month period (see 7.00E).

7.04 *Aplastic anemia, myeloproliferative disorders (such as polycythemia vera or myelofibrosis), or myelodysplastic syndrome* with:

A. Chronic anemia manifested by repeated hemoglobin of 7.0 gm/dl or less despite prescribed therapy (see 7.00F).

OR

B. Documented treatment with parenteral antimicrobial medication occurring at least 3 times in a consecutive 12-month period (see 7.00E).

7.05 *Chronic granulocytopenia* (due to any cause), with both A and B:

A. Absolute neutrophil counts repeatedly below 500/mm3 (see 7.00F).

AND

B. Documented treatment with parenteral antimicrobial medication occurring at least 3 times in a consecutive 12-month period (see 7.00E).

7.06 *Non-malignant hematological diseases treated by allogeneic bone marrow or stem cell transplantation (see 7.00H).* 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.

* * * * *

11.00 NEUROLOGICAL

* * * * *

B. *Brain tumors.* 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 *Benign brain tumors.* Evaluate under 11.02, 11.03, 11.04A or B, or 12.02.

* * * * *

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 wih 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 in individuals with 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?* Except for metastatic carcinoma to the brain or spinal cord (13.13C), 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 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 the individual's 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, it will often happen within 6 months after it 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 an individual from engaging in any gainful activity. If the individual's impairment(s) does not meet the criteria of any of these listings, we must also consider whether the individual has an impairment(s) that satisfies the criteria of a listing in another body system.

(2) If an individual has a medically determinable impairment(s) that does not meet a listing, we will determine whether the impairment(s) medically equals the listings. (See §§ 404.1526 and 416.926.) An individual who has an impairment(s) that does not meet or medically equal the listings may or may not have the residual functional capacity to engage in substantial gainful activity. For such an individual, we proceed to the fourth, and if necessary, the fifth steps of the sequential evaluation process in §§ 404.1520 and 416.920. When we decide whether an adult continues to be disabled, we use the rules in §§ 404.1594 and 416.994.

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 the Malignant Neoplastic Diseases 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 the listings, we must consider its affect on the individual's ability to do substantial gainful activity.

H. *How long do we consider the individual disabled?*

(1) In some listings, we specify that the impairment will be considered disabling until a particular point in time (for example, at least 18 months from the date of diagnosis). We may consider the impairment

to be disabling beyond this point when justified by the medical and other evidence.

(2) When a listing does not contain such a specification, we will find an individual whose impairment(s) meets or medically equals a listing in this body system to be under a disability until at least 3 years after onset of complete remission. When the original tumor and any metastases have not been evident for at least 3 years after complete remission, the impairment(s) no longer meets or equals the criteria under this body system.

(3) Following the appropriate period, we will consider any residual impairment(s), including residuals of the malignancy or therapy (see 13.00G), in determining whether the individual is disabled.

I. *What do these terms in the listings mean?* (1) *Inoperable:* Surgery was thought to be of no therapeutic value or the surgery could not 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. Determining 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:* 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) Medically reported symptoms.

K. *How do we evaluate specific malignant neoplastic diseases?* (1) *Lymphoma.* (a) Many indolent (non-aggressive) lymphomas, although they may produce intermittent symptoms and signs, are often controlled by well-tolerated treatment modalities. Therefore, we will defer adjudication of these cases for an appropriate period after initiation of therapy to determine whether the therapy will achieve its intended effect. (See 13.00E(3).) For an indolent lymphoma, the intended effect of therapy is usually stability of the disease process. When stability has been achieved, severity should be assessed on the basis of the extent of involvement of other organ systems and residuals from therapy.

(b) A change in therapy is usually an indicator that the therapy is not achieving its intended effect. However, it is not an indicator if the change is based on the individual's (or the physician's) choice rather than a failure to achieve stability. If the therapy is changed due solely to choice, the requirements of listing 13.05A.2.a 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/mm^3 for 3 months or longer, or other acceptable diagnostic techniques consistent with the prevailing state of medical knowledge and clinical practice.

