

and attaching Inline XBRL documents to EDGAR submissions are described in a new subsection 5.2.5 of EDGAR Filer Manual, Volume II.

Along with the adoption of the Filer Manual, we are amending Rule 301 of Regulation S–T to provide for the incorporation by reference into the Code of Federal Regulations of today’s revisions. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

The updated EDGAR Filer Manual will be available for Web site viewing and printing; the address for the Filer Manual is <http://www.sec.gov/info/edgar.shtml>. You may also obtain paper copies of the EDGAR Filer Manual from the following address: Public Reference Room, U.S. Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m.

Since the Filer Manual and the corresponding rule changes relate solely to agency procedures or practice, publication for notice and comment is not required under the Administrative Procedure Act (APA).<sup>4</sup> It follows that the requirements of the Regulatory Flexibility Act<sup>5</sup> do not apply.

The effective date for the updated Filer Manual and the rule amendments is July 1, 2016. In accordance with the APA,<sup>6</sup> we find that there is good cause to establish an effective date less than 30 days after publication of these rules. The EDGAR system upgrade to Release 16.2 is scheduled to become available on June 13, 2016. The Commission believes that establishing an effective date less than 30 days after publication of these rules is necessary to coordinate the effectiveness of the updated Filer Manual with these system upgrades.

#### Statutory Basis

We are adopting the amendments to Regulation S–T under Sections 6, 7, 8, 10, and 19(a) of the Securities Act of 1933,<sup>7</sup> Sections 3, 12, 13, 14, 15, 23, and 35A of the Securities Exchange Act of 1934,<sup>8</sup> Section 319 of the Trust Indenture Act of 1939,<sup>9</sup> and Sections 8, 30, 31, and 38 of the Investment Company Act of 1940.<sup>10</sup>

#### List of Subjects in 17 CFR Part 232

Incorporation by reference, Reporting and recordkeeping requirements, Securities.

#### Text of the Amendment

In accordance with the foregoing, title 17, chapter II of the Code of Federal Regulations is amended as follows:

#### PART 232—REGULATION S–T— GENERAL RULES AND REGULATIONS FOR ELECTRONIC FILINGS

■ 1. The authority citation for part 232 continues to read in part as follows:

**Authority:** 15 U.S.C. 77f, 77g, 77h, 77j, 77s(a), 77z–3, 77sss(a), 78c(b), 78l, 78m, 78n, 78o(d), 78w(a), 78ll, 80a–6(c), 80a–8, 80a–29, 80a–30, 80a–37, and 7201 *et seq.*; and 18 U.S.C. 1350, unless otherwise noted.

\* \* \* \* \*

■ 2. Section 232.301 is revised to read as follows:

#### § 232.301 EDGAR Filer Manual.

Filers must prepare electronic filings in the manner prescribed by the EDGAR Filer Manual, promulgated by the Commission, which sets out the technical formatting requirements for electronic submissions. The requirements for becoming an EDGAR Filer and updating company data are set forth in the updated EDGAR Filer Manual, Volume I: “General Information,” Version 24 (December 2015). The requirements for filing on EDGAR are set forth in the updated EDGAR Filer Manual, Volume II: “EDGAR Filing,” Version 37 (June 2016). Additional provisions applicable to Form N–SAR filers are set forth in the EDGAR Filer Manual, Volume III: “N–SAR Supplement,” Version 5 (September 2015). All of these provisions have been incorporated by reference into the Code of Federal Regulations, which action was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You must comply with these requirements in order for documents to be timely received and accepted. The EDGAR Filer Manual is available for Web site viewing and printing; the address for the Filer Manual is <http://www.sec.gov/info/edgar.shtml>. You can obtain paper copies of the EDGAR Filer Manual from the following address: Public Reference Room, U.S. Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. You can also inspect the document at the National Archives and Records Administration (NARA). For information on the

availability of this material at NARA, call 202–741–6030, or go to: [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

By the Commission.

Dated: June 13, 2016.

**Brent J. Fields,**  
Secretary.

[FR Doc. 2016–15510 Filed 6–30–16; 8:45 am]

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#### SOCIAL SECURITY ADMINISTRATION

#### 20 CFR Part 404

[Docket No. SSA–2006–0140]

RIN 0960–AF35

#### Revised Medical Criteria for Evaluating Neurological Disorders

**AGENCY:** Social Security Administration.

**ACTION:** Final rule.

**SUMMARY:** We are revising the criteria in the Listing of Impairments (listings) that we use to evaluate disability claims involving neurological disorders in adults and children under titles II and XVI of the Social Security Act (Act). These revisions reflect our program experience; advances in medical knowledge, treatment, and methods of evaluating neurological disorders; comments we received from medical experts and the public at an outreach policy conference; responses to an advance notice of proposed rulemaking (ANPRM); and public comments we received in response to a Notice of Proposed Rulemaking (NPRM) and a **Federal Register** notice that reopened the NPRM comment period.

**DATES:** This rule is effective September 29, 2016.

**FOR FURTHER INFORMATION CONTACT:** Cheryl A. Williams, Office of Disability Policy, Social Security Administration, 6401 Security Boulevard, Baltimore, Maryland 21235–6401, (410) 965–1020. For information on eligibility or filing for benefits, call our national toll-free number 1–800–772–1213, or TTY 1–800–325–0778, or visit our Internet site, Social Security Online, at <http://www.socialsecurity.gov>.

#### SUPPLEMENTARY INFORMATION:

#### Background

We are making final the rule for evaluating neurological disorders that we proposed in an NPRM published in the **Federal Register** on February 25, 2014 (79 FR 10636). In the preamble to the NPRM, we discussed the revisions to our current rule for the neurological

<sup>4</sup> 5 U.S.C. 553(b).

<sup>5</sup> 5 U.S.C. 601–612.

<sup>6</sup> 5 U.S.C. 553(d)(3).

<sup>7</sup> 15 U.S.C. 77f, 77g, 77h, 77j, and 77s(a).

<sup>8</sup> 15 U.S.C. 78c, 78l, 78m, 78n, 78o, 78w, and 78ll.

<sup>9</sup> 15 U.S.C. 77sss.

<sup>10</sup> 15 U.S.C. 80a–8, 80a–29, 80a–30, and 80a–37.

body system and our reasons for proposing those revisions. To the extent that we are adopting the proposed rule as published, we are not repeating that information here; interested readers may refer to the NPRM preamble. We incorporated into the final rule the portions of Social Security Ruling (SSR) 87-6, "Titles II and XVI: The Role of Prescribed Treatment in the Evaluation of Epilepsy" that continue to be relevant to the treatment of epilepsy. As part of the publication of this final rule, we are rescinding SSR 87-6. We also respond to public comments on the NPRM and explain what changes we are making based on those comments in the "Public Comments on the NPRM" section of the preamble.

### Why are we revising the listings for evaluating neurological disorders?

We are comprehensively revising the listings for evaluating neurological disorders to update the medical criteria, provide additional methods of evaluating neurological disorders, provide more information on how we evaluate neurological disorders, make other changes that reflect our program experience, and address adjudicator questions. We last comprehensively revised the listings for the neurological disorders body system in a final rule published on December 6, 1985.<sup>1</sup> We have made only a few changes since then to meet program purposes.<sup>2</sup>

### Summary of Public Comments on the NPRM

In the NPRM, we provided the public with a 60-day comment period that ended on April 28, 2014. We reopened the comment period for 30 days on May 1, 2014 (70 FR 24634). The last of the two comment periods closed on June 2, 2014. We received and posted 2,103 public comments during the initial period for public comments on the NPRM, and received and posted an additional 921 when we extended the NPRM comment period. We also received and posted 55 comments when we initially made the public aware of our efforts to update this rule, when we

published the ANPRM. The comments came from members of the public, medical professionals, national medical organizations, advocacy groups, disability examiners and other adjudicators, and a national association representing disability examiners in the State agencies that make disability determinations for us.

The majority of the comments was repetitive and expressed support of or agreement with identical recommendations submitted by a few national organizations. For example, we received just over 1,100 comments that repeated, or were in support of recommendations submitted by a few Huntington's disease organizations; approximately 800 comments that repeated, or were in support of recommendations submitted by various headache organizations; and approximately 350 repeat comments that were in support of recommendations from various Parkinson's disease organizations.

In general, the recommendations and concerns raised by the majority of public commenters were very similar or identical. We received several comments suggesting that we create separate listings for various neurological disorders that we address in one comment below. Some commenters noted provisions with which they agreed and did not make suggestions for changes in those provisions. For example, over 300 comments were testimonials from commenters sharing their personal experience with various neurological disorders. Approximately 300 comments were outside the scope of the neurological NPRM, several of those were relevant to other body system disorders; we shared those comments with the appropriate body systems policy teams for consideration. We did not summarize or respond to comments that were in agreement with, or outside the scope of the neurological NPRM. We addressed repetitive comments that raised identical issues as one comment.

We carefully considered all of the relevant comments we received and we responded to all of the significant issues raised by the commenters that were within the scope of this rule. We provide our reasons for adopting or not adopting the comment recommendations in our responses below.

### General Comments

*Comment:* Several commenters suggested that we create separate listings for various neurological disorders, such as migraine, cluster headaches and other severe headache disorders, fetal alcohol syndrome,

cervical dystonias, atypical facial pain, and trigeminal neuralgia. One commenter expressed opposition to creating a separate listing for migraine headaches because the symptoms are too subjective. Other commenters suggested adding several neurological disorders to specific listings.

*Response:* We did not adopt these comments. While we do not have listings for every neurological condition, we are able to evaluate unlisted neurological disorders in several ways under our sequential evaluation process. We will determine whether your impairment medically equals a listing. If your impairment does not medically equal the criteria of a listing, you may or may not have the residual functional capacity to perform your past relevant work or adjust to other work that exists in significant numbers in the national economy, which we determine at the fourth and, if necessary, the fifth steps of the sequential evaluation process. As we work on the next iteration of revisions to the neurological rule, we will consider the suggestions for adding new listings and will consider comments expressing opposition to adding certain new listings.

*Comment:* We received a number of comments related to how we evaluate migraines and other chronic headache disorders. As we mentioned in the previous comment, several commenters asked that we recognize migraines as a disabling impairment and suggested we create a specific listing. Other commenters suggested listing criteria for us to consider. One commenter raised concerns about evaluating chronic headache disorders because of the subjective nature of the disorders.

*Response:* We acknowledge the commenters' concerns. We realize it is appropriate to provide impairment-specific guidance on how we evaluate migraines and other chronic headache disorders. We will address these concerns in training to ensure all adjudicators know how to establish migraine and other chronic headache disorders as medically determinable impairments (MDIs). Once we establish the existence of an MDI(s), we follow the remaining steps in the sequential evaluation process (See §§ 404.1520, 416.920, and 416.924). As noted in the response above to the comments about creating additional listings, we are able to evaluate unlisted neurological disorders in several ways under our sequential evaluation process.

*Comment:* We received several comments expressing concern that the proposed functional criteria for determining disability in individuals with Huntington's disease (HD) and

<sup>1</sup> 50 FR 50068.

<sup>2</sup> On December 12, 1990, we raised the IQ limit in 11.07A, 111.02B1, 111.07B1, and 111.08B2 from 69 to 70 (55 FR 51204). We published a final rule adding section 11.00F for traumatic brain injury on August 21, 2000 (65 FR 50746); made technical revisions to most of the body systems on April 24, 2002 (67 FR 20018), which included some changes to the neurological body system; revised listing 11.10 for Amyotrophic lateral sclerosis (ALS) on August 82, 2003 (68 FR 51689); moved the listings for malignant brain tumors to the body system for malignant neoplastic diseases on November 15, 2004 (69 FR 67018); and made a technical correction in listing 111.09 on March 24, 2011 (76 FR 16531).

