

*Note: This side-by-side chart was produced by SSA as part of its training materials following the final changes to the Immune System Disorders listings published at 73 Fed. Reg. 14570 (Mar. 18, 2008). The changes were effective June 16, 2008.*

The following is a side-by-side chart comparing the prior adult immune system listings (left side) with the new adult immune system disorders listings (right side). We have copied the text of the new listings on the right side. However, on the left side we have cut and pasted the introductory text of the prior listings beside the introductory text of the new listings that it parallels in meaning. The introductory text in the prior listings has many paragraphs that do not have paragraph headings or numbers. Therefore, to assist the reader, we identify paragraphs without a designation in the current listings by placing its section letter and the number of its numerical order in that section in parenthesis at the beginning of the introductory text. In some cases, we have also identified sentences from a paragraph by their numerical order when we compare only part of the introductory text from a prior paragraph with the introductory text in a new paragraph.

<b>14.00 IMMUNE SYSTEM (Adult Prior)</b>	<b>14.00 IMMUNE SYSTEM DISORDERS (Adult Final)</b>
<p><b>A.</b> Listed disorders include impairments involving deficiency of one or more components of the immune system (i.e., antibody-producing B cells; a number of different types of cells associated with cell-mediated immunity including T-lymphocytes, macrophages and monocytes; and components of the complement system).</p> <p><b>(B. ¶6, sentence 1)</b> These disorders may preclude performance of any gainful activity by reason of serious loss of function because of disease affecting a single organ or body system, or lesser degrees of functional loss because of disease affecting two or more organs/body systems associated with significant constitutional symptoms and signs of severe fatigue, fever, malaise, weight loss, and joint pain and stiffness. (14.00B, §6, sentence 1)</p>	<p><i>A. What disorders do we evaluate under the immune system disorders listings?</i></p> <p><i>1. We evaluate immune system disorders that cause dysfunction in one or more components of your immune system.</i></p> <p><i>a. The dysfunction may be due to problems in antibody production, impaired cell-mediated immunity, a combined type of antibody/cellular deficiency, impaired phagocytosis, or complement deficiency.</i></p> <p><i>b. Immune system disorders may result in recurrent and unusual infections, or inflammation and dysfunction of the body’s own tissues. Immune system disorders can cause a deficit in a single organ or body system that results in extreme (that is, very serious) loss of function. They can also cause lesser degrees of limitations in two or more organs or body systems, and when associated with symptoms or signs, such as severe fatigue, fever, malaise, diffuse musculoskeletal pain, or involuntary</i></p>

<p><b>B.</b> Dysregulation of the immune system may result in the development of a connective tissue disorder. Connective tissue disorders include several chronic multisystem disorders that differ in their clinical manifestation, course, and outcome. They generally evolve and persist for months or years, may result in loss of functional abilities, and may require long-term, repeated evaluation and management.</p> <p><b>D.</b> Human immunodeficiency virus (HIV) infection.</p> <p><b>D.1.</b> HIV infection is caused by a specific retrovirus and may be characterized by susceptibility to one or more opportunistic diseases, cancers, or other conditions, as described in 14.08. Any individual with HIV infection, including one with a diagnosis of acquired immunodeficiency syndrome (AIDS), may be found disabled under this listing if his or her impairment meets any of the criteria in 14.08 or is of equivalent severity to any impairment in 14.08.</p>	<p>weight loss, can also result in extreme limitation.</p> <p>c. We organize the discussions of immune system disorders in three categories: Autoimmune disorders; Immune deficiency disorders, excluding human immunodeficiency virus (HIV) infection; and HIV infection.</p> <p>2. <i>Autoimmune disorders (14.00D).</i> Autoimmune disorders are caused by dysfunctional immune responses directed against the body's own tissues, resulting in chronic, multisystem impairments that differ in clinical manifestations, course, and outcome. They are sometimes referred to as rheumatic diseases, connective tissue disorders, or collagen vascular disorders. Some of the features of autoimmune disorders in adults differ from the features of the same disorders in children.</p> <p>3. <i>Immune deficiency disorders, excluding HIV infection (14.00E).</i> Immune deficiency disorders are characterized by recurrent or unusual infections that respond poorly to treatment, and are often associated with complications affecting other parts of the body. Immune deficiency disorders are classified as either <i>primary</i> (congenital) or <i>acquired</i>. Individuals with immune deficiency disorders also have an increased risk of malignancies and of having autoimmune disorders.</p> <p>4. <i>Human immunodeficiency virus (HIV) infection (14.00F).</i> HIV infection may be characterized by increased susceptibility to opportunistic infections, cancers, or other conditions, as described in 14.08.</p>
<p><b>(B. ¶2, sentence 1)</b> The documentation needed to establish the existence of a connective tissue disorder is medical history, physical examination, selected</p>	<p>B. <i>What information do we need to show that you have an immune system disorder?</i> Generally, we need your medical history, a report(s) of a physical</p>

<p>laboratory studies, appropriate medically acceptable imaging, and, in some instances, tissue biopsy.</p> <p><b>(B. ¶3)</b> A longitudinal clinical record of at least 3 months demonstrating active disease despite prescribed treatment during this period with the expectation that the disease will remain active for 12 months is necessary for assessment of severity and duration of impairment.</p>	<p>examination, a report(s) of laboratory findings, and in some instances, appropriate medically acceptable imaging or tissue biopsy reports to show that you have an immune system disorder. Therefore, we will make every reasonable effort to obtain your medical history, medical findings, and results of laboratory tests. We explain the information we need in more detail in the sections below.</p>
<p><b>D2. Definitions.</b> In 14.08, the terms "resistant to treatment," "recurrent," and "disseminated" have the same general meaning as used by the medical community. The precise meaning of any of these terms will depend upon the specific disease or condition in question, the body system affected, the usual course of the disorder and its treatment, and the other circumstances of the case.</p> <p><b>(B. ¶3, sentence 2-5)</b> Medically acceptable imaging includes, but is not limited to, x-ray imaging, computerized axial tomography (CAT scan) or magnetic resonance imaging (MRI), with or without contrast material, myelography, and radionuclear bone scans. "Appropriate" means that the technique used is the proper one to support the evaluation and diagnosis of the impairment. However, the Social Security Administration will not purchase diagnostic tests or procedures that may involve significant risk, such as biopsies or angiograms. Generally, the existing medical evidence will contain this information.</p>	<p><i>C. Definitions</i></p> <p>1. <i>Appropriate medically acceptable imaging</i> includes, but is not limited to, angiography, x-ray imaging, computerized axial tomography (CAT scan) or magnetic resonance imaging (MRI), with or without contrast material, myelography, and radionuclear bone scans. "Appropriate" means that the technique used is the proper one to support the evaluation and diagnosis of the impairment.</p> <p>2. <i>Constitutional symptoms or signs</i>, as used in these listings, means severe fatigue, fever, malaise, or involuntary weight loss. Severe fatigue means a frequent sense of exhaustion that results in significantly reduced physical activity or mental function. Malaise means frequent feelings of illness, bodily discomfort, or lack of well-being that result</p>

**D.2.** "Disseminated" means that a condition is spread widely over a considerable area or body system(s). The type and extent of the spread will depend on the specific disease.

**B.6.b.** The terms *inability to ambulate effectively and inability to perform fine and gross movements effectively* in 14.09A have the same meaning as in 1.00B2b and 1.00B2c and must have lasted, or be expected to last, for at least 12 months.

**B.6.a.** In 14.09A, the term *major joints* refers to the major peripheral joints, which are the hip, knee, shoulder, elbow, wrist-hand, and ankle-foot, as opposed to other peripheral joints (e.g., the joints of the hand or forefoot) or axial joints (i.e., the joints of the spine.) The wrist and hand are considered together as one major joint, as are the ankle and foot. Since only the ankle joint, which consists of the juncture of the bones of the lower leg (tibia and fibula) with the hindfoot (tarsal bones), but not the forefoot, is crucial to weight bearing, the ankle and foot are considered separately in evaluating weight bearing.

in significantly reduced physical activity or mental function.

3. *Disseminated* means that a condition is spread over a considerable area. The type and extent of the spread will depend on your specific disease.

4. *Dysfunction* means that one or more of the body regulatory mechanisms are impaired, causing either an excess or deficiency of immunocompetent cells or their products.

5. *Extra-articular* means "other than the joints"; for example, an organ(s) such as the heart, lungs, kidneys, or skin.

6. *Inability to ambulate effectively* has the same meaning as in 1.00B2b.

7. *Inability to perform fine and gross movements effectively* has the same meaning as in 1.00B2c.

8. *Major peripheral joints* has the same meaning as in 1.00F.

9. *Persistent* means that a sign(s) or symptom(s) has continued over time. The precise meaning will depend on the specific immune system disorder, the usual course of the disorder, and the other circumstances of your clinical course.

10. *Recurrent* means that a condition that previously responded adequately to an appropriate course of

<p><b>(D.2. ¶3)</b> "Recurrent" means that a condition that responded adequately to an appropriate course of treatment has returned after a period of remission or regression. The extent of response (or remission) and the time periods involved will depend on the facts of the particular case.</p> <p><b>(D.2. ¶2)</b> "Resistant to treatment" means that a condition did not respond adequately to an appropriate course of treatment. Whether a response is adequate, or a course of treatment appropriate, will depend on the facts of the particular case.</p> <p><b>(B. ¶6, sentence 2)</b> We use the term "severe" in these listings to describe medical severity; the term does not have the same meaning as it does when we use it in connection with a finding at the second step of the sequential evaluation processes in §§ 404.1520, 416.920, and 416.924.</p>	<p>treatment returns after a period of remission or regression. The precise meaning, such as the extent of response or remission and the time periods involved, will depend on the specific disease or condition you have, the body system affected, the usual course of the disorder and its treatment, and the other facts of your particular case.</p> <p>11. <i>Resistant to treatment</i> means that a condition did not respond adequately to an appropriate course of treatment. Whether a response is adequate or a course of treatment is appropriate will depend on the specific disease or condition you have, the body system affected, the usual course of the disorder and its treatment, and the other facts of your particular case.</p> <p>12. <i>Severe</i> means medical severity as used by the medical community. The term does not have the same meaning as it does when we use it in connection with a finding at the second step of the sequential evaluation processes in §§404.1520, 416.920, and 416.924.</p>
<p><b>(B. ¶4)</b> To permit appropriate application of a listing, the specific diagnostic features that should be documented in the clinical record for each of the disorders are summarized for systemic lupus erythematosus (SLE), systemic vasculitis, systemic sclerosis and scleroderma, polymyositis or dermatomyositis, undifferentiated connective tissue disorders, and the inflammatory arthritides.</p> <p><b>B.1. Systemic lupus erythematosus (14.02)</b>—This disease is characterized clinically by constitutional symptoms and signs (e.g., fever, fatigability, malaise, weight loss), multisystem involvement and, frequently, anemia, leukopenia, or thrombocytopenia. Immunologically, an</p>	<p><i>D. How do we document and evaluate the listed autoimmune disorders?</i></p> <p>1. <i>Systemic lupus erythematosus (14.02).</i></p> <p>a. <i>General.</i> Systemic lupus erythematosus (SLE) is a chronic inflammatory disease that can affect any organ or body system. It is frequently, but not always, accompanied by constitutional symptoms or signs (severe fatigue, fever, malaise, involuntary weight loss). Major</p>

array of circulating serum auto-antibodies can occur, but are highly variable in pattern. Generally the medical evidence will show that patients with this disease will fulfill The 1982 Revised Criteria for the Classification of Systemic Lupus Erythematosus of the American College of Rheumatology. (Tan, E.M., et al., *Arthritis Rheum.* 25: 11271-1277, 1982).

