## **SOCIAL SECURITY ADMINISTRATION**

## 20 CFR Parts 404 and 416

[Docket No. SSA-2006-0112]

RIN 0960-AG38

## Revised Medical Criteria for Evaluating Musculoskeletal Disorders

**AGENCY:** Social Security Administration. **ACTION:** Final rules.

SUMMARY: We are revising the criteria in the Listing of Impairments (listings) that we use to evaluate claims involving musculoskeletal disorders in adults and children under titles II and XVI of the Social Security Act (Act). The revisions reflect our adjudicative experience, advances in medical knowledge, and comments we received from the public in response to a notice of proposed rulemaking (NPRM).

**DATES:** These rules are effective April 2, 2021.

### 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 rules for evaluating musculoskeletal disorders that we proposed in the NPRM published in the Federal Register on May 7, 2018.¹ The preamble to the NPRM provides the background for these revisions. You can view the preamble to the NPRM by visiting http://www.regulations.gov and searching for document "SSA-2006-0112." We are making a number of changes in these final rules in response to public comments to the NPRM, which we explain below. We are also making a conforming change to the endocrine disorders body system to comport with the change we proposed to section 416.926a(m) to be consistent with these final rules.

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

We developed these final rules as part of our ongoing review of the listings. We are revising the listings for evaluating musculoskeletal disorders to update the

183 FR 20646 (2018).

medical criteria and clarify how we evaluate musculoskeletal disorders.

## When will we begin to use these final rules?

As we noted in the dates section of this preamble, these final rules will be effective on April 2, 2021. We delayed the effective date of the rules to give us time to update our systems, and to provide training and guidance to all of our adjudicators before we implement the final rules. The current rules will continue to apply until the effective date of these final rules. When the final rules become effective, we will apply them to new applications filed on or after the effective date of the rules, and to claims that are pending on or after the effective date.<sup>2</sup>

## **Public Comments on the NPRM**

In the NPRM, we provided the public with a 60-day comment period, which ended on July 6, 2018. We received 39 comments.<sup>3</sup> The comments came from advocacy groups, legal services organizations, a State agency that makes disability determinations for us, medical organizations, and individual commenters. A number of the letters provided identical (or very similar) comments and recommendations.

We carefully considered all of the comments that were relevant to this rulemaking. We have tried to summarize the commenters' views accurately and respond to all of the significant issues raised by the commenters that were within the scope of these rules. We have not summarized or responded to comments that were outside the scope of the proposed rules. Some commenters noted provisions with which they agreed and did not make suggestions for changes in those provisions. We did not summarize or respond to those comments.

*Comment:* Several commenters asked us to withdraw this rule because they opined the changes we proposed were more stringent in nature. They asserted

fewer applicants would therefore qualify for disability at the listing level. Consequently, they asserted, further assessment at later steps in the evaluation process would be needed, requiring vocational information and consideration of the person's age, education, and work experience to make a determination. Ultimately, the entire disability process would be prolonged. Commenters also asserted that in some cases, even if we changed certain listing criteria, the functional limitations associated with some musculoskeletal conditions would not necessarily change, but would rather result in further evaluations being needed at steps 4 and 5 (and perhaps disability awards being made at those levels). This too could result in longer decision times

Response: We decline to withdraw this final rule. The listings describe impairments that preclude the ability to perform "any gainful activity" (or, in the case of a child applying for Supplemental Security Income (SSI) payments based on disability, to identify impairments that result in marked and severe functional limitations).4 Even if in some cases (although not all) the revised rule results in more decisions being made at steps 4 and 5, we still have a statutory obligation to ensure the listings are up to date and accurately reflect current medical criteria. Contrary to the commenters' assertion, changing the listing does affect the associated functional criteria as well. The updated functional criteria are uniform and specific severity criteria, which represent the level of dysfunction of the upper and lower extremities that would cause a person to be unable to do any work or would cause a child to be unable to perform age-appropriate activities.

Comment: One commenter believes that the functional criteria we use for adults (Part A) and for children (Part B) should not be the same, because children with disabilities are defined by their ability to participate in activities at a level comparable to children of the same age without disabilities.

Response: We disagree. The functional criteria for musculoskeletal disorders in children age 3 and older are appropriately comparable to the functional criteria for musculoskeletal disorders in adults. When we evaluate a child's functioning for purposes of the disability program, including under these listings, we consider whether the child does the things that other children their age typically do, or whether they

<sup>&</sup>lt;sup>2</sup>This means that we will use these final rules on and after their effective date in any case in which we make a determination or decision. We expect that Federal courts will review our final decisions using the rules that were in effect at the time we issued the decisions. If a court reverses our final decision and remands a case for further administrative proceedings after the effective date of these final rules, we will apply these final rules to the entire period at issue in the decision we make after the court's remand.

<sup>&</sup>lt;sup>3</sup> The docket summary on *Regulations.gov* indicates 46 comments were received; however, this number includes seven comments we received for a prior final rule in which we sought comments with a comment period that closed in January 2002 (66 FR 58009, November 19, 2001). Thus, we actually only received a total of 39 public comments in response to these rules.

<sup>420</sup> CFR 404.1525(a) and 416.925(a).

have limitations and restrictions because of their medically determinable impairment(s). We also look at how well children do the activities and how much help they need from family, teachers, or others. Information about what children can and cannot do, and how they function on a day-to-day basis at home, school, and in the community, allows us to compare their activities to the activities of children the same age who do not have impairments.<sup>5</sup> In 101.00E1 (How do we use the functional criteria to evaluate your musculoskeletal disorder under these listings?), we explain that under these rules we compare the musculoskeletal functioning of a child age 3 and older to the functioning of children the same age who do not have impairments, whereas we explain in 1.00E2 (Work environment) that we evaluate musculoskeletal functioning for adults with respect to the work environment. Furthermore, we provide unique criteria for evaluating musculoskeletal disorders in infants and toddlers in listing 101.24 (Musculoskeletal disorders of infants and toddlers, from birth to attainment of age 3, with developmental motor delay), which take into account the rapid development of motor function during the infant and toddler stages.

Comment: Many commenters asked that, in addition to considering a 0 to 5 grading scale of muscle function, we consider alternative, equivalent, medically acceptable grading scales. One commenter expressed that a 0 to 5 grading scale may not be reliable for children who are age 5 or younger, or for older children and adults with cognitive impairments, because of these groups' presumed inability to follow the test instructions.

Response: We agree with these comments, and provide clarification in 1.00C2c (Physical examination report(s)) and 101.00C2c (Physical examination report(s)). We revised the introductory text for reduction in muscle strength to indicate that the measurement should be based on a muscle strength grading system that is considered medically acceptable for the person's age and impairments. We also state that we will accept muscle strength tests using scales other than the 0 to 5 scale, provided the scales used are equivalent, medically acceptable scales.<sup>6</sup> Furthermore, we added an

explanation of what we consider reduction in muscle strength present when the evidence demonstrates that the person's muscle strength is less than active range of motion against gravity with maximum resistance. Since Table 1—Grading System of Muscle Function in 1.00C2c (Physical examination report(s)) and 101.00C2c (Physical examination report(s)) already includes multiple examples of alternative scales, including those suggested, and we added the clarification that we will accept equivalent, medically acceptable scales, we did not add the additional suggested alternative percentage scale used by Kendall and McCreary. If a person's musculoskeletal disorder causes a reduction in muscle strength, and we do not have a report documenting the strength of the muscle(s) in question because the person cannot participate in muscle strength testing, we will consider other objective clinical findings appropriate to the specific musculoskeletal disorder. As well, we note that adults and children with cognitive impairments also may be found disabled on another basis without consideration of their musculoskeletal impairments. We will cover this information, about equivalent, medically acceptable scales, including the Kendall and McCreary scale, during our training on these final rules to fully ensure that adjudicators are aware.

Comment: One commenter suggested that we should not require a positive straight-leg raising test, but should instead use a "cluster of tests" and allow flexibility in evaluations.

Response: We disagree. The straightleg raising test is a longstanding requirement for current listing 1.04 (Disorders of the spine), and it provides objective medical evidence in cases involving lumbar nerve root compromise. The straight-leg raising test is routinely used in medical examinations and is well-accepted by the medical community. It does not require specialty equipment and is considered reliable, accurate, and non-invasive. 78 Furthermore, the commenter

did not specify the "cluster of tests" that should be used instead.

Comment: One commenter asked that we clarify which sources we consider to be acceptable medical sources, and that we consider physical therapists as acceptable medical sources.

Response: We need objective medical evidence from an "acceptable medical source" to establish the existence of a medically determinable impairment(s). We define in 20 CFR 404.1502(a) and 416.902(a) which sources we consider to be "acceptable medical sources." To the extent that information is already provided at length in our existing regulations, we do not repeat it here. However, in response to the commenter's specific concern, we note that physical therapists are not included in the list of acceptable medical sources. As we explained when we updated our medical evidence rules in 2017,9 our acceptable medical sources have licensure requirements that are more nationally consistent, which is essential for us to administer a national disability program. For physical therapists, States significantly vary on titles, the required hours of experience for licensure, and the scope of practice, such as clinical and non-clinical practice. Thus, we do not include them in the list of acceptable medical sources.

When we evaluate the severity of musculoskeletal disorders throughout the sequential evaluation process, we consider all relevant evidence we receive from all medical sources, including physical therapists, regardless of whether they are an acceptable medical source. We therefore note that while evidence from physical therapists cannot establish a medically determinable impairment, the evidence can still help us establish what, if any, functional limitations arise from the medically determinable impairment.

Comment: One commenter asked that we use the terms "arm" instead of "upper extremity" and "leg" instead of "lower extremity."

Response: We did not adopt this comment. An upper extremity includes not just the arm, but also structures such as the fingers, hand, wrist, elbow, forearm, upper arm, and shoulder; and a lower extremity includes not just the leg, but also the toes, feet, ankles, lower leg, knee, upper leg, and hip.

Comment: One commenter asked that we define the ankle as the talocrural joint, instead of the tarsal joint, as the talocrural joint is the ankle proper.

<sup>&</sup>lt;sup>5</sup> 20 CFR 416.924a and Social Security Ruling (SSR) 09–1p: Title XVI: Determining Childhood Disability Under the Functional Equivalence Rule—The "Whole Child" Approach. Available at: https://mwww.ba.ssa.gov/OP\_Home/rulings/ssi/02/SSR2009-01-ssi-02.html.

 $<sup>^6\,\</sup>mathrm{For}$  example, Table 1 (included in the NPRM and again here) includes, under the muscle strength

chart, the none/trace/poor/fair/good/normal alternate scale.

<sup>&</sup>lt;sup>7</sup> Fajolu, O.K., Pencle, F.J.R., Rosas, S., & Chin, K.R. (2018). A prospective analysis of the supine and sitting straight-leg raise test and its performance in litigation patients. Journal of Spine Surgery, 12(1), 58–63. https://doi.org/10.14444/5010.

<sup>&</sup>lt;sup>8</sup>Rabin, A., Gerszten, P.C., Karausky, P., Bunker, C.H., Potter, D.M., & Welch, W.C. (2007). The sensitivity of the seated straight-leg raise test compared with the supine straight-leg raise test in patients presenting with magnetic resonance imaging evidence of lumbar nerve root compression. Archives of Physical Medicine and

Rehabilitation, 88(7), 840–43. https://doi.org/ 10.1016/j.apmr.2007.04.016.

<sup>982</sup> FR 5844 (2017).

Response: We agree with the comment. In 1.00M (What do we consider when we evaluate non-healing or complex fractures of the femur, tibia, pelvis, or one or more of the talocrural bones (1.22)?), 1.20C (Amputation due to any cause), 1.20D (Amputation due to any cause), 101.00M (What do we consider when we evaluate non-healing or complex fractures of the femur, tibia, pelvis, or one or more of the talocrural bones (101.22)?), 101.20C (Amputation due to any cause), and 101.20D (Amputation due to any cause), we referred to the ankle as the "tarsal joint," which is incorrect. We replaced 'tarsal" with "talocrural" in these sections, and also in listings 1.22 (Nonhealing or complex fractures of the femur, tibia, pelvis, or one or more of the talocrural bones) and 101.22 (Nonhealing or complex fractures of the femur, tibia, pelvis, or one or more of the talocrural bones).

Comment: One commenter asked that we clarify whether these rules consider

Syme amputations.

Response: We did not make any changes in the final rules based on this comment. The criteria in 1.20D (Amputation due to any cause) and 101.20D (Amputation due to any cause) require amputation of one or both lower extremities, occurring at or above the ankle. A Syme amputation does not meet the criteria in 1.20D and 101.20D, because it is an amputation done through the ankle in which the tibia and fibular are left intact, the foot is removed, and the heel pad is saved. This is done so that the body's weight can be borne over the distal end of the stump.<sup>10</sup> A Syme amputation offers early post-operative weight-bearing without the need for gait training, better gait pattern with less energy expenditure, and less pressure on the distal stump.<sup>11</sup> As a result, a person with a Syme amputation often requires only a cane and walking boot to ambulate post-surgery. Once the stump has sufficiently healed, a prosthesis is fitted to allow near-normal functioning. For this reason, the impairment, in and of itself, does not rise to listing-level

severity. In cases involving a Syme amputation we would then evaluate the claim under the guidance in 1.00S (How do we evaluate musculoskeletal disorders that do not meet one of these listings?) and 101.00R (How do we evaluate musculoskeletal disorders that do not meet one of these listings?).

Comment: Many commenters asked that we clarify that the terms ''compromise" and ''impingement'' are not required for listings 1.15 (Disorders of the skeletal spine resulting in compromise of a nerve root(s)) and 101.15 (Disorders of the skeletal spine resulting in compromise of a nerve root(s)), because other terms such as "displacement" and "foraminal stenosis" also may indicate compromise of a nerve root.

Response: We did not make any changes in the final rules based on these comments. Listings 1.15 (Disorders of the skeletal spine resulting in compromise of a nerve root(s)) and 101.15 (Disorders of the skeletal spine resulting in compromise of a nerve root(s)) require symptoms of radicular distribution of one or more manifestations, radicular neurological signs, findings on imaging, and physical limitation of musculoskeletal functioning. We explain in 1.00F1 (What do we consider when we evaluate disorders of the skeletal spine resulting in a compromise of a nerve root(s)? (1.15)) and 101.00F1 (What do we consider when we evaluate disorders of the skeletal spine resulting in a compromise of a nerve root(s)? (101.15)) that compromise of a nerve root may be referred to as "nerve root impingement," and both are terms used when a physical object, such as a tumor or herniated disc, is seen pushing on the nerve root in an imaging study or during surgery. Moreover, while the proposed terms of "displacement" and "foraminal stenosis" may indicate compromise of a nerve root, they are not exclusively alternative terms for compromise of a nerve root but instead have separate meanings. 13 14 "Disc displacement" is an alternative term for "disc herniation" and "foraminal stenosis" refers to narrowing of the openings between the bones of the spine. Both of these conditions may occur in people without nerve root compromise as described by

these listings. We do not include every possible term indicating compromise of a nerve root. We consider all evidence regardless of whether the terms we include in the rules, or other comparable terms, appear in the evidence. We also note that our medical consultants are acceptable medical sources with formal medical training, and they will not be confused by commonly accepted alternative medical terms.

Comment: Many commenters asked that we include "pseudoclaudication" as an alternative term for "neurogenic claudication."

Response: We adopted these comments. In 1.00G2 (Compromise of the cauda equina) and 101.00G2 (Compromise of the cauda equina), we added "pseudoclaudication" as an alternative term for "neurogenic claudication.'

Comment: Some commenters objected to the removal of listing criteria for spinal arachnoiditis found in current 1.04B (Disorders of the spine).

Response: Spinal arachnoiditis is a rare spinal disorder involving inflammation of the arachnoid, which is one of the membranes surrounding the spinal cord. The inflammation can result in adhesion of the nerve roots, which, in turn, affects nerve function.15 16 The disorder is characterized by neurological signs and symptoms, including, but not limited to, pain, numbness or weakness in the legs, muscle cramps or spasms, and motor paralysis.<sup>17</sup> <sup>18</sup> We believe spinal arachnoiditis is more appropriately evaluated under the neurological body system due to its origins in the nervous system. Listings 11.08 (Spinal cord disorders) and 111.08 (Spinal cord disorders) offer different methods of evaluating functional limitations resulting from spinal cord disorders, such as spinal arachnoiditis, including extreme limitation in motor function or marked limitation in physical and mental functioning, which may be appropriate for evaluating the functional limitations caused by spinal arachnoiditis depending on the medical evidence we receive. We added a statement to 1.00F (What do we consider when we evaluate disorders of the skeletal spine resulting in compromise

<sup>&</sup>lt;sup>10</sup> Diveley, R.L., & Kiene, R.H. (2008). An improved prosthesis for a syme amputation: Rex L. Diveley MD (1893–1980), Richard H. Kiene MD. Clinical orthopaedics and related research, 466(1), 127-129. https://doi.org/10.1007/s11999-007-0027-

<sup>&</sup>lt;sup>11</sup> Syme Amputation for Limb Salvage: Early Experience with 26 Cases, Frykberg, R., Abraham, S., Tierney, E., and Hall, J. The Journal of Foot and Ankle Surgery, Volume 45, Issue 2, March-April 2007, pp 93-100. Doi: 10.1053/j.jfras.2006.11.005.

<sup>&</sup>lt;sup>12</sup> Syme Amputation and Prosthetic Fitting Challenges, Philbin, T., DeLuccia, D., Nitsch, R., Maurus, P. Techniques in Foot & Ankle Surgery, Sept. 2007-Volume 6-Issue 3-p147-155. Doi: 10.1097/BTF.0b013e31814255b9.

 $<sup>^{13}</sup>$  Raja, A., Hoang, S, Viswanath, O., Herman, J.A., & Mesfin, F.B. (2020). Spinal stenosis. In *StatPearls*. Retrieved from https://www.ncbi.nlm.nih.gov/ books/NBK441989/.

<sup>&</sup>lt;sup>14</sup> Leonardi, M. & Boos, N. (2008). Disc herniation and radiculopathy. In N. Boos & M. Aebi, (Eds.), Spinal Disorders Fundamentals of Diagnosis and Treatment (pp. 481-512). Berlin: Springer. Available from https://link.springer.com/content/ pdf/10.1007%2F978-3-540-69091-7\_18.pdf.

<sup>&</sup>lt;sup>15</sup> Wright, M.H. + Denney, L.C. (2003). A comprehensive review of spinal arachnoiditis. Orthopaedic Nursing, 22(3), 215-9. doi: 10.1097/ 00006416-200305000-00010.

<sup>16</sup> https://rarediseases.info.nih.gov/diseases/ 5839/arachnoiditis.

<sup>17</sup> https://my.clevelandclinic.org/health/diseases/ 12062-arachnoiditis.

<sup>18</sup> https://www.ncbi.nlm.nih.gov/pmc/articles/ PMC3237290/.

of a nerve root(s) (1.15)?) and 101.00F (What do we consider when we evaluate disorders of the skeletal spine resulting in compromise of a nerve root(s) (101.15)?) indicating that spinal arachnoiditis should be evaluated under 11.00 and 111.00. Additionally, we will highlight this clarification during our training on these final rules.

Comment: Several commenters asked that we use plain language terminology instead of medical terminology in these rules, and gave an example of using "pins and needles" instead of

"paresthesia."

Response: We did not make any changes in the final rules based on these comments. While we drafted these rules using plain language to the extent possible, the rules specify the medical criteria we use to evaluate musculoskeletal disorders. The appropriate medical term is paresthesia. We note that the term "pins and needles" is at times used in medical literature 19 20 21 but as a specific medical criteria we believe it is overly colloquial. As such, while we acknowledge that the term "pins and needles" may appear in medical records, we choose to not include the colloquialism in the regulatory text. We will cover this information during our training on these final rules to fully remind adjudicators that colloquialisms such as "pins and needles" may be seen in medical records.

Comment: One commenter stated that many of the terms used in these rules are "not defined well enough" for adjudicators and others to be sure what they mean and gave the examples of "unable," "walk," "fine and gross motor movements," "picking," "pinching," "manipulating and fingering," "handling," "gripping and grasping," "holding," "turning," "lifting and "holding," "turning," "lifting and carrying," "seriously limit," and 'prescribed treatment."

Response: We disagree with these comments. These rules use "fine and gross movements" (not "fine and gross motor movements"), which is a term defined in 1.00E4 (Fine and gross movements) and 101.00E4 (Fine and gross movements). The majority of the other terms identified by this commenter are examples of fine movements (picking, pinching, manipulating, and fingering) and gross movements (handling, gripping, grasping, holding, turning, lifting, and

carrying), and we use these terms, as well as "unable" and "walk," in these rules as they are defined in common English usage. The proposed rules did not include the terms "prescribed treatment" or "seriously limit."

Comment: One commenter expressed concern with the guidance in 101.00C5b (Response to treatment) for child claims (which is also in 1.00C5b (Response to treatment) for adult claims) that explains we may defer our determination or decision under these listings for up to 3 months from the date treatment began. The commenters recommended that the length of deferral time be considered in consultation with a physician or other medical professional.

Response: We agree with and are adopting these comments. We revised 1.00C5b (Response to treatment) and 101.00C5b (Response to treatment) by removing the last sentence, which stated that we may defer our determination or decision under these listings for up to 3 months. The remaining guidance continues to explain that we need information about treatment over a sufficient period of time to determine its effect on a person's musculoskeletal functioning. We use medical consultants and our adjudicative experience to determine the appropriate amount of time. We will not defer our determination or decision when the evidence establishes that the claimant is disabled, either under these listings or on another basis.

