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CLINICAL DATA STANDARDS

# 2022 AHA/ACC Key Data Elements and Definitions for Cardiovascular and Noncardiovascular Complications of COVID-19



A Report of the American College of Cardiology/American Heart Association  
Task Force on Clinical Data Standards

Endorsed by the Heart Failure Society of America and Society for Cardiac Angiography  
and Interventions

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This document was approved by the American College of Cardiology Clinical Policy Approval Committee and the American Heart Association Science Advisory and Coordinating Committee in February 2022, and the American Heart Association Executive Committee in April 2022.

The American College of Cardiology requests that this document be cited as follows: Bozkurt B, Das SR, Addison D, Gupta A, Jneid H, Khan SS, Koromia GA, Kulkarni PA, LaPoint K, Lewis EF, Michos ED, Peterson PN, Turagam MK, Wang TY, Yancy CW. 2022 AHA/ACC key data elements and definitions for cardiovascular and noncardiovascular complications of COVID-19: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Data Standards. *J Am Coll Cardiol.* 2022;80:388-465.

This article is copublished in *Circulation: Cardiovascular Quality and Outcomes*.

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## TABLE OF CONTENTS

|  |     |
|--|-----|
| <b>TOP 10 TAKE-HOME MESSAGES</b> .....   | 389 |
| <b>PREAMBLE</b> .....  | 390 |
| <b>1. INTRODUCTION</b> .....   | 391 |
| 1.1. Special Considerations .....  | 392 |
| 1.2. Abbreviations .....   | 392 |
| <b>2. METHODOLOGY</b> .....  | 392 |
| 2.1. Writing Committee Composition .....   | 392 |
| 2.2. Relationships With Industry and Other Entities .....  | 392 |
| 2.3. Review of Literature and Existing Data Definitions .....  | 392 |
| 2.4. Development of Terminology Concepts .....   | 392 |
| 2.5. Consensus Development .....   | 393 |
| 2.6. Relation to Other Standards .....   | 393 |
| 2.7. Peer Review, Public Review, and Board Approval .....  | 393 |
| <b>3. DATA ELEMENTS AND DEFINITIONS</b> .....  | 393 |
| 3.1. Patient Demographics Including Age, Sex, Race, Ethnicity, and Social Determinants of Health ..... | 393 |
| 3.2. COVID-19 Diagnosis .....  | 393 |
| 3.3. COVID-19 Cardiovascular Complications .....   | 394 |
| 3.4. COVID-19 Noncardiovascular Complications .....  | 394 |
| 3.5. Symptoms and Signs .....  | 394 |
| 3.6. Diagnostic Procedures .....   | 395 |
| 3.7. Pharmacological Therapy .....   | 395 |
| 3.8. Preventive, Therapeutic, and Supportive Procedures for COVID-19 .....                             | 396 |
| 3.9. End-of-Life Management .....  | 396 |
| <b>REFERENCES</b> .....  | 397 |
| <b>APPENDIX 1</b>  |     |
| Author Relationships With Industry and Other Entities (Relevant) .....                                 | 401 |
| <b>APPENDIX 2</b>  |     |
| Reviewer Relationships With Industry and Other Entities (Comprehensive) .....                          | 402 |
| <b>APPENDIX 3</b>  |     |
| COVID-19 Diagnosis .....   | 404 |

|  |     |
|--|-----|
| <b>APPENDIX 4</b>  |     |
| COVID-19 Cardiovascular Complications .....              | 409 |
| <b>APPENDIX 5</b>  |     |
| COVID-19 Noncardiovascular Complications .....           | 424 |
| <b>APPENDIX 6</b>  |     |
| Symptoms and Signs .....                                 | 427 |
| <b>APPENDIX 7</b>  |     |
| Diagnostic Procedures .....                              | 437 |
| <b>APPENDIX 8</b>  |     |
| Pharmacological Therapy .....                            | 447 |
| <b>APPENDIX 9</b>  |     |
| Therapeutic and Supportive Procedures for COVID-19 ..... | 456 |
| <b>APPENDIX 10</b>                                       |     |
| End-of-Life Management .....                             | 465 |

## TOP 10 TAKE-HOME MESSAGES

1. This document presents a clinical lexicon comprising data elements related to cardiovascular and non-cardiovascular complications of COVID-19 (coronavirus disease-2019). The writing committee considered data elements that are pertinent to the full range of care provided to these patients and intended to be useful for all care venues, including presentations related to acute COVID-19 in the ambulatory as well as the hospital setting.
2. Data elements for COVID-19 diagnoses include confirmed, probable, and suspected acute COVID-19 case definitions. Postacute sequelae of SARS-CoV-2 (severe acute respiratory syndrome-coronavirus-2) infection were also included.
3. Acute cardiovascular complications related to COVID-19, including acute myocardial injury, heart failure, shock, arrhythmia, thromboembolic complications, and stroke, were defined.
4. Data elements related to COVID-19 vaccination status, comorbidities, and preexisting cardiovascular conditions were provided.
5. Postacute cardiovascular sequelae of SARS-CoV-2 infection and long-term cardiovascular complications of COVID-19 were defined.
6. Data elements for cardiovascular mortality during acute COVID-19 were provided.

7. Data elements for noncardiovascular complications were provided to help document severity of illness and other competing diagnoses and complications that may affect cardiovascular outcomes.
  8. Symptoms and signs related to COVID-19 and cardiovascular complications were listed.
  9. Data elements for diagnostic and therapeutic strategies for COVID-19 and cardiovascular conditions were provided.
  10. Advanced therapies, including mechanical ventilation, extracorporeal membrane oxygenation, and end-of-life management strategies, were provided.
2. To facilitate the exchange of data across systems through harmonized, standardized definitions of key data elements
  3. To facilitate further development of clinical registries, implementable clinical guidelines, quality and performance improvement programs, outcomes evaluations, public reporting, and clinical research, including the comparison of results within and across these initiatives
  4. To ensure equity across all endeavors related to clinical data standards

## PREAMBLE

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The American College of Cardiology (ACC) and the American Heart Association (AHA) support their members' goal to improve the prevention and treatment of cardiovascular diseases (CVDs) through professional education, research, the development of guidelines and standards, and by fostering policy that supports optimal patient care and outcomes. The ACC and AHA also recognize the importance of using clinical data standards for patient management, assessment of outcomes, and conduct of research, as well as the importance of defining the processes and outcomes of clinical care, whether in randomized trials, observational studies, registries, or quality improvement initiatives.

Clinical data standards aim to identify, define, and standardize data elements relevant to clinical topics in cardiovascular medicine, with the primary goal of assisting data collection and use by providing a corpus of data elements and definitions applicable to various conditions. Broad agreement on common vocabulary and definitions is needed to pool or compare data from the electronic health records (EHRs), clinical registries, administrative datasets, and other databases and to assess whether these data are applicable to clinical practice and research endeavors. Emerging federal standards, such as the U.S. Department of Health & Human Services, Office of the National Coordinator for Health Information Technology, and the U.S. Core Data for Interoperability support efforts to "promote interoperability" and the more effective use of EHR data to improve health care quality. The purpose of clinical data standards is to contribute to the infrastructure necessary to accomplish the ACC's mission to transform cardiovascular care and improve heart health and the AHA's mission of being a relentless force for a world of longer and healthier lives for all individuals.

The specific goals of clinical data standards are:

1. To establish a consistent, interoperable, and universal clinical vocabulary as a foundation for clinical care and research

The key data elements and definitions are a compilation of variables intended to facilitate the consistent, accurate, and reproducible capture of clinical concepts; standardize the terminology used to describe CVDs and procedures; create a data environment conducive to the implementation of clinical guidelines, assessment of patient management and outcomes for quality and performance improvement, and clinical and translational research; and increase opportunities for sharing data across disparate data sources. The ACC/AHA Task Force on Clinical Data Standards (Task Force) selects cardiovascular conditions, procedures, and other topics related to cardiovascular health and medicine that will benefit from the creation of a clinical data standard set. Experts in the subject area are selected to examine and consider existing standards and develop a comprehensive, yet not exhaustive, data standard set. When undertaking a data collection effort, only a subset of the elements contained in a clinical data standard listing may be needed or, conversely, users may want to consider whether it may be necessary to collect and incorporate additional elements. For example, in the setting of a randomized, clinical trial of a new drug, additional information would likely be required regarding study procedures and medical therapies. Alternatively, if a data set is to be used for quality improvement, safety initiatives, or administrative functions, elements such as Current Procedural Terminology (CPT) codes, International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) codes, or outcomes may be added. The intent of the Task Force is to standardize clinical concepts, focusing on the patient and clinical care and not on administrative billing or coding concepts. The clinical concepts selected for development are commonly cardiovascular specific, where a standardized terminology does not already exist. The clinical data standards can, therefore, serve as a guide to develop administrative data sets, and complementary administrative or quality assurance elements can evolve from these core clinical concepts and elements. Thus, rather than forcing the clinical data standards to harmonize with existing administrative codes, such as ICD-10-CM or CPT codes, we envision the

administrative codes to follow the lead of the clinical data standards. This approach would allow clinical care to lead standardization of cardiovascular health care terminology.

The ACC and AHA recognize that there are other national efforts to establish clinical data standards, and every attempt is made to harmonize newly published standards with existing ones. Writing committees are instructed to consider adopting or adapting existing nationally recognized data standards if the definitions and characteristics are validated, useful, and applicable to the set under development. In addition, the ACC and AHA are committed to continually expanding their portfolio of clinical data standards and will create new standards and update existing ones as needed to maintain their currency and promote harmonization with other standards as health information technology and clinical practice evolve.

The Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA) privacy regulations, which went into effect in April 2003, heightened all health care providers' awareness of our professional commitment to safeguard patients' privacy. HIPAA privacy regulations specify which information elements are considered "protected health information." These elements may not be disclosed to third parties (including registries and research studies) without the patient's permission and meeting all relevant privacy sharing requirements. Protected health information may be included in databases used for health care operations under a data use agreement. Research studies using protected health information must be reviewed by an institutional review board. We have included identifying information in all clinical data standards to facilitate uniform collection of these elements when appropriate. For example, a longitudinal clinic database may contain these elements because access is restricted to the patient's health care team.

In clinical care, health care providers communicate with each other through a common vocabulary. In an analogous manner, the integrity of clinical research depends on firm adherence to prespecified procedures for patient enrollment and follow-up; these procedures are guaranteed through careful attention to definitions enumerated in the study design and case report forms. Harmonizing data elements and definitions across studies facilitates comparisons and enables the conduct of pooled analyses and meta-analyses, thus deepening our understanding of individual study results.

The recent development of quality performance measurement initiatives, particularly those for which the comparison of health care providers and institutions is an implicit or explicit aim, has further raised awareness about the importance of clinical data standards. Indeed, a

wide audience, including nonmedical professionals such as payers, regulators, and consumers, may draw conclusions about care and outcomes from these comparisons. To understand and compare care patterns and outcomes, the data elements that characterize them must be clearly defined, consistently used, and properly interpreted.

*Hani Jneid, MD, FACC, FAHA*

*Chair, ACC/AHA Task Force on Clinical Data Standards*

## 1. INTRODUCTION

The Task Force has undertaken the task to standardize the lexicon of cardiovascular medicine. This document provides data standards for cardiovascular and other complications related to COVID-19 infection caused by SARS-CoV-2. Our intent is to provide data elements consistent with current practice guidance and to include updated terminology and attributes in compliance with the methodology of the Task Force<sup>1</sup> and with current policies of the ACC and AHA regarding harmonization of data across organizations and disciplines. There is increased importance of understanding acute and longitudinal impact of COVID-19 on cardiovascular health. Unfortunately, there has not been clarity or consensus on definitions of cardiovascular conditions related to COVID-19. Different diagnostic terminologies are being used for overlapping conditions such as "myocardial injury," "myocarditis," "type II myocardial infarction," "stress cardiomyopathy," or "inflammatory cardiomyopathy."

These data standards will help standardize definitions and set the framework to capture and better understand how COVID-19 impacts cardiovascular health. This document is intended for use by researchers, registry developers, and clinicians and is proposed as a framework for ICD-10 code development of COVID-19-related cardiovascular conditions.

Specifically, COVID-19 cardiovascular data standards are of great importance to patients, providers, investigators, scientists, administrators, public health officials, policy makers, and payers. The ACC/AHA Writing Committee on Clinical Data Standards for COVID-19 (writing committee) envisions these data elements would be useful in the following broad additional categories:

- Communication with patients
- Inpatient and outpatient clinical programs
- Clinical registries
- Basic and translational research programs
- Clinical research, particularly where eventual pooled analysis or meta-analysis is anticipated
- Public health organizations
- Organization and design of electronic medical information initiatives, such as EHRs, pharmacy databases, computerized decision support, and cloud technologies

- Public health policy, health insurance coverage, and legislation development
- Health system administrators for estimation of necessary resources such as protective personal equipment (PPE), testing, space and staffing needs, isolation, sanitation, or quarantine requirements
- Alternative models of health care such as telemedicine, virtual visits, and point-of-care diagnostic platforms.

The data element tables are also included as an Excel file in the [Online Data Supplement](#).

### 1.1. Special Considerations

In this document, data elements were not differentiated for specific encounters, such as for inpatients versus outpatients, dates of encounter, number of encounters, baseline or repeated data elements. Databases can be built and customized according to users' needs to capture such information. The intent of this writing committee was not to provide recommendations regarding COVID-19 treatment, and the writing committee recommends that readers follow prevailing COVID-19 management guidelines.

### 1.2. Abbreviations

| Abbreviation | Meaning/Phrase   |
|--------------|--|
| ACE          | angiotensin-converting enzyme  |
| ACS          | acute coronary syndrome  |
| ARB          | angiotensin receptor blocker   |
| CDC          | Centers for Disease Control and Prevention                                     |
| COVID-19     | coronavirus disease-2019   |
| CPT          | Current Procedural Terminology   |
| CT           | computed tomography  |
| CVD          | cardiovascular disease   |
| ECMO         | extracorporeal membrane oxygenation  |
| EHR          | electronic health record   |
| HIPAA        | Health Insurance Portability and Accountability Act                            |
| ICD-10-CM    | International Classification of Diseases, 10th Revision, Clinical Modification |
| MIS          | multisystem inflammatory syndrome  |
| MRI          | magnetic resonance imaging   |
| NCDR         | National Cardiovascular Data Registry  |
| PASC         | postacute sequelae of SARS-CoV-2 infection                                     |
| PPE          | protective personal equipment  |
| SARS-CoV-2   | severe acute respiratory syndrome-coronavirus-2                                |

## 2. METHODOLOGY

### 2.1. Writing Committee Composition

The Task Force selected the members of this writing committee. The writing committee consisted of 15

individuals with domain expertise in cardiomyopathy, infectious disease, CVD, myocarditis, cardiovascular registries, outcomes assessment, medical informatics, health information management, and health care services research and delivery.

### 2.2. Relationships With Industry and Other Entities

The Task Force made every effort to avoid actual or potential conflicts of interest because of personal, professional, or business interests or relationships of any member of the writing committee. Specifically, all members of the writing committee were required to disclose all such relationships that could be perceived as real or potential conflicts of interest in writing. The included documentation was updated when any changes occurred. Authors' and peer reviewers' relationships with industry and other entities pertinent to this data standards document are disclosed in [Appendixes 1 and 2](#), respectively. In addition, for complete transparency, the disclosure information of each writing committee member—including relationships not pertinent to this document—is available in a [Supplemental Appendix](#). The work of the writing committee was supported exclusively by the AHA and ACC without commercial support. Writing committee members volunteered their time for this effort. Meetings of the writing committee were confidential and attended only by committee members and staff.

### 2.3. Review of Literature and Existing Data Definitions

A substantial body of literature was reviewed for this manuscript. The primary sources of information were the "Infectious Diseases Society of America Guidelines on the Treatment and Management of Patients with COVID-19"<sup>2</sup>, NIH COVID-19 Treatment Guidelines,<sup>3</sup> data definitions from the U.S. Centers of Disease Control and Prevention (CDC), and previous Task Force publications. This information was augmented by multiple peer-reviewed references listed in the tables under the column "Mapping/Source of Definition."

### 2.4. Development of Terminology Concepts

The writing committee aggregated, reviewed, harmonized, and extended these terms to develop a controlled, semantically interoperable, machine computable terminology set that would be usable in as many contexts as possible. As necessary, the writing committee identified contexts where individual terms required differentiation according to their proposed use (ie, research/regulatory vs. clinical care contexts).

This publication was developed to serve as a common lexicon and base infrastructure by end users to augment work related to standardization and health care interoperability including, but not limited to, structural, administrative, and technical metadata development. The

resulting appendixes ([Appendixes 3 to 10](#)) list the data element in the first column, followed by the clinical definition of the data element. The allowed responses (“permissible values”) for each data element in the next column are the acceptable means of recording this information. For data elements with multiple permissible values, a bulleted list of the permissible values is provided in the row listing the data element, followed by multiple rows listing each permissible value and corresponding permissible value definition, as needed. Where possible, clinical definitions (and clinical definitions of the corresponding permissible values) are repeated verbatim as previously published in reference documents.

### 2.5. Consensus Development

The Task Force established the writing committee as described in the Task Force’s methodology paper.<sup>1</sup> The primary responsibility of the writing committee was to aggregate existing information relevant to the care of patients with CVD from external sources, such as society guidelines and existing COVID-19 data elements from the National Cardiovascular Data Registry (NCDR)<sup>4</sup> and AHA COVID-19 Registry.<sup>5</sup> The work of the writing committee was accomplished via a series of virtual meetings, along with extensive email correspondence. The review work was distributed among subgroups of the writing committee based on interest and expertise in the components of the terminology set. The proceedings of the workgroups were then assembled, resulting in the vocabulary and associated descriptive text in [Appendixes 3 to 10](#). All members reviewed and approved the final lexicon.

### 2.6. Relation to Other Standards

The writing committee reviewed the available published data standards, including relevant data dictionaries from registries. Relative to published data standards, the writing committee anticipates that this terminology set will facilitate the uniform adoption of these terms, where appropriate, by the clinical, clinical and translational research, regulatory, quality and outcomes, and EHR communities.

### 2.7. Peer Review, Public Review, and Board Approval

The “2022 AHA/ACC Key Data Elements and Definitions for Cardiovascular and Noncardiovascular Complications of COVID-19” was reviewed by official reviewers nominated by the ACC and AHA. To increase its applicability, the document was posted on the ACC and AHA websites for a 30-day public comment period. This document was approved by the ACC Clinical Policy Approval Committee and the AHA Science Advisory and Coordinating Committee in February 2022, and the AHA Executive Committee in March 2022. The writing committee anticipates that these data standards will require review and

updating in the same manner as other published guidelines, performance measures, and appropriate use criteria. The writing committee will therefore review the set of data elements on a periodic basis, starting with the anniversary of publication of the standards, to ascertain whether modifications should be considered.

## 3. DATA ELEMENTS AND DEFINITIONS

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The writing committee explicitly elected not to include patient identification, demographic, and administrative information, such as patient sex or site of service, diagnosis, and other fundamental concept terms, including data by specific medication, as defined data elements. Comprehensive EHR solutions are anticipated to collect this information as discrete data. Furthermore, a robust solution for patient identification (eg, the unique patient identifier) is a universal requirement, whether within the context of the EHR of an individual practice or the registry aggregation of information across multiple disparate inpatient and ambulatory encounters.

### 3.1. Patient Demographics Including Age, Sex, Race, Ethnicity, and Social Determinants of Health

Patient age, sex, race, ethnicity, and social determinants of health are key elements in risk of infection and outcomes for COVID-19. Age, sex, race, and ethnicity are expected to be available in all EHR solutions and therefore have not been listed. We recognize the critical importance of social determinants of health, including race/ethnicity and sex, to COVID-19 and its outcomes and would like to emphasize that these variables should be captured. The Task Force has commissioned a separate data standards document to address social determinants of health for overall CVD, which we expect to be pertinent and complementary to this document, in addition to other documents published and being developed.<sup>6</sup>

### 3.2. COVID-19 Diagnosis

[Appendix 3](#) provides definitions for the diagnosis of COVID-19. A case of COVID-19 can be confirmed, probable, or suspected based on definitions from the CDC.<sup>7</sup> A person with COVID-19 might be symptomatic or asymptomatic. Other categories of COVID-19 diagnosis provided include postacute sequelae of SARS-CoV-2 infection (PASC) (also termed “postacute COVID-19 syndrome” or “long COVID” in the literature); persons with COVID-19 who continue to have persistently positive molecular or antigen tests after the end of their isolation period; multisystem inflammatory syndrome (MIS), a rare postinfectious inflammatory condition; prior COVID-19; and COVID-19 reinfection. The category of COVID-19 reinfection is divided into reinfection with best evidence, moderate evidence, and poor evidence, as outlined by the CDC.<sup>8</sup> Other data elements

included in this section are date of diagnosis of acute COVID-19, whether a patient was hospitalized for COVID-19 specifically or was found to have incidental SARS-CoV-2 infection at the time of hospitalization for another cause, and dates of initial hospitalization. A category also exists for exposure to someone with COVID-19 during their infectious period, with criteria based on CDC recommendations.

