SOCIAL SECURITY ADMINISTRATION

20 CFR Parts 404 and 416

[Docket No. SSA–2019–0013]

RIN 0960–AI43

Revised Medical Criteria for Evaluating Cardiovascular Disorders

AGENCY: Social Security Administration.

ACTION: Final rule.

SUMMARY: We are revising the criteria in the Listing of Impairments (listings) that we use to evaluate claims involving cardiovascular 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: This rule is effective October 30, 2026.

FOR FURTHER INFORMATION CONTACT: Michael J. Goldstein, 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

The listings describe medical conditions that are so severe that we presume any adult who has a medical condition(s) that satisfies the criteria of a listing is unable to perform any gainful activity regardless of their age, education, or work experience and, therefore, is disabled.[1] For children, the listings describe impairments we consider severe enough to cause marked and severe functional limitations.[2] We use the listings at step 3 of the sequential evaluation process to identify claims that we should clearly allow.[3] We do not deny any claim solely because a person's medical condition(s) does not satisfy the criteria of a listing.

We last published final rules that comprehensively revised the cardiovascular disorders listings on January 13, 2006.[4] We published an Advance Notice of Proposed Rulemaking (ANPRM) for cardiovascular disorders in the **Federal Register** on April 16, 2008.[5]

We are making final the rule for evaluating cardiovascular disorders that we proposed in the NPRM published in the **Federal Register** on June 29, 2022.[6] The preamble to the NPRM provides the background and rationale for these revisions. As explained in the NPRM, the revisions were informed by recommendations from the Institute of Medicine (IOM)[7] contained in their report titled ''*Cardiovascular Disability: Updating the Social Security Listings*'' (IOM report).[8] The IOM report provides an important foundation because it was prepared within the context of the statutory definition of disability and the cardiovascular listings. The considerations under our disability program may be different than those found in a clinical or research setting. For example, the medical listings account for the most severe impairments that limit a person's function and ability to engage in any gainful activity, while clinical or research settings may seek to address all those affected by a condition or impairment and focus on decision-making regarding diagnosis and treatment of the medical problem; their focus is not necessarily on the ability to engage in any gainful activity. The IOM report specifically discusses these differences: for example, the IOM notes that generally, clinical guidelines do not address patient disability or employability as a major topic of discussion and rarely indicate the relationship of impairment severity to functional limitations that might affect work capacity.[9]

However, the revisions to our listings are not based solely on the IOM report. We have additionally reviewed a comprehensive body of relevant and reliable medical research, consulted with agency medical experts, and reviewed disability claims involving cardiovascular disorders to ensure that the revised criteria still reflect listing-level severity based on current medical practice. You can view the preamble to the NPRM by visiting *http://www.regulations.gov* and searching for document ''SSA–2019–0013.'' There are some differences in the introductory text and listing text from the NPRM to this final rule, which we explain below. Those differences reflect, in large part, our response to public comments we received about our proposed rule.

Why are we revising the listings for evaluating cardiovascular disorders?

We developed this final rule as part of our ongoing review of the listings. We are revising the listings for evaluating cardiovascular disorders to update their medical criteria, and to clarify how we evaluate cardiovascular disorders.

When will we begin to use this final rule?

As we noted in the dates section of this preamble, this final rule will be effective on October 30, 2026.

We delayed the effective date of the rule to give us time to update our systems and to provide training and guidance to all of our adjudicators before we implement the final rule. The current rules will continue to apply until the effective date of the final rule. When the final rule becomes effective, we will apply it to new applications filed on or after the effective date of the rule, and to claims that are pending on or after the effective date.[10]

We present a series of tables below. These tables summarize the revisions we are making to the cardiovascular disorders introductory text and listings. Following the tables, we discuss the changes in detail.

The following table summarizes the current and revised sections of the adult cardiovascular disorders introductory text and listings:

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[1] 20 CFR 404.1525(a) and 416.925(a).

[2] 20 CFR 416.925(a).

[3] 20 CFR 404.1520, 404.1525(a), 416.920, 416.924, and 416.925(a).

[4] 71 FR 2312 (2006).

[5] 73 FR 20564 (2008).

[6] 87 FR 38838 (2022).

[7] Institute of Medicine (IOM). (2010). *Cardiovascular Disability: Updating the Social Security Listings.* Washington, DC: The National Academies Press. Note: We did not adopt all of the IOM report's recommendations. In some instances, certain recommendations were already addressed in another listing, or they conflicted with existing SSA policy. However, we did adopt multiple IOM recommendations. See IOM Adoption Chart in Supporting and Related Materials to this Docket for more details (see also 87 FR 38838).

[8] On April 28, 2015, the membership of the National Academy of Science voted to change the name of the IOM to the National Academy of Medicine. At that time, reports and studies of the IOM continued as activities of the Health and Medicine Division, a program unit operating under the direction of the National Academies of Sciences, Engineering, and Medicine. We will continue to use ''IOM'' and ''Institute of Medicine'' throughout this rule, as this is the name reflected in the cited report.

[9] IOM. (2010), 274.

[10] This means that we will use this final rule on and after the effective date in any case in which we make a determination or decision, including new applications, pending claims, and continuing disability reviews (CDRs), as applicable. See 20 CFR 404.901, 404.1590, 416.990, and 416.1401. 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 this final rule, we will apply this final rule to the entire period at issue in the decision we make after the court's remand.

Sections of the Adult Introductory Text and Listings for the Cardiovascular System Prior to the Effective Date of this Final Rule	Revised Sections of the Adult Introductory Text and Listings for Cardiovascular Disorders
Introductory Text, 4.00	
A. General	A. How do we define cardiovascular disorders and cardiovascular terms?
B. Documenting Cardiovascular Impairment	B. What documentation do we need to evaluate cardiovascular disorders?
C. Using Cardiovascular Test Results	C. How do we use cardiovascular test results?
D. Evaluating Chronic Heart Failure	D. How do we evaluate chronic heart failure?
E. Evaluating Ischemic Heart Disease	E. How do we evaluate ischemic heart disease?
F. Evaluating Arrhythmias	F. How do we evaluate arrhythmias?
G. Evaluating Peripheral Vascular Disease	G. How do we evaluate peripheral vascular disease?
	H. How do we evaluate congenital heart disease?
H. Evaluating Other Cardiovascular Impairments	I. How do we evaluate other cardiovascular disorders?
I. Other Evaluation Issues	J. How do we evaluate other issues that affect the cardiovascular system?
	K. How do we evaluate cardiovascular disorders that do not meet one of these listings?
Listings	
4.01 Category of Impairments, Cardiovascular System	4.01 Category of Impairments, Cardiovascular Disorders
4.02 Chronic heart failure	4.02 Chronic heart failure
	4.03 [Reserved]
4.04 Ischemic heart disease	4.04 Ischemic heart disease
4.05 Recurrent arrhythmias	4.05 Recurrent arrhythmias
4.06 Symptomatic congenital heart disease	4.06 Congenital heart disease
	4.07 Aortic valvular disease
	4.08 Cardiomyopathy
4.09 Heart transplant	4.09 Heart transplantation
4.10 Aneurysm of aorta or major branches	4.10 Dissecting aneurysm of the aorta or major branches
4.11 Chronic venous insufficiency	4.11 Chronic venous insufficiency
4.12 Peripheral arterial disease	4.12 Peripheral artery disease
	4.13 – 4.15 [Reserved]
	4.16 Cardiac allograft vasculopathy

The following table summarizes the current and revised sections of the childhood cardiovascular disorders introductory text and listings:

Sections of the Childhood Introductory Text and Listings for the Cardiovascular System Prior to the Effective Date of this Final Rule	Revised Sections of the Childhood Introductory Text and Listings for Cardiovascular Disorders
Introductory Text, 104.00	
A. General	A. How do we define cardiovascular disorders and cardiovascular terms?
B. Documenting Cardiovascular Impairment	B. What documentation do we need to evaluate cardiovascular disorders?
C. Evaluating Chronic Heart Failure	C. How do we evaluate chronic heart failure?
D. Evaluating Congenital Heart Disease	D. How do we evaluate congenital heart disease?
E. Evaluating Arrhythmias	E. How do we evaluate arrhythmias?
F. Evaluating Other Cardiovascular Impairments	F. How do we evaluate other cardiovascular disorders?
G. Other Evaluation Issues	G. How do we evaluate other issues that affect the cardiovascular system?
	H. How do we evaluate cardiovascular disorders that do not meet one of these listings?
Listings	
104.01 Category of Impairments, Cardiovascular System	104.01 Category of Impairments, Cardiovascular Disorders
104.02 Chronic heart failure	104.02 Chronic heart failure
	104.03 – 104.04 [Reserved]
104.05 Recurrent arrhythmias	104.05 Recurrent arrhythmias
104.06 Congenital heart disease	104.06 Congenital heart disease
	104.07 – 104.08 [Reserved]
104.09 Heart transplant	104.09 Heart transplantation
104.13 Rheumatic heart disease	104.10 – 104.15 [Reserved]
	104.16 Cardiac allograft vasculopathy

Listings 4.07 (*Aortic valvular disease*), 4.08 (*Cardiomyopathy*), and 4.16/104.16 (*Cardiac allograft vasculopathy*) are new listings. We added these listings to more directly address very serious conditions that can progress quickly and significantly limit an adult's ability to perform gainful activity or cause marked and severe limitations in a child's function. The impairments in these listings were previously evaluated under listings 4.02, 4.04, 4.05, 4.06, 4.09, 11.00, and 104.09.

The following tables show the revisions to the cardiovascular disorders listings criteria that involve changes to healthcare utilization and condition/episode requirements, along with the rationale for each change, and supporting resources.[11] A version of this table was in the Notice of Proposed Rulemaking; this updated version includes current resources and changes in the criteria which were made in the final rule. Following this table, we discuss all of the changes to the cardiovascular disorders listings in more detail.

Please be advised that the tables below contain only the changes that we are finalizing that relate to healthcare utilization, and not all revised listing criteria contain changes that relate to healthcare utilization.

[11] *Note:* We made several additions and changes to the tables based on feedback from public comments described later in this document, including updating listing criteria and terminology, adding more detailed rationales for our changes, and replacing or supplementing some of the older resources with newer references and guidelines.

Adult Cardiovascular Disorders Listings Criteria– Changes in Healthcare Utilization and Condition or Episode Requirements			
Listing 4.02 Chronic heart failure			
Listing Criterion Prior to the Effective Date of this Final Rule	Revised Listing Criterion	Rationale	Resources
4.02A. Medically documented presence of one of the following: 1. Systolic failure (see 4.00D1a(i)), with left ventricular end diastolic dimensions greater than 6.0 cm or ejection fraction of 30 percent or less during a period of stability (not during an episode of acute heart failure); or	4.02A. Medically documented presence of one of the following: 1. Heart failure with reduced ejection fraction documented by appropriate medically acceptable imaging during a period of stability (not during an episode of exacerbation of heart failure), with either a. or b. a. Left ventricular end diastolic dimension greater than 6.8 cm for males or 6.1 for females during a period of stability (not during an episode of exacerbation	Revised 4.02A1 requires an increased left ventricular end diastolic dimension (LVEDD) greater than 6.8 centimeters (cm) for males and 6.1 cm for females instead of an LVEDD greater than 6.0 cm. We followed medical research and consulted with agency medical experts in determining that an increased LVEDD of greater than 6.8 cm for males and greater than 6.1 cm for females more clearly establishes a severely enlarged heart with signs and symptoms indicating listing-level heart failure.	IOM. (2010). *Cardiovascular Disability: Updating the Social Security Listings* (pp. 88-89). Washington, DC: The National Academies Press. Harkness A., Ring L., Augustine D.X. et al. (2020). Normal Reference Intervals for Cardiac Dimensions and Function For Use In Echocardiographic Practice: A Guideline from the British Society of Echocardiography. *Echo Research & Practice*, *7*:X1. (https://doi.org/10.1530/ERP-19-0050e). American Society of Echocardiography. (2018, July). *The American Society of Echocardiography Recommendations For Cardiac Chamber Quantification In Adults: A Quick Reference Guide From The ASE Workflow And Lab Management Task Force*. (https://www.asecho.org/wp-content/uploads/2018/08/WFTF-Chamber-Quantification-Summary-Doc-Final-July-18.pdf). Lang, R. M., Badano, L. P., Mor-Avi, V., Afilalo, J., Armstrong, A., Ernande, L., Flachskampf, F. A., Foster, E., Goldstein, S. A., Kuznetsova, T.,

	of heart failure); or b. Ejection fraction of 30 percent or less during a period of stability (not during an episode of exacerbation of heart failure).		Lancellotti, P., Muraru, D., Picard, M. H., Rietzschel, E. R., Rudski, L., Spencer, K. T., Tsang, W., & Voigt, J.U. (2015). Recommendations for Cardiac Chamber Quantification by Echocardiography in Adults: An Update from the American Society of Echocardiography and the European Association of Cardiovascular Imaging. *Journal of the American Society of Echocardiography*, *28*(1), 1-39.e14. (https://doi.org/10.1016/j.echo.2014.10.003). Narayanan, K., Reinier, K., Teodorescu, C., Uy-Evanado, A., Aleong, R., Chugh, H., Nichols, G. A., Gunson, K., London, B., Jui, J., & Chugh, S. S. (2014). Left Ventricular Diameter and Risk Stratification for Sudden Cardiac Death. *Journal of the American Heart Association*, *3*(5), e001193. (https://doi.org/10.1161/JAHA.114.001193).
4.02B2. Three or more separate episodes of acute congestive heart failure within a consecutive 12-month period (see 4.00A3e), with evidence of fluid retention (see 4.00D2b(ii)) from clinical and imaging	4.02B3. Exacerbations or complications of chronic heart failure (see 4.00D1b) requiring three hospitalizations within a consecutive 12-month period (see 4.00A3e) and at least 30 days apart. Each hospitalization must last at least 48 hours, including hours in a hospital emergency	We removed "three or more separate episodes of acute congestive heart failure" to evaluate these episodes under 4.02B3 as recommended by the IOM. An impairment resulting in exacerbations or complications that require three hospitalizations within a consecutive 12-month period and at least 30 days	IOM. (2010), 89, 91. Khan, M. S., Sreenivasan, J., Lateef, N., Abougergi, M. S., Greene, S. J., Ahmad, T., Anker, S. D., Fonarow, G. C., & Butler, J. (2021). Trends in 30- and 90-Day Readmission Rates for Heart Failure. *Circulation Heart Failure*, *14*(4), e008335. (https://doi.org/10.1161/circheartfailure.121.008335).

assessments at the time of the episodes, requiring acute extended physician intervention such as hospitalization or emergency room treatment for 12 hours or more, separated by periods of stabilization (see 4.00D4c)	department immediately before the hospitalization (see 4.00J3). (Note: The revised 4.02B2 in this Final Rule is not in this table because it does not involve a change in healthcare utilization.)	apart is a very severe impairment. We require these hospitalizations to be at least 30 days apart to ensure we are evaluating separate episodes of exacerbations or complications.	
No current listing criteria.	4.02C. Heart failure with left ventricular ejection fraction of 20 percent or less while on a regimen of prescribed therapy, on two evaluations at least 90 days apart within a consecutive 12-month period (see 4.00A3e) during a period of stability (not during an episode of exacerbation of heart failure).	The IOM recommended a criterion for chronic heart failure with an ejection fraction (EF) on a sustained basis of 20 percent or less. An EF of only 20 percent means the heart's pumping action is less than a third of normal, and critically affects a person's ability to perform gainful activity.	IOM. (2010), 84, 89. University of Rochester Medical Center. (n.d.). *What is Ejection Fraction?* (https://www.urmc.rochester.edu/encyclopedia/content?contenttypeid=56&contentid=DM14). Runge, M. S., Patterson, C., Stouffer, G. A., & Netter, F. H. (2010). Netter's Cardiology (2nd ed.). Philadelphia, PA: Saunders Elsevier. Fukunaga, N., Ribeiro, R. V. P., Lafreniere-Roula, M., Manlhiot, C., Badiwala, M. V., & Rao, V. (2020). Left Ventricular Size and Outcomes in Patients with Left Ventricular Ejection Fraction Less Than 20%. *The Annals of Thoracic Surgery*, *110*(3), 863–869. (https://doi.org/10.1016/j.athoracsur.2020.01.005).

No current listing criteria.	4.02D. One of the following while hospitalized, at home, or both: 1. An implanted mechanical circulatory support device except extracorporeal membrane oxygenation (ECMO) (see 4.00D4e). Consider under a disability for 1 year from the date of implantation; after that, evaluate any residual impairment(s) under the criteria for the affected body system. 2. Continuous intravenous administration of inotropic medication (for example, milrinone) for at least 30 consecutive days. Consider under a disability for 1 year from the date of initiation of the treatment; after that, evaluate any residual impairment(s) under the criteria for the	Implanted mechanical circulatory support devices (MCSD) help the heart pump blood and may be used as a "bridge" while a person waits for a heart transplant. Adding this new criterion ensures that people with heart failure treated with MCSD are consistently identified. People who require continuous intravenous administration of inotropic medication (for example, milrinone) have very serious heart failure, and the length of this treatment can be an accurate predictor of impairment severity. Accordingly, 4.02D2 requires continuous intravenous inotropic medications for 30 or more consecutive days.	Heidenreich, P. A., Bozkurt, B., Aguilar, D., Allen, L. A., Byun, J. J., Colvin, M. M., Deswal, A., Drazner, M. H., Dunlay, S. M., Evers, L. R., Fang, J. C., Fedson, S. E., Fonarow, G. C., Hayek, S. S., Hernandez, A. F., Khazanie, P., Kittleson, M. M., Lee, C. S., Link, M. S., Milano, C. A., … ACC/AHA Joint Committee Members (2022). 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation*, *145*(18), e895–e1032. (https://doi.org/10.1161/CIR.0000000000001063). Malotte, K., Saguros, A., & Groninger, H. (2018). Continuous Cardiac Inotropes in Patients with End-Stage Heart Failure: An Evolving Experience. *Journal of pain symptom management*, 55(1), 159-163. (https://doi.org/10.1016/j.jpainsymman.2017.09.026). Bistola, V., Arfaras-Melainis, A., Polyzogopoulou, E., Ikonomidis, I., & Parissis, J. (2019). Inotropes in Acute Heart Failure: From Guidelines to Practical Use: Therapeutic Options and Clinical Practice. *Cardiac Failure Review*, 5(3), 133-139. doi: 10.15420/cfr.2019.11.2 (https://pubmed.ncbi.nlm.nih.gov/31768269).

	affected body system.		
Listing 4.04 Ischemic heart disease			
4.04B. Three separate ischemic episodes, each requiring revascularization or not amenable to revascularization (see 4.00E9f), within a consecutive 12-month period (see 4.00A3e).	4.04C. Documentation of three separate ischemic episodes (see 4.00E9c) requiring unplanned hospitalization (inpatient or observation status) within a consecutive 12-month period (see 4.00A3e).	This revised listing ensures we are only evaluating urgent ischemic episodes. People who have ischemic episodes that result in unplanned hospitalizations may need intensive care, can have long hospital stays, may require multiple procedures, and can be at high risk for post-discharge morbidity and mortality.	Hua, M., Gong, M. N., Brady, J., & Wunsch, H. (2015). Early and Late Unplanned Rehospitalizations for Survivors of Critical Illness. *Critical Care Medicine, 43*(2), 430-438. (https://doi.org/10.1097/CCM.0000000000000717). Arnold S.V., Smolderen K.G., Kennedy K.F., et al. (2015). Risk Factors for Rehospitalization for Acute Coronary Syndromes and Unplanned Revascularization Following Acute Myocardial Infarction. *Journal of the American Heart Association, 4*(2), e001352. (https://doi.org/doi:10.1161/JAHA.114.001352).
No current criterion for repeated exacerbations or complications from ischemic heart disease, 4.04B (above) only considers episodes requiring revascularization or that are not amenable to revascularization.	4.04E. Exacerbations or complications of ischemic heart disease (see 4.00E2-4.00E7) requiring three hospitalizations within a consecutive 12-month period (see 4.00A3e) and at least 30 days apart. Each hospitalization must last at least 48 hours, including hours in a hospital emergency	An impairment resulting in exacerbations or complications that require three or more hospitalizations in 12 months is a very severe impairment. The new criterion requires these hospitalizations to be at least 30 days apart to ensure we are evaluating separate episodes of exacerbations or complications of ischemic heart disease.	Hua, M., Gong, M. N., Brady, J., & Wunsch, H. (2015). Early and Late Unplanned Rehospitalizations for Survivors of Critical Illness. *Critical care medicine, 43*(2), 430-438. (https://doi.org/10.1097/CCM.0000000000000717).

	department immediately before the hospitalization (see 4.00J3).		
Listing 4.06 Congenital heart disease			
4.06A. Cyanosis at rest, and: 1. Hematocrit of 55 percent or greater; or 2. Arterial O_2 saturation of less than 90 percent in room air, or resting arterial PO_2 of 60 Torr or less.	4.06A. Chronic hypoxemia, and 1, 2, or 3: 1. Hematocrit of 55 percent or greater on two evaluations at least 90 days apart within a consecutive 12-month period (see 4.00A3e); or 2. Arterial blood gas test measurement obtained at rest while breathing room air, as described in either a or b: a. S_aO_2 (arterial oxygen saturation) less than or equal to 89 percent; or b. PO_2 or P_aO_2 (partial pressure of oxygen) less than or equal to 60 millimeters of mercury (mmHg); 3. S_pO_2 (percentage of oxygen saturation of blood hemoglobin)	Revised 4.06A requires "hypoxemia" rather than "cyanosis or acyanosis." Cyanosis is a more subjective assessment subject to misinterpretation due to many factors, such as skin complexion, lighting conditions, and thickness of skin. Thus, the term "hypoxemia" relates more to the objective laboratory and pulse oximetry findings than the term "cyanosis." We require two hematocrit measurements instead of a single measurement. Two measurements, at least 90 days apart within a consecutive 12-month period ensure the person's hematocrit level is associated with chronic hypoxemia and	Stout, K. K., Daniels, C. J., Aboulhosn, J. A., Bozkurt, B., Broberg, C. S., Colman, J. M., … Van Hare, G. F. (2019). 2018 AHA/ACC Guideline for the Management of Adults With Congenital Heart Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *Journal of the American College of Cardiology, 73* (12), e81-e192. (https://doi.org/10.1016/j.jacc.2018.08.1029). Stack, S. W., & Berger, S. A. (2009). The effects of high hematocrit arterial flow—A phenomenological study of health risk implications. *Chemical Engineering Science, 64* (22), 4701-4706. (https://doi.org/10.1016/j.ces.2009.07.017). IOM. (2010), 178. Oster, M. E., & Kochilas, L.K. (2016). Screening for Critical Congenital Heart Disease. *Clinics in Perinatology, 43*(1), 73-80. (https://doi.org/10.1016/j.clp.2015.11.005). Mechem, C. C. (2014). Pulse oximetry. In P. E. Parsons (Ed.), UpToDate (Jan. 2014). Retrieved from (https://www.uptodate.com/contents/pulse-oximetry).

	measured by pulse oximetry either at rest, during a 6-minute walk test (6MWT), or after a 6MWT, while breathing room air, less than or equal to 87 percent on three evaluations at least 30 days apart within a consecutive 12-month period (see 4.00A3e).	not the result of a reversible condition. 4.06A3 requires three S_pO_2 measurements 30 days apart within a consecutive 12-month period showing hypoxemia. This documents that the condition is chronic and persistent, and the measurements are not related to a reversible condition or an inaccurate reading. We added a criterion for S_pO_2 (percentage of oxygen saturation of blood hemoglobin) measured by pulse oximetry, including measurements taken while the person is at rest or while doing a six-minute walk test (6MWT). Pulse oximetry measurements are a non-invasive alternative to invasive testing. A person's medical evidence often provides S_pO_2 findings, and S_pO_2	Pahal P., Goyal A. Central and Peripheral Cyanosis. 2022 Oct 3. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan. PMID: 3264459. (https://pubmed.ncbi.nlm.nih.gov/32644593/). Torp K.D., Modi P., Pollard E.J., et al. Pulse Oximetry. 2023 Jul 30. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan. PMID: 29262014. (https://www.ncbi.nlm.nih.gov/books/NBK470348/). Yale Medicine. (2023, January 3). *Pulse Oximetry.* (https://www.yalemedicine.org/conditions/pulse-oximetry). MedlinePlus. (2025, November 28). *Pulse Oximetry*. (https://medlineplus.gov/lab-tests/pulse-oximetry/).

		measured by pulse oximetry reflects an advance in medical technology that provides another way to establish listing-level severity.	
No current criteria	4.06E. Exacerbations or complications of congenital heart disease (see 4.00J3) requiring three hospitalizations within a consecutive 12-month period (see 4.00A3e) and at least 30 days apart. Each hospitalization must last at least 48 hours, including hours in a hospital emergency department immediately before the hospitalization (see 4.00J3).	An impairment resulting in exacerbations or complications that require three or more hospitalizations in 12 months is a very severe impairment. We require these hospitalizations to be at least 30 days apart to ensure we are evaluating separate episodes of exacerbations or complications.	Hua, M., Gong, M. N., Brady, J., & Wunsch, H. (2015). Early and Late Unplanned Rehospitalizations for Survivors of Critical Illness. *Critical Care Medicine, 43(*2), 430-438. (https://doi.org/10.1097/CCM.0000000000000717).
Listing 4.08 Cardiomyopathy			
No current listing	4.08D. Exacerbations or complications of cardiomyopathy requiring three hospitalizations within a consecutive 12-month period (see 4.00A3e) and at least 30	Consistent with the IOM's recommendations, we added this new cardiomyopathy listing to address several types of cardiomyopathy, including hypertrophic cardiomyopathy, endomyocardial	IOM. (2010), 80. In addition, SSA has designated endomyocardial fibrosis and cardiac amyloidosis AL type as Compassionate Allowance (CAL) conditions. (See Compassionate Allowances Website Home Page at: https://www.ssa.gov/compassionateallowances/index.htm).

	days apart. Each hospitalization must last at least 48 hours, including hours in a hospital emergency department immediately before the hospitalization (see 4.00J3).	fibrosis, and cardiac amyloidosis AL (light-chain) type, which are more serious types of cardiomyopathy. Specific criteria for each of these types of cardiomyopathy are included in 4.08A, 4.08B, and 4.08C. An impairment resulting in exacerbations or complications that require three or more hospitalizations in 12 months is a very serious impairment. We require these hospitalizations to be at least 30 days apart to ensure we are evaluating separate episodes of exacerbations or complications. 4.08D provides another way to evaluate claimants with very serious cardiomyopathy that does not meet 4.08A, 4.08B, or 4.08C.	Bhatti K., Bandlamudi M., Lopez-Mattei J. Endomyocardial Fibrosis. 2024 Oct 6. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan. PMID: 30020665. (https://pubmed.ncbi.nlm.nih.gov/30020665/). Shams P., Ahmed I. Cardiac Amyloidosis. 2023 Jul 30. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan. PMID: 35593829. (https://pubmed.ncbi.nlm.nih.gov/35593829/). Ommen, S. R., Ho, C. Y., Asif, I. M., Balaji, S., Burke, M. A., Day, S. M., Dearani, J. A., Epps, K. C., Evanovich, L., Ferrari, V. A., Joglar, J. A., Khan, S. S., Kim, J. J., Kittleson, M. M., Krittanawong, C., Martinez, M. W., Mital, S., Naidu, S.S., Saberi, S., …Waldman, C.B. (2024). 2024 AHA/ACC/AMSSM/HRS/PACES/SCMR Guideline for the Management of Hypertrophic Cardiomyopathy: A Report of the American Heart Association/American College of Cardiology Joint Committee on Clinical Practice Guidelines. *Circulation*, *149*(23), e1239–e1311. (https://doi.org/10.1161/CIR.0000000000001250).
Listing 4.11 Chronic venous insufficiency			
4.11 Chronic venous insufficiency of a lower	4.11 Chronic venous insufficiency (see 4.00G) of a lower extremity	As recommended by the IOM, the revised listing requires confirmation of	IOM. (2010), 161. Baliyan V., Tajmir S., Hedgire S.S., Ganguli S., Prabhakar A.M. (2016). Lower extremity venous

extremity with incompetency or obstruction of the deep venous system and one of the following:	with reflux or obstruction of the venous system documented by duplex ultrasound or other appropriate diagnostic technique, with A or B:	chronic venous insufficiency (CVI) by duplex ultrasound or other appropriate diagnostic technique. The medical community considers the use of duplex ultrasound to be the best method for detecting reflux or obstruction.	reflux. *Cardiovasc Diagnosis and Therapy, 6*(6), 533-543. (https://doi.org/10.21037/cdt.2016.11.14). Azar, J., Rao, A., & Oropallo, A. (2022). Chronic venous insufficiency: a comprehensive review of management. *Journal of Wound Care*, *31*(6), 510–519. (https://doi.org/10.12968/jowc.2022.31.6.510).
4.11 A. Extensive brawny edema (see 4.00G3) involving at least two-thirds of the leg between the ankle and knee or the distal one-third of the lower extremity between the ankle and hip.	4.11 A. Extensive trophic changes of skin (for example, hyperpigmentation, lipodermatosclerosis, brawny edema, etc.) involving at least two-thirds of the leg below the knee, on two evaluations at least 90 days apart within a consecutive 12-month period (see 4.00A3e), with both 1 and 2: 1. Consistent with chronic venous insufficiency; and 2. Unresponsive to compression therapy.	We adopted the IOM's recommendations and broadened the listing criteria we apply to trophic changes of the skin. For example, in addition to brawny edema, trophic changes evaluated under this listing include hyperpigmentation and lipodermatosclerosis. The CVI must be unresponsive to compression therapy, because this therapy usually enables people to return to a good level of functioning. We revised the previous requirement that these skin changes involve	IOM. (2010), 157-161. Ruggiero M., Grande R., Naso A., Butrico L., Rubino P., Placida G.D., Cannistrà M., Serra R. (2016). Symptoms in patients with skin changes due to chronic venous insufficiency often lead to emergency care service: an Italian observational study. *International Wound Journal, 13*(5), 967-71. (https://doi.org/10.1111/iwj.12498). Geist R.S., Crane J.S. Lipodermatosclerosis. 2023 Jul 21. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan. PMID: 37603653. (https://www.ncbi.nlm.nih.gov/sites/books/NBK594262/). Patel, S. K., & Surowiec, S. M. Venous Insufficiency. 2024 Feb 14. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan. PMID: 28613694. (https://pubmed.ncbi.nlm.nih.gov/28613694/). Berszakiewicz A., Sieroń A., Krasiński Z., Cholewka A.,

		"at least two-thirds of the leg between the ankle and knee or the distal one-third of the lower extremity between the ankle and hip." Instead, we require extensive skin changes involving at least two-thirds of the leg below the knee, which is easier to understand and apply. This revision is consistent with the IOM's recommendation to require skin changes below the knee. We require the skin changes under 4.11A to be consistent with CVI, and we require documentation of the skin changes over a period of at least 90 days to ensure they are chronic.	Stanek A. (2020). Compression therapy in venous diseases: current forms of compression materials and techniques. *Postepy Dermatol Alergol, 37*(6), 836-841. doi: 10.5114/ada.2019.86991 (https://pubmed.ncbi.nlm.nih.gov/33603599/). Azar, J., Rao, A., & Oropallo, A. (2022). Chronic venous insufficiency: a comprehensive review of management. *Journal of Wound Care*, *31*(6), 510–519. (https://doi.org/10.12968/jowc.2022.31.6.510).
4.11B. Superficial varicosities, stasis dermatitis, and either recurrent ulceration or persistent ulceration that has not healed following at	4.11B. Two or more episodes of ulceration that have not healed following at least 6 months of prescribed treatment.	This revised requirement is more conclusive than the previous requirement of 3 months of unsuccessful prescribed treatment, as it demonstrates the condition has persisted despite treatment for a	IOM. (2010), 161. Azar, J., Rao, A., & Oropallo, A. (2022). Chronic venous insufficiency: a comprehensive review of management. *Journal of Wound Care*, *31*(6), 510–519. (https://doi.org/10.12968/jowc.2022.31.6.510).

least 3 months of prescribed treatment.		longer period of time.	