Comment: We sought comment on whether the proposed functional criteria in 1.00C6 (Assistive devices) and 101.00C6 (Assistive devices) were appropriate and sufficient. In response, one commenter asked that we add a fourth category of assistive devices, specifically wheeled mobility devices, including manual and power wheelchairs, to the list of assistive devices in 1.00C6 (Assistive devices) and 101.00C6 (Assistive devices). Most of the other commenters made similar comments, recommending that we add "wheelchairs and scooters" wherever we include "a documented medical need for a walker, bilateral canes, or bilateral crutches" in these rules, because people with a documented need for a wheelchair or scooter require "at least as much assistance in walking as those with a need for other assistive devices." These commenters also asked that we "examine how a patient will use an assistive device, not merely why it is needed," and that we require documentation of distance, cadence, and level of assistance.

Response: We are partially adopting the suggestions offered. The functional

criteria in these rules do not require an inability to walk, so the relative assistance in walking offered by different assistive devices is not the point of consideration. Rather, the functional criteria in these rules represent functional limitations related to the upper extremities. These functional limitations either directly represent upper extremity limitations, as with the criteria for an inability to perform fine and gross movements, or indirectly represent upper extremity limitations, as with the criteria for the use of a hand-held assistive device(s). which necessarily limits the use of the upper extremity holding the assistive device. Further, as we explain in 1.00C6d (Hand-held assistive devices) and 101.00C6d (Hand-held assistive devices), "[w]hen you use a one-handed, hand-held assistive device (such as a cane) with one upper extremity to walk and you cannot use your other upper extremity for fine or gross movements (see 1.00E4), the need for the assistive device limits the use of both upper extremities."

To be responsive to the commenters, however, we added wheeled and seated mobility devices to the functional criteria based on how the wheeled and seated mobility device affects the person's use of the upper extremities. As suggested by the commenters, these modifications to the functional criteria are reflected everywhere hand-held assistive devices were proposed in the NPRM. We also added explanation to the introductory text about how we will consider wheeled and seated mobility devices in 1.00C6e (Wheeled and seated mobility devices), 1.00E3 (Functional criteria), 1.00K4 (Amputation of one upper extremity and one lower extremity (1.20C)), 1.00K5 (Amputation of one lower extremity or both lower extremities with complications of the residual limb(s) (1.20D)), 101.00C6e (Wheeled and seated mobility devices), 101.00E3 (Functional criteria), 101.00K4 (Amputation of one upper extremity and one lower extremity (101.20C)), and 101.00K5 (Amputation of one lower extremity or both lower extremities with complications of the residual limbs(s) (101.20D)). We further clarified that any assistive device, regardless of whether it is wheeled, hand-held, or worn, must be supported by medical documentation of the medical need for the assistive device for a continuous period of at least 12 months in 1.00C6a (General) and 101.00C6a (General). With respect to the requests that we require documentation of distance, cadence, and level of assistance, we decline to do so. Most records already supply the information

<sup>&</sup>lt;sup>19</sup> Harrison's Principles of Internal Medicine, Chapter 22 (https://accessmedicine.mhmedical.com /content.aspx?sectionid=192011473& bookid=2129#196882079).

<sup>&</sup>lt;sup>20</sup> https://www.ncbi.nlm.nih.gov/medgen/14619.

<sup>&</sup>lt;sup>21</sup> Bates' Guide to Physical Examination and History Taking Twelfth Edition.

needed to assess the new functional criteria whereas information about the requested items, especially distance, is not typically provided and would necessitate additional development and burden to the claimant to obtain that information.

Comment: One commenter asked that we clarify that hand-held assistive devices are devices you hold onto.

Response: We adopted this comment. In 1.00C6d (Hand-held assistive devices) and 101.C6d (Hand-held assistive devices), we clarified that hand-held assistive devices are devices you hold onto, not carry, with your hands.

Comment: One commenter expressed that the statement in 1.00C6d (Handheld assistive devices) about the need for evidence from a medical source describing how the person walks when using a hand-held assistive device is vague and open to interpretation.

Response: We did not make changes in response to this comment. Depending on the specific musculoskeletal impairment causing the functional limitation, there is variability in the type of device being used, how a person uses an assistive device, and how this device affects mobility. Requiring specific details from the medical source may not adequately address the facts in an individual case. For these reasons, we are intentionally leaving the type of description provided to the discretion of the medical source rather than prescribing a specific type of description. This allows the medical source necessary flexibility in providing a description.

Comment: Many commenters suggested we explain in 1.00D (How do we consider symptoms, including pain, under these listings?) and 101.00D (How do we consider symptoms, including pain, under these listings?) of the introductory text of the listings that a lack of opioid prescription or a person's attempt to reduce or avoid opioid use does not indicate the severity of a musculoskeletal disorder.

Response: In 1.00C5b (Response to treatment) and 101.00C5b (Response to *treatment*), we clarified that a person's musculoskeletal disorder may meet or medically equal one of these listings regardless of whether the person was prescribed opioid medication, or whether the person was prescribed opioid medication and did not follow this prescribed treatment. In addition to how we consider opioids in the context of treatment, in 1.00D (How do we consider symptoms, including pain, under these listings?) and 101.00D (How do we consider symptoms, including pain, under these listings?), we explain how we consider symptoms, including

pain, under these listings. The disability program rules require the presence of a medically determinable impairment that could reasonably be expected to produce the symptoms (including pain), a description of the person's medications (see 1.00C5b (Response to treatment) and 101.00C5b (Response to treatment)), and the effects of those medications on the allegations of pain. Our regulations in 20 CFR 404.1529 and 416.929 and Social Security Ruling (SSR) 16-3p: Titles II and XVI: Evaluation of Symptoms in Disability Claims,<sup>22</sup> explain how we evaluate symptoms, including pain, in disability adjudication.

Our rules about the failure to follow prescribed treatment are found in 20 CFR 404.1530 and 416.930, with additional guidance found in SSR 18-3p: Titles II and XVI: Failure to Follow Prescribed Treatment.<sup>23</sup> If a person is prescribed opioid medication, and chooses to not take the medication, we consider these rules for any medical condition(s), not just musculoskeletal disorders. SSR 18-3p specifically references the "risk of addiction to opioid medication" as an example of a "good cause" reason for not following prescribed treatment with opioid medication.<sup>24</sup> We further note that the musculoskeletal disorders listings are used at step three of our sequential evaluation process, and are used to establish medical criteria to help expedite allowances. Therefore, we do not deny adult claims at this step for any reason and only deny childhood claims if the child's medically determinable impairment(s) does not meet, medically equal, or functionally equal the listings.<sup>25</sup>

Comment: A number of commenters asked that we continue to consider obesity and its effects on the musculoskeletal system.

Response: We agree with the comments. We have not changed our policy on evaluating obesity. We consider all medically determinable impairments when we evaluate claims for disability purposes. If obesity is a

medically determinable impairment, we consider its effects on functioning throughout the sequential evaluation process. These final rules do not eliminate or prevent our consideration of obesity. We added section 1.00Q (How do we consider the effects of obesity when we evaluate your musculoskeletal disorder?), which explains that the combined effects of obesity with musculoskeletal impairments can be greater than the effects of each impairment considered separately. We also provide guidance in SSR 19-2p: Titles II and XVI: Evaluating Cases Involving Obesity, which explains how we consider obesity in disability claims.<sup>26</sup> The removal of the prior section 1.00Q (Effects of obesity), which explained that the combined effects of obesity with musculoskeletal impairments can be greater than the effects of each impairment considered separately, does not change our policy on evaluating obesity.

Comment: One commenter asked how these rules account for fibromyalgia, considering there are no diagnostic tests for this condition; no clear physical, anatomical, or psychological abnormalities resulting from fibromyalgia; and that it is difficult to fully assess pain as part of a medical evaluation, which is particularly challenging given that pain is the primary presenting symptom of fibromyalgia.

Response: These final rules do not change how we consider fibromyalgia. Fibromyalgia is a complex medical condition characterized primarily by widespread pain in the joints, muscles, tendons, or nearby soft tissues that has persisted for at least 3 months. SSR 12-2p: Titles II and XVI: Evaluation of Fibromyalgia explains how we consider fibromyalgia in disability claims, including how we evaluate it at step 3 of our sequential evaluation process.<sup>27</sup> We consider all medically determinable impairments when we evaluate claims for disability purposes. Once fibromvalgia is established as a medically determinable impairment based on appropriate medical evidence, we consider its effects on functioning throughout the sequential evaluation

process.

Comment: Several commenters
disagreed with our introduction into the
regulations of an explicit requirement
that all applicable listing criteria must

 $<sup>^{22}\,81</sup>$  FR 14166 (03/16/16), 81 FR 15776 (03/24/16) (Correction), 82 FR 49462 (10/25/17) (Republished).

<sup>&</sup>lt;sup>23</sup> SSR 18–3p: Titles II and XVI: Failure to Follow Prescribed Treatment. Available at: https:// www.ssa.gov/OP\_Home/rulings/di/02/SSR2018-03di-02.html.

<sup>&</sup>lt;sup>24</sup> SSR 18–3p: Titles II and XVI: Failure to Follow Prescribed Treatment. Available at: https:// www.ssa.gov/OP\_Home/rulings/di/02/SSR2018-03di-02.html.

<sup>&</sup>lt;sup>25</sup> We use a five-step sequential evaluation process to determine whether an adult is disabled under titles II and XVI. 20 CFR 404.1520 and 416.920. We use a different process to decide whether a child is disabled under title XVI of the Act. 20 CFR 416.924.

<sup>&</sup>lt;sup>26</sup> SSR 19–2p: Titles II and XVI: Evaluating Cases Involving Obesity. Available at: https:// www.ssa.gov/OP\_Home/rulings/di/01/SSR2019-02di-01.html.

<sup>&</sup>lt;sup>27</sup> SSR 12–2p: Titles II and XVI: Evaluation of Fibromyalgia. Available at: https://www.ssa.gov/OP\_Home/rulings/di/01/SSR2012-02-di-01.html.

be present simultaneously, and asked that we change our policy to reflect the holding with respect to prior 1.04A in *Radford* v. *Colvin*, 734 F.3d 288 (4th Cir. 2013).<sup>28</sup>

Response: We did not adopt these comments. The holding of the Court of Appeals in Radford differs from our interpretation of the listing requirement, and is inconsistent with our understanding of the degree of severity requirements at step 3 of the sequential evaluation process.

In Radford,29 the United States Court of Appeals for the Fourth Circuit held that Listing 1.04A required a claimant to show only "that each of the symptoms are present, and that the claimant has suffered or can be expected to suffer from nerve root compression continuously for at least 12 months." Contrary to our policy that the requisite level of severity requires the simultaneous presence of all the medical criteria in paragraph A of former 1.04, the Court of Appeals held that a claimant need not show that each criterion was present simultaneously or in particularly close proximity. Because this holding was contrary to our policy, we issued AR 15-1(4), which implemented the Court of Appeals' holding within the Fourth Circuit.30

These final rules clarify our interpretation of the regulations. For a medically determinable impairment to meet a listing, the criteria must be present simultaneously to establish listing-level severity. Once that is established, evidence must show that this level of severity has lasted, or is expected to last, for at least 12 months.

We note that in reaching its conclusion in *Radford*, the Court of Appeals declined to give our interpretation deference because the agency had not previously published any regulation or other agency guidance

supporting our interpretation.31 The Court of Appeals also found that our interpretation was "plainly inconsistent with the text and structure of the regulation because the regulation said "nothing about a claimant's need to show that the symptoms present simultaneously in the claimant or in close proximity to one another"  $^{32}$  Thus, the Court of Appeals decision itself does not preclude us from developing regulations to explicit state this requirement and establish national consistency. Furthermore, our acquiescence rules also allow us to subsequently clarify, modify, or revoke regulations that are the subject of a circuit holding that we determine conflicts with our interpretation of the regulations.<sup>33</sup> In accordance with these rules, we will rescind AR 15-1(4) when these final rules become effective.

Comment: These commenters also stated that the 4-month duration period, during which all of the relevant criteria must be present, if not "present simultaneously," in the medical evidence, should not be a requirement for these listings, and that we should allow medical sources to opine whether the criteria occurred within a 4-month period regardless of whether these findings are actually recorded in the medical record. One commenter suggested that we change the 4-month period to a 6-month period.

Response: We did not adopt these comments. None of these commenters submitted any supporting research or data to justify such a change to these rules. The intention of a 4-month time period was to best ensure all relevant criteria are "present simultaneously," while also providing leeway in cases where multiple visitations or examinations are necessary, such as when a physical examination might not have been performed or symptoms might not have been documented at a given appointment. In the absence of research or data to support these comments, we are not changing the 4month period, which is consistent with the standard of care and common industry practice. For example, a 2012 study of over 100,000 patients with chronic lower back pain found that the median patient visited a physician office 10 times in the study year, with an interquartile range between 6 and 17 outpatient visits.34 This is consistent

with a requirement to document all relevant criteria within a four-month duration can reasonably be accommodated by most patients' routine visitation frequencies. As another example, a two-year study using data from the Medical Panel Expenditure Survey regarding utilization of healthcare showed that for people with spine disease, arthritis/joint disease, musculoskeletal injuries, and other musculoskeletal disease, the average total visits to physician and nonphysician ambulatory services was greater in frequency than once every three months. 35 Other studies also suggest that for chronic ailments, including certain musculoskeletal disorders, re-visitation within 3-4 months is normative.<sup>36</sup>

Moreover, it is generally perceived that providers are trained to schedule their patients for visits every 3 to 4 months routinely, regardless of disease severity.37 This is further backed by clinical practice guidelines. For example, the Veteran's Health Administration (VHA) and Department of Defense's (DoD) Clinical Practice Guideline for the Management of Medically Unexplained Symptoms: Chronic Pain and Fatigue (2001) recommends "initially, a revisit at two to three weeks would be appropriate. As soon as the patient is doing well, then revisits every 3 to 4 months would be recommended." 38 Similarly, the VHA/ DoD 2017 guide Clinical Practice Guideline for Diagnosis and Treatment of Low Back Pain recommends reassessment monthly after initiation of therapy if low back pain continues and

<sup>&</sup>lt;sup>28</sup> Acquiescence Ruling (AR) 15–1(4): Radford v. Colvin, 734 F.3d 288 (4th Cir. 2013): Standard for Meeting Section 1.04A of the Listing of Impairments—Disorders of the Spine with Evidence of Nerve Root Compression—Titles II and XVI of the Social Security Act. Available at: https://www.ssa.gov/OP\_Home/rulings/ar/04/AR2015-01-ar-04.html. The Radford Court held that "[a] claimant need not show that each symptom was present at precisely the same time—i.e., simultaneously—in order to establish the chronic nature of his condition. Nor need a claimant show that the symptoms were present in the claimant in particularly close proximity."

<sup>&</sup>lt;sup>29</sup> Radford v. Colvin, 734 F.3d 288 (4th Cir. 2013).
<sup>30</sup> Acquiescence Ruling (AR) 15–1(4): Radford v. Colvin, 734 F.3d 288 (4th Cir. 2013): Standard for Meeting Section 1.04A of the Listing of Impairments—Disorders of the Spine with Evidence of Nerve Root Compression—Titles II and XVI of the Social Security Act. Available at: https://www.ssa.gov/OP\_Home/rulings/ar/04/AR2015-01-ar-04.html.

 $<sup>^{31}\</sup>mathit{Radford}$ v.  $\mathit{Colvin},$  734 F.3d at 294.

<sup>&</sup>lt;sup>32</sup> Id.

<sup>33 20</sup> CFR 404.985(e)(4) and 416.1485(e)(4).

<sup>&</sup>lt;sup>34</sup> Gore, M., Sadosky, A., Stacey, B.R., Tai, K.S., & Leslie, D. (2012). The burden of chronic low back pain: Clinical comorbidities, treatment patterns, and health care costs in usual care settings. *Spine*,

<sup>37(11),</sup> E668–E677. https://doi.org/10.1097/ BRS.0b013e318241e5de.

<sup>&</sup>lt;sup>35</sup> BMUS: The Burden of Musculoskeletal Diseases in the United States. In: BMUS: The Burden of Musculoskeletal Diseases in the United States [internet]. [cited 15 July 2020]. https:// www.boneandjointburden.org/fourth-edition/viiic2/ utilization-condition-group.

<sup>&</sup>lt;sup>36</sup> J Gen Intern Med. 1999 Apr; 14(4): 230–235. doi: 10.1046/j.1525–1497.1999.00322.x Lisa M. Schwartz, MD, MS, Steven Woloshin, MD, MS, John H. Wasson, MD, Roger A. Renfrew, MD, and H. Gilbert Welch, MD, MPH, Dartmouth Primary Care Cooperative Research Network<sup>1</sup>.

<sup>&</sup>lt;sup>37</sup>Bavafa, H., Savin, S., & Terwiesch, C. (2019). Redesigning Primary Care Delivery: Customized Office Revisit Intervals and E-Visits. https://dx.doi.org/10.2139/ssrn.2363685 Paper referenced by Bavafa: Schectman, G., G. Barnas, P. Laud, L. Cantwell, M. Horton, E.J. Zarling. 2005. Prolonging the return visit interval in primary care. The American Journal of Medicine, 118(4) 393–399.

<sup>&</sup>lt;sup>38</sup> Veterans Health Administration & Department of Defense. (2001). VHA/DoD Clinical Practice Guideline for the Management of Medically Unexplained Symptoms: Chronic Pain and Fatigue. https://www.healthquality.va.gov/guidelines/MR/mus\_fulltext.pdf (2001 VA Practice Guideline for Medically Unexplained Chronic Pain and Fatigue).

no serious specific underlying cause for

low back pain is found.39

We believe our review of available medical literature and clinical guidelines reflects the appropriateness of selecting a 4-month time period. We recognize that one routine visit alone does not necessarily ensure that all necessary criterion for a medical listing are appropriately documented; however the 4-month time period provides sufficient buffer to ensure the criteria are present within a close proximity of time.

We cannot accept a medical opinion that opines that otherwise undocumented medical findings would have occurred during a 4-month period in the absence of any other supporting evidence to bolster that view. We note that when prescribing how we should consider medical opinions, our existing regulations 40 make clear that the most important factors are supportability and consistency. The medical opinions must be supportive of and consistent with other evidence in the case file for us to find them persuasive.

Comment: Several commenters expressed concern about the criterion for imaging in 1.15C (Disorders of the skeletal spine resulting in compromise of a nerve root(s)), 1.16C (Lumbar spinal stenosis resulting in compromise of the cauda equina), 101.15C (Disorders of the skeletal spine resulting in compromise of a nerve root(s)), and 101.16C (Lumbar spinal stenosis resulting in compromise of the cauda equina). These comments noted that there may be people eligible for disability under current rules who may not be able to afford medical imaging or feel that medical imaging is necessary to treat their condition. These commenters asked that we remove this criterion because many claimants cannot afford imaging.

Response: We do not believe that final rule introduces new medical imaging requirements that were not already present under existing rules. Current 1.04 (Disorders of the spine) establishes three potential means for meeting the medical listing. Current 1.04C (Disorders of the spine) explicitly requires appropriate medically acceptable imaging. Current 1.04B (Disorders of the spine) pertains to spinal arachnoiditis and explicitly requires medical imaging, an operative note, or pathology report of tissue

biopsy. As discussed elsewhere in this preamble, spinal arachnoiditis is more appropriately evaluated under the neurological body system (for example, under listings 11.08 (Spinal cord disorders) and 111.08 (Spinal cord disorders) and will be assessed using the requirements in the neurological listings. Finally, current 1.04A does not have an explicit medical imaging requirement. In full, 1.04A reads: "[e]vidence of nerve root compression characterized by neuro-anatomic distribution of pain, limitation of motion of the spine, motor loss (atrophy with associated muscle weakness or muscle weakness) accompanied by sensory or reflex loss and, if there is involvement of the lower back, positive straight-leg raising test (sitting and supine)". Despite not having an explicit medical imaging requirement, under current adjudication policy we would always consider the "evidence of nerve root compression" required in 1.04A to necessarily include medical imaging. Because of this, while 1.15 is more explicit than 1.04A in its requirements pertaining to medical imaging, it does not impose any new medical imaging requirements nor does it impose additional costs on applicants.

Comment: One commenter asked that we replace the medical term "cauda equina involvement" with "nerve root impingement," since "nerve root impingement" is more commonly used in the medical community.

Response: The term "nerve root impingement" is not interchangeable with "cauda equina involvement," so we did not make changes in response to this comment. As we explain in 1.00F (What do we consider when we evaluate disorders of the skeletal spine resulting in compromise of a nerve root(s) (1.15)?) and 101.00F (What do we consider when we evaluate disorders of the skeletal spine resulting in compromise of a nerve root(s) (101.15)?), "compromise of a nerve root," which is an alternative term to "nerve root impingement," is used when a physical object is pushing on the nerve root and results in related symptoms that follow the path of the affected nerve root. Compromise of the cauda equina, as we explain in 1.00G (What do we consider when we evaluate lumbar spinal stenosis resulting in compromise of the cauda equina (1.16)?) and 101.00G (What do we consider when we evaluate lumbar spinal stenosis resulting in compromise of the cauda equina (101.16)?), involves the bundle of nerves descending from the lower part of the spinal cord and typically results in nonradicular pain, because it is not associated with a specific nerve root.