(ii) We will evaluate the complications and residual impairments from CLL under the appropriate listing, such as 13.05A2, 7.03A, and 7.05.

(d) *Elevated white cell counts.* 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 7.03 or 7.04, or of 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.* We consider an individual who undergoes bone marrow or stem cell transplantation for any of these disorders 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.* We consider an individual who undergoes bone marrow or stem cell transplantation for any of these disorders 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 consider an individual whose impairment is evaluated under 13.28 to be disabled depends on whether the individual undergoes allogeneic or autologous transplantation.

(a) *Allogeneic bone marrow or stem cell transplantation.* We will consider an individual who undergoes allogeneic transplantation (transplantation from an unrelated donor or a related donor other than an identical twin) disabled until at least 12 months from the date of transplantation.

(b) *Autologous bone marrow or stem cell transplantation.* We will consider an individual who undergoes autologous transplantation (transplantation of the individual's own cells or cells from an identical twin (syngeneic transplantation)) 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 the individual for transplantation.

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

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

(b) Immunosuppressant therapy, such as frequent infections.

(c) Significant deterioration of other organ systems.

13.01 Category of Impairments, 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. Epidermoid carcinoma occurring in the pyriform sinus.

OR

F. Soft tissue tumors of the head and neck not addressed in A–E, 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. Recurrence 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 13.00K(1).)

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 1 antineoplastic treatment regimen within a consecutive 12-month period. Consider under a disability from 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 13.00K(2).)

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),* with 1 or 2:

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

2. 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 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 13.00K(4).)

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 infratemporal 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 with regional or distant metastases.

OR

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

13.13 *Nervous system.* (See 13.00K(6).)

A. Central nervous system neoplasms (brain and spinal cord), including:

1. Highly malignant tumors, such as Grades III and IV astrocytoma, glioblastoma multiforme, ependymoblastoma, 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.

OR

C. Metastatic carcinoma to brain or spinal cord (includes epidural metastases).

13.14 *Lungs.*

A. Non-small-cell carcinoma—inoperable, unresectable, recurrent, or metastatic disease to or beyond the mediastinal or subcarinal lymph 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. Metastatic.

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 the regional lymph nodes or beyond.

13.22 *Urinary bladder*—carcinoma, with:

A. Infiltration beyond the bladder wall.

OR

B. Recurrent after total cystectomy.

OR

C. Inoperable or unresectable.

OR

D. 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 tube, 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. Recurrence 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.

* * * * *

14.08 Human Immunodeficiency Virus (HIV) Infection

* * * * *

G. Hematologic abnormalities:

1. Anemia, as described under the criteria in 7.02C; or

2. Granulocytopenia, as described under the criteria in 7.05; or

3. Thromobocytopenia, as described under the criteria in 7.03A.

* * * * *

Part B

* * * * *

107.00 Hematological Disorders

* * * * *

113.00 Malignant Neoplastic Diseases

* * * * *

107.00 Hematological Disorders

A. *What do we consider when we evaluate hematological disorders under these listings?* We consider factors such as the:

(1) Type of disorder.

(2) Response to therapy.

(3) Side effects of therapy.

(4) Effects of any post-therapeutic residuals.

(5) Degree of limitation the disorder imposes on the child.

(6) Expected duration.

B. *What documentation do we need?*

(1) We generally need a longitudinal clinical record covering a period of at least 3 months of observations and treatment, unless we can make a fully favorable determination or decision without it. The record should include laboratory findings, such as hemoglobin values or platelet counts, obtained on more than one examination over the 3-month period.

(2) Any longitudinal clinical record should also include a description of the therapy prescribed by the treating source and the child's response to treatment, because medical management may improve functional status. The longitudinal record should provide information regarding functional recovery, if any.

(3) Even when a child does not receive ongoing treatment or have an ongoing relationship with a medical source, it is important to obtain evidence from relevant sources over a sufficient period. Such evidence may provide information about the:

(a) Ongoing medical severity of the impairment.

(b) Frequency, severity, and duration of symptoms.

(c) Level of the child's functioning.