### 3.3. COVID-19 Cardiovascular Complications

Patients with underlying cardiovascular risk factors or established CVD are at greater risk for severe presentations of COVID-19. COVID-19 can also confer significant cardiovascular morbidity and mortality in patients with or without prior CVD. Approximately 10% to 20% of hospitalized patients can have evidence of myocardial injury in the setting of COVID-19.<sup>9</sup> Proposed mechanisms include activation of inflammatory and thrombotic cascades, direct viral injury to myocytes or vascular endothelium, and worsening of underlying baseline atherosclerotic and structural abnormalities. Acute cardiovascular presentations are varied and include myocardial injury, myocarditis, acute coronary syndrome (ACS), heart failure, cardiogenic shock, arrhythmia, thromboembolic and cerebrovascular complications, and cardiac involvement and coronary artery ectasia in the setting of MIS in children (MIS-C). COVID-19 can trigger acute heart failure or cardiogenic shock. New-onset left ventricular systolic dysfunction is hypothesized to be related to myocarditis, endothelial and microvascular injury, myocardial stress in the setting of increased myocardial demand and reduced myocardial oxygenation in the setting of hypoxia, myocardial inflammation, and proinflammatory cytokine surge.<sup>10</sup> New-onset right ventricular dysfunction can result from acute pulmonary embolism or strain from acute respiratory distress syndrome and elevated pulmonary artery pressures. Both atrial and ventricular arrhythmias have been noted.<sup>10</sup> COVID-19 is associated with an increased risk of stroke, transient ischemic attack, and venous and arterial thromboembolic events.<sup>10</sup> [Appendix 4A](#) summarizes the more common acute cardiovascular presentations and lists of standard data elements that describe these presentations.

A significant proportion of patients may experience long-term complications of SARS-CoV-2 infection  $\geq 4$  weeks from the index infection, sometimes called post-acute COVID-19 syndrome.<sup>11-13</sup> Long-term cardiovascular sequelae of COVID-19 may include chest pain, palpitations, inappropriate sinus tachycardia, postural orthostatic tachycardia syndrome, atrial arrhythmia, cardiomyopathy, and thromboembolism.<sup>14-16</sup> Possible mechanisms for long-term cardiovascular complications of COVID-19 include direct and indirect viral-mediated

cellular damage, procoagulant state, the immunologic response affecting the structural integrity of the myocardium, pericardium, and conduction system, and downregulation of angiotensin-converting enzyme-2 (ACE2).<sup>17-19</sup> Myocardial abnormalities and injury have been reported on magnetic resonance imaging (MRI), and cardiac troponin elevations have occurred in some patients  $> 2$  months after diagnosis of COVID-19.<sup>20</sup> Myocardial fibrosis or scar associated with cardiomyopathy from viral infection can lead to arrhythmias.<sup>21</sup> The risk for occurrence of thromboembolic complications in the postacute COVID-19 phase is possibly associated with the duration and severity of hyperinflammatory state.<sup>13</sup> Standard data elements that describe the long-term cardiovascular complications of COVID-19 are summarized in [Appendix 4B](#), and data elements pertaining to cardiovascular mortality from COVID-19 are summarized in [Appendix 4C](#).

### 3.4. COVID-19 Noncardiovascular Complications

[Appendix 5](#) defines the broad range of noncardiovascular complications that can occur in a probable or confirmed case of COVID-19. SARS-CoV-2 is primarily a respiratory virus that infects the upper airway and, in severe cases, can progress into a lower airway infection (pneumonia), progressive respiratory failure (acute respiratory distress syndrome), and many other systemic complications. It is uncertain whether extrapulmonary cardiovascular, as well as noncardiovascular, complications are related to indirect injury caused by systemic inflammation or to direct viral tissue damage, or both. Shock and multiorgan failure observed in severe cases of COVID-19 may be related to septic shock, cytokine storm, cardiogenic shock, obstructive shock, or mixed distributive combined with cardiogenic shock. In addition to lung and heart complications, COVID-19 can contribute to renal, hepatic, hematologic, and neurological complications. Pregnant women with COVID-19 have been identified by the CDC to be at increased risk for severe illness, and COVID-19 may be associated with pregnancy loss and other adverse pregnancy outcomes. Many other noncardiovascular symptoms during COVID-19 have been noted and include microvascular thrombosis, thrombophilia, cerebral venous thrombosis, anosmia, ageusia, rhabdomyolysis, peripheral neuropathy, gastrointestinal symptoms, de novo or acute worsening of chronic hyperglycemia, ocular symptoms, encephalopathy, skin changes, and livedo reticularis.

### 3.5. Symptoms and Signs

[Appendix 6](#) outlines and defines common cardiovascular and noncardiovascular symptoms in patients with COVID-19, as well as an abbreviated list of physical examination findings. Symptom data elements may be derived from



structured variables within the EHR (eg, chief complaint or problem list), as components of patient-reported outcomes in applied survey instruments, or as free text within clinical source documents. Because COVID-19 physical examination findings are less uniformly captured, this list focuses on signs related to potential acute cardiovascular complications from COVID-19. Future research on the postacute COVID-19 syndrome will elucidate important persistent or postacute symptoms and signs of relevance.

Although the signs and symptoms of SARS-CoV-2 infection in children may be similar to those in adults, many children are asymptomatic or may have only a few symptoms. The most common signs and symptoms of COVID-19 in hospitalized children are fever, nausea/vomiting, cough, shortness of breath, and upper respiratory symptoms.<sup>3</sup> Although the true incidence of asymptomatic SARS-CoV-2 infection is unknown, asymptomatic infection was reported in up to 45% of children who underwent surveillance testing at the time of hospitalization for a non-COVID-19 indication.<sup>3</sup> SARS-CoV-2 has been associated with a potentially severe inflammatory syndrome in children (MIS-C) and young adults (MIS-A) (Appendix 3).

### 3.6. Diagnostic Procedures

As discussed previously, COVID-19 may result in a number of cardiovascular complications. The approach to these complications can involve a number of standard diagnostic procedures. Laboratory testing, including cardiac troponin, natriuretic peptide levels, complete metabolic profile, blood cell counts, coagulation parameters, and inflammatory biomarkers, can be helpful. Electrocardiography is used to identify rhythm and conduction abnormalities. Echocardiography is the most common means of assessing left ventricular ejection fraction, right ventricular function, wall motion abnormalities, and pulmonary artery systolic pressure. Other imaging procedures such as MRI may be used to assess myocardial involvement (ie, myocarditis, myocardial wall edema, myocardial fibrosis and scar), as well as other structural abnormalities and ventricular function. Several imaging techniques, including computed tomography (CT), nuclear, and coronary angiography, may be used to evaluate for obstructive coronary disease. Coronary angiography can be used to evaluate for ACS. Chest x-ray is first line for evaluating acute lung processes, and chest CT angiography may be used to further define or to evaluate for pulmonary embolus. Right heart catheterization may be used to diagnose cardiogenic shock, evaluate filling pressures, or evaluate pulmonary pressures. Venous and arterial thromboses are known to occur and can often be identified by ultrasonography, vascular, or nuclear imaging. In the case of arterial thrombosis and stroke, CT and MRI are used

to define the extent and nature (ischemic vs. hemorrhagic). Appendix 7 summarizes the more common diagnostic procedures and lists standard data elements that describe the diagnostic procedures and potential findings.

### 3.7. Pharmacological Therapy

A growing body of available evidence primarily supports the continuation of traditional cardiovascular therapies, including ACE inhibitors and angiotensin receptor blockers (ARBs).<sup>22-25</sup> These agents, as well as most other cardiovascular therapeutics, do not appear to confer an increased risk of acquiring SARS-CoV-2 infection.<sup>26,27</sup> Large multicenter studies have demonstrated no difference in infection or mortality associated with ACE inhibitors, ARB, or any other cardiovascular therapies (antihypertensives in most cases) when continued after development of COVID-19.<sup>22-24</sup> Appendix 8A summarizes the more common cardiovascular therapies and provides definitions for their associated data elements.

The clinical manifestations of COVID-19 can range from asymptomatic or mild respiratory disease to severe, life-threatening respiratory and hemodynamic failure. Supportive therapies are a common part of the management strategy for treatment of COVID-19. In addition to therapies used for direct antiviral activity (eg, remdesivir), other interventions (eg, proning) or medications without direct antiviral activity (eg, steroids) can be used in selected patients to decrease the morbidity and mortality associated with COVID-19. In cases of cardiogenic shock and low cardiac output associated with COVID-19, intravenous inotropic and vasopressor agents can be administered as supportive therapies. COVID-19 is also associated with a prothrombotic state and an increased incidence of thromboembolic disease.<sup>28</sup> Prophylactic anticoagulation against venous thromboembolism is recommended.<sup>29</sup> Therapeutic anticoagulation needs to be individualized. In critically ill patients with COVID-19, an initial strategy of therapeutic-dose anticoagulation with heparin did not result in a greater probability of survival to hospital discharge or a greater number of days free of cardiovascular or respiratory organ support than did usual-care pharmacological thromboprophylaxis.<sup>30</sup> However, in noncritically ill patients with COVID-19, an initial strategy of therapeutic-dose anticoagulation with heparin increased the probability of survival to hospital discharge with reduced use of cardiovascular or respiratory organ support compared with usual-care thromboprophylaxis.<sup>31,32</sup> The management of COVID-19 from the standpoint of antiviral and anti-inflammatory agents continues to evolve as new insights are discovered. In addition, although certain supportive strategies have now been shown to be effective in addressing the exaggerated inflammatory response and uncontrolled cytokine release, this remains an ongoing area of active study. Appendix 8C briefly summarizes these

supportive therapies and provides definitions for their associated data elements.

Guidance for the treatment of COVID-19 in children is mostly extrapolated from recommendations for adults with COVID-19.<sup>33,34</sup> High-quality studies, including randomized trials, are urgently needed in children and in other special populations.<sup>3</sup> With emerging new variants of SARS-CoV-2, further studies will be needed to better understand the epidemiology, prevention, and treatment of COVID-19.

### 3.8. Preventive, Therapeutic, and Supportive Procedures for COVID-19

COVID-19 vaccinations have been demonstrated to be highly effective and safe in tested populations and confer protection against COVID-19.<sup>35,36</sup> As of February 2022, the US CDC recommends vaccination for everyone  $\geq 5$  years of age. Vaccination prevents not only COVID-19 but also potential cardiovascular complications related to COVID-19.<sup>37,38</sup> In addition to vaccinations, wearing face masks, physical distancing, hand hygiene, and compliance with public health guidelines are effective in reducing spread of COVID-19.<sup>39-42</sup>

Comprehensive and reliable capture of data elements pertinent to therapeutic procedures in patients with COVID-19 is important to monitor and assess quality of care of these patients with the goal to improve their outcomes. These include but are not limited to data elements pertinent to ventilation and circulatory support, percutaneous interventional therapies, and electrophysiological procedures (Appendix 9).

Some patients with COVID-19 may experience severe cardiopulmonary complications, which can include acute respiratory distress syndrome, ACS, cardiomyopathy, acute congestive heart failure, cardiogenic shock, isolated respiratory failure, malignant ventricular arrhythmias, and cardiopulmonary arrest.<sup>43</sup> Ventilatory support may range from noninvasive support to mechanical support, depending on severity of hypoxia. COVID-19 can result in renal injury attributable to systemic inflammation, multi-organ failure, and massive release of inflammatory cytokines, resulting in tubular and glomerular cell damage.<sup>44</sup> Renal replacement therapy can be considered supportive in those patients without antecedent end-stage kidney disease, for whom these therapies are considered temporary. Some patients may have concomitant cardiogenic shock necessitating mechanical circulatory support, such as intra-aortic balloon pumps to more advanced percutaneous ventricular assist devices, such as Impella or TandemHeart, which unload the left ventricle directly or upstream from the left atrium.<sup>45</sup> Patients with cardiogenic shock unresponsive to vasoactive therapies may require a circulatory support device, such as venoarterial extracorporeal membrane oxygenation (ECMO). In specialized

centers, ECMO devices may be used to provide adequate oxygenation (venovenous ECMO) or cardiac circulatory support (venoarterial ECMO) in patients with advanced cardiac and cardiopulmonary failure.<sup>45</sup>

### 3.9. End-of-Life Management

Patients who experience COVID-19 can have life-threatening conditions attributable to respiratory, cardiovascular, and multisystem organ failure. Decisions are often made regarding escalation (and de-escalation) of therapies based on clinical course, probability of survival, and the possibility and severity of residual deficits after recovery from the acute illness. Patients who were healthy prior to COVID-19 may have different perceptions and needs about goals of care than patients with preexisting CVD. Advance care planning with the patient or family is recommended to clarify patient preferences and goals of care. Advance care planning should include advance directives and explicit documentation by health care providers regarding preferences for resuscitation and treatment preferences. For patients with severe illness, limited probability of recovery to an acceptable functional status, or poor prognosis, multidisciplinary care coordination with involvement of palliative care providers and social workers in tandem with the primary team is important. Appendix 10 provides data elements for end-of-life management.

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**KEY WORDS** ACC/AHA Clinical Data Standards, cardiogenic shock, cardiovascular diseases, coronavirus infections, COVID-19, extracorporeal membrane oxygenation, medical informatics, myocarditis, SARS-CoV-2

**APPENDIX 1. AUTHOR RELATIONSHIPS WITH INDUSTRY AND OTHER ENTITIES (RELEVANT)—  
 2022 AHA/ACC KEY DATA ELEMENTS AND DEFINITIONS FOR CARDIOVASCULAR AND  
 NONCARDIOVASCULAR COMPLICATIONS OF COVID-19**

| <b>Committee Member</b>        | <b>Employment</b>  | <b>Consultant</b> | <b>Speakers Bureau</b> | <b>Ownership/ Partnership/ Principal</b> | <b>Personal Research</b> | <b>Institutional, Organizational, or Other Financial Benefit</b> | <b>Expert Witness</b> |
|--------------------------------|--|-------------------|------------------------|--|--------------------------|--|-----------------------|
| Biykem Bozkurt<br>(Chair)      | Baylor College of Medicine—Mary and Gordon Cain Chair Professor of Medicine and Director, Winters Center for Heart Failure Research; Michael E. DeBakey VA Medical Center—Chief, Cardiology Section    | None              | None                   | None                                     | None                     | None   | None                  |
| Sandeep R. Das<br>(Vice Chair) | UT Southwestern Medical Center—Professor of Internal Medicine, Division of Cardiology  | None              | None                   | None                                     | None                     | None   | None                  |
| Daniel Addison                 | The Ohio State University—Assistant Professor and Co-Director, Cardio-Oncology Program, Division of Cardiovascular Medicine  | None              | None                   | None                                     | None                     | None   | None                  |
| Aakriti Gupta                  | Cedars-Sinai Medical Center—Structural Interventional Fellow   | None              | None                   | None                                     | None                     | None   | None                  |
| Hani Jneid                     | Baylor College of Medicine—Associate Professor of Medicine and Director of Interventional Cardiology Fellowship and Research; Michael E. DeBakey VA Medical Center—Director, Interventional Cardiology | None              | None                   | None                                     | None                     | None   | None                  |
| Sadiya S. Khan                 | Northwestern University Feinberg School of Medicine—Assistant Professor of Medicine (Cardiology) and Preventive Medicine (Epidemiology)  | None              | None                   | None                                     | None                     | None   | None                  |
| George Augustine Koromia       | Marshall University Cardiology—Fellow, Joan C. Edwards School of Medicine  | None              | None                   | None                                     | None                     | None   | None                  |
| Prathit A. Kulkarni            | Baylor College of Medicine—Assistant Professor, Infectious Diseases; Michael E. DeBakey VA Medical Center—Assistant Chief of Medicine  | None              | None                   | None                                     | ■ Vessel Health, Inc.*   | None   | None                  |
| Kathleen LaPoint†              | American College of Cardiology/American Heart Association—Clinical Healthcare Data Manager   | None              | None                   | None                                     | None                     | None   | None                  |
| Eldrin F. Lewis                | Stanford University School of Medicine—Simon H. Stertzer, MD, Professor of Medicine and Chief, Cardiovascular Medicine   | None              | None                   | None                                     | None                     | None   | None                  |
| Erin D. Michos                 | Johns Hopkins University School of Medicine—Associate Professor of Medicine and Epidemiology; Director, Women's Cardiovascular Health; and Associate Director, Preventive Cardiology                   | None              | None                   | None                                     | None                     | None   | None                  |
| Pamela N. Peterson             | University of Colorado School of Medicine—Professor of Medicine, Cardiology; Denver Health Medical Center—Cardiologist   | None              | None                   | None                                     | None                     | None   | None                  |
| Mohit K. Turagam               | Icahn School of Medicine at Mount Sinai—Assistant Professor of Medicine, Cardiology  | None              | None                   | None                                     | None                     | None   | None                  |
| Tracy Y. Wang                  | Duke University Medical Center—Professor of Medicine and Director, Health Services & Outcomes Research   | None              | None                   | None                                     | None                     | None   | None                  |
| Clyde W. Yancy                 | Northwestern University Feinberg School of Medicine—Vice Dean, Diversity & Inclusion; Magerstadt Professor of Medicine; Chief, Division of Cardiology  | None              | None                   | None                                     | None                     | None   | None                  |

This table represents the relationships of committee members with industry and other entities that were determined to be relevant to this document. These relationships were reviewed and updated in conjunction with all meetings and/or conference calls of the writing committee during the document development process. The table does not necessarily reflect relationships with industry at the time of publication. A person is deemed to have a significant interest in a business if the interest represents ownership of ≥5% of the voting stock or share of the business entity, or ownership of ≥\$5,000 of the fair market value of the business entity; or if funds received by the person from the business entity exceed 5% of the person's gross income for the previous year. Relationships that exist with no financial benefit are also included for the purpose of transparency. Relationships in this table are modest unless otherwise noted. According to the ACC/AHA, a person has a relevant relationship if: a) the relationship or interest relates to the same or similar subject matter, intellectual property or asset, topic, or issue addressed in the document; or b) the company/entity (with whom the relationship exists) makes a drug, drug class, or device addressed in the document or makes a competing drug or device addressed in the document; or c) the person or a member of the person's household, has a reasonable potential for financial, professional or other personal gain or loss as a result of the issues/content addressed in the document.

\*Significant relationship.

†Kathleen LaPoint is an ACC/AHA joint staff member and acts as the Clinical Healthcare Data Manager for the "2022 AHA/ACC Key Data Elements and Definitions for Cardiovascular and Noncardiovascular Complications of COVID-19." No relevant relationships to report. Not included/counted in the RWI balance for this committee.

ACC indicates American College of Cardiology; AHA, American Heart Association; COVID-19, coronavirus disease-2019; UT, University of Texas; and VA, Veterans Affairs.