**B.2. (sentences 1-4)** Systemic vasculitis (14.03)—This disease occurs acutely in association with adverse drug reactions, certain chronic infections and, occasionally, malignancies. More often it is idiopathic and chronic. There are several clinical patterns, including classical polyarteritis nodosa, aortic arch arteritis, giant cell arteritis, Wegener's granulomatosis, and vasculitis associated with other connective tissue disorders (e.g., rheumatoid arthritis, SLE, Sjögren's syndrome, cryoglobulinemia). Cutaneous vasculitis may or may not be associated with systemic involvement and the patterns of vascular and ischemic involvement are highly variable.

**B.2. (sentences 5 &6)** The diagnosis is

organ or body system involvement can include: Respiratory (pleuritis, pneumonitis), cardiovascular (endocarditis, myocarditis, pericarditis, vasculitis), renal (glomerulonephritis), hematologic (anemia, leukopenia, thrombocytopenia), skin (photosensitivity), neurologic (seizures), mental (anxiety, fluctuating cognition (“lupus fog”), mood disorders, organic brain syndrome, psychosis), or immune system disorders (inflammatory arthritis). Immunologically, there is an array of circulating serum auto-antibodies and pro- and anti-coagulant proteins that may occur in a highly variable pattern.

b. *Documentation of SLE.*

Generally, but not always, the medical evidence will show that your SLE satisfies the criteria in the current “Criteria for the Classification of Systemic Lupus Erythematosus” by the American College of Rheumatology found in the most recent edition of the *Primer on the Rheumatic Diseases* published by the Arthritis Foundation.

2. *Systemic vasculitis (14.03).*

a. *General.*

(i) Vasculitis is an inflammation of blood vessels. It may occur acutely in association with adverse drug reactions, certain chronic infections, and occasionally, malignancies. More often, it is chronic and the cause is unknown. Symptoms vary depending on which blood vessels are involved. Systemic vasculitis may also be associated with other autoimmune disorders; for example, SLE or dermatomyositis.

(ii) There are several clinical patterns, including but not limited to polyarteritis nodosa, Takayasu’s arteritis

confirmed by angiography or tissue biopsy when the disease is suspected clinically. Most patients who are stated to have this disease will have the results of the confirmatory angiogram or biopsy in their medical records.

**B.3. (sentences 1-3)** Systemic sclerosis and scleroderma (14.04)—These disorders constitute a spectrum of disease in which thickening of the skin is the clinical hallmark. Raynaud's phenomena, often severe and progressive, are especially frequent and may be the peripheral manifestation of a generalized vasospastic abnormality in the heart, lungs, and kidneys. The CREST syndrome (calcinosis, Raynaud's phenomena, esophageal dysmotility, sclerodactyly, telangiectasia) is a variant that may slowly progress to the generalized process, systemic sclerosis, over years.

**B.3. (sentences 4 & 5)** In addition to skin and blood vessels, the major organ/body system involvement includes the gastrointestinal tract, lungs, heart, kidneys, and muscle. Although arthritis can occur, joint dysfunction results primarily from soft tissue/cutaneous thickening, fibrosis, and contractures. (14.00.B.3, sentence 4)

(aortic arch arteritis), giant cell arteritis (temporal arteritis), and Wegener's granulomatosis.

b. *Documentation of systemic vasculitis.* Angiography or tissue biopsy confirms a diagnosis of systemic vasculitis when the disease is suspected clinically. When you have had angiography or tissue biopsy for systemic vasculitis, we will make every reasonable effort to obtain reports of the results of that procedure. However, we will not purchase angiography or tissue biopsy.

3. *Systemic sclerosis (scleroderma) (14.04).*

a. *General.* Systemic sclerosis (scleroderma) constitutes a spectrum of disease in which thickening of the skin is the clinical hallmark. Raynaud's phenomenon, often medically severe and progressive, is present frequently and may be the peripheral manifestation of a vasospastic abnormality in the heart, lungs, and kidneys. The CREST syndrome (calcinosis, Raynaud's phenomenon, esophageal dysmotility, sclerodactyly, and telangiectasia) is a variant that may slowly progress over years to the generalized process, systemic sclerosis.

b. *Diffuse cutaneous systemic sclerosis.* In diffuse cutaneous systemic sclerosis (also known as diffuse scleroderma), major organ or systemic involvement can include the gastrointestinal tract, lungs, heart, kidneys, and muscle in addition to skin or blood vessels. Although arthritis can occur, joint dysfunction results primarily from soft tissue/cutaneous thickening, fibrosis, and contractures.

c. *Localized scleroderma (linear*

<p><b>B.4. (sentences 1-3)</b> Polymyositis or dermatomyositis (14.05)—This disorder is primarily an inflammatory process in striated muscle, which can occur alone or in association with other connective tissue disorders or malignancy. Weakness and, less frequently, pain and tenderness of the proximal limb-girdle musculature are the cardinal manifestations. Involvement of the cervical muscles, the cricopharyngeals, the intercostals, and diaphragm may occur in those with listing-level disease.</p> <p><b>B.4. (sentence 7)</b> The diagnosis is supported by elevated serum muscle</p>	<p><i>scleroderma and morphea</i>).</p> <p>(i) Localized scleroderma (linear scleroderma and morphea) is more common in children than in adults. However, this type of scleroderma can persist into adulthood. To assess the severity of the impairment, we need a description of the extent of involvement of linear scleroderma and the location of the lesions. For example, linear scleroderma involving the arm but not crossing any joints is not as functionally limiting as sclerodactyly (scleroderma localized to the fingers). Linear scleroderma of a lower extremity involving skin thickening and atrophy of underlying muscle or bone can result in contractures and leg length discrepancy. In such cases, we may evaluate your impairment under the musculoskeletal listings (1.00).</p> <p>(ii) When there is isolated morphea of the face causing facial disfigurement from unilateral hypoplasia of the mandible, maxilla, zygoma, or orbit, adjudication may be more appropriate under the criteria in the affected body system, such as special senses and speech (2.00) or mental disorders (12.00).</p> <p>(iii) Chronic variants of these syndromes include disseminated morphea, Shulman’s disease (diffuse fasciitis with eosinophilia), and eosinophilia-myalgia syndrome (often associated with toxins such as toxic oil or contaminated tryptophan), all of which can impose medically severe musculoskeletal dysfunction and may also lead to restrictive pulmonary disease. We evaluate these variants of the disease under the criteria in the musculoskeletal listings (1.00) or respiratory system listings (3.00).</p> <p>d. <i>Documentation of systemic</i></p>
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enzymes (creatine phosphokinase (CPK), aminotransferases, aldolase), characteristic abnormalities on electromyography, and myositis on muscle biopsy.

**B.4. (sentences 4 & 5)** Weakness of the pelvic girdle, as contemplated in Listing 14.05A, may result in significant difficulty climbing stairs or rising from a chair without use of the arms. Proximal limb weakness in the upper extremities may result in inability to lift objects, and interference with dressing and combing hair. (14.00.B.4, sentence 2)

**B.4 (sentence 6)** Weakness of the anterior neck flexors may impair the ability to lift the head from the pillow in bed.

**B.5.** Undifferentiated connective tissue disorder (14.06)—This listing includes syndromes with clinical and immunologic features of several connective tissue disorders, but that do not satisfy the criteria for any of the disorders described; for instance, the individual may have clinical features of systemic lupus erythematosus and systemic vasculitis and the serologic

*sclerosis (scleroderma).* Documentation involves differentiating the clinical features of systemic sclerosis (scleroderma) from other autoimmune disorders. However, there may be an overlap.

*4. Polymyositis and dermatomyositis (14.05).*

a. *General.* Polymyositis and dermatomyositis are related disorders that are characterized by an inflammatory process in striated muscle, occurring alone or in association with other autoimmune disorders or malignancy. The most common manifestations are symmetric weakness, and less frequently, pain and tenderness of the proximal limb-girdle (shoulder or pelvic) musculature. There may also be involvement of the cervical, cricopharyngeal, esophageal, intercostal, and diaphragmatic muscles.

b. *Documentation of polymyositis and dermatomyositis.* Generally, but not always, polymyositis is associated with elevated serum muscle enzymes (creatine phosphokinase (CPK), aminotransferases, and aldolase), and characteristic abnormalities on electromyography and muscle biopsy. In dermatomyositis there are characteristic skin findings in addition to the findings of polymyositis. When you have had electromyography or muscle biopsy for polymyositis or dermatomyositis, we will make every reasonable effort to obtain reports of the results of that procedure. However, we will not purchase electromyography or muscle biopsy.

c. *Additional information about how we evaluate polymyositis and dermatomyositis under the listings.*

(i) Weakness of your pelvic girdle

findings of rheumatoid arthritis. It also includes overlap syndromes with clinical features of more than one established connective tissue disorder. For example, the individual may have features of both rheumatoid arthritis and scleroderma. The correct designation of this disorder is important for assessment of prognosis.

**B.6. (sentence 1)** *Inflammatory arthritis (14.09)* includes a vast array of disorders that differ in cause, course, and outcome.

**B.6. (sentence 4)** Clinically, inflammation of major joints may be the dominant problem causing difficulties with ambulation or fine and gross movements, or the arthritis may involve other joints or cause less restriction of ambulation or other movements but be complicated by extra-articular features that cumulatively result in serious functional deficit.

**B.6. (sentence 2)** For example, inflammatory spondyloarthropathies include ankylosing spondylitis, Reiter's syndrome and other reactive arthropathies, psoriatic arthropathy, Behçet's disease, and Whipple's disease, as well as undifferentiated spondylitis.

muscles that results in your inability to rise independently from a squatting or sitting position or to climb stairs may be an indication that you are unable to ambulate effectively. Weakness of your shoulder girdle muscles may result in your inability to perform lifting, carrying, and reaching overhead, and also may seriously affect your ability to perform activities requiring fine movements. We evaluate these limitations under 14.05A.

(ii) We use the malignant neoplastic diseases listings (13.00ff) to evaluate malignancies associated with polymyositis or dermatomyositis. We evaluate the involvement of other organs/body systems under the criteria for the listings in the affected body system.

*5. Undifferentiated and mixed connective tissue disease (14.06).*

a. *General.* This listing includes syndromes with clinical and immunologic features of several autoimmune disorders, but which do not satisfy the criteria for any of the specific disorders described. For example, you may have clinical features of SLE and systemic vasculitis, and the serologic (blood test) findings of rheumatoid arthritis.

b. *Documentation of undifferentiated and mixed connective tissue disease.* Undifferentiated connective tissue disease is diagnosed when clinical features and serologic (blood test) findings, such as rheumatoid factor or antinuclear antibody (consistent with an autoimmune disorder) are present but do not satisfy the criteria for a specific disease. Mixed connective tissue disease (MCTD) is

**B.6. (sentence 3)** Inflammatory arthritis of peripheral joints likewise comprises many disorders, including rheumatoid arthritis, Sjögren's syndrome, psoriatic arthritis, crystal deposition disorders, and Lyme disease.

**B.6.c.** Inability to ambulate effectively is implicit in 14.09B. Even though individuals who demonstrate the findings of 14.09B will not ordinarily require bilateral upper limb assistance, the required ankylosis of the cervical or dorsolumbar spine will result in an extreme loss of the ability to see ahead, above, and to the side.

**B.6.d. (sentence 1-3)** As in 14.02 through 14.06, extra-articular features of an inflammatory arthritis may satisfy the criteria for a listing in an involved extra-articular body system. Such impairments

diagnosed when clinical features and serologic findings of two or more autoimmune diseases overlap.

