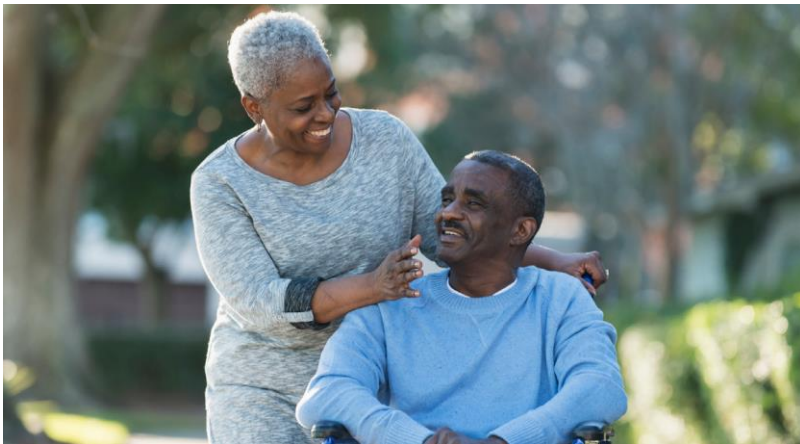


National Academies HMD – Immune System Disorders Task Order

January 11, 2021



Securing today
and tomorrow



National Academies Task Order – Immune System Disorders

Background and basis for task order

- SSA evaluates adult disability claims in a 5-step sequential evaluation
- SSA evaluates childhood disability claims in a 3-step sequential evaluation
- Once the presence of a severe medically determinable impairment is established, we evaluate whether the impairment **meets** or **medically equals** the criteria in the Listing of Impairments
- SSA seeks the most current information available on immune disorders

Objective of Task Order

- Provide an overview of the current status of the diagnosis, treatment, and prognosis of select immune system disorders in the U.S. population, including systemic lupus erythematosus, scleroderma, polymyositis, Sjögren's syndrome, and inflammatory arthritis
- Describe the relative levels of functional limitation typically associated with the immune system disorders, common treatments, and other considerations

The Social Security Act: Two Disability Programs

Social Security Disability Insurance (SSDI)	Supplemental Security Income (SSI)
Title II (Est. 1954)	Title XVI (Est. 1972)
Funded through FICA (Social Security) taxes	Funded through the General Fund
Benefits based on work	Benefits based on need
People who qualify are automatically enrolled in Medicare after being entitled to disability benefits for 24 months	People who qualify also qualify for Medicaid

Statutory Definition of Disability for Adults

The Social Security Act defines disability as:

- The inability to engage in any **substantial gainful activity**
- By reason of any medically determinable impairment(s) (MDI) (physical or mental or combination)
- Which can be expected to result in **death** or
- Which has lasted or can be expected to last for a continuous period of not less than **12 months**

Sequential Evaluation for Adults

The disability determination for adults follows a sequential evaluation:

1. **Substantial Gainful Activity (SGA)** – The 2021 SGA amount is **\$1310**.
2. **Severe Impairment(s)** – The medically determinable impairment(s) must significantly limit the ability to do basic work activities (e.g. walking, sitting, standing, lifting, or remembering). The MDI must last or be expected to last for a continuous period of at least 12 months, or be expected to result in death.
3. **Meets or medically equals a listing** – The listings describe impairments for 14 body systems for adults.
4. **Prevents past relevant work** – We determine the claimant's residual functional capacity (RFC) based on work-related physical and mental limitations from their MDI(s). We then compare the claimant's RFC to the functional demands of their past relevant work, both as they actually performed it and as it is generally performed in the national economy.
5. **Prevents other work** – We compare the claimant's RFC and vocational factors (age, education, and past work experience) to work in the national economy.

Statutory Definition of Disability for Children

The Social Security Act defines disability for children as:

- A medically determinable physical or mental impairment (or combination of impairments); which
- Results in marked and severe functional limitations; and
- Which can be expected to result in **death** or
- Which has lasted or can be expected to last for a continuous period of not less than **12 months**

Sequential Evaluation for Children

The disability determination for children follows a sequential evaluation:

1. **Substantial Gainful Activity (SGA)**
2. **Severe Impairment(s)**
3. **Meets, medically equals, or functionally equals a listing** – The listings describe impairments for 15 body systems for children

Importance of the Listing of Impairments

- The Listing of Impairments describes, for each major body system, impairments considered severe enough to prevent an individual from doing any gainful activity, or, in the case of children under age 18 applying for SSI, severe enough to cause marked and severe functional limitations. Most of the listed impairments are permanent or expected to result in death, or the listing includes a specific statement of duration.
- The criteria in the Listing of Impairments apply only to one step (the third step) of the multi-step sequential evaluation process. At that step, the presence of an impairment that meets the criteria in the Listing of Impairments (or that is of equal severity) is usually sufficient to establish that an individual who is not working is disabled. However, the absence of a listing-level impairment does not mean the individual is not disabled. Rather, it merely requires the adjudicator to move on to the next step of the process and apply other rules in order to resolve the issue of disability.