Comment: One commenter suggested that we incorporate impairment of the muscles controlling joint movements into 1.00I (What do we consider when we evaluate abnormality of a major joint(s) in any extremity (1.18)?) and that we should consider how these impairments impact function.

Response: These suggestions are already included in the introductory text and listing criteria for 1.18 (Abnormality of a major join(s) in any extremity). In 1.00I1 (What do we consider when we evaluate abnormality of a major joint(s) in any extremity (1.18)?), we indicate that "[a]bnormalities of the joints include ligamentous laxity or rupture, soft tissue contracture, or tendon rupture and can cause muscle weakness of the affected joint(s)." We explain functional abnormality in 1.00I1b (What do we consider when we evaluate abnormality of a major joint(s) in any extremity (1.18)?).

Comment: Several commenters asked that we insert "at or" before "above the wrists" because amputation at the wrists causes essentially identical functional limitations as amputation just above the wrists.

Response: We agree with the comments. In 1.00K2 (Amputation of both upper extremities), 1.20A (Amputation due to any cause), 101.00K2 (Amputation of both upper extremities), and 101.20A (Amputation due to any cause), we added "at or" before "above the wrists."

Comment: Several commenters suggested we combine the proposed criteria in 1.15A and B (Disorders of the skeletal spine resulting in compromise of a nerve root(s)) and 101.15A and B (Disorders of the skeletal spine resulting in compromise of a nerve root(s)) and "allow them to be satisfied when at least one of the following neuroanatomicallydistributed (radicular) symptoms is present: . . . pain; limitation of motion of the spine; muscle weakness or fatigue; signs of nerve root irritation, tension, or compression; and paresthesias."

Response: We did not adopt these comments. The commenters mischaracterized muscle weakness and signs of nerve root irritation, tension, or compression as "symptoms" of disorders of the skeletal spine resulting in compromise of a nerve root(s). These are, in fact, medical signs. The commenters' suggestion would conflate the symptoms and signs of skeletal spine disorders. The separation of symptoms and signs into two distinct criteria is appropriate given our requirements establishing a medically

<sup>39</sup> Veterans Health Administration & Department of Defense. (2017). VA/DoD Clinical Practice Guideline for Diagnosis and Treatment of Low Back Pain. https://www.healthquality.va.gov/guidelines/ Pain/lbp/VADoDLBPCPG092917.pdf (Module B in document).

<sup>40 20</sup> CFR 404.1520b and 404.1520c.

determinable impairment.<sup>41</sup> SSA defines a symptom as one's own description of a physical or mental impairment(s),<sup>42</sup> whereas a sign is one or more anatomical, physiological, or psychological abnormalities that can be observed apart from one's own statements. Signs must be "shown by accepted medically acceptable clinical diagnostic techniques." <sup>43</sup>

Comment: Several commenters suggested that we remove the functional criteria for 1.15 (Disorders of the skeletal spine resulting in compromise of a nerve root(s)) and 101.15 (Disorders of the skeletal spine resulting in compromise of a nerve root(s)). For example, they argued that the skeletal spine disorder would have serious limitations that would be disabling without any accompanying need for a hand-held assistive device (which we require for the skeletal spine disorder to be considered listing level).

Response: We agree that skeletal spine disorders can cause significant limitations. However, the signs and symptoms that are included in 1.15A and B (Disorders of the skeletal spine resulting in compromise of a nerve root(s)) and 101.15A and B (Disorders of the skeletal spine resulting in compromise of a nerve root(s) have a wide range of presentation. There can be a similarly wide range of limitations resulting from those signs and symptoms. The functional criteria are designed to specify the level of limitation that results in the inability to perform "any gainful activity," which is the level of severity required to meet or equal a listing.44

Comment: Several commenters asked that we omit the functional criteria from 1.23 (Non-healing or complex fracture of an upper extremity) and 101.23 (Non-healing or complex fracture of an upper extremity), because the proposed criteria makes the new listings more difficult to meet or equal than the prior listings.

Response: We partially adopted this comment. Functional criteria continue to be an important part of establishing the inability to perform "any gainful activity," which is the level of severity required to meet or equal a listing. 45 We did, however, modify the criteria in 1.23 (Non-healing or complex fracture of an upper extremity) and 101.23 (Non-healing or complex fracture of an upper extremity) to remove the proposed criterion for the use of a hand-held assistive device, and to instead focus on

the inability to perform fine and gross movements that would be associated with non-union or complex fracture of an upper extremity.

Comment: Several commenters expressed that the functional criteria in 1.23 (Non-healing or complex fracture of an upper extremity) and 101.23 (Non-healing or complex fracture of an upper extremity) are "flawed because they fail to distinguish whether the dominant or non-dominant extremity is injured, which is a crucial distinction in terms of functional abilities and limitations."

Response: We did not make changes in response to this comment. Although the commenters are correct about the lack of distinction between the dominant and non-dominant upper extremity, the listings for musculoskeletal disorders have never considered the difference between a dominant and non-dominant extremity, because people can still use their nondominant extremities. We more appropriately consider a distinction when we assess manipulative limitations in the residual functional capacity (at a later step in the disability determination process), since manipulations require more targeted motor skills and coordination, and the role of the dominant extremity is more important in that area.

Comment: Some commenters argued that listings 1.22 (Non-healing or complex fracture of the femur, tibia, pelvis, or one or more of the talocrural bones), 1.23 (Non-healing or complex fracture of an upper extremity), 101.22 (Non-healing or complex fracture of the femur, tibia, pelvis, or one or more of the talocrural bones), and 101.23 (Non-healing or complex fracture of an upper extremity) are not sufficient replacements for non-pathologic fractures due to the exclusion of fractures of bones such as the skull, ribs, and clavicle.

Response: We do not agree with these comments. First, listings 1.22 (Nonhealing or complex fracture of the femur, tibia, pelvis, or one or more of the talocrural bones), 1.23 (Non-healing or complex fracture of an upper extremity), 101.22 (Non-healing or complex fracture of the femur, tibia, pelvis, or one or more of the talocrural bones), and 101.23 (Non-healing or complex fracture of an upper extremity) include the same types of fractures as current listings 1.06 (Fracture of the femur, tibia, pelvis, or one or more of the tarsal bones), 1.07 (Fracture of an upper extremity), 101.06 (Fracture of the femur, tibia, pelvis, or one or more of the tarsal bones), and 101.07 (Fracture of an upper extremity), which also did not include fractures of the skull, ribs,

and clavicle. Second, non-pathologic fractures likely result in impairments that are more appropriately evaluated under other listing criteria. For example, a fracture of the skull may accompany a traumatic brain injury, which is better considered under neurological listings 11.18 (*Traumatic brain injury*) and 111.18 (Traumatic brain injury), whereas fractures of the ribs or clavicle may result in soft tissue injury that is more appropriately considered under 1.21 (Soft tissue injury or abnormality under continuing surgical management) and 101.21 (Soft tissue injury or abnormality under continuing surgical management).

Comment: Several commenters suggested we should not limit the criteria for 1.19 (Pathologic fractures due to any cause) and 101.19 (Pathological fractures due to any cause) to pathologic fractures, because the same functional limitations can result from both pathologic and non-pathologic fractures.

Response: We did not make changes as a result of these comments. As we explained in the NPRM, medical treatment and recovery expectations for fractures differ, depending on whether the condition is due to an underlying pathology (such as osteoporosis), or to a traumatic event. For this reason, we are adding separate listings for fractures caused by an underlying pathology to provide specific criteria in 1.19 (Pathologic fractures due to any cause) and 101.19 (Pathologic fractures due to any cause) related to evaluation and adjudication of pathologic fractures. We will evaluate complex or non-healing traumatic fractures under 1.22 (Nonhealing or complex fracture of the femur, tibia, pelvis, or one or more of the talocrural bones), 1.23 (Non-healing or complex fracture of an upper extremity) (Non-healing or complex fracture of the femur, tibia, pelvis, or one or more of the talocrural bones), or 101.23 (Non-healing or complex fracture of an upper extremity).

Furthermore, the criterion in 1.19 (Pathologic fractures due to any cause) and 101.19 (Pathologic fractures due to any cause) for three fractures in a 12month period is not appropriate for nonpathologic fractures. Each traumatic fracture constitutes a separate medically determinable impairment under our program rules, and each would need to be evaluated separately to determine whether the duration requirement is met. As we state in 20 CFR 404.1523(a) and 419.923(a), we cannot combine two or more unrelated severe impairments to meet the 12 month duration test. In contrast, multiple pathologic fractures over an extended period are considered

 $<sup>^{41}\,20</sup>$  CFR 404.1521 and 416.921.

<sup>42 20</sup> CFR 404.1502(i) and 416.902(i).

<sup>&</sup>lt;sup>43</sup> 20 CFR 404.1502(g) and 416.902(g).

<sup>&</sup>lt;sup>44</sup> 20 CFR 404.1525(a) and 416.925(a).

<sup>45</sup> Id.

related impairments because of the underlying medical condition (for example, osteoporosis).

Comment: One commenter expressed concern about children with a diagnosis of osteogenesis imperfecta, and suggested we revise the criteria to only require a "definitive diagnosis" of osteogenesis imperfecta with multiple fractures at one time, rather than the proposed requirement for fractures on separate and distinct occasions.

Response: We did not make changes in response to this comment. Osteogenesis imperfecta is not the only cause of pathologic fractures evaluated under 101.19 (Pathologic fractures due to any cause). Other causes include osteoporosis, other skeletal dysplasias, side effects of medications, and disorders of the endocrine system. The criteria for pathological fractures need to be appropriate for pathologic fractures and not just for one condition that has variable effects such as osteogenesis imperfecta. The terminology "definitive diagnosis" would contradict our other regulations. Our regulations require a medically determinable impairment established by objective medical evidence. We specifically state that we do not use a diagnosis to establish the existence of an impairment.46 Once we establish the presence of a severe medically determinable impairment, we then determine whether the level of impairment results in the inability to perform "any gainful activity," which is the level of severity required to meet or equal a listing.47 A "definitive diagnosis" is not, on its own, indicative of listing level severity.

We describe in 101.00J (What do we consider when we evaluate pathologic fractures due to any cause (101.19)?) that osteogenesis imperfecta is one of the conditions that might result in pathologic fractures. Osteogenesis imperfecta is a genetic disease that can manifest at differing levels of severity. For this reason, there is a recognized classification system for the disorder, from type 1 to type 4, to differentiate between the clinical characteristics of each type.<sup>48</sup> The requirement in 101.19 (Pathologic fractures due to any cause) is that the fractures "must occur on separate, distinct occasions, rather than multiple fractures occurring at the same time, but they may affect the same bone(s) multiple times. There is no required period between the incidents of fracture(s), but they must all occur

within a 12-month period; for example, separate incidents may occur within hours or days of each other. However, the associated limitation(s) of function must last, or be expected to last, at least 12 months." This criterion ensures that the severity of the osteogenesis imperfecta, or any other types of pathological fractures, rises to the level required.

*Comment:* One commenter asked that we clarify when we adjust a child's age

for prematurity.

Response: We did not make any changes in the final rules based on this comment. In 101.00O2a (Severity of motor development delay), we provide a citation to 20 CFR 416.924b(b), which explains at length our rules for correcting the chronological age of premature infants. We have not changed those rules here; as such, we direct the commenter to the rules cited above.

Comment: One commenter expressed concern that the listing will "favor or encourage claimants to engage in medical treatment that they would not otherwise engage in" and that "claimants should make treatment decisions with their medical providers and the other consideration should be whether or not the treatment may be beneficial and if the potential benefits outweigh any risks." A similar comment outlined a series of examples of clients who were found eligible at Step 3 under current rules but who the commenter does not believe would be found eligible at Step 3 under this final rule and would therefore need to move on to subsequent steps in the sequential evaluation process.

Response: We did not make changes in response to this comment. In fact, the Act specifically prevents us from interfering with medical practice.49 At no point do we instruct or require that any form of treatment be prescribed, which would violate the cited section of the Act. We only state that in some cases, we consider some items (for example, the use of handheld assistive devices, for certain disorders) or treatments to be effective functional indicators of the presence of a particular musculoskeletal disorder. However, it is understood that if a person is engaging in medical treatment, that treatment must be prescribed by a medical source, and that source will have documented the need for the treatment or assistive

device. We do not believe that this requirement will cause the affected public to pursue a different course of treatment than they otherwise would have under our existing rules.

We also note that many of our medical listings include a functional limitation component, and in the case of certain musculoskeletal disorders, we believe the use of certain treatments or assistive devices is the only objective functional component we can assess. We do not believe that this requirement will cause the affected public to pursue a different course of treatment than they otherwise would have, including the purchase of assistive devices, for people who may seek to apply for disability. This rule requires only the documented medical need for the assistive device, not the ownership of the device. We do not believe that this final rule will result in people, who previously had a documented medical need for an assistive device but who had chosen not to in consultation with their physician due to a perceived lack of benefit (for example, because they are confined to bed) purchase and assistive device to satisfy the functional requirements of this rule. Conversely, a person without a documented medical need for an assistive device in their record will continue to be evaluated under steps 4 and 5 of the disability determination process even if they are not found eligible at step 3.

Comment: One commenter expressed concern that we do not provide quantitative data to show the validity of these listings, noting that many people engage in work even though their impairments meet the listing requirements. The commenter opined that this challenges the validity of using the listings to determine whether a person is disabled, and that the listings are in conflict with the statutory definition of disability. Several other commenters asserted that we do not provide any justification for making the

substantial changes.

Response: We did not make any changes in the final rules based on these comments. Contrary to the commenters' assertion that we did not provide justification or sources for our changes, our NPRM included a list of 64 references that we relied on in proposing these rules. 50 We also invited the public to comment on these references and the data contained within them. The listings help ensure that determinations and decisions of disability have a sound medical basis, that claimants receive equal treatment throughout the country, and that we can

<sup>&</sup>lt;sup>46</sup> 20 CFR 404.1521 and 416.921.

<sup>&</sup>lt;sup>47</sup> 20 CFR 404.1525(a) and 416.925(a).

<sup>48</sup> https://radiopaedia.org/articles/osteogenesisimperfecta-classification-1?lang=us.

<sup>&</sup>lt;sup>49</sup> Sec. 216(i)1: "Nothing in this title shall be construed as authorizing the Commissioner or any other officer or employee of the United States to interfere in any way with the practice of medicine or with relationships between practitioners of medicine and their patients, or to exercise any supervision or control over the administration or operation of any hospital."

<sup>50 83</sup> FR 20646, 20656-58 (2019).

readily identify the majority of people who are disabled. The level of severity described in the listings is such that we consider a person, who is not engaging in substantial gainful activity (SGA) and has an impairment that meets or medically equals all of the criteria of the listing, is generally considered unable to do any work because of the medical impairment alone at step 3 of the sequential evaluation process. When such a person's impairment or combination of impairments meets or medically equals the level of severity described in the listing for the required duration, we will find the person disabled on the basis of medical facts alone in the absence of evidence to the contrary (for example, the actual performance of substantial gainful activity).

Comment: One commenter opined that our proposed revisions discriminate against the poor because the criteria in the listings depend on specific diagnoses that, in turn, require medical tests that many people cannot afford and that we will not purchase. The commenter notes that these tests are not specifically required by the listings, but that they still help establish disability for those people who are able to afford them.

Response: We did not make any changes in the final rules based on these comments. The Act and our regulations require a claimant to submit medical evidence to establish a medically determinable impairment. We use medical evidence generally accepted in the medical community and available in medical records to establish and determine the severity of an impairment. We consider all available evidence about all of a claimant's impairments, not just information about a particular allegation, such as a musculoskeletal condition. We may also purchase medical examinations or tests to obtain the evidence that we need.51 We may find a person disabled even if he or she does not have a medical diagnosis for his or her impairment(s) when applying for benefits, as long as we are able to establish a medically determinable severe physical or mental impairment or combination of impairments that meets the duration requirements.

Comment: Some commenters expressed concern that our proposed updates would ultimately result in more denials of claims at the initial and reconsideration levels.

Response: In some cases, the revised criteria may result in more denials of claims. However, our updated listing criteria most accurately reflect current medical thought in these areas. As well, we note that not all claimants applying on the basis of a musculoskeletal disorder will necessarily be denied because of these listings. In some cases, the impairment(s) also could be found to medically equal a listing (or, in the case of a child seeking SSI payments, functionally equal the listings). If an adult claimant's impairment(s) does not meet or medically equal any listing, in some cases he or she could be found disabled at a later step in the sequential evaluation process once we consider the person's residual functional capacity and the factors of age, education, and vocational experience and skills.

Comment: One commenter asserted that these rules will negatively affect current disability beneficiaries by taking away their benefits.

*Résponse:* When these rules become final, we will not terminate any person's disability benefits solely because we have revised these listings. We do not readjudicate previously decided cases when we revise our listings.

However, under the Act, we are required to periodically conduct continuing disability reviews (CDR) to determine whether beneficiaries are still disabled.52 When we conduct CDRs, we re-examine an existing beneficiary's or recipient's case using the Medical Improvement Review Standard (MIRS) to determine whether a person continues to meet the disability requirements of the Act.<sup>53</sup> When SSA applies the MIRS, our threshold inquiry is whether the beneficiary or recipient has an impairment that still meets that listing. So, if a disability beneficiary or recipient undergoes a CDR after these final rules becomes effective, the standards these rules contain could potentially be applied; theoretically, then, the new standards could contribute to the possibility of a cessation of benefits or payments. We again, note, however, that we would examine all relevant factors when conducting the CDR, just as we do during an initial or reconsideration claim. These include whether the impairment(s) meets or equals a listing, whether there has been medical improvement in the impairments present at the most recent favorable determination, and, if necessary, whether the person has the ability to engage in SGA, given his or her residual functional capacity, and his or her age, education, and past work experience.

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

Under the Act, we have authority to make rules and regulations and to establish necessary and appropriate procedures to carry out such provisions.<sup>54</sup>

How long will these final rules be in effect?

These final rules will remain in effect for 5 years after the date they become effective, unless we extend them, or revise and issue them again. We will continue to monitor these rules to ensure that they continue to meet program purposes, and may revise them before the end of the 5-year period if warranted.

How we will implement these final rules?

We will begin to apply these final rules to new applications, pending claims, and CDRs, as appropriate, as of the effective date of these final rules.<sup>55</sup>

## **Regulatory Procedures**

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

We consulted with the Office of Management and Budget (OMB) and determined that these final rules meet the criteria for a significant regulatory action under Executive Order 12866, as supplemented by Executive Order 13563. Therefore, OMB reviewed the rules. Details about the economic impacts of our rules follow.

Anticipated Reduction in Transfer Payments Made by Our Programs:

In 2017, we conducted a case study covering about 1,400 initial DDS-level decisions, based on the proposed rules as developed at that time. The case study sample was stratified by specific musculoskeletal diagnosis category and included listing-level allowances as well as denials at the medical-vocational stage of the disability determination process. Implementation of this final rule would result in decisional changes relative to those made under current listings both from allowance to denial and from denial to allowance. Based on the results of the

<sup>&</sup>lt;sup>51</sup> 20 CFR 404.1517, 404.1519, 404.1519a–404.1519f, 404.1519k, 416.917, 416.919, and 416.919a–419.919f.

 $<sup>^{52}\,42</sup>$  U.S.C. 421(i), 20 CFR 404.1589, 416.989.

<sup>&</sup>lt;sup>53</sup> 42 U.S.C. 423(f), 20 CFR 404.1594, 416.994,

 $<sup>^{54}</sup>$  Sections 205(a), 702(a)(5), and 1631(d)(1) (42 U.S.C. 405(a), 902(a)(5), 1383(d)(1)).

<sup>&</sup>lt;sup>55</sup> We will use the final rules beginning on its effective date. We will apply the final rules to new applications filed on or after the effective date, and to claims that are pending on and after the effective date. This means that we will use the final rules on and after its effective date in any case in which we make a determination or decision, including CDRs, as appropriate. 20 CFR 404.902 and 416.1402.

case study, we estimate that for the OASDI program, there would be a net annual reduction in allowances of about 260, the net effect of an estimated 480 annual changes from allowance to denial, and an estimated 220 annual changes from denial to allowance. This small shift is primarily driven by claimants who were allowed at the listing-level (Step 3) under existing regulations but whose case files do not contain medical evidence indicating they would meet the new assistive devices requirements in this final rule, because such documentation is not required under current rules. Under implementation of this final rule, some of these claimants would be expected to be able to provide this information under the new requirement, and would do so. We made a small adjustment to the case study results based on this expectation.

For the SSI program the estimates indicate a net increase in annual allowances of about 180, the net effect of an estimated 285 annual changes from denial to allowance, and an estimated 105 annual changes from allowance to denial. The results of the actuarial analysis using the case study results indicate a net reduction in OASDI benefit payments (\$263 million) and a net increase in Federal SSI payments (\$67 million) over the FY 2021 Budget projection period, FYs 2021–30.

Anticipated Administrative Costs to the Social Security Administration:

In calculating whether the implementation of these final rules will result in administrative costs or savings to the agency, we examine two sources: (1) Work-years and (2) direct financial administrative costs.

We define work-years as a measure of the SSA employee work time these final rules will cost or save during implementation of its policies. We calculate one work-year as 2,080 hours of labor, which represents the amount of hours one SSA employee works per year based on a standard 40-hour workweek.