C. *How do we evaluate impairments that do not meet one of the Hematological Disorders listings?*

(1) These listings are only examples of common hematological disorders that we consider severe enough to result in marked and severe functional limitations. If the child's impairment(s) does not meet the criteria of any of these listings, we must also consider whether the child has an impairment(s) that satisfies the criteria of a listing in another body system.

(2) If a child has a medically determinable impairment(s) that does not meet a listing, we will determine whether the impairment(s) medically equals the listings, or, in the case of a claim for SSI payments, functionally equals the listings. (See §§ 404.1526, 416.926, and 416.926a.) When we decide whether a child receiving SSI payments continues to be disabled, we use the rules in § 416.994a.

D. *How do we assess the effectiveness of treatment?* (1) We assess the effectiveness of treatment by seeing if there is improvement in the signs, symptoms, and laboratory findings of the disorder, and if there are side effects that may result in functional limitations in the child. Because the response to treatment and adverse consequences of treatment may vary widely, we consider each case on an individual basis.

(2) We will request a specific description of the:

(a) Drugs or treatment given.

(b) Dosage, method, and frequency of administration.

(3) We will also request a description of the complications or adverse effects of treatment, such as the following:

(a) Continuing gastrointestinal symptoms.

(b) Persistent weakness.

(c) Neurological complications.

(d) Cardiovascular complications.

(e) Reactive mental disorders.

(4) Because the effects of treatment may be temporary, enough time must pass to allow us to evaluate the impact of treatment.

E. *How do we evaluate episodic hematological disorders?* Some hematological disorders listings are met when a specified number of events have occurred within a specified time period, such as 3 events within a consecutive 12-month period. Events include pain crises, hospitalizations, treatment with parenteral antimicrobial medication, bleeding episodes, and thromboses. When we use such criteria, the period specified in the listing (either 6 months or 12 months) must occur within the period we are considering in connection with an application or continuing disability review. In every listing in which we require more than one event, there must be at least 1 month between the events, in order to ensure that we are evaluating separate episodes.

F. *What do these terms in the listings mean?* (1) *Persistent:* The longitudinal clinical record shows that, with few exceptions, the hemoglobin level has been at or below, or is expected to be at or below, the level specified in the listing for a continuous period of at least 12 months.

(2) *Repeated, repeatedly:* The longitudinal clinical record shows that the platelet count, neutrophil count, or hemoglobin level, as appropriate, satisfies the criteria in the listing most of the time, and that pattern has lasted or is expected to last for a continuous period of at least 12 months.

G. *How do we evaluate specific hematological disorders?* (1) *Anemia.* Anemia refers to decreased oxygen-carrying capacity of the blood and is usually measured as a decrease in hemoglobin

concentration. A gradual reduction in hemoglobin, even to very low levels, is often well tolerated in infants and children with normal cardiovascular and pulmonary systems. We generally evaluate the effects of chronic anemia under the criteria for the underlying disorder or for the affected body system. However, we include listings for hemolytic anemias and aplastic anemia because of their specific manifestations.

(2) *Hemolytic anemias.* (a) *Sickle cell disease or one of its variants.* (i) Sickle cell disease is a chronic hemolytic anemia in which the abnormal sickle cell hemoglobin may be either homozygous or in combination with thalassemia or with another abnormal hemoglobin. The diagnosis of sickle cell disease or one of its variants should be based on appropriate hematological evidence, such as hemoglobin electrophoresis. Frequently, this information is a part of the newborn screening data. We accept medical evidence that is persuasive that a positive diagnosis of sickle cell disease or one of its variants has been confirmed by appropriate laboratory testing at some time prior to evaluation in lieu of a copy of the actual laboratory report.

(ii) We will document the intensity, frequency, duration, and response to treatment of vaso-occlusive or aplastic episodes.

(iii) Parenteral medication as required under 107.02A1 does not include hydration.

(iv) To satisfy the criterion in 107.02A2, hospitalizations for children with sickle cell disease must be due to complications of the disease. We list the most common complications of sickle cell disease requiring hospitalization in the listing. Other complications of sickle cell disease requiring hospitalization may be of equal clinical significance to, and thus be medically equal to the ones listed. When we make a determination whether a complication is of equal clinical significance, we will make reasonable efforts to ensure that a qualified pediatrician or other individual who specializes in childhood hematological disorders evaluates the case.