## APPENDIX 2. REVIEWER RELATIONSHIPS WITH INDUSTRY AND OTHER ENTITIES (COMPREHENSIVE)—2022 AHA/ACC KEY DATA ELEMENTS AND DEFINITIONS FOR CARDIOVASCULAR AND NONCARDIOVASCULAR COMPLICATIONS OF COVID-19 (AUGUST 2021)

| Reviewer                | Representation  | Employment  | Consultant   | Speakers Bureau  | Ownership/<br>Partnership/<br>Principal | Personal<br>Research  | Institutional,<br>Organizational, or Other<br>Financial Benefit  | Expert Witness |
|-------------------------|---|---|--|--|---|---|--|----------------|
| Monica Colvin           | Official Reviewer—<br>ACC/AHA Task Force<br>on Data Standards | University of Michigan Health System—<br>Professor of Medicine, Advanced Heart<br>Failure and Transplant, Cardiovascular<br>Division; Associate Director, Heart<br>Transplant Program | None   | None   | None                                    | <ul style="list-style-type: none"> <li>■ CareDx</li> <li>■ SRTR/HRSA*</li> <li>■ University of Michigan†</li> </ul> | <ul style="list-style-type: none"> <li>■ Abbott‡</li> </ul>  | None           |
| Elissa Driggin          | Content Reviewer—<br>ACC                                      | New York-Presbyterian Hospital/ Columbia<br>University Irving Medical Center—Fellow,<br>Division of Cardiology  | None   | None   | None                                    | None  | None   | None           |
| Nisha Gilotra           | Official Reviewer—<br>AHA                                     | Johns Hopkins University—Director, Cardiac<br>Sarcoidosis Program and Assistant<br>Professor of Medicine  | <ul style="list-style-type: none"> <li>■ scPharmaceuticals</li> </ul>              | None   | None                                    | None  | None   | None           |
| Lee Goldberg            | Content Reviewer—<br>ACC/AHA                                  | University of Pennsylvania—Professor of<br>Medicine, Vice Chair of Medicine for<br>Informatics, and Section Chief, Advanced<br>Heart Failure and Cardiac Transplant                   | <ul style="list-style-type: none"> <li>■ Respicardia*</li> </ul>                   | None   | None                                    | <ul style="list-style-type: none"> <li>■ NIH†</li> <li>■ Respicardia†</li> </ul>                                    | None   | None           |
| Saurabh Gupta           | Content Reviewer—<br>ACC                                      | St. Charles Health System—Chief of<br>Cardiology, and Director, Structural<br>Cardiology  | <ul style="list-style-type: none"> <li>■ Edwards*</li> <li>■ Medtronic*</li> </ul> | None   | None                                    | None  | None   | None           |
| Mary<br>Heitschmidt     | Content Reviewer—<br>AHA                                      | Rush University Medical Center—Director of<br>Clinical Research, Rush College of Nursing  | None   | None   | None                                    | None  | <ul style="list-style-type: none"> <li>■ Rush University, COVID-19<br/>Scientific/Ops. Review<br/>Committee†</li> </ul>  | None           |
| David<br>Herrington     | Content Reviewer—<br>AHA                                      | Wake Forest University School of<br>Medicine—Professor of Internal Medicine/<br>Section on Cardiovascular Medicine  | None   | None   | None                                    | None  | <ul style="list-style-type: none"> <li>■ Amgen‡</li> <li>■ Cardiovascular Science Cen-<br/>ter Director*</li> <li>■ CDC*</li> <li>■ DalCor Pharmaceuticals‡</li> <li>■ Esperion‡</li> <li>■ Mount Sinai Medical Center<br/>(Miami)‡</li> <li>■ NC State Legislature (HHS/<br/>CARES Act)*</li> <li>■ NHLBI*</li> </ul> | None           |
| Norma Keller            | Official Reviewer—<br>ACC                                     | NYU Grossman School of Medicine—<br>Assistant Professor   | None   | None   | None                                    | None  | None   | None           |
| R. Kannan<br>Mutharasan | Content Reviewer—<br>ACC/AHA                                  | Northwestern University Feinberg School<br>of Medicine—Associate Professor of<br>Medicine, Cardiology   | <ul style="list-style-type: none"> <li>■ Abbott*</li> </ul>                        | <ul style="list-style-type: none"> <li>■ AstraZeneca*</li> </ul> | None                                    | None  | <ul style="list-style-type: none"> <li>■ Cardiosense</li> </ul>  | None           |
| Gurusher<br>Panj Rath   | Content Reviewer—<br>ACC/AHA                                  | George Washington School of Medicine &<br>Health Sciences—Associate Professor, and<br>Director, Heart Failure and Mechanical<br>Circulatory Support Program                           | <ul style="list-style-type: none"> <li>■ CVRx</li> </ul>                           | <ul style="list-style-type: none"> <li>■ Pfizer*</li> </ul>      | None                                    | None  | <ul style="list-style-type: none"> <li>■ Abbott‡</li> </ul>  | None           |

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APPENDIX 2. CONTINUED

| Reviewer        | Representation               | Employment  | Consultant     | Speakers Bureau                       | Ownership/<br>Partnership/<br>Principal | Personal<br>Research                   | Institutional,<br>Organizational, or Other<br>Financial Benefit | Expert Witness                              |
|-----------------|------------------------------|---|----------------|---------------------------------------|---|--|---|---|
| Andrea Price    | Official Reviewer—<br>ACC    | Indiana University Health—Director, Quality Reporting & Analytics   | None           | None                                  | None                                    | ■ ACC, Accreditation Foundation Board* | None  | None  |
| Michael Salerno | Content Reviewer—<br>ACC     | University of Virginia—Associate Professor of Medicine, Radiology and Biomedical Engineering                          | ■ Valo Health* | None                                  | None                                    | ■ NIH*                                 | ■ Heart Flow‡<br>■ Siemens†                                     | ■ Defendant, SPECT table malfunction, 2020* |
| Sanjum S. Sethi | Official Reviewer—<br>AHA    | Columbia University Medical Center—Assistant Professor of Medicine  | ■ Inari        | ■ Chiesi<br>■ Janssen Pharmaceuticals | None                                    | None                                   | ■ Terumo‡   | None  |
| Robin Trupp     | Content Reviewer—<br>ACC/AHA |   | None           | None                                  | None                                    | None                                   | None  | None  |
| Eugene Yang     | Content Reviewer—<br>ACC     | University of Washington—Clinical Professor of Medicine, Carl and Renée Behnke Endowed Professorship for Asian Health | ■ Genentech*   | None                                  | ■ Clocktree                             | ■ Amgen*                               | None  | None  |

This table represents all relationships of committee members with industry and other entities that were reported at the time of peer review, including those not deemed to be relevant to this document at the time this document was under review. The table does not necessarily reflect relationships with industry at the time of publication. A person is deemed to have a significant interest in a business if the interest represents ownership of ≥5% of the voting stock or share of the business entity, or ownership of ≥\$5,000 of the fair market value of the business entity; or if funds received by the person from the business entity exceed 5% of the person's gross income for the previous year. Relationships that exist with no financial benefit are also included for the purpose of transparency. Relationships in this table are modest unless otherwise noted. Please refer to <https://www.acc.org/guidelines/about-guidelines-and-clinical-documents/relationships-with-industry-policy> for definitions of disclosure categories or additional information about the ACC/AHA Disclosure Policy for Writing Committees.

\*Significant relationship.

†No financial benefit.

‡This disclosure was entered under the Clinical Trial Enroller category in the ACC's disclosure system. To appear in this category, the individual acknowledges that there is no direct or institutional relationship with the trial sponsor as defined in the (ACCF or ACC/AHA) Disclosure Policy for Writing Committees.

ACC indicates American College of Cardiology; AHA, American Heart Association; CDC, U.S. Centers for Disease Control and Prevention; COVID-19, coronavirus disease-2019; HHS, U.S. Department of Health and Human Services; HRSA, Health Resources and Services Administration; NC, North Carolina; NHLBI, National Heart, Lung, and Blood Institute; NIH, National Institutes of Health; Ops., Operations; NYU, New York University; SPECT, single photon emission computed tomography; SRTR, Scientific Registry of Transplant Recipients; and TFDS, Task Force on Data Standards.

## APPENDIX 3. COVID-19 DIAGNOSIS

| Data Element            | Data Element Definition                                       | Permissible Values  | Permissible Value Definitions   | Mapping/Source of Definition  | Additional Notes   |
|-------------------------|---|---|---|---|--|
| Acute COVID-19 case     | Patient with an episode of acute illness caused by SARS-CoV-2 | <ul style="list-style-type: none"> <li>■ Confirmed acute COVID-19 case</li> <li>■ Probable acute COVID-19 case</li> <li>■ Suspected acute COVID-19 case</li> <li>■ Unknown</li> <li>■ No</li> </ul> |   | Centers for Disease Control and Prevention. Coronavirus disease 2019 (COVID-19). 2020 interim case definition, approved August 5, 2020. Accessed March 4, 2022. <a href="https://ndc.services.cdc.gov/case-definitions/coronavirus-disease-2019-2020-08-05/">https://ndc.services.cdc.gov/case-definitions/coronavirus-disease-2019-2020-08-05/</a> | Can specify date of diagnosis of confirmed COVID-19 status.  |
|                         |   | Confirmed acute COVID-19 case   | Requires detection of SARS-CoV-2 RNA in a clinical or autopsy specimen <b>using a molecular amplification test</b> (eg, RT-PCR)   |   |  |
|                         |   | Probable acute COVID-19 case  | Detection of SARS-CoV-2 by antigen test in a respiratory specimen<br>OR<br>Meets <b>clinical criteria</b> and <b>epidemiological linkage criteria</b> for COVID-19 with no confirmatory laboratory testing performed<br>OR<br>A death certificate that lists COVID-19 disease or SARS-CoV-2 as an underlying cause of death or a significant condition contributing to death with no confirmatory laboratory evidence of SARS-CoV-2 |   | <b>Clinical criteria</b> (In the absence of a more likely diagnosis)<br>At least 2 of the following: fever (measured or subjective), chills, rigors, myalgia, headache, sore throat, nausea or vomiting, diarrhea, fatigue, congestion, or runny nose<br>OR<br>Any 1 of the following: cough, shortness of breath, difficulty breathing, new olfactory disorder, new taste disorder<br>OR<br>Severe respiratory illness with clinical or radiographic evidence of pneumonia or ARDS<br>In hospital setting, probable cases have been sometimes identified as PUI.<br><b>Epidemiological linkage criteria</b> = close contact, as defined by the CDC while the person was deemed to be infectious (see <b>infectious period</b> below), or a member of a risk cohort as defined by public health authorities during an outbreak |
|                         |   | Suspected acute COVID-19 case   | Requires detection of specific antibody in serum, plasma, or whole blood, or detection of specific antigen by immunocytochemistry in an autopsy specimen.   |   | Requires there is no history of previously being a confirmed or probable case.   |
|                         |   | Unknown   | COVID-19 testing not performed and COVID-19 symptoms not addressed  |   |  |
|                         |   | No  | COVID-19 test negative and no symptoms to suggest COVID-19  |   |  |
| COVID-19 symptom status | Presence or absence of symptoms due to acute COVID-19         | <ul style="list-style-type: none"> <li>■ Symptomatic</li> <li>■ Asymptomatic</li> <li>■ Unknown</li> </ul>  |   |   | See list of possible symptoms in <a href="#">Appendix 6</a> .  |

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APPENDIX 3. CONTINUED

| Data Element  | Data Element Definition  | Permissible Values   | Permissible Value Definitions | Mapping/Source of Definition   | Additional Notes   |
|---|--|--|-------------------------------|--|--|
| <b>Exposure to infectious COVID-19 case</b>                       | Being in close contact, as defined by the CDC, with a person with a probable or confirmed acute COVID-19 case while the person was in the presumptive <b>infectious period</b>   | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | Centers for Disease Control and Prevention. Coronavirus disease 2019 (COVID-19). <a href="#">Appendix A - glossary of key terms</a> . Accessed March 4, 2022. <a href="https://www.cdc.gov/coronavirus/2019-ncov/php/contact-tracing/contact-tracing-plan/appendix.html#Key-Terms">https://www.cdc.gov/coronavirus/2019-ncov/php/contact-tracing/contact-tracing-plan/appendix.html#Key-Terms</a> <sup>46</sup>  | <b>Infectious period</b><br>Refer to guidance from the CDC, which monitors the emerging science on when and for how long a person is infectious. <sup>47</sup> |
| <b>Persistently positive SARS-CoV-2 antigen or molecular test</b> | Persistently positive virological test (molecular amplification or antigen test) in a patient who is out of the presumptive infectious period of acute COVID-19  | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | Centers for Disease Control and Prevention. Coronavirus disease 2019 (COVID-19). Ending isolation and precautions for adults with COVID-19: interim guidance. Accessed March 4, 2022. <a href="https://www.cdc.gov/coronavirus/2019-ncov/hcp/duration-isolation.html">https://www.cdc.gov/coronavirus/2019-ncov/hcp/duration-isolation.html</a> <sup>48</sup>  | Any decision on potential retesting for symptoms within 3 mo of an acute COVID infection should be individualized.   |
| <b>Postacute sequelae of SARS-CoV-2 infection (PASC)</b>          | Symptoms that significantly impair quality of life, which started during or after probable or confirmed acute COVID-19 and have persisted 4 wk to 3 mo after the initial diagnosis of COVID-19   | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | World Health Organization. A clinical case definition of post COVID-19 condition by a Delphi consensus, 6 October 2021. Accessed March 4, 2022. <a href="https://www.who.int/publications/i/item/WHO-2019-nCoV-Post-COVID-19_condition-Clinical_case_definition-2021">https://www.who.int/publications/i/item/WHO-2019-nCoV-Post-COVID-19_condition-Clinical_case_definition-2021</a> . <sup>49</sup><br>Nalbandian A, Sehgal K, Gupta A, et al. Post-acute COVID-19 syndrome. <i>Nat Med</i> . 2021;27:601-615. <sup>13</sup><br>Amenta EM, Spallone A, Rodriguez-Barradas MC, et al. Postacute COVID-19: an overview and approach to classification. <i>Open Forum Infect Dis</i> . 2020;7:ofaa509. <sup>50</sup><br>Datta SD, Talwar A, Lee JT. A proposed framework and timeline of the spectrum of disease due to SARS-CoV-2 infection: illness beyond acute infection and public health implications. <i>JAMA</i> . 2020;324:2251-2252. <sup>51</sup><br>National Institutes of Health. NIH launches new initiative to study "Long COVID." Accessed March 4, 2022. <a href="https://www.nih.gov/about-nih/who-we-are/nih-director/statements/nih-launches-new-initiative-study-long-covid">https://www.nih.gov/about-nih/who-we-are/nih-director/statements/nih-launches-new-initiative-study-long-covid</a> <sup>52</sup><br>National Institute for Health and Care Excellence. COVID-19 rapid guideline: managing the long-term effects of COVID-19. Accessed March 4, 2022. <a href="https://www.nice.org.uk/guidance/ng188/resources/covid19-rapid-guideline-managing-the-longterm-effects-of-covid19-pdf-66142028400325">https://www.nice.org.uk/guidance/ng188/resources/covid19-rapid-guideline-managing-the-longterm-effects-of-covid19-pdf-66142028400325</a> <sup>53</sup> | Also referred to as "postacute COVID-19 syndrome" or "long COVID." Not well characterized currently.   |
| <b>Multisystem inflammatory syndrome in children (MIS-C)</b>      | The occurrence of fever, laboratory evidence of inflammation, and evidence of clinically severe illness requiring hospitalization with multisystem (≥2) organ involvement AND No plausible alternative diagnoses AND Positive for current or recent SARS-CoV-2 infection by RT-PCR, serology, or antigen test OR exposure to a suspected or confirmed COVID-19 case within 4 wk prior to symptom onset in an individual aged <21 y | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | Centers for Disease Control and Infection. Information for healthcare providers about multisystem inflammatory syndrome in children (MIS-C). Accessed March 4, 2022. <a href="https://www.cdc.gov/mis-c/hcp/">https://www.cdc.gov/mis-c/hcp/</a> <sup>54</sup>   |  |

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## APPENDIX 3. CONTINUED

| Data Element   | Data Element Definition   | Permissible Values   | Permissible Value Definitions | Mapping/Source of Definition   | Additional Notes |
|--|---|--|-------------------------------|--|------------------|
| <b>Multisystem inflammatory syndrome in adults (MIS-A)</b> | <p>A patient aged <math>\geq 21</math> y hospitalized for <math>\geq 24</math> h, or with an illness resulting in death, who meets the following clinical and laboratory criteria. The patient should not have a more likely alternative diagnosis for the illness (eg, bacterial sepsis, exacerbation of a chronic medical condition).</p> <p>I. Clinical criteria<br/>Subjective fever or documented fever (<math>\geq 38.0^{\circ}\text{C}</math>) for <math>\geq 24</math> h prior to hospitalization or within the first 3 d of hospitalization* and at least 3 of the following clinical criteria occurring prior to hospitalization or within the first 3 d of hospitalization.* At least 1 must be a primary clinical criterion:</p> <p>A. Primary clinical criteria</p> <ol style="list-style-type: none"> <li>1. Severe cardiac illness includes myocarditis, pericarditis, coronary artery dilatation/aneurysm, or new-onset right or left ventricular dysfunction (LVEF <math>&lt; 50\%</math>), 2nd/3rd degree AV block, or ventricular tachycardia. (Note: cardiac arrest alone does not meet this criterion)</li> <li>2. Rash and nonpurulent conjunctivitis</li> </ol> <p>B. Secondary clinical criteria</p> <ol style="list-style-type: none"> <li>1. New-onset neurological signs and symptoms: includes encephalopathy in a patient without prior cognitive impairment, seizures, meningeal signs, or peripheral neuropathy (including Guillain-Barré syndrome)</li> <li>2. Shock or hypotension not attributable to medical therapy (eg, sedation, renal replacement therapy)</li> <li>3. Abdominal pain, vomiting, or diarrhea</li> <li>4. Thrombocytopenia (platelet count <math>&lt; 150,000/\text{microliter}</math>)</li> </ol> <p>II. Laboratory evidence<br/>The presence of laboratory evidence of inflammation and SARS-CoV-2 infection.</p> <p>A. Elevated levels of at least 2 of the following: C-reactive protein, ferritin, IL-6, erythrocyte sedimentation rate, procalcitonin</p> <p>B. A positive SARS-CoV-2 test for current or recent infection by RT-PCR, serology, or antigen detection</p> <p>NOTE: *These criteria must be met by the end of hospital day 3, where the date of hospital admission is hospital day 0.</p> | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | Centers for Disease Control and Prevention. Multisystem inflammatory syndrome in adults (MIS-A). Case definition information for healthcare providers. Accessed March 4, 2022. <a href="https://www.cdc.gov/mis/mis-a/hcp.html">https://www.cdc.gov/mis/mis-a/hcp.html</a> <sup>55</sup> |                  |

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**APPENDIX 3. CONTINUED**

| <b>Data Element</b>   | <b>Data Element Definition</b>   | <b>Permissible Values</b>   | <b>Permissible Value Definitions</b>   | <b>Mapping/Source of Definition</b>   | <b>Additional Notes</b>  |
|---|--|---|--|---|--|
| <b>Prior COVID-19</b>   | Prior evidence of COVID-19 in an individual who is no longer in the infectious period  | <ul style="list-style-type: none"> <li>■ Prior COVID-19 without residual sequelae of postacute COVID-19</li> <li>■ Prior COVID-19 with residual sequelae of postacute COVID-19</li> </ul> |  |   | Out of infectious period of acute COVID-19 as specified by CDC. <sup>47</sup>  |
| <b>COVID-19 reinfection</b>   | New discrete episode of acute COVID-19 in person with a prior history of probable/confirmed COVID-19. Other information can provide supporting but not definitive evidence for reinfection, such as culture or subgenomic mRNA analysis (to detect the presence of replication-competent virus) or serology, which could be useful to document a serological response to SARS-CoV-2. | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul>  | <p>Criteria to distinguish a new case from an existing case</p> <p>The following should be enumerated as a new case:</p> <ul style="list-style-type: none"> <li>■ SARS-CoV-2 sequencing results from the new positive specimen and a positive specimen from the most recent previous case demonstrate a different lineage.</li> <li style="padding-left: 20px;">OR</li> <li>■ Person was most recently enumerated as a confirmed or probable case with onset date (if available) or first positive specimen collection date for that classification &gt;90 d prior.</li> <li style="padding-left: 20px;">OR</li> <li>■ Person was previously reported but not enumerated as a confirmed or probable case (ie, suspect), but now meets the criteria for a confirmed or probable case. Repeat suspect cases should not be enumerated.</li> </ul> | Centers for Disease Control and Prevention. Coronavirus disease 2019 (COVID-19) 2021 case definition. Accessed March 4, 2022. <a href="https://ndc.services.cdc.gov/case-definitions/coronavirus-disease-2019-2021/">https://ndc.services.cdc.gov/case-definitions/coronavirus-disease-2019-2021/</a> <sup>56</sup> | <p>Some individuals (eg, severely immunocompromised persons) can shed SARS-CoV-2 detected by molecular amplification tests &gt;90 d after infection.</p> <p>For severely immunocompromised individuals, clinical judgment should be used to determine if a repeat positive test is likely to result from long-term shedding and, therefore, not be enumerated as a new case. CDC defines severe immunocompromise as certain conditions, such as being on chemotherapy for cancer, untreated HIV infection with CD4 T lymphocyte count &lt;200, combined primary immunodeficiency disorder, and receipt of prednisone &gt;20 mg/d for more than 14 d.</p> |
| <b>Date of acute COVID-19 diagnosis</b>   | Date that viral testing confirming a diagnosis of acute COVID-19 was obtained  | <ul style="list-style-type: none"> <li>■ Date, mm/dd/yyyy</li> </ul>  |  |   |  |
| <b>Hospitalization due to COVID-19</b>  | Hospitalization due to COVID-19  | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul>  |  |   |  |
| <b>Hospitalization for any reason with incidental diagnosis of SARS-CoV-2 infection</b> | Hospitalization for any non-COVID-19-related indication with incidental diagnosis of SARS-CoV-2 infection  | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul>  |  |   |  |
| <b>Date of first COVID-19-related hospitalization</b>                                   | Date that the first COVID-19-related hospitalization occurred  | <ul style="list-style-type: none"> <li>■ Date, mm/dd/yyyy</li> </ul>  |  |   |  |

*Continued on the next page*

## APPENDIX 3. CONTINUED

| Data Element   | Data Element Definition  | Permissible Values  | Permissible Value Definitions | Mapping/Source of Definition  | Additional Notes |
|--|--|---|-------------------------------|---|------------------|
| <b>Date of first hospitalization with incidental diagnosis of SARS-CoV-2 infection</b> | Date that hospitalization for any non-COVID-19-related indication occurred with incidental first diagnosis of SARS-CoV-2 infection | <ul style="list-style-type: none"> <li>■ Date, mm/dd/yyyy</li> </ul>  |                               |   |                  |
| <b>Coinfection of COVID-19 with other respiratory infections</b>                       | Other respiratory infection in patient an episode of acute illness caused by SARS-CoV-2  | <ul style="list-style-type: none"> <li>■ Influenza</li> <li>■ Other viral infection</li> <li>■ Bacterial infection</li> <li>■ Fungal infection</li> </ul>   |                               | <p>Bai L, Zhao Y, Dong J, et al. Coinfection with influenza A virus enhances SARS-CoV-2 infectivity. <i>Cell Res.</i> 2021;31:395-403.<sup>57</sup></p> <p>Belongia EA, Osterholm MT. COVID-19 and flu, a perfect storm. <i>Science.</i> 2020;368:1163.<sup>58</sup></p> <p>Lansbury L, Lim B, Baskaran V, et al. Co-infections in people with COVID-19: a systematic review and meta-analysis. <i>J Infect.</i> 2020;81:266-275.<sup>59</sup></p> <p>Rubin R. What happens when COVID-19 collides with flu season? <i>JAMA.</i> 2020;324:923-925.<sup>60</sup></p> <p>Su S, Liu Z, Jiang S. Double insult: flu bug enhances SARS-CoV-2 infectivity. <i>Cell Res.</i> 2021;31:491-492.<sup>61</sup></p> |                  |
| <b>SARS-CoV-2 variant</b>  | Variant lineage of SARS-CoV-2  | <ul style="list-style-type: none"> <li>■ Alpha (B.1.1.7 and Q lineages)</li> <li>■ Beta (B.1.351 and descendent lineages)</li> <li>■ Delta (B.1.617.2 and AY lineages)</li> <li>■ Gamma (P.1 and descendent lineages)</li> <li>■ Epsilon (B.1.427 and B.1.429)</li> <li>■ Eta (B.1.525)</li> <li>■ Iota (B.1.526)</li> <li>■ Kappa (B.1.617.1)</li> <li>■ B.1.617.3</li> <li>■ Mu (B.1.621, B.1.621.1)</li> <li>■ Zeta (P.2)</li> <li>■ Omicron (B.1.1.529 and BA lineages)</li> <li>■ Other, specify</li> <li>■ Unknown</li> </ul> |                               | <p>Centers for Disease Control and Prevention. SARS-CoV-2 variant classifications and definitions. Accessed March 4, 2022. <a href="https://www.cdc.gov/coronavirus/2019-ncov/variants/variant-info.html">https://www.cdc.gov/coronavirus/2019-ncov/variants/variant-info.html</a><sup>62</sup></p> <p>NCI Thesaurus Codes: C179573, C179575, C179576, C179577, C179579, C179580, C179585, C179586, C179596, C179598, C179599, C180913, C180977, C181075, C181075, C184327<sup>63</sup></p>   |                  |

ARDS indicates acute respiratory distress syndrome; CDC, Centers for Disease Control and Prevention; COVID-19, coronavirus disease-2019; HIV, human immunodeficiency virus; MIS-A, multisystem inflammatory syndrome in adults; MIS-C, multisystem inflammatory syndrome in children; PASC, postacute sequelae of SARS-CoV-2 infection; PUI, person under investigation; RNA, ribonucleic acid; RT-PCR, reverse transcription-polymerase chain reaction; and SARS-CoV-2, severe acute respiratory syndrome-coronavirus-2.