Parkinson's disease still rely on the presence of physical limitations and do not adequately address the common non-physical manifestations of these diseases. The commenters suggested we include the mental criteria from the mental body system in the neurological disorders body system to evaluate the mental aspects of neurological disorders in the absence of physical limitations commonly seen in HD and in Parkinson's disease. They indicated the proposed criteria should include criteria specific to mental functioning in order to address the full range of symptoms often experienced by people who suffer with HD and Parkinson's disease. The commenters also suggested that the proposed introductory text sections where we discuss HD and Parkinson's disease direct adjudicators beyond listing 12.02 to expand to the entire mental body system, as appropriate, when they need to evaluate mental symptoms associated with neurological disorders.

*Response:* We partially adopted this comment. For program purposes, we consider all impairments under all applicable body systems as part of our disability evaluation. In the listings, we describe each of the major body systems impairments we consider severe enough to be disabling, and we list requirements that demonstrate a level of severity and duration consistent with the definition of disability set by Congress under the Act. We evaluate the person's impairment(s) under the most appropriate body system(s). We recognize that neurological disorders may co-occur with impairments we evaluate in other body systems; however, we intend the listings in this final rule to address only neurological disorders and the complications from those disorders. When only mental aspects of neurological disorders are present in the absence of physical limitations commonly seen in HD and Parkinson's disease, we evaluate those limitations under the appropriate mental disorders body system listings. However, when mental aspects of neurological disorders are present and co-occur with the physical limitations of these disorders, we evaluate limitations in physical and mental functioning under the neurological listings. In response to this and similar comments, we provided additional guidance in the introductory text explaining how we evaluate mental disorders under these listings.

We modified our functional criteria and severity rating scale to address the common mental aspects of neurological disorders. Our intent in the new functional criteria for adults is to

provide a way to evaluate impairments and determine disability appropriately, even when those impairments are difficult to evaluate based on medical criteria alone. With functional criteria, we can evaluate the functional impact associated with any neurological impairment in broad areas of physical and mental functioning. The four areas of mental functioning are understanding, remembering, or applying information; interacting with others; concentrating, persisting, or maintaining pace; and adapting or managing oneself. For example, a person with a neurological disorder may demonstrate a limitation in the ability to walk (as addressed under the physical functioning criterion). He or she may also have a mental impairment resulting from the neurological disorder, which is demonstrated by a limitation in the ability to concentrate.

*Comment:* A commenter stated that the definition of social functioning in proposed section 11.00G3 should not focus solely on limitations caused by physical ailments. The commenter suggested that the social functioning criteria should include interpersonal interactions, as well as non-physical symptoms such as irritability, aggression, and perseveration.

*Response:* We adopted this comment. We mentioned in the previous comment we modified our functional criteria to focus on the common mental aspects of neurological disorders. We also changed the criterion from "social functioning" to "interacting with others" to be consistent with the way mental functions are described in the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition*.<sup>3</sup>

*Comment:* Several commenters noted that proposed section 11.00C states, "Medical research shows that these neurological conditions may improve after a period of treatment." The commenters pointed out this statement is false and we should correct it because Parkinson's disease never improves.

*Response:* We adopted this comment. It was not our intent to indicate in listing 11.06 that Parkinson's disease itself may improve with treatment, as the disease is progressive. We removed the statement.

*Comment:* Several commenters asked that we revise proposed section 11.00K to clarify that motor and non-motor symptoms can be equally disabling in Parkinsonian syndromes, and to reflect that symptoms can fluctuate

significantly from hour to hour and minute to minute, often making job performance in a professional environment very difficult.

*Response:* We partially adopted this comment. We agree that non-motor symptoms can be as disabling as motor symptoms in Parkinsonian syndromes. However, limitations resulting from non-motor symptoms are highly variable and we evaluate them on a case-by-case basis. The new functional criteria enable adjudicators to evaluate non-motor symptoms associated with Parkinsonian syndromes under listing 11.06B. We mention that neurological disorders may manifest in a combination of limitations in physical and mental functioning in the adult section, 11.00G. We will also provide guidance in training to adjudicators about the variable manifestations of neurological disorders, such as Parkinsonian syndrome.

*Comment:* One commenter expressed disappointment that the revised epilepsy listing does not include any discussion of how to "deal with claimants who suffer from a mix of tonic-clonic and discognitive seizures." The commenter stated that "although the revised listing explicitly acknowledges that individuals may suffer from a mix of tonic-clonic and discognitive seizures,<sup>4</sup> there is no guidance as to how to evaluate a claimant experiencing both types of seizures."

*Response:* We do not agree with the commenter. In section 11.00H4c, we provide guidance on how to count discognitive seizures that progress into generalized tonic-clonic seizures. However, we do not believe that it is possible to address every permutation of the discognitive and tonic-clonic mixed seizure types. The signs and symptoms of such seizure types will vary from person to person. Adjudicators evaluate limitations caused by mixed seizures on a case-by-case basis.

*Comment:* One commenter was pleased that we included a more detailed explanation for the term "marked" in 11.00G2 but was concerned that this definition relied on the term "seriously," as in "interfere seriously" and "seriously limit," which we did not define. This commenter believed that not defining the term "seriously," while repeatedly relying on it to define the term "marked," creates a significant ambiguity in the listings. The commenter was concerned that adjudicators will apply the term "marked" inconsistently unless we

<sup>3</sup> American Psychiatric Association: *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition*, Arlington, VA, American Psychiatric Association, 2013.

<sup>4</sup> See NPRM 11.00H(4)(c).

include a definition for the term “seriously.”

*Response:* We partially adopted this comment. In the modified final section 11.00D of the introductory text, we include criteria for how to establish disorganization of motor function, descriptions for how to evaluate those criteria, and a definition of an extreme limitation in disorganization of motor function. If we do not find that a person is disabled on the basis of disorganization of motor function alone, as explained in 11.00D, we will find that the person’s neurological disorder is incompatible with the ability to do any gainful activity if it results in marked limitation in physical functioning and marked limitation in one of four areas of mental functioning. In the modified final section 11.00G of the introductory text, we provide definitions for marked limitations drawn from our currently used definitions in section 7.00G4 of the listing of impairments for hematological disorders and section 1.00B of the listing of impairments for musculoskeletal disorders. We also provide descriptions of the considerations for physical and mental functioning in 11.00G2 and 11.00G3.

*Comment:* One commenter suggested that we not remove the intelligence quotient (IQ) requirement from the neurological listings, as the commenter believes it is the best indicator of mental capability.

*Response:* We did not adopt this comment. As we explained in the preamble to the NPRM, we are removing the criterion of an IQ score from our neurological listings because advances in medical knowledge of cerebral palsy (for adults and children), epilepsy (for children), spinal cord insults (for children), and our program experience indicate that an IQ score does not provide the best measure of limitations in cognitive functioning associated with these disorders. Therefore, it may not indicate listing-level severity under the neurological listings and would be more appropriately used to evaluate mental disorders under our mental disorders body system.

*Comment:* One commenter expressed that scales rating function into categories such as “mild,” “moderate,” and “severe,” are clearly subjective on the part of the rater and their meaningfulness is questionable.

*Response:* The word “severe” in the disability program separates step 2 from step 3 in the sequential evaluation process that we use to evaluate a person’s physical or mental impairment or combination of impairments. If we find at step 2 that a person does not

have a “severe” medically determinable impairment (MDI) or combination of MDIs that meet the duration requirement, we will find the person is not disabled. If we find at step 2 that the person has a “severe” MDI or combination of MDIs, we will continue evaluating the impairment(s) at step 3 of the sequential evaluation process. (See §§ 404.1520(a), 416.920(a) and 416.924(a).) With respect to the terms, “mild” and “moderate,” we have used those terms in a five-point rating scale in the mental disorders body system (consisting of none, mild, moderate, marked, and extreme) since 1985 (§§ 404.1520a and 416.920a). We have also used the terms “marked” and “extreme” limitation in childhood functional equivalence policy (§§ 416.926a). Such scales and ratings continue to be standard medical practice, and continue to be effective for evaluating degrees of impairment-related limitation(s). Moreover, in the modified final introductory text (11.00D2, 11.00G2, and 11.02D2), we include guidance for our adjudicators on the meaning and use of these terms.

*Comment:* One commenter said a significant feature of the proposed new criteria is that we will presume individuals (with many different neurological disorders) are disabled if they are unable to stand from a sitting position and are not presently working. The commenter noted that it appears obvious from casual observation that many individuals successfully work in a wide variety of different sedentary positions, such as Wal-Mart greeter, office worker, and physician. Because significant numbers of these individuals work on a regular basis in the national economy, it is quite easy for a lay observer to think it inappropriate for the Social Security Administration to presume that all individuals unable to stand are also unable to work.

*Response:* We did not adopt this comment. As we explain in 11.00D2a, an inability to stand up from a seated position means that, once seated, you are unable to stand and maintain an upright position without the risk of falling unless you have the assistance of another person or the use of an assistive device, such as a walker, two crutches, or two canes. The severity of such a limitation is set at a standard much higher than that applicable to a person who is able to do sedentary work; it thereby constitutes an inability to do any gainful activity in the national economy.

*Comment:* One commenter suggested that when referring to spinal cord insults we use the term “spinal cord

disorders” instead of “spinal cord insults.”

*Response:* We agree with the commenter and adopted this comment.

*Comment:* Some commenters asked how we would evaluate adherence to prescribed treatment for epilepsy patients when we removed the requirement for serum drug levels, particularly for patients prescribed newer antiepileptic drugs.

*Response:* We describe how we consider adherence to prescribed treatment under 11.00C. We consider whether you have taken medications or followed other treatment procedures as prescribed by a physician for three consecutive months. We no longer require serum drug levels. When we last revised the listings in 1985, blood drug levels were strong indicators for prescribed treatment compliance because therapeutic ranges had been established for antiepileptic drugs (AEDs) and the ranges were often noted on laboratory results. Many newer AEDs do not have established therapeutic levels, which makes lab results difficult for our adjudicators to interpret. We removed the requirement for obtaining blood drug levels to address this adjudicative issue and to simplify evaluation of seizures that satisfy the listing criteria. However, we will continue to consider blood drug levels available in the evidence in the context of all evidence in the case record.

#### **What is our authority to make rules and set procedures for determining whether a person is disabled under the statutory definition?**

The Act authorizes us to make rules and regulations and to establish necessary and appropriate procedures to implement them.<sup>5</sup>

#### **When will we begin to use this final rule?**

We will begin to use this final rule on its effective date. We will continue to use the current listings until the date the final rule becomes effective. We will apply the final rule to new applications filed on or after the effective date of the final rule and to claims that are pending on or after the effective date.<sup>6</sup>

<sup>5</sup> 42 U.S.C. 405(a), 902(a)(5), and 1383(d)(1).

<sup>6</sup> This means that we will use the final rule on and after their effective date in any case in which we make a determination or decision. We expect that Federal courts will review the Commissioner’s final decisions using the rule that were in effect at the time we issued the decisions. If a court reverses the Commissioner’s final decision and remands a case for further administrative proceedings after the effective date of the final rule, we will apply the final rule to the entire period at issue in the decision we make after the court’s remand.