*6. Inflammatory arthritis (14.09).*

a. *General.* The spectrum of inflammatory arthritis includes a vast array of disorders that differ in cause, course, and outcome. Clinically, inflammation of major peripheral joints may be the dominant manifestation causing difficulties with ambulation or fine and gross movements; there may be joint pain, swelling, and tenderness. The arthritis may affect other joints, or cause less limitation in ambulation or the performance of fine and gross movements. However, in combination with extra-articular features, including constitutional symptoms or signs (severe fatigue, fever, malaise, involuntary weight loss), inflammatory arthritis may result in an extreme limitation.

b. *Inflammatory arthritis involving the axial spine (spondyloarthropathy).* In adults, inflammatory arthritis involving the axial spine may be associated with disorders such as:

- (i) Reiter's syndrome;
- (ii) Ankylosing spondylitis;
- (iii) Psoriatic arthritis;
- (iv) Whipple's disease;
- (v) Behçet's disease; and
- (vi) Inflammatory bowel disease.

c. *Inflammatory arthritis involving the peripheral joints.* In adults, inflammatory arthritis involving peripheral joints may be associated with disorders such as:

- (i) Rheumatoid arthritis;
- (ii) Sjögren's syndrome;
- (iii) Psoriatic arthritis;

may be found to meet a criterion of 14.09C. Extra-articular impairments of lesser severity should be evaluated under 14.09D and 14.09E

**B.6.d. (sentence 4).** Commonly occurring extra-articular impairments include keratoconjunctivitis sicca, uveitis, iridocyclitis, pleuritis, pulmonary fibrosis or nodules, restrictive lung disease, pericarditis, myocarditis, cardiac arrhythmias, aortic valve insufficiency, coronary arteritis, Raynaud's phenomena, systemic vasculitis, amyloidosis of the kidney, chronic anemia, thrombocytopenia, hypersplenism with compromised immune competence (Felty's syndrome), peripheral neuropathy, radiculopathy, spinal cord or cauda equina compression with sensory and motor loss, and heel enthesopathy with functionally limiting pain.

**B.6. (sentence 5)** When persistent deformity without ongoing inflammation is the dominant feature of the impairment, it should be evaluated under 1.02, or, if there has been surgical reconstruction, 1.03.

**e.** The fact that an individual is dependent on steroids, or any other drug, for the control of inflammatory arthritis is, in and of itself, insufficient to find disability. Advances in the treatment of inflammatory connective tissue disease and in the administration of steroids for its treatment have corrected some of the previously disabling consequences of continuous steroid use. Therefore, each case must be evaluated on its own merits, taking into consideration the severity of the underlying

- (iv) Crystal deposition disorders (gout and pseudogout);
- (v) Lyme disease; and
- (vi) Inflammatory bowel disease.

**d. Documentation of inflammatory arthritis.** Generally, but not always, the diagnosis of inflammatory arthritis is based on the clinical features and serologic findings described in the most recent edition of the *Primer on the Rheumatic Diseases* published by the Arthritis Foundation.

**e. How we evaluate inflammatory arthritis under the listings.**

(i) Listing-level severity in 14.09A and 14.09C1 is shown by an impairment that results in an "extreme" (very serious) limitation. In 14.09A, the criterion is satisfied with persistent inflammation or deformity in one major peripheral weight-bearing joint resulting in the inability to ambulate effectively (as defined in 14.00C6) or one major peripheral joint in each upper extremity resulting in the inability to perform fine and gross movements effectively (as defined in 14.00C7). In 14.09C1, if you have the required ankylosis (fixation) of your cervical or dorsolumbar spine, we will find that you have an extreme limitation in your ability to see in front of you, above you, and to the side. Therefore, inability to ambulate effectively is implicit in 14.09C1, even though you might not require bilateral upper limb assistance.

(ii) Listing-level severity is shown in 14.09B, 14.09C2, and 14.09D by inflammatory arthritis that involves various combinations of complications of one or more major peripheral joints or other joints, such as inflammation or deformity, extra-articular features, repeated manifestations,

<p>impairment and any adverse effects of treatment.</p>	<p>and constitutional symptoms or signs. Extra-articular impairments may also meet listings in other body systems.</p> <p>(iii) Extra-articular features of inflammatory arthritis may involve any body system; for example: Musculoskeletal (heel enthesopathy), ophthalmologic (iridocyclitis, keratoconjunctivitis sicca, uveitis), pulmonary (pleuritis, pulmonary fibrosis or nodules, restrictive lung disease), cardiovascular (aortic valve insufficiency, arrhythmias, coronary arteritis, myocarditis, pericarditis, Raynaud's phenomenon, systemic vasculitis), renal (amyloidosis of the kidney), hematologic (chronic anemia, thrombocytopenia), neurologic (peripheral neuropathy, radiculopathy, spinal cord or cauda equina compression with sensory and motor loss), mental (cognitive dysfunction, poor memory), and immune system (Felty's syndrome (hypersplenism with compromised immune competence)).</p> <p>(iv) If both inflammation and chronic deformities are present, we evaluate your impairment under the criteria of any appropriate listing.</p>
	<p><i>7. Sjögren's syndrome (14.10).</i></p> <p><i>a. General.</i></p> <p>(i) Sjögren's syndrome is an immune-mediated disorder of the exocrine</p>

	<p>glands. Involvement of the lacrimal and salivary glands is the hallmark feature, resulting in symptoms of dry eyes and dry mouth, and possible complications, such as corneal damage, blepharitis (eyelid inflammation), dysphagia (difficulty in swallowing), dental caries, and the inability to speak for extended periods of time. Involvement of the exocrine glands of the upper airways may result in persistent dry cough.</p> <p>(ii) Many other organ systems may be involved, including musculoskeletal (arthritis, myositis), respiratory (interstitial fibrosis), gastrointestinal (dysmotility, dysphagia, involuntary weight loss), genitourinary (interstitial cystitis, renal tubular acidosis), skin (purpura, vasculitis), neurologic (central nervous system disorders, cranial and peripheral neuropathies), mental (cognitive dysfunction, poor memory), and neoplastic (lymphoma). Severe fatigue and malaise are frequently reported. Sjögren’s syndrome may be associated with other autoimmune disorders (for example, rheumatoid arthritis or SLE); usually the clinical features of the associated disorder predominate.</p> <p>b. <i>Documentation of Sjögren’s syndrome.</i> If you have Sjögren’s syndrome, the medical evidence will generally, but not always, show that your disease satisfies the criteria in the current “Criteria for the Classification of Sjögren’s Syndrome” by the American College of Rheumatology found in the most recent edition of the <i>Primer on the Rheumatic Diseases</i> published by the Arthritis Foundation.</p>
	<p>E. <i>How do we document and evaluate immune deficiency disorders, excluding HIV infection?</i></p> <p>1. <i>General.</i></p>

a. Immune deficiency disorders can be classified as:

(i) *Primary* (congenital); for example, X-linked agammaglobulinemia, thymic hypoplasia (DiGeorge syndrome), severe combined immunodeficiency (SCID), chronic granulomatous disease (CGD), C1 esterase inhibitor deficiency.

(ii) *Acquired*; for example, medication-related.

b. Primary immune deficiency disorders are seen mainly in children. However, recent advances in the treatment of these disorders have allowed many affected children to survive well into adulthood. Occasionally, these disorders are first diagnosed in adolescence or adulthood.

2. *Documentation of immune deficiency disorders.* The medical evidence must include documentation of the specific type of immune deficiency. Documentation may be by laboratory evidence or by other generally acceptable methods consistent with the prevailing state of medical knowledge and clinical practice.

3. *Immune deficiency disorders treated by stem cell transplantation.*

a. *Evaluation in the first 12 months.* If you undergo stem cell transplantation for your immune deficiency disorder, we will consider you disabled until at least 12 months from the date of the transplant.

b. *Evaluation after the 12-month period has elapsed.* After the 12-month period has elapsed, we will consider any residuals of your immune deficiency disorder as well as any residual

	<p>impairment(s) resulting from the treatment, such as complications arising from:</p> <ul style="list-style-type: none"> <li>(i) Graft-versus-host (GVH) disease.</li> <li>(ii) Immunosuppressant therapy, such as frequent infections.</li> <li>(iii) Significant deterioration of other organ systems.</li> </ul> <p>4. <i>Medication-induced immune suppression.</i> Medication effects can result in varying degrees of immune suppression, but most resolve when the medication is ceased. However, if you are prescribed medication for long-term immune suppression, such as after an organ transplant, we will evaluate:</p> <ul style="list-style-type: none"> <li>a. The frequency and severity of infections.</li> <li>b. Residuals from the organ transplant itself, after the 12-month period has elapsed.</li> <li>c. Significant deterioration of other organ systems.</li> </ul>
<p><b>D. Human immunodeficiency virus (HIV) infection.</b></p> <p><b>D.3. Documentation of HIV infection.</b> The medical evidence must include documentation of HIV infection. Documentation may be by laboratory evidence or by other generally acceptable methods consistent with the prevailing state of medical knowledge and clinical practice.</p>	<p><b>F. How do we document and evaluate human immunodeficiency virus (HIV) infection?</b> Any individual with HIV infection, including one with a diagnosis of acquired immune deficiency syndrome (AIDS), may be found disabled under 14.08 if his or her impairment meets the criteria in that listing or is medically equivalent to the criteria in that listing.</p> <p>1. <i>Documentation of HIV infection.</i> The medical evidence must include documentation of HIV infection. Documentation may be by laboratory evidence or by other generally acceptable methods consistent with the prevailing state of medical knowledge and clinical practice. When you have had laboratory testing for HIV infection, we will make every reasonable effort to obtain reports of the</p>

<p><b>D.3.a.</b> Documentation of HIV infection by definitive diagnosis. A definitive diagnosis of HIV infection is documented by one or more of the following laboratory tests:</p> <p><b>D.3.a.i.</b> A serum specimen that contains HIV antibodies. HIV antibodies are usually detected by a screening test. The most commonly used screening test is the ELISA. Although this test is highly sensitive, it may yield false positive results. Therefore, positive results from an ELISA must be confirmed by a more definitive test (e.g., Western blot, immunofluorescence assay).</p> <p><b>D.3.a.ii.</b> A specimen that contains HIV antigen (e.g., serum specimen, lymphocyte culture, or cerebrospinal fluid (CSF) specimen).</p> <p><b>D.3.a.iii. (¶1)</b> Other test(s) that are highly specific for detection of HIV (e.g., polymerase chain reaction (PCR)), or that are acceptable methods of detection consistent with the prevailing state of medical knowledge.</p> <p><b>D.3.a.iii. (¶2)</b> When laboratory testing for HIV infection has been performed, every reasonable effort must be made to obtain reports of the results of that testing.</p> <p><b>D.3.b.</b> Other acceptable documentation of HIV infection.</p>	<p>results of that testing. However, we will not purchase laboratory testing to establish whether you have HIV infection.</p> <p><i>a. Definitive documentation of HIV infection.</i> A definitive diagnosis of HIV infection is documented by one or more of the following laboratory tests:</p> <p>(i) HIV antibody tests. HIV antibodies are usually first detected by an ELISA screening test performed on serum. Because the ELISA can yield false positive results, confirmation is required using a more definitive test, such as a Western blot or an immunofluorescence assay.</p> <p>(ii) Positive “viral load” (VL) tests. These tests are normally used to quantitate the amount of the virus present but also document HIV infection. Such tests include the quantitative plasma HIV RNA, quantitative plasma HIV branched DNA, and reverse transcriptase-polymerase chain reaction (RT-PCR).</p> <p>(iii) HIV DNA detection by polymerase chain reaction (PCR).</p> <p>(iv) A specimen that contains HIV antigen (for example, serum specimen, lymphocyte culture, or cerebrospinal fluid).</p> <p>(v) A positive viral culture for HIV from peripheral blood mononuclear cells (PBMC).</p> <p>(vi) Other tests that are highly specific for detection of HIV and that are consistent with the prevailing state of medical knowledge.</p>
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**D.3.b ¶1** (HIV infection may also be documented without the definitive laboratory evidence described in paragraph a, provided that such documentation is consistent with the prevailing state of medical knowledge and clinical practice and is consistent with the other evidence. If no definitive laboratory evidence is available, HIV infection may be documented by the medical history, clinical and laboratory findings, and diagnosis(es) indicated in the medical evidence. For example, a diagnosis of HIV infection will be accepted without definitive laboratory evidence if the individual has an opportunistic disease (e.g., toxoplasmosis of the brain, pneumocystis carinii pneumonia (PCP)) predictive of a defect in cell-mediated immunity, and there is no other known cause of diminished resistance to that disease (e.g., long-term steroid treatment, lymphoma). In such cases, every reasonable effort must be made to obtain full details of the history, medical findings, and results of testing.