**APPENDIX 4. COVID-19 CARDIOVASCULAR COMPLICATIONS**

**A. Acute Cardiovascular Complications Related to COVID-19 Infection**

| <b>Data Element</b>                                      | <b>Data Element Definition</b>   | <b>Permissible Values</b>   | <b>Permissible Value Definitions</b> | <b>Mapping/Source of Definition</b>  | <b>Additional Notes</b>   |
|--|--|---|--------------------------------------|--|---|
| <b>Acute myocardial injury related to acute COVID-19</b> | Acute myocardial injury diagnosed by rise and fall in cardiac troponin above the 99th percentile of a reference population in a patient with probable or confirmed acute COVID-19 and no alternative explanation for acute myocardial injury | <p>Select all that apply</p> <ul style="list-style-type: none"> <li>■ Acute myocardial injury without ischemia, HF, ventricular dysfunction, or myocarditis</li> <li>■ Acute myocardial injury with type I myocardial infarction</li> <li>■ Acute myocardial injury with myocarditis</li> <li>■ Acute myocardial injury with LV dysfunction</li> <li>■ Acute myocardial injury with RV dysfunction</li> <li>■ Acute myocardial injury with HF</li> <li>■ Acute myocardial injury with cardiogenic shock</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                                      | <p>Hendren NS, Drazner MH, Bozkurt B, et al. Description and proposed management of the acute COVID-19 cardiovascular syndrome. <i>Circulation</i>. 2020;141:1903-1914.<sup>10</sup></p> <p>Thygesen K, Alpert JS, Jaffe AS, et al. Fourth universal definition of myocardial infarction (2018). <i>J Am Coll Cardiol</i>. 2018;72:2231-2264.<sup>64</sup></p> | See <a href="#">Appendix 3</a> for the definition of a probable or confirmed acute COVID-19 case. |

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A. Acute Cardiovascular Complications Related to COVID-19 Infection (Continued)

| Data Element | Data Element Definition                                   | Permissible Values  | Permissible Value Definitions   | Mapping/Source of Definition  | Additional Notes  |
|--------------|---|---|---|---|---|
|              |   | Acute myocardial injury without ischemia, HF, ventricular dysfunction, or myocarditis | Acute myocardial injury, without evidence of a newly reduced LVEF or RVEF, HF, cardiogenic shock, myocarditis, or acute ischemia in a patient with probable or confirmed acute COVID-19   |   | See <a href="#">Appendix 3</a> for the definition of a probable or confirmed acute COVID-19 case.   |
|              | Acute myocardial injury with type I myocardial infarction |   | Acute myocardial injury with clinical presentation suggestive of type I myocardial infarction with detection of a rise or fall of cardiac troponin values with at least 1 value above the 99th percentile upper reference limit and with at least 1 of the following: <ul style="list-style-type: none"> <li>■ Symptoms of acute myocardial ischemia;</li> <li>■ New ischemic ECG changes;</li> <li>■ Development of pathological Q waves;</li> <li>■ Imaging evidence of new loss of viable myocardium or new regional wall motion abnormality in a pattern consistent with an ischemic etiology;</li> <li>■ Identification of a coronary thrombus by angiography including intracoronary imaging or by autopsy, occurring in a patient with probable or confirmed acute COVID-19</li> </ul> | Hendren NS, Drazner MH, Bozkurt B, et al. Description and proposed management of the acute COVID-19 cardiovascular syndrome. <i>Circulation</i> . 2020;141:1903-1914. <sup>10</sup><br>Thygesen K, Alpert JS, Jaffe AS, et al. Fourth universal definition of myocardial infarction (2018). <i>J Am Coll Cardiol</i> . 2018;72:2231-2264. <sup>64</sup> | See <a href="#">Appendix 3</a> for the definition of a probable or confirmed acute COVID-19 case.   |
|              | Acute myocardial injury with myocarditis                  |   | Acute myocardial injury with clinical, imaging, and pathology evidence supporting inflammation and myocarditis in a patient with probable or confirmed acute COVID-19   | Kindermann I, Barth C, Mahfoud F, et al. Update on myocarditis. <i>J Am Coll Cardiol</i> . 2012;59:779-792. <sup>55</sup><br>Ferreira VM, Schulz-Menger J, Holmvang G, et al. Cardiovascular magnetic resonance in nonischemic myocardial inflammation: expert recommendations. <i>J Am Coll Cardiol</i> . 2018;72:3158-3176. <sup>66</sup>             | If tissue is available, inflammatory disease of the myocardium and myocarditis can be diagnosed by histological, immunologic, and immunohistochemical criteria of myocarditis.<br>Cardiac MRI evidence of myocardial edema, nonischemic myocardial injury, hyperemia, LV dysfunction, or fibrosis can support diagnosis of myocarditis. See <a href="#">Appendix 3</a> for the definition of a probable or confirmed acute COVID-19 case. |

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APPENDIX 4. CONTINUED

A. Acute Cardiovascular Complications Related to COVID-19 Infection (Continued)

| Data Element | Data Element Definition | Permissible Values                          | Permissible Value Definitions  | Mapping/Source of Definition  | Additional Notes   |
|--------------|-------------------------|---|--|---|--|
|              |                         | Acute myocardial injury with LV dysfunction | Acute myocardial injury with evidence of new systolic dysfunction with reduced LVEF (LVEF <50%) in a patient with probable or confirmed acute COVID-19 | Bozkurt B, Hershberger RE, Butler J, et al. 2021 ACC/AHA key data elements and definitions for heart failure: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Data Standards (Writing Committee to Develop Clinical Data Standards for Heart Failure). <i>J Am Coll Cardiol.</i> 2021;77:2053-2150. <sup>67</sup><br>Hendren NS, Drazner MH, Bozkurt B, et al. Description and proposed management of the acute COVID-19 cardiovascular syndrome. <i>Circulation.</i> 2020;141:1903-1914. <sup>10</sup><br>Bozkurt B, Coats AJ, Tsutsui H, et al. Universal definition and classification of heart failure: a report of the Heart Failure Society of America, Heart Failure Association of the European Society of Cardiology, Japanese Heart Failure Society and Writing Committee of the Universal Definition of Heart Failure. <i>J Card Fail.</i> 2021;27:387-413. <sup>68</sup>   | LV dysfunction can be further subclassified as HFrEF if LVEF is <40%; HFmrEF if LVEF is 41%-49%; and HFpEF if LVEF >50%, if accompanied with HF symptoms. See Appendix 3 for the definition of a probable or confirmed acute COVID-19 case.                      |
|              |                         | Acute myocardial injury with RV dysfunction | Acute myocardial injury with evidence of newly reduced RV function in a patient with probable or confirmed acute COVID-19                              | Hendren NS, Drazner MH, Bozkurt B, et al. Description and proposed management of the acute COVID-19 cardiovascular syndrome. <i>Circulation.</i> 2020;141:1903-1914. <sup>10</sup>  | Right heart strain may be due to pulmonary embolism, elevated pulmonary pressures arising from severe COVID-associated lung disease, left heart dysfunction, or RV infarct.<br>See Appendix 3 for the definition of a probable or confirmed acute COVID-19 case. |
|              |                         | Acute myocardial injury with HF             | Acute myocardial injury with evidence of new or worsening signs and symptoms of HF in a patient with probable or confirmed acute COVID-19              | Bozkurt B, Hershberger RE, Butler J, et al. 2021 ACC/AHA key data elements and definitions for heart failure: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Data Standards (Writing Committee to Develop Clinical Data Standards for Heart Failure). <i>J Am Coll Cardiol.</i> 2021;77:2053-2150. <sup>67</sup><br>Yancy CW, Jessup M, Bozkurt B, et al. 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. <i>J Am Coll Cardiol.</i> 2013;62:e147-239. <sup>69</sup><br>Bozkurt B, Coats AJ, Tsutsui H, et al. Universal definition and classification of heart failure: a report of the Heart Failure Society of America, Heart Failure Association of the European Society of Cardiology, Japanese Heart Failure Society and Writing Committee of the Universal Definition of Heart Failure. <i>J Card Fail.</i> 2021;27:387-413. <sup>68</sup> | HF can be further subclassified as HFrEF if LVEF is <40%; HFmrEF if LVEF is 41%-49%; and HFpEF if LVEF >50% and accompanied by HF symptoms. See Appendix 3 for the definition of a probable or confirmed acute COVID-19 case.                                    |

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APPENDIX 4. CONTINUED

A. Acute Cardiovascular Complications Related to COVID-19 Infection (Continued)

| Data Element                               | Data Element Definition  | Permissible Values   | Permissible Value Definitions   | Mapping/Source of Definition  | Additional Notes  |
|--|--|--|---|---|---|
|  |  | Acute myocardial injury with cardiogenic shock   | Acute myocardial injury with evidence of cardiogenic shock defined as clinical evidence of low cardiac index (eg, <2.2 L/min/m <sup>2</sup> ) accompanied by impaired tissue perfusion in a patient with probable or confirmed acute COVID-19 |   | Cardiogenic shock with or without comorbid distributive shock data element below should be used for patients without evidence of myocardial injury or cardiac troponin elevation.<br>See Appendix 3 for the definition of a probable or confirmed acute COVID-19 case.  |
|  |  | No   |   |   |   |
|  |  | Unknown  | A proper value is applicable but not known.   |   |   |
| Acute heart failure                        | HF with new or worsening signs and symptoms in a patient with probable or confirmed acute COVID-19. Acute HF can be in the setting of either a preserved or reduced LVEF. This can be the first presentation of HF, or it can reflect an acute decompensation in a patient with history of chronic HF. | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |   | Bozkurt B, Hershberger RE, Butler J, et al. 2021 ACC/AHA key data elements and definitions for heart failure: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Data Standards (Writing Committee to Develop Clinical Data Standards for Heart Failure). <i>J Am Coll Cardiol.</i> 2021;77:2053-2150. <sup>67</sup><br>Yancy CW, Jessup M, Bozkurt B, et al. 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. <i>J Am Coll Cardiol.</i> 2013;62:e147-239. <sup>69</sup><br>Bozkurt B, Coats AJ, Tsutsui H, et al. Universal definition and classification of heart failure: a report of the Heart Failure Society of America, Heart Failure Association of the European Society of Cardiology, Japanese Heart Failure Society and Writing Committee of the Universal Definition of Heart Failure. <i>J Card Fail.</i> 2021;27:387-413. <sup>68</sup> | Clinical syndrome resulting from either impairment of LV filling or reduction in LV ejection fraction, accompanied by signs or symptoms of either volume overload (congestion) or low cardiac output (hypoperfusion). Important to distinguish between respiratory failure from acute COVID-19 and concomitant acute HF to identify treatment options. The difference from acute myocardial injury with HF data definition above is acute HF data element does not require a rise in cardiac troponin and patients may not exhibit acute cardiac injury.<br>See Appendix 3 for the definition of a probable or confirmed acute COVID-19 case. |
| Acute pericarditis or pericardial effusion | Inflammatory process involving the pericardium, can occur with or without the new development of a pericardial effusion, in a patient with probable or confirmed acute COVID-19  | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |   | O’Gallagher K, Kanyal R, Sado DM, et al. COVID-19 myopericarditis. Accessed March 4, 2022. <a href="https://www.acc.org/latest-in-cardiology/articles/2020/09/25/17/22/covid-19-myopericarditis">https://www.acc.org/latest-in-cardiology/articles/2020/09/25/17/22/covid-19-myopericarditis</a> <sup>70</sup><br>Chiabrando JG, Bonaventura A, Vecchié A, et al. Management of acute and recurrent pericarditis: JACC state-of-the-art review. <i>J Am Coll Cardiol.</i> 2020;75:76-92. <sup>71</sup>  | Inflammation of the pericardial layers characterized by chest pain, ECG changes, and often pericardial effusion detected by ECG or cardiac MRI. Pericardial effusion associated with COVID-19 is usually exudative reflective of an inflammatory process. Can occur with concomitant myocarditis. However, the size (volume) of the pericardial effusion does not necessarily correlate with the severity of myocardial involvement.<br>See Appendix 3 for the definition of a probable or confirmed acute COVID-19 case.   |

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APPENDIX 4. CONTINUED

A. Acute Cardiovascular Complications Related to COVID-19 Infection (Continued)

| Data Element  | Data Element Definition   | Permissible Values   | Permissible Value Definitions | Mapping/Source of Definition  | Additional Notes   |
|---|---|--|-------------------------------|---|--|
| <b>Sustained ventricular arrhythmia</b>                                 | Sustained ventricular tachycardia ( $\geq 30$ s or requiring DCCV) or ventricular fibrillation in a patient with probable or confirmed acute COVID-19   | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | <p>Hendren NS, Drazner MH, Bozkurt B, et al. Description and proposed management of the acute COVID-19 cardiovascular syndrome. <i>Circulation</i>. 2020;141:1903-1914.<sup>10</sup></p> <p>Turagam MK, Musikantow D, Goldman ME, et al. Malignant arrhythmias in patients with COVID-19: incidence, mechanisms, and outcomes. <i>Circ Arrhythm Electrophysiol</i>. 2020;13:e008920.<sup>72</sup></p>   | <p>A sustained ventricular tachycardia event is one that lasts &gt;30 s in duration or one that lasts &lt;30 s but requires electrical termination due to hemodynamic compromise.</p> <p>For sudden cardiac death, see separate data element below.</p> <p>See Appendix 3 for the definition of a probable or confirmed acute COVID-19 case.</p> |
| <b>New-onset AF or atrial flutter</b>                                   | Newly occurring AF or atrial flutter in a patient with probable or confirmed acute COVID-19, further categorized as: 1) first detected AF, 2) paroxysmal AF: AF that is self-terminating within 7 d of recognized onset, 3) persistent AF: AF that is not self-terminating within 7 d | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | <p>Musikantow DR, Turagam MK, Sartori S, et al. Atrial fibrillation in patients hospitalized with COVID-19: incidence, predictors, outcomes and comparison to influenza. <i>J Am Coll Cardiol EP</i>. 2021;7:1120-1130.<sup>73</sup></p> <p>Hendren NS, Drazner MH, Bozkurt B, et al. Description and proposed management of the acute COVID-19 cardiovascular syndrome. <i>Circulation</i>. 2020;141:1903-1914.<sup>10</sup></p> <p>McNamara RL, Brass LM, Drozda JP Jr, et al. ACC/AHA key data elements and definitions for measuring the clinical management and outcomes of patients with atrial fibrillation: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Data Standards (Writing Committee to Develop Data Standards on Atrial Fibrillation). <i>J Am Coll Cardiol</i>. 2004;44:475-495.<sup>74</sup></p> | <p>See Appendix 3 for the definition of a probable or confirmed acute COVID-19 case.</p>   |
| <b>Sustained atrial tachyarrhythmia other than AF or atrial flutter</b> | Other types of supraventricular tachycardia, including AV nodal reentry, orthodromic re-entrant tachycardia, multifocal atrial tachycardia, other atrial tachycardia, in a patient with probable or confirmed acute COVID-19  | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | <p>Musikantow DR, Turagam MK, Sartori S, et al. Atrial fibrillation in patients hospitalized with COVID-19: incidence, predictors, outcomes and comparison to influenza. <i>J Am Coll Cardiol EP</i>. 2021;7:1120-1130.<sup>73</sup></p> <p>Hendren NS, Drazner MH, Bozkurt B, et al. Description and proposed management of the acute COVID-19 cardiovascular syndrome. <i>Circulation</i>. 2020;141:1903-1914.<sup>10</sup></p> <p>McNamara RL, Brass LM, Drozda JP Jr, et al. ACC/AHA key data elements and definitions for measuring the clinical management and outcomes of patients with atrial fibrillation: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Data Standards (Writing Committee to Develop Data Standards on Atrial Fibrillation). <i>J Am Coll Cardiol</i>. 2004;44:475-495.<sup>74</sup></p> | <p>Supraventricular tachycardias other than AF or atrial flutter</p> <p>See Appendix 3 for the definition of a probable or confirmed acute COVID-19 case.</p>  |

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A. Acute Cardiovascular Complications Related to COVID-19 Infection (Continued)

| Data Element   | Data Element Definition   | Permissible Values   | Permissible Value Definitions | Mapping/Source of Definition   | Additional Notes   |
|--|---|--|-------------------------------|--|--|
| <b>Bradyarrhythmia requiring temporary or permanent pacing</b> | Bradycardia (ventricular rate <60 bpm) that is symptomatic reflecting signs of hypoperfusion and that requires temporary or permanent pacemaker intervention in a patient with probable or confirmed acute COVID-19                       | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | <p>Chinitz JS, Goyal R, Harding M, et al. Bradyarrhythmias in patients with COVID-19: marker of poor prognosis? <i>Pacing Clin Electrophysiol.</i> 2020;43:1199-1204.<sup>75</sup></p> <p>Turagam MK, Musikantow D, Goldman ME, et al. Malignant arrhythmias in patients with COVID-19: incidence, mechanisms, and outcomes. <i>Circ Arrhythm Electrophysiol.</i> 2020;13:e008920.<sup>72</sup></p>                      | Can include sinus bradycardia or 2nd or 3rd degree AV block. See Appendix 3 for the definition of a probable or confirmed acute COVID-19 case. |
| <b>Deep venous thrombosis</b>                                  | Thrombus formation within deep veins in a patient with probable or confirmed acute COVID-19   | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | <p>Bikdeli B, Madhavan MV, Jimenez D, et al. COVID-19 and thrombotic or thromboembolic disease: implications for prevention, antithrombotic therapy, and follow-up: JACC state-of-the-art review. <i>J Am Coll Cardiol.</i> 2020;75:2950-2973.<sup>76</sup></p>  | See Appendix 3 for the definition of a probable or confirmed acute COVID-19 case.  |
| <b>Pulmonary embolus</b>                                       | Thrombus formation or lodging in an artery in the lung in a patient with probable or confirmed acute COVID-19   | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | <p>Poissy J, Goutay J, Caplan M, et al. Pulmonary embolism in patients with COVID-19: awareness of an increased prevalence. <i>Circulation.</i> 2020;142:184-186.<sup>77</sup></p> <p>Shah S, Shah K, Patel SB, et al. Elevated D-dimer levels are associated with increased risk of mortality in coronavirus disease 2019: a systematic review and meta-analysis. <i>Cardiol Rev.</i> 2020;28:295-302.<sup>78</sup></p> | See Appendix 3 for the definition of a probable or confirmed acute COVID-19 case.  |
| <b>Intracardiac thrombus</b>                                   | Thrombus formation in the left or right ventricle or atria of the heart in a patient with probable or confirmed acute COVID-19  | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | <p>Sethi SS, Zilinyi R, Green P, et al. Right ventricular clot in transit in COVID-19: implications for the pulmonary embolism response team. <i>J Am Coll Cardiol Case Rep.</i> 2020;2:1391-1396.<sup>79</sup></p>  | See Appendix 3 for the definition of a probable or confirmed acute COVID-19 case.  |
| <b>Acute ischemic limb</b>                                     | Acute decrease in limb perfusion, usually producing new or worsening symptoms or signs, and often threatening limb viability or resulting in limb amputation in a patient with probable or confirmed acute COVID-19                       | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | <p>Bellosta R, Luzzani L, Natalini G, et al. Acute limb ischemia in patients with COVID-19 pneumonia. <i>J Vasc Surg.</i> 2020;72:1864-1872.<sup>28</sup></p>  | See Appendix 3 for the definition of a probable or confirmed acute COVID-19 case.  |
| <b>Sudden cardiac death with ROSC</b>                          | Unexpected death caused by sudden cardiac arrest with asystole, pulseless electrical activity, sustained ventricular tachycardia, or ventricular fibrillation with successful ROSC in a patient with probable or confirmed acute COVID-19 | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | <p>Turagam MK, Musikantow D, Goldman ME, et al. Malignant arrhythmias in patients with COVID-19: incidence, mechanisms, and outcomes. <i>Circ Arrhythm Electrophysiol.</i> 2020;13:e008920.<sup>72</sup></p>   | See Appendix 3 for the definition of a probable or confirmed acute COVID-19 case.  |