**How long will this final rule be effective?**

This final rule will remain in effect for 5 years after the date it becomes effective, unless we extend it, or revise and issue it again.

**Regulatory Procedures**

**Executive Order 12866, as Supplemented by Executive Order 13563**

We consulted with the Office of Management and Budget (OMB) and determined that this final rule meets the criteria for a significant regulatory action under Executive Order 12866, as supplemented by Executive Order 13563. Therefore, OMB reviewed it.

**Regulatory Flexibility Act**

We certify that this final rule will not have a significant economic impact on a substantial number of small entities because it affects only individuals. Therefore, the Regulatory Flexibility Act, as amended, does not require us to prepare a regulatory flexibility analysis.

**Paperwork Reduction Act**

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

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

**List of Subjects in 20 CFR Part 404**

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

**Carolyn W. Colvin,**

*Acting Commissioner of Social Security.*

For the reasons set out in the preamble, we are amending 20 CFR part 404, subpart P as set forth below:

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

**Subpart P—Determining Disability and Blindness**

■ 1. The authority citation for subpart P of part 404 continues to read as follows:

**Authority:** Secs. 202, 205(a)–(b) and (d)–(h), 216(i), 221(a), (i), and (j), 222(c), 223, 225, and 702(a)(5) of the Social Security Act (42 U.S.C. 402, 405(a)–(b) and (d)–(h), 416(i), 421(a), (i), and (j), 422(c), 423, 425, and 902(a)(5)); sec. 211(b), Pub. L. 104–193, 110 Stat. 2105, 2189; sec. 202, Pub. L. 108–203, 118 Stat. 509 (42 U.S.C. 902 note).

- 2. Amend appendix 1 to subpart P of part 404 as follows:
  - a. Revise item 12 of the introductory text before part A;
  - b. Amend part A by revising the body system name for section 11.00 in the table of contents;
  - c. In section 1.00 of part A, revise the introduction to paragraph K;
  - d. Revise section 11.00 of part A;
  - e. In section 12.00 of part A, revise paragraph D10, listing 12.01, listing 12.09E, and listing 12.09I;
  - f. Amend part B by revising the body system name for section 111.00 in the table of contents;
  - g. In section 101.00 of part B, revise the last sentence of paragraph B1;
  - h. In section 101.00 of part B, revise the last sentence of paragraph B1 and paragraph K; and
  - i. Revise section 111.00 of part B to read as follows:

**APPENDIX 1 TO SUBPART P OF PART 404—LISTING OF IMPAIRMENTS**

*	*	*	*	*
12. Neurological Disorders (11.00 and 111.00): September 29, 2021.				

*	*	*	*	*
Part A				
*	*	*	*	*
11.00 Neurological Disorders				
*	*	*	*	*
1.00 Musculoskeletal System				
*	*	*	*	*

K. *Disorders of the spine*, listed in 1.04, result in limitations because of distortion of the bony and ligamentous architecture of the spine and associated impingement on nerve roots (including the cauda equina) or spinal cord. Such impingement on nerve tissue may result from a herniated nucleus pulposus, spinal stenosis, arachnoiditis, or other miscellaneous conditions.

11.00 NEUROLOGICAL DISORDERS

A. *Which neurological disorders do we evaluate under these listings?* We evaluate epilepsy, amyotrophic lateral sclerosis, coma or persistent vegetative state (PVS), and neurological disorders that cause disorganization of motor function, bulbar and neuromuscular dysfunction, communication impairment, or a combination of limitations in physical and mental functioning. We evaluate neurological disorders that may manifest in a combination of limitations in physical and mental functioning. For example, if you have a neurological disorder that causes mental limitations, such as Huntington’s disease or early-onset Alzheimer’s disease, which may limit executive functioning (e.g., regulating attention, planning, inhibiting responses, decision-making), we evaluate your limitations using the functional criteria under these listings (see 11.00G). Under this body system, we evaluate the limitations resulting from the impact of the neurological disease process itself. If your neurological disorder results in only mental impairment

or if you have a co-occurring mental condition that is not caused by your neurological disorder (for example, dementia), we will evaluate your mental impairment under the mental disorders body system, 12.00.

B. *What evidence do we need to document your neurological disorder?*

1. We need both medical and non-medical evidence (signs, symptoms, and laboratory findings) to assess the effects of your neurological disorder. Medical evidence should include your medical history, examination findings, relevant laboratory tests, and the results of imaging. Imaging refers to medical imaging techniques, such as x-ray, computerized tomography (CT), magnetic resonance imaging (MRI), and electroencephalography (EEG). The imaging must be consistent with the prevailing state of medical knowledge and clinical practice as the proper technique to support the evaluation of the disorder. In addition, the medical evidence may include descriptions of any prescribed treatment and your response to it. We consider non-medical evidence such as statements you or others make about your impairments, your restrictions, your daily activities, or your efforts to work.

2. We will make every reasonable effort to obtain the results of your laboratory and imaging evidence. When the results of any of these tests are part of the existing evidence in your case record, we will evaluate the test results and all other relevant evidence. We will not purchase imaging, or other diagnostic tests, or laboratory tests that are complex, may involve significant risk, or that are invasive. We will not routinely purchase tests that are expensive or not readily available.

C. *How do we consider adherence to prescribed treatment in neurological disorders?* In 11.02 (Epilepsy), 11.06 (Parkinsonian syndrome), and 11.12 (Myasthenia gravis), we require that limitations from these neurological disorders exist despite adherence to prescribed treatment. “Despite adherence to prescribed treatment” means that you have taken medication(s) or followed other treatment procedures for your neurological disorder(s) as prescribed by a physician for three consecutive months but your impairment continues to meet the other listing requirements despite this treatment. You may receive your treatment at a health care facility that you visit regularly, even if you do not see the same physician on each visit.

D. *What do we mean by disorganization of motor function?*

1. *Disorganization of motor function* means interference, due to your neurological disorder, with movement of two extremities; i.e., the lower extremities, or upper extremities (including fingers, wrists, hands, arms, and shoulders). By two extremities we mean both lower extremities, or both upper extremities, or one upper extremity and one lower extremity. All listings in this body system, except for 11.02 (Epilepsy), 11.10 (Amyotrophic lateral sclerosis), and 11.20 (Coma and persistent vegetative state), include criteria for disorganization of motor function that results in an extreme limitation in your ability to:

- a. Stand up from a seated position; or
- b. Balance while standing or walking; or
- c. Use the upper extremities (including fingers, wrists, hands, arms, and shoulders).

2. *Extreme limitation* means the inability to stand up from a seated position, maintain balance in a standing position and while walking, or use your upper extremities to independently initiate, sustain, and complete work-related activities. The assessment of motor function depends on the degree of interference with standing up; balancing while standing or walking; or using the upper extremities (including fingers, hands, arms, and shoulders).

a. Inability to stand up from a seated position means that once seated you are unable to stand and maintain an upright position without the assistance of another person or the use of an assistive device, such as a walker, two crutches, or two canes.

b. Inability to maintain balance in a standing position means that you are unable to maintain an upright position while standing or walking without the assistance of another person or an assistive device, such as a walker, two crutches, or two canes.

c. Inability to use your upper extremities means that you have a loss of function of both upper extremities (including fingers, wrists, hands, arms, and shoulders) that very seriously limits your ability to independently initiate, sustain, and complete work-related activities involving fine and gross motor movements. Inability to perform fine and gross motor movements could include not being able to pinch, manipulate, and use your fingers; or not being able to use your hands, arms, and shoulders to perform gross motor movements, such as handling, gripping, grasping, holding, turning, and reaching; or not being able to engage in exertional movements such as lifting, carrying, pushing, and pulling.

E. *How do we evaluate communication impairments under these listings?* We must have a description of a recent comprehensive evaluation including all areas of communication, performed by an acceptable medical source, to document a communication impairment associated with a neurological disorder. A communication impairment may occur when a medically determinable neurological impairment results in dysfunction in the parts of the brain responsible for speech and language. We evaluate communication impairments associated with neurological disorders under 11.04A, 11.07C, or 11.11B. We evaluate communication impairments due to non-neurological disorders under 2.09.

1. Under 11.04A, we need evidence documenting that your central nervous system vascular accident or insult (CVA) and sensory or motor aphasia have resulted in ineffective speech or communication.

*Ineffective speech or communication* means there is an extreme limitation in your ability to understand or convey your message in simple spoken language resulting in your inability to demonstrate basic communication skills, such as following one-step commands or telling someone about your basic personal needs without assistance.

2. Under 11.07C, we need evidence documenting that your cerebral palsy has

resulted in significant interference in your ability to speak, hear, or see. We will find you have “significant interference” in your ability to speak, hear, or see if your signs, such as aphasia, strabismus, or sensorineural hearing loss, seriously limit your ability to communicate on a sustained basis.

3. Under 11.11B, we need evidence documenting that your post-polio syndrome has resulted in the inability to produce intelligible speech.

F. *What do we mean by bulbar and neuromuscular dysfunction?* The bulbar region of the brain is responsible for controlling the bulbar muscles in the throat, tongue, jaw, and face. Bulbar and neuromuscular dysfunction refers to weakness in these muscles, resulting in breathing, swallowing, and speaking impairments. Listings 11.11 (Post-polio syndrome), 11.12 (Myasthenia gravis), and 11.22 (Motor neuron disorders other than ALS) include criteria for evaluating bulbar and neuromuscular dysfunction. If your neurological disorder has resulted in a breathing disorder, we may evaluate that condition under the respiratory system, 3.00.

G. *How do we evaluate limitations in physical and mental functioning under these listings?*

1. Neurological disorders may manifest in a combination of limitations in physical and mental functioning. We consider all relevant information in your case record to determine the effects of your neurological disorder on your physical and mental functioning. To satisfy the requirement described under 11.00G, your neurological disorder must result in a marked limitation in physical functioning and a marked limitation in at least one of four areas of mental functioning: Understanding, remembering, or applying information; interacting with others; concentrating, persisting, or maintaining pace; or adapting or managing oneself. If your neurological disorder results in an extreme limitation in at least one of the four areas of mental functioning, or results in marked limitation in at least two of the four areas of mental functioning, but you do not have at least a marked limitation in your physical functioning, we will consider whether your condition meets or medically equals one of the mental disorders body system listings, 12.00.