We are estimating net administrative savings of less than \$2 million and 15 work years per year. The administrative savings result from fewer SSI appeals, fewer maintenance actions for OASDI beneficiaries, and administrative efficiencies from decisions made earlier in the sequential evaluation process. Because we project an increase in SSI allowances, we believe there will be fewer SSI appeals once the regulation is implemented. We estimate an increase in OASDI denials. Because more OASDI claims would be denied, there would be fewer OASDI actions to process such as change of address or payment

corrections. Offsetting administrative costs include those to process additional appeals for the net increase in OASDI claims that are denied, as well as costs to train Disability Determination Service (DDS) employees, and for increased maintenance-of-the-rolls actions from the net increase in SSI recipients. Although this rule results in, on net, slightly more overall denials than allowances when compared to the current regulations, because of the administrative efficiencies resulting from decisions made earlier in the sequential evaluation process, the overall impact to this rulemaking is a slight reduction in administrative costs.

## **Anticipated Costs to the Public**

We do not believe there are any more than de minimis costs to the public associated with this rulemaking. First. as discussed earlier in responses to comments on the Notice of Proposed Rulemaking as well as in the *Paperwork* Reduction Act section below, we do not believe any of the requirements contained in this rulemaking will impose new additional costs outside of the normal course of business for applicants. We do not believe that the new rules induce any new medical imaging requirements and do not believe they will result in additional purchasing and documentation of assistive devices.

## **Congressional Review Act**

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), OMB designated these rules as major rules, as defined by 5 U.S.C. 804(2).

## **Executive Order 13132 (Federalism)**

We analyzed these final rules in accordance with the principles and criteria established by Executive Order 13132, and determined that they will not have sufficient Federalism implications to warrant the preparation of a Federalism assessment. We also determined that the final rules will not preempt any State law or State regulations or affect the States' abilities to discharge traditional State governmental functions.

## **Executive Order 13771**

Based upon the criteria established in Executive Order 13771 and M-17-21 ("Guidance Implementing E.O. 13771"), we consider this rule a transfer rule with no more than *de minimis* costs. As such, it is exempt from requirements under E.O. 13771.

## **Regulatory Flexibility Act**

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

## **Paperwork Reduction Act**

These final rules comprehensively revise the regulatory criteria we use to evaluate musculoskeletal disorders, and will affect the OASDI and SSI programs. SSA uses multiple existing OMBapproved information collection (IC) tools to document disability claims for all body system disorders, including musculoskeletal disorders. However, because these ICs are not specific to any particular body system disorders, they do not require modification in any way as a result of these final rules. As well, the regulatory changes are not changing the frequency of reporting or the burden—including documentation involved in musculoskeletal disability claims. So, we are not making any changes under the Paperwork Reduction Act as a result of these rules.

Below we list for informational purposes the ICs that SSA uses to collect information related to Musculoskeletal (and all other) disability Title II & Title XVI claims. However, for the reasons provided above, we are not modifying them in any way due to these final rules.

- OMB No. 0960–0579 (SSA–3368, Disability Report—Adult)
- OMB No. 0960–0577 (SSA–3820, Disability Report—Child)
- OMB No. 0960–0578 (SSA–3369, Work History Report)
- OMB No. 0960–0540 (SSA–3371, Pain Report—Child)
- OMB No. 0960–0681 (SSA–3373, Function Report—Adult)
- OMB No. 0960–0542 (SSA–3375, SSA–3376, SSA–3377, SSA–3378 and SSA–3379, Function Report—Child)
- OMB No. 0960–0635 (SSA–3380, Function Report—Adult—Third Party)
- OMB No. 0960–0623 (SSA–827, Authorization to Disclose Information to the Social Security Administration)
- OMB No. 0960–0598 (SSA–820 or SSA–821, Work Activity Report—Self Employed Person & Work Activity Report—Employee)
- OMB No. 0960–0144 (SSA–3441, Disability Report—Appeal)
- OMB No. 0960–0499 (SSA–3881, Questionnaire for Children Claiming SSI Benefits)
- OMB No. 0960–0720 (SSA–3830, Certification of Low Birth Weight for SSI Eligibility)

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

## List of Subjects

## 20 CFR Part 404

Administrative practice and procedure; Blind, Disability benefits; Old-age, survivors, and disability insurance; Reporting and recordkeeping requirements; Social Security.

## 20 CFR Part 416

Administrative practice and procedure; Aged, Blind, Disability cash payments; Public assistance programs; Reporting and recordkeeping requirements; Supplemental Security Income (SSI).

The Commissioner of Social Security, Andrew Saul, having reviewed and approved this document, is delegating the authority to electronically sign this document to Faye I. Lipsky, who is the primary Federal Register Liaison for the Social Security Administration, for purposes of publication in the **Federal Register**.

## Faye I. Lipsky,

Federal Register Liaison, Office of Legislative and Congressional Affairs, Social Security Administration.

For the reasons set out in the preamble, we are amending subpart P of part 404 of chapter III of title 20 of the Code of Federal Regulations as set forth below:

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

## 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) and (h)–(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) and (h)–(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** a. In the introductory text before part A, revise paragraph 2;
- b. In part A:
- i. Amend the table of contents for part A by revising the entry for section 1.00;
- ii. Revise section 1.00;
- iii. Revise paragraph 4.00G4b;
- iv. Revise paragraphs 14.00C6 through 14.00C8, 14.00C12, 14.00D4c(i),
- 14.00D6a, 14.00D6e(i), and 14.00D6e(ii); and

- v. Under section 14.00, revise listings 14.04B, 14.04C2, 14.05A, 14.09A, and 14.09B introductory text; and
- c. In part B:
- i. Amend the table of contents by revising the entry for section 101.00;
- ii. Revise section 101.00;
- iii. Revise paragraph 104.00F9b;
- iv. Revise paragraph 109.00C;
- v. Revise paragraphs 114.00C6 through 114.00C8, 114.00C12, 114.00D4c(ii), 114.00D6a, 114.00D6e(i), and 114.00D6e(ii); and
- vi. Under section 114.00, revise listings 114.04B, 114.04C2, 114.05A, 114.09A, and 114.09B introductory text. The revisions read as follows:

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

2. Musculoskeletal Disorders (1.00 and 101.00): April 2, 2026.

## Part A

## 1.00 Musculoskeletal Disorders

## 1.00 Musculoskeletal Disorders

A. Which musculoskeletal disorders do we evaluate under these listings?

- 1. We evaluate disorders of the skeletal spine (vertebral column) or of the upper or lower extremities that affect musculoskeletal functioning under these listings. We use the term "skeletal" when we are referring to the structure of the bony skeleton. The  $s\breve{k}eletal$ spine refers to the bony structures, ligaments, and discs making up the spine. We refer to the skeletal spine in some musculoskeletal listings to differentiate it from the neurological spine (see 1.00B1). Musculoskeletal disorders may be congenital or acquired, and may include deformities, amputations, or other abnormalities. These disorders may involve the bones or major joints; or the tendons, ligaments, muscles, or other soft tissues.
- 2. We evaluate soft tissue injuries (including burns) or abnormalities that are under continuing surgical management (see 1.00O1). The injuries or abnormalities may affect any part of the body, including the face and skull.
- 3. We evaluate curvatures of the skeletal spine that affect musculoskeletal functioning under 1.15. If a curvature of the skeletal spine is under continuing surgical management (see 1.00O1), we will evaluate it under 1.21 using our rules for determining medical equivalence. See §§ 404.1526 and 416.926 of this chapter.
- B. Which related disorders do we evaluate under other listings?
- 1. We evaluate a disorder or injury of the skeletal spine that results in damage to, and neurological dysfunction of, the spinal cord and its associated nerves (for example, paraplegia or quadriplegia) under the listings in 11.00.

- 2. We evaluate inflammatory arthritis (for example, rheumatoid arthritis) under the listings in 14.00.
- 3. We evaluate curvatures of the skeletal spine that interfere with your ability to breathe under the listings in 3.00, impair myocardial function under the listings in 4.00, or result in social withdrawal or depression under the listings in 12.00.
- 4. We evaluate non-healing or pathological fractures due to cancer, whether it is a primary site or metastases, under the listings in 13.00.
- 5. We evaluate the leg pain associated with peripheral vascular claudication and foot ulceration associated with peripheral arterial disease under the listings in 4.00.
- 6. We evaluate burns that do not require continuing surgical management under the listings in 8.00.
- C. What evidence do we need to evaluate your musculoskeletal disorder?
- 1. General. We need objective medical evidence from an acceptable medical source to establish that you have a medically determinable musculoskeletal disorder. We also need evidence from both medical and nonmedical sources, who can describe how you function, to assess the severity and duration of your musculoskeletal disorder. We will determine the extent and kinds of evidence we need from medical and nonmedical sources based on the individual facts about your disorder. For our basic rules on evidence, see §§ 404.1512, 404.1513, 404.1520b, 416.912, 416.913, and 416.920b of this chapter. For our rules on evidence about your symptoms, see §§ 404.1529 and 416.929 of this chapter.
- 2. Physical examination report(s). In the report(s) of your physical examination, we require a medical source's detailed description of the orthopedic, neurologic, or other objective clinical findings appropriate to your specific musculoskeletal disorder from his or her direct observations during your physical examination. We will not accept a report of your statements about your symptoms and limitations in place of the medical source's report of objective clinical findings. We will not use findings on imaging or other diagnostic tests (see 1.00C3) as a substitute for findings on physical examination.
- a. When the medical source reports that a clinical test sign(s) is positive, unless we have evidence to the contrary, we will assume that he or she performed the test properly and accept the medical source's interpretation of the test. For example, we will assume a straight-leg raising test was conducted properly (that is, in sitting and supine positions), even if the medical source does not specify the positions in which the test was performed.
- b. If you use an assistive device (see 1.00C6), the report must support the medical need for the device.
- c. If your musculoskeletal disorder causes a reduction in muscle strength, the report must document measurement of the strength of the muscle(s) in question. The measurement should be based on a muscle strength grading system that is considered medically acceptable based on your age and impairments. For example, a grading system

of 0 to 5, with 0 indicating complete loss of strength and 5 indicating maximum strength or equivalent medically acceptable scale (see Table 1). Reduction in muscle strength is demonstrated by evidence that your muscle strength is less than active range of motion (ROM) against gravity with maximum resistance. If the reduction in muscle strength involves one or both of your hands, the report must also document measurements of grip and pinch strength.

### TABLE 1—GRADING SYSTEM OF MUSCLE FUNCTION

Grade	Function of the muscle
	Active ROM against gravity only, without resistance.

- 3. Imaging and other diagnostic tests.
- a. *Imaging* refers to medical imaging techniques, such as x-ray, computed tomography (CT), magnetic resonance imaging (MRI), and radionuclide scanning. For the purpose of these listings, 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.
- b. Findings on imaging must have lasted, or be expected to last, for a continuous period of at least 12 months.
- c. Imaging and other diagnostic tests can provide evidence of physical abnormalities; however, these abnormalities may correlate poorly with your symptoms, including pain, or with your musculoskeletal functioning. Accordingly, we will not use findings on imaging or other diagnostic tests as a substitute for findings on physical examination about your ability to function, nor can we infer severity or functional limitations based solely on such tests.
- d. For our rules on purchasing imaging and other diagnostic tests, see §§ 404.1519k, 404.1519m, 416.919k, and 416.919m of this chapter.
- 4. Operative reports. If you have had a surgical procedure, we need a copy of the operative report, including details of the findings at surgery and information about any medical complications that may have occurred. If we do not have the operative report, we need confirmatory evidence of the surgical procedure from a medical source (for example, detailed follow-up reports or notations in the medical records concerning the surgical procedure in your medical history).
  - 5. Effects of treatment.
- a. General. Treatments for musculoskeletal disorders may have beneficial or adverse effects, and responses to treatment vary from person to person. We will evaluate all of the effects of treatment (including surgical treatment, medications, and therapy) on the symptoms, signs, and laboratory findings of your musculoskeletal disorder, and on your musculoskeletal functioning.

  b. Response to treatment. To evaluate your
- b. Response to treatment. To evaluate your musculoskeletal functioning in response to treatment, we need the following: A description, including the frequency of the administration, of your medications; the type and frequency of therapy you receive; and a description of your response to treatment and any complications you experience related to your musculoskeletal disorder. The effects of

treatment may be temporary or long-term. We need information over a sufficient period to determine the effects of treatment on your current musculoskeletal functioning and permit reasonable projections about your future functioning. We will determine the amount of time that constitutes a sufficient period in consultation with a medical consultant on a case-by-case basis. In some cases, we will need additional evidence to make an assessment about your response to treatment. Your musculoskeletal disorder may meet or medically equal one of these listings regardless of whether you were prescribed opioid medication, or whether you were prescribed opioid medication and did not follow this prescribed treatment.

- 6. Assistive devices.
- a. General. An assistive device, for the purposes of these listings, is any device that you use to improve your stability, dexterity, or mobility. An assistive device can be worn (see 1.00C6b and 1.00C6c), hand-held (see 1.00C6d), or used in a seated position (see 1.00C6e). When we use the phrase "documented medical need," we mean that there is evidence from a medical source that supports your medical need for an assistive device (see 1.00C2b) for a continuous period of at least 12 months (see 1.00C6a). This evidence must describe any limitation(s) in your upper or lower extremity functioning and the circumstances for which you need to use the assistive device. We do not require that you have a specific prescription for the assistive device.
- b. *Prosthesis(es)*. A prosthesis is a wearable device, such as an artificial limb, that takes the place of an absent body part. If you have a prosthesis(es), we need evidence from a medical source documenting your ability to walk, or perform fine and gross movements (see 1.00E4), with the prosthesis(es) in place. When amputation(s) involves one or both lower extremities, it is not necessary for the medical source to evaluate your ability to walk without the prosthesis(es) in place. If you cannot use your prosthesis(es) due to complications affecting your residual limb(s), we need evidence from a medical source documenting the condition of your residual limb(s) and the medical basis for your inability to use the device(s).
- c. Orthosis(es). An orthosis is a wearable device, such as a brace, that prevents or corrects a dysfunction or deformity by aligning or supporting the affected body part. If you have an orthosis(es), we need evidence from a medical source documenting your

- ability to walk, or perform fine and gross movements (see 1.00E4), with the orthosis(es) in place. If you cannot use your orthosis(es), we need evidence from a medical source documenting the medical basis for your inability to use the device(s).
- d. Hand-held assistive devices. Hand-held assistive devices include walkers, canes, or crutches, which you hold onto with your hand(s) to support or aid you in walking. When you use a one-handed, hand-held assistive device (such as a cane) with one upper extremity to walk and you cannot use your other upper extremity for fine or gross movements (see 1.00E4), the need for the assistive device limits the use of both upper extremities. If you use a hand-held assistive device, we need evidence from a medical source describing how you walk with the device.
- e. Wheeled and seated mobility devices. Wheeled and seated mobility devices are assistive devices that you use in a seated position, such as manual wheelchairs, motorized wheelchairs, rollators, and power operated vehicles. If you use a wheeled and seated mobility device, we need evidence from a medical source describing the type of wheeled and seated mobility device that you use and how you use the assistive device including any customizations or modifications to the assistive device itself or for your use of the assistive device. For example, if you use a wheelchair that typically requires the use of both hands but has been customized for your use with one hand, then we will evaluate your use of the assistive device using the criteria in 1.00E3b and not 1.00E3a.
- (i) Wheeled and seated mobility devices involving the use of both hands. Some wheeled and seated mobility devices involve the use of both hands to use the assistive device (for example, most manual wheelchairs). If you use a wheeled and seated mobility device that involves the use of both hands, then the need for the assistive device limits the use of both upper extremities.
- (ii) Wheeled and seated devices involving the use of one hand. Some wheeled and seated mobility devices involve the use of one hand to use the assistive device (for example, most motorized wheelchairs). If you use a wheeled and seated mobility device that involves the use of one upper extremity and you cannot use your other upper extremity for fine or gross movements (see

- 1.00E4), then the need for the assistive device limits the use of both upper extremities.
  - 7. Longitudinal evidence.
- a. We generally need a longitudinal medical record to assess the severity and duration of your musculoskeletal disorder because the severity of symptoms, signs, and laboratory findings related to most musculoskeletal disorders may improve over time or respond to treatment. Evidence over an extended period will show whether your musculoskeletal functioning is improving, worsening, or unchanging.
- b. For 1.15, 1.16, 1.17, 1.18, 1.20C, 1.20D, 1.22, and 1.23, all of the required criteria must be present simultaneously, or within a close proximity of time, to satisfy the level of severity needed to meet the listing. The phrase "within a close proximity of time" means that all of the relevant criteria must appear in the medical record within a consecutive 4-month period. When the criterion is imaging, we mean that we could reasonably expect the findings on imaging to have been present at the date of impairment or date of onset. For listings that use the word "and" to link the elements of the required criteria, the medical record must establish the simultaneous presence, or presence within a close proximity of time, of all the required medical criteria. Once this level of severity is established, the medical record must also show that this level of severity has continued, or is expected to continue, for a continuous period of at least 12 months.
- 8. Surgical treatment and physical therapy. For some musculoskeletal disorders, a medical source may recommend surgery or physical therapy (PT). If you have not yet had the recommended surgery or PT, we will not assume that these interventions will resolve your disorder or improve your functioning. We will assess each case on an individual basis. Depending on your response to treatment, or your medical sources' treatment plans, we may defer our findings regarding the effect of surgery or PT, until a sufficient period has passed to permit proper consideration or judgment about your future functioning. When necessary, we will follow the rules on following prescribed treatment in §§ 404.1530 and 416.930 of this chapter, including consideration of your reasons for failure to follow prescribed treatment.
- D. How do we consider symptoms, including pain, under these listings?
- 1. Musculoskeletal disorders may cause pain or other symptoms; however, your statements about your pain or other symptoms will not alone establish that you are disabled. We will not substitute an alleged or a reported increase in the intensity of a symptom, such as pain, no matter how severe, for a medical sign or diagnostic finding present in the listing criteria. Pain is included as just one consideration in 1.15A, 1.16A, and 1.18A, but it is not required to satisfy the criteria in 1.15, 1.16, and 1.18.
- 2. To consider your symptom(s), we require objective medical evidence from an acceptable medical source showing the existence of a medically determinable musculoskeletal impairment that we could reasonably expect to produce the symptom(s). See §§ 404.1529 and 416.929 of

- this chapter for how we evaluate symptoms, including pain, related to your musculoskeletal disorder.
- E. How do we use the functional criteria to evaluate your musculoskeletal disorder under these listings?
- 1. General. The functional criteria are based on impairment-related physical limitations in your ability to use both upper extremities, one or both lower extremities, or a combination of one upper and one lower extremity. The required impairment-related physical limitation of musculoskeletal functioning must have lasted, or be expected to last, for a continuous period of at least 12 months. We do not use the functional criteria in 1.20A, 1.20B, or 1.21.
- 2. Work environment. We use the relevant evidence that we have to evaluate your musculoskeletal functioning with respect to the work environment rather than the home environment. For example, an ability to walk independently at home without an assistive device does not, in and of itself, indicate an ability to walk without an assistive device in a work environment.
- 3. Functional criteria. A musculoskeletal disorder satisfies the functional criteria of a listing when the medical documentation shows the presence of at least one of the impairment-related limitations cited in the listing. The required impairment-related limitation of musculoskeletal functioning must be medically documented by one of the following:
- a. A documented medical need (see 1.00C6a) for a walker, bilateral canes, or bilateral crutches (see 1.00C6d) or a wheeled and seated mobility device involving the use of both hands (see 1.00C6e(i));
- b. An inability to use one upper extremity to independently initiate, sustain, and complete work-related activities involving fine and gross movements (see 1.00E4), and a documented medical need (see 1.00C6a) for a one-handed, hand-held assistive device (see 1.00C6d) that requires the use of your other upper extremity or a wheeled and seated mobility device involving the use of one hand (see 1.00C6e(ii));
- c. An inability to use both upper extremities to the extent that neither can be used to independently initiate, sustain, and complete work-related activities involving fine and gross movements (see 1.00E4).
- 4. Fine and gross movements. Fine movements, for the purposes of these listings, involve use of your wrists, hands, and fingers; such movements include picking, pinching, manipulating, and fingering. Gross movements involve use of your shoulders, upper arms, forearms, and hands; such movements include handling, gripping, grasping, holding, turning, and reaching. Gross movements also include exertional abilities such as lifting, carrying, pushing, and pulling. Examples of performing fine and gross movements include, but are not limited to, taking care of personal hygiene, sorting and handling papers or files, and placing files in a file cabinet at or above waist level.
- F. What do we consider when we evaluate disorders of the skeletal spine resulting in compromise of a nerve root(s) (1.15)?
- 1. General. We consider musculoskeletal disorders such as herniated nucleus

- pulposus, spinal osteoarthritis (spondylosis), vertebral slippage (spondylolisthesis), degenerative disc disease, facet arthritis, and vertebral fracture or dislocation. Spinal disorders may cause cervical or lumbar spine dysfunction when abnormalities of the skeletal spine compromise nerve roots of the cervical spine, a nerve root of the lumbar spine, or a nerve root of both cervical and lumbar spines. We consider spinal nerve disorders that originate in the nervous system (for example, spinal arachnoiditis), under the neurological disorders body system, 11.00.
- 2. Compromise of a nerve root(s). Compromise of a nerve root, sometimes referred to as "nerve root impingement," is a phrase used when a physical object, such as a tumor, herniated disc, foreign body, or arthritic spur, is pushing on the nerve root as seen on imaging or during surgery. It can occur when a musculoskeletal disorder produces irritation, inflammation, or compression of the nerve root(s) as it exits the skeletal spine between the vertebrae. Related symptoms must be associated with, or follow the path of, the affected nerve root(s).
- a. Compromise of unilateral nerve root of the cervical spine. Compromise of a nerve root as it exits the cervical spine between the vertebrae may affect the functioning of the associated upper extremity. The physical examination reproduces the related symptoms based on radicular signs and clinical tests appropriate to the specific cervical nerve root (for example, a positive Spurling test).
- b. Compromise of bilateral nerve roots of the cervical spine. Although uncommon, if compromise of a nerve root occurs on both sides of the cervical spinal column, functioning of both upper extremities may be limited.
- c. Compromise of a nerve root(s) of the lumbar spine. Compromise of a nerve root as it exits the lumbar spine between the vertebrae may limit the functioning of the associated lower extremity. The physical examination reproduces the related symptoms based on radicular signs and clinical tests. When a nerve root of the lumbar spine is compromised, we require a positive straight-leg raising test (also known as a Lasègue test) in both supine and sitting positions appropriate to the specific lumbar nerve root that is compromised.
- G. What do we consider when we evaluate lumbar spinal stenosis resulting in compromise of the cauda equina (1.16)?
- 1. General. We consider how pain, sensory changes, and muscle weakness caused by compromise of the cauda equina due to lumbar spinal stenosis affect your functioning. The cauda equina is a bundle of nerve roots that descends from the lower part of the spinal cord. Lumbar spinal stenosis can compress the nerves of the cauda equina, causing sensory changes and muscle weakness that may affect your ability to stand or walk. Pain related to compromise of the cauda equina is nonradicular because it is not typically associated with a specific nerve root (as is radicular pain in the cervical or lumbar spine).
- 2. Compromise of the cauda equina due to lumbar spinal stenosis can affect your ability

to walk or stand because of neurogenic claudication (also known as pseudoclaudication), a condition usually causing nonradicular pain that starts in the low back and radiates bilaterally (or less commonly, unilaterally) into the buttocks and lower extremities (or extremity). Extension of the lumbar spine, which occurs when you walk or stand, may provoke the pain of neurogenic claudication. The pain may be relieved by forward flexion of the lumbar spine or by sitting. In contrast, the leg pain associated with peripheral vascular claudication results from inadequate arterial blood flow to a lower extremity. It occurs repeatedly and consistently when a person walks a certain distance and is relieved when the person rests.