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APPENDIX 4. CONTINUED

A. Acute Cardiovascular Complications Related to COVID-19 Infection (Continued)

| Data Element  | Data Element Definition   | Permissible Values | Permissible Value Definitions   | Mapping/Source of Definition  | Additional Notes  |
|---|---|--------------------|---|---|---|
| Cardiogenic shock with or without comorbid distributive shock | Clinical evidence of low cardiac index (eg, <2.2 L/min/m <sup>2</sup> ) accompanied by impaired tissue perfusion in a patient with probable or confirmed acute COVID-19 | ■ Stage A          |   | Bozkurt B, Hershberger RE, Butler J, et al. 2021 ACC/AHA key data elements and definitions for heart failure: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Data Standards (Writing Committee to Develop Clinical Data Standards for Heart Failure). <i>J Am Coll Cardiol</i> . 2021;77:2053-2150. <sup>67</sup><br>Hendren NS, Drazner MH, Bozkurt B, et al. Description and proposed management of the acute COVID-19 cardiovascular syndrome. <i>Circulation</i> . 2020;141:1903-1914. <sup>10</sup><br>Baran DA, Grines CL, Bailey S, et al. SCAI clinical expert consensus statement on the classification of cardiogenic shock. <i>Catheter Cardiovasc Interv</i> . 2019;94:29-37. <sup>80</sup> | COVID-19 may result in septic or vasodilatory shock. If there is cardiac involvement with inability of the heart to pump sufficient blood for the needs of the body, concomitant cardiac failure may result in mixed (cardiogenic and vasodilatory) shock or cardiogenic shock. Note that invasive measurement of cardiac output is not required. See Appendix 3 for the definition of a probable or confirmed acute COVID-19 case. |
|   |   | ■ Stage B          |   |   |   |
|   |   | ■ Stage C          |   |   |   |
|   |   | ■ Stage D          |   |   |   |
|   |   | ■ Stage E          |   |   |   |
|   |   | ■ No               |   |   |   |
|   |   | ■ Unknown          |   |   |   |
|   |   |                    |   |   |   |
|   |   | Stage A            | At risk: A patient who is not currently experiencing signs or symptoms of cardiogenic shock but is at risk for its development. These patients may include those with large acute myocardial infarction or prior infarction, acute or acute on chronic HF symptoms.       |   |   |
|   |   | Stage B            | Beginning cardiogenic shock: A patient who has clinical evidence of relative hypotension or tachycardia without hypoperfusion   |   |   |
|   |   | Stage C            | Classic cardiogenic shock: A patient that manifests with hypoperfusion that requires intervention (inotrope, pressor or mechanical support, including ECMO) beyond volume resuscitation to restore perfusion. These patients typically present with relative hypotension. |   |   |
|   |   | Stage D            | Deteriorating/doom: A patient that is similar to category C but is getting worse. They have failure to respond to initial interventions.  |   |   |
|   |   | Stage E            | Extremis: A patient that is experiencing cardiac arrest with ongoing CPR or ECMO, being supported by multiple interventions   |   |   |
|   |   | No                 |   |   |   |
|   |   | Unknown            |   |   |   |

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A. Acute Cardiovascular Complications Related to COVID-19 Infection (Continued)

| Data Element | Data Element Definition  | Permissible Values  | Permissible Value Definitions  | Mapping/Source of Definition   | Additional Notes   |  |
|--------------|--|---|--|--|--|--|
| Acute stroke | An acute neurological deficit attributed to an acute focal injury of the central nervous system by a vascular cause in a patient with probable or confirmed acute COVID-19, accompanied with neuropathological, neuroimaging, or clinical evidence of permanent injury | <ul style="list-style-type: none"> <li>■ Ischemic stroke</li> <li>■ Intracerebral hemorrhage</li> <li>■ Subarachnoid hemorrhage</li> <li>■ Epidural hemorrhage</li> <li>■ Subdural hemorrhage</li> <li>■ Cerebral venous sinus thrombosis</li> <li>■ Stroke not otherwise specified</li> <li>■ No</li> <li>■ Unknown</li> </ul> |  | <p>Oxley TJ, Mocco J, Majidi S, et al. Large-vessel stroke as a presenting feature of Covid-19 in the young. <i>N Engl J Med</i>. 2020;382:e60.<sup>81</sup></p> <p>Sacco RL, Kasner SE, Broderick JP, et al. An updated definition of stroke for the 21st century: a statement for healthcare professionals from the American Heart Association/American Stroke Association. <i>Stroke</i>. 2013;44:2064-2089.<sup>82</sup></p> <p>Shakil SS, Emmons-Bell S, Rutan C, et al. Stroke among patients hospitalized with COVID-19: results from the American Heart Association COVID-19 Cardiovascular Disease Registry. <i>Stroke</i>. 2022;53:800-807.<sup>83</sup></p> | Hemorrhages in the CNS should be classified as stroke if they are nontraumatic, caused by a vascular event, and result in injury to the CNS. See Appendix 3 for the definition of a probable or confirmed acute COVID-19 case. |  |
|              |  | Ischemic stroke   | An acute episode of focal or global neurological dysfunction caused by brain, spinal cord, or retinal vascular injury as a result of infarction of central nervous system tissue.  | NCDR CathPCI Registry Coder's Data Dictionary v5.0 (data element #9001) <sup>84</sup>  |  |  |
|              |  | Intracerebral hemorrhage  | Rapidly developing clinical signs of neurological dysfunction attributable to a focal collection of blood within the brain parenchyma or ventricular system that is not caused by trauma   | Sacco RL, Kasner SE, Broderick JP, et al. An updated definition of stroke for the 21st century: a statement for healthcare professionals from the American Heart Association/American Stroke Association. <i>Stroke</i> . 2013;44:2064-2089. <sup>82</sup>   |  | Intracerebral hemorrhage includes parenchymal hemorrhages after CNS infarction, types I and II   |
|              |  | Subarachnoid hemorrhage   | Rapidly developing signs of neurological dysfunction or headache because of bleeding into the subarachnoid space (the space between the arachnoid membrane and the pia mater of the brain or spinal cord), which is not caused by trauma | Sacco RL, Kasner SE, Broderick JP, et al. An updated definition of stroke for the 21st century: a statement for healthcare professionals from the American Heart Association/American Stroke Association. <i>Stroke</i> . 2013;44:2064-2089. <sup>82</sup>   |  |  |
|              |  | Epidural hemorrhage   | Intracranial hemorrhage into the epidural space  | NCI Thesaurus Code: C50555 <sup>63</sup>   |  |  |
|              |  | Subdural hemorrhage   | Bleeding between the dura mater and the brain, usually secondary to a tear of the bridging vein  | NCI Thesaurus Code: C50759 <sup>63</sup>   |  |  |
|              |  | Cerebral venous sinus thrombosis  | Stroke because of thrombosis of a cerebral venous structure  | Sacco RL, Kasner SE, Broderick JP, et al. An updated definition of stroke for the 21st century: a statement for healthcare professionals from the American Heart Association/American Stroke Association. <i>Stroke</i> . 2013;44:2064-2089. <sup>82</sup>   |  | Symptoms or signs caused by reversible edema without infarction or hemorrhage do not qualify as stroke. Common locations for sinus thrombosis include the dural sinuses, the cavernous sinus, and deep sinuses of the cortex |
|              |  | Stroke not otherwise specified  | An episode of acute neurological dysfunction presumed to be caused by ischemia or hemorrhage, persisting ≥24 h or until death but without sufficient evidence to be classified as one of the above                                       |  |  |  |
|              |  | No  |  |  |  |  |
|              |  | Unknown   |  |  |  |  |

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APPENDIX 4. CONTINUED

A. Acute Cardiovascular Complications Related to COVID-19 Infection (Continued)

| Data Element                     | Data Element Definition   | Permissible Values   | Permissible Value Definitions | Mapping/Source of Definition   | Additional Notes   |
|----------------------------------|---|--|-------------------------------|--|--|
| <b>Transient ischemic attack</b> | A brief episode of neurological dysfunction, caused by focal brain or retinal ischemia without imaging evidence of acute infarction   | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | Easton JD, Saver JL, Albers GW, et al. Definition and evaluation of transient ischemic attack: a scientific statement for healthcare professionals from the American Heart Association/American Stroke Association Stroke Council; Council on Cardiovascular Surgery and Anesthesia; Council on Cardiovascular Radiology and Intervention; Council on Cardiovascular Nursing; and the Interdisciplinary Council on Peripheral Vascular Disease. <i>Stroke</i> . 2009;40:2276-2293. <sup>85</sup> |  |
| <b>Left ventricular thrombus</b> | New diagnosis of left ventricular thrombus in a patient with probable or confirmed acute COVID-19   | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               |  | See <a href="#">Appendix 3</a> for the definition of a probable or confirmed acute COVID-19 case.  |
| <b>Coronary ectasia</b>          | Diffuse dilation of coronary artery segment ( $\geq 1.5\times$ the adjacent normal segment) in a patient with probable or confirmed acute COVID-19  | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | Boris JR, Béland MJ, Bergensen LJ, et al. 2017 AHA/ACC key data elements and definitions for ambulatory electronic health records in pediatric and congenital cardiology: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Data Standards. <i>J Am Coll Cardiol</i> . 2017;70:1029-1095. <sup>86</sup>   | Coronary ectasia not previously known. See <a href="#">Appendix 3</a> for the definition of a probable or confirmed acute COVID-19 case.         |
| <b>Coronary artery aneurysm</b>  | Focal dilation of a coronary artery ( $\geq 1.5\times$ the adjacent normal segment) in a patient with probable or confirmed acute COVID-19  | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | Boris JR, Béland MJ, Bergensen LJ, et al. 2017 AHA/ACC key data elements and definitions for ambulatory electronic health records in pediatric and congenital cardiology: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Data Standards. <i>J Am Coll Cardiol</i> . 2017;70:1029-1095. <sup>86</sup>   | Coronary artery aneurysm not previously known. See <a href="#">Appendix 3</a> for the definition of a probable or confirmed acute COVID-19 case. |
| <b>Microvascular thrombosis</b>  | Blood clotting that is occurring in small blood vessels in the body in a patient with probable or confirmed acute COVID-19  | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | Bray MA, Sartain SE, Gollamudi J, et al. Microvascular thrombosis: experimental and clinical implications. <i>Transl Res</i> . 2020;225:105-130. <sup>87</sup>   | See <a href="#">Appendix 3</a> for the definition of a probable or confirmed acute COVID-19 case.  |
| <b>Thrombophilia</b>             | A condition characterized by an abnormally high level of thrombi. Causes include thrombotic thrombocytopenic purpura, disseminated intravascular coagulation, bone marrow disorders, and antiphospholipid antibody syndrome in a patient with probable or confirmed acute COVID-19. | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | NCI Thesaurus Code: C84479 <sup>63</sup>   | Thrombophilia not previously known. See <a href="#">Appendix 3</a> for the definition of a probable or confirmed acute COVID-19 case.            |

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A. Acute Cardiovascular Complications Related to COVID-19 Infection (Continued)

| Data Element  | Data Element Definition  | Permissible Values   | Permissible Value Definitions | Mapping/Source of Definition   | Additional Notes |
|---|--|--|-------------------------------|--|------------------|
| <b>Cardiovascular adverse events related to medications aimed at COVID-19</b> | Cardiovascular adverse events attributable to or associated with medications used for COVID-19 | <ul style="list-style-type: none"> <li>■ Arrhythmia</li> <li>■ Coronary artery disorder</li> <li>■ HF</li> <li>■ Blood pressure disorder, shock</li> <li>■ Embolism</li> <li>■ Thrombosis</li> <li>■ Vascular hypertensive disorder</li> <li>■ Other</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | <p>Gérard AO, Laurain A, Fresse A, et al. Remdesivir and acute renal failure: a potential safety signal from disproportionality analysis of the WHO safety database. <i>Clin Pharmacol Ther.</i> 2021;109:1021-1024.<sup>88</sup></p> <p>Rafaniello C, Ferrajolo C, Sullo MG, et al. Cardiac events potentially associated to remdesivir: an analysis from the European spontaneous adverse event reporting system. <i>Pharmaceuticals (Basel).</i> 2021;14:611.<sup>89</sup></p> <p>Naksuk N, Lazar S, Peeraphatdit TB. Cardiac safety of off-label COVID-19 drug therapy: a review and proposed monitoring protocol. <i>Eur Heart J Acute Cardiovasc Care.</i> 2020;9:215-221.<sup>90</sup></p> <p>US Food and Drug Administration. Guideline for industry. Clinical safety data management: definitions and standards for expedited reporting. Accessed March 4, 2022. <a href="https://www.fda.gov/media/71188/download">https://www.fda.gov/media/71188/download</a><sup>91</sup></p> |                  |
| <b>Cardiovascular adverse effects from vaccines to prevent COVID-19</b>       | Cardiovascular adverse events associated with COVID-19 vaccinations                            | <ul style="list-style-type: none"> <li>■ Myocarditis</li> <li>■ Thrombocytopenia and thrombosis</li> <li>■ Other</li> <li>■ No</li> <li>■ Unknown</li> </ul>   |                               | <p>Bozkurt B, Kamat I, Hotez PJ. Myocarditis with COVID-19 mRNA vaccines. <i>Circulation.</i> 2021;144:471-484.<sup>37</sup></p>   |                  |

AF indicates atrial fibrillation; AV, atrioventricular; bpm, beats per minute; CNS, central nervous system; COVID-19, coronavirus disease-2019; CPR, cardiopulmonary resuscitation; CVD, cardiovascular disease; DCCV, DC cardioversion; ECG, electrocardiogram; ECMO, extracorporeal membrane oxygenation; EF, ejection fraction; HF, heart failure; HFmEF, heart failure with mildly reduced ejection fraction; HFREF, heart failure with reduced ejection fraction; LV, left ventricular; LVEF, left ventricular ejection fraction; MRI, magnetic resonance imaging; ROSC, return of spontaneous circulation; RV, right ventricular; and RVEF, right ventricular ejection fraction.



B. Postacute Cardiovascular Sequelae of SARS-CoV-2 Infection or Long-Term Cardiovascular Complications of COVID-19

| Data Element                                | Data Element Definition  | Permissible Values   | Permissible Value Definitions | Mapping/Source of Definition   | Additional Notes   |
|---|--|--|-------------------------------|--|--|
| <b>PASC HF</b>                              | New-onset HF with clinical syndrome of dyspnea, fatigue, fluid retention/peripheral edema that started during probable or confirmed acute COVID-19 and persisted beyond 4 wk after the initial diagnosis of COVID-19. Preexisting cardiovascular conditions, or those that did not develop until after COVID-19 had resolved, should not be listed here.   | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | <p>Bozkurt B, Hershberger RE, Butler J, et al. 2021 ACC/AHA key data elements and definitions for heart failure: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Data Standards (Writing Committee to Develop Clinical Data Standards for Heart Failure). <i>J Am Coll Cardiol</i>. 2021;77:2053-2150.<sup>67</sup></p> <p>Bozkurt B, Coats AJ, Tsutsui H, et al. Universal definition and classification of heart failure: a report of the Heart Failure Society of America, Heart Failure Association of the European Society of Cardiology, Japanese Heart Failure Society and Writing Committee of the Universal Definition of Heart Failure. <i>J Card Fail</i>. 2021;27:387-413.<sup>68</sup></p> <p>Nalbandian A, Sehgal K, Gupta A, et al. Post-acute COVID-19 syndrome. <i>Nat Med</i>. 2021;27:601-615.<sup>13</sup></p> <p>Hendren NS, Drazner MH, Bozkurt B, et al. Description and proposed management of the acute COVID-19 cardiovascular syndrome. <i>Circulation</i>. 2020;141:1903-1914.<sup>10</sup></p> | <p>HF can be subclassified according to LVEF as HF with preserved EF (LVEF ≥50), HF with reduced EF (LVEF &lt;40%), HF with mildly reduced EF (LVEF 41%-49%), or HF with improved EF (HF with a baseline LVEF ≤40%, a ≥10-point increase from baseline LVEF, and a second measurement of LVEF &gt;40%).</p> <p>See Appendix 3 for the definition of a probable or confirmed acute COVID-19 case.</p> |
| <b>PASC ischemic cardiomyopathy</b>         | Reduced LV function with LVEF <50% in a patient with history of suspected or confirmed myocardial ischemia or ACS with confirmed acute COVID-19 and persisted beyond 4 wk after the initial diagnosis of COVID-19. Preexisting cardiovascular conditions, or those that did not develop until after COVID-19 had resolved, should not be listed here.  | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | <p>Nalbandian A, Sehgal K, Gupta A, et al. Post-acute COVID-19 syndrome. <i>Nat Med</i>. 2021;27:601-615.<sup>13</sup></p> <p>Hendren NS, Drazner MH, Bozkurt B, et al. Description and proposed management of the acute COVID-19 cardiovascular syndrome. <i>Circulation</i>. 2020;141:1903-1914.<sup>10</sup></p> <p>Gupta A, Madhavan MV, Sehgal K, et al. Extrapulmonary manifestations of COVID-19. <i>Nat Med</i>. 2020;26:1017-1032.<sup>92</sup></p>   | <p>See Appendix 3 for the definition of a probable or confirmed acute COVID-19 case.</p>   |
| <b>PASC nonischemic cardiomyopathy</b>      | Reduced LV function with LVEF <50% without evidence of myocardial ischemia that started during probable or confirmed acute COVID-19 and persisted beyond 4 wk after the initial diagnosis of COVID-19. Preexisting cardiovascular conditions, or those that did not develop until after COVID-19 had resolved, should not be listed here.  | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | <p>Hendren NS, Drazner MH, Bozkurt B, et al. Description and proposed management of the acute COVID-19 cardiovascular syndrome. <i>Circulation</i>. 2020;141:1903-1914.<sup>10</sup></p> <p>Gupta A, Madhavan MV, Sehgal K, et al. Extrapulmonary manifestations of COVID-19. <i>Nat Med</i>. 2020;26:1017-1032.<sup>92</sup></p>  | <p>See Appendix 3 for the definition of a probable or confirmed acute COVID-19 case.</p>   |
| <b>PASC inappropriate sinus tachycardia</b> | Inappropriate sinus tachycardia at rest with heart rate >100 bpm that cannot be explained by any identifiable cause, including anemia, hypoxia, hypotension, or fever that started during probable or confirmed acute COVID-19 and persisted beyond 4 wk after the initial diagnosis of COVID-19. Preexisting cardiovascular conditions, or those that did not develop until after COVID-19 had resolved, should not be listed here. | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | <p>Nalbandian A, Sehgal K, Gupta A, et al. Post-acute COVID-19 syndrome. <i>Nat Med</i>. 2021;27:601-615.<sup>13</sup></p> <p>Mitrani RD, Dabas N, Goldberger JJ. COVID-19 cardiac injury: implications for long-term surveillance and outcomes in survivors. <i>Heart Rhythm</i>. 2020;17:1984-1990.<sup>93</sup></p> <p>Sheldon RS, Grubb BP 2nd, Olshansky B, et al. 2015 Heart Rhythm Society expert consensus statement on the diagnosis and treatment of postural tachycardia syndrome, inappropriate sinus tachycardia, and vasovagal syncope. <i>Heart Rhythm</i>. 2015;12:e41-e63.<sup>94</sup></p> <p>Ståhlberg M, Reistam U, Fedorowski A, et al. Post-COVID-19 tachycardia syndrome: a distinct phenotype of post-acute COVID-19 syndrome. <i>Am J Med</i>. 2021;134:1451-1456.<sup>95</sup></p>   | <p>See Appendix 3 for the definition of a probable or confirmed acute COVID-19 case.</p>   |