2. *Marked Limitation.* To satisfy the requirements of the functional criteria, your neurological disorder must result in a marked limitation in physical functioning and a marked limitation in one of the four areas of mental functioning (see 11.00G3). Although we do not require the use of such a scale, “marked” would be the fourth point on a five-point scale consisting of no limitation, mild limitation, moderate limitation, marked limitation, and extreme limitation. We consider the nature and overall degree of interference with your functioning. The term “marked” does not require that you must be confined to bed, hospitalized, or in a nursing home.

a. *Marked limitation and physical functioning.* For this criterion, a marked limitation means that, due to the signs and symptoms of your neurological disorder, you are seriously limited in the ability to

independently initiate, sustain, and complete work-related physical activities (see 11.00G3). You may have a marked limitation in your physical functioning when your neurological disease process causes persistent or intermittent symptoms that affect your abilities to independently initiate, sustain, and complete work-related activities, such as standing, balancing, walking, using both upper extremities for fine and gross movements, or results in limitations in using one upper and one lower extremity. The persistent and intermittent symptoms must result in a serious limitation in your ability to do a task or activity on a sustained basis. We do not define “marked” by a specific number of different physical activities or tasks that demonstrate your ability, but by the overall effects of your neurological symptoms on your ability to perform such physical activities on a consistent and sustained basis. You need not be totally precluded from performing a function or activity to have a marked limitation, as long as the degree of limitation seriously limits your ability to independently initiate, sustain, and complete work-related physical activities.

b. *Marked limitation and mental functioning.* For this criterion, a marked limitation means that, due to the signs and symptoms of your neurological disorder, you are seriously limited in the ability to function independently, appropriately, effectively, and on a sustained basis in work settings (see 11.03G3). We do not define “marked” by a specific number of mental activities, such as: The number of activities that demonstrate your ability to understand, remember, and apply information; the number of tasks that demonstrate your ability to interact with others; a specific number of tasks that demonstrate you are able to concentrate, persist or maintain pace; or a specific number of tasks that demonstrate you are able to manage yourself. You may have a marked limitation in your mental functioning when several activities or functions are impaired, or even when only one is impaired. You need not be totally precluded from performing an activity to have a marked limitation, as long as the degree of limitation seriously limits your ability to function independently, appropriately, and effectively on a sustained basis, and complete work-related mental activities.

3. *Areas of physical and mental functioning.*

a. *Physical functioning.* Examples of this criterion include specific motor abilities, such as independently initiating, sustaining, and completing the following activities: Standing up from a seated position, balancing while standing or walking, or using both your upper extremities for fine and gross movements (see 11.00D). Physical functioning may also include functions of the body that support motor abilities, such as the abilities to see, breathe, and swallow (see 11.00E and 11.00F). Examples of when your limitation in seeing, breathing, or swallowing may, on its own, rise to a “marked” limitation include: Prolonged and uncorrectable double vision causing difficulty with balance; prolonged difficulty breathing requiring the use of a prescribed

assistive breathing device, such as a portable continuous positive airway pressure machine; or repeated instances, occurring at least weekly, of aspiration without causing aspiration pneumonia. Alternatively, you may have a combination of limitations due to your neurological disorder that together rise to a “marked” limitation in physical functioning. We may also find that you have a “marked” limitation in this area if, for example, your symptoms, such as pain or fatigue (see 11.00T), as documented in your medical record, and caused by your neurological disorder or its treatment, seriously limit your ability to independently initiate, sustain, and complete these work-related motor functions, or the other physical functions or physiological processes that support those motor functions. We may also find you seriously limited in an area if, while you retain some ability to perform the function, you are unable to do so consistently and on a sustained basis. The limitation in your physical functioning must last or be expected to last at least 12 months. These examples illustrate the nature of physical functioning. We do not require documentation of all of the examples.

**b. Mental functioning.**

(i) *Understanding, remembering, or applying information.* This area of mental functioning refers to the abilities to learn, recall, and use information to perform work activities. Examples include: Understanding and learning terms, instructions, procedures; following one- or two-step oral instructions to carry out a task; describing work activity to someone else; asking and answering questions and providing explanations; recognizing a mistake and correcting it; identifying and solving problems; sequencing multi-step activities; and using reason and judgment to make work-related decisions. These examples illustrate the nature of this area of mental functioning. We do not require documentation of all of the examples.

(ii) *Interacting with others.* This area of mental functioning refers to the abilities to relate to and work with supervisors, co-workers, and the public. Examples include: Cooperating with others; asking for help when needed; handling conflicts with others; stating your own point of view; initiating or sustaining conversation; understanding and responding to social cues (physical, verbal, emotional); responding to requests, suggestions, criticism, correction, and challenges; and keeping social interactions free of excessive irritability, sensitivity, argumentativeness, or suspiciousness. These examples illustrate the nature of this area of mental functioning. We do not require documentation of all of the examples.

(iii) *Concentrating, persisting, or maintaining pace.* This area of mental functioning refers to the abilities to focus attention on work activities and to stay on-task at a sustained rate. Examples include: Initiating and performing a task that you understand and know how to do; working at an appropriate and consistent pace; completing tasks in a timely manner; ignoring or avoiding distractions while working; changing activities or work settings without being disruptive; working close to or with others without interrupting or

distracting them; sustaining an ordinary routine and regular attendance at work; and working a full day without needing more than the allotted number or length of rest periods during the day. These examples illustrate the nature of this area of mental functioning. We do not require documentation of all of the examples.

(iv) *Adapting or managing oneself.* This area of mental functioning refers to the abilities to regulate emotions, control behavior, and maintain well-being in a work setting. Examples include: Responding to demands; adapting to changes; managing your psychologically based symptoms; distinguishing between acceptable and unacceptable work performance; setting realistic goals; making plans for yourself independently of others; maintaining personal hygiene and attire appropriate to a work setting; and being aware of normal hazards and taking appropriate precautions. These examples illustrate the nature of this area of mental functioning. We do not require documentation of all of the examples.

**4. Signs and symptoms of your disorder and the effects of treatment.**

a. We will consider your signs and symptoms and how they affect your ability to function in the work place. When we evaluate your functioning, we will consider whether your signs and symptoms are persistent or intermittent, how frequently they occur and how long they last, their intensity, and whether you have periods of exacerbation and remission.

b. We will consider the effectiveness of treatment in improving the signs, symptoms, and laboratory findings related to your neurological disorder, as well as any aspects of treatment that may interfere with your ability to function. We will consider, for example: The effects of medications you take (including side effects); the time-limited efficacy of some medications; the intrusiveness, complexity, and duration of your treatment (for example, the dosing schedule or need for injections); the effects of treatment, including medications, therapy, and surgery, on your functioning; the variability of your response to treatment; and any drug interactions.

**H. What is epilepsy, and how do we evaluate it under 11.02?**

1. *Epilepsy* is a pattern of recurrent and unprovoked seizures that are manifestations of abnormal electrical activity in the brain. There are various types of generalized and “focal” or partial seizures. However, psychogenic nonepileptic seizures and pseudoseizures are not epileptic seizures for the purpose of 11.02. We evaluate psychogenic seizures and pseudoseizures under the mental disorders body system, 12.00. In adults, the most common potentially disabling seizure types are *generalized tonic-clonic seizures* and *dyscognitive seizures* (formerly complex partial seizures).

a. *Generalized tonic-clonic seizures* are characterized by loss of consciousness accompanied by a tonic phase (sudden muscle tensing causing the person to lose postural control) followed by a clonic phase (rapid cycles of muscle contraction and relaxation, also called convulsions). Tongue

biting and incontinence may occur during generalized tonic-clonic seizures, and injuries may result from falling.

b. *Dyscognitive seizures* are characterized by alteration of consciousness without convulsions or loss of muscle control. During the seizure, blank staring, change of facial expression, and automatism (such as lip smacking, chewing or swallowing, or repetitive simple actions, such as gestures or verbal utterances) may occur. During its course, a dyscognitive seizure may progress into a generalized tonic-clonic seizure (see 11.00H1a).

2. *Description of seizure.* We require at least one detailed description of your seizures from someone, preferably a medical professional, who has observed at least one of your typical seizures. If you experience more than one type of seizure, we require a description of each type.

3. *Serum drug levels.* We do not require serum drug levels; therefore, we will not purchase them. However, if serum drug levels are available in your medical records, we will evaluate them in the context of the other evidence in your case record.

4. *Counting seizures.* The period specified in 11.02A, B, or C cannot begin earlier than one month after you began prescribed treatment. The required number of seizures must occur within the period we are considering in connection with your application or continuing disability review. When we evaluate the frequency of your seizures, we also consider your adherence to prescribed treatment (see 11.00C). When we determine the number of seizures you have had in the specified period, we will:

a. Count multiple seizures occurring in a 24-hour period as one seizure.

b. Count status epilepticus (a continuous series of seizures without return to consciousness between seizures) as one seizure.

c. Count a dyscognitive seizure that progresses into a generalized tonic-clonic seizure as one generalized tonic-clonic seizure.

d. We do not count seizures that occur during a period when you are not adhering to prescribed treatment without good reason. When we determine that you had good reason for not adhering to prescribed treatment, we will consider your physical, mental, educational, and communicative limitations (including any language barriers). We will consider you to have good reason for not following prescribed treatment if, for example, the treatment is very risky for you due to its consequences or unusual nature, or if you are unable to afford prescribed treatment that you are willing to accept, but for which no free community resources are available. We will follow guidelines found in our policy, such as §§ 404.1530(c) and 416.930(c) of this chapter, when we determine whether you have a good reason for not adhering to prescribed treatment.

e. We do not count psychogenic nonepileptic seizures or pseudoseizures under 11.02. We evaluate these seizures under the mental disorders body system, 12.00.

5. *Electroencephalography (EEG) testing.* We do not require EEG test results; therefore,

we will not purchase them. However, if EEG test results are available in your medical records, we will evaluate them in the context of the other evidence in your case record.

I. *What is vascular insult to the brain, and how do we evaluate it under 11.04?*

1. *Vascular insult to the brain* (cerebrum, cerebellum, or brainstem), commonly referred to as stroke or cerebrovascular accident (CVA), is brain cell death caused by an interruption of blood flow within or leading to the brain, or by a hemorrhage from a ruptured blood vessel or aneurysm in the brain. If you have a vision impairment resulting from your vascular insult, we may evaluate that impairment under the special senses body system, 2.00.

2. We need evidence of sensory or motor aphasia that results in ineffective speech or communication under 11.04A (see 11.00E). We may evaluate your communication impairment under listing 11.04C if you have marked limitation in physical functioning and marked limitation in one of the four areas of mental functioning.

3. We generally need evidence from at least 3 months after the vascular insult to evaluate whether you have disorganization of motor functioning under 11.04B, or the impact that your disorder has on your physical and mental functioning under 11.04C. In some cases, evidence of your vascular insult is sufficient to allow your claim within 3 months post-vascular insult. If we are unable to allow your claim within 3 months after your vascular insult, we will defer adjudication of the claim until we obtain evidence of your neurological disorder at least 3 months post-vascular insult.

J. *What are benign brain tumors, and how do we evaluate them under 11.05?* Benign brain tumors are noncancerous (nonmalignant) abnormal growths of tissue in or on the brain that invade healthy brain tissue or apply pressure on the brain or cranial nerves. We evaluate their effects on your functioning as discussed in 11.00D and 11.00G. We evaluate malignant brain tumors under the cancer body system in 13.00. If you have a vision impairment resulting from your benign brain tumor, we may evaluate that impairment under the special senses body system, 2.00.

K. *What is Parkinsonian syndrome, and how do we evaluate it under 11.06?*

Parkinsonian syndrome is a term that describes a group of chronic, progressive movement disorders resulting from loss or decline in the function of dopamine-producing brain cells. Dopamine is a neurotransmitter that regulates muscle movement throughout the body. When we evaluate your Parkinsonian syndrome, we will consider your adherence to prescribed treatment (see 11.00C).

L. *What is cerebral palsy, and how do we evaluate it under 11.07?*

1. *Cerebral palsy (CP)* is a term that describes a group of static, nonprogressive disorders caused by abnormalities within the brain that disrupt the brain's ability to control movement, muscle coordination, and posture. The resulting motor deficits manifest very early in a person's development, with delayed or abnormal progress in attaining developmental milestones. Deficits may

become more obvious as the person grows and matures over time.

2. We evaluate your signs and symptoms, such as ataxia, spasticity, flaccidity, athetosis, chorea, and difficulty with precise movements when we determine your ability to stand up, balance, walk, or perform fine and gross motor movements. We will also evaluate your signs, such as dysarthria and apraxia of speech, and receptive and expressive language problems when we determine your ability to communicate.