Childhood Cardiovascular Disorders Listings Criteria – Changes in Healthcare Utilization and Condition or Episode Requirements			
Listing 104.02 Chronic heart failure			
Listing Criterion Prior to the Effective Date of this Final Rule	Revised Listing Criterion	Rationale	Resources
104.02A. Persistent tachycardia at rest (see Table I);	104.02A. Persistent tachycardia at rest measured at least twice within a consecutive 12-month period and at least 90 days apart documented by apical heart rate greater than or equal to the value in Table I.	We clarify that to satisfy 104.02A, we require two or more tachycardia measurements in a consecutive 12-month period. This requirement ensures that the child has persistent tachycardia despite treatment. We also require that readings of tachycardia occur at least 90 days apart to further document chronic disease.	IOM. (2010), 171,173, 176. Mayo Clinic. (n.d.). *Tachycardia - Diagnosis and Treatment*. (https://www.mayoclinic.org/diseases-conditions/tachycardia/diagnosis-treatment/drc-20355133).
104.02B. Persistent tachypnea at rest (see Table II) or markedly decreased exercise tolerance (see 104.00C2b);	104.02B. Persistent tachypnea at rest measured at least twice within a consecutive 12-month period and at least 90 days apart documented by respiratory rate greater than or equal to the value in Table II or markedly decreased exercise tolerance (see 104.00C2b).	To satisfy 104.02B, we require two or more tachypnea measurements in a consecutive 12-month period. This requirement ensures that the child has persistent tachypnea, despite treatment. We also require that readings of tachypnea occur at least 90 days apart to further document chronic disease.	IOM. (2010), 171,173, 176. Park S.B., Khattar D. Tachypnea. 2024 Apr 20. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan. (https://www.ncbi.nlm.nih.gov/books/NBK541062/).
Listing 104.06 Congenital heart disease			
104.06A. 2. Arterial O_2 saturation of less than 90 percent in room air, or resting arterial PO_2 of 60 Torr or less; or	104.06A. 2. Arterial blood gas test measurement obtained at rest while breathing room air, as described in either a or b:	In 104.06A2, we use the measurement of millimeters of mercury, "mmHg," instead of the measurement of "Torr" that is used in current 104.06A2, and we note that arterial PO_2 is normally measured in room air.	Based on SSA administrative data from FY 2019–2021, of all childhood claims with a primary impairment of congenital heart disease that met or medically equaled

3. Hypercyanotic spells, syncope, characteristic squatting, or other incapacitating symptoms directly related to documented cyanotic heart disease; or 4. Exercise intolerance with increased hypoxemia on exertion.	a. S_aO_2 (arterial oxygen saturation) less than or equal to 89 percent; or b. PO_2 or P_aO_2 (partial pressure of oxygen) less than or equal to 60 mmHg; or 3. S_pO_2 (percentage of oxygen saturation of blood hemoglobin) measured by pulse oximetry either at rest, or after activity, while breathing room air, less than or equal to 87 percent on three evaluations at least 30 days apart within a consecutive 12-month period (see 104.00A3e).	We removed 104.06A3 and 104.06A4, because Agency medical experts indicated that they are less objective and more difficult to document than the other criteria and they are used infrequently. We added another criterion to 104.06A by adding S_pO_2 (percentage of oxygen saturation of blood hemoglobin), measured by pulse oximetry equal to or less than 87 percent. Consistent with the adult listing (4.06), this criterion is the new 104.06A3.	listing 104.06, approximately 0.2 percent cited 104.06A3 or 104.06A4 criteria. See Table A and B in supporting and related materials to this Docket for more information. (see also 87 FR 38838).
No current criteria	104.06E. Exacerbations or complications of congenital heart disease (see 104.00D) requiring three hospitalizations within a consecutive 12-month period (see 104.00A3e) and at least 30 days apart. Each hospitalization must last at least 48 hours, including hours in a hospital emergency	We added 104.06E to evaluate exacerbations or complications of congenital heart disease occurring at least 30 days apart and resulting in at least three hospitalizations within a consecutive 12-month period. An impairment resulting in exacerbations or complications that require this many hospitalizations in 12 months will result in marked and severe functional limitations for children. We require these hospitalizations to be at least 30 days apart	IOM. (2010), 179. 42 CFR 412.152 James, J., Tan, S., Stretton, B., Kovoor, J.G., Gupta, A.K., Gluck, S., Gilbert, T., Sharma, Y. and Bacchi, S. (2023), Why do we evaluate 30-day readmissions in general medicine? A historical perspective and contemporary data. *Internal medicine journal, 53*(6),

	department immediately before the hospitalization (see 104.00G3).	to ensure we are evaluating separate episodes of exacerbations or complications.	1070-1075. (https://doi.org/10.1111/imj.16115). Amdani, S., Conway, J., George, K., Martinez, H. R., Asante-Korang, A., Goldberg, C. S., Davies, R. R., Miyamoto, S. D., Hsu, D. T., & American Heart Association Council on Lifelong Congenital Heart Disease and Heart Health in the Young; Council on Arteriosclerosis, Thrombosis and Vascular Biology; Council on Cardiovascular Surgery and Anesthesia; and Council on Cardiovascular and Stroke Nursing (2024). Evaluation and Management of Chronic Heart Failure in Children and Adolescents With Congenital Heart Disease: A Scientific Statement From the American Heart Association. *Circulation*, *150*(2), e33–e50. (https://doi.org/10.1161/CIR.0000000000001245).

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We are making several changes from the NPRM to this final rule for cardiovascular disorders:

The following is a high-level summary of the major changes from the NPRM to this final rule. Below, in the section titled *Public Comments on the NPRM,* we describe in greater detail our responses to public comments, including the changes we made from the NPRM as a result of the comments. We also made minor, editorial changes from the NPRM for clarity and readability.

• *Chronic heart failure (chronic HF):* We changed the acronym we use for chronic heart failure from ''CHF'' to ''chronic HF.'' We revised the terminology we use to describe the types of heart failure in paragraph 4.00D1 (*What is chronic HF?*) and listing 4.02 (*Chronic heart failure*) to align with current medical terminology. In the introductory text, we expanded the list of appropriate medically acceptable imaging (paragraph 4.00D2 (*What evidence of chronic HF do we need?*)), expanded the discussion of symptoms of chronic HF (paragraph 104.00C2b (Your medical history and physical examination)), and included increased ventricular volume in our discussion of cardiomegaly (paragraph 104.00C2a (Cardiomegaly or ventricular dysfunction)). In 4.02A1a (Left ventricular end diastolic dimension), we changed the threshold criterion for left ventricular end diastolic dimension (LVEDD) and provided different cutoffs for males and females. We also made a minor corresponding revision to the language describing a ''period of stability'' in paragraph 4.02A1b to replace the term ''acute heart failure'' with the term ''exacerbation of heart failure,'' which was our original intent and aligns with the language used in the description of a ''period of stability'' in paragraphs 4.02A1, 4.02A2, and 4.02C and ensures consistency of this description throughout listing 4.02.

• *Ischemic heart disease:* We revised the introductory text in paragraphs 4.00E1 (*What is ischemic heart disease (IHD)?*) and 4.00E2 (*What causes chest discomfort of myocardial origin?*) to fully capture the causes of IHD. We also added language about non-obstructive coronary artery disease (paragraph 4.00E6 (*What is variant angina?*)) and instantaneous wave-free ratio (iFR) (paragraph 4.00E9f (In 4.04D2, instantaneous wave-free ratio (iFR)). We added a new listing 4.04D2 (Instantaneous wave-free ratio) to provide another measure of listing-level IHD.

• *Peripheral vascular disease:* We replaced the term ''peripheral arterial disease'' with ''peripheral artery disease'' throughout section 4.00G (*How do we evaluate peripheral vascular disease?*) and listing 4.12 (*Peripheral artery disease*) to reflect current medical terminology. In the introductory text, we clarified the symptoms associated with peripheral artery disease (PAD) (paragraph 4.00G1 (*What is peripheral vascular disease (PVD)?*)) and lymphedema (paragraphs 4.00G4 and 104.00F9 (*What is lymphedema and how do we evaluate it?*)). We also updated terminology describing ankle-brachial measurements and toe-brachial measurements we use to evaluate PAD to be consistent with modern medical practice (paragraphs 4.00G5 (*When will we purchase exercise Doppler studies for peripheral artery disease (PAD)?),* 4.00G6 *(Are there any other studies that are helpful in evaluating PAD?),* 4.00G7 *(How do we evaluate PAD under 4.12?),* and 4.12 (*Peripheral artery disease*)).

• *Congenital heart disease:* In the introductory text, we added ''pulmonary atresia'' as an example of congenital valvular defects in paragraph 104.00D1c (*Valvular defects or obstructions to ventricular outflow*). We also added ''pulmonary atresia with intact ventricular septum'' to the list of single ventricle anomalies in paragraphs 4.00H3 and 104.00D4 (*What is single ventricle?*).

• *Cardiomyopathy:* We added functional criteria to listing 4.08A.

• *Other Changes:* We revised paragraph 4.00C15b (*Cardiac catheterization reports*) to incorporate language that further describes the type of information typically provided in cardiac catheterization reports. We also added language that discusses the evaluation of genetic connective tissue disorders to paragraphs 4.00I8 and 104.00F10 (*What is Marfan syndrome and how do we evaluate it?*).

• *References to the cardiovascular disorders listings in other body systems:* As we finalize revisions to the cardiovascular disorders listings, we are revising references in the introductory text for other body systems to mirror changes made in the cardiovascular listings. Specifically, we made a revision to the term ''peripheral arterial disease'' in paragraph 1.00B5 and to the term ''Cardiovascular system'' in paragraph 114.00J2m.

Public Comments on the NPRM

In the NPRM, we provided the public with a 60-day comment period, which was scheduled to end on August 29, 2022. During the comment period we received multiple comments requesting that SSA extend the comment period to give commenters more time to evaluate and respond to the proposed rule. In response to those requests, we extended the comment period until September 30, 2022.[12] We received 14 public comments.[13] Those comments came from advocacy groups, legal services organizations, medical organizations, and individual commenters.

We carefully considered all of the public comments related to this rulemaking. Below, we respond to all of the significant issues raised by the commenters that were within the scope of this rulemaking. We have not summarized or responded to comments that were outside the scope of the proposed rule. Some commenters noted provisions with which they agreed. We did not summarize or respond to those comments.

Cardiovascular Disorders

Chronic Heart Failure

Comment: One commenter noted that throughout the child and adult listings, ''chronic heart failure'' is abbreviated as ''CHF.'' They noted that CHF is commonly used in the medical community to refer to congestive heart failure. The commenter recommended using the abbreviation ''chronic HF'' instead.

Response: We adopted this comment.

Comment: Two commenters recommended that we revise the terminology in paragraph 4.00D1 (SSA Note: In the NPRM we identified this section as *What is chronic heart failure (CHF)?*) and listing 4.02A (Medically documented presence of 4.02A1 or A2) to align with current terminology reflecting the two types of chronic HF: heart failure with reduced EF (HFrEF) (EF<40%) and heart failure with preserved EF (HFpEF) (EF>50%). One of these commenters suggested including heart failure with mid-range EF (HFmrEF) (EF 40–49%). Another commenter provided proposed text to describe chronic HF in 4.00D1. The same commenter recommended changing the description of heart failure in paragraph 104.00C1a (*Heart failure*) to match their suggested description in 4.00D1, and recommended replacing the term diastolic heart failure and systolic heart failure in 4.02A with the preferred terminology.

Response: We partially adopted these comments. We revised the terminology in final paragraphs 4.00D1a(i) *(Heart failure with reduced EF (HFrEF))* and 4.00D1a(ii) *(Heart failure with preserved EF (HFpEF))* to add HFrEF and HFpEF

[12] 87 FR 51933 (2022).

[13] Three of the comment letters were requests from the public for an extension of the comment period.

to describe the two types of HF.[14] We also replaced systolic failure with HFrEF in revised listing 4.02A1 (Heart failure with reduced ejection fraction) and diastolic failure with HFpEF in revised listing 4.02A2 (Heart failure with preserved ejection fraction). We did not include HFmrEF in our revisions; although the terminology and identification as a distinct category of HF has been accepted by the clinical community, the available research does not provide a clear picture of the clinical significance of HFmrEF and its impact on a person's functioning. Further, there is a lack of consensus as to whether the addition of HFmrEF can be uniformly applied in practice and clinical trials.[15] Therefore, we did not include HFmrEF in our revisions.

Although the commenter suggested matching the description of chronic HF in paragraph 104.00C1 to their proposed description of chronic HF in 4.00D1, they also provided proposed text that did not align with their suggested revisions for 4.00D1. We adopted portions of their proposed text rather than fully matching the proposed text with the description of chronic HF in 4.00D1 to account for the discrepancy.

Comment: One commenter recommended that we add right ventricular failure as an important refractory cause of heart failure to the definition of chronic HF in paragraph 4.00D1 (SSA Note: In the NPRM we identified this section as *What is chronic heart failure (CHF)*). The same commenter recommended that we add infection and coronary artery insufficiency as possible causes of heart failure to paragraph 104.00C1b (Chronic HF is considered in these listings).

Response: We did not adopt these comments. The introductory text is intended to provide information generally about chronic HF for the public. It is not intended to provide an exhaustive discussion of the underlying causes of heart failure. Specifically, in paragraphs 4.00D1b and 104.00C1b (Chronic HF is considered in these listings), we explain that chronic HF is considered in these listings as a single category regardless of the underlying cause(s).

Comment: A commenter recommended that we expand the list of appropriate medically acceptable imaging in paragraph 4.00D2 (*What evidence of chronic HF do we need?*) to include cardiac magnetic resonance imaging (MRI).

Response: We adopted this comment. A cardiac MRI is a noninvasive test that provides important information in evaluating chronic HF and meets the definition of appropriate medical imaging in paragraph 4.00A3d.[16]

Comment: We received comments recommending that we revise paragraph 4.00D2a(ii) (SSA Note: In the NPRM we identified an EF of 30 percent or less during a period of stability) and listing 4.02A1 (Heart failure with reduced ejection fraction) to require an EF of less than or equal to 40 percent, rather than our current requirement of an EF of 30 percent or less.

Response: We did not adopt these comments. The American Society of Echocardiography (ASE) and the European Association of Cardiovascular Imaging (EACVI) considers an EF in the range of 30 percent to 40 percent as moderately abnormal and less than 30 percent as severely abnormal.[17] While ASE and EACVI do not describe how ''severe'' or ''moderate'' abnormalities relate to a patient's ability to engage in substantial gainful activity, the 2022 ACC/AHA guidelines referenced by commenters only distinguishes between ''mildly reduced'' EF (41–49 percent) and ''reduced'' EF as 40 percent or below. There is a difference between being diagnosed with a heart impairment and having an impairment severe enough to meet a listing. The 40 percent suggested by the commenters is a threshold for a diagnosis of heart failure, but is not indicative of the severity required to meet the listings. For example, for some individuals with an EF of 40 percent, the ACC/AHA guidelines recommend simply treating the impairment with beta blockers, which is not indicative of a level of medical severity necessary to meet a medical listing. We further note that although the ACC/AHA guidelines do not include a formal conclusion or distinction differentiating the severity of EF values below 40 percent, the guidelines do include multiple references to an EF less than 30 percent as a sign of severity, which is consistent with our criteria.[18] An EF between 30 percent and 40 percent does not indicate an impairment that would prevent a person from performing any gainful activity.

Comment: One commenter suggested defining mechanical circulatory support device (MCSD), the type of MCSD utilized, and length of time required to establish severity for listing criterion. The commenter questioned the use of ''Impella devices.''

Response: We partially adopted this comment. We added a discussion of devices using the Impella technology to paragraphs 4.00D4e and 104.00C4 (*How do we evaluate chronic HF treated with a mechanical circulatory support device?*) to clarify that such devices do not satisfy the requirements of listing 4.02D1 (An implanted mechanical circulatory support device except extracorporeal membrane oxygenation (ECMO)) because they are intended for short-term usage only. We did not revise the text to specify a time period for an implanted MCSD to meet the criterion in this listing. The clinical conditions for which an implanted MCSD would be used reflect the underlying severity of chronic HF and the potential complications. Furthermore, the use of an implanted device carries additional risks, such as infections, blood clots, and renal failure. As a result of this comment, we realized that we inadvertently did not include

[14] *Types of heart failure.* (n.d.). American Heart Association. (*https://www.heart.org/en/health-topics/heart-failure/what-is-heart-failure/types-of-heart-failure#:~:text=This%20is%20also%20known%20as%20heart%20failure%20with%20preserved%20ejection,41%25%20and%2049%25%20EF*).

[15] Heidenreich, P.A., Bozkurt, B., Aguilar, D., Allen, L.A., Byun, J.J., Colvin, M.M., Deswal, A., Drazner, M.H., Dunlay, S.M., Evers, L.R., Fang, J.C., Fedson, S.E., Fonarow, G.C., Hayek, S.S., Hernandez, A.F., Khazanie, P., Kittleson, M.M., Lee, C.S., Link, M.S., Milano, C.A., . . . ACC/AHA Joint Committee Members (2022). 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation, 145*(18), e895–e1032. (*https://doi.org/10.1161/CIR.0000000000001063*).

[16] Heidenreich, P.A., Bozkurt, B., Aguilar, D., Allen, L.A., Byun, J.J., Colvin, M.M., Deswal, A., Drazner, M.H., Dunlay, S.M., Evers, L.R., Fang, J.C., Fedson, S.E., Fonarow, G.C., Hayek, S.S., Hernandez, A.F., Khazanie, P., Kittleson, M.M., Lee, C.S., Link, M.S., Milano, C.A., . . . ACC/AHA Joint Committee Members (2022). 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation, 145*(18), e895–e1032. (*https://doi.org/10.1161/CIR.0000000000001063*).

[17] See Supplemental Table 3 in. Lang, R.M., Badano, L.P., Mor-Avi, V., Afilalo, J., Armstrong, A., Ernande, L., Flachskampf, F.A., Foster, E., Goldstein, S.A., Kuznetsova, T., Lancellotti, P., Muraru, D., Picard, M.H., Rietzschel, E.R., Rudski, L., Spencer, K.T., Tsang, W., & Voigt, J.–U. (2015). Recommendations for Cardiac Chamber Quantification by Echocardiography in Adults: An Update from the American Society of Echocardiography and the European Association of Cardiovascular Imaging. *Journal of the American Society of Echocardiography, 28*(1), 1–39.e14, p. 39.e8. (*https://doi.org/10.1016/j.echo.2014.10.003).*

[18] Heidenreich, P.A., Bozkurt, B., Aguilar, D., Allen, L.A., Byun, J.J., Colvin, M.M., Deswal, A., Drazner, M.H., Dunlay, S.M., Evers, L.R., Fang, J.C., Fedson, S.E., Fonarow, G.C., Hayek, S.S., Hernandez, A.F., Khazanie, P., Kittleson, M.M., Lee, C.S., Link, M.S., Milano, C.A., . . . ACC/AHA Joint Committee Members (2022). 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation, 145*(18), e895–e1032. (*https://doi.org/10.1161/CIR.0000000000001063*). See specifically Table 16 (e955) and discussion of ''severely depressed'' EF (e978).

''implanted'' in proposed listings 4.02D1 or 104.02D (Mechanical circulatory support device), as we intended, and we added this term to revised 4.02D1 and 104.02D (An implanted mechanical circulatory support device except extracorporeal membrane oxygenation (ECMO)). We note that adding ''implanted'' to listings 4.02D1 and 104.02D provides additional clarity but does not change the substance of those listings because the acceptable MCSDs described by the listings are always implanted.

Comment: Two commenters suggested that we use a left ventricular end-diastolic dimension (LVEDD) indexed to body size. One of the commenters suggested that we provide separate LVEDD cutoffs for men and women, rather than specifying an absolute cutoff for LVEDD in listing 4.02A1 (Heart failure with reduced ejection fraction).

Response: We partially adopted these comments. We did not include an LVEDD dimension indexed to body size, but we did provide separate cutoffs for men and women. While indexing LVEDD to body size can be useful in clinical practice, uncorrected measurements are generally available in the medical record and sufficient for determining the most severe forms of heart failure.[19] Requiring an indexed LVEDD is not practical for disability evaluation purposes because indexed LVEDD measurements are unavailable in many cases. LVEDD is not a stand-alone criterion for establishing disability; it must be considered in combination with the impact of chronic HF on the functional limitations we describe in listing 4.02B (Resulting in 4.02B1, B2, or B3). After consultation with agency medical experts and reviewing pertinent research, we did not include indexed LVEDD measurements in the listings. In cases where an indexed LVEDD measurement is available in the medical record, adjudicators will evaluate the indexed LVEDD measurement along with all other evidence in the record when evaluating disability.

We agree with the commenter that different LVEDD cutoffs for men and women are appropriate and we have changed the LVEDD threshold to greater than 6.8 cm for men and 6.1 cm for women during a period of stability. Clinical guidelines from the ASE and the EACVI provide these separate cutoffs for identifying severe dilation for males and females, and these cutoffs are easy to apply and are used by practitioners and researchers.[20] Additionally, studies have shown that they correlate with severity.[21] We also made a minor corresponding revision to the language describing a ''period of stability'' in paragraph 4.02A1b to replace the term ''acute heart failure'' with the term ''exacerbation of heart failure,'' which was our original intent, aligns with the language used in the description of a ''period of stability'' in paragraphs 4.02A1, 4.02A2, and 4.02C, and ensures consistency of this description throughout listing 4.02.

Comment: One commenter suggested that we retain the requirement for an LVEDD of greater than 6 cm in listing 4.02A1 (Heart failure with reduced ejection fraction) rather than changing it to a value of equal to or greater than 7 cm. The commenter noted that only patients with the most severe forms of heart failure would be captured under the 7 cm criterion and that 6 cm is likely an appropriate threshold to delineate those patients who will benefit from some advanced cardiovascular therapies. The same commenter recommended that we include an LV volume index in addition to or instead of LVEDD.

Response: We did not adopt these comments, but we did revise the LVEDD criterion to better reflect the cutoffs for males and females used in clinical practice, as discussed in our response to the previous comment. An LVEDD of 6 cm reflects a mildly to moderately abnormal enlargement of the heart.[22] While 6 cm may be an appropriate threshold to delineate patients who will benefit from some advanced cardiovascular therapies, this is not the purpose of our Listing of Impairments. Rather, our listing for chronic HF is meant to capture more severe forms of the condition that represent an inability to perform any gainful activity. An LVEDD threshold of greater than 6.8 cm for males and greater than 6.1 cm for females more clearly establishes a severely enlarged heart with signs and symptoms associated with the functional limitations we require in listing 4.02B (Resulting in 4.02B1, B2, or B3).[23]

In clinical practice, left ventricular volume index scores are most helpful in evaluating ventricular function in the early stages of heart failure with normal or mildly reduced EF. At present, reliable left ventricle volume index scores are time-consuming and not always feasible. Consequently, left ventricle volume index scores are seldomly included in echocardiogram reports, whereas LVEDD are routinely included in echocardiogram reports.[24]

[19] See Hayward, C., Perez, C., Patel, H., Mouyis, K., Patel, K., Akhtar, M., Harding, D., Adasuriya, G., Gillott, H., Harvey, G., Sotto, I., & Bhattacharyya, S. (2019). The impact of misclassifying left ventricular size if indexing to body surface area is not performed. *Imaging,* A11.1–A11. (*https://doi.org/10.1136/heartjnl-2019-bcs.11*). In this study, the uncorrected LVEDD and the indexed LVEDD led to the same clinical classification 89.2 percent of the time. (*See also* Daimon, M., Watanabe, H., Nakanishi, K., Abe, Y., Hirata, K., Ishii, K., Iwakura, K., Izumi, C., Abe, H., Negishi, K., Ito, H., Tanabe, K., Tanaka, N., & Nakatani, S. (2024). Is left ventricular diameter indexed for body surface area appropriate for assessing left ventricular dilation? *Journal of cardiology, 84*(1), 67–69. (*https://doi.org/10.1016/j.jjcc.2024.03.004*)). This study showed that indexing left ventricle (LV) diameters for body surface area (BSA) might overestimate LV dilation, particularly in subjects with a small body size.

[20] Lang, R.M., Badano, L.P., Mor-Avi, V., Afilalo, J., Armstrong, A., Ernande, L., Flachskampf, F.A., Foster, E., Goldstein, S.A., Kuznetsova, T., Lancellotti, P., Muraru, D., Picard, M.H., Rietzschel, E.R., Rudski, L., Spencer, K.T., Tsang, W., & Voigt, J.–U. (2015). Recommendations for Cardiac Chamber Quantification by Echocardiography in Adults: An Update from the American Society of Echocardiography and the European Association of Cardiovascular Imaging. *Journal of the American Society of Echocardiography, 28*(1), 1–39.e14. (*https://doi.org/10.1016/j.echo.2014.10.003*); See page 18 in *The American Society of Echocardiography Recommendations for Cardiac Chamber Quantification In Adults: A Quick Reference Guide From The ASE Workflow And Lab Management Task Force.* (n.d.). (*https://www.asecho.org/wp-content/uploads/2018/08/WFTF-Chamber-Quantification-Summary-Doc-Final-July-18.pdf*).

[21] Narayanan, K., Reinier, K., Teodorescu, C., Uy-Evanado, A., Aleong, R., Chugh, H., Nichols, G.A., Gunson, K., London, B., Jui, J., & Chugh, S.S. (2014). Left Ventricular Diameter and Risk Stratification for Sudden Cardiac Death. *Journal of the American Heart Association, 3*(5), e001193. (*https://doi.org/10.1161/JAHA.114.001193*).

[22] Lang, R.M., Badano, L.P., Mor-Avi, V., Afilalo, J., Armstrong, A., Ernande, L., Flachskampf, F.A., Foster, E., Goldstein, S.A., Kuznetsova, T., Lancellotti, P., Muraru, D., Picard, M.H., Rietzschel, E.R., Rudski, L., Spencer, K.T., Tsang, W., & Voigt, J.–U. (2015). Recommendations for Cardiac Chamber Quantification by Echocardiography in Adults: An Update from the American Society of Echocardiography and the European Association of Cardiovascular Imaging. *Journal of the American Society of Echocardiography, 28*(1), 1–39.e14. (*https://doi.org/10.1016/j.echo.2014.10.003*).

[23] Institute of Medicine (IOM). (2010). *Cardiovascular Disability: Updating the Social Security Listings* (pg. 89). Washington, DC: The National Academies Press; Narayanan, K., Reinier, K., Teodorescu, C., Uy-Evanado, A., Aleong, R., Chugh, H., Nichols, G.A., Gunson, K., London, B., Jui, J., & Chugh, S.S. (2014). Left Ventricular Diameter and Risk Stratification for Sudden Cardiac Death. *Journal of the American Heart Association, 3*(5), e001193. (*https://doi.org/10.1161/JAHA.114.001193*).