**(D.3.a.iii ¶3)** Individuals who have HIV infection or other disorders of the immune system may undergo tests to determine T-helper lymphocyte (CD4) counts. The extent of immune depression correlates with the level or rate of decline of the CD4 count. In general, when the CD4 count is 200/mm<sup>3</sup> or less (14 percent or less), the susceptibility to opportunistic disease is considerably increased. However, a reduced CD4 count alone does not establish a definitive diagnosis of HIV infection, or document the severity or functional effects of HIV infection.

**(D.4.a ¶2)** Although a reduced CD4 lymphocyte count may show that there is an increased susceptibility to opportunistic infections and diseases (see 14.001) 3a, above), that alone does not establish the presence, severity, or functional effects of a

b. *Other acceptable documentation of HIV infection.* We may also document HIV infection without the definitive laboratory evidence described in 14.00F1a, provided that such documentation is consistent with the prevailing state of medical knowledge and clinical practice and is consistent with the other evidence in your case record. If no definitive laboratory evidence is available, we may document HIV infection by the medical history, clinical and laboratory findings, and diagnosis(es) indicated in the medical evidence. For example, we will accept a diagnosis of HIV infection without definitive laboratory evidence of the HIV infection if you have an opportunistic disease that is predictive of a defect in cell-mediated immunity (for example, toxoplasmosis of the brain, *Pneumocystis pneumonia* (PCP)), and there is no other known cause of diminished resistance to that disease (for example, long-term steroid treatment, lymphoma). In such cases, we will make every reasonable effort to obtain full details of the history, medical findings, and results of testing.

2. *CD4 tests.* Individuals who have HIV infection or other disorders of the immune system may have tests showing a reduction of either the absolute count or the percentage of their T-helper lymphocytes (CD4 cells). The extent of immune suppression correlates with the level or rate of decline of the CD4 count. Generally, when the CD4 count is below 200/mm<sup>3</sup> (or below 14 percent of the total lymphocyte count) the susceptibility to opportunistic infection is greatly increased. Although a reduced CD4 count alone does not establish a definitive diagnosis of HIV infection, a CD4 count below 200 does offer supportive evidence when there are clinical findings, but not a definitive diagnosis of an

manifestation of HIV infection.

**D.4.** Documentation of the manifestations of HIV infection. The medical evidence must also include documentation of the manifestations of HIV infection.

Documentation may be by laboratory evidence or by other generally acceptable methods consistent with the prevailing state of medical knowledge and clinical practice.

**D.4.a.** Documentation of the manifestations of HIV infection by definitive diagnosis.

**(D.4.a. ¶1)** The definitive method of diagnosing opportunistic diseases or conditions that are manifestations of HIV infection is by culture, serological test, or microscopic examination of biopsied tissue or other material (e.g., bronchial washings). Therefore, every reasonable effort must be made to obtain specific laboratory evidence of an opportunistic disease or other condition whenever this information is available. If a histological or other test has been performed, the evidence should include a copy of the appropriate report. If the report is not obtainable, the summary of hospitalization or a report from the treating source should include details of the findings and results of the diagnostic studies (including radiographic studies) or microscopic examination of the appropriate tissues or body fluids.

**(D.4.b.)** Other acceptable documentation of the manifestations of HIV infection.

**(D.4.b. ¶1)** Manifestations of HIV infection may also be documented without the definitive laboratory evidence described in paragraph a, provided that such documentation is consistent with the prevailing state of medical knowledge and clinical practice and is consistent with the other evidence. If no definitive laboratory

opportunistic infection(s). However, a reduced CD4 count alone does not document the severity or functional consequences of HIV infection.

*3. Documentation of the manifestations of HIV infection.* The medical evidence must also include documentation of the manifestations of HIV infection. Documentation may be by laboratory evidence or other generally acceptable methods consistent with the prevailing state of medical knowledge and clinical practice.

*a. Definitive documentation of the manifestations of HIV infection.* The definitive method of diagnosing opportunistic diseases or conditions that are manifestations of HIV infection is by culture, serologic test, or microscopic examination of biopsied tissue or other material (for example, bronchial washings). We will make every reasonable effort to obtain specific laboratory evidence of an opportunistic disease or other condition whenever this information is available. If a histologic or other test has been performed, the evidence should include a copy of the appropriate report. If we cannot obtain the report, the summary of hospitalization or a report from the treating source should include details of the findings and results of the diagnostic studies (including appropriate medically acceptable imaging studies) or microscopic examination of the appropriate tissues or body fluids.

*b. Other acceptable documentation of the manifestations of HIV infection.* We may also document manifestations of HIV infection without the definitive laboratory evidence described in 14.00F3a, provided that such documentation is consistent with the prevailing state of medical knowledge

evidence is available, manifestations of HIV infection may be documented by medical history, clinical and laboratory findings, and diagnosis(es) indicated in the medical evidence. In such cases, every reasonable effort must be made to obtain full details of the history, medical findings, and results of testing.

**(D.4.b. ¶2)** Documentation of cytomegalovirus (CMV) disease (14.08D) presents special problems because diagnosis requires identification of viral inclusion bodies or a positive culture from the affected organ, and the absence of any other infectious agent. A positive serology test identifies infection with the virus, but does not confirm a disease process. With the exception of chorioretinitis (which may be diagnosed by an ophthalmologist), documentation of CMV disease requires confirmation by biopsy or other generally acceptable methods consistent with the prevailing state of medical knowledge and clinical practice.

and clinical practice and is consistent with the other evidence in your case record. For example, many conditions are now commonly diagnosed based on some or all of the following: Medical history, clinical manifestations, laboratory findings (including appropriate medically acceptable imaging), and treatment responses. In such cases, we will make every reasonable effort to obtain full details of the history, medical findings, and results of testing. The following are examples of how we may document manifestations of HIV infection with other appropriate evidence.

(i) Although a definitive diagnosis of PCP requires identifying the organism in bronchial washings, induced sputum, or lung biopsy, these tests are frequently bypassed if PCP can be diagnosed presumptively. Supportive evidence may include: Fever, dyspnea, hypoxia, CD4 count below 200, and no evidence of bacterial pneumonia. Also supportive are bilateral lung interstitial infiltrates on x-ray, a typical pattern on CAT scan, or a gallium scan positive for pulmonary uptake. Response to anti-PCP therapy usually requires 5-7 days, and such a response can be supportive of the diagnosis.

(ii) Documentation of *Cytomegalovirus* (CMV) disease (14.08D) may present special problems because definitive diagnosis (except for chorioretinitis, which may be diagnosed by an ophthalmologist or optometrist on funduscopic examination) requires identification of viral inclusion bodies or a positive culture from the affected organ and the absence of any other infectious agent likely to be causing the disease. A positive serology test does not establish a definitive diagnosis of CMV disease, but does offer supportive evidence of a presumptive diagnosis of CMV disease. Other clinical

<p><b>(D.5.¶1)</b> Manifestations specific to women. Most women with severe immunosuppression secondary to HIV infection exhibit the typical opportunistic infections and other conditions, such as pneumocystis carinii pneumonia (PCP), candida esophagitis, wasting syndrome, cryptococcosis, and toxoplasmosis. However, HIV infection may have different manifestations in women than in men. Adjudicators must carefully scrutinize the medical evidence and be alert to the variety of medical conditions specific to or common in women with HIV infection that may affect their ability to function in the workplace.</p> <p><b>(D. 5. ¶2)</b> Many of these manifestations (e.g. vulvovaginal candidiasis, pelvic inflammatory disease) occur in women with or without HIV infection, but can be more severe or resistant to treatment, or occur more frequently in a woman whose immune system is suppressed. Therefore, when evaluating the claim of a woman with HIV infection, it is important to consider gynecologic and other problems specific to women, including any associated symptoms (e.g., pelvic pain), in assessing the severity of the impairment and resulting functional limitations.</p>	<p>findings that support a presumptive diagnosis of CMV may include: Fever, urinary culture positive for CMV, and CD4 count below 200. A clear response to anti-CMV therapy also supports a diagnosis.</p> <p>(iii) A definitive diagnosis of toxoplasmosis of the brain is based on brain biopsy, but this procedure carries significant risk and is not commonly performed. This condition is usually diagnosed presumptively based on symptoms or signs of fever, headache, focal neurologic deficits, seizures, typical lesions on brain imaging, and a positive serology test.</p> <p>(iv) Candidiasis of the esophagus (also known as <i>Candida</i> esophagitis) may be presumptively diagnosed based on symptoms of retrosternal pain on swallowing (odynophagia) and either oropharyngeal thrush (white patches or plaques) diagnosed on physical examination or by microscopic documentation of <i>Candida</i> fungal elements from a noncultured specimen scraped from the oral mucosa. Treatment with oral (systemic) antifungal agents usually produces improvement after 5 or more days of therapy, and such a response can be supportive of the diagnosis.</p> <p>4. <i>HIV infection manifestations specific to women.</i></p> <p>a. <i>General.</i> Most women with severe immunosuppression secondary to HIV infection exhibit the typical opportunistic infections and other conditions, such as PCP, <i>Candida</i> esophagitis, wasting syndrome, cryptococcosis, and toxoplasmosis. However, HIV infection may have different manifestations in women than in men. Adjudicators must carefully scrutinize the</p>
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<p>Manifestations of HIV infection in women may be evaluated under the specific criteria (e.g., cervical cancer under 14.08E), under an applicable general category (e.g., pelvic inflammatory disease under 14.08A5) or, in appropriate cases, under 14.08N.</p> <p><b>(D.2. ¶5)</b> As used in 14.08I, "significant involuntary weight loss" does not correspond to a specific minimum amount or percentage of weight loss. Although, for purposes of this listing, an involuntary weight loss of at least 10 percent of baseline is always considered significant, loss of less than 10 percent may or may not be significant, depending on the individual's baseline weight and body habitus. (For example, a 7-pound weight loss in a 100-pound female who is 63 inches tall might be considered significant; but a 14-pound weight loss in a 200-pound female who is the same height might not be significant.)</p>	<p>medical evidence and be alert to the variety of medical conditions specific to, or common in, women with HIV infection that may affect their ability to function in the workplace.</p> <p>b. <i>Additional considerations for evaluating HIV infection in women.</i> Many of these manifestations (for example, vulvovaginal candidiasis, pelvic inflammatory disease) occur in women with or without HIV infection, but can be more severe or resistant to treatment, or occur more frequently in a woman whose immune system is suppressed. Therefore, when evaluating the claim of a woman with HIV infection, it is important to consider gynecologic and other problems specific to women, including any associated symptoms (for example, pelvic pain), in assessing the severity of the impairment and resulting functional limitations. We may evaluate manifestations of HIV infection in women under the specific criteria (for example, cervical cancer under 14.08E), under an applicable general category (for example, pelvic inflammatory disease under 14.08A4) or, in appropriate cases, under 14.08K.</p> <p>5. <i>Involuntary weight loss.</i> For purposes of 14.08H, an involuntary weight loss of at least 10 percent of baseline is always considered "significant." Loss of less than 10 percent may or may not be significant, depending on the individual's baseline weight and body habitus. For example, a 7-pound weight loss in a 100-pound woman who is 63 inches tall might be considered significant; but a 14-pound weight loss in a 200-pound woman who is the same height might not be significant. HIV infection that affects the digestive system and results in malnutrition can also be evaluated under 5.08.</p>
	<p>G. <i>How do we consider the effects</i></p>

**(D.7. ¶1)** Effect of treatment. Medical treatment must be considered in terms of its effectiveness in ameliorating the signs, symptoms, and laboratory abnormalities of the specific disorder, or of the HIV infection itself (e.g., antiretroviral agents) and in terms of any side effects of treatment that may further impair the individual.

**(D.7. ¶3)** A specific description of the drugs or treatment given (including surgery), dosage, frequency of administration, and a description of the complications or response to treatment should be obtained. The effects of treatment may be temporary or long term. As such, the decision regarding the impact of treatment should be based on a sufficient period of treatment to permit proper consideration.