- H. What do we consider when we evaluate reconstructive surgery or surgical arthrodesis of a major weight-bearing joint (1.17)?
- 1. General. We consider reconstructive surgery or surgical arthrodesis when an acceptable medical source(s) documents the surgical procedure(s) and associated medical treatments to restore function of, or eliminate motion in, the affected major weight-bearing joint. Reconstructive surgery may be done in a single procedure or a series of procedures directed toward the salvage or restoration of functional use of the affected joint.
- 2. Major weight-bearing joints are the hip, knee, and ankle-foot. The ankle and foot are considered together as one major joint.
- 3. *Surgical arthrodesis* is the artificial fusion of the bones that form a joint, essentially eliminating the joint.
- I. What do we consider when we evaluate abnormality of a major joint(s) in any extremity (1.18)?
- 1. General. We consider musculoskeletal disorders that produce anatomical abnormalities of major joints of the extremities, which result in functional abnormalities in the upper or lower extremities (for example, osteoarthritis, chronic infections of bones and joints, and surgical arthrodesis of a joint). Abnormalities of the joints include ligamentous laxity or rupture, soft tissue contracture, or tendon rupture, and can cause muscle weakness of the affected joint(s).
- a. An anatomical abnormality is one that is readily observable by a medical source during a physical examination (for example, subluxation or contracture), or is present on imaging (for example, joint space narrowing, bony destruction, ankylosis, or deformity).
- b. A functional abnormality is abnormal motion or instability of the affected joint(s), including limitation of motion, excessive motion (hypermobility), movement outside the normal plane of motion for the joint (for example, lateral deviation), or fixation of the affected joint(s).
- 2. Major joint of an upper extremity refers to the shoulder, elbow, and wrist-hand. We consider the wrist and hand together as one major joint.
- 3. Major joint of a lower extremity refers to the hip, knee, and ankle-foot. We consider the ankle and hindfoot together as one major joint.
- J. What do we consider when we evaluate pathologic fractures due to any cause (1.19)? We consider pathologic fractures of the bones

in the skeletal spine, extremities, or other parts of the skeletal system. Pathologic fractures result from disorders that weaken the bones, making them vulnerable to breakage. Pathologic fractures may occur with osteoporosis, osteogenesis imperfecta or any other skeletal dysplasias, side effects of medications, and disorders of the endocrine or other body systems. Under 1.19, the fractures must have occurred on separate, distinct occasions, rather than multiple fractures occurring at the same time, but the fractures may affect the same bone(s) multiple times. There is no required time that must elapse between the fractures, but all three must occur within a 12-month period; for example, separate incidents may occur within hours or days of each other. We evaluate non-healing or complex traumatic fractures without accompanying pathology under 1.22 or 1.23.

- K. What do we consider when we evaluate amputation due to any cause (1.20)?
- 1. General. We consider amputation (the full or partial loss or absence of any extremity) due to any cause including trauma, congenital abnormality or absence, surgery for treatment of conditions such as cancer or infection, or complications of peripheral vascular disease or diabetes mellitus.
- 2. Amputation of both upper extremities (1.20A). Under 1.20A, we consider upper extremity amputations that occur at any level at or above the wrists (carpal joints), up to and including disarticulation of the shoulder (glenohumeral) joint. If you have had both upper extremities amputated at any level at or above the wrists up to and including the shoulder, your impairment satisfies the duration requirement in §§ 404.1509 and 416.909 of this chapter. For amputations below the wrist, we will follow the rules described in 1.00S. We do not evaluate amputations below the wrist under 1.20A because the resulting limitation of function of the thumb(s), finger(s), or hand(s) will vary, depending on the extent of loss and corresponding effect on fine and gross movements.
- 3. Hemipelvectomy or hip disarticulation (1.20B). Under 1.20B, we consider hemipelvectomy, which involves amputation of an entire lower extremity through the sacroiliac joint, and hip disarticulation, which involves amputation of an entire lower extremity through the hip joint capsule and closure of the remaining musculature over the exposed acetabular bone. If you have had a hemipelvectomy or hip disarticulation, your impairment satisfies the duration requirement in §§ 404.1509 and 416.909 of this chapter.
- 4. Amputation of one upper extremity and one lower extremity (1.20C). Under 1.20C, we consider the amputation of one upper extremity at any level at or above the wrist and one lower extremity at or above the ankle. If you have a documented medical need for a one-handed, hand-held assistive device (such as a cane) or a wheeled and seated mobility device involving the use of one hand (such as a motorized wheelchair), then you must use your remaining upper extremity to hold the device, making the extremity unavailable to perform other fine and gross movements (see 1.00E4).

- 5. Amputation of one lower extremity or both lower extremities with complications of the residual limb(s) (1.20D). Under 1.20D, we consider the amputation of one lower extremity or both lower extremities at or above the ankle. We also consider the condition of your residual limb(s), whether you can wear a prosthesis(es) (see 1.00C6b). and whether you have a documented medical need (see 1.00C6a) for a hand-held assistive device(s) (see 1.00C6d) or a wheeled and seated mobility device (see 1.00C6e). If you have a non-healing residual limb(s) and are receiving ongoing surgical treatment expected to re-establish or improve function, and that ongoing surgical treatment has not ended, or is not expected to end, within at least 12 months of the initiation of the surgical management (see 1.00L), we evaluate your musculoskeletal disorder under 1.21.
- L. What do we consider when we evaluate soft tissue injuries or abnormalities under continuing surgical management (1.21)?
  - 1. General.
- a. We consider any soft tissue injury or abnormality involving the soft tissues of the body, whether congenital or acquired, when an acceptable medical source(s) documents the need for ongoing surgical procedures and associated medical treatments to restore function of the affected body part(s) (see 1.00O1). Surgical management includes the surgery(ies) itself, as well as various post-surgical procedures, surgical complications, infections or other medical complications, related illnesses, or related treatments that delay your attainment of maximum benefit from therapy (see 1.00O2).
- b. Surgical procedures and associated treatments typically take place over extended periods, which may render you unable to perform work-related activity on a sustained basis. To document such inability, we must have evidence from an acceptable medical source(s) confirming that the surgical management has continued, or is expected to continue, for at least 12 months from the date of the first surgical intervention. These procedures and treatments must be directed toward saving, reconstructing, or replacing the affected part of the body to re-establish or improve its function, and not for cosmetic appearances alone.
- c. Examples include malformations, thirdand fourth-degree burns, crush injuries, craniofacial injuries, avulsive injuries, and amputations with complications of the residual limb(s).
- d. We evaluate skeletal spine abnormalities or injuries under 1.15 or 1.16, as appropriate. We evaluate abnormalities or injuries of bones in the lower extremities under 1.17, 1.18, or 1.22. We evaluate abnormalities or injuries of bones in the upper extremities under 1.18 or 1.23.
- 2. Documentation. In addition to the objective medical evidence we need to establish your soft tissue injury or abnormality, we also need all of the following medically documented evidence about your continuing surgical management:
- a. Operative reports and related laboratory findings;
- b. Records of post-surgical procedures;
- c. Records of any surgical or medical complications (for example, related infections or systemic illnesses);

- d. Records of any prolonged post-operative recovery periods and related treatments (for example, surgeries and treatments for burns);
- e. An acceptable medical source's plans for additional surgeries; and
- f. Records detailing any other factors that have delayed, or that an acceptable medical source expects to delay, the saving, restoring, or replacing of the involved part for a continuous period of at least 12 months following the initiation of the surgical management.
- 3. Burns. Third- and fourth-degree burns damage or destroy nerve tissue, reducing or preventing transmission of signals through those nerves. Such burns frequently require multiple surgical procedures and related therapies to re-establish or improve function, which we evaluate under 1.21. When burns are no longer under continuing surgical management (see 1.00O1), we evaluate the residual impairment(s). When the residual impairment(s) affects the musculoskeletal system, as often occurs in third- and fourthdegree burns, it can result in permanent musculoskeletal tissue loss, joint contractures, or loss of extremities. We will evaluate such impairments under the relevant musculoskeletal disorders listing, for example, 1.18 or 1.20. When the residual impairment(s) involves another body system, we will evaluate the impairment(s) under the listings in the relevant body system(s).
- 4. Craniofacial injuries. Surgeons may treat craniofacial injuries with multiple surgical procedures. These injuries may affect vision, hearing, speech, and the initiation of the digestive process, including mastication. When the craniofacial injury-related residual impairment(s) involves another body system(s), we will evaluate the impairment(s) under the listings in the relevant body system(s).
- M. What do we consider when we evaluate non-healing or complex fractures of the femur, tibia, pelvis, or one or more of the talocrural bones (1.22)?
- 1. Non-healing fracture. A non-healing (nonunion) fracture is a fracture that has failed to unite completely. Nonunion is usually established when a minimum of 9 months has elapsed since the injury and the fracture site has shown no, or minimal, progressive signs of healing for a minimum of 3 months.
- 2. Complex fracture. A complex fracture is a fracture with one or more of the following:
- a. Comminuted (broken into many pieces) bone fragments:
  - b. Multiple fractures in a single bone;
  - c. Bone loss due to severe trauma;
  - d. Damage to the surrounding soft tissue;
- e. Severe cartilage damage to the associated joint; or
- f. Dislocation of the associated joint.
- 3. When a complex fracture involves soft tissue damage, the treatment may involve continuing surgical management to restore or improve functioning. In such cases, we may evaluate the fracture(s) under 1.21.
- N. What do we consider when we evaluate non-healing or complex fracture of an upper extremity (1.23)?
- 1. Non-healing fracture. A non-healing (nonunion) fracture is a fracture that has failed to unite completely. Nonunion is

- usually established when a minimum of 9 months has elapsed since the injury and the fracture site has shown no, or minimal, progressive signs of healing for a minimum of 3 months.
- 2. Complex fracture. A complex fracture is a fracture with one or more of the following:
- a. Comminuted (broken into many pieces) bone fragments;
  - b. Multiple fractures in a single bone;
  - c. Bone loss due to severe trauma;
- d. Damage to the surrounding soft tissue; e. Severe cartilage damage to the associated joint; or
  - f. Dislocation of the associated joint.
- 3. When a complex fracture involves soft tissue damage, the treatment may involve continuing surgical management to restore or improve functioning. In such cases, we may evaluate the fracture(s) under 1.21.
- O. How will we determine whether your soft tissue injury or abnormality or your upper extremity fracture is no longer under continuing surgical management or you have received maximum benefit from therapy?
- 1. We will determine that your soft tissue injury or abnormality, or your upper extremity fracture, is no longer under continuing surgical management, as used in 1.21 and 1.23, when the last surgical procedure or medical treatment directed toward the re-establishment or improvement of function of the involved part has occurred.
- 2. We will determine that you have received maximum benefit from therapy, as used in 1.21, if there are no significant changes in physical findings or on appropriate imaging for any 6-month period after the last surgical procedure or medical treatment. We may also determine that you have received maximum benefit from therapy if your medical source(s) indicates that further improvement is not expected after the last surgical procedure or medical treatment.
- 3. When you have received maximum benefit from therapy, we will evaluate any impairment-related residual symptoms, signs, and laboratory findings (including those on imaging), any complications associated with your surgical procedures or medical treatments, and any residual limitations in your functioning (see 1.00S).
- P. How do we evaluate your musculoskeletal disorder if there is no record of ongoing treatment?
- 1. Despite having a musculoskeletal disorder, you may not have received ongoing treatment, may have just begun treatment, may not have access to prescribed medical treatment, or may not have an ongoing relationship with the medical community. In any of these situations, you will not have a longitudinal medical record for us to review when we evaluate your disorder and we may ask you to attend a consultative examination to determine the severity and potential duration of your disorder. See §§ 404.1519a(b) and 416.919a(b) of this chapter.
- 2. In some instances, we may be able to assess the severity and duration of your musculoskeletal disorder based on your medical record and current evidence alone. If the information in your case record is not sufficient to show that you have a musculoskeletal disorder that meets the

- criteria of one of the musculoskeletal disorders listings, we will follow the rules described in 1.00S.
- Q. How do we consider the effects of obesity when we evaluate your musculoskeletal disorder? Obesity is a medically determinable impairment that is often associated with musculoskeletal disorders. Obesity increases stress on weightbearing joints and may contribute to limitation of the range of motion of the skeletal spine and extremities. The combined effects of obesity with a musculoskeletal disorder can be greater than the effects of each of the impairments considered separately. We consider the additional and cumulative effects of your obesity when we determine whether you have a severe musculoskeletal disorder, a listing-level musculoskeletal disorder, a combination of impairments that medically equals the severity of a listed impairment, and when we assess your residual functional capacity.
- R. How do we evaluate your musculoskeletal disorder if there is evidence establishing a substance use disorder? If we find that you are disabled and there is medical evidence in your case record establishing that you have a substance use disorder, we will determine whether your substance use disorder is a contributing factor material to the determination of disability. See §§ 404.1535 and 416.935 of this chapter.
- S. How do we evaluate musculoskeletal disorders that do not meet one of these listings?
- 1. These listings are only examples of musculoskeletal disorders that we consider severe enough to prevent you from doing any gainful activity. If your impairment(s) does not meet the criteria of any of these listings, we must also consider whether you have an impairment(s) that meets the criteria of a listing in another body system.
- 2. If you have a severe medically determinable impairment(s) that does not meet a listing, we will determine whether your impairment(s) medically equals a listing. See §§ 404.1526 and 416.926 of this chapter. If your impairment(s) does not meet or medically equal a listing, you may or may not have the residual functional capacity to engage in substantial gainful activity. We proceed to the fourth step and, if necessary, the fifth step 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.

## 1.01 Category of Impairments, Musculoskeletal Disorders

- 1.15 Disorders of the skeletal spine resulting in compromise of a nerve root(s) (see 1.00F), documented by A, B, C, and D:
- A. Neuro-anatomic (radicular) distribution of one or more of the following *symptoms* consistent with compromise of the affected nerve root(s):
  - 1. Pain; or
  - 2. Paresthesia; or
  - 3. Muscle fatigue.

AND

- B. Radicular distribution of neurological *signs* present during physical examination (see 1.00C2) or on a diagnostic test (see 1.00C3) and evidenced by 1, 2, and either 3 or 4:
  - 1. Muscle weakness; and
- 2. Sign(s) of nerve root irritation, tension, or compression, consistent with compromise of the affected nerve root (see 1.00F2); and
  - 3. Sensory changes evidenced by:
  - a. Decreased sensation; or
- b. Sensory nerve deficit (abnormal sensory nerve latency) on electrodiagnostic testing; or
  - 4. Decreased deep tendon reflexes.

#### AND

C. Findings on imaging (see 1.00C3) consistent with compromise of a nerve root(s) in the cervical or lumbosacral spine.

#### ANT

- D. Impairment-related physical limitation of musculoskeletal functioning that has lasted, or is expected to last, for a continuous period of at least 12 months, and medical documentation of at least *one* of the following:
- 1. A documented medical need (see 1.00C6a) for a walker, bilateral canes, or bilateral crutches (see 1.00C6d) or a wheeled and seated mobility device involving the use of both hands (see 1.00C6e(i)); or
- 2. An inability to use *one* upper extremity to independently initiate, sustain, and complete work-related activities involving fine and gross movements (see 1.00E4), *and* a documented medical need (see 1.00C6a) for a one-handed, hand-held assistive device (see 1.00C6d) that requires the use of the other upper extremity or a wheeled and seated mobility device involving the use of one hand (see 1.00C6e(ii)); or
- 3. An inability to use *both* upper extremities to the extent that neither can be used to independently initiate, sustain, and complete work-related activities involving fine and gross movements (see 1.00E4).
- 1.16 Lumbar spinal stenosis resulting in compromise of the cauda equina (see 1.00G), documented by A, B, C, and D:
- A. Symptom(s) of neurological compromise manifested as:
- 1. Nonradicular distribution of pain in one or both lower extremities; or
- 2. Nonradicular distribution of sensory loss in one or both lower extremities; or
- 3. Neurogenic claudication.

## AND

- B. Nonradicular neurological signs present during physical examination (see 1.00C2) or on a diagnostic test (see 1.00C3) and evidenced by 1 and either 2 or 3:
  - 1. Muscle weakness.
  - 2. Sensory changes evidenced by:
  - a. Decreased sensation; or
- b. Sensory nerve deficit (abnormal sensory nerve latency) on electrodiagnostic testing; or c. Areflexia, trophic ulceration, or bladder
- or bowel incontinence.

  3 Decreased deep tendon reflexes in one
- 3. Decreased deep tendon reflexes in one or both lower extremities.

### AND

C. Findings on imaging (see 1.00C3) or in an operative report (see 1.00C4) consistent with compromise of the cauda equina with lumbar spinal stenosis.

#### AND

- D. Impairment-related physical limitation of musculoskeletal functioning that has lasted, or is expected to last, for a continuous period of at least 12 months, and medical documentation of at least *one* of the following:
- 1. A documented medical need (see 1.00C6a) for a walker, bilateral canes, or bilateral crutches (see 1.00C6d) or a wheeled and seated mobility device involving the use of both hands (see 1.00C6e(i)); or
- 2. An inability to use *one* upper extremity to independently initiate, sustain, and complete work-related activities involving fine and gross movements (see 1.00E4), *and* a documented medical need (see 1.00C6a) for a one-handed, hand-held assistive device (see 1.00C6d) that requires the use of the other upper extremity or a wheeled and seated mobility device involving the use of one hand (see 1.00C6e(ii)).
- 1.17 Reconstructive surgery or surgical arthrodesis of a major weight-bearing joint (see 1.00H), documented by A, B, and C:
- A. History of reconstructive surgery or surgical arthrodesis of a major weight-bearing joint.

#### AND

B. Impairment-related physical limitation of musculoskeletal functioning that has lasted, or is expected to last, for a continuous period of at least 12 months.