[24] Ito, K., Li, S., Homma, S., Thompson, J.L.P., Buchsbaum, R., Matsumoto, K., Anker, S.D., Qian, M., Di Tullio, M.R., & WARCEF Investigators (2021). Left ventricular dimensions and cardiovascular outcomes in systolic heart failure: the WARCEF trial. *ESC heart failure, 8*(6), 4997–5009. *https://doi.org/10.1002/ehf2.13560.* (*See also* Lang, R.M., Badano, L.P., Mor-Avi, V., Afilalo, J., Armstrong, A., Ernande, L., Flachskampf, F.A., Foster, E., Goldstein, S.A., Kuznetsova, T., Lancellotti, P., Muraru, D., Picard, M.H., Rietzschel, E.R., Rudski, L., Spencer, K.T., Tsang, W., & Voigt, J.–U. (2015). Recommendations for Cardiac Chamber Quantification by Echocardiography in Adults: An Update from the American Society of Echocardiography and the European Association of Cardiovascular Imaging. *Journal of the American*

After consulting with agency medical experts and reviewing pertinent research, we did not include left ventricular volume index scores in the listings.

Comment: Several commenters suggested that we revise the proposed requirements in listing 4.02A2 (Heart failure with preserved ejection fraction), including revising the required left atrial volume index (LAVI) score and adding alternative criteria. One commenter suggested that an LAVI of greater than 34 ml/m^2 should be the required cutoff, while another commenter suggested the cutoff should be an LAVI of 34 ml/m^2. Another commenter suggested that the cutoff should be greater than or equal to 30 ml/m^2. One of the commenters also suggested that we add diastolic function requirements as an alternative, while another specifically suggested that we include a tricuspid regurgitant jet velocity greater than 2.8 m/s and abnormal tissue dopplers over the mitral valve as a requirement. One of the commenters also suggested that we include a left ventricular EF (LVEF) of greater than or equal to 50 percent, a tissue velocity septal E/e ratio on echocardiography greater than 9, or a lateral E/e ratio greater than 13.

Response: We did not adopt these comments. An LAVI of 34 ml/m^2, as suggested by some commenters, falls within the normal range and serves as a cutoff measurement to identify a heart abnormality. Generally, higher LAVI measurements indicate greater severity of the condition. While an LAVI value between 34 and 40 ml/m^2 may support a diagnosis of heart failure, as indicated in one public commenter's reference to a 2016 article from the Journal of American Society of Echocardiography, such scores are consistent with only mild enlargement.[25] By contrast, an LAVI value of 40 ml/m^2 or greater identifies people with more severe forms of heart failure and more clearly establishes an inability to perform any gainful activity than the other suggested thresholds.[26]

We did not include additional criteria to evaluate diastolic function because we already provide criteria, including the LAVI, to evaluate diastolic function. We did not add the suggested LVEF criterion because the suggested EF is implicit in the HFpEF category (*i.e.,* a normal EF). Furthermore, we did not add criteria to include tricuspid regurgitant jet velocity, abnormal tissue dopplers, or tissue velocity septal E/e ratios. These measurements may provide value in the overall evaluation of one's cardiovascular condition; however, they are not consistently contained in echocardiogram reports. The measurements we include in listing 4.02A (Medically documented presence of 4.02A1 or A2) are meant to capture the most severe conditions that prevent a person from being able to engage in any gainful activity. The criteria we include in 4.02A2 are not a comprehensive list of every measurement used to diagnose and assess heart failure. Alternative measures that are not included in the listing criteria may be evaluated under our rules for medical equivalence.[27]

Comment: One commenter noted that the proposed criterion in listing 4.02A2 (Heart failure with preserved ejection fraction) may not be standard criterion, and questioned whether the proposed criterion captures diastolic failure of a non-hypertrophic etiology. They noted it was unclear which criteria were needed to establish a diagnosis.

Response: We disagree with the commenter's concern that the criteria are not standard. The measurements in 4.02A2 are commonly included in echocardiogram reports and used to identify left atrial enlargement, which leads to chronic HF. We use the criteria in 4.02A2 to identify people with diastolic failure that may prevent a person from engaging in any gainful activity. Satisfying the criteria in 4.02A2 is insufficient to find a person disabled at the listing level; the person's limitations caused by the heart failure must also satisfy the criteria in listing 4.02B (Resulting in 4.02B1, B2, or B3). There are many non-hypertrophic causes of diastolic dysfunction, including, but not limited to, coronary artery disease, arrythmias (such as atrial fibrillation), and non-hypertrophic cardiomyopathy. These and other non-hypertrophic causes of diastolic dysfunction may be evaluated under other listings, such as 4.04 (*Ischemic heart disease*), 4.05 (*Recurrent arrythmias*), and 4.08 (*Cardiomyopathy*).

Comment: Several commenters suggested that we add elevated b-type natriuretic peptide (BNP) levels as another way to assess chronic HF at listing 4.02A2 (Heart failure with preserved ejection fraction).

Response: We did not adopt this comment. BNP (and Immunoreactive amino terminal pro-brain natriuretic peptide (NT-proBNP)) measurements alone are insufficient for determining listing-level severity. These levels vary in relation to heart failure severity and may be influenced by other factors such as age, sex, body mass index, and other medical conditions. Further, these measurements are most often obtained during periods of instability, while the listings contemplate functional ability during periods of stability. We discuss how we use BNP and NT-proBNP in paragraph 4.00D1b (Chronic HF is considered in these listings).

Comment: One commenter suggested that we remove the requirement of an EF of 20 percent or less from listing 4.02C (Heart failure with left ventricular ejection fraction of 20 percent or less), noting the cutoff is too low and arbitrary.

Response: We did not adopt this comment. The IOM recommended a criterion for chronic HF with an EF on a sustained basis of 20 percent or less.[28] An EF of only 20 percent means the heart's pumping action is less than a third of normal, and therefore critically affects a person's ability to perform gainful activity.[29] Most people with heart disease this advanced have a greater risk of mortality and major functional limitations, such as shortness of breath or fatigue, even during mild exertion. In addition to consulting with the IOM and reviewing the medical research supporting this criterion, we reviewed disability claims involving chronic HF to ensure that the revised

Society of Echocardiography, 28(1), 1–39.e14. (*https://doi.org/10.1016/j.echo.2014.10.003*)). These guidelines indicate that there are limitations with each method of measuring and calculating LV end diastolic volume, and that indexing to BSA, and 3D measurement and reporting of LV volumes are recommended when feasible depending on image quality.

[25] See Table 3 in Nagueh SF, Smiseth OA, Appleton CP, et al. (2016). Recommendations for the Evaluation of Left Ventricular Diastolic Function by Echocardiography: An Update from the American Society of Echocardiography and the European Association of Cardiovascular Imaging *Journal of the American Society of Echocardiography, 29*(4), 277–314, p. 288. (*https://doi.org/10.1016/j.echo.2016.01.011*).

[26] See page 18 in *The American Society of Echocardiography Recommendations for Cardiac Chamber Quantification In Adults: A Quick Reference Guide From The ASE Workflow And Lab Management Task Force.* (n.d.). (*https://www.asecho.org/wp-content/uploads/2018/08/WFTF-Chamber-Quantification-Summary-Doc-Final-July-18.pdf*).

[27] 20 CFR 404.1526 and 416.926.

[28] IOM. (2010), 84, 89.

[29] *Content—Health Encyclopedia—University of Rochester Medical Center.* (n.d.). (*https://www.urmc.rochester.edu/encyclopedia/content?contenttypeid=56&contentid=DM14*); IOM. (2010), 84, 89; Runge, M.S., Patterson, C., Stouffer, G.A., & Netter, F.H. (2010). Netter's Cardiology (2nd ed.). Philadelphia, PA: Saunders Elsevier; Fukunaga, N., Ribeiro, R. V.P., Lafreniere-Roula, M., Manlhiot, C., Badiwala, M.V., & Rao, V. (2020). Left Ventricular Size and Outcomes in Patients With Left Ventricular Ejection Fraction Less Than 20%. *The Annals of Thoracic Surgery, 110*(3), 863–869. (*https://doi.org/10.1016/j.athoracsur.2020.01.005*).

criteria reflect listing-level severity based on medical practice. This criterion is an administrative expedient to quickly identify people whose chronic HF is at a listing-level of severity.

Ischemic Heart Disease

Comment: One commenter suggested several revisions to more fully capture the causes of ischemic heart disease in paragraphs 4.00E1 (*What is ischemic heart disease (IHD)?)* and 4.00E2 (*What causes chest discomfort of myocardial origin?*). The same commenter also suggested revisions to paragraph 4.00E6 (*What is variant angina?*) to include non-obstructive coronary artery disease in our discussion of variant angina.

Response: We partially adopted the commenter's suggestion to revise 4.00E1, 4.00E2, and 4.00E6. Although we did not propose changes to these sections in the NPRM, we agree that it is appropriate to include language addressing non-obstructive coronary artery disease to more fully explain potential sources of chest discomfort. These changes do not affect the substantive criteria of the listings, as they describe other possible origins of chest discomfort as background information but do not contain additional requirements to meet any listing.

Comment: One commenter stated that the term ''fractional flow reserve'' (FFR) at listing 4.04D1 (Fractional flow reserve) was too restrictive and would exclude other similarly effective measures of coronary physiology that are commonly used (including other non-hyperemic pressure ratios such as diastolic hyperemia-free ratio (DFR), resting full-cycle ratio (RFR), diastolic pressure ratio (DPR), and/or instantaneous wave-free ratio (iFR)). The commenter suggested we use the term ''coronary artery physiology'' instead. Another commenter suggested adding iFR as another method to measure stenosis severity in section 4.00E (*How do we evaluate ischemic heart disease?*) and 4.04D1.

Response: We partially adopted these comments. We added iFR as a second method to measure the severity of stenosis in 4.00E and 4.04D2 because iFR and FFR are two of the most commonly used physiological methods of assessment and have been thoroughly validated for clinical use.[30] However, we did not add the term ''coronary artery physiology'' to 4.04D1 because it does not align with specific measures of stenosis severity that are required in the listing.

Comment: One commenter suggested we replace the term ''irregular heartbeat'' in listing 4.04C (Documentation of three separate ischemic episodes) with ''arrythmia thought to be due to ischemic cause'' because the term is nonspecific.

Response: We did not adopt this suggestion. We do not use the term ''irregular heartbeat'' in 4.04C. We used that term in the Supplementary Information section of the NPRM and in paragraph 4.00I2 (*What is cardiomyopathy and how do we evaluate it?*). We did not use the language suggested by the commenter for any listing criteria because the listing criteria must identify specific evidence required to meet the listing, and the phrase ''thought to be due to ischemic cause'' is not specific.

Comment: Listing 4.04E (Exacerbations or complications of ischemic heart disease) includes both planned and unplanned hospital admissions for ischemic heart disease. One commenter questioned whether this included planned staged interventions of coronary artery disease.

Response: Planned staged interventions are not exacerbations nor would they be separate events showing symptoms requiring hospitalization with improvement in the meantime to show it is an exacerbation. The staged surgical treatment plan, which may be in response to a complication or exacerbation, would be a single event and would not, by itself, satisfy the criterion in 4.04E.

Congenital Heart Disease

Comment: One commenter expressed concerns that section 4.00H (*How do we evaluate congenital heart disease?*) does not adequately cover all forms of congenital heart disease. Specifically, their concern was that we do not include congenital heart diseases that can progress to heart failure, including right-sided heart failure. The commenter recommended that we allow exceptions for congenital heart disease that are not characterized in the listings.

Response: We did not adopt these comments. Section 4.00H1 (*What is congenital heart disease?*) states that congenital heart disease is any abnormality of the heart or the major blood vessels that is present at birth. When congenital heart disease results in chronic HF, we evaluate it under listing 4.02 (*Chronic heart failure*), regardless of the underlying cause. As we have explained elsewhere, we do not intend to provide exhaustive discussions of congenital heart conditions that may be disabling or provide listing criteria for each condition. Notably, our rules for medical equivalence provide flexibility in determining whether an impairment is disabling by allowing us to consider whether the person's impairment is at least equal in severity and duration to the criteria of any listed impairment.[31] Moreover, if we are unable to find a person's cardiovascular disorder disabling based on meeting or equaling a listed impairment, we will continue the sequential evaluation and may find the person disabled at the final step of the process.[32]

Comment: One commenter proposed that we change the heading at paragraph 4.00H3 (*What is single ventricle?*) to read ''What is unrepaired congenital heart disease'' to ''include definitions of single ventricle.'' Another commenter urged us to include ''unrepaired cyanotic congenital heart disease'' in listing 4.06D (Single ventricle (with or without Fontan procedures)), as they broadly interpret Fontan circulation as ''unrepaired.''

Response: We did not adopt these comments. Paragraph 4.00H3 states that the term ''single ventricle'' (also known as single ventricle physiology or functional single ventricle) describes a diverse group of congenital cardiac anomalies sharing the common feature that only one of the two heart ventricles is adequately developed.[33] This applies whether the single ventricle has been repaired or not. Furthermore, we note in 4.06D that the criterion applies whether or not Fontan procedures have been performed.

Comment: A commenter suggested that while there is a theoretical value in linking hypoxia to hematocrit in listing 4.06A1(Hematocrit of 55 percent or greater), there may be more variables that affect hematocrit. The commenter provided specific variables they indicated affect hematocrit in addition

[30] Lawton, J.S., Tamis-Holland, J., Bangalore, S., Bates, E., Beckie, T., Bischoff, J., Bittl, J., Cohen, M., DiMaio, J.M., Don, C., Fremes, S., Gaudine, M., Goldberger, Z., Grant, M., Jaswal, J., Kurlansky, P., Mehran, R., Metkus, Jr., T., Nnacheta, L., Rao, S., C.A, . . . 2021 ACC/AHA/SCAI Guideline for Coronary Artery Revascularization: A Report of the American College of Cariology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation, 145* (3), e18–e114. (*https://doi.org/10.1161/CIR.0000000000001038*).

[31] 20 CFR 404.1520 and 416.920.

[32] 20 CFR 404.1520(a)(4) and (g) and 416.920(a)(4) and (g).

[33] Of note, the AHA guidelines use the term ''single ventricle.'' Stout, K.K., Daniels, C.J., Aboulhosn, J.A., Bozkurt, B., Broberg, C.S., Colman, J.M., . . . Van Hare, G.F. (2019). 2018 AHA/ACC Guideline for the Management of Adults With Congenital Heart Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *Journal of the American College of Cardiology, 73* (12), e81–e192. (*https://doi.org/10.1016/j.jacc.2018.08.1029*).

to hypoxia. They noted that unless the criterion accounts for all such variables, there may be no value in linking hypoxia to hematocrit. They included specific variables that are not discussed in proposed 4.06A1.

Response: We did not make changes based on this comment. Listing 4.06A1 discusses chronic hypoxemia, not hypoxia. We agree there may be variables other than hypoxemia that affect hematocrit, including the examples the commenter provided. Although the comment specifically referenced 4.06A1, which applies to adults, some of the commenter's examples relate to conditions in children. The criterion in 4.06A1 is only one of several alternatives for evaluating hypoxemia in congenital heart disease. We also use arterial blood gas measurements and pulse oximetry for evaluating hypoxemia when considering congenital heart disease. Other causes of elevated hematocrit levels would not be evaluated under this listing.

Comment: We received several comments related to use of pulse oximetry in the adult and childhood listings related to hypoxemia. One commenter noted that the 87 percent oxygen saturation rate under listings 4.06A and 104.06A (Chronic hypoxemia) seemed low and added that people can be limited when resting saturation is 90 percent. Another commenter suggested the saturation cut-off should be set at less than or equal to 89 percent.

Response: We did not adopt these comments. We use a threshold of 89 percent or below when oxygen saturation is obtained through arterial blood gas (ABG) measurements. Pulse oximeter measurements may be between 2 and 4 percent higher or lower than ABG measurements.[34] The 87 percent measurement in listings 4.06A3 (S_pO_2) and 104.06A3 (S_pO_2) accounts for this known discrepancy between pulse oximeter and ABG measurements. In addition to consulting with the IOM and reviewing the medical research supporting this criterion, we reviewed disability claims involving congenital heart disease to ensure that the revised criteria reflect listing-level severity based on medical practice.

Comment: One commenter noted that the proposal in listing 4.06A (Chronic hypoxemia) to require three separate S_pO_2 measurements 30 days apart within a 12-month period to show chronic hypoxemia may be onerous, unnecessary, and would delay appropriate diagnosis.

Response: We do not agree that the requirements in 4.06A would delay appropriate diagnosis. The requirements in our listings are intended to evaluate the severity of a person's congenital heart disease, not to establish a diagnosis. The criteria for three separate measurements 30 days apart within a 12-month period demonstrates chronicity of a person's hypoxemia. Although we indicate that the evaluations must occur within a 12-month period, people may have the requisite findings in a shorter time period. Further, gathering three separate S_pO_2 measurements is one alternative for documenting chronic hypoxemia in our listings.

Comment: One commenter noted that proposed listing 4.06 (*Congenital heart disease*) includes no specific mention of target threshold stats after the 6-minute walk test (6MWT) and encouraged more specificity towards a cardiac versus chronic pulmonary issue. The same commenter suggested we revise listing 4.06A3 (S_pO_2) to include people who are unable to perform the 6MWT.

Response: We did not adopt these comments. The criterion in listing 4.06A3 requires a target threshold amount of less than or equal to 87 percent of oxygen saturation of blood hemoglobin on three evaluations at least 30 days apart within a consecutive 12-month period, during a 6MWT or after a 6MWT. We do not need to differentiate between cardiac and pulmonary conditions in listing 4.06 because the listing requires a diagnosis of congenital heart disease documented by appropriate medically acceptable imaging or cardiac catheterization. The listing criteria cannot be met without first fulfilling one of these requirements, which relate directly to cardiac conditions, not pulmonary conditions.

If a person is unable to perform the 6MWT, we provide other criteria for evaluating congenital heart disease under listing 4.06A (Chronic hypoxemia), including hematocrit, arterial blood gas levels, and oxygen saturation levels measured by pulse oximetry at rest.

Comment: Under their comments identified as pertaining to listing criteria 4.06A (Chronic hypoxemia), one commenter indicated that criteria should also exist for those patients who are not cyanotic or hypoxic.

Response: We did not adopt this comment. In listing 4.06 (*Congenital heart disease*), we provide several alternatives for evaluating congenital heart disease that do not require hypoxemia or cyanosis, including hypertension (4.06C) and exacerbations or complications requiring three hospitalizations in a 12-month period (4.06E). While listing 4.06A requires a diagnosis of chronic hypoxemia, a person with congenital heart disease who is not cyanotic or hypoxic may still be found disabled under one of the other criteria in listing 4.06, other cardiovascular listings, our rules for functional equivalence in children,[35] or at step 5 of the adult sequential evaluation process.[36]

Comment: One commenter suggested that we include criterion pertaining to cardiac surgery and complications from cardiac intervention in listing 4.06A1 (Hematocrit of 55 percent or greater).

Response: We did not adopt this comment. The occurrence of a surgery does not necessarily mean a person will have limitations that prevent them from performing substantial gainful activity and meet the durational requirement. If the person has complications resulting from a surgery, we will evaluate them under listing 4.06E (Exacerbations or complications of congenital heart disease).

Comment: One commenter encouraged SSA to consider the duration of a hospitalization as a marker for complexity, not just the need for readmission under listing 4.06E (Exacerbations or complications of congenital heart disease). The same commenter similarly encouraged SSA to consider prolonged hospitalizations under listing 104.06E (Exacerbations or complications of congenital heart disease). They noted concerns that a person who is chronically hospitalized, which they defined as more than 90 days, would not qualify for disability under 104.06E but likely should.

Response: We did not make any changes based on these comments. We consider the duration of a person's hospitalization as a marker of complexity; both 4.06E and 104.06E require that each hospitalization last at least 48 hours, including hours in a hospital emergency department immediately before the hospitalization. A person with prolonged hospitalization as described by the commenter is likely to have medical findings that satisfy another criterion. The condition(s) leading to the prolonged hospitalization may also medically equal another cardiac listing under our equivalence

[34] Torp KD, Modi P, Pollard EJ, et al. Pulse Oximetry. 2023 Jul 30. In: StatPearls [internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. PMID: 29262014; *Yale Medicine. (2023, January 3). Pulse Oximetry.* (*https://www.yalemedicine.org/conditions/pulse-oximetry*). See also MedlinePlus. (2025, November 28). *Pulse Oximetry.* (*https://medlineplus.gov/lab-tests/pulse-oximetry/*).

[35] 20 CFR 416.926a.

[36] 20 CFR 404 1520(g) and 416.920(g).

policy.[37] Furthermore, satisfying the hospitalization criteria is only one way that we may find a person disabled under the adult and childhood listings for congenital heart disease.

Vascular Disease

Comment: We received comments suggesting that we use the term ''peripheral artery disease'' in place of ''peripheral arterial disease'' throughout section 4.00G (*How do we evaluate peripheral vascular disease?)* and listing 4.12 (SSA Note: In the NPRM we titled this section ''*Peripheral arterial disease*''), and replace the term ''ankle-brachial systolic blood pressure ratio'' with ''ankle-brachial index,'' which is the common term used for the test.

Response: We adopted these comments. We must use appropriate modern medical terminology to specify the medical criteria we use to evaluate cardiovascular disorders. Our research indicates that ''ankle-brachial index'' is the more commonly used term among professionals in the field of cardiology.[38] For consistency, we also replaced the term ''arterial'' with ''artery'' (in this final rule listing 4.12 is now titled ''Peripheral artery disease''). Additionally, we replaced ''toe/brachial systolic blood pressure ratio'' with ''toe-brachial index.''

Comment: A commenter recommended adding ''lymphatics'' to the list describing disorders of the veins or arteries at paragraph 4.00A1c (Disorders of the veins or arteries) and adding text that describes the symptoms of lymphedema to paragraph 4.00G1 (*What is peripheral vascular disease (PVD)?*). The same commenter recommended broadening paragraph 104.00F9 (*What is lymphedema and how do we evaluate it?*) to address ''lymphatic disorder'' or ''lymphatic perfusion disorder.''

Response: We partially adopted these comments. We added language to paragraph 4.00G4a and 104.00F9a (*Lymphedema*) that describes lymphedema. We did not revise paragraphs 4.00A1c or 4.00G1. The lymphatic system is not part of the cardiovascular system. Disorders of lymphatic circulation, such as lymphedema, are related to the immune system of the body. Although the signs and symptoms of lymphatic disease are similar to those associated with peripheral vascular disease, lymphatic disease is not part of the vascular system and is treated in a completely different manner. We believe it is more appropriate to provide general guidance about lymphedema in this section rather than focus on specific lymphatic disorders.

Comment: One commenter suggested editorial changes to paragraph 4.00G6 (*Are there any other studies that are helpful in evaluating PAD?*) to include brief discussion of Doppler waveforms and plethysmographic tracings. The commenter further suggested that we include ''stenting'' along with our discussion of peripheral grafting in paragraph 4.00G9 (*How do we use listing 4.12 if you have had a peripheral graft?*) to better reflect current medical technologies and treatment.

Response: We adopted the suggested editorial changes.

Comment: One commenter questioned whether venous dopplers are the only method to establish the diagnosis of chronic venous insufficiency.

Response: Venous dopplers are not the only method to establish a diagnosis of chronic venous insufficiency. In listing 4.11 (*Chronic venous insufficiency*), we allow for a person's chronic venous insufficiency to be documented by duplex ultrasound ''or other appropriate diagnostic technique.''

Comment: One commenter recommended clarifying section 4.00G (*How do we evaluate peripheral vascular disease?*) to include that peripheral artery disease can cause leg or foot pain.

Response: We adopted this comment. This change better encapsulates symptoms of claudication, which include pain not only in the calf, but also other parts of the lower extremities, such as the thighs or buttocks. This wording is consistent with the language in listing 4.12 (*Peripheral artery disease*), which discusses intermittent claudication or leg pain, as opposed to simply calf pain.

Comment: One commenter recommended that we add a third option to the criteria in listing 4.11 (*Chronic venous insufficiency*) to account for leg pain that interferes with mobility and provided a specific criterion for consideration.

Response: We did not adopt this comment. The commenter suggested a standalone criterion that does not include objective medical findings and does not quantify the limitation in mobility. Without specific quantified criteria for limitations in mobility, we would not be able to ensure the consistent application of the proposed criterion. To consider pain as a listing criterion, we would also require medical signs documenting the chronic venous insufficiency. Symptoms such as pain are subjective and difficult to quantify. We will not substitute symptoms such as pain for a medical sign (or diagnostic finding) in the listing criteria. However, if we are unable to find a person's cardiovascular disorder meets or medically equals a listed impairment, we will continue the sequential evaluation process and evaluate the person's symptoms, including pain, as set forth in our regulations.[39]

Comment: A commenter had questions pertaining to the duration requirement of listing 4.11B (Two or more episodes of ulceration), specifically whether this listing requires the presence of an ulceration that has not healed following at least 6 months of treatment, or whether it would also need to last for 12 continuous months.

Response: A temporal requirement such as the requirement described in 4.11B serves as a specific indicator of listing-level severity and does not establish that the medically determinable impairment (MDI) meets the duration requirement. To meet the duration requirement, the MDI(s) must have lasted, or be expected to last, for a continuous period of at least 12 months and the person's resulting inability to perform substantial gainful activity by reason of the MDI(s) must also have lasted, or be expected to last, for not less than 12 months without interruption or stopping.[40]

Comment: One commenter inquired as to why we did not include a listing addressing deep venous thromboses (DVT) or pulmonary emboli (PE).

Response: We understand the commenter's concerns related to DVTs and PEs. When DVTs or PEs are chronic, there are a number of factors we consider in determining the appropriate body system(s) for evaluation. When the chronic DVT or PE has a specific cause, we will evaluate the impairment under the listing related to that cause. For example, an underlying disorder of thrombosis would be evaluated under the hematological body system. In other cases, the chronic DVT or PE may result in another MDI. For example, the chronic DVTs may cause heart failure which would be evaluated under listing 4.02 (*Chronic heart failure*). In many cases, the chronic DVT may result in signs and symptoms similar to those for chronic venous insufficiency. In such cases, we would evaluate the impairment under the medical

[37] 20 CFR 404.1526 and 416.926.

[38] A review of the website for the Journal of the American Medical Association (JAMA), a peer-reviewed medical journal published 48 times a year by the American Medical Association, found that the term ''ankle-brachial index'' was used more than ''ankle-brachial systolic blood pressure ratio.''

[39] 20 CFR 404.1529 and 416.929.

[40] 20 CFR 404.1509 and 416.909. *See also* SSR 23–1p (2023). Available at: *https://www.ssa.gov/OP_Home/rulings/di/01/SSR2023-01-di-01.html.*

equivalence policy for listing 4.11 (*Chronic venous insufficiency*).

Other Cardiovascular Disorders

Comment: One commenter suggested broadening listing 4.07 (*Aortic valvular disease*) to include all valvular heart diseases, as all valve diseases can cause heart failure symptoms and disability.

Response: We did not adopt this comment. The introductory text at paragraph 4.00I3 (*How do we evaluate valvular heart disease?*) specifically notes we may evaluate other forms of valvular disease under listings 4.02 (*Chronic heart failure*), 4.04 (*Ischemic heart disease*), 4.05 (*Recurrent arrhythmias*), 4.06 (*Congenital heart disease*), or a listing in 11.00 (*Neurological Disorders*), depending on its effects on the person. The listings are not intended to be an exhaustive compilation of disabling conditions. Rather, they are used to identify cases at an early stage of the sequential evaluation process that meet a strict threshold for the statutory definition of disability. They describe impairments that we consider severe enough to prevent an adult from doing any gainful activity. If an impairment does not meet a listing, this does not mean that we will deny a claim. Rather, we will continue the sequential evaluation.

Comment: One commenter suggested that listing 4.08 (*Cardiomyopathy*) should include a functional component and should not be dependent on an exercise tolerance test (ETT). The commenter expressed concerns about logistical barriers related to practices of locally available physician's offices that may inhibit access to vendors who can properly perform ETTs for some offices (*e.g.,* Disability Determination Services), and suggested that the listing needs to take this into consideration. The same commenter expressed concerns about the ability to order echocardiograms and the resulting effect on the ability of those offices to evaluate claimants under listings 4.02C and 4.07. Another commenter suggested that functional details would help clarify guidelines regarding the cardiomyopathy listing.

Response: We adopted the suggestion to add functional criteria to listing 4.08. Although proposed listing 4.08 provided criteria for evaluating cardiomyopathy when ETTs present significant risks to the person, we agree that consideration of a person's functioning is appropriate. This criterion is consistent with the criterion we provide in listing 4.02B1b (Very serious limitation) for evaluating chronic HF when ETTs cannot be performed.

Regarding the commenter's concern about some offices having barriers to ordering ETTs or echocardiograms, the listing criteria are based on a person's medical condition and the types of findings typically present in disability claims. An echocardiogram is a common diagnostic test that is typically included in the medical evidence of record for claimants with these impairments. In addition, we allow other acceptable medical testing. Furthermore, listing 4.08 provides several alternative criteria that do not consider ETTs or echocardiograms for evaluating cardiomyopathy. SSA would follow the existing processes (which are outside of the scope of the listing criteria and this rulemaking) to address any logistical concerns and barriers to acquiring the necessary medical evidence, which may include, when appropriate, ordering an echocardiogram.

Comment: One commenter suggested we establish sex-specific criteria in evaluating hypertrophic cardiomyopathy in listing 4.08 (*Cardiomyopathy*) to account for differences in body size and heart dimensions.