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B. Postacute Cardiovascular Sequelae of SARS-CoV-2 Infection or Long-Term Cardiovascular Complications of COVID-19 (continued)

| Data Element   | Data Element Definition  | Permissible Values   | Permissible Value Definitions | Mapping/Source of Definition   | Additional Notes  |
|--|--|--|-------------------------------|--|---|
| <b>PASC POTS</b>   | PASC POTS is a clinical syndrome that started during probable or confirmed acute COVID-19 and lasts ≥3 mo. POTS is defined as 1) sustained heart rate increment ≥30 bpm within 10 min of standing or head-up tilt (for individuals who are age 12-19 y, the required heart rate increment is ≥40 bpm); 2) absence of orthostatic hypotension (ie, no sustained systolic blood pressure drop of ≥20 mm Hg); 3) frequent symptoms of orthostatic intolerance during standing, with rapid improvement on return to a supine position. Symptoms may include lightheadedness, palpitations, tremulousness, generalized weakness, blurred vision, and fatigue; 4) duration of symptoms for at least 3 mo; and 5) absence of other conditions explaining sinus tachycardia such as anorexia nervosa, primary anxiety disorders, hyperventilation, anemia, fever, pain, infection, dehydration, hyperthyroidism, pheochromocytoma, use of cardioactive drugs (eg, sympathomimetics, anticholinergics) or severe deconditioning caused by prolonged bed rest. | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | <p>Vernino S, Bourne KM, Stiles LE, et al. Postural orthostatic tachycardia syndrome (POTS): state of the science and clinical care from a 2019 National Institutes of Health Expert Consensus Meeting - part 1. <i>Auton Neurosci</i>. 2021;235:102828.<sup>96</sup></p> <p>Boris JR, Béland MJ, Bergensen LJ, et al. 2017 AHA/ACC key data elements and definitions for ambulatory electronic health records in pediatric and congenital cardiology: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Data Standards. <i>J Am Coll Cardiol</i>. 2017;70:1029-1095.<sup>86</sup></p> <p>Bryarly M, Phillips LT, Fu Q, et al. Postural orthostatic tachycardia syndrome: JACC focus seminar. <i>J Am Coll Cardiol</i>. 2019;73:1207-1228.<sup>97</sup></p> | See <a href="#">Appendix 3</a> for the definition of a probable or confirmed acute COVID-19 case. |
| <b>PASC AF or atrial flutter</b>   | AF or atrial flutter in a patient without prior history of atrial tachyarrhythmias that started during probable or confirmed acute COVID-19 and persisted beyond 4 wk after the initial diagnosis of COVID-19. Preexisting cardiovascular conditions, or those that did not develop until after COVID-19 had resolved, should not be listed here.  | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | <p>Nalbandian A, Sehgal K, Gupta A, et al. Post-acute COVID-19 syndrome. <i>Nat Med</i>. 2021;27:601-615.<sup>13</sup></p> <p>Mitrani RD, Dabas N, Goldberger JJ. COVID-19 cardiac injury: implications for long-term surveillance and outcomes in survivors. <i>Heart Rhythm</i>. 2020;17:1984-1990.<sup>93</sup></p>   | See <a href="#">Appendix 3</a> for the definition of a probable or confirmed acute COVID-19 case. |
| <b>PASC supraventricular tachyarrhythmia other than AF or atrial flutter</b> | Supraventricular tachycardia other than AF or atrial flutter in a patient without prior history of atrial tachyarrhythmias that started during probable or confirmed acute COVID-19 and persisted beyond 4 wk after the initial diagnosis of COVID-19. Preexisting cardiovascular conditions, or those that did not develop until after COVID-19 had resolved, should not be listed here.  | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | <p>Mitrani RD, Dabas N, Goldberger JJ. COVID-19 cardiac injury: implications for long-term surveillance and outcomes in survivors. <i>Heart Rhythm</i>. 2020;17:1984-1990.<sup>93</sup></p>  | See <a href="#">Appendix 3</a> for the definition of a probable or confirmed acute COVID-19 case. |
| <b>PASC pericarditis/pericardial effusion</b>                                | Pericarditis characterized by chest pain, electrocardiographic changes or pericardial effusion, that started during probable or confirmed acute COVID-19 and persisted beyond 4 wk after the initial diagnosis of COVID-19. Preexisting cardiovascular conditions, or those that did not develop until after COVID-19 had resolved, should not be listed here.   | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | <p>NCDR Auxiliary Data Collection CathPCI Registry Data Dictionary v1.0 (data element #14617)<sup>98</sup></p> <p>Carfi A, Bernabei R, Landi F. Persistent symptoms in patients after acute COVID-19. <i>JAMA</i>. 2020;324:603-605.<sup>14</sup></p>  | See <a href="#">Appendix 3</a> for the definition of a probable or confirmed acute COVID-19 case. |

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APPENDIX 4. CONTINUED

B. Postacute Cardiovascular Sequelae of SARS-CoV-2 Infection or Long-Term Cardiovascular Complications of COVID-19 (continued)

| Data Element                                 | Data Element Definition   | Permissible Values   | Permissible Value Definitions | Mapping/Source of Definition   | Additional Notes  |
|--|---|--|-------------------------------|--|---|
| <b>PASC cardiac structural abnormalities</b> | Cardiac structural changes or abnormalities characterized by myocardial systolic dysfunction or myocardial edema or fibrosis on noninvasive cardiac imaging that started during probable or confirmed acute COVID-19 and persisted beyond 4 wk after the initial diagnosis of COVID-19. Preexisting cardiovascular conditions, or those that did not develop until after COVID-19 had resolved, should not be listed here.  | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul>   |                               | Huang L, Zhao P, Tang D, et al. Cardiac involvement in patients recovered from COVID-2019 identified using magnetic resonance imaging. <i>J Am Coll Cardiol Img.</i> 2020;13:2330-2339. <sup>99</sup><br>Bajaj R, Sinclair HC, Patel K, et al. Delayed-onset myocarditis following COVID-19. <i>Lancet Respir Med.</i> 2021;9:e32-34. <sup>100</sup>   | See <a href="#">Appendix 3</a> for the definition of a probable or confirmed acute COVID-19 case. |
| <b>PASC deep venous thrombosis</b>           | Formation of ≥1 blood clots or thrombi in large veins of the body, diagnosed with Doppler ultrasound, occurring most frequently in lower extremities or upper extremities that started during probable or confirmed acute COVID-19 and persisted beyond 4 wk after the initial diagnosis of COVID-19. Preexisting cardiovascular conditions, or those that did not develop until after COVID-19 had resolved, should not be listed here.  | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul>   |                               | Gupta A, Madhavan MV, Sehgal K, et al. Extrapulmonary manifestations of COVID-19. <i>Nat Med.</i> 2020;26:1017-1032. <sup>92</sup><br>Bikdeli B, Madhavan MV, Jimenez D, et al. COVID-19 and thrombotic or thromboembolic disease: implications for prevention, antithrombotic therapy, and follow-up: JACC state-of-the-art review. <i>J Am Coll Cardiol.</i> 2020;75:2950-2973. <sup>76</sup>  | See <a href="#">Appendix 3</a> for the definition of a probable or confirmed acute COVID-19 case. |
| <b>PASC pulmonary thromboembolic disease</b> | Intravascular migration of a venous thrombus or embolus to the pulmonary arterial circulation, microvascular thrombosis in the pulmonary capillaries, or pulmonary artery thrombus in situ diagnosed by a positive pulmonary angiogram, an unequivocally positive helical CT scan, a high-probability ventilation-perfusion scan, or autopsy that started during probable or confirmed acute COVID-19 and persisted beyond 4 wk after the initial diagnosis of COVID-19. Preexisting cardiovascular conditions, or those that did not develop until after COVID-19 had resolved, should not be listed here. | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul>   |                               | Gupta A, Madhavan MV, Sehgal K, et al. Extrapulmonary manifestations of COVID-19. <i>Nat Med.</i> 2020;26:1017-1032. <sup>92</sup><br>Bikdeli B, Madhavan MV, Jimenez D, et al. COVID-19 and thrombotic or thromboembolic disease: implications for prevention, antithrombotic therapy, and follow-up: JACC state-of-the-art review. <i>J Am Coll Cardiol.</i> 2020;75:2950-2973. <sup>76</sup><br>Ackermann M, Verleden SE, Kuehnel M, et al. Pulmonary vascular endothelialitis, thrombosis, and angiogenesis in Covid-19. <i>N Engl J Med.</i> 2020;383:120-128. <sup>101</sup>   | See <a href="#">Appendix 3</a> for the definition of a probable or confirmed acute COVID-19 case. |
| <b>PASC neurovascular disorder</b>           | Disorder of the nervous system related to a vascular etiology that started during probable or confirmed acute COVID-19 and persisted beyond 4 wk after the initial diagnosis of COVID-19. Preexisting cardiovascular conditions, or those that did not develop until after COVID-19 had resolved, should not be listed here.  | <ul style="list-style-type: none"> <li>■ Ischemic stroke</li> <li>■ Hemorrhagic stroke</li> <li>■ Cerebral venous thrombosis</li> <li>■ Myalgic encephalomyelitis/chronic fatigue syndrome</li> <li>■ Other</li> </ul> |                               | Carfi A, Bernabei R, Landi F. Persistent symptoms in patients after acute COVID-19. <i>JAMA.</i> 2020;324:603-605. <sup>14</sup><br>Moghimi N, Di Napoli M, Biller J, et al. The neurological manifestations of post-acute sequelae of SARS-CoV-2 infection. <i>Curr Neurol Neurosci Rep.</i> 2021;21:44. <sup>102</sup><br>Clark DE, Dendy JM, Li DL, et al. Cardiovascular magnetic resonance evaluation of soldiers after recovery from symptomatic SARS-CoV-2 infection: a case-control study of cardiovascular post-acute sequelae of SARS-CoV-2 infection (CV PASC). <i>J Cardiovasc Magn Reson.</i> 2021;23:106. <sup>103</sup><br>Oh ES, Vannorsdall TD, Parker AM. Post-acute sequelae of SARS-CoV-2 infection and subjective memory problems. <i>JAMA Netw Open.</i> 2021;4:e2119335. <sup>104</sup> |   |

ACS indicates acute coronary syndrome; AF, atrial fibrillation; bpm, beats per minute; COVID-19, coronavirus disease 2019; CT, computed tomography; EF, ejection fraction; HF, heart failure; LV, left ventricular; LVEF, left ventricular ejection fraction; PASC, postacute sequelae of SARS-CoV-2 infection; SARS-CoV-2, severe acute respiratory syndrome-coronavirus-2 and POTS, postural orthostatic tachycardia syndrome.

C. Cardiovascular Mortality During Acute COVID-19 Infection

| Data Element                          | Data Element Definition  | Permissible Value  |             | Mapping/Source of Definition  | Additional Notes  |
|---------------------------------------|--|--|-------------|---|---|
|                                       |  | Permissible Values   | Definitions |   |   |
| <b>Death attributable to acute MI</b> | Death by any cardiovascular mechanism (eg, arrhythmia, sudden death, HF, stroke, pulmonary embolus, peripheral arterial disease) ≤30 d after a MI, related to the immediate consequences of the MI, such as progressive HF or recalcitrant arrhythmia in a patient with probable or confirmed acute COVID-19<br><br>There may be assessable mechanisms of cardiovascular death during this time period, but for simplicity, if the cardiovascular death occurs ≤30 d of the MI, it will be considered a death attributable to MI.  | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |             | Hicks KA, Mahaffey KW, Mehran R, et al. 2017 Cardiovascular and stroke endpoint definitions for clinical trials. <i>J Am Coll Cardiol</i> . 2018;71:1021-1034. <sup>105</sup>   | Acute MI should be verified to the extent possible by the diagnostic criteria outlined for acute MI or by autopsy findings showing recent MI or recent coronary thrombosis.<br><br>Death resulting from a procedure to treat an MI (PCI, CABG), or to treat a complication resulting from MI, should also be considered death attributable to acute MI. Death resulting from an elective coronary procedure to treat myocardial ischemia (ie, chronic stable angina), or death attributable to an MI that occurs as a direct consequence of a cardiovascular investigation/procedure/operation, should be considered as a death attributable to a cardiovascular procedure. |
| <b>Sudden cardiac death</b>           | Death that occurs unexpectedly and suddenly without ROSC in a patient with probable or confirmed acute COVID-19 and not within 30 d of an acute MI. Sudden cardiac death includes the following scenarios:<br>a. Death witnessed and occurring without new or worsening symptoms<br>b. Death witnessed within 60 min of the onset of new or worsening cardiac symptoms, unless the symptoms suggest acute MI<br>c. Death witnessed and attributed to an identified arrhythmia (eg, captured on an ECG recording, witnessed on a monitor, with asystole, pulseless electrical activity, ventricular tachycardia, or ventricular fibrillation, or unwitnessed but found on implantable cardioverter-defibrillator review)<br>d. Unwitnessed death in a subject seen alive and clinically stable ≤24 h prior to being found dead without any evidence supporting a specific noncardiovascular cause of death (information regarding the patient's clinical status preceding death should be provided, if available) | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |             | Hicks KA, Mahaffey KW, Mehran R, et al. 2017 Cardiovascular and stroke endpoint definitions for clinical trials. <i>J Am Coll Cardiol</i> . 2018;71:1021-1034. <sup>105</sup> Turagam MK, Musikantow D, Goldman ME, et al. Malignant arrhythmias in patients with COVID-19: incidence, mechanisms, and outcomes. <i>Circ Arrhythm Electrophysiol</i> . 2020;13:e008920. <sup>72</sup> | Unless additional information suggests an alternate specific cause of death (eg, death attributable to other cardiovascular causes), if a patient is seen alive ≤24 h of being found dead, sudden cardiac death should be recorded. For patients who were not observed alive within 24 h of death, undetermined cause of death should be recorded (eg, a subject found dead in bed, but who had not been seen by family for >24 h). Patients with respiratory failure, progressive hypoxia, multiorgan failure, septic shock attributable to COVID-19 should not be categorized as sudden cardiac death.  |
| <b>Death attributable to HF</b>       | Death in association with clinically worsening symptoms or signs of HF regardless of HF etiology in a patient with probable or confirmed acute COVID-19. Deaths attributable to HF with COVID-19 can have various etiologies, including myocarditis, myocardial injury, cardiogenic shock, cardiomyopathy, MI, ischemic or nonischemic cardiomyopathy.   | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |             | Hicks KA, Mahaffey KW, Mehran R, et al. 2017 Cardiovascular and stroke endpoint definitions for clinical trials. <i>J Am Coll Cardiol</i> . 2018;71:1021-1034. <sup>105</sup>   |   |
| <b>Death attributable to stroke</b>   | Death after a stroke that is either a direct consequence of the stroke or a complication of the stroke in a patient with probable or confirmed acute COVID-19. Acute stroke should be verified to the extent possible by the diagnostic criteria outlined for stroke.  | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |             | Hicks KA, Mahaffey KW, Mehran R, et al. 2017 Cardiovascular and stroke endpoint definitions for clinical trials. <i>J Am Coll Cardiol</i> . 2018;71:1021-1034. <sup>105</sup>   |   |

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APPENDIX 4. CONTINUED

C. Cardiovascular Mortality During Acute COVID-19 Infection (Continued)

| Data Element   | Data Element Definition   | Permissible Values   | Permissible Value Definitions | Mapping/Source of Definition   | Additional Notes |
|--|---|--|-------------------------------|--|------------------|
| <b>Death attributable to cardiovascular procedure</b>    | Death caused by the immediate complications of a cardiovascular procedure in a patient with probable or confirmed acute COVID-19  | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | Hicks KA, Mahaffey KW, Mehran R, et al. 2017 Cardiovascular and stroke endpoint definitions for clinical trials. <i>J Am Coll Cardiol.</i> 2018;71:1021-1034. <sup>105</sup> |                  |
| <b>Death attributable to cardiovascular hemorrhage</b>   | Death related to hemorrhage such as a nonstroke intracranial hemorrhage (eg, subdural hematoma), nonprocedural or nontraumatic vascular rupture (eg, aortic aneurysm), or hemorrhage causing cardiac tamponade in a patient with probable or confirmed acute COVID-19 | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | Hicks KA, Mahaffey KW, Mehran R, et al. 2017 Cardiovascular and stroke endpoint definitions for clinical trials. <i>J Am Coll Cardiol.</i> 2018;71:1021-1034. <sup>105</sup> |                  |
| <b>Death attributable to pulmonary embolus</b>           | Death caused by pulmonary embolus in a patient with probable or confirmed acute COVID-19  | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | Hicks KA, Mahaffey KW, Mehran R, et al. 2017 Cardiovascular and stroke endpoint definitions for clinical trials. <i>J Am Coll Cardiol.</i> 2018;71:1021-1034. <sup>105</sup> |                  |
| <b>Death attributable to other cardiovascular causes</b> | Cardiovascular death not included in the above categories but with a specific, known cause (eg, peripheral arterial disease)  | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | Hicks KA, Mahaffey KW, Mehran R, et al. 2017 Cardiovascular and stroke endpoint definitions for clinical trials. <i>J Am Coll Cardiol.</i> 2018;71:1021-1034. <sup>105</sup> |                  |

CABG indicates coronary artery bypass graft surgery; COVID-19, coronavirus disease 2019; ECG, electrocardiogram; HF, heart failure; MI, myocardial infarction; PCI, percutaneous coronary intervention; and ROSC, return of spontaneous circulation.

APPENDIX 5. COVID-19 NONCARDIOVASCULAR COMPLICATIONS

| Data Element   | Data Element Definition   | Permissible Values   | Permissible Value Definitions | Mapping/Source of Definition   | Additional Notes  |
|--|---|--|-------------------------------|--|---|
| <b>ARDS</b>  | ARDS meeting standard clinical criteria in a patient with probable or confirmed COVID-19 and felt to be secondary to COVID-19   | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | <p>Guan WJ, Ni ZY, Hu Y, et al. Clinical characteristics of coronavirus disease 2019 in China. <i>N Engl J Med.</i> 2020;382:1708-1720.<sup>106</sup></p> <p>Ranieri VM, Rubenfeld GD, Thompson BT, et al. Acute respiratory distress syndrome: the Berlin definition. <i>JAMA.</i> 2012;307:2526-2533.<sup>107</sup></p>  | ARDS could be defined according to the Berlin criteria.   |
| <b>Pneumonia</b>   | Clinical pneumonia or asymptomatic pulmonary infiltrates in a patient with probable or confirmed COVID-19 and felt to be secondary to COVID-19  | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | Guan WJ, Ni ZY, Hu Y, et al. Clinical characteristics of coronavirus disease 2019 in China. <i>N Engl J Med.</i> 2020;382:1708-1720. <sup>106</sup>  |   |
| <b>Distributive shock</b>                                    | Distributive shock (eg, attributable to sepsis or SIRS), defined as an inadequate supply of oxygen at the tissue level to meet metabolic needs in a vasodilated state in a patient with probable or confirmed COVID-19  | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | <p>Haberman R, Axelrad J, Chen A, et al. Covid-19 in immune-mediated inflammatory diseases—case series from New York. <i>N Engl J Med.</i> 2020;383:85-88.<sup>108</sup></p> <p>Channappanavar R, Perlman S. Pathogenic human coronavirus infections: causes and consequences of cytokine storm and immunopathology. <i>Semin Immunopathol.</i> 2017;39:529-539.<sup>109</sup></p> | <p>Cytokine release syndrome was also observed in patients with SARS-CoV and MERS-CoV and may also be referred to as cytokine storm syndrome.</p> <p>For patients with both distributive and cardiogenic shock, both should be coded.</p> |
| <b>Acute kidney injury with renal replacement therapy</b>    | Abrupt reduction in kidney function in a patient with probable or confirmed COVID-19, measured by urine output and renal biomarkers requiring any renal replacement therapy   | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | <p>Guan WJ, Ni ZY, Hu Y, et al. Clinical characteristics of coronavirus disease 2019 in China. <i>N Engl J Med.</i> 2020;382:1708-1720.<sup>106</sup></p> <p>Gupta A, Madhavan MV, Sehgal K, et al. Extrapulmonary manifestations of COVID-19. <i>Nat Med.</i> 2020;26:1017-1032.<sup>92</sup></p>   | Only for patients who were not previously on chronic renal replacement therapy for end-stage kidney disease   |
| <b>Acute kidney injury without renal replacement therapy</b> | Abrupt reduction in kidney function in a patient with probable or confirmed COVID-19, measured by urine output and renal biomarkers not requiring temporary or permanent renal replacement therapy  | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | <p>Guan WJ, Ni ZY, Hu Y, et al. Clinical characteristics of coronavirus disease 2019 in China. <i>N Engl J Med.</i> 2020;382:1708-1720.<sup>106</sup></p> <p>Gupta A, Madhavan MV, Sehgal K, et al. Extrapulmonary manifestations of COVID-19. <i>Nat Med.</i> 2020;26:1017-1032.<sup>92</sup></p>   | Only for patients who were not previously on chronic renal replacement therapy for end-stage kidney disease   |
| <b>Acute liver injury with fulminant failure</b>             | Acute liver injury manifested by abnormalities in liver enzymes in a patient with probable or confirmed COVID-19. A minority of patients experience severe liver injury that can result in hepatic failure, defined as rapid loss of liver function during acute COVID-19, which is associated with coagulopathy or encephalopathy, and often multiorgan failure. | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | <p>Guan WJ, Ni ZY, Hu Y, et al. Clinical characteristics of coronavirus disease 2019 in China. <i>N Engl J Med.</i> 2020;382:1708-1720.<sup>106</sup></p> <p>Phipps MM, Barraza LH, LaSota ED, et al. Acute liver injury in COVID-19: prevalence and association with clinical outcomes in a large US cohort. <i>Hepatology.</i> 2020;72:807-817.<sup>110</sup></p>                |   |
| <b>Acute liver injury without fulminant failure</b>          | Acute liver injury in a patient with probable or confirmed COVID-19, defined as abnormal liver chemistries >2× ULN in the absence of signs of hepatic failure (eg, no coagulopathy or encephalopathy), is usually mild, transient, and does not require intervention.   | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | Fix OK, Hameed B, Fontana RJ, et al. Clinical best practice advice for hepatology and liver transplant providers during the COVID-19 pandemic: AASLD expert panel consensus statement. <i>Hepatology.</i> 2020;72:287-304. <sup>111</sup>  |   |