3. We will consider your other impairments or signs and symptoms that develop secondary to the disorder, such as post-impairment syndrome (a combination of pain, fatigue, and weakness due to muscle abnormalities); overuse syndromes (repetitive motion injuries); arthritis; abnormalities of proprioception (perception of the movements and position of the body); abnormalities of stereognosis (perception and identification of objects by touch); learning problems; anxiety; and depression.

M. *What are spinal cord disorders, and how do we evaluate them under 11.08?*

1. *Spinal cord disorders* may be congenital or caused by injury to the spinal cord. Motor signs and symptoms of spinal cord disorders include paralysis, flaccidity, spasticity, and weakness.

2. *Spinal cord disorders with complete loss of function* (11.08A) addresses spinal cord disorders that result in a complete lack of motor, sensory, and autonomic function of the affected part(s) of the body.

3. *Spinal cord disorders with disorganization of motor function* (11.08B) addresses spinal cord disorders that result in less than a complete loss of function of the affected part(s) of the body, reducing, but not eliminating, motor, sensory, and autonomic function.

4. When we evaluate your spinal cord disorder, we generally need evidence from at least 3 months after your symptoms began in order to evaluate your disorganization of motor function. In some cases, evidence of your spinal cord disorder may be sufficient to allow your claim within 3 months after the spinal cord disorder. If the medical evidence demonstrates total cord transection causing a loss of motor and sensory functions below the level of injury, we will not wait 3 months but will make the allowance decision immediately.

N. *What is multiple sclerosis, and how do we evaluate it under 11.09?*

1. *Multiple sclerosis (MS)* is a chronic, inflammatory, degenerative disorder that damages the myelin sheath surrounding the nerve fibers in the brain and spinal cord. The damage disrupts the normal transmission of nerve impulses within the brain and between the brain and other parts of the body, causing impairment in muscle coordination, strength, balance, sensation, and vision. There are several forms of MS, ranging from mildly to highly aggressive. Milder forms generally involve acute attacks (exacerbations) with partial or complete recovery from signs and symptoms (remissions). Aggressive forms generally exhibit a steady progression of signs and symptoms with few or no remissions. The effects of all forms vary from person to person.

2. We evaluate your signs and symptoms, such as flaccidity, spasticity, spasms, incoordination, imbalance, tremor, physical fatigue, muscle weakness, dizziness, tingling, and numbness when we determine your ability to stand up, balance, walk, or perform fine and gross motor movements. When determining whether you have limitations of physical and mental functioning, we will consider your other impairments or signs and symptoms that develop secondary to the disorder, such as fatigue; visual loss; trouble sleeping; impaired attention, concentration, memory, or judgment; mood swings; and depression. If you have a vision impairment resulting from your MS, we may evaluate that impairment under the special senses body system, 2.00.

O. *What is amyotrophic lateral sclerosis, and how do we evaluate it under 11.10?* *Amyotrophic lateral sclerosis (ALS)* is a type of motor neuron disorder that rapidly and progressively attacks the nerve cells responsible for controlling voluntary muscles. We establish ALS under 11.10 when you have a documented diagnosis of ALS. We require documentation based on generally accepted methods consistent with the prevailing state of medical knowledge and clinical practice. We require laboratory testing to establish the diagnosis when the clinical findings of upper and lower motor neuron disease are not present in three or more regions. Electrophysiological studies, such as nerve conduction velocity studies and electromyography (EMG), may support your diagnosis of ALS; however, we will not purchase these studies.

P. *What are neurodegenerative disorders of the central nervous system, such as Huntington's disease, Friedreich's ataxia, and spinocerebellar degeneration, and how do we evaluate them under 11.17?*

Neurodegenerative disorders of the central nervous system are disorders characterized by progressive and irreversible degeneration of neurons or their supporting cells. Over time, these disorders impair many of the body's motor, cognitive, and other mental functions. We consider neurodegenerative disorders of the central nervous system under 11.17 that we do not evaluate elsewhere in section 11.00, such as Huntington's disease (HD), Friedreich's ataxia, spinocerebellar degeneration, Creutzfeldt-Jakob disease (CJD), progressive supranuclear palsy (PSP), early-onset Alzheimer's disease, and frontotemporal dementia (Pick's disease). When these disorders result in solely cognitive and other mental function effects, we will evaluate the disorder under the mental disorder listings.

Q. *What is traumatic brain injury, and how do we evaluate it under 11.18?*

1. *Traumatic brain injury (TBI)* is damage to the brain resulting from skull fracture, collision with an external force leading to a closed head injury, or penetration by an object that enters the skull and makes contact with brain tissue. We evaluate TBI that results in coma or persistent vegetative state (PVS) under 11.20.

2. We generally need evidence from at least 3 months after the TBI to evaluate whether you have disorganization of motor function under 11.18A or the impact that your



disorder has on your physical and mental functioning under 11.18B. In some cases, evidence of your TBI is sufficient to determine disability within 3 months post-TBI. If we are unable to allow your claim within 3 months post-TBI, we will defer adjudication of the claim until we obtain evidence of your neurological disorder at least 3 months post-TBI. If a finding of disability still is not possible at that time, we will again defer adjudication of the claim until we obtain evidence at least 6 months after your TBI.

R. *What are coma and persistent vegetative state, and how do we evaluate them under 11.20?* Coma is a state of unconsciousness in which a person does not exhibit a sleep/wake cycle, and is unable to perceive or respond to external stimuli. People who do not fully emerge from coma may progress into a persistent vegetative state (PVS). PVS is a condition of partial arousal in which a person may have a low level of consciousness but is still unable to react to external stimuli. In contrast to coma, a person in a PVS retains sleep/wake cycles and may exhibit some key lower brain functions, such as spontaneous movement, opening and moving eyes, and grimacing. Coma or PVS may result from TBI, a nontraumatic insult to the brain (such as a vascular insult, infection, or brain tumor), or a neurodegenerative or metabolic disorder. Medically induced comas are not considered under 11.20 and should be considered under the section pertaining to the underlying reason the coma was medically induced and not under this section.

S. *What are motor neuron disorders, other than ALS, and how do we evaluate them under 11.22?* Motor neuron disorders such as progressive bulbar palsy, primary lateral sclerosis (PLS), and spinal muscular atrophy (SMA) are progressive neurological disorders that destroy the cells that control voluntary muscle activity, such as walking, breathing, swallowing, and speaking. We evaluate the effects of these disorders on motor functioning, bulbar and neuromuscular functioning, oral communication, or limitations in physical and mental functioning.

T. *How do we consider symptoms of fatigue in these listings?* Fatigue is one of the most common and limiting symptoms of some neurological disorders, such as multiple sclerosis, post-polio syndrome, and myasthenia gravis. These disorders may result in physical fatigue (lack of muscle strength) or mental fatigue (decreased awareness or attention). When we evaluate your fatigue, we will consider the intensity, persistence, and effects of fatigue on your functioning. This may include information such as the clinical and laboratory data and other objective evidence concerning your neurological deficit, a description of fatigue considered characteristic of your disorder, and information about your functioning. We consider the effects of physical fatigue on your ability to stand up, balance, walk, or perform fine and gross motor movements using the criteria described in 11.00D. We consider the effects of physical and mental fatigue when we evaluate your physical and mental functioning described in 11.00G.

U. *How do we evaluate your neurological disorder when it does not meet one of these listings?*

1. If your neurological disorder does not meet the criteria of any of these listings, we must also consider whether your impairment(s) meets the criteria of a listing in another body system. If you have a severe medically determinable impairment(s) that does not meet a listing, we will determine whether your impairment(s) medically equals a listing. See §§ 404.1526 and 416.926 of this chapter.

2. If your impairment(s) does not meet or medically equal the criteria of a listing, you may or may not have the residual functional capacity to perform your past relevant work or adjust to other work that exists in significant numbers in the national economy, which we determine at the fourth and, if necessary, the fifth steps of the sequential evaluation process in §§ 404.1520 and 416.920 of this chapter.

3. We use the rules in §§ 404.1594 and 416.994 of this chapter, as appropriate, when we decide whether you continue to be disabled.

#### 11.01 Category of Impairments, Neurological Disorders

11.02 *Epilepsy*, documented by a detailed description of a typical seizure and characterized by A, B, C, or D:

A. Generalized tonic-clonic seizures (see 11.00H1a), occurring at least once a month for at least 3 consecutive months (see 11.00H4) despite adherence to prescribed treatment (see 11.00C); or

B. Dyscognitive seizures (see 11.00H1b), occurring at least once a week for at least 3 consecutive months (see 11.00H4) despite adherence to prescribed treatment (see 11.00C); or

C. Generalized tonic-clonic seizures (see 11.00H1a), occurring at least once every 2 months for at least 4 consecutive months (see 11.00H4) despite adherence to prescribed treatment (see 11.00C); and a marked limitation in one of the following:

1. Physical functioning (see 11.00G3a); or

2. Understanding, remembering, or applying information (see 11.00G3b(i)); or

3. Interacting with others (see 11.00G3b(ii)); or

4. Concentrating, persisting, or maintaining pace (see 11.00G3b(iii)); or

5. Adapting or managing oneself (see 11.00G3b(iv)); or

D. Dyscognitive seizures (see 11.00H1b), occurring at least once every 2 weeks for at least 3 consecutive months (see 11.00H4) despite adherence to prescribed treatment (see 11.00C); and a marked limitation in one of the following:

1. Physical functioning (see 11.00G3a); or

2. Understanding, remembering, or applying information (see 11.00G3b(i)); or

3. Interacting with others (see 11.00G3b(ii)); or

4. Concentrating, persisting, or maintaining pace (see 11.00G3b(iii)); or

5. Adapting or managing oneself (see 11.00G3b(iv)).

11.03 [Reserved]

11.04 *Vascular insult to the brain*, characterized by A, B, or C:

A. Sensory or motor aphasia resulting in ineffective speech or communication (see 11.00E1) persisting for at least 3 consecutive months after the insult; or

B. Disorganization of motor function in two extremities (see 11.00D1), resulting in an extreme limitation (see 11.00D2) in the ability to stand up from a seated position, balance while standing or walking, or use the upper extremities, persisting for at least 3 consecutive months after the insult; or

C. Marked limitation (see 11.00G2) in physical functioning (see 11.00G3a) and in one of the following areas of mental functioning, both persisting for at least 3 consecutive months after the insult:

1. Understanding, remembering, or applying information (see 11.00G3b(i)); or

2. Interacting with others (see 11.00G3b(ii)); or

3. Concentrating, persisting, or maintaining pace (see 11.00G3b(iii)); or

4. Adapting or managing oneself (see 11.00G3b(iv)).

11.05 *Benign brain tumors*, characterized by A or B:

A. Disorganization of motor function in two extremities (see 11.00D1), resulting in an extreme limitation (see 11.00D2) in the ability to stand up from a seated position, balance while standing or walking, or use the upper extremities; or

B. Marked limitation (see 11.00G2) in physical functioning (see 11.00G3a), and in one of the following:

1. Understanding, remembering, or applying information (see 11.00G3b(i)); or

2. Interacting with others (see 11.00G3b(ii)); or

3. Concentrating, persisting, or maintaining pace (see 11.00G3b(iii)); or

4. Adapting or managing oneself (see 11.00G3b(iv)).

11.06 *Parkinsonian syndrome*, characterized by A or B despite adherence to prescribed treatment for at least 3 consecutive months (see 11.00C):