**(D.7. ¶2)** Response to treatment and adverse or beneficial consequences of treatment may vary widely. For example, an individual with HIV infection who develops pneumonia or tuberculosis may respond to the same antibiotic regimen used in treating individuals without HIV

*of treatment in evaluating your autoimmune disorder, immune deficiency disorder, or HIV infection?*

1. *General.* If your impairment does not otherwise meet the requirements of a listing, we will consider your medical treatment in terms of its effectiveness in improving the signs, symptoms, and laboratory abnormalities of your specific immune system disorder or its manifestations, and in terms of any side effects that limit your functioning. We will make every reasonable effort to obtain a specific description of the treatment you receive (including surgery) for your immune system disorder. We consider:

- a. The effects of medications you take.
- b. Adverse side effects (acute and chronic).
- c. The intrusiveness and complexity of your treatment (for example, the dosing schedule, need for injections).
- d. The effect of treatment on your mental functioning (for example, cognitive changes, mood disturbance).
- e. Variability of your response to treatment (see 14.00G2).
- f. The interactive and cumulative effects of your treatments. For example, many individuals with immune system disorders receive treatment both for their immune system disorders and for the manifestations of the disorders or co-occurring impairments, such as treatment for HIV infection and hepatitis C. The interactive and cumulative effects of these treatments may be greater than the effects of each treatment considered separately.
- g. The duration of your treatment.
- h. Any other aspects of treatment that may interfere with your ability to function.

infection, but another individual with HIV infection may not respond to the same regimen. Therefore, each case must be considered on an individual basis, along with the effects of treatment on the individual's ability to function.

**(D.7. ¶3 sentence 2)** The effects of treatment may be temporary or long term.

**(B. ¶5)** In addition to the limitations caused by the connective tissue disorder per se, the chronic adverse effects of treatment (e.g., corticosteroid-related ischemic necrosis of bone) may result in functional loss.

*2. Variability of your response to treatment.* Your response to treatment and the adverse or beneficial consequences of your treatment may vary widely. The effects of your treatment may be temporary or long term. For example, some individuals may show an initial positive response to a drug or combination of drugs followed by a decrease in effectiveness. When we evaluate your response to treatment and how your treatment may affect you, we consider such factors as disease activity before treatment, requirements for changes in therapeutic regimens, the time required for therapeutic effectiveness of a particular drug or drugs, the limited number of drug combinations that may be available for your impairment(s), and the time-limited efficacy of some drugs. For example, an individual with HIV infection or another immune deficiency disorder who develops pneumonia or tuberculosis may not respond to the same antibiotic regimen used in treating individuals without HIV infection or another immune deficiency disorder, or may not respond to an antibiotic that he or she responded to before. Therefore, we must consider the effects of your treatment on an individual basis, including the effects of your treatment on your ability to function.

*3. How we evaluate the effects of treatment for autoimmune disorders on your ability to function.* Some medications may have acute or long-term side effects. When we consider the effects of corticosteroids or other treatments for autoimmune disorders on your ability to function, we consider the factors in 14.00G1 and 14.00G2. Long-term corticosteroid treatment can cause ischemic necrosis of bone, posterior subcapsular cataract, weight gain, glucose intolerance, increased susceptibility to infection, and

**D.7.** Effect of treatment. Medical treatment must be considered in terms of its effectiveness in ameliorating the signs, symptoms, and laboratory abnormalities of the specific disorder, or of the HIV infection itself (e.g., antiretroviral agents) and in terms of any side effects of treatment that may further impair the individual.

osteoporosis that may result in a loss of function. In addition, medications used in the treatment of autoimmune disorders may also have effects on mental functioning, including cognition (for example, memory), concentration, and mood.

*4. How we evaluate the effects of treatment for immune deficiency disorders, excluding HIV infection, on your ability to function.* When we consider the effects of your treatment for your immune deficiency disorder on your ability to function, we consider the factors in 14.00G1 and 14.00G2. A frequent need for treatment such as intravenous immunoglobulin and gamma interferon therapy can be intrusive and interfere with your ability to work. We will also consider whether you have chronic side effects from these or other medications, including severe fatigue, fever, headaches, high blood pressure, joint swelling, muscle aches, nausea, shortness of breath, or limitations in mental function including cognition (for example, memory), concentration, and mood.

*5. How we evaluate the effects of treatment for HIV infection on your ability to function.*

*a. General.* When we consider the effects of antiretroviral drugs (including the effects of highly active antiretroviral therapy (HAART)) and the effects of treatments for the manifestations of HIV infection on your ability to function, we consider the factors in 14.00G1 and 14.00G2. Side effects of antiretroviral drugs include, but are not limited to: Bone marrow suppression, pancreatitis, gastrointestinal intolerance (nausea, vomiting, diarrhea), neuropathy, rash, hepatotoxicity, lipodystrophy (fat redistribution, such as “buffalo hump”), glucose intolerance, and lactic acidosis. In addition, medications used in the treatment

of HIV infection may also have effects on mental functioning, including cognition (for example, memory), concentration, and mood, and may result in malaise, severe fatigue, joint and muscle pain, and insomnia. The symptoms of HIV infection and the side effects of medication may be indistinguishable from each other. We will consider all of your functional limitations, whether they result from your symptoms or signs of HIV infection or the side effects of your treatment.

b. *Structured treatment interruptions.* A structured treatment interruption (STI, also called a “drug holiday”) is a treatment practice during which your treating source advises you to stop taking your medications temporarily. An STI in itself does not imply that your medical condition has improved; nor does it imply that you are noncompliant with your treatment because you are following your treating source’s advice. Therefore, if you have stopped taking medication because your treating source prescribed or recommended an STI, we will not find that you are failing to follow treatment or draw inferences about the severity of your impairment on this fact alone. We will consider why your treating source has prescribed or recommended an STI and all the other information in your case record when we determine the severity of your impairment.

6. *When there is no record of ongoing treatment.* If you have not received ongoing treatment or have not had an ongoing relationship with the medical community despite the existence of a severe impairment(s), we will evaluate the medical severity and duration of your immune system disorder on the basis of the current objective medical evidence and other evidence in your case record, taking

	<p>into consideration your medical history, symptoms, clinical and laboratory findings, and medical source opinions. If you have just begun treatment and we cannot determine whether you are disabled based on the evidence we have, we may need to wait to determine the effect of the treatment on your ability to function. The amount of time we need to wait will depend on the facts of your case. If you have not received treatment, you may not be able to show an impairment that meets the criteria of one of the immune system disorders listings, but your immune system disorder may medically equal a listing or be disabling based on a consideration of your residual functional capacity, age, education, and work experience.</p>
	<p>H. <i>How do we consider your symptoms, including your pain, severe fatigue, and malaise?</i> Your symptoms, including pain, severe fatigue, and malaise, may be important factors in our determination whether your immune system disorder(s) meets or medically equals a listing or in our determination whether you are otherwise able to work. In order for us to consider your symptoms, you must have medical signs or laboratory findings showing the existence of a medically determinable impairment(s) that could reasonably be expected to produce the symptoms. If you have such an impairment(s), we will evaluate the intensity, persistence, and functional effects of your symptoms using the rules throughout 14.00 and in our other regulations. See §§404.1528, 404.1529, 416.928, and 416.929. Additionally, when we assess the credibility of your complaints about your symptoms and their functional effects, we will not draw any inferences from the fact that you do not receive treatment or that you are not following treatment without considering all of the relevant evidence in your case record,</p>

	<p>including any explanations you provide that may explain why you are not receiving or following treatment.</p>
<p><b>D.8.</b> Functional criteria. Paragraph N of 14.08 establishes standards for evaluating manifestations of HIV infection that do not meet the requirements listed in 14.08A-M. Paragraph N is applicable for manifestations that are not listed in 14.08A-M, as well as those listed in 14.08A-M that do not meet the criteria of any of the rules in 14.08A-M.</p> <p><b>(D.8. ¶2)</b> For individuals with HIV infection evaluated under 14.08N, listing-level severity will be assessed in terms of the functional limitations imposed by the impairment. The full impact of signs, symptoms, and laboratory findings on the claimant's ability to function must be considered. Important factors to be considered in evaluating the functioning of individuals with HIV infection include, but are not limited to: symptoms, such as fatigue and pain; characteristics of the illness, such as the frequency and duration of manifestations or periods of exacerbation and remission in the disease course; and the functional impact of treatment for the disease, including the side effects of medication.</p> <p><b>(D.8 ¶3)</b> As used in 14.08N, "repeated" means that the conditions occur on an average of 3 times a year, or once every 4 months, each lasting 2 weeks or more; or the conditions do not last for 2 weeks but occur substantially more frequently than 3 times in a year or once every 4 months; or they occur less often than an average of 3</p>	<p><i>I. How do we use the functional criteria in these listings?</i></p> <p>1. The following listings in this body system include standards for evaluating the functional limitations resulting from immune system disorders: 14.02B, for systemic lupus erythematosus; 14.03B, for systemic vasculitis; 14.04D, for systemic sclerosis (scleroderma); 14.05E, for polymyositis and dermatomyositis; 14.06B, for undifferentiated and mixed connective tissue disease; 14.07C, for immune deficiency disorders, excluding HIV infection; 14.08K, for HIV infection; 14.09D, for inflammatory arthritis; and 14.10B, for Sjögren's syndrome.</p> <p>2. When we use one of the listings cited in 14.00I1, we will consider all relevant information in your case record to determine the full impact of your immune system disorder on your ability to function on a sustained basis. Important factors we will consider when we evaluate your functioning under these listings include, but are not limited to: Your symptoms, the frequency and duration of manifestations of your immune system disorder, periods of exacerbation and remission, and the functional impact of your treatment, including the side effects of your medication.</p> <p>3. As used in these listings, "repeated" means that the manifestations occur on an average of three times a year, or once every 4 months, each lasting 2 weeks or more; or the manifestations do not last for 2 weeks but occur substantially more frequently than three times in a year</p>

times a year or once every 4 months but last substantially longer than 2 weeks.

**(D.8. ¶4)** To meet the criteria in 14.08N, an individual with HIV infection must demonstrate a marked level of restriction in one of three general areas of functioning: activities of daily living; social functioning; and difficulties in completing tasks due to deficiencies in concentration, persistence, or pace. Functional restrictions may result from the impact of the disease process itself on mental or physical functioning, or both. This could result from extended or intermittent symptoms, such as depression, fatigue, or pain, resulting in a limitation of the ability to concentrate, to persevere at a task, or to perform the task at an acceptable rate of speed. Limitations may also result from the side effects of medication.

**(D.8. ¶5)** When "marked" is used as a standard for measuring the degree of functional limitation, it means more than moderate, but less than extreme. A marked limitation does not represent a quantitative measure of the individual's ability to do an activity for a certain percentage of the time. A marked limitation may be present when several activities or functions are impaired or even when only one is impaired. However, an individual need not be totally precluded from performing an activity to have a marked limitation, as long as the degree of limitation is such as to seriously interfere with the ability to function

or once every 4 months; or they occur less frequently than an average of three times a year or once every 4 months but last substantially longer than 2 weeks. Your impairment will satisfy this criterion regardless of whether you have the same kind of manifestation repeatedly, all different manifestations, or any other combination of manifestations; for example, two of the same kind of manifestation and a different one. You must have the required number of manifestations with the frequency and duration required in this section. Also, the manifestations must occur within the period covered by your claim.

4. To satisfy the functional criterion in a listing, your immune system disorder must result in a "marked" level of limitation in one of three general areas of functioning: Activities of daily living, social functioning, or difficulties in completing tasks due to deficiencies in concentration, persistence, or pace. Functional limitation may result from the impact of the disease process itself on your mental functioning, physical functioning, or both your mental and physical functioning. This could result from persistent or intermittent symptoms, such as depression, severe fatigue, or pain, resulting in a limitation of your ability to do a task, to concentrate, to persevere at a task, or to perform the task at an acceptable rate of speed. You may also have limitations because of your treatment and its side effects (see 14.00G).