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APPENDIX 5. CONTINUED

| Data Element   | Data Element Definition   | Permissible Values   | Permissible Value Definitions | Mapping/Source of Definition   | Additional Notes   |
|--|---|--|-------------------------------|--|--|
| <b>Disseminated intravascular coagulation</b>            | Abnormalities in coagulation and fibrinolysis, resulting in a condition in which blood clots form throughout the body, thereby causing clotting in small blood vessels and increasing risk for hemorrhage, in a patient with probable or confirmed COVID-19 | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | <p>Guzik TJ, Mohiddin SA, Dimarco A, et al. COVID-19 and the cardiovascular system: implications for risk assessment, diagnosis, and treatment options. <i>Cardiovasc Res.</i> 2020;116:1666-1687.<sup>112</sup></p> <p>Connors JM, Levy JH. COVID-19 and its implications for thrombosis and anticoagulation. <i>Blood.</i> 2020;135:2033-2040.<sup>113</sup></p> | Coagulopathy may occur in acute COVID-19 in the absence of disseminated intravascular coagulation. |
| <b>Rhabdomyolysis</b>                                    | Destruction or degeneration of muscle tissue accompanied by the release of breakdown products from muscle cells into the bloodstream (eg, creatine kinase, aldolase) that may lead to acute kidney injury in a patient with probable or confirmed COVID-19  | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | Jin M, Tong Q. Rhabdomyolysis as potential late complication associated with COVID-19. <i>Emerg Infect Dis.</i> 2020;26:1618-1620. <sup>114</sup>  |  |
| <b>Seizures</b>  | Convulsions, sensory, cognitive disturbances, or loss of consciousness resulting from abnormal electrical discharges in the brain in a patient with probable or confirmed COVID-19  | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | Mao L, Jin H, Wang M, et al. Neurologic Manifestations of hospitalized patients with coronavirus disease 2019 in Wuhan, China. <i>JAMA Neurol.</i> 2020;77:683-690. <sup>115</sup>   |  |
| <b>Encephalopathy</b>                                    | A functional or structural disorder of the brain  | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | Liotta EM, Batra A, Clark JR, et al. Frequent neurologic manifestations and encephalopathy-associated morbidity in Covid-19 patients. <i>Ann Clin Transl Neurol.</i> 2020;7:2221-2230. <sup>116</sup>  |  |
| <b>Loss of smell (anosmia)</b>                           | Loss or impairment of olfactory function during COVID-19  | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | Centers for Disease Control and Prevention. Coronavirus disease 2019 (COVID-19). Symptoms of coronavirus. Accessed March 4, 2022. <a href="https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html">https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html</a> <sup>117</sup>   |  |
| <b>Loss of taste (ageusia)</b>                           | Loss or impairment of gustatory function during COVID-19  | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | Centers for Disease Control and Prevention. Coronavirus disease 2019 (COVID-19). Symptoms of coronavirus. Accessed March 4, 2022. <a href="https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html">https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html</a> <sup>117</sup>   |  |
| <b>Pregnancy loss or other adverse pregnancy outcome</b> | Pregnancy loss or other adverse pregnancy outcome (hypertensive disorders of pregnancy, preterm delivery, small for gestational age birth, gestational diabetes) in a patient with probable or confirmed COVID-19   | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | Zambrano LD, Ellington S, Strid P, et al. Update: characteristics of symptomatic women of reproductive age with laboratory-confirmed SARS-CoV-2 infection by pregnancy status - United States, January 22-October 3, 2020. <i>MMWR Morb Mortal Wkly Rep.</i> 2020;69:1641-1647. <sup>118</sup>   |  |

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## APPENDIX 5. CONTINUED

| Data Element                                 | Data Element Definition   | Permissible Values   | Permissible Value Definitions | Mapping/Source of Definition   | Additional Notes  |
|--|---|--|-------------------------------|--|---|
| <b>Syncope</b>                               | Abrupt, transient, complete loss of consciousness, associated with the inability to maintain postural tone and rapid, spontaneous recovery in a patient with probable or confirmed COVID-19   | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | <p>Shen WK, Sheldon RS, Benditt DG, et al. 2017 ACC/AHA/HRS guideline for the evaluation and management of patients with syncope: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. <i>J Am Coll Cardiol</i>. 2017;70:e39-e110.<sup>119</sup></p> <p>Oates CP, Turagam MK, Musikantow D, et al. Syncope and presyncope in patients with COVID-19. <i>Pacing Clin Electrophysiol</i>. 2020;43:1139-1148.<sup>120</sup></p> | The presumed mechanism is cerebral hypoperfusion. There should not be clinical features of other nonsyncopal causes of loss of consciousness, such as septic shock, seizure, antecedent head trauma, or apparent loss of consciousness (ie, pseudosyncope). |
| <b>Presyncope</b>                            | The symptoms before syncope. These symptoms could include extreme lightheadedness; visual sensations, such as "tunnel vision" or "graying out"; and variable degrees of altered consciousness without complete loss of consciousness. Presyncope could progress to syncope, or it could abort without syncope.  | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | <p>Shen WK, Sheldon RS, Benditt DG, et al. 2017 ACC/AHA/HRS guideline for the evaluation and management of patients with syncope: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. <i>J Am Coll Cardiol</i>. 2017;70:e39-e110.<sup>119</sup></p>   |   |
| <b>Cerebral vein thrombosis</b>              | The formation of a blood clot in a cerebral vein  | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | NCI Thesaurus Code: C132727 <sup>63</sup>  |   |
| <b>Other non-cardiovascular complication</b> | Other noncardiovascular symptom(s) in a patient with probable or confirmed COVID-19 such as peripheral neuropathy, gastrointestinal distress or diarrhea, de novo or acute worsening of chronic hyperglycemia, ocular symptoms, and livedo reticularis, which may be related to direct viral tissue damage or systemic inflammation and immunopathological damage | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | <p>Gupta A, Madhavan MV, Sehgal K, et al. Extrapulmonary manifestations of COVID-19. <i>Nat Med</i>. 2020;26:1017-1032.<sup>92</sup></p>   |   |

ARDS indicates acute respiratory distress syndrome; COVID-19, coronavirus disease 2019; MERS-CoV, Middle East respiratory syndrome coronavirus; SARS-CoV-2, severe acute respiratory syndrome-coronavirus-2; SIRS, systemic inflammatory response syndrome; and ULN, upper limit of normal.



## APPENDIX 6. SYMPTOMS AND SIGNS

### A. Current Symptoms and Signs: Clinical Symptoms

| Data Element                            | Data Element Definition  | Permissible Values   | Permissible Value Definitions | Mapping/Source of Definition   | Additional Notes   |
|---|--|--|-------------------------------|--|--|
| <b>Cough</b>                            | A sudden, often repetitive, spasmodic contraction of the thoracic cavity, resulting in violent release of air from the lungs, and usually accompanied by a distinctive sound | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul>   |                               | Boris JR, Béland MJ, Bergensen LJ, et al. 2017 AHA/ACC key data elements and definitions for ambulatory electronic health records in pediatric and congenital cardiology: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Data Standards. <i>J Am Coll Cardiol</i> . 2017;70:1029-1095. <sup>86</sup>   |  |
| <b>Presence and severity of dyspnea</b> | Indicate degree of activity required to elicit dyspnea symptom.  | <ul style="list-style-type: none"> <li>■ No limitation of physical activity by dyspnea</li> <li>■ Dyspnea with moderate physical activity</li> <li>■ Dyspnea with mild physical activity</li> <li>■ Dyspnea at rest</li> </ul> |                               | Yancy CW, Jessup M, Bozkurt B, et al. 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. <i>J Am Coll Cardiol</i> . 2013;62:e147-e239. <sup>69</sup><br>Bozkurt B, Coats AJ, Tsutsui H, et al. Universal definition and classification of heart failure: a report of the Heart Failure Society of America, Heart Failure Association of the European Society of Cardiology, Japanese Heart Failure Society and Writing Committee of the Universal Definition of Heart Failure. <i>J Card Fail</i> . 2021;27:387-413. <sup>68</sup> | Consider reporting extent of activity required to elicit dyspnea.                |
| <b>Orthopnea</b>                        | Uncomfortable awareness of breathing while in a supine position, improved by sitting upright or standing   | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul>   |                               | Yancy CW, Jessup M, Bozkurt B, et al. 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. <i>J Am Coll Cardiol</i> . 2013;62:e147-e239. <sup>69</sup><br>Bozkurt B, Coats AJ, Tsutsui H, et al. Universal definition and classification of heart failure: a report of the Heart Failure Society of America, Heart Failure Association of the European Society of Cardiology, Japanese Heart Failure Society and Writing Committee of the Universal Definition of Heart Failure. <i>J Card Fail</i> . 2021;27:387-413. <sup>68</sup> | Recurrent supine cough without other known cause may be an orthopnea equivalent. |
| <b>Paroxysmal nocturnal dyspnea</b>     | Sudden awakening from sleep with uncomfortable awareness of breathing, relieved by sitting upright or standing. A reported duration >5 min is considered positive.           | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul>   |                               | Yancy CW, Jessup M, Bozkurt B, et al. 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. <i>J Am Coll Cardiol</i> . 2013;62:e147-e239. <sup>69</sup><br>Bozkurt B, Coats AJ, Tsutsui H, et al. Universal definition and classification of heart failure: a report of the Heart Failure Society of America, Heart Failure Association of the European Society of Cardiology, Japanese Heart Failure Society and Writing Committee of the Universal Definition of Heart Failure. <i>J Card Fail</i> . 2021;27:387-413. <sup>68</sup> |  |

Continued on the next page

A. Current Symptoms and Signs: Clinical Symptoms (Continued)

| Data Element                   | Data Element Definition  | Permissible Values   | Permissible Value Definitions | Mapping/Source of Definition  | Additional Notes  |
|--------------------------------|--|--|-------------------------------|---|---|
| <b>Fatigue</b>                 | Unusual tiredness and inability to perform usual activities  | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | <p>Yancy CW, Jessup M, Bozkurt B, et al. 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. <i>J Am Coll Cardiol.</i> 2013;62:e147-e239.<sup>69</sup></p> <p>Bozkurt B, Coats AJ, Tsutsui H, et al. Universal definition and classification of heart failure: a report of the Heart Failure Society of America, Heart Failure Association of the European Society of Cardiology, Japanese Heart Failure Society and Writing Committee of the Universal Definition of Heart Failure. <i>J Card Fail.</i> 2021;27:387-413.<sup>68</sup></p> |   |
| <b>Syncope</b>                 | Abrupt, transient, complete loss of consciousness, associated with inability to maintain postural tone, with rapid and spontaneous recovery  | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | <p>Shen WK, Sheldon RS, Benditt DG, et al. 2017 ACC/AHA/HRS guideline for the evaluation and management of patients with syncope: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. <i>J Am Coll Cardiol.</i> 2017;70:e39-e110.<sup>119</sup></p> <p>Oates CP, Turagam MK, Muskantow D, et al. Syncope and presyncope in patients with COVID-19. <i>Pacing Clin Electrophysiol.</i> 2020;43:1139-1148.<sup>120</sup></p>   | The presumed mechanism is cerebral hypoperfusion. There should not be clinical features of other nonsyncopal causes of loss of consciousness, such as septic shock, seizure, antecedent head trauma, or apparent loss of consciousness (ie, pseudosyncope). |
| <b>Presyncope</b>              | The symptoms before syncope. These symptoms could include extreme lightheadedness, visual sensations, such as "tunnel vision" or "graying out," and variable degrees of altered consciousness without complete loss of consciousness. Presyncope could progress to syncope, or it could abort without syncope. | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | <p>Shen WK, Sheldon RS, Benditt DG, et al. 2017 ACC/AHA/HRS guideline for the evaluation and management of patients with syncope: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. <i>J Am Coll Cardiol.</i> 2017;70:e39-e110.<sup>119</sup></p>  |   |
| <b>Acute pulmonary edema</b>   | Acute onset or rapid progression of pulmonary edema causing significant hypoxemia or need for supplemental oxygen  | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | <p>American Heart Association. Get With The Guidelines - Heart Failure. Accessed March 4, 2022. <a href="https://www.heart.org/en/professional/quality-improvement/getwith-the-guidelines/get-with-the-guidelines-heartfailure">https://www.heart.org/en/professional/quality-improvement/getwith-the-guidelines/get-with-the-guidelines-heartfailure</a><sup>121</sup></p>   |   |
| <b>Fever</b>                   | Temperature $\geq 100.4^{\circ}\text{F}$ ( $38.0^{\circ}\text{C}$ )  | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | <p>O'Grady NP, Barie PS, Bartlett JG, et al. Guidelines for evaluation of new fever in critically ill adult patients: 2008 update from the American College of Critical Care Medicine and the Infectious Diseases Society of America. <i>Crit Care Med.</i> 2008;36:1330-1349.<sup>122</sup></p>  |   |
| <b>Loss of smell (anosmia)</b> | Loss or impairment of olfactory function during COVID-19   | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | <p>Centers for Disease Control and Prevention. Coronavirus disease 2019 (COVID-19). Symptoms of coronavirus. Accessed March 4, 2022. <a href="https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html">https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html</a><sup>117</sup></p>  |   |

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APPENDIX 6. CONTINUED

A. Current Symptoms and Signs: Clinical Symptoms (Continued)

| Data Element            | Data Element Definition  | Permissible Values   | Permissible Value Definitions | Mapping/Source of Definition  | Additional Notes |
|-------------------------|--|--|-------------------------------|---|------------------|
| Loss of taste (ageusia) | Loss or impairment of gustatory function during COVID-19   | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | Centers for Disease Control and Prevention. Coronavirus disease 2019 (COVID-19). Symptoms of coronavirus. Accessed March 4, 2022. <a href="https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html">https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html</a> <sup>117</sup>  |                  |
| Diarrhea                | Passage of ≥3 loose or liquid stools per day (or more frequent passage than is normal for the individual)  | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | World Health Organization. Diarrhoeal disease. Accessed March 4, 2022. <a href="https://www.who.int/en/news-room/fact-sheets/detail/diarrhoeal-disease">https://www.who.int/en/news-room/fact-sheets/detail/diarrhoeal-disease</a> <sup>123</sup>   |                  |
| Nausea or vomiting      | Vomiting or the inclination to vomit   | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | NCI Thesaurus Codes: C3258, C3442 <sup>63</sup>   |                  |
| Seizures                | Transient neurological symptoms due to abnormal excessive or synchronous neuronal activity in the brain  | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | Hauser WA, Beghi E. First seizure definitions and worldwide incidence and mortality. <i>Epilepsia</i> . 2008;49(Suppl 1):8-12. <sup>124</sup>   |                  |
| Skin rash               | Any change in the skin that affects its appearance or texture. A rash may be localized to one part of the body or affect all the skin. Rashes may cause the skin to change color, itch, become warm, bumpy, dry, cracked, or blistered, swell, and may be painful. | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | Boris JR, Béland MJ, Bergensen LJ, et al. 2017 AHA/ACC key data elements and definitions for ambulatory electronic health records in pediatric and congenital cardiology: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Data Standards. <i>J Am Coll Cardiol</i> . 2017;70:1029-1095. <sup>86</sup>                |                  |
| Limb edema              | Swelling of upper or lower extremities   | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | American Heart Association. Get With The Guidelines - Heart Failure. Accessed March 4, 2022. <a href="https://www.heart.org/en/professional/quality-improvement/getwith-the-guidelines/get-with-the-guidelines-heartfailure">https://www.heart.org/en/professional/quality-improvement/getwith-the-guidelines/get-with-the-guidelines-heartfailure</a> <sup>121</sup> |                  |
| Myalgias                | Painful sensation originating from a muscle or group of muscles  | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | NCI Thesaurus Code: C27009 <sup>63</sup>  |                  |
| Headache                | Pain in any region of the head   | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | American Academy of Neurology. Understanding of headaches improves with revised criteria. Accessed March 4, 2022. <a href="https://www.aan.com/PressRoom/home/PressRelease/223">https://www.aan.com/PressRoom/home/PressRelease/223</a> <sup>125</sup>  |                  |
| Altered mental state    | A change to an individual's judgment, orientation (to place, time, and self), intellectual functioning, or mood from their baseline  | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | Díaz-Pérez C, Ramos C, López-Cruz A, et al. Acutely altered mental status as the main clinical presentation of multiple strokes in critically ill patients with COVID-19. <i>Neural Sci</i> . 2020;41:2681-2684. <sup>126</sup><br>NCI Thesaurus Code: C121628 <sup>63</sup>  |                  |

COVID-19 indicates coronavirus disease-2019.

B. Physical Examination

| Data Element                    | Data Element Definition   | Permissible Values   | Permissible Value Definitions | Mapping/Source of Definition  | Additional Notes |
|---------------------------------|---|--|-------------------------------|---|------------------|
| <b>Heart rate</b>               | Number of heartbeats per unit of time (typically 1 min) recorded closest to the time of presentation to the health care facility or on discharge (for inpatient)  | <ul style="list-style-type: none"> <li>■ Numeric, bpm</li> <li>■ Unknown</li> </ul>              |                               | NCI Thesaurus Code: C49677 <sup>63</sup>  |                  |
| <b>Systolic blood pressure</b>  | Systolic blood pressure value recorded closest to the time of presentation to the health care facility  | <ul style="list-style-type: none"> <li>■ Numeric, mm Hg</li> <li>■ Unknown</li> </ul>            |                               | NCI Thesaurus Code: C25298 <sup>63</sup>  |                  |
| <b>Diastolic blood pressure</b> | Diastolic blood pressure value recorded closest to the time of presentation to the health care facility   | <ul style="list-style-type: none"> <li>■ Numeric, mm Hg</li> <li>■ Unknown</li> </ul>            |                               | NCI Thesaurus Code: C25299 <sup>63</sup>  |                  |
| <b>Pulse pressure</b>           | The force of a heart contraction measured by the difference between the diastolic and systolic blood pressure measurements  | <ul style="list-style-type: none"> <li>■ Numeric, mm Hg</li> <li>■ Unknown</li> </ul>            |                               | NCI Thesaurus Code: C100945 <sup>63</sup>   |                  |
| <b>Respiratory rate</b>         | A measurement that describes the rate of breathing (inhalation and exhalation) measured within a unit time (typically 1 min)  | <ul style="list-style-type: none"> <li>■ Numeric, cycles/min</li> <li>■ Unknown</li> </ul>       |                               | Boris JR, Béland MJ, Bergensen LJ, et al. 2017 AHA/ACC key data elements and definitions for ambulatory electronic health records in pediatric and congenital cardiology: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Data Standards. <i>J Am Coll Cardiol.</i> 2017;70:1029-1095. <sup>86</sup> |                  |
| <b>Height</b>                   | A measurement that describes the vertical measurement or distance from the base, or bottom, of the patient, to the top of the patient; this can be taken as the dimension of extension of a patient who cannot stand. | <ul style="list-style-type: none"> <li>■ Numeric, cm</li> <li>■ Unknown</li> </ul>               |                               | Boris JR, Béland MJ, Bergensen LJ, et al. 2017 AHA/ACC key data elements and definitions for ambulatory electronic health records in pediatric and congenital cardiology: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Data Standards. <i>J Am Coll Cardiol.</i> 2017;70:1029-1095. <sup>86</sup> |                  |
| <b>Weight at encounter</b>      | A measurement that describes the vertical force exerted by a mass of the patient as a result of gravity   | <ul style="list-style-type: none"> <li>■ Numeric, kg</li> <li>■ Unknown</li> </ul>               |                               | Boris JR, Béland MJ, Bergensen LJ, et al. 2017 AHA/ACC key data elements and definitions for ambulatory electronic health records in pediatric and congenital cardiology: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Data Standards. <i>J Am Coll Cardiol.</i> 2017;70:1029-1095. <sup>86</sup> |                  |
| <b>Body mass index</b>          | A measurement that is used to indicate the body fat an individual is carrying based on the ratio of weight to height as measured in kilograms per square meters   | <ul style="list-style-type: none"> <li>■ Numeric, kg/m<sup>2</sup></li> <li>■ Unknown</li> </ul> |                               | Boris JR, Béland MJ, Bergensen LJ, et al. 2017 AHA/ACC key data elements and definitions for ambulatory electronic health records in pediatric and congenital cardiology: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Data Standards. <i>J Am Coll Cardiol.</i> 2017;70:1029-1095. <sup>86</sup> |                  |