A. Disorganization of motor function in two extremities (see 11.00D1), resulting in an extreme limitation (see 11.00D2) in the ability to stand up from a seated position, balance while standing or walking, or use the upper extremities; or

B. Marked limitation (see 11.00G2) in physical functioning (see 11.00G3a), and in one of the following:

1. Understanding, remembering, or applying information (see 11.00G3b(i)); or

2. Interacting with others (see 11.00G3b(ii)); or

3. Concentrating, persisting, or maintaining pace (see 11.00G3b(iii)); or

4. Adapting or managing oneself (see 11.00G3b(iv)).

11.07 *Cerebral palsy*, characterized by A, B, or C:

A. Disorganization of motor function in two extremities (see 11.00D1), resulting in an extreme limitation (see 11.00D2) in the ability to stand up from a seated position, balance while standing or walking, or use the upper extremities; or

B. Marked limitation (see 11.00G2) in physical functioning (see 11.00G3a), and in one of the following:

1. Understanding, remembering, or applying information (see 11.00G3b(i)); or

2. Interacting with others (see 11.00G3b(ii)); or

3. Concentrating, persisting, or maintaining pace (see 11.00G3b(iii)); or

4. Adapting or managing oneself (see 11.00G3b(iv)); or

C. Significant interference in communication due to speech, hearing, or visual deficit (see 11.00E2).

11.08 *Spinal cord disorders*, characterized by A, B, or C:

A. Complete loss of function, as described in 11.00M2, persisting for 3 consecutive months after the disorder (see 11.00M4); or

B. Disorganization of motor function in two extremities (see 11.00D1), resulting in an extreme limitation (see 11.00D2) in the ability to stand up from a seated position, balance while standing or walking, or use the upper extremities persisting for 3 consecutive months after the disorder (see 11.00M4); or

C. Marked limitation (see 11.00G2) in physical functioning (see 11.00G3a) and in one of the following areas of mental functioning, both persisting for 3 consecutive months after the disorder (see 11.00M4):

1. Understanding, remembering, or applying information (see 11.00G3b(i)); or

2. Interacting with others (see 11.00G3b(ii)); or

3. Concentrating, persisting, or maintaining pace (see 11.00G3b(iii)); or

4. Adapting or managing oneself (see 11.00G3b(iv)).

11.09 *Multiple sclerosis*, characterized by A or B:

A. Disorganization of motor function in two extremities (see 11.00D1), resulting in an extreme limitation (see 11.00D2) in the ability to stand up from a seated position, balance while standing or walking, or use the upper extremities; or

B. Marked limitation (see 11.00G2) in physical functioning (see 11.00G3a), and in one of the following:

1. Understanding, remembering, or applying information (see 11.00G3b(i)); or

2. Interacting with others (see 11.00G3b(ii)); or

3. Concentrating, persisting, or maintaining pace (see 11.00G3b(iii)); or

4. Adapting or managing oneself (see 11.00G3b(iv)).

11.10 *Amyotrophic lateral sclerosis (ALS)* established by clinical and laboratory findings (see 11.00O).

11.11 *Post-polio syndrome*, characterized by A, B, C, or D:

A. Disorganization of motor function in two extremities (see 11.00D1), resulting in an extreme limitation (see 11.00D2) in the ability to stand up from a seated position, balance while standing or walking, or use the upper extremities; or

B. Unintelligible speech (see 11.00E3); or

C. Bulbar and neuromuscular dysfunction (see 11.00F), resulting in:

1. Acute respiratory failure requiring mechanical ventilation; or

2. Need for supplemental enteral nutrition via a gastrostomy or parenteral nutrition via a central venous catheter; or

D. Marked limitation (see 11.00G2) in physical functioning (see 11.00G3a), and in one of the following:

1. Understanding, remembering, or applying information (see 11.00G3b(i)); or

2. Interacting with others (see 11.00G3b(ii)); or

3. Concentrating, persisting, or maintaining pace (see 11.00G3b(iii)); or

4. Adapting or managing oneself (see 11.00G3b(iv)).

11.12 *Myasthenia gravis*, characterized by A, B, or C despite adherence to prescribed treatment for at least 3 months (see 11.00C):

A. Disorganization of motor function in two extremities (see 11.00D1), resulting in an extreme limitation (see 11.00D2) in the ability to stand up from a seated position, balance while standing or walking, or use the upper extremities; or

B. Bulbar and neuromuscular dysfunction (see 11.00F), resulting in:

1. One myasthenic crisis requiring mechanical ventilation; or

2. Need for supplemental enteral nutrition via a gastrostomy or parenteral nutrition via a central venous catheter; or

C. Marked limitation (see 11.00G2) in physical functioning (see 11.00G3a), and in one of the following:

1. Understanding, remembering, or applying information (see 11.00G3b(i)); or

2. Interacting with others (see 11.00G3b(ii)); or

3. Concentrating, persisting, or maintaining pace (see 11.00G3b(iii)); or

4. Adapting or managing oneself (see 11.00G3b(iv)).

11.13 *Muscular dystrophy*, characterized by A or B:

A. Disorganization of motor function in two extremities (see 11.00D1), resulting in an extreme limitation (see 11.00D2) in the ability to stand up from a seated position, balance while standing or walking, or use the upper extremities; or

B. Marked limitation (see 11.00G2) in physical functioning (see 11.00G3a), and in one of the following:

1. Understanding, remembering, or applying information (see 11.00G3b(i)); or

2. Interacting with others (see 11.00G3b(ii)); or

3. Concentrating, persisting, or maintaining pace (see 11.00G3b(iii)); or

4. Adapting or managing oneself (see 11.00G3b(iv)).

11.14 *Peripheral neuropathy*, characterized by A or B:

A. Disorganization of motor function in two extremities (see 11.00D1), resulting in an extreme limitation (see 11.00D2) in the ability to stand up from a seated position, balance while standing or walking, or use the upper extremities; or

B. Marked limitation (see 11.00G2) in physical functioning (see 11.00G3a), and in one of the following:

1. Understanding, remembering, or applying information (see 11.00G3b(i)); or

2. Interacting with others (see 11.00G3b(ii)); or

3. Concentrating, persisting, or maintaining pace (see 11.00G3b(iii)); or

4. Adapting or managing oneself (see 11.00G3b(iv)).

11.15 [Reserved]

11.16 [Reserved]

11.17 *Neurodegenerative disorders of the central nervous system, such as Huntington's disease, Friedreich's ataxia, and*

*spinocerebellar degeneration*, characterized by A or B:

A. Disorganization of motor function in two extremities (see 11.00D1), resulting in an extreme limitation (see 11.00D2) in the ability to stand up from a seated position, balance while standing or walking, or use the upper extremities; or

B. Marked limitation (see 11.00G2) in physical functioning (see 11.00G3a), and in one of the following:

1. Understanding, remembering, or applying information (see 11.00G3b(i)); or

2. Interacting with others (see 11.00G3b(ii)); or

3. Concentrating, persisting, or maintaining pace (see 11.00G3b(iii)); or

4. Adapting or managing oneself (see 11.00G3b(iv)).

11.18 *Traumatic brain injury*, characterized by A or B:

A. Disorganization of motor function in two extremities (see 11.00D1), resulting in an extreme limitation (see 11.00D2) in the ability to stand up from a seated position, balance while standing or walking, or use the upper extremities, persisting for at least 3 consecutive months after the injury; or

B. Marked limitation (see 11.00G2) in physical functioning (see 11.00G3a), and in one of the following areas of mental functioning, persisting for at least 3 consecutive months after the injury:

1. Understanding, remembering, or applying information (see 11.00G3b(i)); or

2. Interacting with others (see 11.00G3b(ii)); or

3. Concentrating, persisting, or maintaining pace (see 11.00G3b(iii)); or

4. Adapting or managing oneself (see 11.00G3b(iv)).

11.19 [Reserved]

11.20 *Coma or persistent vegetative state*, persisting for at least 1 month.

11.21 [Reserved]

11.22 *Motor neuron disorders other than ALS*, characterized by A, B, or C:

A. Disorganization of motor function in two extremities (see 11.00D1), resulting in an extreme limitation (see 11.00D2) in the ability to stand up from a seated position, balance while standing or walking, or use the upper extremities; or

B. Bulbar and neuromuscular dysfunction (see 11.00F), resulting in:

1. Acute respiratory failure requiring invasive mechanical ventilation; or

2. Need for supplemental enteral nutrition via a gastrostomy or parenteral nutrition via a central venous catheter; or

C. Marked limitation (see 11.00G2) in physical functioning (see 11.00G3a), and in one of the following:

1. Understanding, remembering, or applying information (see 11.00G3b(i)); or

2. Interacting with others (see 11.00G3b(ii)); or

3. Concentrating, persisting, or maintaining pace (see 11.00G3b(iii)); or

4. Adapting or managing oneself (see 11.00G3b(iv)).

\* \* \* \* \*

12.00 MENTAL DISORDERS

\* \* \* \* \*

D. \* \* \*

10. *Traumatic brain injury (TBI)*. In cases involving TBI, follow the documentation and evaluation guidelines in 11.00Q.

\* \* \* \* \*

12.01 Category of Impairments, Mental Disorders

\* \* \* \* \*

12.09 \* \* \*

E. Peripheral neuropathy. Evaluate under 11.14.

\* \* \* \* \*

I. Seizures. Evaluate under 11.02.

\* \* \* \* \*

Part B

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111.00 Neurological Disorders

\* \* \* \* \*

101.00 MUSCULOSKELETAL SYSTEM

\* \* \* \* \*

B. *Loss of function.*

1. *General.* \* \* \* We evaluate impairments with neurological causes under 111.00, as appropriate.

\* \* \* \* \*

K. *Disorders of the spine*, listed in 101.04, result in limitations because of distortion of the bony and ligamentous architecture of the spine and associated impingement on nerve roots (including the cauda equina) or spinal cord. Such impingement on nerve tissue may result from a herniated nucleus pulposus, spinal stenosis, arachnoiditis, or other miscellaneous conditions.

\* \* \* \* \*

**111.00 NEUROLOGICAL DISORDERS**

A. *Which neurological disorders do we evaluate under these listings?* We evaluate epilepsy, coma or persistent vegetative state (PVS), and neurological disorders that cause disorganization of motor function, bulbar and neuromuscular dysfunction, or communication impairment. Under this body system, we evaluate the limitations resulting from the impact of the neurological disease process itself. If you have a neurological disorder(s) that affects your physical and mental functioning, we will evaluate your impairments under the rules we use to determine functional equivalence. If your neurological disorder results in only mental impairment or if you have a co-occurring mental condition that is not caused by your neurological disorder (for example, Autism spectrum disorder), we will evaluate your mental impairment under the mental disorders body system, 112.00.

B. *What evidence do we need to document your neurological disorder?*

1. We need both medical and non-medical evidence (signs, symptoms, and laboratory findings) to assess the effects of your neurological disorder. Medical evidence should include your medical history, examination findings, relevant laboratory tests, and the results of imaging. Imaging refers to medical imaging techniques, such as x-ray, computerized tomography (CT), magnetic resonance imaging (MRI), and electroencephalography (EEG). The imaging must be consistent with the prevailing state of medical knowledge and clinical practice as the proper technique to support the

evaluation of the disorder. In addition, the medical evidence may include descriptions of any prescribed treatment and your response to it. We consider non-medical evidence such as statements you or others make about your impairments, your restrictions, your daily activities, or, if you are an adolescent, your efforts to work.