5. When "marked" is used as a standard for measuring the degree of functional limitation, it means more than moderate but less than extreme. We do not define "marked" by a specific number of different activities of daily living in which your functioning is impaired, different

independently, appropriately, and effectively. The term "marked" does not imply that the impaired individual is confined to bed, hospitalized, or in a nursing home.

**(D.8. ¶6)** Activities of daily living include, but are not limited to, such activities as doing household chores, grooming and hygiene, using a post office, taking public transportation, and paying bills. An individual with HIV infection who, because of symptoms such as pain imposed by the illness or its treatment, is not able to maintain a household or take public transportation on a sustained basis or without assistance (even though he or she is able to perform some self-care activities) would have marked limitation of activities of daily living.

**(D.8. ¶7)** Social functioning includes the capacity to interact appropriately and communicate effectively with others. An individual with HIV infection who, because of symptoms or a pattern of exacerbation and remission caused by the illness or its treatment, cannot engage in social interaction on a sustained basis (even though he or she is able to communicate with close friends or relatives) would have marked difficulty maintaining social functioning.

**(D.8. ¶8)** Completing tasks in a timely manner involves the ability to sustain concentration, persistence, or pace to permit timely completion of tasks commonly found in work settings. An individual with HIV infection who,

behaviors in which your social functioning is impaired, or tasks that you are able to complete, but by the nature and overall degree of interference with your functioning. You may have a marked limitation when several activities or functions are impaired, or even when only one is impaired. Also, you need not be totally precluded from performing an activity to have a marked limitation, as long as the degree of limitation seriously interferes with your ability to function independently, appropriately, and effectively. The term "marked" does not imply that you must be confined to bed, hospitalized, or in a nursing home.

6. *Activities of daily living* include, but are not limited to, such activities as doing household chores, grooming and hygiene, using a post office, taking public transportation, or paying bills. We will find that you have a "marked" limitation of activities of daily living if you have a serious limitation in your ability to maintain a household or take public transportation because of symptoms, such as pain, severe fatigue, anxiety, or difficulty concentrating, caused by your immune system disorder (including manifestations of the disorder) or its treatment, even if you are able to perform some self-care activities.

7. *Social functioning* includes the capacity to interact independently, appropriately, effectively, and on a sustained basis with others. It includes the ability to communicate effectively with others. We will find that you have a "marked" limitation in maintaining social functioning if you have a serious limitation in social interaction on a sustained basis because of symptoms, such as pain, severe fatigue, anxiety, or difficulty concentrating, or a pattern of exacerbation and remission,

<p>because of HIV-related fatigue or other symptoms, is unable to sustain concentration or pace adequate to complete simple work-related tasks (even though he or she is able to do routine activities of daily living) would have marked difficulty completing tasks.</p>	<p>caused by your immune system disorder (including manifestations of the disorder) or its treatment, even if you are able to communicate with close friends or relatives.</p> <p>8. <i>Completing tasks in a timely manner</i> involves the ability to sustain concentration, persistence, or pace to permit timely completion of tasks commonly found in work settings. We will find that you have a “marked” limitation in completing tasks if you have a serious limitation in your ability to sustain concentration or pace adequate to complete work-related tasks because of symptoms, such as pain, severe fatigue, anxiety, or difficulty concentrating, caused by your immune system disorder (including manifestations of the disorder) or its treatment, even if you are able to do some routine activities of daily living.</p>
<p><b>D.6. Evaluation.</b> The criteria in 14.08 do not describe the full spectrum of diseases or conditions manifested by individuals with HIV infection. As in any case, consideration must be given to whether an individual's impairment(s) meets or equals in severity any other listing in appendix 1 of subpart P (e.g., a neoplastic disorder listed in 13.00ff). Although 14.08 includes cross-references to other listings for the more common manifestations of HIV infection, other listings may apply.</p> <p><b>(D.6. ¶2)</b> In addition, the impact of all impairments, whether or not related to HIV infection, must be considered. For example, individuals with HIV infection may manifest signs and symptoms of a mental impairment (e.g., anxiety, depression), or of another physical impairment. Medical evidence should</p>	<p><i>J. How do we evaluate your immune system disorder when it does not meet one of these listings?</i></p> <p>1. These listings are only examples of immune system disorders that we consider severe enough to prevent you from doing any gainful activity. If your impairment(s) does not meet the criteria of any of these listings, we must also consider whether you have an impairment(s) that satisfies the criteria of a listing in another body system.</p> <p>2. Individuals with immune system disorders, including HIV infection, may manifest signs or symptoms of a mental impairment or of another physical impairment. We may evaluate these impairments under any affected body system. For example, we will evaluate:</p>

include documentation of all physical and mental impairments, and the impairment(s) should be evaluated not only under the relevant listing(s) in 14.08, but under any other appropriate listing(s).

C. Allergic disorders (e.g., asthma or atopic dermatitis) are discussed and evaluated under the appropriate listing of the affected body system. (14.00.C)

**(D.6. ¶3)** It is also important to remember that individuals with HIV infection, like all other individuals, are evaluated under the full five-step sequential evaluation process described in §404.1520 and §416.920. If an individual with HIV infection is working

a. Musculoskeletal involvement, such as surgical reconstruction of a joint, under 1.00.

b. Ocular involvement, such as dry eye, under 2.00.

c. Respiratory impairments, such as pleuritis, under 3.00.

d. Cardiovascular impairments, such as cardiomyopathy, under 4.00.

e. Digestive impairments, such as hepatitis (including hepatitis C) or weight loss as a result of HIV infection that affects the digestive system, under 5.00.

f. Genitourinary impairments, such as nephropathy, under 6.00.

g. Hematologic abnormalities, such as anemia, granulocytopenia, and thrombocytopenia, under 7.00.

h. Skin impairments, such as persistent fungal and other infectious skin eruptions, and photosensitivity, under 8.00.

i. Neurologic impairments, such as neuropathy or seizures, under 11.00.

j. Mental disorders, such as depression, anxiety, or cognitive deficits, under 12.00.

k. Allergic disorders, such as asthma or atopic dermatitis, under 3.00 or 8.00 or under the criteria in another affected body system.

l. Syphilis or neurosyphilis under the criteria for the affected body system; for example, 2.00 Special senses and speech, 4.00 Cardiovascular system, or 11.00 Neurological.

<p>and engaging in substantial gainful activity (SGA), or does not have a severe impairment, the case will be decided at the first or second step of the sequential evaluation process, and does not require evaluation under these listings. For an individual with HIV infection who is not engaging in SGA and has a severe impairment, but whose impairment(s) does not meet or equal in severity the criteria of a listing, evaluation must proceed through the final steps of the sequential evaluation process (or, as appropriate, the steps in the medical improvement review standard) before any conclusion can be reached on the issue of disability.</p>	<p>3. If you have a severe medically determinable impairment(s) that does not meet a listing, we will determine whether your impairment(s) medically equals a listing. (See §§404.1526 and 416.926.) If it does not, you may or may not have the residual functional capacity to engage in substantial gainful activity. Therefore, we proceed to the fourth, and if necessary, the fifth steps of the sequential evaluation process in §§404.1520 and 416.920. We use the rules in §§404.1594, 416.994, and 416.994a as appropriate, when we decide whether you continue to be disabled.</p>
<p><b><i>14.01 Category of Impairments, Immune System</i></b></p>	<p><b><i>14.01 Category of Impairments, Immune System Disorders</i></b></p>
<p><i>14.02 Systemic lupus erythematosus.</i> Documented as described in 14.00B1, with:</p> <p>A. One of the following:</p> <ol style="list-style-type: none"> <li>1. Joint involvement, as described under the criteria in 1.00; or</li> <li>2. Muscle involvement, as described under the criteria in 14.05; or</li> <li>3. Ocular involvement, as described under the criteria in 2.00ff; or</li> <li>4. Respiratory involvement, as described under the criteria in 3.00ff; or</li> <li>5. Cardiovascular involvement, as described under the criteria in 4.00ff or 14.04D; or</li> <li>6. Digestive involvement, as described under the criteria in 5.00ff; or</li> <li>7. Renal involvement, as described under the criteria in 6.00ff; or</li> </ol>	<p><i>14.02 Systemic lupus erythematosus.</i> As described in 14.00D1. With:</p> <p>A. Involvement of two or more organs/body systems, with:</p> <ol style="list-style-type: none"> <li>1. One of the organs/body systems involved to at least a moderate level of severity; and</li> <li>2. At least two of the constitutional symptoms or signs (severe fatigue, fever, malaise, or involuntary weight loss).</li> </ol> <p>or</p> <p>B. Repeated manifestations of SLE, with at least two of the constitutional symptoms or signs (severe fatigue, fever, malaise, or involuntary weight loss) and one of the following at the marked level:</p> <ol style="list-style-type: none"> <li>1. Limitation of activities of daily living.</li> <li>2. Limitation in maintaining social functioning.</li> <li>3. Limitation in completing tasks in</li> </ol>

<p>8. Hematologic involvement, as described under the criteria in 7.00ff; or</p> <p>9. Skin involvement, as described under the criteria in 8.00ff; or</p> <p>10. Neurological involvement, as described under the criteria in 11.00ff; or</p> <p>11. Mental involvement, as described under the criteria in 12.00ff.</p> <p>or</p> <p>B. Lesser involvement of two or more organs/body systems listed in paragraph A, with significant, documented, constitutional symptoms and signs of severe fatigue, fever, malaise, and weight loss. At least one of the organs/body systems must be involved to at least a moderate level of severity.</p>	<p>a timely manner due to deficiencies in concentration, persistence, or pace.</p>
<p><i>14.03 Systemic vasculitis.</i> Documented as described in 14.00B2, including documentation by angiography or tissue biopsy, with:</p> <p>A. Involvement of a single organ or body system, as described under the criteria in 14.02A.</p> <p>or</p> <p>B. Lesser involvement of two or more organs/body systems listed in 14.02A, with significant, documented, constitutional symptoms and signs of severe fatigue, fever, malaise, and weight loss. At least one of the organs/body systems must be involved to at least a moderate level of severity.</p>	<p><i>14.03 Systemic vasculitis.</i> As described in 14.00D2. With:</p> <p>A. Involvement of two or more organs/body systems, with:</p> <ol style="list-style-type: none"> <li>1. One of the organs/body systems involved to at least a moderate level of severity; and</li> <li>2. At least two of the constitutional symptoms or signs (severe fatigue, fever, malaise, or involuntary weight loss).</li> </ol> <p>or</p> <p>B. Repeated manifestations of systemic vasculitis, with at least two of the constitutional symptoms or signs (severe fatigue, fever, malaise, or involuntary weight loss) and one of the following at the marked level:</p> <ol style="list-style-type: none"> <li>1. Limitation of activities of daily living.</li> </ol>