(b) *Thalassemia.* Thalassemia is a type of hemolytic disorder in which the rate of erythropoeisis (red cell formation in the bone marrow) is inappropriate for the degree of anemia. Documentation of the disorder requires analysis of levels of hemoglobin types together with measurement of red cell size. Compensatory intra-medullary hematopoiesis, which results in bone marrow expansion, can lead to pathologic fractures and marked hepatosplenomegaly, especially in children with thalassemia major (the homozygous form) or those in whom the thalassemic state is combined with hemoglobin E (E thalassemia). We evaluate these, or any other, residual impairments resulting from this disorder under the criteria for the affected body system.

(c) *Prophylactic transfusion programs.* Many children with sickle cell disease or thalassemia major are on prophylactic transfusion programs. Even though these children may have pre-transfusion hemoglobin values of less than 7.0 gm/dl, they are usually asymptomatic. Therefore, we will not use pre-transfusion hemoglobin values to determine if sickle cell disease or thalessemia major meet the requirements of 107.02A or 107.02B. We may use pre-transfusion hemoglobin values to evaluate these disorders in children who are not on prophylactic transfusion programs, or to evaluate other hematological disorders.

(d) *Chronic iron overload.* Chronic iron overload (transfusion hemosiderosis) is a serious consequence of chronic transfusion programs. It is generally treated with iron chelation therapy. We will evaluate residuals of this impairment under the criteria for the affected body system, such as cardiovascular or digestive.

(3) *Disorders of hemostasis.* (a) ''Disorders of hemostasis'' refers to abnormalities in the ability of the blood to clot. These disorders must be documented by appropriate laboratory evidence, including platelet counts and evaluation of plasma clotting factors such as Factor VIII or Factor V Leiden.

(b) We will document the frequency, severity, and treatment of bleeding episodes or thromboses. Prophylactic therapy, such as factor concentrates or antithrombotic agents, does not, by itself, indicate any specific degree of severity.

(c) We must consider complications such as development of inhibitors against clotting factors, intrusiveness of treatment, and limitation of function. We must also consider effects on other body systems. For example, we will evaluate hemarthrosis with joint deformity under 101.02, and intracranial bleeding under 111.06 or 111.09.

(4) *Hematological malignancies.* With the exception of lymphoma associated with human immunodeficiency virus (HIV) infection, we use the criteria in 113.05 (Lymphoma), 113.06 (Leukemia), and 113.28 (Malignant neoplastic diseases treated by bone marrow or stem cell transplantation) to evaluate hematological malignancies. We evaluate lymphoma associated with HIV infection under the criteria in 114.08E.

H. *How do we evaluate non-malignant hematological disorders treated by allogeneic bone marrow or stem cell transplantation?* Allogeneic bone marrow or stem cell transplantation is performed for a variety of non-malignant hematological diseases, such as sickle cell disease and aplastic anemia. We will evaluate any non-malignant hematological disorder that is treated with allogeneic bone marrow or stem cell transplantation under 107.06, regardless of whether there is another listing that addresses that impairment. Under 107.06, we consider a child disabled until at least 12 months from the date of transplantation. Thereafter, for purposes of evaluating disability, we consider any residual impairment(s), such as complications arising from:

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

(2) Immunosuppressive therapy, such as frequent infections.

(3) Significant deterioration of other organ systems.

107.01 Category of Impairments, Hematological Disorders

107.02 Anemia

A. Sickle cell disease or one of its variants, with either 1, 2, or 3:

1. Documented painful (vaso-occlusive) crises requiring parenteral medication, occurring at least 3 times in a consecutive 6-month period (see 107.00E).

2. Hospitalization (for 24 hours or more) occurring at least 3 times in a consecutive 12-month period (see 107.00E), due to any of the following complications of sickle cell disease:

a. Hand/foot syndrome.

b. Chest syndrome.

c. Sequestration crisis.

d. Hyperhemolytic crisis.

e. Aplastic crisis.

f. Stroke.

g. Fever requiring treatment with parenteral antimicrobial medication.