2. We will make every reasonable effort to obtain the results of your laboratory and imaging evidence. When the results of any of these tests are part of the existing evidence in your case record, we will evaluate the test results and all other relevant evidence. We will not purchase imaging, or other diagnostic tests or laboratory tests that are complex, may involve significant risk, or that are invasive. We will not routinely purchase tests that are expensive or not readily available.

C. *How do we consider adherence to prescribed treatment in neurological disorders?* In 111.02 (Epilepsy) and 111.12 (Myasthenia gravis), we require that limitations from these neurological disorders exist despite adherence to prescribed treatment. "Despite adherence to prescribed treatment" means that you have taken medication(s) or followed other treatment procedures for your neurological disorder(s) as prescribed by a physician for three consecutive months but your impairment continues to meet the other listing requirements despite this treatment. You may receive your treatment at a health care facility that you visit regularly, even if you do not see the same physician on each visit.

D. *What do we mean by disorganization of motor function?*

1. *Disorganization of motor function* means interference, due to your neurological disorder, with movement of two extremities; *i.e.*, the lower extremities, or upper extremities (including fingers, wrists, hands, arms, and shoulders). By two extremities we mean both lower extremities, or both upper extremities, or one upper extremity and one lower extremity. All listings in this body system, except for 111.02 (Epilepsy) and 111.20 (Coma and persistent vegetative state), include criteria for disorganization of motor function that results in an extreme limitation in your ability to:

- Stand up from a seated position; or
- Balance while standing or walking; or
- Use the upper extremities (*e.g.*, fingers, wrists, hands, arms, and shoulders).

2. *Extreme limitation* means the inability to stand up from a seated position, maintain balance in a standing position and while walking, or use your upper extremities to independently initiate, sustain, and complete age-appropriate activities. The assessment of motor function depends on the degree of interference with standing up; balancing while standing or walking; or using the upper extremities (including fingers, hands, arms, and shoulders).

a. Inability to stand up from a seated position means that once seated you are unable to stand and maintain an upright position without the assistance of another person or the use of an assistive device, such as a walker, two crutches, or two canes.

b. Inability to maintain balance in a standing position means that you are unable

to maintain an upright position while standing or walking without the assistance of another person or an assistive device, such as a walker, two crutches, or two canes.

c. Inability to use your upper extremities means that you have a loss of function of both upper extremities (*e.g.*, fingers, wrists, hands, arms, and shoulders) that very seriously limits your ability to independently initiate, sustain, and complete age-appropriate activities involving fine and gross motor movements. Inability to perform fine and gross motor movements could include not being able to pinch, manipulate, and use your fingers; or not being able to use your hands, arms, and shoulders to perform gross motor movements, such as handling, gripping, grasping, holding, turning, and reaching; or not being able to engage in exertional movements such as lifting, carrying, pushing, and pulling.

3. For children who are not yet able to balance, stand up, or walk independently, we consider their function based on assessments of limitations in the ability to perform comparable age-appropriate activities with the lower and upper extremities, given normal developmental milestones. For such children, an extreme level of limitation means developmental milestones at less than one-half of the child's chronological age.

E. *What do we mean by bulbar and neuromuscular dysfunction?* The bulbar region of the brain is responsible for controlling the bulbar muscles in the throat, tongue, jaw, and face. Bulbar and neuromuscular dysfunction refers to weakness in these muscles, resulting in breathing, swallowing, and speaking impairments. Listings 111.12 (Myasthenia gravis) and 111.22 (Motor neuron disorders) include criteria for evaluating bulbar and neuromuscular dysfunction. If your neurological disorder has resulted in a breathing disorder, we may evaluate that condition under the respiratory system, 103.00.

F. *What is epilepsy, and how do we evaluate it under 111.02?*

1. *Epilepsy* is a pattern of recurrent and unprovoked seizures that are manifestations of abnormal electrical activity in the brain. There are various types of generalized and "focal" or partial seizures. In children, the most common potentially disabling seizure types are *generalized tonic-clonic seizures*, *dyscognitive seizures* (formerly complex partial seizures), and *absence seizures*. However, psychogenic nonepileptic seizures and pseudoseizures are not epileptic seizures for the purpose of 111.02. We evaluate psychogenic seizures and pseudoseizures under the mental disorders body system, 112.00.

a. *Generalized tonic-clonic seizures* are characterized by loss of consciousness accompanied by a tonic phase (sudden muscle tensing causing the child to lose postural control) followed by a clonic phase (rapid cycles of muscle contraction and relaxation, also called convulsions). Tongue biting and incontinence may occur during generalized tonic-clonic seizures, and injuries may result from falling.

b. *Dyscognitive seizures* are characterized by alteration of consciousness without

convulsions or loss of muscle control. During the seizure, blank staring, change of facial expression, and automatisms (such as lip smacking, chewing or swallowing, or repetitive simple actions, such as gestures or verbal utterances) may occur. During its course, a dyscognitive seizure may progress into a generalized tonic-clonic seizure (see 111.00F1a).

c. *Absence seizures (petit mal)* are also characterized by an alteration in consciousness, but are shorter than other generalized seizures (e.g., tonic-clonic and dyscognitive) seizures, generally lasting for only a few seconds rather than minutes. They may present with blank staring, change of facial expression, lack of awareness and responsiveness, and a sense of lost time after the seizure. An aura never precedes absence seizures. Although absence seizures are brief, frequent occurrence may limit functioning. This type of seizure usually does not occur after adolescence.

d. *Febrile seizures* may occur in young children in association with febrile illnesses. We will consider seizures occurring during febrile illnesses. To meet 111.02, we require documentation of seizures during nonfebrile periods and epilepsy must be established.

2. *Description of seizure.* We require at least one detailed description of your seizures from someone, preferably a medical professional, who has observed at least one of your typical seizures. If you experience more than one type of seizure, we require a description of each type.

3. *Serum drug levels.* We do not require serum drug levels; therefore, we will not purchase them. However, if serum drug levels are available in your medical records, we will evaluate them in the context of the other evidence in your case record.

4. *Counting seizures.* The period specified in 111.02A or B cannot begin earlier than one month after you began prescribed treatment. The required number of seizures must occur within the period we are considering in connection with your application or continuing disability review. When we evaluate the frequency of your seizures, we also consider your adherence to prescribed treatment (see 111.00C). When we determine the number of seizures you have had in the specified period, we will:

a. Count multiple seizures occurring in a 24-hour period as one seizure.

b. Count status epilepticus (a continuous series of seizures without return to consciousness between seizures) as one seizure.

c. Count a dyscognitive seizure that progresses into a generalized tonic-clonic seizure as one generalized tonic-clonic seizure.

d. We do not count seizures that occur during a period when you are not adhering to prescribed treatment without good reason. When we determine that you had a good reason for not adhering to prescribed treatment, we will consider your physical, mental, educational, and communicative limitations (including any language barriers). We will consider you to have good reason for not following prescribed treatment if, for example, the treatment is very risky for you due to its consequences or unusual nature, or

if you are unable to afford prescribed treatment that you are willing to accept, but for which no free community resources are available. We will follow guidelines found in our policy, such as § 416.930(c) of this chapter, when we determine whether you have a good reason for not adhering to prescribed treatment.

e. We do not count psychogenic nonepileptic seizures or pseudoseizures under 111.02. We evaluate these seizures under the mental disorders body system, 112.00.

5. *Electroencephalography (EEG) testing.* We do not require EEG test results; therefore, we will not purchase them. However, if EEG test results are available in your medical records, we will evaluate them in the context of the other evidence in your case record.

G. *What is vascular insult to the brain, and how do we evaluate it under 111.04?*

1. *Vascular insult to the brain* (cerebrum, cerebellum, or brainstem), commonly referred to as stroke or cerebrovascular accident (CVA), is brain cell death caused by an interruption of blood flow within or leading to the brain, or by a hemorrhage from a ruptured blood vessel or aneurysm in the brain. If you have a vision impairment resulting from your vascular insult, we may evaluate that impairment under the special senses body system, 102.00.

2. We generally need evidence from at least 3 months after the vascular insult to determine whether you have disorganization of motor function under 111.04. In some cases, evidence of your vascular insult is sufficient to allow your claim within 3 months post-vascular insult. If we are unable to allow your claim within 3 months after your vascular insult, we will defer adjudication of the claim until we obtain evidence of your neurological disorder at least 3 months post-vascular insult.

H. *What are benign brain tumors, and how do we evaluate them under 111.05?* Benign brain tumors are noncancerous (nonmalignant) abnormal growths of tissue in or on the brain that invade healthy brain tissue or apply pressure on the brain or cranial nerves. We evaluate their effects on your functioning as discussed in 111.00D. We evaluate malignant brain tumors under the cancer body system in 113.00. If you have a vision impairment resulting from your benign brain tumor, we may evaluate that impairment under the special senses body system, 102.00.

I. *What is cerebral palsy, and how do we evaluate it under 111.07?*

1. *Cerebral palsy (CP)* is a term that describes a group of static, nonprogressive disorders caused by abnormalities within the brain that disrupt the brain's ability to control movement, muscle coordination, and posture. The resulting motor deficits manifest very early in a child's development, with delayed or abnormal progress in attaining developmental milestones; deficits may become more obvious as the child grows and matures over time.

2. We evaluate your signs and symptoms, such as ataxia, spasticity, flaccidity, athetosis, chorea, and difficulty with precise movements when we determine your ability to stand up, balance, walk, or perform fine

and gross motor movements. We will also evaluate your signs, such as dysarthria and apraxia of speech, and receptive and expressive language problems when we determine your ability to communicate.

3. We will consider your other impairments or signs and symptoms that develop secondary to the disorder, such as post-impairment syndrome (a combination of pain, fatigue, and weakness due to muscle abnormalities); overuse syndromes (repetitive motion injuries); arthritis; abnormalities of proprioception (perception of the movements and position of the body); abnormalities of stereognosis (perception and identification of objects by touch); learning problems; anxiety; and depression.

J. *What are spinal cord disorders, and how do we evaluate them under 111.08?*

1. *Spinal cord disorders* may be congenital or caused by injury to the spinal cord. Motor signs and symptoms of spinal cord disorders include paralysis, flaccidity, spasticity, and weakness.

2. *Spinal cord disorders with complete loss of function* (111.08A) addresses spinal cord disorders that result in complete lack of motor, sensory, and autonomic function of the affected part(s) of the body.

3. *Spinal cord disorders with disorganization of motor function* (111.08B) addresses spinal cord disorders that result in less than complete loss of function of the affected part(s) of the body, reducing, but not eliminating, motor, sensory, and autonomic function.

4. When we evaluate your spinal cord disorder, we generally need evidence from at least 3 months after your symptoms began in order to evaluate your disorganization of motor function. In some cases, evidence of your spinal cord disorder may be sufficient to allow your claim within 3 months after the spinal cord disorder. If the medical evidence demonstrates total cord transection causing a loss of motor and sensory functions below the level of injury, we will not wait 3 months but will make the allowance decision immediately.

K. *What are communication impairments associated with neurological disorders, and how do we evaluate them under 111.09?*

1. Communication impairments result from medically determinable neurological disorders that cause dysfunction in the parts of the brain responsible for speech and language. Under 111.09, we must have recent comprehensive evaluation including all areas of affective and effective communication, performed by a qualified professional, to document a communication impairment associated with a neurological disorder.