Response: We did not adopt this comment. In the clinical guidelines for diagnosing and evaluating hypertrophic cardiomyopathy, the American College of Cardiology, the American Society of Echocardiology, and the American Heart Association do not provide standards for cardiac wall measurements based on sex or body size.[41] Therefore, we think it is inappropriate to incorporate such requirements in our listings.

Comment: One commenter suggested adding all etiologic factors to listing 4.10 (*Dissecting aneurysm of the aorta or major branches),* as it currently does not specifically mention other connective tissue disorders or penetrating aortic ulcers as other etiological factors.

Response: We did not adopt this comment. Under listing 4.10, we evaluate dissecting aneurysm of the aorta or major branches due to any cause. The listing text is not meant to be an exhaustive compilation of the causes of dissecting aneurysms; therefore, it is not necessary to list other etiological factors.

Comment: One commenter asked if listings 4.16 and 104.16 (*Cardiac allograft vasculopathy)* address issues such as vasculitis, including Kawasaki disease.

Response: Cardiac allograft vasculopathy is a condition that affects the blood vessels of the heart in people who have had a heart transplant. The condition does not include those who develop narrowing of the arteries due to other conditions. People who develop narrowing or blockage of arteries of the heart in the absence of a heart transplant are evaluated under listing 4.04 (*Ischemic heart disease).* Systemic vasculitis is an immune system disorder which we evaluate under listings 14.03 and 114.03 (*Systematic vasculitis*). We provide information about how we evaluate Kawasaki disease in paragraph 104.00F8 (*How do we evaluate Kawasaki disease?*).

Comment: One commenter suggested we include other genetic connective tissue disorders with serious cardiovascular effects, such as Loeys-Dietz Syndrome, in paragraphs 4.00I8 and 104.00F10 (*What is Marfan syndrome and how do we evaluate it?*).

Response: We adopted this comment to explain how genetic connective tissue disorders other than Marfan syndrome are evaluated under the listings. We added a new paragraph to sections 4.00I and 104.00F (*How do we evaluate other cardiovascular disorders?*) that discusses the evaluation of connective tissue disorders with cardiovascular effects, such as Loeys-Dietz syndrome and Ehlers-Danlos syndrome.

Miscellaneous

Comment: One commenter questioned why ''reduced oxygen concentration'' is listed as a mechanism for hypoxemia in paragraphs 4.00A1b(iv) and 104.00A1b(iv) (Hypoxemia), when hypoxemia is synonymous with reduced oxygen concentration.

Response: We agree that including the words ''reduced oxygen concentration'' is redundant. Therefore, we removed ''reduced oxygen concentration in the arterial blood'' as a cause of hypoxemia.

Comment: One commenter noted that in paragraph 4.00C8d (We will wait to purchase an exercise test), ''percutaneous transluminal coronary angioplasty'' and ''percutaneous coronary intervention'' are the same procedure, and we should consider using only one term.

Response: We did not adopt this comment. While these terms are both names for the same procedure, they are each used in medical records. We kept

[41] Heidenreich, P.A., Bozkurt, B., Aguilar, D., Allen, L.A., Byun, J.J., Colvin, M.M., Deswal, A., Drazner, M.H., Dunlay, S.M., Evers, L.R., Fang, J.C., Fedson, S.E., Fonarow, G.C., Hayek, S.S., Hernandez, A.F., Khazanie, P., Kittleson, M.M., Lee, C.S., Link, M.S., Milano, C.A., . . . ACC/AHA Joint Committee Members (2022). 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation, 145*(18), e895–e1032. (*https://doi.org/10.1161/CIR.0000000000001063*).

both terms in 4.00C8d to account for the use of both terms in medical records.

Comment: One commenter recommended that we revise our language in paragraph 4.00C15 (*How do we evaluate cardiac catheterization evidence?)* to better describe the type of information commonly provided by a cardiac catheterization. The commenter also provided specific language for consideration.

Response: We partially adopted this comment. As the commenter suggested, we removed the last sentence of paragraph 4.00C15a (We will not purchase) and we revised paragraph 4.00C15b (Cardiac catheterization reports). Specifically, we incorporated additional information into the description of typical cardiac catheterization report content, while retaining other findings commonly seen by adjudicators in medical evidence. We did not include some of the suggested language that only described background information and was less helpful in understanding the requirements to meet any listing.

Comment: One commenter recommended clarifying that paragraph 4.00C16 (*What details should exercise Doppler test reports contain?*) applies to Doppler studies of the lower extremities and recommended specific language.

Response: We partially adopted this comment. While relatively rare, exercise Doppler tests can be performed for conditions other than peripheral vascular disease. We recognize that this distinction was not clear in our proposed language; therefore, while we did not include all of the exact language suggested by the commenter, we revised the language to distinguish between elements of a report common to all exercise Doppler tests and those specific to exercise Doppler tests for peripheral vascular disease.

Comment: A commenter noted that the 3-month waiting period after treatment begins under paragraph 4.00J2 (*How do we relate treatment to functional status?*) may be unnecessary due to the rapid progression of some peoples' disease and the improbable improvement with treatment.

Response: We did not adopt this comment. In paragraph 4.00B4 (*When will we wait before we ask for more evidence?*), we explain that we may need to defer evaluation of an impairment for a period of up to 3 months from the date treatment began. We further state in paragraph 4.00B4b (In these situations) that ''we will not wait if we have enough information to make a determination or decision based on all of the relevant evidence in your case.''

Comment: One commenter questioned whether determinations regarding ability to perform an ETT made by ''medical sources'' in listing 4.02B1a (A medical source has concluded) and listing 4.08 (*Cardiomyopathy*) includes medical consultants.

Response: We did not make any changes in response to this comment. Paragraph 4.00D4c(i) (Your impairment satisfies the first part) states that if the case record does not include a conclusion from a medical source that an ETT would present a significant risk to you, a medical consultant as defined in paragraph 4.00A3a (*Medical consultant*) may make such a conclusion.

Comment: A commenter indicated that the term ''prescribed treatment'' lacked clarity and suggested replacing it with ''guideline-recommended treatment'' in listing 4.12 (SSA Note: In the NPRM we titled this section ''Peripheral arterial disease'').

Response: We did not adopt this comment. The term ''failure to follow prescribed treatment'' is a term of art that is described in our regulations at 20 CFR 404.1530 and 416.930. We hold a person responsible to follow treatment prescribed by their medical source if that treatment is expected to restore the ability to work. The term ''guideline-recommended treatment'' does not adequately convey that requirement.

Comments Specific To Evaluating Cardiovascular Disorders in Children

Comment: A commenter suggested replacing the word ''corrective'' with ''palliative'' in paragraph 104.00B4 (*When will we wait before we ask for more evidence?*).

Response: We did not adopt this comment. Paragraph 104.00B4 discusses when we will wait before we ask for additional evidence. The term ''corrective'' covers conditions where improvement may occur post-surgery and is appropriate for a situation when we will wait before asking for more evidence. The term ''palliative'' implies a likeliness that the person will have significant lifelong impairment in function. This term would not be an appropriate replacement, because the term would apply to situations when we do not wait for additional evidence.

Comment: One commenter recommended removing the word ''congestive'' from paragraph 104.00B4a(iii) (If you have started new drug therapy).

Response: We adopted this comment. Although we did not propose changing the wording in 104.00B4a(iii), we agree removing ''congestive'' reflects the terminology more commonly used in the medical field.

Comment: A commenter recommended we add ''volume'' as a measure of ventricle size as evidence necessary to show cardiomegaly in paragraph 104.00C2b(i) (Symptoms of congestion). The same commenter recommended we remove the requirement for a 6-foot PA film to show cardiomegaly.

Response: Although the commenter identified the incorrect section for the discussion of cardiomegaly, we adopted the recommendation and added increased ventricular volume in the discussion of cardiomegaly in paragraph 104.00C2a (Cardiomegaly or ventricular dysfunction) because increased ventricular volume is a finding that is helpful in evaluating cardiomegaly and is often documented in medical records. However, we did not make additional changes based on the recommendation to remove the requirement for 6-foot PA film, as we had already proposed removing this requirement in the NPRM and ultimately did so in this final rule.

Comment: A commenter noted that the absence of tachycardia may no longer be a relevant assessment of the severity of heart failure in discussing listing 104.02A (Persistent tachycardia at rest).

Response: We did not make changes based on this comment. Assessment of tachycardia is an important and common factor in evaluating heart failure. Even in its absence, listing 104.02 (*Chronic heart failure*) provides several criteria by which a person may be found disabled, including several criteria that do not consider tachycardia.

Comment: A commenter recommended that we consider revising the criterion under listing 104.02A (Persistent tachycardia at rest) and listing 104.02B (Persistent tachypnea at rest) to define tachycardia and tachypnea as a resting heart rate or respiratory rate (respectively) in excess of the upper limit of normal for that age. The commenter also suggested that we use the criteria on more than one evaluation more than 3 days apart, rather than at least 90 days apart. The same commenter also noted that the 12-month assessment period is too long and would result in delays.

Response: We did not adopt these comments. The commenter appears to suggest that we use a broad definition of tachycardia and tachypnea rather than providing specific cutoffs for each age range. The definition suggested is overly broad and there does not appear to be consensus among the medical community as to what the ''upper limit of normal'' is for various age ranges.

Furthermore, the use of a definition without specific cutoffs could lead to inconsistent determinations and decisions because of the underlying variation in the cutoffs used by the medical community.

Regarding the commenter's suggestion to require more than 3 days between evaluations, as we stated in the NPRM, we believe that a longer time period between evaluations is necessary to ensure that the underlying condition is chronic and not acute. We believe that requiring evaluations to occur at least 90 days apart is an appropriate time period for establishing the chronicity of the underlying condition. Although we indicate that the evaluations must occur within a 12-month period, we expect that many people may have the requisite findings in a shorter time period.

Comment: With respect to listing 104.02A (Persistent tachycardia at rest), a commenter noted that tachycardia and tachypnea are not exclusive to chronic HF and may also be seen in acute or chronic HF or heart failure exacerbation.

Response: Although we understand the commenter's concern, listing 104.02 (*Chronic heart failure*) is specifically used to evaluate chronic HF, and not other disorders which may present with tachycardia and tachypnea.

Comment: One commenter noted that persistent tachycardia can also include measurement by palpation of pulse, in addition to the proposed apical heart rate.

Response: We did not make changes based on this comment. A pulse rate taken by palpation is a measurement of the pressure waves created by contraction of the left ventricle, an indirect measurement, whereas measurement of the apical pulse rate is a direct measurement of the left ventricle's contraction; therefore, this direct measurement is a more accurate measurement of the child's heart rate than the indirect measurement. The apical pulse gives the most accurate reading.[42]

Comment: One commenter suggested we consider growth failure instead of persistent tachycardia and tachypnea for the pediatric population under listing 104.02 (*Chronic heart failure).* Another commenter expressed concerns that growth failure over the 12-month evaluation period under listing 104.02C (Growth failure) may not be reflected on growth charts as it is generally treated aggressively, with providers not waiting 12 months to initiate treatment. The same commenter also suggested expanding the symptoms of chronic HF in paragraph 104.00C2b (Your medical history and physical examination) to include signs and symptoms related to feeding intolerance and associated complications.

Response: We did not adopt the first comment because we already provide criteria for evaluating growth failure in chronic HF in 104.02C. It is one of several ways to evaluate chronic HF in children, along with persistent tachycardia and tachypnea. Additionally, although we understand the second commenter's concerns, the criteria for growth failure in 104.02C are intended to establish that the growth failure persists while on a regimen of prescribed treatment, including nutritional support. Furthermore, while we indicate that the evaluations must occur within a 12-month period, many people will have the requisite findings in a shorter time period. We adopted the suggestion to expand the symptoms of chronic HF in 104.00C2b to include signs and symptoms related to feeding intolerance and associated complications.

Comment: One commenter questioned the requirement in listing 104.02E (Exacerbations or complications of chronic heart failure) that children with chronic heart failure experience three hospitalizations within a consecutive 12-month period. They noted three hospitalizations ''seems high'' and suggested requiring only two hospitalizations within a consecutive 12-month period. The same commenter similarly suggested that we reconsider the hospitalization criterion in listing 104.06E (Exacerbations or complications of congenital heart disease), which also requires three hospitalizations within a 12-month period.

Response: We did not make changes based on these comments. For children, the requirement for three hospitalizations within a consecutive 12-month period is grounded in our rules for functional equivalence, specifically how we define ''marked'' and ''extreme'' limitations in the ''Health and physical well-being'' domain.[43] If a child has frequent exacerbations of their impairment (*i.e.,* episodes of illness or exacerbations that occur on average of three times per year, or once every 4 months, each lasting 2 weeks or more) that result in significant, documented signs or symptoms, we may consider that to be a ''marked'' limitation in this domain.[44] If the frequent exacerbations result in significant, documented symptoms or signs that are substantially in excess of the requirements for showing a ''marked'' limitation, we may find the child to have an ''extreme'' limitation in this domain.[45] Although the hospitalization requirement is less than the 2 weeks contemplated in the definition of a ''marked'' limitation, the 2-week period will also consider the period immediately before the hospitalization and the post-hospitalization recovery. Exacerbations and complications requiring frequent hospitalization demonstrate a level of care beyond the usual course of treatment for cardiovascular disorders and are consistent with listing-level severity.

Further, the hospitalization criterion in 104.02E and 104.06E is just one of several ways to document listing-level severity under each of these listings. We are also able to evaluate exacerbations or complications of chronic HF and congenital heart disease resulting in fewer than three hospitalizations in a consecutive 12-month period using our rules for medical equivalence,[46] under our rules for functional equivalence,[47] or under other listing criteria.

Comment: In response to a question we posed on the consideration of the atrial measurements in listing 4.02A2 (Heart failure with preserved ejection fraction), one commenter noted that the criteria found in listing 4.02A1 (Heart failure with reduced ejection fraction) are not applicable to children. They suggested that eligibility for children should be determined based on z-scores, biomarkers, or clinical findings as opposed to diastolic dimensions and wall thickness. They noted that left atrial enlargement is difficult to use as a criterion in children since there is no normative data for all age groups and the presence of some types of heart disease precludes this measurement. Furthermore, they noted that other end organ failure (renal disease, growth failure, neurodevelopmental disorders) needs to be considered for their impact.

Response: We did not make any changes in the final rule based on the commenter's concerns. Our final criteria for evaluating chronic HF in children do not include the types of specific measurements we use for adults. As we noted in the NPRM, we proposed to revise paragraph 104.00C2 (*What evidence of chronic HF do we need?*) to

[42] Zimmerman B., Williams D. Peripheral Pulse. 2025 July 6. In: StatPearls [internet]. Treasure Island (FL): StatPearls publishing; 2025 Jan. PMID: 31194332. (*https://www.ncbi.nlm.nih.gov/books/NBK542175/*).; Cleveland Clinic. *Apical Pulse.* (*https://my.clevelandclinic.org/health/articles/23346-apical-pulse*).

[43] 20 CFR 416.926a(e)(2)(iv) and 416.926a(e)(3)(iv).

[44] 20 CFR 416.926a(e)(2)(iv).

[45] 20 CFR 416.926a(e)(3)(iv).

[46] 20 CFR 404.1526 and 416.926.

[47] 20 CFR 416.926a.

remove ''specific findings for documenting cardiomegaly,'' because such findings are infrequently included in a child's case record and this absence presents difficulty in case adjudication. We believe that requiring z-scores or biomarkers would also be infrequently present and thus poses similar difficulty in case adjudication. Our rules already provide for evaluating other end organ failure. If the chronic HF results in end organ failure, such as renal disease and neurodevelopmental disorders, we will evaluate the effects under the appropriate body system or under our rules for functional equivalence.[48] We already provide specific guidance for evaluating growth failure in paragraph 104.00C3 (*How do we evaluate growth failure due to chronic HF?*).

Comment: One commenter recommended revisions to paragraph 104.00D1 (*What is congenital heart disease?*) to include additional treatments, such as an interventional catheterization procedure, and examples of congenital heart abnormalities, such as truncus arteriosus, total anomalous pulmonary venous return, and Epstein malformation.

Response: We adopted the recommended revisions to provide additional examples of congenital heart disease and its treatment.

Comment: One commenter recommended that we expand the list of impairments that may require life-saving surgery before age 1 in paragraph 104.00D2c (For 104.06D, life-threatening congenital heart disease) to include ''pulmonary atresia'' and ''critical pulmonary stenosis.''

Response: We did not adopt this comment. The examples of life-saving surgeries in 104.00D2c are not meant to be an exhaustive list of every life-saving surgery before age 1. However, we did make a related change to introductory text paragraph 104.00D1 (*What is congenital heart disease?)* as a result of the comment. We added pulmonary atresia as an example of congenital valvular defects in paragraph 104.00D1c (*Valvular defects or obstructions to ventricular outflow*).

Comment: A commenter suggested revising the text in paragraph 104.00D4 (*What is single ventricle?*) and adding ''pulmonary atresia with intact ventricular septum'' to the list of single ventricle anomalies.

Response: We partially adopted this comment. We added ''pulmonary atresia with intact ventricular septum'' to the list of single ventricle anomalies. We did not make the suggested minor edits to the text, because this paragraph describes background information, and the minor edits had unnecessary detail that is not informative for adjudication. However, we did include the additional discussion of Fontan circulation in 104.00D4. We made parallel changes to paragraph 4.00H3 (*What is single ventricle?*).

Comment: We received a comment related to the use of arterial saturation in listing 104.06 (*Congenital heart disease*). A commenter recommended we consider replacing the proposed emphasis on arterial saturation with oximetry and imaging diagnosis at listing 104.06A (Chronic hypoxemia), but if arterial saturation were to be used, the commenter recommended that the threshold should be set to less than 95 percent in room air. The commenter noted that the current threshold would not be appropriate for children considering that the adult threshold is set to 89 percent. The commenter also suggested a better alternative would be an echocardiographic diagnosis of anatomic abnormality.

Response: We did not adopt this comment. As we previously stated, the criterion for ABG measurements is only one alternative for establishing disability under the listing for congenital heart disease. Although ABGs may be infrequently done on children, these tests may be found in the medical evidence for some children. A threshold of less than 95 percent on room air is not appropriate because it does not reflect a level of hypoxemia that would result in marked and severe limitations (*i.e.,* that threshold does not reflect a disabling impairment).

Echocardiography is appropriate medically acceptable imaging that we use to establish congenital heart disease as an MDI. However, an anatomical abnormality established by echocardiography does not necessarily establish a degree of limitation that a child would experience. To establish the degree of limitations, we consider chronic hypoxemia or other medical findings.

Comment: One commenter suggested revising the description of congenital heart disease in listing 104.06C (Single ventricle) to account for those with single ventricle congenital heart disease. The commenter provided specific language they suggested we include in the listing, including specific functional limitations.

Response: We did not adopt this comment. The criterion in 104.06C is sufficient to establish a disabling impairment and it is not necessary to include the functional component suggested by the commenter. In addition to consulting with the IOM and reviewing the medical research supporting this criterion, we reviewed disability claims involving single ventricle congenital heart disease to ensure that the revised criteria reflect listing-level severity based on medical practice.

Comment: One commenter suggested we consider additional assessments to evaluate chronic HF and congenital heart disease in children. They specifically recommended including poor feeding, poor weight gain, frequent respiratory infections, irritability, and hepatomegaly.

Response: We did not adopt this comment. We provide a criterion for evaluating poor weight gain in listing 104.02C (Growth failure). We also provide a criterion for considering frequent respiratory infections in listings 104.02E (Exacerbations or complications of chronic heart failure) and 104.06E (Exacerbations or complications of congenital heart disease). Furthermore, the listings are not meant to be an exhaustive list of all signs, symptoms, and complications of cardiac impairments. They are meant to identify the common medical findings that cause marked and severe limitation in most children. Signs and symptoms not found in the listings may still be evaluated under the functional equivalence rules.[49] Some conditions may also be evaluated under their related body system, such as evaluating hepatomegaly under the Digestive Disorders listings.

Comment: One commenter recommended that we revise the text in paragraph 104.00E4a (Implanted cardiac defibrillators), describing children at risk for sudden cardiac arrest due to arrhythmias, including adding ''hypertrophic cardiomyopathy'' and ''rare forms of ischemic cardiomyopathy'' to the description.

Response: We did not adopt this comment. This section addresses the evaluation of children with implanted cardiac defibrillators who do not meet the listing requirements. The information about cardiomyopathy merely identifies the largest group of children at risk for sudden cardiac death and is not intended to provide information about the evaluation of cardiomyopathy. We provide more specific information about cardiomyopathy in paragraph 104.00F3 (*What is cardiomyopathy and how do we evaluate it?*).

Comment: One commenter suggested adding specific language to paragraph 104.00F1 (*What is ischemic heart disease (IHD) and how do we evaluate*

[48] 20 CFR 416.926a.

[49] 20 CFR 416.926a.

it in children?) to address the causes of IHD in children.

Response: We did not adopt the commenter's suggested language. Our evaluation of IHD in children focuses on the functional limitations resulting from IHD and thus addressing specific causes of IHD is not required for adjudication of these cases.

Comment: One commenter suggested revising the description of cardiomyopathy we proposed in paragraph 104.00F3a (There are various types of cardiomyopathy) to include subtypes of dilated, hypertrophic, restrictive, noncompaction, and arrhythmogenic.

Response: We partially adopted this comment. We included the suggested ''arrhythmogenic'' as it is a more common type of cardiomyopathy and removed ''hypertensive,'' because it is less commonly used to categorize cardiomyopathies. However, we did not include all the suggested types because there is lack of consensus as to what constitutes a separate type of cardiomyopathy. We also made these changes in the introductory text for consistency. Although the final text does not enumerate all five subtypes listed by the commenter, our text already refers to several of them. These are included for illustrative purposes and are not meant to be an exhaustive list of every type or subtype of cardiomyopathy.[50] The specific subtype of cardiomyopathy is not a consideration under our childhood listings. We will evaluate cardiomyopathy in children under listing 4.04 (*Ischemic heart disease*) in part A, listing 104.02 (*Chronic heart failure*), or listing 104.05 (*Recurrent arrhythmias*), depending on its effects on the child.

Comment: One commenter noted that we should consider the person's status classification when evaluating children listed for a transplant under paragraph 104.00F5c (We will not assume). They noted that children placed on the transplant list as category ''1A'' are most certainly disabled as they require extensive medical intervention including intensive care hospitalization, life support measures, and certain cardiac supporting intravenous medications with a Swan-Ganz catheter, or mechanical-assist devices.

Response: We did not adopt this comment. Although we do not consider a child's status on the transplant waiting list, we will consider the evidence that resulted in that classification. For children who are in classification 1A, we expect that the evidence supporting 1A will, in most cases, result in a finding of disability based on meeting or medically equaling a cardiovascular disorder listing or functionally equaling the listings.[51]

Comment: One commenter suggested we retain the listing for rheumatic heart disease (current listing 104.13).

Response: We did not adopt this suggestion. As we state in final paragraph 104.00F6 (*How do we evaluate chronic rheumatic fever or rheumatic heart disease?*), we evaluate the manifestations of rheumatic heart disease under other criteria, such as listing 104.02 (*Chronic heart failure*) or listing 104.05 (*Recurrent arrhythmias*). If a child's rheumatic heart disease does not meet or medically equal a listing, we will evaluate it under our functional equivalence rules.[52]

Other Concerns Raised by Commenters

Comment: We received several comments expressing concerns with the age of the IOM report and that our updates to the listings are based on outdated science. One commenter noted our changes to the listings may not make the listings more scientifically accurate and may result in some people no longer qualifying for benefits through the listings.

Response: The IOM report is one of several sources that informed these revisions to the cardiovascular disorders listings. Despite the age of the IOM report, it remains relevant because it was drafted within the context of the statutory definition of disability and the cardiovascular listings. These considerations may be different than those found in a strictly clinical setting. However, in drafting the NPRM and this final rule, we additionally reviewed current research, consulted with agency cardiologists and other medical experts, and reviewed disability claims involving cardiovascular disorders to ensure the IOM recommendations are still relevant. We are confident the policy changes we are finalizing reflect relevant and current medical practice, and the impact of cardiovascular impairments on the person's ability to sustain gainful activity, or ability to perform age-appropriate activities (for children).

We recognize the importance of clinical practice in formulating policy. In drafting this final rule, we reviewed and considered information more recently released, including the joint guidelines promulgated by the American Heart Association, the American College of Cardiologists, and the Heart Failure Society of America.[53] However, the clinical guidelines focus on the diagnosis and treatment of people with cardiac conditions and do not necessarily consider a person's level of impairment or functioning as it relates to the definition of disability in the Act.[54] In addition, we considered recent information from other sources, including the comments we received from the public in response to the NPRM and the published sources of medical literature and research we list in the references section of the NPRM and those cited in this final rule.

Comment: One commenter suggested that we consider whether reliance on healthcare use as a proxy for severity raises concerns regarding racial equity.

Response: We appreciate the commenter's suggestion. However, to be disabled under the Act, a person must have one or more medically determinable impairments—impairments that result from anatomical, physiological, or psychological abnormalities shown by medically acceptable clinical and laboratory diagnostic techniques.[55] If there is insufficient medical evidence for us to determine whether a person is disabled, we may ask the person to attend one or more examinations or tests at our expense.[56] Once we have evidence that shows a medically determinable impairment, we consider all the available evidence from all sources, medical and non-medical, when we make a disability determination.

The listings describe impairments that are so severe they prevent people from doing any substantial gainful activity regardless of their age, education, or

[50] National Heart, Lung, and Blood Institute (2024, December 6). *Cardiomyopathy Types.* (*https://www.nhlbi.nih.gov/health/cardiomyopathy/types*); Brieler, J., Breeden, M., Tucker, J. (2017). Cardiomyopathy: An Overview. *American Family Physician,* 96 (10), 640–646, (*https://www.aafp.org/pubs/afp/issues/2017/1115/p640.html*). These articles illustrate the diversity of classifications of cardiomyopathy.

[51] 20 CFR 416.924.

[52] 20 CFR 416.924.

[53] Heidenreich, P.A., Bozkurt, B., Aguilar, D., Allen, L.A., Byun, J.J., Colvin, M.M., Deswal, A., Drazner, M.H., Dunlay, S.M., Evers, L.R., Fang, J.C., Fedson, S.E., Fonarow, G.C., Hayek, S.S., Hernandez, A.F., Khazanie, P., Kittleson, M.M., Lee, C.S., Link, M.S., Milano, C.A., . . . ACC/AHA Joint Committee Members (2022). 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation, 145*(18), e895–e1032. (*https://doi.org/10.1161/CIR.0000000000001063*).

[54] See sections 216(i)(1), 223(d), and 1614(a)(3) of the Act (42 U.S.C. 416(i)(1), 423(d), 1382c(a)(3)).

[55] See sections 216(i)(1), 223(d)(1) and 1614(a)(3) of the Act (42 U.S.C. 416(i)(1), 423(d)(1), and 1382c(a)(3)). 20 CFR 404.1521 and 416.921.

[56] 20 CFR 404.1517 and 416.917.

work experience.[57] People with very serious cardiovascular disorders, such as those described in these listings, often receive the kinds of diagnostic treatments and tests discussed in the listings because of urgent medical need.

However, we do not penalize those who do not have access to the kinds of medical evidence that we describe in these listings. Furthermore, we provide several alternative criteria for people with cardiovascular impairments to establish that their impairment is of listing-level severity. If a person's cardiovascular disorder does not meet the requirements of any listing, we can still find that person disabled based on a finding of medical equivalence or functional equivalence in child claims or at a later step in our adjudication process.[58]

Comment: We received several comments expressing concerns with the hospitalization criteria in our listings for cardiovascular disorders. Several commenters noted our listings do not account for current medical practice or updated research on the role of healthcare utilization as a proxy for severity. They noted that SSA does not provide compelling evidence to explain why hospitalizations are an appropriate metric by which to measure severity. Another commenter noted that many procedures that used to require inpatient hospitalization are now routinely performed on an outpatient basis, and that using hospitalizations as a predictor of disability would exclude people who are getting the exact same treatment as those in 2010. Another commenter suggested that severity and prognosis should be classified based on trajectory of symptoms rather than frequencies of exacerbations or number of hospitalizations. Several commenters expressed concerns that using hospitalization as a proxy for disability would disproportionately disadvantage low-income people in rural areas.

Response: We decided to retain the hospitalization criteria as one of several alternative criteria in the affected listings because our intent is to reflect impairments that are so severe they result in an inability to perform any gainful activity. The hospitalization criteria reflect a need for a level of care beyond conventional outpatient treatments or isolated or brief hospitalizations for cardiovascular disorders. We understand the concerns regarding the decrease in hospitalizations due to the use of outpatient procedures and other advances in treatment. For people who are able to access these outpatient procedures and other advances in treatment, our other listing criteria specify the documentation required to evaluate cardiovascular disorders. However, in many locations, especially rural settings, people do not have access to preventative care, regular treatment, or more advanced treatment. As such, their only recourse for treating and managing severe cardiovascular disease is hospitalization.[59] None of the cardiovascular listings require a specific number of hospitalizations as the only way to meet the listing. The hospitalization criterion in the listings for chronic heart failure (4.02 and 104.02), ischemic heart disease (4.04), congenital heart disease (4.06 and 104.06), and cardiomyopathy (4.08) gives people another avenue of establishing a listing-level impairment.