### AND

- C. A documented medical need (see 1.00C6a) for a walker, bilateral canes, or bilateral crutches (see 1.00C6d) or a wheeled and seated mobility device involving the use of both hands (see 1.00C6e(i)).
- 1.18 Abnormality of a major joint(s) in any extremity (see 1.00I), documented by A, B, C, and D:
- A. Chronic joint pain or stiffness.
- B. Abnormal motion, instability, or immobility of the affected joint(s).
- C. Anatomical abnormality of the affected joint(s) noted on:
- 1. Physical examination (for example, subluxation, contracture, or bony or fibrous ankylosis); or
- 2. Imaging (for example, joint space narrowing, bony destruction, or ankylosis or arthrodesis of the affected joint).
- D. Impairment-related physical limitation of musculoskeletal functioning that has lasted, or is expected to last, for a continuous period of at least 12 months, and medical documentation of at least *one* of the following:
- 1. A documented medical need (see 1.00C6a) for a walker, bilateral canes, or bilateral crutches (see 1.00C6d) or a wheeled and seated mobility device involving the use of both hands (see 1.00C6e(i)); or
- 2. An inability to use *one* upper extremity to independently initiate, sustain, and complete work-related activities involving fine and gross movements (see 1.00E4), *and* a documented medical need (see 1.00C6a) for a one-handed, hand-held assistive device (see 1.00C6d) that requires the use of the other

- upper extremity or a wheeled and seated mobility device involving the use of one hand (see 1.00C6e(ii)); or
- 3. An inability to use *both* upper extremities to the extent that neither can be used to independently initiate, sustain, and complete work-related activities involving fine and gross movements (see 1.00E4).
- 1.19 Pathologic fractures due to any cause (see 1.00J), documented by A and B:
- A. Pathologic fractures occurring on three separate occasions within a 12-month period. AND
- B. Impairment-related physical limitation of musculoskeletal functioning that has lasted, or is expected to last, for a continuous period of at least 12 months, and medical documentation of at least *one* of the following:
- 1. A documented medical need (see 1.00C6a) for a walker, bilateral canes, or bilateral crutches (see 1.00C6d) or a wheeled and seated mobility device involving the use of both hands (see 1.00C6e(i)); or
- 2. An inability to use *one* upper extremity to independently initiate, sustain, and complete work-related activities involving fine and gross movements (see 1.00E4), *and* a documented medical need (see 1.00C6a) for a one-handed, hand-held assistive device (see 1.00C6d) that requires the use of the other upper extremity or a wheeled and seated mobility device involving the use of one hand (see 1.00C6e(ii)); or
- 3. An inability to use *both* upper extremities to the extent that neither can be used to independently initiate, sustain, and complete work-related activities involving fine and gross movements (see 1.00E4).
- 1.20 Amputation due to any cause (see 1.00K), documented by A, B, C, or D:
- A. Amputation of both upper extremities, occurring at any level at or above the wrists (carpal joints), up to and including the shoulder (glenohumeral) joint.
- B. Hemipelvectomy or hip disarticulation. OR
- C. Amputation of one upper extremity, occurring at any level at or above the wrist (carpal joints), and amputation of one lower extremity, occurring at or above the ankle (talocrural joint), and medical documentation of at least *one* of the following:
- 1. A documented medical need (see 1.00C6a) for a walker, bilateral canes, or bilateral crutches (see 1.00C6d) or a wheeled and seated mobility device involving the use of both hands (see 1.00C6e(i)); or
- 2. A documented medical need (see 1.00C6a) for a one-handed, hand-held assistive device (see 1.00C6d) requiring the use of the other upper extremity or a wheeled and seated mobility device involving the use of one hand (see 1.00C6e(ii)); or
- 3. The inability to use the remaining upper extremity to independently initiate, sustain, and complete work-related activities involving fine and gross movements (1.00E4).
- D. Amputation of one or both lower extremities, occurring at or above the ankle (talocrural joint), with complications of the residual limb(s) that have lasted, or are

expected to last, for a continuous period of at least 12 months, *and* medical documentation of 1 and 2:

- 1. The inability to use a prosthesis(es); and
- 2. A documented medical need (see 1.00C6a) for a walker, bilateral canes, or bilateral crutches (see 1.00C6d) or a wheeled and seated mobility device involving the use of both hands (see 1.00C6e(i)).
- 1.21 Soft tissue injury or abnormality under continuing surgical management (see 1.00L), documented by A, B, and C:
- A. Evidence confirms continuing surgical management (see 1.0001) directed toward saving, reconstructing, or replacing the affected part of the body.

#### AND

B. The surgical management has been, or is expected to be, ongoing for a continuous period of at least 12 months.

#### ANI

- C. Maximum benefit from therapy (see 1.00O2) has not yet been achieved.
- 1.22 Non-healing or complex fracture of the femur, tibia, pelvis, or one or more of the talocrural bones (see 1.00M), documented by A, B, and C:
- A. Solid union not evident on imaging (see 1.00C3) and not clinically solid.
- B. Impairment-related physical limitation of musculoskeletal functioning that has lasted, or is expected to last, for a continuous period of at least 12 months.

## AND

- C. A documented medical need (see 1.00C6a) for a walker, bilateral canes, or bilateral crutches (see 1.00C6d) or a wheeled and seated mobility device involving the use of both hands (see 1.00C6e(i)).
- 1.23 Non-healing or complex fracture of an upper extremity (see 1.00N), documented by A and B:
- A. Nonunion or complex fracture of the shaft of the humerus, radius, or ulna, under continuing surgical management (see 1.00O1) directed toward restoration of functional use of the extremity.

## AND

B. Medical documentation of an inability to independently initiate, sustain, and complete work-related activities involving fine and gross movements (see 1.00E4) that has lasted, or is expected to last, for a continuous period of at least 12 months.

## 4.00 Cardiovascular System

\* \* \* \* \*

- G. Evaluating Peripheral Vascular Disease

  \* \* \* \* \* \*
- 4. What is lymphedema and how will we evaluate it?

b. Lymphedema does not meet the requirements of 4.11, although it may medically equal the severity of that listing. We will evaluate lymphedema by considering whether the underlying cause meets or medically equals any listing or whether the lymphedema medically equals a cardiovascular listing, such as 4.11, or a musculoskeletal disorders listing, such as

1.18. If no listing is met or medically equaled, we will evaluate any functional limitations imposed by your lymphedema when we assess your residual functional capacity.

## 14.00 Immune System Disorders

## \* \* \* \*

C. Definitions

- \* \* \* \* \*
- 6. Documented medical need has the same meaning as in 1.00C6a.
- 7. Fine and gross movements has the same meaning as in 1.00E4.
- 8. Major joint of an upper or a lower extremity has the same meaning as in 1.00I2 and 1.00I3.

\* \* \* \* \*

- 12. Severe means medical severity as used by the medical community. The term does not have the same meaning as it does when we use it in connection with a finding at the second step of the sequential evaluation process in §§ 404.1520 and 416.920 of this chapter.
- D. How do we document and evaluate the listed autoimmune disorders?
- \* \* \* \* \* \*

  4. Polymyositis and dermatomyositis
  (14.05).

\* \* \* \* \* \* \*
C. \* \* \*

(i) Weakness of your pelvic girdle muscles that results in your inability to rise independently from a squatting or sitting position or to climb stairs may be an indication that you are unable to walk without assistance. Weakness of your shoulder girdle muscles may result in your inability to perform lifting, carrying, and reaching overhead, and also may seriously affect your ability to perform activities requiring fine movements. We evaluate these limitations under 14.05A.

\* \* \* \* \* \* 6. \* \* \*

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

\* \* \* \*

(i) Listing-level severity in 14.09A and 14.09C1 is shown by the presence of an impairment-related physical limitation of functioning. In 14.09C1, if you have the required ankylosis (fixation) of your cervical or dorsolumbar spine, we will find that you have a listing-level impairment-related physical limitation in your ability to see in front of you, above you, and to the side, even

though you might not require bilateral upper limb assistance.

(ii) Listing-level severity in 14.09B, 14.09C2, and 14.09D is shown by inflammatory arthritis that involves various combinations of complications (such as inflammation or deformity, extra-articular features, repeated manifestations, and constitutional symptoms and signs) of one or more major joints in an upper or a lower extremity (see 14.00C8) or other joints. Extra-articular impairments may also meet listings in other body systems.

\*

## 14.01 Category of Impairments, Immune System Disorders

14.04 Systemic sclerosis (scleroderma). As described in 14.00D3. With:

\* \* \* \* \*

B. One of the following:

- 1. Toe contractures or fixed deformity of one or both feet and medical documentation of at least *one* of the following:
- a. A documented medical need (see 14.00C6) for a walker, bilateral canes, or bilateral crutches (see 1.00C6d) or a wheeled and seated mobility device involving the use of both hands (see 1.00C6e(i)); or
- b. An inability to use *one* upper extremity to independently initiate, sustain, and complete work-related activities involving fine and gross movements (see 14.00C7), and a documented medical need (see 14.00C6) for a one-handed, hand-held assistive device (see 1.00C6d) that requires the use of the other upper extremity or a wheeled and seated mobility device involving the use of one hand (see 1.00C6e(ii)); or
- 2. Finger contractures or fixed deformity in both hands and medical documentation of an inability to use *both* upper extremities to the extent that neither can be used to independently initiate, sustain, and complete work-related activities involving fine and gross movements (see 14.00C7); or
- 3. Atrophy with irreversible damage in one or both lower extremities and medical documentation of at least *one* of the following:
- a. A documented medical need (see 14.00C6) for a walker, bilateral canes, or bilateral crutches (see 1.00C6d) or a wheeled and seated mobility device involving the use of both hands (see 1.00C6e(i)); or
- b. An inability to use *one* upper extremity to independently initiate, sustain, and complete work-related activities involving fine and gross movements (see 14.00C7), and a documented medical need (see 14.00C6) for a one-handed, hand-held assistive device (see 1.00C6d) that requires the use of the other upper extremity or a wheeled and seated mobility device involving the use of one hand (see 1.00C6e(ii)); or
- 4. Atrophy with irreversible damage in both upper extremities and medical documentation of an inability to use both upper extremities to the extent that neither can be used to independently initiate, sustain, and complete work-related activities involving fine and gross movements (see 14.00C7); or

- C. Raynaud's phenomenon, characterized by:
- 2. Ischemia with ulcerations of toes or fingers and medical documentation of at least

one of the following:

- a. A documented medical need (see 14.00C6) for a walker, bilateral canes, or bilateral crutches (see 1.00C6d) or a wheeled and seated mobility device involving the use of both hands (see 1.00C6e(i)); or
- b. An inability to use *one* upper extremity to independently initiate, sustain, and complete work-related activities involving fine and gross movements (see 14.00C7), and a documented medical need (see 14.00C6) for a one-handed, hand-held assistive device (see 1.00C6d) that requires the use of the other upper extremity or a wheeled and seated mobility device involving the use of one hand (see 1.00C6e(ii)); or
- c. An inability to use *both* upper extremities to the extent that neither can be used to independently initiate, sustain, and complete work-related activities involving fine and gross movements (see 14.00C7); or
- 14.05 Polymyositis and dermatomyositis. As described in 14.00D4. With:
- A. Proximal limb-girdle (pelvic or shoulder) muscle weakness and medical documentation of at least *one* of the following:
- 1. A documented medical need (see 14.00C6) for a walker, bilateral canes, or bilateral crutches (see 1.00C6d) or a wheeled and seated mobility device involving the use of both hands (see 1.00C6e(i)); or
- 2. An inability to use *one* upper extremity to independently initiate, sustain, and complete work-related activities involving fine and gross movements (see 14.00C7), and a documented medical need (see 14.00C6) for a one-handed, hand-held assistive device (see 1.00C6d) that requires the use of the other upper extremity or a wheeled and seated mobility device involving the use of one hand (see 1.00C6e(ii)); or
- 3. An inability to use *both* upper extremities to the extent that neither can be used to independently initiate, sustain, and complete work-related activities involving fine and gross movements (see 14.00C7); or
- 14.09 *Inflammatory arthritis.* As described in 14.00D6. With:
- A. Persistent inflammation or persistent deformity of:
- 1. One or more major joints in a lower extremity (see 14.00C8) and medical documentation of at least *one* of the following:
- a. A documented medical need (see 14.00C6) for a walker, bilateral canes, or bilateral crutches (see 1.00C6d) or a wheeled and seated mobility device involving the use of both hands (see 1.00C6e(i)); or
- b. An inability to use *one* upper extremity to independently initiate, sustain, and complete work-related activities involving fine and gross movements (see 14.00C7), and a documented medical need (see 14.00C6) for a one-handed, hand-held assistive device (see 1.00C6d) that requires the use of the other upper extremity or a wheeled and seated

- mobility device involving the use of one hand (see 1.00C6e(ii)); or
- 2. One or more major joints in each upper extremity (see 14.00C8) and medical documentation of an inability to use *both* upper extremities to the extent that neither can be used to independently initiate, sustain, and complete work-related activities involving fine and gross movements (see 14.00C7); or
- B. Inflammation or deformity in one or more major joints of an upper or a lower extremity (see 14.00C8) with:

## Part B

## 101.00 Musculoskeletal Disorders

## 101.00 Musculoskeletal Disorders

A. Which musculoskeletal disorders do we evaluate under these listings?

- 1. We evaluate disorders of the skeletal spine (vertebral column) or of the upper or lower extremities that affect musculoskeletal functioning under these listings. We use the term "skeletal" when we are referring to the structure of the bony skeleton. The skeletal *spine* refers to the bony structures, ligaments, and discs making up the spine. We refer to the skeletal spine in some musculoskeletal listings to differentiate it from the neurological spine (see 101.00B1). Musculoskeletal disorders may be congenital or acquired, and may include deformities, amputations, or other abnormalities. These disorders may involve the bones or major joints; or the tendons, ligaments, muscles, or other soft tissues.
- 2. We evaluate soft tissue injuries (including burns) or abnormalities that are under continuing surgical management (see 101.00P1). The injuries or abnormalities may affect any part of the body, including the face and skull.
- 3. We evaluate curvatures of the skeletal spine that affect musculoskeletal functioning under 101.15. If a curvature of the skeletal spine is under continuing surgical management (see 101.00P1), we will evaluate it under 101.21 using our rules for determining medical equivalence. See § 416.926 of this chapter.
- B. Which related disorders do we evaluate under other listings?
- 1. We evaluate a disorder or injury of the skeletal spine that results in damage to, and neurological dysfunction of, the spinal cord and its associated nerves (for example, paraplegia or quadriplegia) under the listings in 111.00.
- 2. We evaluate inflammatory arthritis (for example, rheumatoid arthritis) under the listings in 114.00.
- 3. We evaluate curvatures of the skeletal spine that interfere with your ability to breathe under the listings in 103.00, impair myocardial function under the listings in 104.00, or result in social withdrawal or depression under the listings in 112.00.
- 4. We evaluate non-healing or pathological fractures due to cancer, whether it is a primary site or metastases, under the listings in 113.00.

- 5. We evaluate the leg pain associated with peripheral vascular claudication under the listings in 104.00.
- 6. We evaluate burns that do not require continuing surgical management under the listings in 108.00.
- C. What evidence do we need to evaluate your musculoskeletal disorder?
- 1. General. We need objective medical evidence from an acceptable medical source to establish that you have a medically determinable musculoskeletal disorder. We also need evidence from both medical and nonmedical sources, who can describe how you function, to assess the severity and duration of your musculoskeletal disorder. We will determine the extent and kinds of evidence we need from medical and nonmedical sources based on the individual facts about your disorder. For our basic rules on evidence, see §§ 416.912, 416.913, and 416.920b of this chapter. For our rules on evidence about your symptoms, see § 416.929 of this chapter.
- 2. Physical examination report(s). In the report(s) of your physical examination, we require a medical source's detailed description of the orthopedic, neurologic, or other objective clinical findings appropriate to your specific musculoskeletal disorder from his or her direct observations during your physical examination. We will not accept a report of your statements about your symptoms and limitations in place of the medical source's report of objective clinical findings. We will not use findings on imaging or other diagnostic tests (see 101.00C3) as a substitute for findings on physical examination.
- a. When the medical source reports that a clinical test sign(s) is positive, unless we have evidence to the contrary, we will assume that he or she performed the test properly and accept the medical source's interpretation of the test. For example, we will assume a straight-leg raising test was conducted properly (that is, in sitting and supine positions), even if the medical source does not specify the positions in which the test was performed.
- b. If you use an assistive device (see 101.00C6), the report must support the medical need for the device.
- c. If your musculoskeletal disorder causes a reduction in muscle strength, the report must document measurement of the strength of the muscle(s) in question. The measurement should be based on a muscle strength grading system that is considered medically acceptable based on your age and impairments. For example, a grading system of 0 to 5, with 0 indicating complete loss of strength and 5 indicating maximum strength or equivalent medically acceptable scale (see Table 1). Reduction in muscle strength is demonstrated by evidence that your muscle strength is less than active range of motion (ROM) against gravity with maximum resistance. If the reduction in muscle strength involves one or both of your hands, the report must also document measurements of grip and pinch strength.

TABLE 1—GRADING	SYSTEM OF	MUSCLE	FUNCTION
-----------------	-----------	--------	----------

Grade	Function of the muscle
0—None 1—Trace 2—Poor 3—Fair 4—Good 5—Normal	Visible or palpable contraction with no motion. Active ROM with gravity eliminated. Active ROM against gravity only, without resistance.

- 3. Imaging and other diagnostic tests.
- a. *Imaging* refers to medical imaging techniques, such as x-ray, computed tomography (CT), magnetic resonance imaging (MRI), and radionuclide scanning. For the purpose of these listings, 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.
- b. Findings on imaging must have lasted, or be expected to last, for a continuous period of at least 12 months.
- c. Imaging and other diagnostic tests can provide evidence of physical abnormalities; however, these abnormalities may correlate poorly with your symptoms, including pain, or with your musculoskeletal functioning. Accordingly, we will not use findings on imaging or other diagnostic tests as a substitute for findings on physical examination about your ability to function, nor can we infer severity or functional limitations based solely on such tests.
- d. For our rules on purchasing imaging and other diagnostic tests, see §§ 416.919k and 416.919m of this chapter.
- 4. Operative reports. If you have had a surgical procedure, we need a copy of the operative report, including details of the findings at surgery and information about any medical complications that may have occurred. If we do not have the operative report, we need confirmatory evidence of the surgical procedure from a medical source (for example, detailed follow-up reports or notations in the medical records concerning the surgical procedure in your medical history).
  - 5. Effects of treatment.
- a. General. Treatments for musculoskeletal disorders may have beneficial or adverse effects, and responses to treatment vary from person to person. We will evaluate all of the effects of treatment (including surgical treatment, medications, and therapy) on the symptoms, signs, and laboratory findings of your musculoskeletal disorder, and on your musculoskeletal functioning.
- b. Response to treatment. To evaluate your musculoskeletal functioning in response to treatment, we need the following: A description, including the frequency of the administration, of your medications; the type and frequency of therapy you receive; and a description of your response to treatment and any complications you experience related to your musculoskeletal disorder. The effects of treatment may be temporary or long-term. We need information over a sufficient period to determine the effects of treatment on your current musculoskeletal functioning and permit reasonable projections about your

future functioning. We will determine the amount of time that constitutes a sufficient period in consultation with a medical consultant on a case by case basis. In some cases, we will need additional evidence to make an assessment about your response to treatment. Your musculoskeletal disorder may meet or medically equal one of these listings regardless of whether you were prescribed opioid medication, or whether you were prescribed opioid medication and did not follow this prescribed treatment.

- 6. Assistive devices.
- a. General. An assistive device, for the purposes of these listings, is any device that you use to improve your stability, dexterity, or mobility. An assistive device can be worn (see 101.00C6b and 101.00C6c), hand-held (see 101.00C6d), or used in a seated position (see 101.00C6e). When we use the phrase "documented medical need," we mean that there is evidence from a medical source that supports your medical need for an assistive device (see 101.00C2b) for a continuous period of at least 12 months (see 101.00c2a). This evidence must describe any limitation(s) in your upper or lower extremity functioning and the circumstances for which you need to use the assistive device. We do not require that you have a specific prescription for the assistive device.
- b. Prosthesis(es). A prosthesis is a wearable device, such as an artificial limb, that takes the place of an absent body part. If you have a prosthesis(es), we need evidence from a medical source documenting your ability to walk, or perform fine and gross movements (see 101.00E4), with the prosthesis(es) in place. When amputation(s) involves one or both lower extremities, it is not necessary for the medical source to evaluate your ability to walk without the prosthesis(es) in place. If you cannot use your prosthesis(es) due to complications affecting your residual limb(s), we need evidence from a medical source documenting the condition of your residual limb(s) and the medical basis for your inability to use the device(s).
- c. Orthosis(es). An orthosis is a wearable device, such as a brace, that prevents or corrects a dysfunction or deformity by aligning or supporting the affected body part. If you have an orthosis(es), we need evidence from a medical source documenting your ability to walk, or perform fine and gross movements (see 101.00E4), with the orthosis(es) in place. If you cannot use your orthosis(es), we need evidence from a medical source documenting the medical basis for your inability to use the device(s).
- d. *Hand-held assistive devices*. Hand-held assistive devices include walkers, canes, or crutches, which you hold onto with your

- hand(s) to support or aid you in walking. When you use a one-handed, hand-held assistive device (such as a cane) with one upper extremity to walk and you cannot use your other upper extremity for fine or gross movements (see 101.00E4), the need for the assistive device limits the use of both upper extremities. If you use a hand-held assistive device, we need evidence from a medical source describing how you walk with the device.
- e. Wheeled and seated mobility devices. Wheeled and seated mobility devices are assistive devices that you use in a seated position, such as manual wheelchairs, motorized wheelchairs, rollators, and power operated vehicles. If you use a wheeled and seated mobility device, we need evidence from a medical source describing the type of wheeled and seated mobility device that you use and how you use the assistive device, including any customizations or modifications to the assistive device itself or for your use of the assistive device. For example, if you use a wheelchair that typically requires the use of both hands but has been customized for your use with one hand, then we will evaluate your use of the assistive device using the criteria in 101.00E3b and not 101.00E3a.
- (i) Wheeled and seated mobility devices involving the use of both hands. Some wheeled and seated mobility devices involve the use of both hands to use the assistive device (for example, most manual wheelchairs). If you use a wheeled and seated mobility device that involves the use of both hands, then the need for the assistive device limits the use of both upper extremities.
- (ii) Wheeled and seated devices involving the use of one hand. Some wheeled and seated mobility devices involve the use of one hand to use the assistive device (for example, most motorized wheelchairs). If you use a wheeled and seated mobility device that involves the use of one upper extremity and you cannot use your other upper extremity for fine or gross movements (see 101.00E4), then the need for the assistive device limits the use of both upper extremities.
  - 7. Longitudinal evidence.
- a. We generally need a longitudinal medical record to assess the severity and duration of your musculoskeletal disorder because the severity of symptoms, signs, and laboratory findings related to most musculoskeletal disorders may improve over time or respond to treatment. Evidence over an extended period will show whether your musculoskeletal functioning is improving, worsening, or unchanging.