2. Under 111.09A, we need documentation from a qualified professional that your neurological disorder has resulted in a speech deficit that significantly affects your ability to communicate. *Significantly affects* means that you demonstrate a serious limitation in communicating, and a person who is unfamiliar with you cannot easily understand or interpret your speech.

3. Under 111.09B, we need documentation from a qualified professional that shows that your neurological disorder has resulted in a comprehension deficit that results in ineffective verbal communication for your

age. For the purposes of 111.09B, *comprehension deficit* means a deficit in receptive language. Ineffective verbal communication means that you demonstrate serious limitation in your ability to communicate orally on the same level as other children of the same age and level of development.

4. Under 111.09C, we need documentation of a neurological disorder that has resulted in hearing loss. Your hearing loss will be evaluated under listing 102.10 or 102.11.

5. We evaluate speech deficits due to non-neurological disorders under 2.09.

L. *What are neurodegenerative disorders of the central nervous system, such as Juvenile-onset Huntington's disease and Friedreich's ataxia, and how do we evaluate them under 111.17?* Neurodegenerative disorders of the central nervous system are disorders characterized by progressive and irreversible degeneration of neurons or their supporting cells. Over time, these disorders impair many of the body's motor or cognitive and other mental functions. We consider neurodegenerative disorders of the central nervous system under 111.17 that we do not evaluate elsewhere in section 111.00, such as juvenile-onset Huntington's disease (HD) and Friedreich's ataxia. When these disorders result in solely cognitive and other mental functional limitations, we will evaluate the disorder under the mental disorder listings, 112.00.

M. *What is traumatic brain injury, and how do we evaluate it under 111.18?*

1. *Traumatic brain injury (TBI)* is damage to the brain resulting from skull fracture, collision with an external force leading to a closed head injury, or penetration by an object that enters the skull and makes contact with brain tissue. We evaluate a TBI that results in coma or persistent vegetative state (PVS) under 111.20.

2. We generally need evidence from at least 3 months after the TBI to evaluate whether you have disorganization of motor function under 111.18. In some cases, evidence of your TBI is sufficient to determine disability. If we are unable to allow your claim within 3 months post-TBI, we will defer adjudication of the claim until we obtain evidence of your neurological disorder at least 3 months post-TBI. If a finding of disability still is not possible at that time, we will again defer adjudication of the claim until we obtain evidence at least 6 months after your TBI.

N. *What are coma and persistent vegetative state, and how do we evaluate them under 111.20?* Coma is a state of unconsciousness in which a child does not exhibit a sleep/wake cycle, and is unable to perceive or respond to external stimuli. Children who do not fully emerge from coma may progress into persistent vegetative state (PVS). PVS is a condition of partial arousal in which a child may have a low level of consciousness but is still unable to react to external stimuli. In contrast to coma, a child in a PVS retains sleep/wake cycles and may exhibit some key lower brain functions, such as spontaneous movement, opening and moving eyes, and grimacing. Coma or PVS may result from a TBI, a nontraumatic insult to the brain (such as a vascular insult, infection, or brain

tumor), or a neurodegenerative or metabolic disorder. Medically induced comas should be considered under the section pertaining to the underlying reason the coma was medically induced and not under this section.

O. *What is multiple sclerosis, and how do we evaluate it under 111.21?*

1. *Multiple sclerosis (MS)* is a chronic, inflammatory, degenerative disorder that damages the myelin sheath surrounding the nerve fibers in the brain and spinal cord. The damage disrupts the normal transmission of nerve impulses within the brain and between the brain and other parts of the body causing impairment in muscle coordination, strength, balance, sensation, and vision. There are several forms of MS, ranging from slightly to highly aggressive. Milder forms generally involve acute attacks (exacerbations) with partial or complete recovery from signs and symptoms (remissions). Aggressive forms generally exhibit a steady progression of signs and symptoms with few or no remissions. The effects of all forms vary from child to child.

2. We evaluate your signs and symptoms, such as flaccidity, spasticity, spasms, incoordination, imbalance, tremor, physical fatigue, muscle weakness, dizziness, tingling, and numbness when we determine your ability to stand up, balance, walk, or perform fine and gross motor movements, such as using your arms, hands, and fingers. If you have a vision impairment resulting from your MS, we may evaluate that impairment under the special senses body system, 102.00.

P. *What are motor neuron disorders, and how do we evaluate them under 111.22?* Motor neuron disorders are progressive neurological disorders that destroy the cells that control voluntary muscle activity, such as walking, breathing, swallowing, and speaking. The most common motor neuron disorders in children are progressive bulbar palsy and spinal muscular dystrophy syndromes. We evaluate the effects of these disorders on motor functioning or bulbar and neuromuscular functioning.

Q. *How do we consider symptoms of fatigue in these listings?* Fatigue is one of the most common and limiting symptoms of some neurological disorders, such as multiple sclerosis and myasthenia gravis. These disorders may result in physical fatigue (lack of muscle strength) or mental fatigue (decreased awareness or attention). When we evaluate your fatigue, we will consider the intensity, persistence, and effects of fatigue on your functioning. This may include information such as the clinical and laboratory data and other objective evidence concerning your neurological deficit, a description of fatigue considered characteristic of your disorder, and information about your functioning. We consider the effects of physical fatigue on your ability to stand up, balance, walk, or perform fine and gross motor movements using the criteria described in 111.00D.

R. *How do we evaluate your neurological disorder when it does not meet one of these listings?*

1. If your neurological disorder does not meet the criteria of any of these listings, we must also consider whether your

impairment(s) meets the criteria of a listing in another body system. 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 § 416.926 of this chapter.

2. If your impairment(s) does not meet or medically equal a listing, we will consider whether your impairment(s) functionally equals the listings. See § 416.926a of this chapter.

3. We use the rules in § 416.994a of this chapter when we decide whether you continue to be disabled.

111.01 Category of Impairments, Neurological Disorders

111.02 *Epilepsy*, documented by a detailed description of a typical seizure and characterized by A or B:

A. Generalized tonic-clonic seizures (see 111.00F1a), occurring at least once a month for at least 3 consecutive months (see 111.00F4) despite adherence to prescribed treatment (see 111.00C); or

B. Dyscognitive seizures (see 111.00F1b) or absence seizures (see 111.00F1c), occurring at least once a week for at least 3 consecutive months (see 111.00F4) despite adherence to prescribed treatment (see 111.00C).

111.03 [Reserved]

111.04 *Vascular insult to the brain*, characterized by disorganization of motor function in two extremities (see 111.00D1), resulting in an extreme limitation (see 111.00D2) in the ability to stand up from a seated position, balance while standing or walking, or use the upper extremities, persisting for at least 3 consecutive months after the insult.

111.05 *Benign brain tumors*, characterized by disorganization of motor function in two extremities (see 111.00D1), resulting in an extreme limitation (see 111.00D2) in the ability to stand up from a seated position, balance while standing or walking, or use the upper extremities.

111.06 [Reserved]

111.07 *Cerebral palsy*, characterized by disorganization of motor function in two extremities (see 111.00D1), resulting in an extreme limitation (see 111.00D2) in the ability to stand up from a seated position, balance while standing or walking, or use the upper extremities.

111.08 *Spinal cord disorders*, characterized by A or B:

A. Complete loss of function, as described in 111.00J2, persisting for 3 consecutive months after the disorder (see 111.00J4); or

B. Disorganization of motor function in two extremities (see 111.00D1), resulting in an extreme limitation (see 111.00D2) in the ability to stand up from a seated position, balance while standing or walking, or use the upper extremities persisting for 3 consecutive months after the disorder (see 111.00J4).

111.09 *Communication impairment*, associated with documented neurological disorder and one of the following:

A. Documented speech deficit that significantly affects (see 111.00K1) the clarity and content of the speech; or

B. Documented comprehension deficit resulting in ineffective verbal communication (see 111.00K2) for age; or

C. Impairment of hearing as described under the criteria in 102.10 or 102.11.

111.10 [Reserved]

111.11 [Reserved]

111.12 *Myasthenia gravis*, characterized by A or B despite adherence to prescribed treatment for at least 3 months (see 111.00C):

A. Disorganization of motor function in two extremities (see 111.00D1), resulting in an extreme limitation (see 111.00D2) in the ability to stand up from a seated position, balance while standing or walking, or use the upper extremities; or

B. Bulbar and neuromuscular dysfunction (see 111.00E), resulting in:

1. One myasthenic crisis requiring mechanical ventilation; or

2. Need for supplemental enteral nutrition via a gastrostomy or parenteral nutrition via a central venous catheter.

111.13 *Muscular dystrophy*, characterized by disorganization of motor function in two extremities (see 111.00D1), resulting in an extreme limitation (see 111.00D2) in the ability to stand up from a seated position, balance while standing or walking, or use the upper extremities.

111.14 *Peripheral neuropathy*, characterized by disorganization of motor function in two extremities (see 111.00D1), resulting in an extreme limitation (see 111.00D2) in the ability to stand up from a seated position, balance while standing or walking, or use the upper extremities.

111.15 [Reserved]

111.16 [Reserved]

111.17 *Neurodegenerative disorders of the central nervous system, such as Juvenile-onset Huntington's disease and Friedreich's ataxia*, characterized by disorganization of motor function in two extremities (see 111.00D1), resulting in an extreme limitation (see 111.00D2) in the ability to stand up from a seated position, balance while standing or walking, or use the upper extremities.

111.18 *Traumatic brain injury*, characterized by disorganization of motor function in two extremities (see 111.00D1), resulting in an extreme limitation (see 111.00D2) in the ability to stand up from a seated position, balance while standing or walking, or use the upper extremities, persisting for at least 3 consecutive months after the injury.

111.19 [Reserved]

111.20 *Coma or persistent vegetative state*, persisting for at least 1 month.

111.21 *Multiple sclerosis*, characterized by disorganization of motor function in two extremities (see 111.00D1), resulting in an extreme limitation (see 111.00D2) in the ability to stand up from a seated position, balance while standing or walking, or use the upper extremities.

111.22 *Motor neuron disorders*, characterized by A or B:

A. Disorganization of motor function in two extremities (see 111.00D1), resulting in an extreme limitation (see 111.00D2) in the ability to stand up from a seated position, balance while standing or walking, or use the upper extremities; or

B. Bulbar and neuromuscular dysfunction (see 111.00E), resulting in:

1. Acute respiratory failure requiring invasive mechanical ventilation; or

2. Need for supplemental enteral nutrition via a gastrostomy or parenteral nutrition via a central venous catheter.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 101

[Docket No. FDA-2015-D-1839]

#### The Food and Drug Administration's Policy on Declaring Small Amounts of Nutrients and Dietary Ingredients on Nutrition Labels; Guidance for Industry; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notification of availability.

**SUMMARY:** The Food and Drug Administration (FDA, we, or the Agency) is announcing the availability of a guidance for industry entitled "FDA's Policy on Declaring Small Amounts of Nutrients and Dietary Ingredients on Nutrition Labels: Guidance for Industry." The guidance explains to manufacturers of conventional foods and dietary supplements our policy on determining the amount to declare on the nutrition label for certain nutrients and dietary ingredients that are present in a small amount.

**DATES:** The guidance is available on July 1, 2016. Submit either electronic or written comments on FDA guidances at any time.

**ADDRESSES:** You may submit comments as follows:

#### Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that

identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All submissions received must include the Docket No. FDA-2015-D-1839. Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions—*To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of