Although some of our listings include criteria for repeated hospitalizations, our rules for medical equivalence [60] and functional equivalence in children [61] provide a means for adjudicators to consider the clinical care that emphasizes quality of, rather than quantity of, medical treatment. These rules consider all findings and other evidence in the record, including those impacted by a person's level of access to medical care (as well as the preference of some medical providers to reduce the use of emergency department and hospital-level medical interventions). The medical equivalence rules provide some flexibility in determining whether a person is disabled at step 3 of the sequential evaluation process by considering whether the person's impairment is at least equal in severity and duration to the criteria of any listed impairment. If we are unable to find a person's cardiovascular disorder meets or medically equals a listing, we may still find the person disabled at the final step of the sequential evaluation process.[62] In children, we may still find the person disabled under our rules for functional equivalence.[63]

Comment: We received several comments expressing concerns with our proposed listings that require at least 30-days elapse between hospitalizations to constitute a separate event. One commenter called the requirement ''arbitrary.''

Response: We decided to retain the requirement that at least 30 days elapse between hospitalizations to ensure that we are evaluating separate listing-level episodes of exacerbations or complications. We disagree that the 30-day requirement is arbitrary in defining separate events. The Centers for Medicare and Medicaid Services (CMS) uses 30 days between hospitalizations as a benchmark in their regulations. For example, the CMS defines ''readmission'' as the admission of a person to the same or another applicable hospital within a time period of 30 days from the date of a previous discharge.[64] CMS determined that 30 days is a ''clinically meaningful period'' for hospitals to work with their communities to reduce readmissions by ensuring patients are clinically ready at discharge and they receive appropriate planning for follow-up care after discharge.[65] Further, clinical research often uses 30 days as a benchmark in studying readmission rates.[66] While admission rates may trend lower in the future, the current 30-day benchmark is an appropriate period to delineate separate events in evaluating the severity of cardiovascular disorders. In some instances, hospitalizations that are less than 30 days apart may be evaluated using our rules for medical equivalence [67] or our rules for functional equivalence in children.[68]

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.[69] Furthermore, the Act directs us to adopt rules and regulations that ''provide for the nature and extent of the proofs and evidence'' needed to establish the right to benefits.[70]

[57] 20 CFR 404.1525(a) and 416.925(a).

[58] 20 CFR 404.1520, 416.920, and 416.924.

[59] National Academies of Sciences, Engineering, and Medicine. 2018. *Health-Care Utilization as a Proxy in Disability Determination.* Washington, DC: The National Academies Press. (*https://doi.org/10.17226/24969*).

[60] 20 CFR 404.1526 and 416.926.

[61] 20 CFR 416.926a.

[62] 20 CFR 404.1520(g) and 416.920(g).

[63] 20 CFR 416.926a.

[64] 42 CFR 412.152.

[65] 77 FR 53258, 53377 (2012).

[66] Jiang, H.J., & Hensche, M. (2023). *Characteristics of 30-Day All-Cause Hospital Readmissions, 2016–2020* (Healthcare Cost and Utilization Project Statistical Brief #304). Agency for Healthcare Research and Quality. (*www.hcup-us.ahrq.gov/reports/statbriefs/sb304-readmissions-2016–2020.pdf*); James, J., Tan, S., Stretton, B., Kovoor, J.G., Gupta, A.K., Gluck, S., Gilbert, T., Sharma, Y. and Bacchi, S. (2023). Why do we evaluate 30-day readmissions in general medicine? A historical perspective and contemporary data. *Internal Medicine Journal, 53*(6), 1070–1075. (*https://doi.org/10.1111/imj.16115*).

[67] 20 CFR 404.1526 and 416.926.

[68] 20 CFR 416.926a.

[69] See sections 205(a), 702(a)(5), and 1631(d)(1) of the Act (42 U.S.C. 405(a), 902(a)(5), 1383(d)(1)).

[70] See sections 205(a) and 1631(d)(1) of the Act (42 U.S.C. 205(a), 1383(d)(1)).

How long will this final rule be in effect?

This final rule will remain in effect for 5 years after the date it becomes effective, unless we extend, revise, or issue it again. We will continue to monitor this rule to ensure that it continues to meet program purposes, and we may revise it before the end of the 5-year period if warranted.

How will we implement this final rule?

We will begin to apply this final rule to new applications, pending claims, and continuing disability reviews (CDR), as applicable, as of the effective date of this final rule.[71]

Regulatory Procedures

Executive Order 12866

We consulted with the Office of Management and Budget (OMB) and determined that this final rule meets the criteria for a significant regulatory action under section 3(f) of Executive Order (E.O.) 12866, and is subject to OMB review. Therefore, OMB reviewed the rule. Details about the economic impacts of this rule follow.

Anticipated Accounting Costs of This Final Rule

Anticipated Costs to Our Programs

Our Actuarial Services currently estimate that implementation of the final rule will result in net increases of $446 million in scheduled Old-Age, Survivors, and Disability Insurance (OASDI) benefit payments and $94 million in Federal Supplemental Security Income (SSI) payments for the 10-year period covering fiscal years (FYs) 2026–2035. This estimate assumes the final rule will be implemented and effective for all disability determinations made on or after February 1, 2026. At the time of NPRM publication, Actuarial Services estimated net increases of $308 million in scheduled OASDI benefits and $71 million in Federal SSI payments for the 10-year period covering FYs 2022–2031, and assumed the rule would be effective for all disability determinations made on or after April 1, 2023.

We note that the 10-year projection period used for all of Actuarial Services' regulatory estimates is not arbitrarily selected. The period over which estimates are provided corresponds precisely to the 10-year projection period in the President's Budget used as the baseline for the estimates. Therefore, if the assumed effective date of a regulatory action provided to Actuarial Services is not the beginning of that 10-year period, then the estimates will cover less than 10 years.

The current estimates are higher than those included in the NPRM for three primary reasons: (1) the 10-year estimate in the NPRM covered 8 years and 6 months in which the rule was effective, while the 10-year estimate for this final rule covers 9 years and 8 months in which the rule is effective, so the estimate for this final rule effectively includes more than one year of additional OASDI and SSI payments; (2) the Cost-of-Living Adjustment (COLA) effective for benefits paid in 2023 was 8.7 percent, which was significantly larger than the 2023 COLA of 2.5 percent that was assumed in the NPRM estimate; and (3) the estimation window has shifted from 2022–2031 to 2026–2035, so the average monthly benefits assumed for this final rule are higher than in the NPRM because of assumed benefit increases over time. The changes we made from the proposed to the final rule did not cause any estimated change in allowances.

Anticipated Net Administrative Costs to the Social Security Administration

SSA's Finance, and Management division estimates a net administrative savings of less than 15 work years and $2 million annually.

Anticipated Costs to the Public

We do not believe there are any more than de minimis costs to the public associated with this rulemaking. As discussed earlier in our responses to comments on the Notice of Proposed Rulemaking as well as in the Paperwork Reduction Action section below, the requirements contained in this rulemaking will not impose new additional costs outside of the normal course of business for applicants or change how the public interacts with our disability programs. We do not anticipate that the requirements contained in the new cardiovascular listings will impose additional costs or documentation requirements on applicants or cause the affected applicants to pursue a different course of treatment than they otherwise would have done under our existing rules.

Anticipated Benefits to the Public

The revisions to the cardiovascular listings update the medical criteria and clarify how we evaluate cardiovascular disorders. The revisions also improve the clarity, readability, and application of the listings as well as consistency across the listings as a whole. The revisions also help promote uniform national disability policy and can simplify claims adjudication.

Congressional Review Act

Pursuant to Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act, 5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this final rule as not meeting the criteria in 5 U.S.C. 804(2), and it is therefore not a major rule as defined by the Congressional Review Act.

Executive Order 13132 (Federalism)

We analyzed this final rule in accordance with the principles and criteria established by E.O. 13132 and determined that it will not have sufficient Federalism implications to warrant the preparation of a Federalism assessment. We also determined that the final rule will not preempt any State law or State regulations or affect the States' abilities to discharge traditional State governmental functions.

Executive Order 14192

As previously discussed in the NPRM, we consider this rule a transfer rule with no more than *de minimis* costs.[72] As such, it is not a regulatory action under E.O. 14192.

Regulatory Flexibility Act

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

Paperwork Reduction Act

This final rule only updates the criteria in the Listing of Impairments that we use to evaluate disability claims involving cardiovascular disorders under titles II and XVI of the Social Security Act. It does not create any new or affect any existing collections. Accordingly, this final rule does not impose any burdens under the Paperwork Reduction Act and does not require further OMB approval.

(Catalog of Federal Domestic Assistance Program Nos. 96.001, Social Security—Disability Insurance; 96.002, Social

[71] We will use the final rule beginning on its effective date. We will apply the final rule 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 rule on and after its effective date in any case in which we make a determination or decision, including CDRs, as applicable. See 20 CFR 404.901, 404.1590, 416.990, and 416.1401.

[72] Based upon the criteria established in E.O. 13771, now superseded by E.O. 14192. For further information *see* OMB M- Memo 25–20 (''Guidance Implementing Section 3 of Executive Order 14192, Titled 'Unleashing Prosperity Through Deregulation' '').

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).

Mark Steffensen,

General Counsel, 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: 42 U.S.C. 402, 405(a)–(b) and (d)–(h), 416(i), 421(a) and (h)–(j), 422(c), 423, 425, 902(a)(5), and 1320e–3; sec. 211(b), Pub. L. 104–193, 110 Stat. 2105, 2189; sec. 202, Pub. L. 108–203, 118 Stat. 509 (42 U.S.C. 902 note).

■ 2. Amend appendix 1 to subpart P of part 404 as follows:
■ a. Revise item 5 of the introductory text before part A;
■ b. Revise the body system name for section 4.00 in the table of contents in part A;
■ c. Amend section 1.00 by revising paragraph 1.00B5;
■ d. Revise and republish section 4.00;
■ e. Revise the body system name for section 104.00 in the table of contents in part B;
■ f. Revise and republish section 104.00;
■ g. Amend section 114.00 by revising paragraph 114.00J2m.

The revisions read as follows:

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

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5. Cardiovascular Disorders (4.00 and 104.00): October 30, 2031.

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Part A

Sec.

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4.00 Cardiovascular Disorders

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1.00 Musculoskeletal Disorders

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B. * * *

5. We evaluate leg pain associated with peripheral vascular claudication and foot ulceration associated with peripheral artery disease under the listings in 4.00.

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4.00 Cardiovascular Disorders

A. How do we define cardiovascular disorders and cardiovascular terms?

1. *What do we mean by a cardiovascular disorder?*

a. We mean any disorder that affects the proper functioning of the heart or the circulatory system (that is, arteries, veins, capillaries, and the lymphatic drainage). The disorder can be congenital or acquired.

b. Cardiovascular disorders result from one or more of four consequences of heart disease:

(i) Chronic heart failure (chronic HF) or ventricular dysfunction.

(ii) Discomfort or pain due to myocardial ischemia, with or without necrosis of the heart muscle.

(iii) Syncope, or near syncope, due to inadequate cerebral perfusion from any cardiac cause, such as obstruction of flow or disturbance in rhythm or conduction resulting in inadequate cardiac output.

(iv) Hypoxemia (reduced oxygen concentration in the blood) due to right-to-left shunt or pulmonary vascular disease.

c. Disorders of the veins or arteries (for example, obstruction, rupture, or aneurysm) may cause impairments of the lower extremities (peripheral vascular disease), the central nervous system, the eyes, the kidneys, and other organs. We will evaluate peripheral vascular disease under 4.11 or 4.12 and impairments of another body system(s) under the listings for that body system(s).

2. *What do we consider in evaluating cardiovascular disorders?* The listings in this section describe cardiovascular disorders based on the medical and other evidence, including response to a regimen of prescribed treatment and functional limitations.

3. *What do the following terms or phrases mean in these listings?*

a. *Medical consultant* is a person defined in §§ 404.1616(a) and 416.1016(a) of this chapter. This term does not include medical sources who provide consultative examinations for us. We use the abbreviation ''MC'' throughout this section to designate a medical consultant.

b. *Persistent* means that the longitudinal clinical record shows that, with few exceptions, the required finding(s) has been present, or is expected to be present, for a continuous period of at least 12 months, such that a pattern of continuing severity is established. By ''exceptions,'' we mean brief periods when the required finding(s) is greatly reduced or gone. These periods are so brief or inconsequential, the required finding(s) remains a factor in the person's condition.

c. *Recurrent* means that the longitudinal clinical record shows that, within a consecutive 12-month period, the finding(s) occurs at least three times, with intervening periods of improvement of sufficient duration that it is clear that separate events are involved. By ''improvement of sufficient duration,'' we mean the finding is greatly reduced or not present for long enough that the required finding(s) is no longer a factor in the person's condition.

d. *Appropriate medically acceptable imaging* means that the technique used is the proper one to evaluate and diagnose the impairment and is commonly recognized as accurate for assessing the cited finding.

e. *A consecutive 12-month period* means a period of 12 consecutive months, all or part of which must occur within the period we are considering in connection with an application or continuing disability review.

B. What documentation do we need to evaluate cardiovascular disorders?

1. *What basic documentation do we need?* We need sufficiently detailed reports of history, physical examinations, laboratory studies, and any prescribed treatment and response to allow us to assess the severity and duration of your cardiovascular disorder. A longitudinal clinical record covering a period of not less than 3 months of observations and treatment is usually necessary, unless we can make a determination or decision based on the current evidence we already have.

2. *Why is a longitudinal clinical record important?* We will usually need a longitudinal clinical record to assess the severity and expected duration of your impairment(s). If you have a listing-level impairment, you probably will have received medically prescribed treatment. Whenever there is evidence of such treatment, your longitudinal clinical record should include a description of the ongoing management and evaluation provided by your medical source(s). It should also include your response to this medical management, as well as information about the nature and severity of your impairment. The record will provide us with information on your functional status over an extended period of time and show whether your ability to function is improving, worsening, or unchanging.

3. *What if you have not received ongoing medical treatment?*

a. You may not have received ongoing treatment or have an ongoing relationship with the medical community despite the existence of a severe impairment(s). In this situation, we will base our evaluation on the current evidence we have. If you do not receive treatment, you cannot show an impairment that meets the criteria of most of these listings. However, we may find you disabled because you have another impairment(s) that, in combination with your cardiovascular disorder, medically equals a listing, or we may find you disabled at a later step in the evaluation process based on a consideration of your residual functional

capacity and age, education, and work experience.

b. Unless we can decide your claim favorably on the basis of the current evidence we already have, a longitudinal record is still important. In instances when there is no or insufficient longitudinal evidence, we may purchase a consultative examination(s) to help us establish the existence, severity, and duration of your impairment.

4. *When will we wait before we ask for more evidence?*

a. We will wait when we have information showing that your impairment is not yet stable and the expected change in your impairment might affect our determination or decision. In these situations, we need to wait to properly evaluate the severity and duration of your impairment during a stable period. Examples of when we might wait are:

(i) If you have had a recent acute event; for example, a myocardial infarction (heart attack);

(ii) If you have recently had a corrective cardiac procedure; for example, coronary artery bypass grafting;

(iii) If you have started new drug therapy and your response to this treatment has not yet been established; for example, beta-blocker therapy for dilated cardiomyopathy.

b. In these situations, we will obtain more evidence 3 months following the event before we evaluate your impairment. However, we will not wait if we have enough information to make a determination or decision based on all of the relevant evidence in your case.

5. *Will we purchase any studies?* In appropriate situations, we may purchase studies necessary to substantiate the existence of a medically determinable impairment or to document the severity of your impairment, generally after we have evaluated the evidence we already have. We will not purchase studies involving exercise testing if there is significant risk involved or if there is another medical reason not to perform the test. We will follow 4.00C6, 4.00C7, and 4.00C8 when we decide whether to purchase exercise testing.

6. *What studies will we not purchase?* We will not purchase any studies involving cardiac catheterization, such as coronary angiography, arteriograms, or electrophysiological studies. However, if the results of a catheterization are part of the existing evidence we have, we will consider them together with the other relevant evidence. See 4.00C15a.

C. How do we use cardiovascular test results?

1. *What is an ECG?*

a. *ECG* stands for *electrocardiograph* or *electrocardiogram.* An electrocardiograph is a machine that records electrical impulses of your heart on a strip of paper called an electrocardiogram or a *tracing.* To record the ECG, a technician positions a number of small contacts (or *leads*) on your arms, legs, and across your chest to connect them to the ECG machine. An ECG may be done while you are resting or exercising.

b. The ECG tracing may indicate that you have a heart abnormality. It may indicate that your heart muscle is not getting as much oxygen as it needs (ischemia), that your heart rhythm is abnormal (arrhythmia), or that there are other abnormalities of your heart, such as left ventricular enlargement.

How do we evaluate ECG evidence? We consider a number of factors when we evaluate ECG evidence:

a. An original or legible copy of the 12-lead ECG obtained at rest must be appropriately dated and labeled, with the standardization inscribed on the tracing. Alteration in standardization of specific leads (such as to accommodate large QRS amplitudes) must be identified on those leads.

(i) Detailed descriptions or computer-averaged signals without original or legible copies of the ECG as described in 4.00C2a are not acceptable.

(ii) The effects of drugs or electrolyte abnormalities must be considered as possible noncardiac causes of ECG abnormalities of ventricular repolarization; that is, those involving the ST segment and T wave. If available, the predrug (especially digitalis glycosides) ECG should be submitted.

b. ECGs obtained in conjunction with treadmill, bicycle, or arm exercise tests should meet the following specifications:

(i) ECG reports must include the original calibrated ECG tracings or a legible copy;

(ii) A 12-lead baseline ECG must be recorded in the upright position before exercise;

(iii) A 12-lead ECG should be recorded at the end of each minute of exercise;

(iv) If ECG documentation of the effects of hyperventilation is obtained, the exercise test should be deferred for at least 10 minutes because metabolic changes of hyperventilation may alter the physiologic and ECG-recorded response to exercise;

(v) Post-exercise ECGs should be recorded using a generally accepted protocol consistent with the prevailing state of medical knowledge and clinical practice; and

(vi) All resting, exercise, and recovery ECG strips must have the standardization inscribed on the tracing. The ECG strips should be labeled to indicate the date, the times recorded and the relationship to the stage of the exercise protocol. The speed and grade (treadmill test) or work rate (bicycle or arm ergometric test) should be recorded. The highest level of exercise achieved, heart rate and blood pressure levels during testing, and the reason(s) for terminating the test (including limiting signs or symptoms) must be recorded.

3. *What are exercise tests and what are they used for?*

a. Exercise tests have you perform physical activity and record how your cardiovascular system responds. Exercise tests usually involve walking on a treadmill, but other forms of exercise, such as an exercise bicycle or an arm exercise machine, may be used. Exercise testing may be done for various reasons, such as to evaluate the severity of your coronary artery disease or peripheral vascular disease or to evaluate your progress after a cardiac procedure or an acute event, like a myocardial infarction (heart attack). Exercise testing is the most widely used testing for identifying the presence of myocardial ischemia and for estimating maximal aerobic capacity (usually expressed in METs—metabolic equivalents) if you have heart disease.

b. We include exercise tolerance test (ETT) criteria in 4.02B2, 4.04A, 4.06B, and 4.08A2. To meet the ETT criteria in these listings, the ETT must be a sign- or symptom-limited test in which you exercise while connected to an ECG until you develop a sign or symptom that indicates that you have exercised as much as is considered safe for you.

c. In 4.12B, we also refer to exercise testing for peripheral vascular disease. In this test, you walk on a treadmill, usually for a specified period of time, and the person who administers the test measures the effect of exercise on the flow of blood in your legs, usually by using ultrasound. The test is also called an exercise Doppler test. Even though this test is intended to evaluate peripheral vascular disease, it will be stopped for your safety if you develop abnormal signs or symptoms because of heart disease.

d. Each type of test is done in a certain way following specific criteria, called a *protocol.* For our program, we also specify certain aspects of how any exercise test we purchase is to be done. See 4.00C10 and 4.00C17.

4. *Do ETTs have limitations?* An ETT provides an estimate of aerobic capacity for walking on a grade, bicycling, or moving one's arms in an environmentally controlled setting. Therefore, ETT results do not correlate with the ability to perform other types of exertional activities, such as lifting and carrying heavy loads, and do not provide an estimate of the ability to perform activities required for work in all possible work environments or throughout a workday. Also, certain medications (such as beta blockers) and conduction disorders (such as left or right bundle branch blocks) can cause false-negative or false-positive results. Therefore, we must consider the results of an ETT together with all the other relevant evidence in your case record.

5. *How does an ETT with measurement of maximal or peak oxygen uptake (VO_2)* differ from other ETTs? Occasionally, medical evidence will include the results of an ETT with VO_2, which is also called a cardiopulmonary exercise test. While ETTs without measurement of VO_2 provide only an estimate of aerobic capacity, measured maximal or peak oxygen uptake provides an accurate measurement of aerobic capacity, which is often expressed in METs (metabolic equivalents). The MET level may not be indicated in the report of attained maximal or peak VO_2 testing, but can be calculated as follows: 1 MET = 3.5 milliliters (ml) of oxygen uptake per kilogram (kg) of body weight per minute. For example, a 70 kg (154 lb.) person who achieves a maximal or peak VO_2 of 1225 ml in 1 minute has attained 5 METs (1225 ml/70 kg/1 min = 17.5 ml/kg/min. 17.5/3.5 = 5 METs). In listings 4.02B2, 4.06B, and 4.08A2, we use the peak VO_2 (oxygen uptake) measurement when evaluating the results of a cardiopulmonary exercise test.

6. *When will we consider whether to purchase an exercise test?*

a. We will consider whether to purchase an exercise test when:

(i) There is a question whether your cardiovascular disorder meets or medically equals the severity of one of the listings, or there is no timely test in the evidence we

have (see 4.00C9), and we cannot find you disabled on some other basis; or

(ii) We need to assess your residual functional capacity and there is insufficient evidence in the record to make a determination or decision.

b. We will not purchase an exercise test when we can make our determination or decision based on the evidence we already have.

7. *What must we do before purchasing an exercise test?*

a. Before we purchase an exercise test, an MC, preferably one with experience in the care of patients with cardiovascular disease, must review the pertinent history, physical examinations, and laboratory tests that we have to determine whether the test would present a significant risk to you or if there is some other medical reason not to purchase the test (see 4.00C8).

b. If you are under the care of a medical source (see §§ 404.1502 and 416.902 of this chapter) for a cardiovascular disorder, this source has not performed an exercise test, and there are no reported significant risks to testing, we will request a statement from that source explaining why it was not done or should not be done before we decide whether we will purchase the test.

c. The MC, in accordance with the regulations and other instructions on consultative examinations, will generally not override the medical source's conclusion about the risk of exercise testing to you. In the rare situation in which the MC does override the medical source's conclusion, the MC must prepare a written rationale documenting the reasons for overriding the conclusion.

d. If you do not have a medical source or we cannot obtain a statement from your medical source, the MC is responsible for assessing the risk of exercise testing based on a review of the records we have before purchasing an exercise test for you.

e. We must also provide your records to the medical source who performs the exercise test for review prior to conducting the test if the source does not already have them. The medical source who performs the exercise test has the ultimate responsibility for deciding whether you would be at risk.

8. *When will we not purchase an exercise test or wait before we purchase an exercise test?*

a. We will not purchase an exercise test when an MC finds that you have one of the following significant risk factors:

(i) Unstable angina not previously stabilized by medical treatment;

(ii) Uncontrolled cardiac arrhythmias causing symptoms or hemodynamic compromise;

(iii) An implanted cardiac defibrillator;

(iv) Symptomatic severe aortic stenosis;

(v) Uncontrolled symptomatic heart failure;

(vi) Aortic dissection;

(vii) Severe pulmonary hypertension (pulmonary artery systolic pressure greater than 60 mm Hg);

(viii) Left main coronary stenosis of 50 percent or greater that has not been bypassed;

(ix) Moderate stenotic valvular disease with a systolic gradient across the aortic valve of 50 mm Hg or greater;

(x) Severe arterial hypertension (systolic greater than 200 mm Hg or diastolic greater than 110 mm Hg); or

(xi) Hypertrophic cardiomyopathy with a systolic gradient of 50 mm Hg or greater.

b. We also will not purchase an exercise test when you are prevented from performing exercise testing due to another impairment affecting your ability to use your arms and legs.

c. We will not purchase an ETT to document the presence of a cardiac arrhythmia.

d. We will wait to purchase an exercise test until 3 months after you have had one of the following events. This will allow for maximal, attainable restoration of functional capacity.

(i) Acute myocardial infarction;

(ii) Surgical myocardial revascularization (bypass surgery);

(iii) Other open-heart surgical procedures; or

(iv) Percutaneous transluminal coronary angioplasty (PTCA) or percutaneous coronary intervention (PCI) with or without stenting.

e. If you are deconditioned after an extended period of bedrest or inactivity and could improve with activity, or if you are in acute heart failure and are expected to improve with treatment, we will wait an appropriate period of time until you are ready and there are no medical reasons that prevent us from purchasing an exercise test.

9. *What do we mean by a ''timely'' test?*

a. We consider exercise test results to be timely for 12 months after the date they are performed, provided there has been no change in your clinical status that may alter the severity of your cardiovascular disorder.

b. However, an exercise test that is older than 12 months, especially an abnormal one, can still provide information important to our adjudication. For example, a test that is more than 12 months old can provide evidence of ischemic heart disease or peripheral vascular disease, information on decreased aerobic capacity, or information about the duration or onset of your impairment. Such tests can be an important component of the longitudinal record.

c. When we evaluate a test that is more than 12 months old, we must consider the results in the context of all the relevant evidence, including why the test was performed and whether there has been an intervening event or improvement or worsening of your impairment.

d. We will purchase a new exercise test only if we cannot make a determination or decision based on the evidence we have.

10. *How must ETTs we purchase be performed?*

a. The ETT must be a sign- or symptom-limited test characterized by a progressive multistage regimen. It must be performed using a generally accepted protocol consistent with the prevailing state of medical knowledge and clinical practice. A description of the protocol that was followed must be provided, and the test must meet the requirements of 4.00C2b and this section. A radionuclide perfusion scan may be useful for detecting or confirming ischemia when resting ECG abnormalities, medications, or other factors may decrease the accuracy of ECG interpretation of ischemia. (The perfusion imaging is done at the termination of exercise, which may be at a higher MET level than that at which ischemia first occurs. If the imaging confirms the presence of reversible ischemia, the exercise ECG may be useful for detecting the MET level at which ischemia initially appeared.) Exercise tests may also be performed using echocardiography to detect stress-induced ischemia and left ventricular dysfunction (see 4.00C12 and 4.00C13).

b. The exercise test must be paced to your capabilities and be performed following the generally accepted standards for adult exercise test laboratories. With a treadmill test, the speed, grade (incline), and duration of exercise must be recorded for each exercise test stage performed. Other exercise test protocols or techniques should use similar workloads. The exercise protocol may need to be modified in individual cases to allow for a lower initial workload with more slowly graded increments than the standard Bruce protocol.

c. Levels of exercise must be described in terms of workload and duration of each stage; for example, treadmill speed and grade, or bicycle ergometer work rate in kpm/min or watts.

d. The exercise laboratory's physical environment, staffing, and equipment must meet the generally accepted standards for adult exercise test laboratories.

11. *How do we evaluate ETT results?* We evaluate ETT results on the basis of the work level at which the test becomes abnormal, as documented by onset of signs or symptoms and any ECG or imaging abnormalities. The absence of an ischemic response on an ETT alone does not exclude the diagnosis of ischemic heart disease. We must consider the results of an ETT in the context of all of the other evidence in your case record.

12. *When are ETTs done with imaging?* When resting ECG abnormalities preclude interpretation of ETT tracings relative to ischemia, a radionuclide (for example, thallium-201 or technetium-99m) perfusion scan or echocardiography in conjunction with an ETT provides better results. You may have resting ECG abnormalities when you have a conduction defect—for example, Wolff-Parkinson-White syndrome, left bundle branch block, left ventricular hypertrophy—or when you are taking digitalis or other antiarrhythmic drugs, or when resting ST changes are present. Also, these techniques can provide a reliable estimate of ejection fraction.

13. *Will we purchase ETTs with imaging?* We may purchase an ETT with imaging in your case after an MC, preferably one with experience in the care of patients with cardiovascular disease, has reviewed your medical history and physical examination, any report(s) of appropriate medically acceptable imaging, ECGs, and other appropriate tests. We will consider purchasing an ETT with imaging when other information we have is not adequate for us to assess whether you have severe ventricular dysfunction or myocardial ischemia, there is no significant risk involved (see 4.00C8a), and we cannot make our determination or decision based on the evidence we already have.

14. *What are drug-induced stress tests?* These tests are designed primarily to provide evidence about myocardial ischemia or prior myocardial infarction, but do not require you to exercise. These tests are used when you cannot exercise or cannot exercise enough to achieve the desired cardiac stress. Drug-induced stress tests can also provide evidence about heart chamber dimensions and function; however, these tests do not provide information about your aerobic capacity and cannot be used to help us assess your ability to function. Some of these tests use agents, such as Persantine or adenosine, that dilate the coronary arteries and are used in combination with nuclear agents, such as thallium or technetium (for example, Cardiolyte or Myoview), and a myocardial scan. Other tests use agents, such as dobutamine, that stimulate the heart to contract more forcefully and faster to simulate exercise and are used in combination with a 2-dimensional echocardiogram. We may, when appropriate, purchase a drug-induced stress test to confirm the presence of myocardial ischemia after a review of the evidence in your file by an MC, preferably one with experience in the care of patients with cardiovascular disease.