- b. For 101.15, 101.16, 101.17, 101.18, 101.20C, 101.20D, 101.22, and 101.23, all of the required criteria must be present simultaneously, or within a close proximity of time, to satisfy the level of severity needed to meet the listing. The phrase "within a close proximity of time" means that all of the relevant criteria must appear in the medical record within a consecutive 4-month period. When the criterion is imaging, we mean that we could reasonably expect the findings on imaging to have been present at the date of impairment or date of onset. For listings that use the word "and" to link the elements of the required criteria, the medical record must establish the simultaneous presence, or presence within a close proximity of time, of all the required medical criteria. Once this level of severity is established, the medical record must also show that this level of severity has continued, or is expected to continue, for a continuous period of at least 12 months.
- 8. Surgical treatment or physical therapy. For some musculoskeletal disorders, a medical source may recommend surgery, or physical therapy (PT). If you have not yet had the recommended surgery or PT, we will not assume that these interventions will resolve your disorder or improve your functioning. We will assess each case on an individual basis. Depending on your response to treatment, or your medical sources' treatment plans, we may defer our findings regarding the effect of surgery or PT, until a sufficient period has passed to permit proper consideration or judgment about your future functioning. When necessary, we will follow the rules on following prescribed treatment in § 416.930 of this chapter, including consideration of your reasons for failure to follow prescribed treatment.
- D. How do we consider symptoms, including pain, under these listings?
- 1. Musculoskeletal disorders may cause pain or other symptoms; however, your statements about your pain or other symptoms will not alone establish that you are disabled. We will not substitute an alleged or a reported increase in the intensity of a symptom, such as pain, no matter how severe, for a medical sign or diagnostic finding present in the listing criteria. Pain is included as just one consideration in 101.15A, 101.16A, and 101.18A, but it is not required to satisfy the criteria in 101.15, 101.16, and 101.18.
- 2. To consider your symptom(s), we require objective medical evidence from an acceptable medical source showing the existence of a medically determinable musculoskeletal impairment that we could reasonably expect to produce the symptom(s). See § 416.929 of this chapter for how we evaluate symptoms, including pain, related to your musculoskeletal disorder.
- E. How do we use the functional criteria to evaluate your musculoskeletal disorder under these listings?
- 1. General. The functional criteria for children age 3 and older are based on impairment-related physical limitations in your ability to use both upper extremities, one or both lower extremities, or a combination of one upper and one lower extremity. We will use the relevant evidence

- that we have to compare your musculoskeletal functioning to the functioning of children your age who do not have impairments. The required impairment-related physical limitation of musculoskeletal functioning must have lasted, or be expected to last, for a continuous period of at least 12 months. We do not use the functional criteria in 101.20A, 101.20B, 101.21, or 101.24.
- 2. Medical and functional criteria, birth to attainment of age 3. The medical and functional criteria for children in this age group are in 101.24.
- 3. Functional criteria, age 3 to attainment of age 18. The functional criteria are based on impairment-related physical limitations in your ability to use both upper extremities, one or both lower extremities, or a combination of one upper and one lower extremity. A musculoskeletal disorder satisfies the functional criteria of a listing when the medical documentation shows the presence of at least one of the impairmentrelated limitations cited in the listing. The functional criteria require impairment-related physical limitation of musculoskeletal functioning that has lasted, or can be expected to last, for a continuous period of at least 12 months, medically documented by one of the following:
- a. A documented medical need (see 101.00C6a) for a walker, bilateral canes, or bilateral crutches (see 101.00C6d) or a wheeled and seated mobility device involving the use of both hands (see 101.00C6e(i));
- b. An inability to use one upper extremity to independently initiate, sustain, and complete age-appropriate activities involving fine and gross movements (see 101.00E4), and a documented medical need (see 101.00C6a) for a one-handed, hand-held assistive device (see 101.00C6d) that requires the use of your other upper extremity or a wheeled and seated mobility device involving the use of one hand (see 101.00C6e(ii));
- c. An inability to use both upper extremities to the extent that neither can be used to independently initiate, sustain, and complete age-appropriate activities involving fine and gross movements (see 101.00E4).
- 4. Fine and gross movements. Fine movements, for the purposes of these listings, involve use of your wrists, hands, and fingers; such movements include picking, pinching, manipulating, and fingering. Gross movements involve use of your shoulders, upper arms, forearms, and hands; such movements include handling, gripping, grasping, holding, turning, and reaching. Gross movements also include exertional abilities such as lifting, carrying, pushing, and pulling.
- F. What do we consider when we evaluate disorders of the skeletal spine resulting in compromise of a nerve root(s) (101.15)?
- 1. General. We consider musculoskeletal disorders such as skeletal dysplasias, caudal regression syndrome, tethered spinal cord syndrome, vertebral slippage (spondylolisthesis), scoliosis, and vertebral fracture or dislocation. Spinal disorders may cause cervical or lumbar spine dysfunction when abnormalities of the skeletal spine

- compromise nerve roots of the cervical spine, a nerve root of the lumbar spine, or a nerve root of both cervical and lumbar spines. We consider spinal nerve disorders that originate in the nervous system (for example, spinal arachnoiditis), under the neurological disorders body system, 111.00.
- 2. Compromise of a nerve root(s). Compromise of a nerve root, sometimes referred to as "nerve root impingement," is a phrase used when a physical object, such as a tumor, herniated disc, foreign body, or arthritic spur, is pushing on the nerve root as seen on imaging or during surgery. It can occur when a musculoskeletal disorder produces irritation, inflammation, or compression of the nerve root(s) as it exits the skeletal spine between the vertebrae. Related symptoms must be associated with, or follow the path of, the affected nerve root(s).
- a. Compromise of unilateral nerve root of the cervical spine. Compromise of a nerve root as it exits the cervical spine between the vertebrae may affect the functioning of the associated upper extremity. The physical examination reproduces the related symptoms based on radicular signs and clinical tests appropriate to the specific cervical nerve root (for example, a positive Spurling test).
- b. Compromise of bilateral nerve roots of the cervical spine. Although uncommon, if compromise of a nerve root occurs on both sides of the cervical spinal column, functioning of both upper extremities may be limited.
- c. Compromise of a nerve root(s) of the lumbar spine. Compromise of a nerve root as it exits the lumbar spine between the vertebrae may limit the functioning of the associated lower extremity. The physical examination reproduces the related symptoms based on radicular signs and clinical tests. When a nerve root of the lumbar spine is compromised, we require a positive straight-leg raising test (also known as a Lasègue test) in both supine and sitting positions appropriate to the specific lumbar nerve root that is compromised.
- G. What do we consider when we evaluate lumbar spinal stenosis resulting in compromise of the cauda equina (101.16)?
- 1. General. We consider how pain, sensory changes, and muscle weakness caused by compromise of the cauda equina due to lumbar spinal stenosis affect your functioning. The cauda equina is a bundle of nerve roots that descends from the lower part of the spinal cord. Lumbar spinal stenosis can compress the nerves of the cauda equina, causing sensory changes and muscle weakness that may affect your ability to stand or walk. Pain related to compromise of the cauda equina is nonradicular because it is not typically associated with a specific nerve root (as is radicular pain in the cervical or lumbar spine).
- 2. Compromise of the cauda equina due to lumbar spinal stenosis can affect your ability to walk or stand because of neurogenic claudication (also known as pseudoclaudication), a condition usually causing nonradicular pain that starts in the low back and radiates bilaterally (or less commonly, unilaterally) into the buttocks

and lower extremities (or extremity). Extension of the lumbar spine, which occurs when you walk or stand, may provoke the pain of neurogenic claudication. The pain may be relieved by forward flexion of the lumbar spine or by sitting. In contrast, the leg pain associated with peripheral vascular claudication results from inadequate arterial blood flow to a lower extremity. It occurs repeatedly and consistently when a person walks a certain distance and is relieved when the person rests.

- H. What do we consider when we evaluate reconstructive surgery or surgical arthrodesis of a major weight-bearing joint (101.17)?
- 1. General. We consider reconstructive surgery or surgical arthrodesis when an acceptable medical source(s) documents the surgical procedure(s) and associated medical treatments to restore function of, or eliminate motion in, the affected major weight-bearing joint(s). Reconstructive surgery may be done in a single procedure or a series of procedures directed toward the salvage or restoration of functional use of the affected joint.
- 2. Major weight-bearing joints are the hip, knee, and ankle-foot. The ankle and foot are considered together as one major joint.
- 3. *Surgical arthrodesis* is the artificial fusion of the bones that form a joint, essentially eliminating the joint.
- I. What do we consider when we evaluate abnormality of a major joint(s) in any extremity (101.18)?
- 1. General. We consider musculoskeletal disorders that produce anatomical abnormalities of major joints of the extremities, which result in functional abnormalities in the upper or lower extremities (for example, chronic infections of bones and joints, and surgical arthrodesis of a joint). Abnormalities of the joints include ligamentous laxity or rupture, soft tissue contracture, or tendon rupture, and can cause muscle weakness of the affected joint(s).
- a. An anatomical abnormality is one that is readily observable by a medical source during a physical examination (for example, subluxation or contracture), or is present on imaging (for example, joint space narrowing, bony destruction, ankylosis, or deformity).
- b. A functional abnormality is abnormal motion or instability of the affected joint(s), including limitation of motion, excessive motion (hypermobility), movement outside the normal plane of motion for the joint (for example, lateral deviation), or fixation of the affected joint(s).
- 2. Major joint of an upper extremity refers to the shoulder, elbow, and wrist-hand. We consider the wrist and hand together as one major joint.
- 3. Major joint of a lower extremity refers to the hip, knee, and ankle-foot. We consider the ankle and hindfoot together as one major joint.
- J. What do we consider when we evaluate pathologic fractures due to any cause (101.19)? We consider pathologic fractures of the bones in the skeletal spine, extremities, or other parts of the skeletal system. Pathologic fractures result from disorders that weaken the bones, making them vulnerable to breakage. Pathologic fractures may occur with osteoporosis, osteogenesis

imperfecta or any other skeletal dysplasias, side effects of medications, and disorders of the endocrine or other body systems. Under 101.19, the fractures must have occurred on separate, distinct occasions, rather than multiple fractures occurring at the same time, but the fractures may affect the same bone(s) multiple times. There is no required time that must elapse between the fractures, but all three must occur within a 12-month period; for example, separate incidents may occur within hours or days of each other. We evaluate non-healing or complex traumatic fractures without accompanying pathology under 101.22 or 101.23.

K. What do we consider when we evaluate amputation due to any cause (101.20)?

- 1. General. We consider amputation (the full or partial loss or absence of any extremity) due to any cause including trauma, congenital abnormality or absence, surgery for treatment of conditions such as cancer or infection, or complications of peripheral vascular disease or diabetes mellitus.
- 2. Amputation of both upper extremities (101.20A). Under 101.20A, we consider upper extremity amputations that occur at any level at or above the wrists (carpal joints), up to and including disarticulation of the shoulder (glenohumeral) joint. If you have had both upper extremities amputated at any level at or above the wrists up to and including the shoulder, your impairment satisfies the duration requirement in § 416.909 of this chapter. For amputations below the wrist, we will follow the rules described in 101.00R. We do not evaluate amputations below the wrists under 101.20A because the resulting limitation of function of the thumb(s), finger(s), or hand(s) will vary, depending on the extent of loss and corresponding effect on fine and gross movements.
- 3. Hemipelvectomy or hip disarticulation (101.20B). Under 101.20B, we consider hemipelvectomy, which involves amputation of an entire lower extremity through the sacroiliac joint, and hip disarticulation, which involves amputation of an entire lower extremity through the hip joint capsule and closure of the remaining musculature over the exposed acetabular bone. If you have had a hemipelvectomy or hip disarticulation, your impairment satisfies the duration requirement in § 416.909 of this chapter.
- 4. Amputation of one upper extremity and one lower extremity (101.20C). Under 101.20C, we consider the amputation of one upper extremity at any level at or above the wrist and one lower extremity at or above the ankle. If you have a documented medical need for a one-handed, hand-held assistive device (such as a cane) or a wheeled and seated mobility device involving the use of one hand (such as a motorized wheelchair), then you must use your remaining upper extremity to hold the device, making the extremity unavailable to perform other fine and gross movements (see 101.00E4).
- 5. Amputation of one lower extremity or both lower extremities with complications of the residual limb(s) (101.20D). Under 101.20D, we consider the amputation of one lower extremity or both lower extremities at or above the ankle. We also consider the

- condition of your residual limb(s), whether you can wear a prosthesis(es) (see 101.00C6b), and whether you have a documented medical need (see 101.00C6a) for a hand-held assistive device(s) (see 101.00C6d) or a wheeled and seated mobility device (see 101.00C6e). If you have a non-healing residual limb(s) and are receiving ongoing surgical treatment expected to reestablish or improve function, and that ongoing surgical treatment has not ended, or is not expected to end, within at least 12 months of the initiation of the surgical management (see 101.00L), we evaluate your musculoskeletal disorder under 101.21.
- L. What do we consider when we evaluate soft tissue injury or abnormality under continuing surgical management (101.21)?
  - 1. General.
- a. We consider any soft tissue injury or abnormality involving the soft tissues of the body, whether congenital or acquired, when an acceptable medical source(s) documents the need for ongoing surgical procedures and associated medical treatments to restore function of the affected body part(s) (see 101.00P1). Surgical management includes the surgery(ies) itself, as well as various postsurgical procedures, surgical complications, infections or other medical complications, related illnesses, or related treatments that delay your attainment of maximum benefit from therapy (see 101.00P2).
- b. Surgical procedures and associated treatments typically take place over extended periods, which may render you unable to perform age-appropriate activity on a sustained basis. To document such inability, we must have evidence from an acceptable medical source(s) confirming that the surgical management has continued, or is expected to continue, for at least 12 months from the date of the first surgical intervention. These procedures and treatments must be directed toward saving, reconstructing, or replacing the affected part of the body to re-establish or improve its function, and not for cosmetic appearances alone.
- c. Examples include malformations, thirdand fourth-degree burns, crush injuries, craniofacial injuries, avulsive injuries, and amputations with complications of the residual limb(s).
- d. We evaluate skeletal spine abnormalities or injuries under 101.15 or 101.16, as appropriate. We evaluate abnormalities or injuries of bones in the lower extremities under 101.17, 101.18, or 101.22. We evaluate abnormalities or injuries of bones in the upper extremities under 101.18 or 101.23.
- 2. Documentation. In addition to the objective medical evidence we need to establish your soft tissue injury or abnormality, we also need all of the following medically documented evidence about your continuing surgical management:
- a. Operative reports and related laboratory findings;
- b. Records of post-surgical procedures;
- c. Records of any surgical or medical complications (for example, related infections or systemic illnesses);
- d. Records of any prolonged post-operative recovery periods and related treatments (for example, surgeries and treatments for burns);

- e. An acceptable medical source's plans for additional surgeries; and
- f. Records detailing any other factors that have delayed, or that an acceptable medical source expects to delay, the saving, restoring, or replacing of the involved part for a continuous period of at least 12 months following the initiation of the surgical management.
- 3. Burns. Third- and fourth-degree burns damage or destroy nerve tissue, reducing or preventing transmission of signals through those nerves. Such burns frequently require multiple surgical procedures and related therapies to re-establish or improve function, which we evaluate under 101.21. When burns are no longer under continuing surgical management (see 101.00P1), we evaluate the residual impairment(s). When the residual impairment(s) affects the musculoskeletal system, as often occurs in third- and fourth-degree burns, it can result in permanent musculoskeletal tissue loss, joint contractures, or loss of extremities. We will evaluate such impairments under the relevant musculoskeletal disorders listing, for example, 101.18 or 101.20. When the residual impairment(s) involves another body system, we will evaluate the impairment(s) under the listings in the relevant body system(s).
- 4. Craniofacial injuries or congenital abnormalities. Surgeons may treat craniofacial injuries or congenital abnormalities with multiple surgical procedures. These injuries or abnormalities may affect vision, hearing, speech, and the initiation of the digestive process, including mastication. When the craniofacial injury-related or congenital abnormality-related residual impairment(s) involves another body system(s), we will evaluate the impairment(s) under the listings in the relevant body system(s).
- M. What do we consider when we evaluate non-healing or complex fractures of the femur, tibia, pelvis, or one or more of the talocrural bones (101.22)?
- 1. Non-healing fracture. A non-healing (nonunion) fracture is a fracture that has failed to unite completely. Nonunion is usually established when a minimum of 9 months has elapsed since the injury and the fracture site has shown no, or minimal, progressive signs of healing for a minimum of 3 months.
- 2. Complex fracture. A complex fracture is a fracture with one or more of the following: a. Comminuted (broken into many pieces)
- bone fragments;
  - b. Multiple fractures in a single bone;
  - c. Bone loss due to severe trauma;
- d. Damage to the surrounding soft tissue;
- e. Severe cartilage damage to the associated joint; or
  - f. Dislocation of the associated joint.
- 3. When a complex fracture involves soft tissue damage, the treatment may involve continuing surgical management to restore or improve functioning. In such cases, we may evaluate the fracture(s) under 101.21.
- N. What do we consider when we evaluate non-healing or complex fractures of an upper extremity (101.23)?
- 1. Non-healing fracture. A non-healing (nonunion) fracture is a fracture that has

- failed to unite completely. Nonunion is usually established when a minimum of 9 months has elapsed since the injury and the fracture site has shown no, or minimal, progressive signs of healing for a minimum of 3 months.
- 2. Complex fracture. A complex fracture is a fracture with one or more of the following: a. Comminuted (broken into many pieces) bone fragments;
  - b. Multiple fractures in a single bone;
  - c. Bone loss due to severe trauma;
  - d. Damage to the surrounding soft tissue;
- e. Severe cartilage damage to the associated joint; or
  - f. Dislocation of the associated joint.
- 3. When a complex fracture involves soft tissue damage, the treatment may involve continuing surgical management to restore or improve functioning. In such cases, we may evaluate the fracture(s) under 101.21.
- O. What do we consider when we evaluate musculoskeletal disorders of infants and toddlers from birth to attainment of age 3 with developmental motor delay (101.24)?
- 1. General. Under 101.24, we require reports from an acceptable medical source(s) to establish a delay in your motor development as a medically determinable impairment. Examples of disorders we evaluate under this listing include arthrogryposis, clubfoot, osteogenesis imperfecta, caudal regression syndrome, fracture complications, disorders affecting the hip and pelvis, and complications associated with your musculoskeletal disorder or its treatment. Some medical records may simply document your condition as "developmental motor delay."
- 2. Severity of developmental motor delay. To evaluate the severity of your developmental motor delay, we need developmental test reports from an acceptable medical source, or from early intervention specialists, physical and occupational therapists, and other sources.
- a. If there is a standardized developmental assessment in your medical record, we will use the results to evaluate your developmental motor delay under 101.24A. Such an assessment compares your level of development to the level typically expected for children of your chronological age. If you were born prematurely, we use your corrected chronological age for comparison. See § 416.924b(b) of this chapter.
- b. If there is no standardized developmental assessment in your medical record, we will use narrative developmental reports from a medical source(s) to evaluate your developmental motor delay under 101.24B. These reports must provide detailed information sufficient for us to assess the severity of your motor delay. If we cannot obtain sufficient detail from narrative reports, we may purchase standardized developmental assessments.
- (i) A narrative developmental report is based on clinical observations, progress notes, and well-baby check-ups, and must include your developmental history, examination findings (with abnormal findings noted on repeated examinations), and an overall assessment of your development (that is, more than one or two isolated skills) by the medical source.

- (ii) Some narrative developmental reports may include results from developmental screening tests, which can show that you are not developing or achieving skills within expected timeframes. Although medical sources may refer to screening test results as supporting evidence in the narrative developmental report, screening test results alone cannot establish a medically determinable impairment or the severity of developmental motor delay.
- P. How will we determine whether your soft tissue injury or abnormality or your upper extremity fracture is no longer under continuing surgical management or you have received maximum benefit from therapy?
- 1. We will determine that your soft tissue injury or abnormality, or your upper extremity fracture, is no longer under continuing surgical management, as used in 101.21 and 101.23, when the last surgical procedure or medical treatment directed toward the re-establishment or improvement of function of the involved part has occurred.
- 2. We will determine that you have received maximum benefit from therapy, as used in 101.21, if there are no significant changes in physical findings or on appropriate imaging for any 6-month period after the last surgical procedure or medical treatment. We may also determine that you have received maximum benefit from therapy if your medical source(s) indicates that further improvement is not expected after the last surgical procedure or medical treatment.
- 3. When you have received maximum benefit from therapy, we will evaluate any impairment-related residual symptoms, signs, and laboratory findings (including those on imaging), any complications associated with your surgical procedures or medical treatments, and any residual limitations in your functioning (see 101.00R).
- Q. How do we evaluate your musculoskeletal disorder if there is no record of ongoing treatment?
- 1. Despite having a musculoskeletal disorder, you may not have received ongoing treatment, may have just begun treatment, may not have access to prescribed medical treatment, or may not have an ongoing relationship with the medical community. In any of these situations, you will not have a longitudinal medical record for us to review when we evaluate your disorder and we may ask you to attend a consultative examination to determine the severity and potential duration of your disorder. See § 416.919a(b) of this chapter.
- 2. In some instances, we may be able to assess the severity and duration of your musculoskeletal disorder based on your medical record and current evidence alone. If the information in your case record is not sufficient to show that you have a musculoskeletal disorder that meets the criteria of one of the musculoskeletal disorders listings, we will follow the rules described in 101.00R.
- R. How do we evaluate musculoskeletal disorders that do not meet one of these listings?
- 1. These listings are only examples of musculoskeletal disorders that we consider severe enough to result in marked and severe functional limitations. If your impairment(s)

does not meet the criteria of any of these listings, we must also consider whether you have an impairment(s) that meets the criteria of a listing in another body system.