Immune System Disorders Listings (14.00 and 114.00) – Overview

Scope & Application of Immune System Disorders Listings (14.00 and 114.00)

- **What impairments do these listings cover?**

- Autoimmune Diseases – 7 listings
- Immune Deficiency Disorders Excluding HIV Infection (listing 14.07/114.07)
- HIV Infection (listing 14.11/114.11 – formerly 14.08/114.08)
 - Updated recently (2017)

- **How do immune system disorders cause listing-level impairment?**

- 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 weight loss, can also result in extreme limitation.

Immune System Disorders Listings (14.00 and 114.00) – Overview

What are the specific autoimmune disorders addressed in Listings 14.00 and 114.00?

- **14.02 Systemic Lupus Erythematosus**
- **14.03 Systemic Vasculitis**
- **14.04 Systemic Sclerosis (Scleroderma)**
- **14.05 Polymyositis and Dermatomyositis**
- **14.06 Undifferentiated and Mixed Connective Tissue Disorder**
- **14.10 Sjögren's syndrome**
- **14.09 Inflammatory Arthritis**
 - **Does not include osteoarthritis – evaluated in musculoskeletal listings**
 - **Includes peripheral and axial inflammatory arthritic conditions such as:**
 - Rheumatoid Arthritis
 - Crystal deposition disorders (i.e. gout, psuedogout)
 - Lyme disease
 - Reactive arthritis (“Reiter's syndrome”)
 - Ankylosing spondylitis
 - Psoriatic arthritis
 - Whipple's disease
 - Behçet's disease
 - IBD– related spondyloarthropathies

Immune System Disorders Listings (14.00 and 114.00) – Overview

How are immune disorders addressed in Listings 14.00 and 114.00?

- **Recognizing the systemic nature of immune disease**
 - Introductory text (14.00A-I and 114.00A-I) describes the body systems and organs typically impacted by the disease in addition to defining the various criteria and documentation requirements
- **All but one of the autoimmune listings includes criteria for involvement of two or more organs/body systems, with:**
 - One involved to at least a moderate level of severity; and
 - At least two of the four constitutional symptoms or signs (severe fatigue, fever, malaise, or involuntary weight loss)
- **All adult immune listings include criteria for repeated manifestations of the disorder, with at least two of the constitutional symptoms or signs and marked limitations in one of the following (“functional criteria”):**
 - Activities of daily living
 - Maintaining social functioning
 - Completing tasks in a timely manner due to deficiencies in concentration, persistence, or pace

Immune System Disorders Listings (14.00 and 114.00) – Overview

How are immune disorders addressed in Listings 14.00 and 114.00?

- **How do we use the functional criteria in these listings?**
 - We consider: symptoms (physical and mental, including pain and fatigue), frequency and duration of manifestations, periods of exacerbation and remission, and functional impact of treatment
 - “Repeated” manifestations mean average of 3 times per year lasting 2 weeks or more
 - “Marked” limitation means that the disorder seriously interferes with ability to function independently, appropriately, and effectively
 - Does not require complete inability to do the activity/activities
 - Can be limitations in one or more activities within each area of function – does not have to be all
 - Activities of daily living include: doing household chores, grooming and hygiene, using a post office, taking public transportation, or paying bills
 - Social functioning includes: capacity to interact independently, appropriately, effectively, and on a sustained basis with others
 - Completing tasks in a timely manner involves: ability to sustain concentration, persistence, or pace to permit timely completion of tasks commonly found in work settings

Immune System Disorders Listings (14.00 and 114.00) – Overview

How are immune disorders addressed in Listings 14.00 and 114.00?

- **How do we evaluate functional impact due to joint damage or other impacts on musculoskeletal function?**
 - Currently, we consider the impact on the ability to ambulate effectively or perform fine and gross movements (with the upper extremities) effectively in the following listings: 14.04/114.04, 14.05/114.05, and 14.09/114.09
 - We recently published a new Final Rule for musculoskeletal disorders, which includes some changes to the immune system disorders listings, and will be effective on **April 2, 2021**. We now assess the following when evaluating severity of musculoskeletal limitation:
 - A documented medical need for a walker, bilateral canes, or bilateral crutches or a wheeled and seated mobility device involving the use of both hands;
 - An inability to use one upper extremity to independently initiate, sustain, and complete work-related activities involving fine and gross movements, and a documented medical need for a one-handed, hand-held assistive device that requires the use of your other upper extremity or a wheeled and seated mobility device involving the use of one hand; or
 - An inability to use both upper extremities to the extent that neither can be used to independently initiate, sustain, and complete work-related activities involving fine and gross movements.