15. *How do we evaluate cardiac catheterization evidence?*

a. We will not purchase cardiac catheterization; however, if you have had catheterization, we will make every reasonable effort to obtain the report and any ancillary studies. We will consider the quality and type of data provided and its relevance to the evaluation of your impairment.

b. Cardiac catheterization reports commonly include an evaluation of each main coronary artery and whether there is evidence of obstruction, as well as the grade of obstruction (percent stenosis). Cardiac catheterization reports may include information about the pressures of left and right side of the heart, evidence of coronary artery size and flow patterns, and chamber size. These reports may also include evaluation of left ventricular wall motion, left ventricular ejection fraction (left ventriculography), fractional flow reserve (FFR) (a measure of flow access across an obstruction), and the instantaneous wave-free ratio (iFR) (a measure of stenosis severity).

16. *What details should exercise Doppler test reports contain?* The reports of exercise Doppler tests must describe the level of exercise; for example, the speed and grade of the treadmill settings, the duration of exercise, changes in the person's condition during exercise (including the presence and location of leg symptoms), and the reasons for stopping exercise if the expected level of exercise was not attained. If the exercise Doppler test was done to evaluate peripheral vascular disease, the report must also provide the blood pressures at the ankle and other pertinent sites measured after exercise, and also provide the time required for the systolic blood pressure to return toward or to the pre-exercise level. The graphic tracings, if available, should also be included with the report. All tracings must be annotated with the standardization used by the testing facility.

17. *How must exercise Doppler tests we purchase be performed?* When we purchase an exercise Doppler test, you must exercise on a treadmill at 2 mph on a 12 percent grade for up to 5 minutes. The reports must include the information specified in 4.00C16. Because this is an exercise test, we must evaluate whether such testing would put you at significant risk, in accordance with the guidance found in 4.00C6, 4.00C7, and 4.00C8.

D. How do we evaluate chronic heart failure?

1. *What is chronic heart failure (chronic HF)?*

a. *Heart failure* is the inability of the heart to pump enough oxygenated blood to body tissues. This syndrome is characterized by symptoms and signs of pulmonary or systemic congestion (fluid retention) or limited cardiac output. Certain laboratory findings of cardiac functional and structural abnormality support the diagnosis of chronic HF. Ejection fraction (EF) is the percentage of the blood in the ventricle actually pumped out with each contraction. EF in heart failure is a continuum ranging from low EF due to muscle dysfunction to preserved EF resulting from high intracardiac pressures. We consider heart failure to be chronic when the condition persists or recurs over time despite treatment. There are two main types of chronic HF:

(i) *Heart failure with reduced EF (HFrEF) or predominant systolic dysfunction* is characterized by the inability of the heart to contract normally and expel sufficient blood due to a dilated, poorly contracting left ventricle, and

(ii) *Heart failure with preserved EF (HFpEF) or predominant diastolic dysfunction* is characterized by the inability of the heart to relax and fill normally due to a thickened ventricular muscle, poor ability of the left ventricle to distend, and increased ventricular filling pressure.

b. Chronic HF is considered in these listings as a single category whether due to atherosclerosis (narrowing of the arteries), cardiomyopathy, hypertension, or rheumatic, congenital, or other heart disease. If the chronic HF is the result of primary pulmonary hypertension secondary to disease of the lung, we evaluate your impairment under the listings in 3.00 (for example, 3.09) or 4.00, as appropriate. For the purposes of 4.02B3, a finding of elevated B-type natriuretic peptide (BNP) or N-terminal pro-B-type natriuretic peptide (NT-proBNP) in the blood assists in differentiating chronic HF from non-heart failure symptoms.

2. *What evidence of chronic HF do we need?*

a. Cardiomegaly or ventricular dysfunction must be present and demonstrated by appropriate medically acceptable imaging, such as cardiac magnetic resonance imaging (MRI), chest x-ray, echocardiography (M-Mode, 2-dimensional, and Doppler), radionuclide studies, or cardiac catheterization.

(i) Abnormal cardiac imaging provides objective measures of both left ventricular function and structural abnormality in heart failure. Examples of abnormal findings include increased left ventricular end-diastolic dimension (LVEDD), decreased EF, increased left atrial chamber size, increased left atrial volume index (LAVI), increased ventricular filling pressures measured at cardiac catheterization, or increased left ventricular wall or septum thickness.

(ii) An LVEDD greater than 6.8 cm for males or 6.1 cm for females, *or* an EF of 30 percent or less during a period of stability (that is, not during an episode of exacerbation of heart failure) may be associated clinically with systolic dysfunction.

(iii) LAVI is measured in milliliters (ml) indexed to body surface area (BSA) measured in squared meters (m^2). Indexing is a method of standardizing measurements to different body sizes. Diastolic dysfunction may be clinically associated with LAVI of 40 ml, BSA/m^2 or greater. The imaging report will contain a measurement for the left atrium volume. The index is calculated by dividing the left atrium volume by BSA.

(iv) However, these measurements alone do not reflect your functional capacity, which we evaluate by considering all of the relevant evidence. In some situations, we may need to purchase an ETT to help us assess your functional capacity.

(v) Other findings on appropriate medically acceptable imaging may include increased pulmonary vascular markings, pleural effusion, and pulmonary edema. These findings need not be present on each report, since chronic HF may be controlled by prescribed treatment.

(vi) Other findings on an echocardiogram report (such as an LVEDD indexed to BSA) may be at least of medically equal significance to required findings in the listing criteria. These findings may be evaluated under our medical equivalence policy, as appropriate. See §§ 404.1526 and 416.926 of this chapter.

b. Your medical history and physical examination should describe characteristic symptoms and signs of pulmonary or systemic congestion (fluid retention) or of limited cardiac output associated with the abnormal findings on appropriate medically acceptable imaging. When an acute episode of heart failure is triggered by a remediable factor, such as an arrhythmia, dietary sodium overload, or high altitude, cardiac function may be restored and a chronic impairment may not be present.

(i) Symptoms of congestion or of limited cardiac output include easy fatigue, weakness, shortness of breath (dyspnea), cough, or chest discomfort at rest or with activity. People with chronic HF may also experience shortness of breath upon lying flat (orthopnea) or episodes of shortness of breath that wake them from sleep (paroxysmal nocturnal dyspnea). They may also experience cardiac arrhythmias resulting in palpitations, lightheadedness, or fainting.

(ii) Signs of congestion may include hepatomegaly, ascites, increased jugular venous distention or pressure, rales, peripheral edema, or rapid weight gain. However, these signs need not be found on all examinations because congestion may be controlled by prescribed treatment or may not be present at the time of evaluation.

3. *Is it safe for you to have an ETT if you have chronic HF?* The presence of chronic HF is not necessarily a contraindication to an ETT, unless you are having an acute episode of heart failure. Measures of cardiac performance are valuable in helping us evaluate your ability to do work-related activities. ETT has been used safely in people with chronic HF. Therefore, we may purchase an ETT for evaluation under 4.02B2 if an MC, preferably one experienced in the care of patients with cardiovascular disease, determines that the test poses no significant risk to you. ST segment changes from digitalis use in the treatment of chronic HF do not preclude the purchase of an ETT. (See 4.00C6 for when we will consider the purchase of an ETT. See 4.00C7–4.00C8 for what we must do before we purchase an ETT and when we will not purchase one.)

4. *How do we evaluate chronic HF using 4.02?*

a. We must have objective evidence, as described in 4.00D2, that you have chronic HF.

b. To meet the required level of severity for this listing, your impairment must satisfy the requirements of the criteria in A and B or satisfy either C or D.

c. In 4.02B1, we follow a two-part process to evaluate your impairment. Your impairment must satisfy the requirements in the first part of this process before we will move to the second part.

(i) Your impairment satisfies the first part if a medical source has concluded that the performance of an ETT would present a significant risk to you. This medical source, such as a cardiologist, may be providing your care. If your case record does not include a conclusion from a medical source that an ETT would present a significant risk to you, an MC as defined in 4.00A3a may make such a conclusion if evidence in your case record supports it.

(ii) In the second part of the process, we will evaluate activities of daily living (ADL). ADLs include, but are not limited to, such activities as doing household chores, grooming and hygiene, shopping at a grocery store, taking public transportation, or paying bills. We will assess whether you have persistent symptoms of chronic heart failure (for example, easy fatigue, weakness, shortness of breath, or chest discomfort) at rest or with activity that very seriously limit your ability to perform ADLs independently, appropriately, effectively, and on a sustained basis. Even if you are able to perform some ADLs, we may find your ability is very seriously limited and that your impairment satisfies the second part of the evaluation.

d. Listing 4.02B2b requires a decrease in systolic blood pressure below the baseline level or below any systolic pressure reading recorded during exercise. We have this requirement because, normally, systolic blood pressure and heart rate increase gradually with exercise. Decreases in systolic blood pressure below the baseline level that occur during exercise are often associated with ischemia-induced left ventricular dysfunction resulting in decreased cardiac output. However, a blunted response (that is, failure of the systolic blood pressure to rise 10 mm Hg or more), particularly in the first 3 minutes of exercise, may be drug-related and is not necessarily associated with left ventricular dysfunction. Also, some people with increased sympathetic responses because of deconditioning or apprehension may increase their systolic blood pressure and heart rate above their baseline level just before and early into exercise. This can be associated with a drop in systolic pressure in early exercise that is not due to left ventricular dysfunction. Therefore, an early decrease in systolic blood pressure must be interpreted within the total context of the test; that is, the presence or absence of symptoms such as lightheadedness, ischemic changes, or arrhythmias on the ECG.

e. *How do we evaluate chronic HF treated with a mechanical circulatory support device?* We use 4.02D1 to evaluate chronic HF treated with an implanted mechanical circulatory support device (MCSD), such as a left ventricle assistive device (LVAD) or a right ventricle assistive device (RVAD). Implanted MCSDs are intended for long-term circulatory support in helping the heart pump blood. For the purposes of 4.02D1, an MCSD does not include extracorporeal membrane oxygenation (ECMO) or devices using Impella technology. Although these are forms of mechanical circulatory support, we do not include them in 4.02D1 because they are intended only for short-term circulatory support (maximum 30 days), used in a setting of imminent or actual cardiac arrest.

E. How do we evaluate ischemic heart disease?

1. *What is ischemic heart disease (IHD)? IHD* is a condition in which the heart muscle does not receive enough blood to function normally (ischemia). Ischemia can result when one or more of your coronary arteries is narrowed or obstructed or, in rare situations, constricted due to vasospasm. The obstruction may be the result of an embolus, a thrombus, or plaque. When heart muscle tissue dies as a result of the reduced blood supply, it is called a myocardial infarction (heart attack). In the absence of coronary artery obstruction, ischemia can also occur due to coronary microvascular dysfunction, which results in the heart muscle getting insufficient oxygen.

2. *What causes chest discomfort of myocardial origin?*

a. Chest discomfort of myocardial ischemic origin, commonly known as angina pectoris, is usually caused by obstructive coronary artery disease (CAD). However, ischemic discomfort may be caused by a noncoronary artery impairment, such as aortic stenosis, hypertrophic cardiomyopathy, pulmonary hypertension, or anemia. Ischemic chest discomfort may also be caused by microvascular coronary artery dysfunction with non-obstructive CAD or in the absence of CAD.

b. Instead of typical angina pectoris, some people with IHD experience atypical angina, anginal equivalent, variant angina, or silent ischemia, all of which we may evaluate using 4.04. We discuss the various manifestations of ischemia in 4.00E3–4.00E7.

3. *What are the characteristics of typical angina pectoris?* Discomfort of myocardial ischemic origin (angina pectoris) is discomfort that is precipitated by effort or emotion and promptly relieved by rest, sublingual nitroglycerin (that is, nitroglycerin tablets that are placed under the tongue), or other rapidly acting nitrates. Typically, the discomfort is located in the chest (usually substernal) and described as pressing, crushing, squeezing, burning, aching, or oppressive. Sharp, sticking, or cramping discomfort is less common. Discomfort occurring with activity or emotion should be described specifically as to timing and usual inciting factors (type and intensity), character, location, radiation, duration, and response to nitrate treatment or rest.

4. *What is atypical angina? Atypical angina* describes discomfort or pain from myocardial ischemia that is felt in places other than the chest. The common sites of cardiac pain are the inner aspect of the left arm, neck, jaw(s), upper abdomen, and back, but the discomfort or pain can be elsewhere. When pain of cardiac ischemic origin presents in an atypical site in the absence of chest discomfort, the source of the pain may be difficult to diagnose. To represent atypical angina, your discomfort or pain should have precipitating and relieving factors similar to those of typical chest discomfort, and we must have objective medical evidence of myocardial ischemia; for example, ECG or ETT evidence or appropriate medically acceptable imaging.

5. *What is anginal equivalent?* Often, people with IHD will complain of shortness of breath (dyspnea) on exertion without chest pain or discomfort. In a minority of such situations, the shortness of breath is due to myocardial ischemia; this is called *anginal equivalent.* To represent anginal equivalent, your shortness of breath should have precipitating and relieving factors similar to those of typical chest discomfort, and we must have objective medical evidence of myocardial ischemia; for example, ECG or ETT evidence or appropriate medically acceptable imaging. In these situations, it is essential to establish objective evidence of myocardial ischemia to ensure that you do not have effort dyspnea due to non-ischemic or non-cardiac causes.

6. *What is variant angina?*

a. *Variant angina* (Prinzmetal's angina, vasospastic angina) refers to the occurrence of anginal episodes at rest, especially at night, accompanied by transitory ST segment elevation (or, at times, ST depression) on an ECG. It is due to severe spasm of a coronary artery, causing ischemia of the heart wall, and is often accompanied by major ventricular arrhythmias, such as ventricular tachycardia. We will consider variant angina under 4.04 only if you have spasm of a coronary artery in relation to an obstructive lesion of the vessel. If you have an arrhythmia as a result of variant angina, we may consider your impairment under 4.05.

b. Variant angina may also occur in the absence of obstructive CAD. In this situation, an ETT will not demonstrate ischemia. The diagnosis will be established by showing the typical transitory ST segment changes during attacks of pain, and the absence of obstructive lesions shown by catheterization. In the absence of obstructive CAD, the treatment of ischemia due to coronary

vasospasm or microvascular dysfunction is limited to medications such as calcium channel blockers, statins, and nitrates. In such situations, we will consider the frequency of anginal episodes despite prescribed treatment when evaluating your residual functional capacity.

c. Vasospasm that is catheter-induced during coronary angiography is not variant angina.

7. *What is silent ischemia?*

a. Myocardial ischemia, and even myocardial infarction, can occur without perception of pain or any other symptoms; when this happens, we call it *silent ischemia.* Pain sensitivity may be altered by a variety of diseases, most notably diabetes mellitus and other neuropathic disorders. People also vary in their threshold for pain.

b. Silent ischemia occurs most often in:

(i) People with documented past myocardial infarction or established angina without prior infarction who do not have chest pain on ETT, but have a positive test with ischemic abnormality on ECG, perfusion scan, or other appropriate medically acceptable imaging.

(ii) People with documented past myocardial infarction or angina who have ST segment changes on ambulatory monitoring (Holter monitoring) that are similar to those that occur during episodes of angina. ST depression shown on the ambulatory recording should not be interpreted as positive for ischemia unless similar depression is also seen during chest pain episodes annotated in the diary that the person keeps while wearing the Holter monitor.

(iii) People who have diabetes mellitus with neuropathy. People with diabetes mellitus can have a higher threshold for pain because of the neuropathy and may not feel chest pain or discomfort from cardiac ischemia.

c. ST depression can result from a variety of factors, such as postural changes and variations in cardiac sympathetic tone. In addition, there are differences in how different Holter monitors record the electrical responses. Therefore, we do not consider the Holter monitor reliable for the diagnosis of silent ischemia except in the situation described in 4.00E7b(ii).

8. *What other sources of chest discomfort are there?* Chest discomfort of nonischemic origin may result from other cardiovascular disorders, such as pericarditis. Noncardiac disorders may also produce symptoms mimicking that of myocardial ischemia. These disorders include acute anxiety or panic attacks, gastrointestinal tract disorders (such as esophageal spasm, esophagitis, hiatal hernia, biliary tract disease, gastritis, peptic ulcer, and pancreatitis), and musculoskeletal syndromes (such as chest wall muscle spasm, chest wall syndrome (especially after coronary bypass surgery), costochondritis, and cervical or dorsal spine arthritis). Hyperventilation may also mimic ischemic discomfort. Thus, in the absence of documented myocardial ischemia, such disorders should be considered as possible causes of chest discomfort.

9. *How do we evaluate IHD using 4.04?*

a. We must have objective evidence, as described under 4.00C, that your symptoms are due to myocardial ischemia.

b. In 4.04A, we need evidence, such as an ECG interpretation, from an acceptable medical source who reviewed your ETT findings and found them positive for ischemia. These ETT findings may include ECG tracings or systolic blood pressure measurements. If your case record does not have such an interpretation from an acceptable medical source, an MC, as defined in 4.00A3a, may review your ETT findings and interpret them as being positive for ischemia if evidence in your case record supports it.

(i) ETT findings may show the classically accepted changes in ECG tracings of horizontal or down sloping ST depression or of ST elevation. For example, ECG tracings may show horizontal or down sloping depression, in the absence of digitalis glycoside treatment or hypokalemia, of the ST segment of at least −0.10 millivolts (−1.0 mm) in at least three consecutive complexes that are on a level baseline in any lead other than a VR, and depression of at least −0.10 millivolts lasting for at least 1 minute of recovery. Alternatively, the ECG tracings may show at least 0.10 millivolt (1 mm) ST elevation above resting baseline in non-infarct leads during both exercise and 1 or more minutes of recovery.

(ii) ETT findings may also show a decrease of 10 mmHg or more in systolic pressure below the baseline systolic blood pressure or the preceding systolic pressure measured during exercise due to left ventricular dysfunction, despite an increase in workload. This finding is the same finding required in 4.02B2b. See 4.00D4d for full details.

c. In 4.04C, each ischemic episode must result in an unplanned hospitalization. Examples of ischemic episodes that may result in unplanned hospitalizations include unplanned revascularizations, myocardial infarctions, unstable angina, or dysrhythmias. *Revascularization* means angioplasty (with or without stent placement) or bypass surgery.

(i) How do we calculate separate ischemic episodes? Reocclusion that occurs after a revascularization procedure but during the same hospitalization and that requires a second procedure during the same hospitalization will not be counted as another ischemic episode. If you are hospitalized for documented myocardial infarction and have a revascularization procedure during the same hospitalization, this event will be counted as one ischemic episode.

(ii) How do we evaluate ischemic episodes not amenable to revascularizations? If your ischemic episodes are not amenable to revascularization, we will evaluate them using the appropriate listing (for example, 4.04D). *Not amenable* means that the revascularization procedure could not be done because of another medical impairment or because the vessel was not suitable for revascularization.

d. We will use 4.04D only when you have symptoms due to myocardial ischemia as described in 4.00E3–4.00E7 while on a regimen of prescribed treatment, you are at risk for ETT (see 4.00C8), *and* we do not have a timely ETT or a timely normal drug-induced stress test for you. See 4.00C9 for what we mean by a timely test.

e. In 4.04D1, fractional flow reserve (FFR) is a measurement of the pressure differences across an obstructive lesion, giving an estimate of the severity of stenosis. An FFR measurement of 1.0 indicates normal blood flow. An FFR measurement equal to or less than 0.80 indicates stenosis capable of producing serious myocardial ischemia in an artery appropriate for revascularization. An FFR measurement that is greater than 0.80 indicates stenosis not likely to produce significant ischemia. FFR also helps define the adequacy of collateral flow that directly affects function in ischemic heart disease.

f. In 4.04D2, instantaneous wave-free ratio (iFR) measures the pressure ratio during a specified period of diastole when the coronary resistance is minimized and stable. An iFR value equal to or less than 0.89 indicates a hemodynamically significant stenosis that is appropriately treated with percutaneous coronary intervention.

g. In 4.04D3 and 4.04D4, the term ''nonbypassed'' means that the blockage is in a vessel that is potentially bypassable; that is, large enough to be bypassed and considered to be a cause of your ischemia. These vessels are usually major arteries or one of a major artery's major branches. A vessel that has become obstructed again after angioplasty or stent placement and has remained obstructed or is not amenable to another revascularization is considered a nonbypassed vessel for purposes of the listings. When you have had revascularization, we will not use the pre-operative findings to assess the current severity of your coronary artery disease under 4.04D, although we will consider the severity and duration of your impairment before your surgery in making our determination or decision.

F. How do we evaluate arrhythmias?

1. *What is an arrhythmia?* An *arrhythmia* is a change in the regular beat of the heart. Your heart may seem to skip a beat or beat irregularly, very quickly (tachycardia), or very slowly (bradycardia). Although we use the term *arrhythmia* in the listings, the term ''dysrhythmia'' may also be used in the medical evidence to describe this condition.

2. *What are the different types of arrhythmias?*

a. There are many types of arrhythmias. Arrhythmias are identified by where they occur in the heart (atria or ventricles) and by what happens to the heart's rhythm when they occur.

b. Arrhythmias arising in the cardiac atria (upper chambers of the heart) are called atrial or supraventricular arrhythmias. Ventricular arrhythmias begin in the ventricles (lower chambers). In general, ventricular arrhythmias caused by heart disease are the most serious.

3. *How do we evaluate arrhythmias using 4.05?*

a. We will use 4.05 when you have arrhythmias that are not fully controlled by medication, an implanted pacemaker, or an

implanted cardiac defibrillator, and you have recurrent episodes of syncope or near syncope. If your arrhythmias are controlled, we will evaluate your underlying heart disease using the appropriate listing. For other considerations when we evaluate arrhythmias in the presence of an implanted cardiac defibrillator, see 4.00F4.

b. We consider *near syncope* to be a period of altered consciousness, since *syncope* is a loss of consciousness or a faint. It is not merely a feeling of light-headedness, momentary weakness, or dizziness.

c. For purposes of 4.05, there must be a documented association between the syncope or near syncope and the recurrent arrhythmia. The recurrent arrhythmia, not some other cardiac or non-cardiac disorder, must be established as the cause of the associated symptom. This documentation of the association between the symptoms and the arrhythmia may come from the usual diagnostic methods, including Holter monitoring (also called ambulatory electrocardiography) and tilt-table testing with a concurrent ECG. Although an arrhythmia may be a coincidental finding on an ETT, we will not purchase an ETT to document the presence of a cardiac arrhythmia.

4. *What do we consider when you have an implanted cardiac defibrillator and you do not have arrhythmias that meet the requirements of 4.05?*

a. Implanted cardiac defibrillators are used to prevent sudden cardiac death in people who have had, or are at high risk for, cardiac arrest from life-threatening ventricular arrhythmias. The largest group at risk for sudden cardiac death consists of people with cardiomyopathy (ischemic or non-ischemic) and reduced ventricular function. However, life-threatening ventricular arrhythmias can also occur in people with little or no ventricular dysfunction. The shock from the implanted cardiac defibrillator rescues a person from what may have been cardiac arrest. However, as a consequence of the shock(s), similar to the effects of treatments for other cardiovascular disease, a person may experience psychological distress, which we may evaluate under the listings in 12.00.

b. Most implantable cardiac defibrillators have rhythm-correcting and pacemaker capabilities. In some people, these functions may result in the termination of ventricular arrhythmias without an otherwise painful shock. (The shock is like being kicked in the chest.) Implanted cardiac defibrillators may deliver inappropriate shocks, often repeatedly, in response to benign arrhythmias or electrical malfunction. Also, exposure to strong electrical or magnetic fields, such as from magnetic resonance imaging, can trigger or reprogram an implanted cardiac defibrillator, resulting in inappropriate shocks. We must consider the frequency of, and the reason(s) for, the shocks when evaluating the severity and duration of your impairment.

c. In general, the exercise limitations imposed on people with an implanted cardiac defibrillator are those dictated by the underlying heart impairment. However, the exercise limitations may be greater when the implanted cardiac defibrillator delivers an inappropriate shock in response to the increase in heart rate with exercise, or when there is exercise-induced ventricular arrhythmia.

G. How do we evaluate peripheral vascular disease?

1. *What is peripheral vascular disease (PVD)?* Generally, *PVD* is any impairment that affects either the arteries (peripheral artery disease) or the veins (venous insufficiency) in the extremities, particularly the lower extremities. The usual effect is blockage of the flow of blood either from the heart (arterial) or back to the heart (venous). If you have peripheral artery disease, you may have pain in your leg after walking a distance that goes away when you rest (intermittent claudication); at more advanced stages, you may have pain in your leg or foot at rest or you may develop ulceration or gangrene. Neuropathy may mask these typical symptoms. If you have venous insufficiency, you may have swelling, varicose veins, skin pigmentation changes, or skin ulceration.

2. *How do we assess limitations resulting from PVD?* We will assess your limitations based on your symptoms together with physical findings and Doppler studies or other appropriate diagnostic techniques. However, if the PVD has resulted in amputation, we will evaluate any limitations related to the amputation under the listings in 1.00.

3. *What is brawny edema? Brawny edema* (4.11A) is swelling that is usually dense and feels firm due to the presence of increased connective tissue; it is also associated with characteristic skin pigmentation changes. It is not the same thing as pitting edema. Brawny edema generally does not pit (indent on pressure), and the terms are not interchangeable. Pitting edema does not satisfy the requirements of 4.11A.

4. *What is lymphedema and how do we evaluate it?*

a. *Lymphedema* is edema of the extremities due to a disorder of the lymphatic circulation; at its worst, it is called elephantiasis. Primary lymphedema is caused by abnormal development of lymph vessels and may be present at birth (congenital lymphedema), but more often develops during the teens (lymphedema praecox). It may also appear later, usually after age 35 (lymphedema tarda). Secondary lymphedema is due to obstruction or destruction of normal lymphatic channels due to tumor, surgery, repeated infections, or parasitic infection such as filariasis. Lymphedema most commonly affects one extremity. Symptoms of lymphedema include but are not limited to swelling in an extremity, changes in skin, and pain or sensory changes in the affected area. The symptoms may limit movement in affected joints.

b. Lymphedema does not meet the requirements of 4.11, although it may medically equal the listing. We evaluate lymphedema by considering whether the underlying cause meets or medically equals any listing, or whether the lymphedema medically equals a cardiovascular disorders listing such as 4.11 or a listing in 1.00 or 14.00. If no listing is met or medically equaled, we evaluate any functional limitations imposed by your lymphedema when we assess your residual functional capacity.

5. *When will we purchase exercise Doppler studies for evaluating peripheral artery disease (PAD)?* If we need additional evidence of your PAD, we will generally purchase exercise Doppler studies (see 4.00C16 and 4.00C17) when your resting ankle-brachial index is at least 0.50 but less than 0.80, and only rarely when it is 0.80 or above. We will not purchase exercise Doppler testing if you have a disease that results in abnormal arterial calcification or small vessel disease, but will use your resting toe systolic blood pressure or resting toe-brachial index. (See 4.00G7c and 4.00G8.) There are no current medical standards for evaluating exercise toe pressures. Because any exercise test stresses your entire cardiovascular system, we will purchase exercise Doppler studies only after an MC, preferably one with experience in the care of patients with cardiovascular disease, has determined that the test would not present a significant risk to you and that there is no other medical reason not to purchase the test (see 4.00C6, 4.00C7, and 4.00C8).

6. *Are there any other studies that are helpful in evaluating PAD?* Doppler studies done using a recording ultrasonic Doppler unit and strain-gauge or air plethysmography are other useful tools for evaluating PAD. A recording Doppler, which prints a tracing of the arterial pulse wave in the femoral, popliteal, dorsalis pedis, and posterior tibial arteries, is an evaluation tool that compares waveforms in normal and compromised peripheral blood flow. Qualitative analysis of the Doppler waveforms and plethysmographic tracings is helpful in the overall assessment of the severity of the occlusive disease. Tracings help in assessing severity if you have small vessel disease related to diabetes mellitus or other diseases with similar vascular changes, or diseases causing medial calcifications when ankle pressure is either normal or falsely high. When there is evidence of medial calcification of the ankle arteries or the ankle-brachial index is 0.50 or greater, other appropriate tests for PAD include magnetic resonance angiography, computed tomography angiography, contrast angiography, and graded treadmill tests.

7. *How do we evaluate PAD under 4.12?*

a. The ankle blood pressure referred to in 4.12A and B is the higher of the pressures recorded from the posterior tibial and dorsalis pedis arteries in the affected leg. The higher pressure recorded from the two sites is the more significant measurement in assessing the extent of arterial insufficiency. Techniques for obtaining ankle systolic blood pressures include Doppler (See 4.00C16 and 4.00C17), plethysmographic studies, or other techniques. We will request any available tracings generated by these studies so that we can review them.

b. In 4.12A, the ankle-brachial index is the ratio of the systolic blood pressure at the ankle to the systolic blood pressure at the brachial artery; both taken at the same time

while you are lying on your back. We do not require that the ankle and brachial pressures be taken on the same side of your body. This is because, as with the ankle pressure, we will use the higher brachial systolic pressure measured. The criterion in 4.12A is met when your resting ankle-brachial index is less than 0.50. If your resting ankle-brachial index is 0.50 or above, we will use 4.12B to evaluate the severity of your PAD, unless you also have a disease causing abnormal arterial calcification or small vessel disease, such as diabetes mellitus. See 4.00G7c and 4.00G8.

c. We will use resting toe systolic blood pressures or resting toe-brachial indices (determined the same way as the ankle-brachial index, see 4.00G7b) when you have intermittent claudication and a disease that results in abnormal arterial calcification (for example, Monckeberg's sclerosis or diabetes mellitus) or small vessel disease (for example, diabetes mellitus). These diseases may result in misleadingly high blood pressure readings at the ankle. However, high blood pressures due to vascular changes related to these diseases seldom occur at the toe level. While the criteria in 4.12C and 4.12D are intended primarily for people who have a disease causing abnormal arterial calcification or small vessel disease, we may also use them for evaluating anyone with PAD.