- 2. If you have a severe medically determinable impairment(s) that does not meet a listing, we will determine whether your impairment(s) medically equals a listing. See § 416.926 of this chapter. If your impairment(s) does not meet or medically equal a listing, we will determine whether it 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.

## 101.01 Category of Impairments, Musculoskeletal Disorders

- 101.15 Disorders of the skeletal spine resulting in compromise of a nerve root(s) (see 101.00F), documented by A, B, C, and D.
- A. Neuro-anatomic (radicular) distribution of one or more of the following *symptoms* consistent with compromise of the affected nerve root(s):
  - 1. Pain; or
  - 2. Paresthesia; or
  - 3. Muscle fatigue.

#### AND

- B. Radicular distribution of neurological *signs* present during physical examination (see 101.00C2) or on a diagnostic test (see 101.00C3) and evidenced by 1, 2, and either 3 or 4:
  - 1. Muscle weakness; and
- 2. Sign(s) of nerve root irritation, tension, or compression, consistent with compromise of the affected nerve root (see 101.00F2)
  - 3. Sensory changes evidenced by:
  - a. Decreased sensation; or
- b. Sensory nerve deficit (abnormal sensory nerve latency) on electrodiagnostic testing; or
- 4. Decreased deep tendon reflexes.

### AND

- C. Findings on imaging (see 101.00C3) consistent with compromise of a nerve root(s) in the cervical or lumbosacral spine.
- D. Impairment-related physical limitation of musculoskeletal functioning that has lasted, or is expected to last, for a continuous period of at least 12 months, and medical documentation of at least *one* of the following:
- 1. A documented medical need (see 101.C6a) for a walker, bilateral canes, or bilateral crutches (see 101.00C6d) or a wheeled and seated mobility device involving the use of both hands (see 101.00C6e(i)); or
- 2. An inability to use *one* upper extremity to independently initiate, sustain, and complete age-appropriate activities involving fine and gross movements (see 101.00E4), and a documented medical need (see 101.00C6a) for a one-handed, hand-held assistive device (see 101.00C6d) that requires the use of the other upper extremity or a wheeled and seated mobility device involving the use of one hand (see 101.00C6e(ii)); or
- 3. An inability to use *both* upper extremities to the extent that neither can be

- used to independently initiate, sustain, and complete age-appropriate activities involving fine and gross movements (see 101.00E4).
- 101.16 Lumbar spinal stenosis resulting in compromise of the cauda equina (see 101.00G), documented by A, B, C, and D:
- A. Symptom(s) of neurological compromise manifested as:
- 1. Nonradicular distribution of pain in one or both lower extremities; or
- 2. Nonradicular distribution of sensory loss in one or both lower extremities; or
  - 3. Neurogenic claudication.

#### AND

- B. Nonradicular neurological signs present during physical examination (see 101.00C2) or on a diagnostic test (see 101.00C3) and evidenced by 1 and either 2 or 3:
  - 1. Muscle weakness.
  - 2. Sensory changes evidenced by:
  - a. Decreased sensation; or
- b. Sensory nerve deficit (abnormal sensory nerve latency) on electrodiagnostic testing; or
- c. Areflexia, trophic ulceration, or bladder or bowel incontinence.
- 3. Decreased deep tendon reflexes in one or both lower extremities.

#### AND

C. Findings on imaging (see 101.00C3) or in an operative report (see 101.00C4) consistent with compromise of the cauda equina with lumbar spinal stenosis.

#### AND

- D. Impairment-related physical limitation of musculoskeletal functioning that has lasted, or is expected to last, for a continuous period of at least 12 months, and medical documentation of at least *one* of the following:
- 1. A documented medical need (see 101.00C6a) for a walker, bilateral canes, or bilateral crutches (see 101.00C6d) or a wheeled and seated mobility device involving the use of both hands (see 101.00C6e(i)); or
- 2. An inability to use *one* upper extremity to independently initiate, sustain, and complete age-appropriate activities involving fine and gross movements (see 101.00E4), and a documented medical need (see 101.00C6a) for a one-handed, hand-held assistive device (see 101.00C6d) that requires the use of the other upper extremity or a wheeled and seated mobility device involving the use of one hand (see 101.00C6e(ii)).
- 101.17 Reconstructive surgery or surgical arthrodesis of a major weight-bearing joint (see 101.00H), documented by A, B, and C:
- A. History of reconstructive surgery or surgical arthrodesis of a major weight-bearing joint.

### ANI

B. Impairment-related physical limitation of musculoskeletal functioning that has lasted, or is expected to last, for a continuous period of at least 12 months.

### AΝΓ

C. A documented medical need (see 101.00C6a) for a walker, bilateral canes, or bilateral crutches (see 101.00C6d) or a wheeled and seated mobility device involving the use of both hands (see 101.00C6e(i)).

- 101.18 Abnormality of a major joint(s) in any extremity (see 101.00I), documented by A, B, C, and D:
- A. Chronic joint pain or stiffness. AND
- B. Abnormal motion, instability, or immobility of the affected joint(s).
- C. Anatomical abnormality of the affected joint(s) noted on:
- 1. Physical examination (for example, subluxation, contracture, or bony or fibrous ankylosis); or
- 2. Imaging (for example, joint space narrowing, bony destruction, or ankylosis or arthrodesis of the affected joint).
- D. Impairment-related physical limitation of musculoskeletal functioning that has lasted, or is expected to last, for a continuous period of at least 12 months, and medical documentation of at least *one* of the
- 1. A documented medical need (see 101.00C6a) for a walker, bilateral canes, or bilateral crutches (see 101.00C6d) or a wheeled and seated mobility device involving the use of both hands (see 101.00C6e(i)); or
- 2. An inability to use *one* upper extremity to independently initiate, sustain, and complete age-appropriate activities involving fine and gross movements (see 101.00E4), and a documented medical need (see 101.00C6a) for a one-handed, hand-held assistive device (see 101.00C6d) that requires the use of the other upper extremity or a wheeled and seated mobility device involving the use of one hand (see 101.00C6e(ii)): or
- 3. An inability to use *both* upper extremities to the extent that neither can be used to independently initiate, sustain, and complete age-appropriate activities involving fine and gross movements (see 101.00E4).
- 101.19 Pathologic fractures due to any cause (see 101.00J), documented by A and B:
- A. Pathologic fractures occurring on three separate occasions within a 12-month period. AND
- B. Impairment-related physical limitation of musculoskeletal functioning that has lasted, or is expected to last, for a continuous period of at least 12 months, and medical documentation of at least *one* of the following:
- 1. A documented medical need (see 101.00C6a) for a walker, bilateral canes, or bilateral crutches (see 101.00C6d) or a wheeled and seated mobility device involving the use of both hands (see 101.00C6e(i)); or
- 2. An inability to use *one* upper extremity to independently initiate, sustain, and complete age-appropriate activities involving fine and gross movements (see 101.00E4), and a documented medical need (see 101.00C6a) for a one-handed, hand-held assistive device (see 101.00C6d) that requires the use of the other upper extremity or a wheeled and seated mobility device involving the use of one hand (see 101.00C6e(ii)); or
- 3. An inability to use *both* upper extremities to the extent that neither can be

used to independently initiate, sustain, and complete age-appropriate activities involving fine and gross movements (see 101.00E4).

101.20 Amputation due to any cause (see 101.00K), documented by A, B, C, or D:

A. Amputation of both upper extremities, occurring at any level at or above the wrists (carpal joints), up to and including the shoulder (glenohumeral) joint.

OR

- B. Hemipelvectomy or hip disarticulation.
  OR
- C. Amputation of one upper extremity, occurring at any level at or above the wrist (carpal joints), and amputation of one lower extremity, occurring at or above the ankle (talocrural joint), and medical documentation of at least *one* of the following:
- 1. A documented medical need (see 101.00C6a) for a walker, bilateral canes, or bilateral crutches (see 101.00C6d) or a wheeled and seated mobility device involving the use of both hands (see 101.00C6e(i)); or
- 2. A documented medical need (see 101.00C6a) for a one-handed, hand-held assistive device (see 101.00C6d) requiring the use of the other upper extremity or a wheeled and seated mobility device involving the use of one hand (see 101.00C6e(ii)); or
- 3. The inability to use the remaining upper extremity to independently initiate, sustain, and complete age-appropriate activities involving fine and gross movements (101.00E4).
- D. Amputation of one or both lower extremities, occurring at or above the ankle (talocrural joint), with complications of the residual limb(s) that have lasted, or are expected to last, for a continuous period of at least 12 months, and medical documentation of 1 and 2:
  - 1. The inability to use a prosthesis(es); and
- 2. A documented medical need (see 101.00C6a) for a walker, bilateral canes, or bilateral crutches (see 101.00C6d) or a wheeled and seated mobility device involving the use of both hands (see 101.00C6e(i)).
- 101.21 Soft tissue injury or abnormality under continuing surgical management (see 101.00L), documented by A, B, and C:
- A. Evidence confirms continuing surgical management (see 101.00P1) directed toward saving, reconstructing, or replacing the affected part of the body.

AND

B. The surgical management has been, or is expected to be, ongoing for a continuous period of at least 12 months.

AND

- C. Maximum benefit from therapy (see 101.00P2) has not yet been achieved.
- 101.22 Non-healing or complex fracture of the femur, tibia, pelvis, or one or more of the talocrural bones (see 101.00M), documented by A, B, and C:
- A. Solid union not evident on imaging (see 101.00C3) and not clinically solid.

  AND
- B. Impairment-related physical limitation of musculoskeletal functioning that has

lasted, or is expected to last, for a continuous period of at least 12 months.

AND

C. A documented medical need (see 101.00C6a) for a walker, bilateral canes, or bilateral crutches (see 101.00C6d) or a wheeled and seated mobility device involving the use of both hands (see 101.00C6e(i)).

101.23 Non-healing or complex fracture of an upper extremity (see 101.00N), documented by A and B:

A. Nonunion or complex fracture, of the shaft of the humerus, radius, or ulna, under continuing surgical management (see 101.00P1) directed toward restoration of functional use of the extremity.

B. Medical documentation of an inability to independently initiate, sustain, and complete age-appropriate activities involving fine and gross movements (see 101.00E4) that has lasted, or is expected to last, for a continuous period of at least 12 months.

101.24 Musculoskeletal disorders of infants and toddlers, from birth to attainment of age 3, with developmental motor delay (see 101.000), documented by A or B:

- A. A standardized developmental motor assessment that:
- 1. Shows motor development not more than one-half of the level typically expected for the child's age; or
- 2. Results in a valid score that is at least three standard deviations below the mean. OR
- B. Two narrative developmental reports that:
- Are dated at least 120 days apart; and
   Indicate current motor development not

more than one-half of the level typically expected for the child's age.

## 104.00 Cardiovascular System

F. Evaluating Other Cardiovascular Impairments

9. What is lymphedema and how will we evaluate it?

b. Lymphedema does not meet the requirements of 4.11 in part A, although it may medically equal the severity of that listing. We will evaluate lymphedema by considering whether the underlying cause meets or medically equals any listing or whether the lymphedema medically equals a cardiovascular listing, such as 4.11, or a musculoskeletal disorders listing, such as 101.18. If no listing is met or medically equaled, we will evaluate any functional limitations imposed by your lymphedema when we consider whether you have an impairment that functionally equals the listings.

## 109.00 Endocrine Disorders

\* \* \* \* \*

C. How do we evaluate DM in children? Listing 109.08 is only for children with DM who have not attained age 6 and who require daily insulin. For all other children (that is, children with DM who are age 6 or older and require daily insulin, and children of any age with DM who do not require daily insulin), we follow our rules for determining whether the DM is severe, alone or in combination with another impairment, whether it meets or medically equals the criteria of a listing in another body system, or functionally equals the listings under the criteria in § 416.926a of this chapter, considering the factors in § 416.924a of this chapter. The management of DM in children can be complex and variable from day to day, and all children with DM require some level of adult supervision. For example, if a child age 6 or older has a medical need for 24-hour-a-day adult supervision of insulin treatment, food intake, and physical activity to ensure survival, we will find that the child's impairment functionally equals the listings based on the example in § 416.926a(m)(2) of this chapter.

### 114.00 Immune System Disorders

C. Definitions

C. Definitions

- 6. Documented medical need has the same meaning as in 101.00C6a.
- 7. Fine and gross movements has the same meaning as in 101.00E4.
- 8. Major joint of an upper or a lower extremity has the same meaning as in 101.00I2 and 101.00I3.

9. \* \* \* \* \* \* \*

12. Severe means medical severity as used by the medical community. The term does not have the same meaning as it does when we use it in connection with a finding at the second step of the sequential evaluation process in § 416.920 of this chapter.

D. How do we document and evaluate the listed autoimmune disorders?

4. Polymyositis and dermatomyositis (114.05).

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

\* \* \* \* \*

(ii) If you are of preschool age through adolescence (age 3 to attainment of age 18), weakness of your pelvic girdle muscles that results in your inability to rise independently from a squatting or sitting position or to climb stairs may be an indication that you are unable to walk without assistance. Weakness of your shoulder girdle muscles may result in your inability to perform lifting, carrying, and reaching overhead, and also may seriously affect your ability to perform activities requiring fine movements. We evaluate these limitations under 114.05A.

\* \* \* \* \* \* 6. \* \* \*

a. General. The spectrum of inflammatory arthritis includes a vast array of disorders that differ in cause, course, and outcome. Clinically, inflammation of major joints in an

upper or a lower extremity may be the dominant manifestation causing difficulties with walking or fine and gross movements; there may be joint pain, swelling, and tenderness. The arthritis may affect other joints, or cause less limitation in walking or fine and gross movements. However, in combination with extra-articular features, including constitutional symptoms or signs (severe fatigue, fever, malaise, and involuntary weight loss), inflammatory arthritis may result in an extreme limitation.

\* \* \* \* \* \* e. \* \* \*

- (i) Listing-level severity in 114.09A and 114.09C1 is shown by the presence of an impairment-related physical limitation of functioning. In 114.09C1, if you have the required ankylosis (fixation) of your cervical or dorsolumbar spine, we will find that you have a listing-level impairment-related physical limitation in your ability to see in front of you, above you, and to the side, even though you might not require bilateral upper limb assistance.
- (ii) Listing-level severity in 114.09B and 114.09C2 is shown by inflammatory arthritis that involves various combinations of complications (such as inflammation or deformity, extra-articular features, repeated manifestations, and constitutional symptoms and signs) of one or more major joints in an upper or a lower extremity (see 114.00C8) or other joints. Extra-articular impairments may also meet listings in other body systems.

114.04 Systemic sclerosis (scleroderma). As described in 114.00D3. With:

B. One of the following:

1. Toe contractures or fixed deformity of one or both feet and medical documentation of at least *one* of the following:

- a. A documented medical need (see 114.00C6) for a walker, bilateral canes, or bilateral crutches (see 101.00C6d) or a wheeled and seated mobility device involving the use of both hands (see 101.00C6e(i)); or
- b. An inability to use *one* upper extremity to independently initiate, sustain, and complete age-appropriate activities involving fine and gross movements (see 114.00C7), and a documented medical need (see 114.00C6) for a one-handed, hand-held assistive device (see 101.00C6d) that requires the use of the other upper extremity or a wheeled and seated mobility device involving the use of one hand (see 101.00C6e(ii)); or
- 2. Finger contractures or fixed deformity in both hands and medical documentation of an inability to use *both* upper extremities to the extent that neither can be used to independently initiate, sustain, and complete age-appropriate activities involving fine and gross movements (see 114.00C7); or
- 3. Atrophy with irreversible damage in one or both lower extremities and medical documentation of at least *one* of the following:
- a. A documented medical need (see 114.00C6) for a walker, bilateral canes, or bilateral crutches (see 101.00C6d) or a wheeled and seated mobility device

involving the use of both hands (see 101.00C6e(i)); or

- b. An inability to use *one* upper extremity to independently initiate, sustain, and complete age-appropriate activities involving fine and gross movements (see 114.00C7), and a documented medical need (see 114.00C6) for a one-handed, hand-held assistive device (see 101.00C6d) that requires the use of the other upper extremity or a wheeled and seated mobility device involving the use of one hand (see 101.00C6e(ii)); or
- 4. Atrophy with irreversible damage in both upper extremities and medical documentation of an inability to use both upper extremities to the extent that neither can be used to independently initiate, sustain, and complete age-appropriate activities involving fine and gross movements (see 114.00C7); or
- C. Raynaud's phenomenon, characterized by:

2. Ischemia with ulcerations of toes or fingers and medical documentation of at least *one* of the following:

- a. A documented medical need (see 114.00C6) for a walker, bilateral canes, or bilateral crutches (see 101.00C6d) or a wheeled and seated mobility device involving the use of both hands (see 101.00C6e(i)); or
- b. An inability to use *one* upper extremity to independently initiate, sustain, and complete age-appropriate activities involving fine and gross movements (see 114.00C7), and a documented medical need (see 114.00C6) for a one-handed, hand-held assistive device (see 101.00C6d) that requires the use of the other upper extremity or a wheeled and seated mobility device involving the use of one hand (see 101.00C6e(ii)); or
- c. An inability to use *both* upper extremities to the extent that neither can be used to independently initiate, sustain, and complete age-appropriate activities involving fine and gross movements (see 114.00C7).

114.05 Polymyositis and dermatomyositis. As described in 114.00D4. With:

A. Proximal limb-girdle (pelvic or shoulder) muscle weakness and medical documentation of at least *one* of the following:

- 1. A documented medical need (see 114.00C6) for a walker, bilateral canes, or bilateral crutches (see 101.00C6d) or a wheeled and seated mobility device involving the use of both hands (see 101.00C6e(i)); or
- 2. An inability to use *one* upper extremity to independently initiate, sustain, and complete age-appropriate activities involving fine and gross movements (see 114.00C7), and a documented medical need (see 114.00C6) for a one-handed, hand-held assistive device (see 101.00C6d) that requires the use of the other upper extremity or a wheeled and seated mobility device involving the use of one hand (see 101.00C6e(ii)); or
- 3. An inability to use *both* upper extremities to the extent that neither can be

used to independently initiate, sustain, and complete age-appropriate activities involving fine and gross movements (see 114.00C7); or

114.09 *Inflammatory arthritis.* As described in 114.00D6. With:

- A. Persistent inflammation or persistent deformity of:
- 1. One or more major joints in a lower extremity (see 114.00C8) and medical documentation of at least *one* of the following:
- a. A documented medical need (see 114.00C6) for a walker, bilateral canes, or bilateral crutches (see 101.00C6d) or a wheeled and seated mobility device involving the use of both hands (see 101.00C6e(i)); or
- b. An inability to use *one* upper extremity to independently initiate, sustain, and complete age-appropriate activities involving fine and gross movements (see 114.00C7), and a documented medical need (see 114.00C6) for a one-handed, hand-held assistive device (see 101.00C6d) that requires the use of the other upper extremity or a wheeled and seated mobility device involving the use of one hand (see 101.00C6e(ii)); or
- 2. One or more major joints in each upper extremity (see 114.00C8) and medical documentation of an inability to use *both* upper extremities to the extent that neither can be used to independently initiate, sustain, and complete age-appropriate activities involving fine and gross movements (see 114.00C7); or
- B. Inflammation or deformity in one or more major joints of an upper or lower extremity (see 114.00C8) with:

# PART 416—SUPPLEMENTAL SECURITY INCOME FOR THE AGED, BLIND, AND DISABLED

## Subpart I—Determining Disability and Blindness

 $\blacksquare$  3. The authority citation for subpart I of part 416 continues to read as follows:

**Authority:** Secs. 221(m), 702(a)(5), 1611, 1614, 1619, 1631(a), (c), (d)(1), and (p), and 1633 of the Social Security Act (42 U.S.C. 421(m), 902(a)(5), 1382, 1382c, 1382h, 1383(a), (c), (d)(1), and (p), and 1383(b)); secs. 4(c) and 5, 6(c)–(e), 14(a), and 15, Pub. L. 98–460, 98 Stat. 1794, 1801, 1802, and 1808 (42 U.S.C. 421 note, 423 note, and 1382h note).

## § 416.926a [Amended]

■ 4. Amend § 416.926a by removing paragraphs (m)(1) and (2) and redesignating paragraphs (m)(3) through (5) as (m)(1) through (3).

[FR Doc. 2020-25250 Filed 12-2-20; 8:45 am]

BILLING CODE 4191-02-P