3. Chronic anemia manifested by persistent hemoglobin of 7.0 gm/dl or less despite prescribed therapy (see 107.00F).

OR

B. Other hemolytic anemias (such as thalassemia) with chronic anemia manifested by persistent hemoglobin of 7.0 gm/dl or less despite prescribed therapy (see 107.00F).

OR

C. Aplastic anemia, with either 1 or 2:

1. Chronic anemia manifested by repeated hemoglobin of 7.0 gm/dl or less despite prescribed therapy (see 107.00F).

2. Documented treatment with parenteral antimicrobial medication occurring at least 3 times in a consecutive 12-month period (see 107.00E).

107.03 Disorders of Hemostasis

A. Chronic thrombocytopenia (due to any cause), with either 1 or 2:

1. Platelet counts repeatedly below 10,000/mm^3 despite prescribed therapy (see 107.00F).

2. Platelet counts repeatedly below 20,000/mm^3 and spontaneous bleeding despite prescribed therapy requiring red cell or platelet transfusions at least 3 times in a consecutive 12-month period (see 107.00E, 107.00F). Consider under a disability for 12 months from the date of the last transfusion. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

OR

B. Hemophilia with spontaneous bleeding despite prophylactic factor replacement, occurring at least 3 times in a consecutive 12-month period (see 107.00E).

OR

C. Other hypocoagulable states (such as von Willebrand's disease or thrombasthenia) with spontaneous bleeding requiring hospitalization (for 24 hours or more), occurring at least 3 times in a consecutive 12-month period (see 107.00E).

OR

D. Hypercoagulable states (deficiency of anti-coagulant proteins such as protein C, protein S, and antithrombin, or the presence of abnormal proteins such as Factor V Leiden) with documented thromboses occurring at least 3 times in a consecutive 12-month period (see 107.00E).

107.05 Chronic Granulocytopenia (Due to Any Cause), With Both A and B

A. Absolute neutrophil counts repeatedly below 500/mm^3 (see 107.00F).

AND

B. Documented treatment with parenteral antimicrobial medication occurring at least 3

times in a consecutive 12-month period (see 107.00E).

107.06 Non-malignant hematological diseases treated by allogeneic bone marrow or stem cell transplantation (see 107.00H)

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.

* * * * *

111.00 Neurological

* * * * *

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).

* * * * *

111.05 Benign Brain Tumors

Evaluate under the criteria for the resulting neurological impairment.

* * * * *

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 listing 114.08E to evaluate carcinoma of the cervix, Kaposi's sarcoma, lymphoma, and squamous cell carcinoma of the anus in children with 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?* Except for metastatic carcinoma to the brain or spinal cord (113.13C), 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.

(2) For operative procedures, including a biopsy or a needle aspiration, we 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 the child's 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, it will often happen within 6 months after it 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 the child's impairment(s) does not meet the criteria of any of these listings, we must also consider whether the child has an impairment(s) that satisfies the criteria of a listing in another body system.

(2) If a child has a medically determinable impairment(s) that does not meet a listing, we will determine whether the impairment(s) medically equals or, in the case of a claim for SSI payments, functionally equals the listings. (See §§ 404.1526, 416.926, and 416.926a.) When we decide whether a child receiving SSI payments continues to be disabled, we use the rules in § 416.994a.

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 the Malignant Neoplastic Diseases 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 the listings, or, as appropriate, functionally equals the listings.

H. *How long do we consider the child disabled?* (1) In some listings, we specify that the impairment will be considered disabling until a particular point in time (for example, at least 12 months from the date of diagnosis). We may consider the impairment to be disabling beyond this point when justified by the medical and other evidence.

(2) When a listing does not contain such a specification, we will find a child whose impairment(s) meets or medically equals a listing in this body system to be under a disability until at least 3 years after onset of complete remission. When the original tumor and any metastases have not been evident for at least 3 years after complete remission, the impairment(s) no longer meets or equals the criteria under this body system.