8. *How are toe pressures measured?* Toe pressures are measured routinely in most vascular laboratories through one of three methods: most frequently, photoplethysmography; less frequently, plethysmography using strain gauge cuffs; and Doppler ultrasound. Toe pressure can also be measured by using any blood pressure cuff that fits snugly around the big toe and is neither too tight nor too loose. A neonatal cuff or a cuff designed for use on fingers or toes can be used in the measurement of toe pressure.

9. *How do we use listing 4.12 if you have had a peripheral graft or stenting?* Peripheral grafting serves the same purpose as coronary grafting; that is, to bypass a narrow or obstructed arterial segment. If intermittent claudication recurs or persists after peripheral grafting, we may purchase Doppler studies to assess the flow of blood through the bypassed vessel and to establish the current severity of the peripheral artery impairment. However, if you have had peripheral grafting or stenting done for your PAD, we will not use the findings from before the surgery to assess the current severity of your impairment, although we will consider the severity and duration of your impairment prior to your surgery in making our determination or decision.

H. How do we evaluate congenital heart disease?

1. *What is congenital heart disease?* Congenital heart disease is any abnormality of the heart or the major blood vessels that is present at birth. Congenital heart disease includes abnormal structure of the individual heart chambers, valves, and blood vessels, and abnormal relative relationship of the chambers to each other that alters the normal pattern of blood flow. Surgery in childhood is the usual treatment, and with improving surgical techniques and medical management, more children with congenital heart disease are surviving into adulthood. Rarely, a person with congenital heart disease may not have received the usual surgery in childhood, and later, as an adult, they are no longer a surgical candidate, as for example, in Eisenmenger syndrome.

2. *What is Eisenmenger syndrome?* Eisenmenger syndrome refers to any surgically untreated congenital heart defect with intracardiac communication that over time leads to pulmonary hypertension, reversal of blood flow, and hypoxemia.

a. Lesions in Eisenmenger syndrome, such as large septal defects, are characterized by elevated pulmonary pressures or a high pulmonary flow rate. In response, the pulmonary blood vessels pathologically change, leading eventually to pulmonary hypertension. Development of Eisenmenger syndrome represents a point at which pulmonary hypertension is irreversible and the cardiac lesion is likely inoperable.

b. Examples of congenital heart disease that if untreated may cause pulmonary vascular disease leading to Eisenmenger syndrome include atrial septal defect (ASD), ventricular septal defect (VSD), and large patent ductus arteriosus (PDA).

3. *What is single ventricle?* The term ''single ventricle'' (also known as ''single ventricle physiology'' or ''functional single ventricle'') describes a diverse group of congenital cardiac anomalies sharing the common feature that only one of the two heart ventricles is adequately developed. At birth, one ventricle must functionally do the work of two, pumping blood for both the body (systemic) and the lungs (pulmonary). Because of this feature, the ultimate plan for cardiac reconstruction is similar for most of these anomalies. People with single ventricle will generally undergo staged reconstructive ''Fontan procedures,'' ultimately resulting in a ''Fontan circulation.'' Fontan circulation describes the hemodynamic state in which virtually all systemic venous return-blood passively flows directly into the pulmonary arteries via surgical or catheter-placed shunts, without the blood passing through a ventricle. The Fontan circulation results in difficulties augmenting, and sometimes maintaining, cardiac output. Some of the anomalies described as single ventricle include the following:

(a) Hypoplastic left heart syndrome;
(b) Hypoplastic right ventricle;
(c) Tricuspid valve atresia;
(d) Pulmonary atresia with intact ventricular septum;
(e) Double inlet left ventricle; and
(f) Some variations of double outlet right ventricle.

4. *How do we evaluate conditions associated with congenital heart disease?*

a. We evaluate congenital heart disease that results in chronic heart failure with evidence of ventricular dysfunction or in recurrent arrhythmias under 4.02 or 4.05, respectively. Otherwise, we evaluate your impairment under 4.06.

b. We evaluate pulmonary hypertension due to congenital heart disease under 4.06B or 4.06C. We evaluate pulmonary hypertension not due to congenital heart disease under the listings in 3.00 (for example, 3.09).

c. We need pulse oximetry measurements documented by medical sources using methods consistent with the prevailing state of medical knowledge and clinical practice to evaluate chronic hypoxemia in congenital heart disease under 4.06A3. These pulse oximetry measurements also must be consistent with the other evidence in the case record.

d. We evaluate single ventricle physiology under 4.06D and will consider you disabled if your medical evidence documents that you have any congenital heart disorder that results in single ventricle physiology (functional single ventricle). In addition to the above congenital heart disorders, examples of palliative surgical procedures that indicate single ventricle physiology include the Glenn, Fontan, and Norwood procedures.

I. How do we evaluate other cardiovascular disorders?

1. *How do we evaluate hypertension? Hypertension* (high blood pressure) over time may significantly raise the pressures in the heart to the point of ineffective heart muscle function known generally as hypertensive heart disease that we can evaluate under 4.02. Other body systems, such as the brain, kidneys, or eyes may also be affected. We evaluate these impairments by reference to the specific body system(s) that is affected. We will also consider any limitations imposed by your hypertension when we assess your residual functional capacity.

2. *What is cardiomyopathy and how do we evaluate it*? *Cardiomyopathy* is a disease of the heart muscle. The heart loses its ability to pump blood (heart failure), and in some instances, heart rhythm is disturbed, leading to irregular heartbeats (arrhythmias). Usually, the exact cause of the muscle damage is never found (idiopathic cardiomyopathy).

a. There are various types of cardiomyopathy, which fall into two major categories: ischemic and nonischemic cardiomyopathy. Ischemic cardiomyopathy typically refers to heart muscle damage that results from coronary artery disease, including heart attacks. Nonischemic cardiomyopathy includes, but is not limited to several types: dilated, hypertrophic, restrictive, and arrhythmogenic. Cardiomyopathy includes hypertrophic cardiomyopathy, endomyocardial fibrosis, or cardiac amyloidosis AL (light-chain) type.

b. We evaluate cardiomyopathy under 4.08. Depending on the underlying cause of the cardiomyopathy or its effects on you, we may also evaluate your cardiomyopathy under 4.02, 4.04, or 4.05. If your cardiomyopathy results in vascular insult to the brain, we may also evaluate it under 11.04.

c. Under 4.08A1a, we need a conclusion from a medical source that the performance of an exercise test would present a significant risk to you. If your case record does not have a conclusion from a medical source that an exercise test would present a significant risk to you, an MC as defined in 4.00A3a may make such a conclusion if evidence in your case record supports it.

3. *How do we evaluate valvular heart disease?* We evaluate aortic valvular disease

under 4.07. We may also evaluate aortic valvular disease, as well as other forms of valvular disease, under 4.02, 4.04, 4.05, 4.06, or a listing in 11.00, depending on its effects on you.

4. *What do we consider when we evaluate heart transplant recipients?*

a. After your heart transplant, we will consider you disabled under 4.09 for 1 year following the surgery because there is a greater likelihood of rejection of the organ and infection during the first year. If you develop cardiac allograft vasculopathy after your transplant, we will evaluate this impairment under 4.16.

b. However, heart transplant patients generally meet our definition of disability before they undergo transplantation. We will determine the onset of your disability based on the facts in your case.

c. We will not assume that you became disabled when your name was placed on a transplant waiting list. This is because you may be placed on a waiting list soon after diagnosis of the cardiac disorder that may eventually require a transplant. Physicians recognize that candidates for transplantation often have to wait months or even years before a suitable donor heart is found, so they place their patients on the list as soon as permitted.

d. When we do a continuing disability review to determine whether you are still disabled, we will evaluate your residual impairment(s), as shown by the evidence in your case record, including any side effects of medication. We will consider all evidence indicative of cardiac dysfunction in deciding whether medical improvement (as defined in §§ 404.1594 and 416.994 of this chapter) has occurred.

5. *What is cardiac allograft vasculopathy and how do we evaluate it? Cardiac allograft vasculopathy* (CAV) may affect a person who has received a heart transplant and involves thickening in the walls of the coronary arteries that may progress quickly into serious vascular stenosis and heart dysfunction. Stenosis in CAV is caused by a pathological process different from classic atherosclerosis and treatment often is only palliative. We evaluate CAV under 4.16.

6. *When does an aneurysm have ''dissection not controlled by prescribed treatment,'' as required under 4.10?* An aneurysm (or bulge in the aorta or one of its major branches) is *dissecting* when the inner lining of the artery begins to separate from the arterial wall. We consider the dissection not controlled when you have persistence of chest pain due to progression of the dissection, an increase in the size of the aneurysm, or compression of one or more branches of the aorta supplying the heart, kidneys, brain, or other organs. An aneurysm with dissection can cause heart failure, renal (kidney) failure, or neurological complications. If you have an aneurysm that does not meet the requirements of 4.10 and you have one or more of these associated conditions, we will evaluate the condition(s) using the appropriate listing.

7. *What is hyperlipidemia and how do we evaluate it? Hyperlipidemia* is the general term for an elevation of any or all of the lipids (fats or cholesterol) in the blood; for example, hypertriglyceridemia, hypercholesterolemia, and hyperlipoproteinemia. These disorders of lipoprotein metabolism and transport can cause defects throughout the body. The effects most likely to interfere with function are those produced by atherosclerosis (narrowing of the arteries) and coronary artery disease. We will evaluate your lipoprotein disorder by considering its effects on you.

8. *What is Marfan syndrome and how do we evaluate it?*

a. *Marfan syndrome* is a genetic connective tissue disorder that affects multiple body systems, including the skeleton, eyes, heart, blood vessels, nervous system, skin, and lungs. There is no specific laboratory test to diagnose Marfan syndrome. The diagnosis is generally made by medical history (including family history), physical examination (including an evaluation of the ratio of arm/leg size to trunk size), a slit lamp eye examination, and a heart test(s) (such as an echocardiogram). In some cases, a genetic analysis may be useful, but such analyses may not provide any additional helpful information.

b. The effects of Marfan syndrome can range from mild to severe. In most cases, the disorder progresses as you age. Most people with Marfan syndrome have abnormalities associated with the heart and blood vessels. Your heart's mitral valve may leak, causing a heart murmur. Small leaks may not cause symptoms, but larger ones may cause shortness of breath, fatigue, and palpitations. Another effect is that the wall of the aorta may be weakened and abnormally stretch (aortic dilation). This aortic dilation may tear, dissect, or rupture, causing serious heart problems or sometimes sudden death. We will evaluate the cardiovascular manifestations of your Marfan syndrome under the appropriate criteria, such as 4.10, or, if necessary, consider the functional limitations imposed by your impairment.

c. Other genetic connective tissue disorders, such as Loeys-Dietz syndrome or Ehlers-Danlos syndrome, may have abnormalities associated with the heart and blood vessels. We will evaluate the cardiovascular manifestations of your genetic connective tissue disorder under the appropriate criteria, such as 4.10, or, if necessary, consider the functional limitations imposed by your impairment.

J. How do we evaluate other issues that affect the cardiovascular system?

1. *How do we consider the effects of obesity when we evaluate your cardiovascular disorder? Obesity* is a medically determinable impairment that may be associated with cardiovascular disorders. The additional body mass may make it harder for the chest and lungs to expand or may cause the heart to work harder to pump blood to carry oxygen to the body. The combined effects of obesity with a cardiovascular disorder can be greater than the effects of each of the impairments considered separately. We consider the additional and cumulative effects of obesity when we determine whether you have a severe cardiovascular disorder, a listing-level cardiovascular disorder, a combination of impairments that medically equals the severity of a listed impairment, and when we assess your residual functional capacity.

2. *How do we relate treatment to functional status?* In general, conclusions about the severity of a cardiovascular disorder cannot be made on the basis of the type of treatment rendered or anticipated. The amount of function restored and the time required for improvement after treatment (medical, surgical, or a prescribed program of progressive physical activity) vary with the nature and extent of the disorder, the type of treatment, and other factors. Depending upon the timing of this treatment in relation to the alleged onset date of disability, we may need to defer evaluation of the impairment for a period of up to 3 months from the date treatment began to permit consideration of treatment effects, unless we can make a determination or decision using the evidence we have. See 4.00B4.

3. *How do we consider hospitalizations?* When we evaluate hospitalizations for chronic heart failure (4.02B3), ischemic heart disease (4.04E), congenital heart disease (4.06E), and cardiomyopathy (4.08D), the hospitalizations do not all have to be for the same cardiovascular disorder(s). They may be for three different exacerbations or complications resulting from your cardiovascular disorder. The hospitalizations must be at least 30 days apart, and each one must last at least 48 hours, including hours in a hospital emergency department immediately before the hospitalization.

K. How do we evaluate cardiovascular disorders that do not meet one of these listings?

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

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

4.01 Category of Impairments, Cardiovascular Disorders

4.02 *Chronic heart failure* (see 4.00D) while on a regimen of prescribed treatment, with symptoms and signs described in 4.00D2. The required level of severity for this impairment is met when the requirements are satisfied by A and B; or C alone; or D alone.

A. Medically documented presence of one of the following:

1. Heart failure with reduced ejection fraction documented by appropriate medically acceptable imaging during a period of stability (not during an episode of exacerbation of heart failure), with either a. or b.

a. Left ventricular end diastolic dimension greater than 6.8 cm for males or 6.1 cm for females during a period of stability (not during an episode of exacerbation of heart failure); or

b. Ejection fraction of 30 percent or less during a period of stability (not during an episode of exacerbation of heart failure); OR

2. Heart failure with preserved ejection fraction documented by appropriate medically acceptable imaging during a period of stability (not during an episode of exacerbation of heart failure), with either a. or b.

a. Left ventricular posterior wall plus septal thickness totaling 2.5 cm or greater, with an enlarged left atrium greater than or equal to 4.5 cm, or

b. Left atrial volume index (LAVI) greater than or equal to 40 ml, BSA/m^2 (milliliters to body surface area in squared meters).

AND

B. Resulting in one of the following:

1. Recurrent (see 4.00A3c) symptoms of heart failure, resulting in both a and b:

a. A medical source (see 4.00D4c(i)) has concluded that the performance of an exercise test would present a significant risk to the person; and

b. Very serious limitation in the ability to perform activities of daily living independently, appropriately, effectively, and on a sustained basis; or

2. Inability to perform on an exercise tolerance test at a workload equivalent to 5 METs or less if using a standard treadmill (or bicycle) test without gas exchange, or at 15 ml/kg/min peak VO_2 (oxygen consumption) on a cardiopulmonary exercise test, due to either a or b.

a. Dyspnea, fatigue, palpitations, or chest discomfort; or

b. Decrease of 10 mmHg or more in systolic pressure below the baseline systolic blood pressure or the preceding systolic pressure measured during exercise (see 4.00D4d) due to left ventricular dysfunction, despite an increase in workload; or

3. Exacerbations or complications of chronic heart failure (see 4.00D1b) requiring three hospitalizations within a consecutive 12-month period (see 4.00A3e) and at least 30 days apart. Each hospitalization must last at least 48 hours, including hours in a hospital emergency department immediately before the hospitalization (see 4.00J3);

OR

C. Heart failure with left ventricular ejection fraction of 20 percent or less while on a regimen of prescribed therapy, on two evaluations at least 90 days apart within a consecutive 12-month period (see 4.00A3e) during a period of stability (not during an episode of exacerbation of heart failure);

OR

D. One of the following while hospitalized, at home, or both:

1. An implanted mechanical circulatory support device except extracorporeal membrane oxygenation (ECMO) (see 4.00D4e). Consider under a disability for 1 year from the date of implantation; after that, evaluate any residual impairment(s) under the criteria for the affected body system.

2. Continuous intravenous administration of inotropic medication (for example, milrinone) for at least 30 consecutive days. Consider under a disability for 1 year from the date of initiation of the treatment; after that, evaluate any residual impairment(s) under the criteria for the affected body system.

4.03 [Reserved]

4.04 *Ischemic heart disease* (see 4.00E), with symptoms due to myocardial ischemia, while on a regimen of prescribed treatment (see 4.00B3 if there is no regimen of prescribed treatment), with A, B, C, D, or E:

A. Inability to perform on an exercise tolerance test at a workload equivalent to 5 METs or less with findings interpreted by an acceptable medical source as positive for ischemia (see 4.00E9b).

OR

B. Ischemic response with exercise or pharmacological (drug-induced) stress testing (see 4.00C14) on medically appropriate imaging, with either 1 or 2:

1. At least two reversible or fixed regional myocardial perfusion defects and either a or b:

a. Transient ischemic dilatation; or

b. Resting left ventricular ejection fraction of less than 50 percent; or

2. At least two reversible or fixed regional wall motion abnormalities and either a or b:

a. Decrease in left ventricular ejection fraction during testing; or

b. Resting left ventricular ejection fraction of less than 50 percent.

OR

C. Documentation of three separate ischemic episodes (see 4.00E9c) requiring unplanned hospitalization (inpatient or observation status) within a consecutive 12-month period (see 4.00A3e).

OR

D. Coronary artery disease, documented by coronary angiography (obtained independently of Social Security disability evaluation) with 1, 2, 3 or 4:

1. Fractional flow reserve (FFR) (see 4.00E9e) measurement of equal to or less than 0.80 of a proximal segment or mid segment coronary artery not amenable to revascularization (see 4.00E9c(ii)).

2. Instantaneous wave-free ratio (iFR) (see 4.00E9f) measurement of equal to or less than 0.89 of a proximal segment or mid segment coronary artery not amenable to revascularization (see 4.00E9c(ii)).

3. History of coronary artery bypass graft surgery with manifestations of ischemia, as described in 4.00E3–4.00E7, while on a regimen of prescribed treatment (see 4.00B3 if there is no regimen of prescribed treatment) with a, b, c, or d:

a. 50 percent or more stenosis of a nonbypassed left main coronary artery; or

b. 70 percent or more stenosis in the proximal segment or mid segment of another nonbypassed coronary artery; or

c. 50 percent or more stenosis in the proximal segment or mid segment of at least two nonbypassed coronary arteries; or

d. 70 percent or more stenosis of a bypass graft vessel.

4. Resting left ventricular ejection fraction of less than 50 percent while medically stable (see 4.00B4) with manifestations of ischemia, as described in 4.00E3–4.00E7, while on a regimen of prescribed treatment (see 4.00B3 if there is no regimen of prescribed treatment) with a, b, or c:

a. 50 percent or more stenosis of a nonbypassed left main coronary artery; or

b. 70 percent stenosis in the proximal segment or mid segment of another nonbypassed coronary artery; or

c. 50 percent or more stenosis in the proximal segment or mid segment of at least two nonbypassed coronary arteries.

OR

E. Exacerbations or complications of ischemic heart disease (see 4.00E2–4.00E7) requiring three hospitalizations within a consecutive 12-month period (see 4.00A3e) and at least 30 days apart. Each hospitalization must last at least 48 hours, including hours in a hospital emergency department immediately before the hospitalization (see 4.00J3).

4.05 *Recurrent arrhythmias* (see 4.00F), not related to reversible causes such as electrolyte abnormalities or digitalis glycoside or antiarrhythmic drug toxicity, while on a regimen of prescribed treatment (see 4.00B3 if there is no prescribed treatment), demonstrated by both A and B:

A. Coincident with recurrent (see 4.00A3c) episodes of cardiac syncope or near syncope (see 4.00F3b).

AND

B. Documented by either 1 or 2:

1. Resting or ambulatory (Holter) electrocardiography; or

2. Other appropriate medically acceptable testing.

4.06 *Congenital heart disease* (see 4.00H), documented by appropriate medically acceptable imaging (see 4.00A3d) or cardiac catheterization, with A, B, C, D, or E:

A. Chronic hypoxemia, and 1, 2, or 3:

1. Hematocrit of 55 percent or greater on two evaluations at least 90 days apart within a consecutive 12-month period (see 4.00A3e); or

2. Arterial blood gas test measurement obtained at rest while breathing room air, as described in either a or b:

a. S_aO_2 (arterial oxygen saturation) less than or equal to 89 percent; or

b. PO_2 or P_aO_2 (partial pressure of oxygen) less than or equal to 60 mmHg; or

3. S_pO_2 (percentage of oxygen saturation of blood hemoglobin) measured by pulse oximetry either at rest, during a 6-minute walk test (6MWT), or after a 6MWT, while breathing room air, less than or equal to 87 percent on three evaluations at least 30 days apart within a consecutive 12-month period (see 4.00A3e).

OR

B. Intermittent right-to-left shunting (for example, Eisenmenger syndrome; see 4.00H2) during cardiopulmonary exercise testing while breathing room air, resulting in oxygen desaturation on exertion at a workload equivalent to 5 METs or less, or peak VO_2 (oxygen uptake) of 15.0 ml/kg/min or less, *and* arterial blood gas test measurement, with either 1 or 2:

1. S_aO_2 less than or equal to 89 percent; or
2. PO_2 or P_aO_2 less than or equal to 60 mmHg.

OR

C. Pulmonary hypertension documented by cardiac catheterization while medically stable, as described in 1, 2, or 3:

1. Pulmonary arterial systolic pressure elevated to at least 70 percent of the systemic arterial systolic pressure; or
2. Pulmonary arterial systolic pressure equal to or greater than 70 mmHg; or
3. Mean pulmonary artery pressure equal to or greater than 40 mmHg.

OR

D. Single ventricle (with or without Fontan procedures) (see 4.00H3).

OR

E. Exacerbations or complications of congenital heart disease (see 4.00J3) requiring three hospitalizations within a consecutive 12-month period (see 4.00A3e) and at least 30 days apart. Each hospitalization must last at least 48 hours, including hours in a hospital emergency department immediately before the hospitalization (see 4.00J3).

4.07 *Aortic valvular disease* (see 4.00I3), with symptoms due to stenosis, determined by appropriate test or tests showing an aortic valve area of less than 1.0 cm^2.

4.08 *Cardiomyopathy* (see 4.00I2) while on a regimen of prescribed treatment, with A, B, C, or D:

A. Hypertrophic cardiomyopathy documented by appropriate medically acceptable imaging, with left ventricular or septal wall thickness equal to or greater than 20 mm in the absence of other causes of left ventricular hypertrophy (for example, hypertension or aortic valvular disease) and either 1 or 2:

1. Recurrent (see 4.00A3c) symptoms of cardiomyopathy, resulting in both a and b:

a. A medical source (see 4.00I2c) has concluded that the performance of an exercise tolerance test would present a significant risk to the person; and

b. Very serious limitation in the ability to perform activities of daily living independently, appropriately, effectively, and on a sustained basis; or

2. Inability to perform on an exercise tolerance test at a workload equivalent to 5 METs or less if using a standard treadmill (or bicycle) test without gas exchange, or at 15 ml/kg/min peak VO_2 (oxygen consumption) on a cardiopulmonary exercise test.

OR

B. Endomyocardial fibrosis documented by appropriate medically acceptable imaging, with 1, 2, and 3:

1. Loss of chamber volume due to fibrosis of the endocardium of at least one ventricle; and
2. Right or left atrial dilatation (chamber enlargement); and
3. Regurgitant (backward) blood flow through the mitral or tricuspid valve.

OR

C. Cardiac amyloidosis AL (light-chain) type documented by biopsy.

OR

D. Exacerbations or complications of cardiomyopathy requiring three hospitalizations within a consecutive 12-month period (see 4.00A3e) and at least 30 days apart. Each hospitalization must last at least 48 hours, including hours in a hospital emergency department immediately before the hospitalization (see 4.00J3).

4.09 *Heart transplantation* (see 4.00I4). Consider under a disability for 1 year from the date of the transplant; after that, evaluate the residual impairment(s).

4.10 *Dissecting aneurysm of the aorta or major branches* (see 4.00I6), due to any cause (for example, atherosclerosis, cystic medial necrosis, Marfan syndrome, or trauma), with A and B:

A. Documented by appropriate medically acceptable imaging.

AND

B. Dissection not controlled by prescribed treatment.

4.11 *Chronic venous insufficiency* (see 4.00G) of a lower extremity with reflux or obstruction of the venous system documented by duplex ultrasound or other appropriate diagnostic technique, with A or B:

A. Extensive trophic changes of skin (for example, hyperpigmentation, lipodermatosclerosis, brawny edema) involving at least two-thirds of the leg below the knee, on two evaluations at least 90 days apart within a consecutive 12-month period (see 4.00A3e), with both 1 and 2:

1. Consistent with chronic venous insufficiency; and
2. Unresponsive to compression therapy.

OR

B. Two or more episodes of ulceration that have not healed following at least 6 months of prescribed treatment.

4.12 *Peripheral artery disease* (see 4.00G7) while on a regimen of prescribed treatment resulting in intermittent claudication or leg pain that interferes with mobility (see 4.00G1), with A, B, C, or D, as determined by an appropriate test(s) (see 4.00G5–4.00G6):

A. Resting ankle-brachial index of less than 0.50 (see 4.00G7b).

OR

B. Decrease in systolic blood pressure at the ankle on exercise test (see 4.00G7a) of 50 percent or more of the pre-exercise level and requiring 10 minutes or more to return to pre-exercise level.

OR

C. Resting toe systolic pressure of less than 30 mmHg (see 4.00G7c and 4.00G8).

OR

D. Resting toe-brachial index of less than 0.40 (see 4.00G7c).

4.13–4.15 [Reserved]

4.16 *Cardiac allograft vasculopathy* (see 4.00I5), documented by appropriate medically acceptable imaging (for example, intravascular ultrasonography or coronary angiography) (see 4.00A3d), with A, B, C, or D:

A. Cardiac index (CI) or cardiac output (CO) less than 2 l/min/m^2.

OR

B. Left ventricular ejection fraction equal to or less than 45 percent.

OR

C. Right atrial pressure (RAP) greater than 12 mmHg.

OR

D. Pulmonary capillary wedge pressure (PCWP) greater than 15 mmHg.

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Part B

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Sec.

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104.00 Cardiovascular Disorders

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104.00 CARDIOVASCULAR DISORDERS

A. How do we define cardiovascular disorders and cardiovascular terms?

1. *What do we mean by a cardiovascular disorder?*

a. We mean any disorder that affects the proper functioning of the heart or the circulatory system (that is, arteries, veins, capillaries, and the lymphatic drainage). The disorder can be congenital or acquired.

b. Cardiovascular disorders result from one or more of four consequences of heart disease:

(i) Chronic heart failure (chronic HF) or ventricular dysfunction.

(ii) Discomfort or pain due to myocardial ischemia, with or without necrosis of the heart muscle.

(iii) Syncope, or near syncope, due to inadequate cerebral perfusion from any cardiac cause, such as obstruction of flow or disturbance in rhythm or conduction resulting in inadequate cardiac output.

(iv) Hypoxemia (reduced oxygen concentration in the blood) due to right-to-left shunt, or pulmonary vascular disease.

c. Disorders of the veins or arteries (for example, obstruction, rupture, or aneurysm) may cause impairments of the lower extremities (peripheral vascular disease), the central nervous system, the eyes, the kidneys, and other organs. We will evaluate peripheral vascular disease under 4.11 or 4.12 in part A, and impairments of another body system(s) under the listings for that body system(s).

2. *What do we consider in evaluating cardiovascular disorders?* The listings in this section describe cardiovascular disorders based on the medical and other evidence, including response to a regimen of prescribed treatment and functional limitations.

3. *What do the following terms or phrases mean in these listings?*

a. *Medical consultant* is a person defined in § 416.1016(a) of this chapter. This term does not include medical sources who provide consultative examinations for us. We use the abbreviation ''MC'' throughout this section to designate a medical consultant.

b. *Persistent* means that the longitudinal clinical record shows that, with few exceptions, the required finding(s) has been present, or is expected to be present, for a continuous period of at least 12 months, such that a pattern of continuing severity is established. By ''exceptions,'' we mean brief periods when the required finding(s) is greatly reduced or gone. These periods are so brief or inconsequential, the required finding(s) remains a factor in the person's condition.

c. *Recurrent* means that the longitudinal clinical record shows that, within a

consecutive 12-month period, the finding(s) occurs at least three times, with intervening periods of improvement of sufficient duration that it is clear that separate events are involved. By ''improvement of sufficient duration,'' we mean the finding is greatly reduced or not present for long enough that the required finding(s) is no longer a factor in the person's condition.

d. *Appropriate medically acceptable imaging* means that the technique used is the proper one to evaluate and diagnose the impairment and is commonly recognized as accurate for assessing the cited finding.

e. *A consecutive 12-month period* means a period of 12 consecutive months, all or part of which must occur within the period we are considering in connection with an application or continuing disability review.

B. What documentation do we need to evaluate cardiovascular disorders?

1. *What basic documentation do we need?* We need sufficiently detailed reports of history, physical examinations, laboratory studies, and any prescribed treatment and response to allow us to assess the severity and duration of your cardiovascular disorder. A longitudinal clinical record covering a period of not less than 3 months of observations and treatment is usually necessary, unless we can make a determination or decision based on the current evidence we already have.

2. *Why is a longitudinal clinical record important?* We will usually need a longitudinal clinical record to assess the severity and expected duration of your impairment(s). If you have a listing-level impairment, you probably will have received medically prescribed treatment. Whenever there is evidence of such treatment, your longitudinal clinical record should include a description of the ongoing management and evaluation provided by your medical source(s). It should also include your response to this medical management, as well as information about the nature and severity of your impairment. The record will provide us with information on your functional status over an extended period of time and show whether your ability to function is improving, worsening, or unchanging.