	<p>2. Limitation in maintaining social functioning.</p> <p>3. Limitation in completing tasks in a timely manner due to deficiencies in concentration, persistence, or pace.</p>
<p><i>14.04 Systemic sclerosis and scleroderma.</i> Documented as described in 14.00B3, with:</p> <p>A. One of the following:</p> <p>1. Muscle involvement, as described under the criteria in 14.05; or</p> <p>2. Respiratory involvement, as described under the criteria in 3.00ff; or</p> <p>3. Cardiovascular involvement, as described under the criteria in 4.00ff; or</p> <p>4. Digestive involvement, as described under the criteria in 5.00ff; or</p> <p>5. Renal involvement, as described under the criteria in 6.00ff.</p> <p>or</p> <p>B. Lesser involvement of two or more organs/body systems listed in paragraph A, with significant, documented, constitutional symptoms and signs of severe fatigue, fever, malaise, and weight loss. At least one of the organs/body systems must be involved to at least a moderate level of severity.</p> <p>or</p> <p>C. Generalized scleroderma with digital contractures.</p> <p>or</p> <p>D. Severe Raynaud's phenomena, characterized by digital ulcerations, ischemia, or gangrene.</p>	<p><i>14.04 Systemic sclerosis (scleroderma).</i> As described in 14.00D3. With:</p> <p>A. Involvement of two or more organs/body systems, with:</p> <p>1. One of the organs/body systems involved to at least a moderate level of severity; and</p> <p>2. At least two of the constitutional symptoms or signs (severe fatigue, fever, malaise, or involuntary weight loss).</p> <p>or</p> <p>B. With one of the following:</p> <p>1. Toe contractures or fixed deformity of one or both feet, resulting in the inability to ambulate effectively as defined in 14.00C6; or</p> <p>2. Finger contractures or fixed deformity in both hands, resulting in the inability to perform fine and gross movements effectively as defined in 14.00C7; or</p> <p>3. Atrophy with irreversible damage in one or both lower extremities, resulting in the inability to ambulate effectively as defined in 14.00C6; or</p> <p>4. Atrophy with irreversible damage in both upper extremities, resulting in the inability to perform fine and gross movements effectively as defined in 14.00C7.</p>

	<p>or</p> <p>C. Raynaud's phenomenon, characterized by:</p> <ol style="list-style-type: none"> <li>1. Gangrene involving at least two extremities; or</li> <li>2. Ischemia with ulcerations of toes or fingers, resulting in the inability to ambulate effectively or to perform fine and gross movements effectively as defined in 14.00C6 and 14.00C7;</li> </ol> <p>or</p> <p>D. Repeated manifestations of systemic sclerosis (scleroderma), with at least two of the constitutional symptoms or signs (severe fatigue, fever, malaise, or involuntary weight loss) and one of the following at the marked level:</p> <ol style="list-style-type: none"> <li>1. Limitation of activities of daily living.</li> <li>2. Limitation in maintaining social functioning.</li> <li>3. Limitation in completing tasks in a timely manner due to deficiencies in concentration, persistence, or pace.</li> </ol>
<p><i>14.05 Polymyositis or dermatomyositis.</i> Documented as described in 14.00B4, with:</p> <p>A. Severe proximal limb-girdle (shoulder and/or pelvic) muscle weakness, as described in 14.00B4.</p> <p>or</p> <p>B. Less severe limb-girdle muscle weakness than in 14.05A, associated with cervical muscle weakness and one of the following to at least a moderate level of severity:</p>	<p><i>14.05 Polymyositis and dermatomyositis.</i> As described in 14.00D4. With:</p> <p>A. Proximal limb-girdle (pelvic or shoulder) muscle weakness, resulting in inability to ambulate effectively or inability to perform fine and gross movements effectively as defined in 14.00C6 and 14.00C7.</p> <p>or</p> <p>B. Impaired swallowing (dysphagia) with aspiration due to muscle weakness.</p>

<p>1. Impaired swallowing with dysphagia and episodes of aspiration due to cricopharyngeal weakness, or</p> <p>2. Impaired respiration due to intercostal and diaphragmatic muscle weakness.</p> <p>or</p> <p>C. If associated with malignant tumor, as described under the criteria in 13.00ff.</p> <p>or</p> <p>D. If associated with generalized connective tissue disease, described under the criteria in 14.02, 14.03, 14.04, or 14.06.</p>	<p>or</p> <p>C. Impaired respiration due to intercostal and diaphragmatic muscle weakness.</p> <p>or</p> <p>D. Diffuse calcinosis with limitation of joint mobility or intestinal motility.</p> <p>or</p> <p>E. Repeated manifestations of polymyositis or dermatomyositis, with at least two of the constitutional symptoms or signs (severe fatigue, fever, malaise, or involuntary weight loss) and one of the following at the marked level:</p> <ol style="list-style-type: none"> <li>1. Limitation of activities of daily living.</li> <li>2. Limitation in maintaining social functioning.</li> <li>3. Limitation in completing tasks in a timely manner due to deficiencies in concentration, persistence, or pace.</li> </ol>
<p><i>14.06 Undifferentiated connective tissue disorder.</i> Documented as described in 14.00B5, and with impairment as described under the criteria in 14.02A, 14.02B, or 14.04.</p>	<p><i>14.06 Undifferentiated and mixed connective tissue disease.</i> As described in 14.00D5. With:</p> <p>A. Involvement of two or more organs/body systems, with:</p> <ol style="list-style-type: none"> <li>1. One of the organs/body systems involved to at least a moderate level of severity; and</li> <li>2. At least two of the constitutional symptoms or signs (severe fatigue, fever, malaise, or involuntary weight loss).</li> </ol> <p>or</p> <p>B. Repeated manifestations of undifferentiated or mixed connective tissue</p>

	<p>disease, with at least two of the constitutional symptoms or signs (severe fatigue, fever, malaise, or involuntary weight loss) and one of the following at the marked level:</p> <ol style="list-style-type: none"> <li>1. Limitation of activities of daily living.</li> <li>2. Limitation in maintaining social functioning.</li> <li>3. Limitation in completing tasks in a timely manner due to deficiencies in concentration, persistence, or pace.</li> </ol>
<p><i>14.07 Immunoglobulin deficiency syndromes or deficiencies of cell-mediated immunity, excepting HIV infection.</i> Associated with documented, recurrent severe infection occurring 3 or more times within a 5-month period.</p>	<p><i>14.07 Immune deficiency disorders, excluding HIV infection.</i> As described in 14.00E. With:</p> <p>A. One or more of the following infections. The infection(s) must either be resistant to treatment or require hospitalization or intravenous treatment three or more times in a 12-month period.</p> <ol style="list-style-type: none"> <li>1. Sepsis; or</li> <li>2. Meningitis; or</li> <li>3. Pneumonia; or</li> <li>4. Septic arthritis; or</li> <li>5. Endocarditis; or</li> <li>6. Sinusitis documented by appropriate medically acceptable imaging.</li> </ol> <p>or</p> <p>B. Stem cell transplantation as described under 14.00E3. 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.</p> <p>or</p>

	<p>C. Repeated manifestations of an immune deficiency disorder, with at least two of the constitutional symptoms or signs (severe fatigue, fever, malaise, or involuntary weight loss) and one of the following at the marked level:</p> <ol style="list-style-type: none"> <li>1. Limitation of activities of daily living.</li> <li>2. Limitation in maintaining social function.</li> <li>3. Limitation in completing tasks in a timely manner due to deficiencies in concentration, persistence, or pace.</li> </ol>
<p><i>14.08 Human immunodeficiency virus (HIV) infection.</i> With documentation as described in 14.00D3 and one of the following:</p> <p>A. Bacterial infections:</p> <ol style="list-style-type: none"> <li>1. Mycobacterial infection (e.g., caused by <i>M. avium-intracellulare</i>, <i>M. kansasii</i>, or <i>M. tuberculosis</i>) at a site other than the lungs, skin, or cervical or hilar lymph nodes; or pulmonary tuberculosis resistant to treatment; or</li> <li>2. Nocardiosis; or</li> <li>3. <i>Salmonella</i> bacteremia, recurrent non-typhoid; or</li> <li>4. Syphilis or neurosyphilis—evaluate sequelae under the criteria for the affected body system (e.g., 2.00 Special Senses and Speech, 4.00 Cardiovascular System, 11.00 Neurological); or</li> <li>5. Multiple or recurrent bacterial infection(s), including pelvic inflammatory disease, requiring hospitalization or intravenous antibiotic treatment 3 or more times in 1 year.</li> </ol>	<p><i>14.08 Human immunodeficiency virus (HIV) infection.</i> With documentation as described in 14.00F and one of the following:</p> <p>A. Bacterial infections:</p> <ol style="list-style-type: none"> <li>1. Mycobacterial infection (for example, caused by <i>M. avium-intracellulare</i>, <i>M. kansasii</i>, or <i>M. tuberculosis</i>) at a site other than the lungs, skin, or cervical or hilar lymph nodes, or pulmonary tuberculosis resistant to treatment; or</li> <li>2. Nocardiosis; or</li> <li>3. <i>Salmonella</i> bacteremia, recurrent non-typhoid; or</li> <li>4. Multiple or recurrent bacterial infections, including pelvic inflammatory disease, requiring hospitalization or intravenous antibiotic treatment three or more times in a 12-month period.</li> </ol> <p>or</p>