Immune System Disorders Listings (14.00 and 114.00) – Overview

How are immune disorders addressed in Listings 14.00 and 114.00?

- **How do we evaluate functional impact due to joint damage or other impacts on musculoskeletal function?**
 - The new musculoskeletal functional criteria consider the inability to use both upper extremities for fine and gross movements (whether due to upper extremity impairment or use of the hand(s) to operate an assistive device, or a combination of both) as indicative of listing-level functional limitation
 - The required impairment-related physical limitation of musculoskeletal functioning must have lasted, or be expected to last, for a continuous period of at least 12 months.

Immune System Disorders Listings (14.00 and 114.00) – Overview

Examples of Listing Criteria: Systemic Lupus Erythematosus

14.02 Systemic lupus erythematosus. As described in 14.00D1. With:

A. Involvement of two or more organs/body systems, with:

1. One of the organs/body systems involved to at least a moderate level of severity; and
2. At least two of the constitutional symptoms or signs (severe fatigue, fever, malaise, or involuntary weight loss).

OR

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:

1. Limitation of activities of daily living.
2. Limitation in maintaining social functioning.
3. Limitation in completing tasks in a timely manner due to deficiencies in concentration, persistence, or pace.

Note: Listings 14.03 (Systemic Vasculitis), 14.06 (Undifferentiated and Mixed CTD), and 14.10 (Sjögren's syndrome) are nearly identical to listing 14.02 (SLE).

Immune System Disorders Listings (14.00 and 114.00) – Overview

Examples of Listing Criteria: Scleroderma

14.04 Scleroderma with:

Two organs involved with at least one moderate severity and at least two constitutional symptoms and signs

OR

Toe or finger contractures or fixed deformity in one or both feet or both hands, or atrophy with irreversible damage in one or both lower extremities or both upper extremities, *resulting in the inability to ambulate effectively or the inability to perform fine and gross movements effectively**

OR

Raynaud's phenomenon, characterized by gangrene involving at least two extremities; or by ischemia with ulcerations of toes or fingers, *resulting in the inability to ambulate effectively or to perform fine and gross movements effectively**

OR

Repeated manifestations with at least two constitutional symptoms/signs resulting in marked functional limitations in one of the three areas of function

**Note: beginning 4/2/21, these criteria will be replaced with the new functional criteria referenced on slide 13*

Immune System Disorders Listings (14.00 and 114.00) – Overview

Examples of Listing Criteria: Polymyositis and Dermatomyositis

14.05 Polymyositis and dermatomyositis with:

Proximal limb-girdle (pelvic or shoulder) muscle weakness, resulting in *inability to ambulate effectively or inability to perform fine and gross movements effectively**

OR

Impaired swallowing (dysphagia) with aspiration due to muscle weakness.

OR

Impaired respiration due to intercostal and diaphragmatic muscle weakness.

OR

Diffuse calcinosis with limitation of joint mobility or intestinal motility.

OR

Repeated manifestations with at least two constitutional symptoms/signs resulting in marked functional limitations in one of the three areas of function

**Note: beginning 4/2/21, these criteria will be replaced with the new functional criteria referenced on slide 13*

Immune System Disorders Listings (14.00 and 114.00) – Overview

Examples of Listing Criteria: Inflammatory Arthritis

14.09 Inflammatory Arthritis with:

Persistent inflammation or persistent deformity of major peripheral joint(s) in one or more lower extremities or each upper extremity resulting in *the inability to ambulate effectively or perform fine and gross movements effectively**

OR

Inflammation or deformity in one or more major peripheral joints with two organs involved with at least one moderate severity and at least two constitutional symptoms and signs

OR

Ankylosing spondylitis or other spondyloarthropathies, with:

- Ankylosis (fixation) of the dorsolumbar or cervical spine at 45° or more of flexion from the vertical position, or
- Ankylosis (fixation) of the dorsolumbar or cervical spine at 30° or more of flexion (but less than 45°) and involvement of two or more organs/body systems with at least one moderate severity

OR

Repeated manifestations with at least two constitutional symptoms/signs resulting in marked functional limitations in one of the three areas of function

**Note: beginning 4/2/21, these criteria will be replaced with the new functional criteria referenced on slide 13*

Immune System Disorders Listings (14.00 and 114.00) – Overview

Examples of Listing Criteria: Immune Deficiency Disorders, Excluding HIV infection

14.07 Immune deficiency disorders, excluding HIV infection with:

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.

- | | | |
|--------------|--------------------|-----------------------------------------------|
| • Sepsis | • Pneumonia | • Endocarditis |
| • Meningitis | • Septic arthritis | • Sinusitis documented by appropriate imaging |

OR

Stem cell transplantation

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

OR

Repeated manifestations with at least two constitutional symptoms/signs resulting in marked functional limitations in one of the three areas of function

Questions?

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