3. *What if you have not received ongoing medical treatment?*

a. You may not have received ongoing treatment or have an ongoing relationship with the medical community despite the existence of a severe impairment(s). In this situation, we will base our evaluation on the current evidence we have. If you do not receive treatment, you cannot show an impairment that meets the criteria of these listings. However, we may find you disabled because you have another impairment(s) that, in combination with your cardiovascular disorder, medically equals a listing or functionally equals the listings.

b. Unless we can decide your claim favorably on the basis of the current evidence we already have, a longitudinal record is still important. In instances when there is no or insufficient longitudinal evidence, we may purchase a consultative examination(s) to help us establish the existence, severity, and duration of your impairment.

4. *When will we wait before we ask for more evidence?*

a. We will wait when we have information showing that your impairment is not yet stable and the expected change in your impairment might affect our determination or decision. In these situations, we need to wait to properly evaluate the severity and duration of your impairment during a stable period. Examples of when we might wait are:

(i) If you have had a recent acute event; for example, acute heart failure.

(ii) If you have recently had a corrective cardiac procedure; for example, open-heart surgery.

(iii) If you have started new drug therapy and your response to this treatment has not yet been established; for example, beta-blocker therapy for dilated cardiomyopathy.

b. In these situations, we will obtain more evidence 3 months following the event before we evaluate your impairment. However, we will not wait if we have enough information to make a determination or decision based on all of the relevant evidence in your case.

5. *Will we purchase any studies?* In appropriate situations, we may purchase studies necessary to substantiate the existence of a medically determinable impairment or to document the severity of your impairment, generally after we have evaluated the evidence we already have. We will not purchase studies involving exercise testing if there is significant risk involved or if there is another medical reason not to perform the test. We will follow sections 4.00C6, 4.00C7, 4.00C8 in part A, and 104.00B7, when we decide whether to purchase exercise testing. We will make a reasonable effort to obtain any additional studies from a qualified medical source in an office or center experienced in pediatric cardiac assessment. (See § 416.919g of this chapter.)

6. *What studies will we not purchase?* We will not purchase any studies involving cardiac catheterization, such as coronary angiography, arteriograms, or electrophysiological studies. However, if the results of a catheterization are part of the existing evidence we have, we will consider them together with the other relevant evidence. See 4.00C15a in part A.

7. *Will we use exercise tolerance tests (ETT) for evaluating children with cardiovascular disorders?*

a. ETTs, though increasingly used, are still less frequently indicated in children than in adults, and can rarely be performed successfully by children under 6 years of age. An ETT may be of value in the assessment of some arrhythmias, and may be considered in 104.05B2. ETTs may also be used in the assessment of the severity of chronic heart failure and in the assessment of recovery of function following cardiac surgery or other treatment.

b. We will purchase an ETT only if we cannot make a determination or decision based on the evidence we have and an MC, preferably one with experience in the care of children with cardiovascular disorders, has determined that an ETT is needed to evaluate your impairment. We will not purchase an ETT if you are less than 6 years of age. If we do purchase an ETT for a child age 12 or younger, it must be performed by a qualified medical source in a specialty center for pediatric cardiology or other facility qualified to perform exercise tests of children.

c. For full details on ETT requirements and usage, see 4.00C3 in part A.

C. How do we evaluate chronic heart failure?

1. *What is chronic heart failure (chronic HF)?*

a. *Heart failure* is the inability of the heart to pump enough oxygenated blood to body tissues. This syndrome is characterized by symptoms and signs of pulmonary or systemic congestion (fluid retention) or limited cardiac output. Certain laboratory findings of cardiac functional and structural abnormality support the diagnosis of chronic HF. Heart failure can range from low ejection fraction due to muscle dysfunction to preserved ejection fraction with impaired relaxation of the left ventricle. We consider heart failure to be chronic when the condition persists or recurs over time despite treatment.

b. Chronic HF is considered in these listings as a single category whether due to atherosclerosis (narrowing of the arteries), cardiomyopathy, hypertension, congenital, or other heart disease. If the chronic HF is the result of primary pulmonary hypertension secondary to disease of the lung, we will evaluate your impairment under the listings in 3.00 (for example, 3.09) or 4.00 in part A, as appropriate.

2. *What evidence of chronic HF do we need?*

a. Cardiomegaly or ventricular dysfunction must be present and demonstrated by appropriate medically acceptable imaging, such as cardiac magnetic resonance imaging (MRI), chest x-ray, echocardiography (M-Mode, 2-dimensional, and Doppler), radionuclide studies, or cardiac catheterization. Other findings on appropriate medically acceptable imaging may include increased ventricular volume, increased pulmonary vascular markings, pleural effusion, and pulmonary edema.

b. Your medical history and physical examination should describe characteristic symptoms and signs of pulmonary or systemic congestion (fluid retention) or of limited cardiac output associated with the abnormal findings on appropriate medically acceptable imaging. When an acute episode of heart failure is triggered by a remediable factor, such as an arrhythmia, dietary sodium overload, or high altitude, cardiac function may be restored and a chronic impairment may not be present.

(i) Symptoms of congestion or of limited cardiac output include easy fatigue, weakness, shortness of breath (dyspnea), cough, feeding intolerance, gastrointestinal distress, or chest discomfort at rest or with activity. Children with chronic HF may also experience shortness of breath on lying flat (orthopnea) or episodes of shortness of breath that wake them from sleep (paroxysmal nocturnal dyspnea). They may also experience cardiac arrhythmias resulting in palpitations, lightheadedness, or fainting. Fatigue or exercise intolerance in an infant may result in prolonged feeding time or tube

feeding, often associated with excessive respiratory effort and sweating.

(ii) Other manifestations of chronic HF may include repeated lower respiratory tract infections, wheezing, or growth failure (failure to thrive).

(iii) Signs of congestion may include hepatomegaly, ascites, increased jugular venous distention or pressure, rales, peripheral edema, rapid shallow breathing (tachypnea), or rapid weight gain. However, these signs need not be found on all examinations because congestion may be controlled by prescribed treatment or may not be present at the time of evaluation.

3. *How do we evaluate growth failure due to chronic HF?*

a. To evaluate growth failure due to chronic HF, we require documentation of the clinical findings of chronic HF described in 104.00C2 and the growth measurements in 104.02C within the same consecutive 12-month period. The dates of clinical findings may be different from the dates of growth measurements.

b. Under 104.02C, we use the appropriate table(s) under 105.08B in the digestive system to determine whether your growth is less than the third percentile.

(i) If you have not attained age 2, we use the weight-for-length table corresponding to your sex (Table I or Table II).

(ii) If you have attained age 2 but have not attained age 18, we use the body mass index (BMI)-for-age table corresponding to your sex (Table III or Table IV).

(iii) BMI is the ratio of your weight to the square of your height. We calculate BMI using the formulas in the digestive disorders body system (105.00).

4. *How do we evaluate chronic HF treated with a mechanical circulatory support device?* We use 104.02D to evaluate chronic HF treated with an implanted mechanical circulatory support device (MCSD), such as a left ventricle assistive device (LVAD) or a right ventricle assistive device (RVAD). Implanted MCSDs are intended for long-term circulatory support in helping the heart pump blood. For the purposes of 104.02D, an MCSD does not include extracorporeal membrane oxygenation (ECMO) or devices using Impella technology. Although these are forms of mechanical circulatory support, we do not include them in 104.02D because they are intended only for short-term circulatory support (maximum 30 days), used in a setting of imminent or actual cardiac arrest.

D. How do we evaluate congenital heart disease?

1. *What is congenital heart disease? Congenital heart disease* is any abnormality of the heart or the major blood vessels that is present at birth. Congenital heart disease includes abnormal structure of the individual heart chambers, valves, and blood vessels, and abnormal relative relationship of the chambers to each other that alters the normal pattern of blood flow. Surgery or an interventional catheterization procedure is the usual treatment, and with improving surgical techniques and medical management, more children with congenital heart disease are surviving into adulthood. Examples of congenital heart disease include:

a. *Abnormalities of cardiac septation,* including atrial or ventricular septal defect or atrioventricular canal;

b. *Abnormalities resulting in cyanotic heart disease,* including tetralogy of Fallot, transposition of the great arteries, truncus arteriosus, total anomalous pulmonary venous return, or Epstein malformation;

c. *Valvular defects with obstructions or regurgitation to ventricular inflow or outflow,* including pulmonary or aortic stenosis, pulmonary atresia, or coarctation of the aorta; and

d. *Major abnormalities of ventricular development,* including hypoplastic left heart syndrome or tricuspid atresia with hypoplastic right ventricle.

2. *How do we evaluate conditions associated with congenital heart disease?*

a. We will evaluate congenital heart disease that results in chronic HF with evidence of ventricular dysfunction or in recurrent arrhythmias under 104.02 or 104.05, respectively. Otherwise, we will evaluate your impairment under 104.06.

b. We need pulse oximetry measurements documented by medical sources using methods consistent with the prevailing state of medical knowledge and clinical practice to evaluate chronic hypoxemia in congenital heart disease under 104.06A3. These pulse oximetry measurements also must be consistent with the other evidence in the case record.

c. For 104.06D, life-threatening congenital heart disease does not include single ventricle; we evaluate single ventricle physiology separately under 104.06C. When we evaluate life-threatening congenital heart disease under 104.06D, we consider whether it responds to surgical treatment and, therefore, may not meet the 12-month duration requirement. Examples of impairments that in most instances will require life-saving surgery or a combination of surgery and other major interventional procedures (for example, multiple ''balloon'' catheter procedures) before age 1 include, but are not limited to, the following:

(i) Critical aortic stenosis with neonatal heart failure;

(ii) Critical coarctation of the aorta, with associated anomalies;

(iii) Complete atrioventricular canal defects;

(iv) Transposition of the great arteries;

(v) Tetralogy of Fallot; and

(vi) Multiple ventricular septal defects.

3. *What is Eisenmenger syndrome?* Eisenmenger syndrome refers to any surgically untreated congenital heart defect with intracardiac communication that over time leads to pulmonary hypertension, reversal of blood flow, and hypoxemia.

a. Lesions in Eisenmenger syndrome, such as large septal defects, are characterized by elevated pulmonary pressures or a high pulmonary flow rate. In response, the pulmonary blood vessels pathologically change, leading eventually to pulmonary hypertension. Development of Eisenmenger syndrome represents a point at which pulmonary hypertension is irreversible and the cardiac lesion is likely inoperable.

b. Examples of congenital heart disease that if untreated may cause pulmonary vascular disease leading to Eisenmenger syndrome include atrial septal defect (ASD), ventricular septal defect (VSD), and large patent ductus arteriosus (PDA). We evaluate Eisenmenger syndrome under 104.06A or 104.06B.

4. *What is single ventricle?* The term ''single ventricle'' (also known as ''single ventricle physiology'' or ''functional single ventricle'') describes a diverse group of congenital cardiac anomalies sharing the common feature that only one of the two heart ventricles is adequately developed. At birth, one ventricle must functionally do the work of two, pumping blood for both the body (systemic) and the lungs (pulmonary). Because of this feature, the ultimate plan for cardiac reconstruction is similar for most of these anomalies. People with single ventricle will generally undergo staged reconstructive ''Fontan procedures,'' ultimately resulting in a ''Fontan circulation.'' Fontan circulation describes the hemodynamic state in which virtually all systemic venous return-blood passively flows directly into the pulmonary arteries via surgical or catheter-placed shunts, without (the blood) passing through a ventricle. The Fontan circulation results in difficulties augmenting, and sometimes maintaining, cardiac output. Some of the anomalies described as single ventricle include the following:

(a) Hypoplastic left heart syndrome;

(b) Hypoplastic right ventricle;

(c) Tricuspid valve atresia;

(d) Pulmonary atresia with intact ventricular septum;

(e) Double inlet left ventricle; and

(f) Some variations of double outlet right ventricle.

E. How do we evaluate arrhythmias?

1. *What is an arrhythmia?* An *arrhythmia* is a change in the regular beat of the heart. Your heart may seem to skip a beat or beat irregularly, very quickly (tachycardia), or very slowly (bradycardia). Although we use the term ''arrhythmia'' in the listings, the term ''dysrhythmia'' may also be used in the medical evidence to describe this condition.

2. *What are the different types of arrhythmias?*

a. There are many types of arrhythmias. Arrhythmias are identified by where they occur in the heart (atria or ventricles) and by what happens to the heart's rhythm when they occur.

b. Arrhythmias arising in the cardiac atria (upper chambers of the heart) are called atrial or supraventricular arrhythmias. Ventricular arrhythmias begin in the ventricles (lower chambers). In general, ventricular arrhythmias caused by heart disease are the most serious.

3. *How do we evaluate arrhythmias using 104.05?*

a. We will use 104.05 when you have arrhythmias that are not fully controlled by medication, an implanted pacemaker, or an implanted cardiac defibrillator, and you have recurrent episodes of syncope or near syncope. If your arrhythmias are controlled, we will evaluate your underlying heart disease using the appropriate listing. For other considerations when we evaluate arrhythmias in the presence of an implanted cardiac defibrillator, see 104.00E4.

b. We consider *near syncope* to be a period of altered consciousness, since *syncope* is a loss of consciousness or a faint. It is not merely a feeling of light-headedness, momentary weakness, or dizziness.

c. For purposes of 104.05, there must be a documented association between the syncope or near syncope and the recurrent arrhythmia. The recurrent arrhythmia, not some other cardiac or non-cardiac disorder, must be established as the cause of the associated symptom. This documentation of the association between the symptoms and the arrhythmia may come from the usual diagnostic methods, including Holter monitoring (also called ambulatory electrocardiography) and tilt-table testing with a concurrent ECG. Although an arrhythmia may be a coincidental finding on an ETT, we will not purchase an ETT to document the presence of a cardiac arrhythmia.

4. *What do we consider when you have an implanted cardiac defibrillator and you do not have arrhythmias that meet the requirements of 104.05?*

a. Implanted cardiac defibrillators are used to prevent sudden cardiac death in children who have had, or are at high risk for, cardiac arrest from life-threatening ventricular arrhythmias. The largest group of children at risk for sudden cardiac death consists of children with cardiomyopathy (ischemic or non-ischemic) and reduced ventricular function. However, life-threatening ventricular arrhythmias can also occur in children with little or no ventricular dysfunction. The shock from the implanted cardiac defibrillator rescues a child from what may have been cardiac arrest. However, as a consequence of the shock(s), similar to the effects of treatments for other cardiovascular disease, a child may experience psychological distress, which we may evaluate under the listings in 112.00.

b. Most implantable cardiac defibrillators have rhythm-correcting and pacemaker capabilities. In some children, these functions may result in the termination of ventricular arrhythmias without an otherwise painful shock. (The shock is like being kicked in the chest.) Implanted cardiac defibrillators may deliver inappropriate shocks, often repeatedly, in response to benign arrhythmias or electrical malfunction. Also, exposure to strong electrical or magnetic fields, such as from magnetic resonance imaging, can trigger or reprogram an implanted cardiac defibrillator, resulting in inappropriate shocks. We must consider the frequency of, and the reason(s) for, the shocks when evaluating the severity and duration of your impairment.

c. In general, the exercise limitations imposed on children with an implanted cardiac defibrillator are those dictated by the underlying heart impairment. However, the exercise limitations may be greater when the implanted cardiac defibrillator delivers an inappropriate shock in response to the increase in heart rate with exercise, or when there is exercise-induced ventricular arrhythmia.

F. How do we evaluate other cardiovascular disorders?

1. *What is ischemic heart disease (IHD) and how do we evaluate it in children?* IHD results when one or more of your coronary arteries is narrowed or obstructed or, in rare situations, constricted due to vasospasm, interfering with the normal flow of blood to your heart muscle (ischemia). The obstruction may be the result of an embolus, a thrombus, or plaque. When heart muscle tissue dies as a result of the reduced blood supply, it is called a myocardial infarction (heart attack). Ischemia is rare in children, but when it occurs, its effects on children are the same as on adults. If you have IHD, we evaluate it under 4.04 in part A.

2. *How do we evaluate hypertension? Hypertension* (high blood pressure) generally causes disability in children through its effects on other body systems, such as the brain, kidneys, or eyes, and we will evaluate these impairments by reference to the specific body system(s) that is affected. We also consider any limitations imposed by your hypertension when we consider whether you have an impairment that functionally equals the listings.

3. *What is cardiomyopathy and how do we evaluate it?*

a. *Cardiomyopathy* is a disease of the heart muscle. The heart loses its ability to pump blood (heart failure), and in some instances, heart rhythm is disturbed, leading to irregular heartbeats (arrhythmias). Usually, the exact cause of the muscle damage is never found (idiopathic cardiomyopathy).

b. There are various types of cardiomyopathy, which fall into two major categories: ischemic and nonischemic cardiomyopathy. Ischemic cardiomyopathy typically refers to heart muscle damage that results from coronary artery disease, including heart attacks. Nonischemic cardiomyopathy includes, but is not limited to several types: dilated, hypertrophic, restrictive, and arrhythmogenic.

c. We evaluate cardiomyopathy under 4.04 in part A, 104.02, or 104.05, depending on its effects on you.

4. *How do we evaluate valvular heart disease?* We evaluate aortic valvular disease under 4.07 in part A. We may also evaluate aortic valvular disease, as well as other forms of valvular disease, under 4.04 in part A, 104.02, 104.05, 104.06, or a listing in 111.00, depending on its effects on you.

5. *What do we consider when we evaluate heart transplant recipients?*

a. After your heart transplant, we consider you disabled under 104.09 for 1 year following the surgery because there is a greater likelihood of rejection of the organ and infection during the first year. If you develop cardiac allograft vasculopathy after your transplant, we will evaluate this impairment under 104.16.

b. However, heart transplant patients generally meet our definition of disability before they undergo transplantation. We will determine the onset of your disability based on the facts in your case.

c. We will not assume that you became disabled when your name was placed on a transplant waiting list. This is because you may be placed on a waiting list soon after diagnosis of the cardiac disorder that may eventually require a transplant. Physicians recognize that candidates for transplantation often have to wait months or even years before a suitable donor heart is found, so they place their patients on the list as soon as permitted.

d. When we do a continuing disability review to determine whether you are still disabled, we will evaluate your residual impairment(s), as shown by the evidence in your case record, including any side effects of medication. We will consider all evidence indicative of cardiac dysfunction in deciding whether medical improvement (as defined in § 416.994a of this chapter) has occurred.

6. *How do we evaluate chronic rheumatic fever or rheumatic heart disease?* We evaluate rheumatic fever or rheumatic heart disease under the listing appropriate to its effects on you, which may include heart failure or recurrent arrhythmias. If you have evidence of chronic heart failure or recurrent arrhythmias associated with rheumatic heart disease, we evaluate these disorders under 104.02 or 104.05, respectively.

7. *What is hyperlipidemia and how do we evaluate it? Hyperlipidemia* is the general term for an elevation of any or all of the lipids (fats or cholesterol) in the blood; for example, hypertriglyceridemia, hypercholesterolemia, and hyperlipoproteinemia. These disorders of lipoprotein metabolism and transport can cause defects throughout the body. The effects most likely to interfere with function are those produced by atherosclerosis (narrowing of the arteries) and coronary artery disease. We evaluate your lipoprotein disorder by considering its effects on you.

8. *How do we evaluate Kawasaki disease?* We evaluate Kawasaki disease under the listing appropriate to its effects on you, which may include major coronary artery aneurysm or heart failure. A major coronary artery aneurysm may cause ischemia or arrhythmia, which we evaluate under 4.04 in part A or 104.05. We will evaluate chronic heart failure under 104.02.

9. *What is lymphedema and how do we evaluate it?*

a. *Lymphedema* is edema of the extremities due to a disorder of the lymphatic circulation; at its worst, it is called elephantiasis. Primary lymphedema is caused by abnormal development of lymph vessels and may be present at birth (congenital lymphedema), but more often develops during the teens (lymphedema praecox). Secondary lymphedema is due to obstruction or destruction of normal lymphatic channels due to tumor, surgery, repeated infections, or parasitic infection such as filariasis. Lymphedema most commonly affects one extremity. Symptoms of lymphedema include but are not limited to swelling in an extremity, changes in skin, and pain or sensory changes in the affected area. The symptoms may limit movement in affected joints.

b. Lymphedema does not meet the requirements of 4.11 in part A, although it may medically equal the listing. We evaluate lymphedema by considering whether the underlying cause meets or medically equals any listing or whether the lymphedema

medically equals a cardiovascular disorders listing, such as 4.11 in part A, or a listing in 101.00 or 114.00. If no listing is met or medically equaled, we evaluate any functional limitations imposed by your lymphedema when we consider whether you have an impairment(s) that functionally equals the listings.

10. *What is Marfan syndrome and how do we evaluate it?*

a. *Marfan syndrome* is a genetic connective tissue disorder that affects multiple body systems, including the skeleton, eyes, heart, blood vessels, nervous system, skin, and lungs. There is no specific laboratory test to diagnose Marfan syndrome. The diagnosis is generally made by medical history (including family history), physical examination (including an evaluation of the ratio of arm/leg size to trunk size), a slit lamp eye examination, and a heart test(s) (such as an echocardiogram). In some cases, a genetic analysis may be useful, but such analyses may not provide any additional helpful information.

b. The effects of Marfan syndrome can range from mild to severe. In most cases, the disorder progresses as you age. Most people with Marfan syndrome have abnormalities associated with the heart and blood vessels. Your heart's mitral valve may leak, causing a heart murmur. Small leaks may not cause symptoms, but larger ones may cause shortness of breath, fatigue, and palpitations. Another effect is that the wall of the aorta may be weakened and stretch (aortic dilation). This aortic dilation may tear, dissect, or rupture, causing serious heart problems or sometimes sudden death. We evaluate the cardiovascular manifestations of your Marfan syndrome under the appropriate criteria, such as 4.10 in part A, or, if necessary, consider the functional limitations imposed by your impairment.

c. Other genetic connective tissue disorders, such as Loeys-Dietz syndrome or Ehlers-Danlos syndrome, may have abnormalities associated with the heart and blood vessels. We evaluate the cardiovascular manifestations of your genetic connective tissue disorder under the appropriate criteria, such as 4.10 in part A, or, if necessary, consider the functional limitations imposed by your impairment.

11. *What is cardiac allograft vasculopathy and how do we evaluate it? Cardiac allograft vasculopathy* (CAV) may affect a person who has received a heart transplant and involves thickening in the walls of the coronary arteries that may progress quickly into serious vascular stenosis and heart dysfunction. Stenosis in CAV is caused by a pathological process different from classic atherosclerosis and treatment often is only palliative. We evaluate CAV under 104.16.

G. How do we evaluate other issues that affect the cardiovascular system?

1. How do we consider the effects of obesity when we evaluate your cardiovascular disorder? Obesity is a medically determinable impairment that may be associated with cardiovascular disorders. The additional body mass may make it harder for the chest and lungs to expand or may cause the heart to work harder to pump blood to carry oxygen to the body. The combined effects of obesity with a cardiovascular disorder can be greater than the effects of each of the impairments considered separately. We consider the additional and cumulative effects of obesity when we determine whether you have a severe cardiovascular disorder, a listing-level cardiovascular disorder, a combination of impairments that medically equals the severity of a listed impairment, and when we determine whether your impairment(s) functionally equals the listings.

2. *How do we relate treatment to functional status?* In general, conclusions about the severity of a cardiovascular disorder cannot be made on the basis of the type of treatment rendered or anticipated. The amount of function restored and the time required for improvement after treatment (medical, surgical, or a prescribed program of progressive physical activity) vary with the nature and extent of the disorder, the type of treatment, and other factors. Depending upon the timing of this treatment in relation to the alleged onset date of disability, we may need to defer evaluation of the impairment for a period of up to 3 months from the date treatment began to permit consideration of treatment effects, unless we can make a determination or decision using the evidence we have. See 104.00B4.

3. *How do we consider hospitalizations?* The hospitalizations in 104.02E and 104.06E do not all have to be for the same exacerbation or complication of your cardiovascular disorder(s). They may be for three different exacerbations or complications resulting from your cardiovascular disorder. The hospitalizations must be at least 30 days apart, and each one must last at least 48 hours, including hours in a hospital emergency department immediately before the hospitalization.

H. How do we evaluate cardiovascular disorders that do not meet one of these listings?

1. These listings are only examples of common cardiovascular 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 satisfies 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 also consider whether it functionally equals the listings. See § 416.926a of this chapter. We will use the rules in § 416.994a of this chapter when we decide whether you continue to be disabled.

104.01 Category of Impairments, Cardiovascular Disorders

104.02 *Chronic heart failure* (see 104.00C) while on a regimen of prescribed treatment with symptoms and signs described in 104.00C2, and with A, B, C, D, or E:

A. Persistent tachycardia at rest measured at least twice within a consecutive 12-month period and at least 90 days apart documented by apical heart rate greater than or equal to the value in Table I.

TABLE I—TACHYCARDIA—AT REST

Age	Apical heart rate (beats per minute)
Under 1 year	150
1 through 3 years	130
4 through 9 years	120
10 through 15 years	110
Over 15 years	100

OR

B. Persistent tachypnea at rest measured at least twice within a consecutive 12-month period and at least 90 days apart documented by respiratory rate greater than or equal to the value in Table II *or* markedly decreased exercise tolerance (see 104.00C2b).

TABLE II—TACHYPNEA—AT REST

Age	Respiratory rate (per minute)
Under 1 year	40
1 through 5 years	35
6 through 9 years	30
Over 9 years	25

OR

C. Growth failure as required in 1 or 2:

1. *For children from birth to attainment of age 2,* three weight-for-length measurements that are:

a. Within a consecutive 12-month period; and

b. At least 60 days apart; and

c. Less than the third percentile on the appropriate weight-for-length table under 105.08B1; or

2. *For children age 2 to attainment of age 18,* three BMI-for-age measurements that are:

a. Within a consecutive 12-month period; and

b. At least 60 days apart; and

c. Less than the third percentile on the appropriate BMI-for-age table under 105.08B2.

OR

D. An implanted mechanical circulatory support device (except an extracorporeal membrane oxygenation (ECMO) while hospitalized, at home, or both (see 104.00C4). Consider under a disability for 1 year from the date of implantation; after that, evaluate any residual impairment(s) under the criteria for the affected body system.

OR

E. Exacerbations or complications of chronic heart failure (see 104.00C1b) requiring three hospitalizations within a consecutive 12-month period and at least 30 days apart. Each hospitalization must last at least 48 hours, including hours in a hospital emergency department immediately before the hospitalization (see 104.00G3).

104.03–104.04 [Reserved]

104.05 *Recurrent arrhythmias* (see 104.00E), not related to reversible causes such as electrolyte abnormalities or digitalis glycoside or antiarrhythmic drug toxicity, while on a regimen of prescribed treatment (see 104.00B3 if there is no prescribed treatment), demonstrated by both A and B:

A. Coincident with recurrent (see 104.00A3c) episodes of cardiac syncope or near syncope (see 104.00E3b).

AND

B. Documented by either 1 or 2:

1. Resting or ambulatory (Holter) electrocardiography; or

2. Other appropriate medically acceptable testing.

104.06 *Congenital heart disease* (see 104.00D), documented by appropriate medically acceptable imaging (see 104.00A3d) or cardiac catheterization, with A, B, C, D, or E:

A. Chronic hypoxemia, and 1, 2, or 3:

1. Hematocrit of 55 percent or greater on two evaluations at least 90 days apart within a consecutive 12-month period (see 104.00A3e); or

2. Arterial blood gas test measurement obtained at rest while breathing room air, as described in either a or b:

a. S_aO_2 (arterial oxygen saturation) less than or equal to 89 percent; or

b. PO_2 or P_aO_2 (partial pressure of oxygen) less than or equal to 60 mmHg; or

3. S_pO_2 (percentage of oxygen saturation of blood hemoglobin) measured by pulse oximetry either at rest, or after activity, while breathing room air, less than or equal to 87 percent on three evaluations at least 30 days apart within a consecutive 12-month period (see 104.00A3e).

OR

B. Pulmonary hypertension documented by cardiac catheterization while medically stable, as described in 1, 2, or 3:

1. Pulmonary arterial systolic pressure elevated to at least 70 percent of the systemic arterial systolic pressure; or

2. Pulmonary arterial systolic pressure equal to or greater than 70 mmHg; or

3. Mean pulmonary artery pressure equal to or greater than 40 mmHg.

OR

C. Single ventricle (for example, hypoplastic left or right ventricle) that has or will require Fontan procedures (see 104.00D4).

OR

D. For infants under 1 year of age at the time of filing, with life-threatening congenital heart disease (see 104.00D2c) that will require or already has required surgical treatment in the first year of life, and the impairment is expected to be disabling (because of residual impairment following surgery, or the recovery time required, or both) until the attainment of at least 1 year of age, consider under a disability until the attainment of at least age 1; after that, evaluate impairment severity with the appropriate listing.

OR

E. Exacerbations or complications of congenital heart disease (see 104.00D) requiring three hospitalizations within a consecutive 12-month period (see 104.00A3e) and at least 30 days apart. Each hospitalization must last at least 48 hours, including hours in a hospital emergency department immediately before the hospitalization (see 104.00G3).

104.07–104.08 [Reserved]

104.09 *Heart transplantation* (see 104.00F5). Consider under a disability for 1 year from the date of the transplant; after that, evaluate the residual impairment(s).

104.10–104.15 [Reserved]

104.16 *Cardiac allograft vasculopathy* (see 104.00F11), documented by appropriate medically acceptable imaging (for example, intravascular ultrasonography or coronary angiography).

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114.00 Immune System Disorders

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J. * * *

2. * * *

m. Syphilis or neurosyphilis under the criteria for the affected body system; for example, 102.00 Special senses and speech, 104.00 Cardiovascular disorders, or 111.00 Neurological.

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