<p>or</p> <p>B. Fungal infections:</p> <ol style="list-style-type: none"> <li>1. Aspergillosis; or</li> <li>2. Candidiasis, at a site other than the skin, urinary tract, intestinal tract, or oral or vulvovaginal mucous membranes; or candidiasis involving the esophagus, trachea, bronchi, or lungs; or</li> <li>3. Coccidioidomycosis, at a site other than the lungs or lymph nodes; or</li> <li>4. Cryptococcosis, at a site other than the lungs (e.g., cryptococcal meningitis); or</li> <li>5. Histoplasmosis, at a site other than the lungs or lymph nodes; or</li> <li>6. Mucormycosis.</li> </ol> <p>or</p> <p>C. Protozoan or helminthic infections:</p> <ol style="list-style-type: none"> <li>1. Cryptosporidiosis, isosporiasis, or microsporidiosis, with diarrhea lasting for 1 month or longer; or</li> <li>2. <i>Pneumocystis carinii</i> pneumonia or extrapulmonary <i>pneumocystis carinii</i> infection; or</li> <li>3. Strongyloidiasis, extra-intestinal; or</li> <li>4. Toxoplasmosis of an organ other than the liver, spleen, or lymph nodes.</li> </ol> <p>or</p> <p>D. Viral infections:</p>	<p>B. Fungal infections:</p> <ol style="list-style-type: none"> <li>1. Aspergillosis; or</li> <li>2. Candidiasis involving the esophagus, trachea, bronchi, or lungs, or at a site other than the skin, urinary tract, intestinal tract, or oral or vulvovaginal mucous membranes; or</li> <li>3. Coccidioidomycosis, at a site other than the lungs or lymph nodes; or</li> <li>4. Cryptococcosis, at a site other than the lungs (for example, cryptococcal meningitis); or</li> <li>5. Histoplasmosis, at a site other than the lungs or lymph nodes; or</li> <li>6. Mucormycosis; or</li> <li>7. <i>Pneumocystis</i> pneumonia or extrapulmonary <i>Pneumocystis</i> infection.</li> </ol> <p>or</p> <p>C. Protozoan or helminthic infections:</p> <ol style="list-style-type: none"> <li>1. Cryptosporidiosis, isosporiasis, or microsporidiosis, with diarrhea lasting for 1 month or longer; or</li> <li>2. Strongyloidiasis, extra-intestinal;</li> <li>3. Toxoplasmosis of an organ other than the liver, spleen, or lymph nodes.</li> </ol> <p>or</p> <p>D. Viral infections:</p>
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<p>1. Cytomegalovirus disease (documented as described in 14.00D4b) at a site other than the liver, spleen, or lymph nodes; or</p> <p>2. Herpes simplex virus causing:</p> <p>a. Mucocutaneous infection (e.g., oral, genital, perianal) lasting for 1 month or longer; or</p> <p>b. Infection at a site other than the skin or mucous membranes (e.g., bronchitis, pneumonitis, esophagitis, or encephalitis); or</p> <p>c. Disseminated infection; or</p> <p>3. Herpes zoster, either disseminated or with multidermatomal eruptions that are resistant to treatment; or</p> <p>4. Progressive multifocal leukoencephalopathy; or</p> <p>5. Hepatitis, as described under the criteria in 5.05.</p> <p>or</p> <p>E. Malignant neoplasms:</p> <p>1. Carcinoma of the cervix, invasive, FIGO stage II and beyond; or</p> <p>2. Kaposi's sarcoma with:</p> <p>a. Extensive oral lesions; or</p> <p>b. Involvement of the gastrointestinal tract, lungs, or other visceral organs; or</p>	<p>1. <i>Cytomegalovirus</i> disease (documented as described in 14.00F3b(ii)) at a site other than the liver, spleen or lymph nodes; or</p> <p>2. Herpes simplex virus causing:</p> <p>a. Mucocutaneous infection (for example, oral, genital, perianal) lasting for 1 month or longer; or</p> <p>b. Infection at a site other than the skin or mucous membranes (for example, bronchitis, pneumonitis, esophagitis, or encephalitis); or</p> <p>c. Disseminated infection; or</p> <p>3. Herpes zoster:</p> <p>a. Disseminated; or</p> <p>b. With multidermatomal eruptions that are resistant to treatment; or</p> <p>4. Progressive multifocal leukoencephalopathy.</p> <p>or</p> <p>E. Malignant neoplasms:</p> <p>1. Carcinoma of the cervix, invasive, FIGO stage II and beyond; or</p> <p>2. Kaposi's sarcoma with:</p> <p>a. Extensive oral lesions; or</p> <p>b. Involvement of the gastrointestinal tract, lungs, or other visceral organs; or</p>
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<p>c. Involvement of the skin or mucous membranes, as described under the criteria in 14.08F; or</p> <p>3. Lymphoma (e.g., primary lymphoma of the brain, Burkitt's lymphoma, immunoblastic sarcoma, other non-Hodgkins lymphoma, Hodgkin's disease); or</p> <p>4. Squamous cell carcinoma of the anus.</p> <p>or</p> <p>F. Conditions of the skin or mucous membranes (other than described in B2, D2, or D3, above) with extensive fungating or ulcerating lesions not responding to treatment (e.g., dermatological conditions such as eczema or psoriasis, vulvovaginal or other mucosal candida, condyloma caused by human papillomavirus, genital ulcerative disease), or evaluate under the criteria in 8.00ff.</p> <p>or</p> <p>G. Hematologic abnormalities:</p> <p>1. Anemia, as described under the criteria in 7.02; or</p> <p>2. Granulocytopenia, as described under the criteria in 7.15; or</p> <p>3. Thrombocytopenia, as described under the criteria in 7.06.</p> <p>or</p> <p>H. Neurological abnormalities:</p> <p>1. HIV encephalopathy, characterized by cognitive or motor dysfunction that limits function and progresses; or</p>	<p>3. Lymphoma (for example, primary lymphoma of the brain, Burkitt's lymphoma, immunoblastic sarcoma, other non-Hodgkin's lymphoma, Hodgkin's disease); or</p> <p>4. Squamous cell carcinoma of the anal canal or anal margin.</p> <p>or</p> <p>F. Conditions of the skin or mucous membranes (other than described in B2, D2, or D3, above), with extensive fungating or ulcerating lesions not responding to treatment (for example, dermatological conditions such as eczema or psoriasis, vulvovaginal or other mucosal <i>Candida</i>, condyloma caused by human <i>Papillomavirus</i>, genital ulcerative disease).</p> <p>or</p> <p>G. HIV encephalopathy, characterized by cognitive or motor dysfunction that limits function and progresses.</p> <p>or</p>
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<p>2. Other neurological manifestations of HIV infection (e.g., peripheral neuropathy) as described under the criteria in 11.00ff.</p> <p>or</p> <p>I. HIV wasting syndrome, characterized by involuntary weight loss of 10 percent or more of baseline (or other significant involuntary weight loss, as described in 14.00D2) and, in the absence of a concurrent illness that could explain the findings, either:</p> <p>1. Chronic diarrhea with two or more loose stools daily lasting for 1 month or longer; or</p> <p>2. Chronic weakness and documented fever greater than 38 °C (100.4 °F) for the majority of 1 month or longer.</p> <p>or</p> <p>J. Diarrhea, lasting for 1 month or longer, resistant to treatment, and requiring intravenous hydration, intravenous alimentation, or tube feeding.</p> <p>or</p> <p>K. Cardiomyopathy, as described under the criteria in 4.00ff or 11.04.</p> <p>or</p> <p>L. Nephropathy, as described under the criteria in 6.00ff.</p> <p>or</p> <p>M. One or more of the following infections (other than described in A-L, above), resistant to treatment or requiring</p>	<p>H. HIV wasting syndrome, characterized by involuntary weight loss of 10 percent or more of baseline (computed based on pounds, kilograms, or body mass index (BMI)) or other significant involuntary weight loss as described in 14.00F5, and in the absence of a concurrent illness that could explain the findings. With either:</p> <p>1. Chronic diarrhea with two or more loose stools daily lasting for 1 month or longer; or</p> <p>2. Chronic weakness and documented fever greater than 38°C (100.4°F) for the majority of 1 month or longer.</p> <p>or</p> <p>I. Diarrhea, lasting for 1 month or longer, resistant to treatment, and requiring intravenous hydration, intravenous alimentation, or tube feeding.</p> <p>or</p> <p>J. One or more of the following infections (other than described in A-I, above). The infection(s) must either be resistant to treatment or require hospitalization or intravenous treatment three or more times in a 12-month period.</p> <p>1. Sepsis; or</p>
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<p>hospitalization or intravenous treatment 3 or more times in 1 year (or evaluate sequelae under the criteria for the affected body system).</p> <ol style="list-style-type: none"> <li>1. Sepsis; or</li> <li>2. Meningitis; or</li> <li>3. Pneumonia; or</li> <li>4. Septic arthritis; or</li> <li>5. Endocarditis; or</li> <li>6. Sinusitis documented by appropriate medically acceptable imaging.</li> </ol> <p>or</p> <p>N. Repeated (as defined in 14.00D8) manifestations of HIV infection (including those listed in 14.08A-M, but without the requisite findings, e.g., carcinoma of the cervix not meeting the criteria in 14.08E, diarrhea not meeting the criteria in 14.08J, or other manifestations, e.g., oral hairy leukoplakia, myositis) resulting in significant, documented symptoms or signs (e.g., fatigue, fever, malaise, weight loss, pain, night sweats) and one of the following at the marked level (as defined in 14.00D8):</p> <ol style="list-style-type: none"> <li>1. Restriction of activities of daily living; or</li> <li>2. Difficulties in maintaining social functioning; or</li> <li>3. Difficulties in completing tasks in a timely manner due to deficiencies in concentration, persistence, or pace.</li> </ol>	<ol style="list-style-type: none"> <li>2. Meningitis; or</li> <li>3. Pneumonia; or</li> <li>4. Septic arthritis; or</li> <li>5. Endocarditis; or</li> <li>6. Sinusitis documented by appropriate medically acceptable imaging.</li> </ol> <p>or</p> <p>K. Repeated (as defined in 14.00I3) manifestations of HIV infection, including those listed in 14.08A-J, but without the requisite findings for those listings (for example, carcinoma of the cervix not meeting the criteria in 14.08E, diarrhea not meeting the criteria in 14.08I), or other manifestations (for example, oral hairy leukoplakia, myositis, pancreatitis, hepatitis, peripheral neuropathy, glucose intolerance, muscle weakness, cognitive or other mental limitation) resulting in significant, documented symptoms or signs (for example, severe fatigue, fever, malaise, involuntary weight loss, pain, night sweats, nausea, vomiting, headaches, or insomnia) and one of the following at the marked level:</p> <ol style="list-style-type: none"> <li>1. Limitation of activities of daily living.</li> <li>2. Limitation in maintaining social functioning.</li> <li>3. Limitation in completing tasks in a timely manner due to deficiencies in concentration, persistence, or pace.</li> </ol>
<p>14.09 <i>Inflammatory arthritis</i>. Documented as described in 14.00B6, with one of the following:</p> <p>A. History of joint pain, swelling, and tenderness, and signs on current physical</p>	<p>14.09 <i>Inflammatory arthritis</i>. As described in 14.00D6. With:</p> <p>A. Persistent inflammation or persistent deformity of:</p>

<p>examination of joint inflammation or deformity in two or more major joints resulting in inability to ambulate effectively or inability to perform fine and gross movements effectively, as defined in 14.00B6b and 1.00B2b and B2c; or</p> <p>B. Ankylosing spondylitis or other spondyloarthropathy, with diagnosis established by findings of unilateral or bilateral sacroiliitis (e.g., erosions or fusions), shown by appropriate medically acceptable imaging, with both:</p> <ol style="list-style-type: none"> <li>1. History of back pain, tenderness, and stiffness, and</li> <li>2. Findings on physical examination of ankylosis (fixation) of the dorsolumbar or cervical spine at 45° or more of flexion measured from the vertical position (zero degrees);</li> </ol> <p>or</p> <p>C. An impairment as described under the criteria in 14.02A.</p> <p>or</p> <p>D. Inflammatory arthritis, with signs of peripheral joint inflammation on current examination, but with lesser joint involvement than in A and lesser extra-articular features than in C, and:</p> <ol style="list-style-type: none"> <li>1. Significant, documented constitutional symptoms and signs (e.g., fatigue, fever, malaise, weight loss), and</li> <li>2. Involvement of two or more organs/body systems (see 14.00B6d). At least one of the organs/body systems must be involved to at least a moderate level of severity.</li> </ol>	<ol style="list-style-type: none"> <li>1. One or more major peripheral weight-bearing joints resulting in the inability to ambulate effectively (as defined in 14.00C6); or</li> <li>2. One or more major peripheral joints in each upper extremity resulting in the inability to perform fine and gross movements effectively (as defined in 14.00C7).</li> </ol> <p>or</p> <p>B. Inflammation or deformity in one or more major peripheral joints with:</p> <ol style="list-style-type: none"> <li>1. Involvement of two or more organs/body systems with one of the organs/body systems involved to at least a moderate level of severity; and</li> <li>2. At least two of the constitutional symptoms or signs (severe fatigue, fever, malaise, or involuntary weight loss).</li> </ol> <p>or</p> <p>C. Ankylosing spondylitis or other spondyloarthropathies, with:</p> <ol style="list-style-type: none"> <li>1. Ankylosis (fixation) of the dorsolumbar or cervical spine as shown by appropriate medically acceptable imaging and measured on physical examination at 45° or more of flexion from the vertical position (zero degrees); or</li> <li>2. Ankylosis (fixation) of the dorsolumbar or cervical spine as shown by appropriate medically acceptable imaging and measured on physical examination at 30° or more of flexion (but less than 45°) measured from the vertical position (zero degrees), and involvement of two or more organs/body systems with one of the organs/body systems involved to at least a</li> </ol>
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<p>or</p> <p>E. Inflammatory spondylitis or other inflammatory spondyloarthropathies, with lesser deformity than in B and lesser extra-articular features than in C, with signs of unilateral or bilateral sacroiliitis on appropriate medically acceptable imaging; and with the extra-articular features described in 14.09D.</p>	<p>moderate level of severity.</p> <p>or</p> <p>D. Repeated manifestations of inflammatory arthritis, with at least two of the constitutional symptoms or signs (severe fatigue, fever, malaise, or involuntary weight loss) and one of the following at the marked level:</p> <ol style="list-style-type: none"> <li>1. Limitation of activities of daily living.</li> <li>2. Limitation in maintaining social functioning.</li> <li>3. Limitation in completing tasks in a timely manner due to deficiencies in concentration, persistence, or pace.</li> </ol>
	<p>14.10 <i>Sjögren's syndrome</i>. As described in 14.00D7. With:</p> <p>A. Involvement of two or more organs/body systems, with:</p> <ol style="list-style-type: none"> <li>1. One of the organs/body systems involved to at least a moderate level of severity; and</li> <li>2. At least two of the constitutional symptoms or signs (severe fatigue, fever, malaise, or involuntary weight loss).</li> </ol> <p>or</p> <p>B. Repeated manifestations of Sjögren's syndrome, with at least two of the constitutional symptoms or signs (severe fatigue, fever, malaise, or involuntary weight loss) and one of the following at the marked level:</p> <ol style="list-style-type: none"> <li>1. Limitation of activities of daily living.</li> <li>2. Limitation in maintaining social functioning.</li> <li>3. Limitation in completing tasks in</li> </ol>

	a timely manner due to deficiencies in concentration, persistence, or pace.
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