(3) Following the appropriate period, we will consider any residual impairment(s), including residuals of the malignancy or therapy (see 113.00G), in determining whether the child is disabled.

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

(1) *Inoperable:* Surgery was thought to be of no therapeutic value or the surgery could not be performed. Examples of when surgery cannot be performed include a tumor that is too large or 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. Determining 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:* 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) Medically reported 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 these impairments 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. We will consider the duration and effects of treatment when we determine disability (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 which is aggressive and clinically similar to acute myelogenous leukemia. We evaluate JCML under 113.06A.

(d) *Elevated white cell counts.* 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) *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.

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.* We consider a child who undergoes bone marrow or stem cell transplantation for any of these disorders 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.* We consider a child who undergoes bone marrow or stem cell transplantation for either of these disorders 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 113.28, regardless of whether there is another listing that addresses that impairment. The length of time we consider a child whose impairment is evaluated under 113.28 to be disabled depends on whether the child undergoes allogeneic or autologous transplantation.

(a) *Allogeneic bone marrow or stem cell transplantation.* We will consider a child who undergoes allogeneic transplantation (transplantation from an unrelated donor or a related donor other than an identical twin) disabled until at least 12 months from the date of transplantation.

(b) *Autologous bone marrow or stem cell transplantation.* We consider a child who undergoes autologous transplantation (transplantation of the child's own cells or cells from an identical twin (syngeneic transplantation)) 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 the child for transplantation.

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

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

(b) Immunosuppressant therapy, such as frequent infections.

(c) Significant deterioration of other organ systems.

113.01 Category of Impairments, Malignant Neoplastic Diseases.

113.04 Soft Tissue Sarcoma (Including Ewing's Sarcoma, Primitive Neuroectodermal Tumor (PNET))

A. Localized tumor with or without metastases. Consider under a disability until at least 12 months from the date of diagnosis. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

OR

B. Persistent or recurrent following initial antineoplastic therapy.

113.05 Lymphoma (Excluding T-Cell Lymphoblastic Lymphoma—113.06) (See 113.00K(1))

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 clinical 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 113.00K(2))

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.

113.10 Retinoblastoma

A. With extension beyond the orbit.

OR

B. Persistent or recurrent following initial antineoplastic therapy.

OR

C. With regional or distant metastases.

113.11 Osteogenic 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 osteogenic sarcoma. 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.

113.13 Nervous System (See 113.00K(3))

A. Central nervous system neoplasms (brain and spinal cord), including:

1. 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 sarcoma.

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

OR

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

1. Metastatic.

2. Progressive or recurrent following initial antineoplastic therapy.

OR

C. Metastatic carcinoma to brain or spinal cord (includes epidural metastases).

113.21 Kidneys and Adrenal Glands

A. Neuroblastoma, as described in 1 or 2:

1. With DNA index less than or equal to 1, amplified N-*myc* or unfavorable Shimada histology. 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.

2. For children age 1 or older with tumor crossing the midline, unilateral tumor with bilateral lymph node involvement, or disseminated tumor excluding disease confined to the skin, liver or bone marrow. 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.

OR

B. Wilms' tumor persistent or recurrent following initial antineoplastic therapy.

113.25 Testicles—Tumor With Metastatic Disease Progressive or Recurrent Following Initial Chemotherapy

113.26 Germ Cell Tumors—Gonadal or Extragonadal

Persistent or recurrent following initial antineoplastic therapy.

113.28 Malignant Neoplastic Diseases Treated by Bone Marrow or Stem Cell Transplantation (See 113.00L.)

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 the transplantation. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

* * * * *

114.08 Human Immunodeficiency Virus (HIV) Infection

* * * * *

G. Hematologic abnormalities:

1. Anemia, as described under the criteria in 107.02A.3; or

2. Granulocytopenia, as described under the criteria in 107.05; or

3. Thromobocytopenia, as described under the criteria in 107.03A.

* * * * *

[FR Doc. 01–29224 Filed 11–26–01; 8:45 am]

BILLING CODE 4191–02–P