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APPENDIX 6. CONTINUED

B. Physical Examination (Continued)

| Data Element                              | Data Element Definition   | Permissible Values   | Permissible Value Definitions | Mapping/Source of Definition  | Additional Notes |
|---|---|--|-------------------------------|---|------------------|
| <b>Jugular venous pressure</b>            | The estimated height of the mean jugular venous waveform above the right atrium, measured at a 45° angle<br>When expressed in cm without further description, the number should be recorded as written.<br>When it is expressed as cm above the sternal angle, 5 cm should be added to the number recorded. | <ul style="list-style-type: none"> <li>■ Numeric, cm</li> <li>■ Unknown</li> </ul>       |                               | Yancy CW, Jessup M, Bozkurt B, et al. 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/ American Heart Association Task Force on Practice Guidelines. <i>J Am Coll Cardiol.</i> 2013;62:e147-e239. <sup>69</sup>  |                  |
| <b>Jugular venous distention</b>          | Increased pressure of the superior vena cava causing the jugular vein to bulge, making it visualized at a level of the neck that is higher than normal  | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | Yancy CW, Jessup M, Bozkurt B, et al. 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/ American Heart Association Task Force on Practice Guidelines. <i>J Am Coll Cardiol.</i> 2013;62:e147-e239. <sup>69</sup>  |                  |
| <b>Hepatojugular reflux</b>               | Distention of the neck veins precipitated by the maneuver of firm sustained pressure over the liver. Also referred to as abdomino-jugular reflux.   | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | Wiese J. The abdominojugular reflux sign. <i>Am J Med.</i> 2000;109:59-61. <sup>127</sup>   |                  |
| <b>Third heart sound (S<sub>3</sub>)</b>  | Presence of a third (mid-diastolic) heart sound   | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | Yancy CW, Jessup M, Bozkurt B, et al. 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/ American Heart Association Task Force on Practice Guidelines. <i>J Am Coll Cardiol.</i> 2013;62:e147-e239. <sup>69</sup>  |                  |
| <b>Fourth heart sound (S<sub>4</sub>)</b> | Presence of a fourth (late-diastolic) heart sound   | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | Yancy CW, Jessup M, Bozkurt B, et al. 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/ American Heart Association Task Force on Practice Guidelines. <i>J Am Coll Cardiol.</i> 2013;62:e147-e239. <sup>69</sup>  |                  |
| <b>Rub</b>                                | An auscultated finding describing high or medium pitched and scratchy sound, generated by inflammation of the pericardial sac   | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | Boris JR, Béland MJ, Bergensen LJ, et al. 2017 AHA/ACC key data elements and definitions for ambulatory electronic health records in pediatric and congenital cardiology: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Data Standards. <i>J Am Coll Cardiol.</i> 2017;70:1029-1095. <sup>86</sup> |                  |
| <b>Heart murmur</b>                       | An auscultated finding describing a series of audible vibrations of varying intensity (loudness), frequency (pitch), quality, configuration, and duration created by turbulent blood flow in the heart or surrounding vessels   | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | Boris JR, Béland MJ, Bergensen LJ, et al. 2017 AHA/ACC key data elements and definitions for ambulatory electronic health records in pediatric and congenital cardiology: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Data Standards. <i>J Am Coll Cardiol.</i> 2017;70:1029-1095. <sup>86</sup> |                  |

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B. Physical Examination (Continued)

| Data Element                                | Data Element Definition  | Permissible Values   | Permissible Value Definitions | Mapping/Source of Definition  | Additional Notes   |  |
|---|--|--|-------------------------------|---|--|--|
| Heart murmur - timing                       | The classification of a heart murmur based on the phase of the cardiac cycle or timing of its occurrence | <ul style="list-style-type: none"> <li>■ Systolic</li> <li>■ Diastolic</li> </ul>  |                               | NCI Thesaurus Code: C167438 <sup>63</sup>   |  |  |
| Heart sounds - location (including murmurs) | The classification of a heart murmur based on location   | <ul style="list-style-type: none"> <li>■ Apex</li> <li>■ Left lower sternal border</li> <li>■ Left middle sternal border</li> <li>■ Left upper sternal border</li> <li>■ Right upper sternal border</li> </ul> |                               | Boris JR, Béland MJ, Bergensen LJ, et al. 2017 AHA/ACC key data elements and definitions for ambulatory electronic health records in pediatric and congenital cardiology: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Data Standards. <i>J Am Coll Cardiol.</i> 2017;70:1029-1095. <sup>86</sup> |  |  |
|   |  |  | Apex                          | The location on the precordium that corresponds to the location of the blunt extremity of the heart formed by the left ventricle.   | <i>Stedman's Medical Dictionary.</i> 28th ed. Wolters Kluwer; 2006 <sup>128</sup>  |  |
|   |  |  | Left lower sternal border     | The location on the precordium that corresponds to the tricuspid region, between the fifth and sixth intercostal spaces at the left sternal border  | Tavel ME. Cardiac auscultation. A glorious past-but does it have a future? <i>Circulation.</i> 1996;93:1250-1253. <sup>129</sup> |  |
|   |  |  | Left middle sternal border    | The location on the precordium that corresponds to the region between the third and fifth intercostal spaces at the left sternal border   |  |  |
|   |  |  | Left upper sternal border     | The location on the precordium that corresponds to the pulmonic region, between the second and third intercostal spaces at the left sternal border  | Tavel ME. Cardiac auscultation. A glorious past-but does it have a future? <i>Circulation.</i> 1996;93:1250-1253. <sup>129</sup> |  |
|   |  |  | Right upper sternal border    | The location on the precordium that corresponds to the aortic region, between the second and third intercostal spaces at the right sternal border   | Tavel ME. Cardiac auscultation. A glorious past-but does it have a future? <i>Circulation.</i> 1996;93:1250-1253. <sup>129</sup> |  |

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APPENDIX 6. CONTINUED

B. Physical Examination (Continued)

| Data Element                          | Data Element Definition               | Permissible Values   | Permissible Value Definitions  | Mapping/Source of Definition              | Additional Notes                                  |
|---------------------------------------|---------------------------------------|--|--|---|---|
| Lung (pulmonary) examination findings | Findings on auscultation of the lungs | <ul style="list-style-type: none"> <li>■ Clear or normal</li> <li>■ Rales</li> <li>■ Decreased breath sounds or dullness</li> <li>■ Rhonchi</li> <li>■ Wheezing</li> <li>■ Crepitations</li> <li>■ Pleural friction rub</li> <li>■ Absent breath sounds</li> <li>■ Other findings</li> </ul> |  |   |   |
|                                       |                                       | Clear or normal  | Lungs are normal on auscultation.  |   |   |
|                                       |                                       | Rales  | Abnormal breath sounds (crackles) heard on auscultation indicating inflammation, fluid, or infection of the lung   | NCI Thesaurus Code: C119216 <sup>63</sup> |   |
|                                       |                                       | Decreased breath sounds or dullness  | Diminished breath sounds   |   |   |
|                                       |                                       | Rhonchi  | Abnormal breath sounds similar to snoring heard on auscultation of the bronchial airways, suggesting a partial obstruction attributable to thick secretions, a muscular spasm, or a neoplasm                           | NCI Thesaurus Code: C87116 <sup>63</sup>  |   |
|                                       |                                       | Wheezing   | Abnormal breath sounds characterized by a high-pitched, whistling sounds during breathing  | NCI Thesaurus Code: C78718 <sup>63</sup>  | End-expiratory wheezes may indicate bronchospasm. |
|                                       |                                       | Crepitations   | Crackling sounds typically heard in lung infection or with pulmonary fibrosis  | NCI Thesaurus Code: C26860 <sup>63</sup>  |   |
|                                       |                                       | Pleural friction rub   | An abnormal lung sound that is caused by inflammation of the pleural layer of the lungs rubbing together. Pleural friction rub is heard on inspiration and expiration and sounds like a low-pitch harsh/grating noise. |   |   |
|                                       |                                       | Absent breath sounds   | Absence of breath sounds during auscultation   |   |   |
| Other findings                        |                                       |  |  |   |   |

Continued on the next page

B. Physical Examination (Continued)

| Data Element                      | Data Element Definition  | Permissible Values   | Permissible Value Definitions | Mapping/Source of Definition   | Additional Notes   |
|-----------------------------------|--|--|-------------------------------|--|--|
| Peripheral edema                  | Increased tissue fluid indicated by perceptible indentation on lower leg or foot after palpation | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul>   |                               | Yancy CW, Jessup M, Bozkurt B, et al. 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/ American Heart Association Task Force on Practice Guidelines. <i>J Am Coll Cardiol.</i> 2013;62:e147-e239. <sup>69</sup>   |  |
| Ascites                           | Intra-abdominal fluid accumulation as determined by physical examination                         | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul>   |                               | Yancy CW, Jessup M, Bozkurt B, et al. 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/ American Heart Association Task Force on Practice Guidelines. <i>J Am Coll Cardiol.</i> 2013;62:e147-e239. <sup>69</sup>   | Abdominal ultrasound may also demonstrate presence of ascites. |
| Hepatomegaly                      | Liver edge detectable below the right costal margin during examination                           | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul>   |                               | Yancy CW, Jessup M, Bozkurt B, et al. 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/ American Heart Association Task Force on Practice Guidelines. <i>J Am Coll Cardiol.</i> 2013;62:e147-e239. <sup>69</sup>   |  |
| Neurological examination findings |  | <ul style="list-style-type: none"> <li>■ Dizziness</li> <li>■ Headache</li> <li>■ Impaired consciousness</li> <li>■ Seizure</li> <li>■ Agitation</li> <li>■ Confusion</li> <li>■ Visual agnosia</li> <li>■ Encephalopathy</li> <li>■ Acute cerebrovascular accident</li> <li>■ Corticospinal tract signs (eg, enhanced tendon reflexes, clonus, hyperreflexia)</li> <li>■ Stroke</li> <li>■ Guillain-Barré syndrome</li> <li>■ Critical illness polyneuropathy/myopathy</li> <li>■ Miller-Fisher syndrome</li> <li>■ Other, specify</li> </ul> |                               | Whittaker A, Anson M, Harky A. Neurological manifestations of COVID-19: a systematic review and current update. <i>Acta Neurol Scand.</i> 2020;142:14-22. <sup>130</sup><br>Heneka MT, Golenbock D, Latz E, et al. Immediate and long-term consequences of COVID-19 infections for the development of neurological disease. <i>Alzheimers Res Ther.</i> 2020;12:69. <sup>131</sup> |  |

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APPENDIX 6. CONTINUED

B. Physical Examination (Continued)

| Data Element | Data Element Definition   | Permissible Values   | Permissible Value Definitions  | Mapping/Source of Definition   | Additional Notes   |
|--------------|---|--|--|--|--|
| Frailty      | Canadian Study of Health and Aging Clinical Frailty Scale score | <ul style="list-style-type: none"> <li>■ 1 (very fit)</li> <li>■ 2 (well)</li> <li>■ 3 (managing well)</li> <li>■ 4 (vulnerable)</li> <li>■ 5 (mildly frail)</li> <li>■ 6 (moderately frail)</li> <li>■ 7 (severely frail)</li> <li>■ 8 (very severely frail)</li> <li>■ 9 (terminally ill)</li> </ul> |  | NCDR CathPCI Registry Coder's Data Dictionary v5.0 (data element # 4561) <sup>84</sup><br>Rockwood K, Song X, MacKnight C, et al. A global clinical measure of fitness and frailty in elderly people. <i>CMAJ</i> . 2005;173:489-495. <sup>132</sup> | Scoring frailty in people with dementia:<br>The degree of frailty corresponds to the degree of dementia. Common symptoms in mild dementia include forgetting the details of a recent event, although still remembering the event itself, repeating the same question/story, and social withdrawal. In moderate dementia, recent memory is very impaired, even though they seemingly can remember their past life events well. They can do personal care with prompting. In severe dementia, they cannot do personal care without help. |
|              |   | 1 (very fit)   | People who are robust, active, energetic, and motivated. These people commonly exercise regularly. They are among the fittest for their age.             |  |  |
|              |   | 2 (well)   | People who have no active disease symptoms but are less fit than category 1. Often, they exercise or are very active occasionally (eg, seasonally)       |  |  |
|              |   | 3 (managing well)  | People whose medical problems are well controlled but are not regularly active beyond routine walking  |  |  |
|              |   | 4 (vulnerable)   | Although not dependent on others for daily help, symptoms often limit activities. A common complaint is being "slowed up" or being tired during the day. |  |  |

Continued on the next page

B. Physical Examination (Continued)

| Data Element | Data Element Definition | Permissible Values      | Permissible Value Definitions   | Mapping/Source of Definition | Additional Notes |
|--------------|-------------------------|-------------------------|---|------------------------------|------------------|
|              |                         | 5 (mildly frail)        | These people often have more evident slowing and need help in high-order instrumental activities of daily living (finances, transportation, heavy housework, medications). Typically, mild frailty progressively impairs shopping and walking outside alone, meal preparation, and housework. |                              |                  |
|              |                         | 6 (moderately frail)    | People need help with all outside activities and with keeping house. Inside, they often have problems with stairs and need help with bathing and might need minimal assistance (cueing, standby) with dressing.   |                              |                  |
|              |                         | 7 (severely frail)      | Completely dependent for personal care, from whatever cause (physical or cognitive). Even so, they seem stable and not at high risk of dying (within ~6 mo).  |                              |                  |
|              |                         | 8 (very severely frail) | Completely dependent, approaching the end of life. Typically, they could not recover even from a minor illness.   |                              |                  |
|              |                         | 9 (terminally ill)      | Approaching the end of life. This category applies to people with a life expectancy <6 mo, who are not otherwise evidently frail.   |                              |                  |

bpm indicates beats per minute.

## APPENDIX 7. DIAGNOSTIC PROCEDURES

| Data Element            | Data Element Definition   | Permissible Values   | Permissible Value Definitions   | Mapping/Source of Definition              | Additional Notes   |
|-------------------------|---|--|---|---|--|
| <b>EF, quantitative</b> | Proportion of blood pumped out of the left ventricle of the heart with each contraction, expressed as a percentage            | <ul style="list-style-type: none"> <li>■ EF, %</li> <li>■ When a quantitative range is given, the midpoint of the range</li> </ul>   | The fraction of blood expelled from the left ventricle with each cardiac systole (stroke volume/end diastolic volume)   | NCI Thesaurus Code: C80418 <sup>63</sup>  | When multiple determinations are present, the most recent is preferred. Please note modality (eg, radionuclide ventriculography, MRI, ECG, contrast, ventriculography, nuclear imaging). |
| <b>EF, qualitative</b>  | Proportion of blood pumped out of the left ventricle of the heart with each contraction, expressed as qualitative description | <ul style="list-style-type: none"> <li>■ Normal (ie, ≥50%)</li> <li>■ Mildly reduced (ie, ≥40% and &lt;50%)</li> <li>■ Moderately reduced (ie, ≥30% and &lt;40%)</li> <li>■ Severely reduced (ie, &lt;30%)</li> </ul>                            | The qualitative estimate of the amount of blood expelled from the left ventricle with each cardiac systole  | NCI Thesaurus Code: C80418 <sup>63</sup>  | If a quantitative EF is provided, it is preferred to enter the quantitative value rather than the qualitative ranges.  |
| <b>EF modality</b>      | Modality used to determine the EF   | <ul style="list-style-type: none"> <li>■ Radionuclide ventriculography</li> <li>■ Cardiac MRI</li> <li>■ Echocardiography</li> <li>■ Invasive contrast left ventriculography</li> <li>■ Myocardial perfusion imaging</li> <li>■ Other</li> </ul> |   |   |  |
|                         |   | Radionuclide ventriculography  | A multigated acquisition scan and a form of radionuclide imaging that provides a comprehensive look at blood flow and the function of the lower chambers of the heart ventricles  | NCI Thesaurus Code: C38073 <sup>63</sup>  |  |
|                         |   | Cardiac MRI  | Imaging that uses radiofrequency waves and a strong field rather than x-rays to provide amazingly clear and detailed pictures of cardiac structures. The technique is valuable for the diagnosis of many cardiovascular pathological conditions, including myocarditis, wall motion abnormalities, structural cardiac abnormalities, infiltrative diseases, intracardiac thrombus, and pericardial disease. | NCI Thesaurus Code: C16809 <sup>63</sup>  |  |
|                         |   | Echocardiography   | A test that uses high-frequency sound waves (ultrasound) to create an image of the heart  | NCI Thesaurus Code: C16525 <sup>63</sup>  |  |
|                         |   | Invasive contrast left ventriculography  | A medical imaging test that involves injecting contrast media into the heart's ventricle(s) to determine a patient's cardiac function   | NCI Thesaurus Code: C124142 <sup>63</sup> |  |
|                         |   | Myocardial perfusion imaging   | A procedure that captures pictures of blood flow throughout the heart muscle  | NCI Thesaurus Code: C102676 <sup>63</sup> |  |
|                         |   | Other  |   |   |  |

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## APPENDIX 7. CONTINUED

| Data Element                          | Data Element Definition   | Permissible Values   | Permissible Value Definitions | Mapping/Source of Definition   | Additional Notes |
|---------------------------------------|---|--|-------------------------------|--|------------------|
| <b>Echocardiography data elements</b> | Refer to the 2019 ACC/AHA/ASE Key Data Elements and Definitions for Transthoracic Echocardiography. |  |                               | Douglas PS, Carabello BA, Lang RM, et al. 2019 ACC/AHA/ASE key data elements and definitions for transthoracic echocardiography: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Data Standards (Writing Committee to Develop Clinical Data Standards for Transthoracic Echocardiography) and the American Society of Echocardiography. <i>J Am Coll Cardiol.</i> 2019;74:403-469. <sup>133</sup> |                  |
| <b>Electrocardiographic elements</b>  | 12-lead electrocardiographic data elements  | <ul style="list-style-type: none"> <li>■ Rhythm</li> <li>■ Heart rate, bpm</li> <li>■ QRS axis</li> <li>■ LBBB</li> <li>■ RBBB</li> <li>■ Nonspecific intraventricular conduction delay</li> <li>■ Presence of abnormal Q waves</li> <li>■ Mean QRS duration, ms</li> <li>■ PR interval</li> <li>■ QTc interval</li> <li>■ AV block</li> <li>■ ST-segment changes</li> </ul> |                               |  |                  |

Continued on the next page

APPENDIX 7. CONTINUED

| Data Element | Data Element Definition | Permissible Values | Permissible Value Definitions  | Mapping/Source of Definition  | Additional Notes |
|--------------|-------------------------|--------------------|--|---|------------------|
|              |                         | Rhythm             | <p>Presence of:</p> <ul style="list-style-type: none"> <li>■ Sinus rhythm: an electrocardiographic finding of a cardiac rhythm that originates in the sinoatrial node</li> <li>■ AF: an arrhythmia characterized by uncoordinated atrial myocardium attributable to multiple reentry circuits with consequent deterioration of atrial mechanical function. Instead of intermittently contracting, the atria quiver continuously in a chaotic pattern, causing a totally irregular often tachycardic ventricular rate</li> <li>■ Atrial flutter: a disorder characterized by an electrocardiographic finding of an organized, regular atrial rhythm with atrial rate of 240-340 bpm. Multiple P waves typically appear in the inferior leads in a sawtooth-like pattern between the QRS complexes.</li> <li>■ Ventricular arrhythmia: a disorder characterized by an electrocardiographic finding of an atypical cardiac rhythm resulting from a pathological process in the cardiac ventricles</li> <li>■ Supraventricular tachycardia: a disorder characterized by an electrocardiographic finding of a tachycardia that does not originate in the ventricles or His Purkinje system</li> <li>■ Paced rhythm: an electrocardiographic finding that the cardiac rhythm is initiated by an electrical impulse from a mechanical cardiac pacemaker</li> <li>■ Other</li> </ul> | NCI Thesaurus Codes: C100076, C50466, C51224, C26924, C35061, C111094, C88140 <sup>63</sup> |                  |
|              |                         | Heart rate, bpm    | The number of heartbeats per unit of time, usually expressed as beats per min  | NCI Thesaurus Code: C49677 <sup>63</sup>  |                  |
|              |                         | QRS axis           | A numerical representation of the electrocardiographic vector assessed at maximum deviation of the QRS complex from the isoelectric baseline, usually reported for the frontal plane   | NCI Thesaurus Code: C118165 <sup>63</sup>   |                  |
|              |                         | LBBB               | An electrocardiographic finding of delayed conduction to the left ventricle, manifested as a widened QRS complex and absence of Q waves in leads V5, V6, I, and aVL with QRS duration $\geq 120$ ms  | NCI Thesaurus Code: C62269 <sup>63</sup>  |                  |

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| Data Element             | Data Element Definition  | Permissible Values   | Permissible Value Definitions  | Mapping/Source of Definition              | Additional Notes |
|--------------------------|--|--|--|---|------------------|
|                          |  | RBBB   | An electrocardiographic finding of delayed conduction to the right ventricle, manifested by a widened QRS in V <sub>1</sub> and V <sub>2</sub> , a widened S-wave in V <sub>5</sub> , V <sub>6</sub> , I and aVL, and with QRS duration ≥120 ms. An RsR' complex is typically present in leads V <sub>1</sub> and V <sub>2</sub> | NCI Thesaurus Code: C62270 <sup>63</sup>  |                  |
|                          |  | Nonspecific intraventricular conduction delay  | An electrocardiographic finding of a widened QRS duration typically >110 ms that does not meet the morphological criteria for any of the standard bundle branch or fascicular block patterns   | NCI Thesaurus Code: C62271 <sup>63</sup>  |                  |
|                          |  | Presence of abnormal Q waves   | ≥0.03 s in width and ≥1 mm (0.1 mV) in depth in at least 2 contiguous leads  |   |                  |
|                          |  | Mean QRS duration, ms  | The mean duration of the QRS interval, obtained from a set of measurements of the QRS interval. The QRS interval is defined as the time from the beginning of the QRS complex to the end of the QRS complex, representing the time it takes for the ventricles to depolarize.  | NCI Thesaurus Code: C62087 <sup>63</sup>  |                  |
|                          |  | PR interval  | The time interval between the start of the P-wave and the beginning of the QRS complex in the cardiac cycle  | NCI Thesaurus Code: C83502 <sup>63</sup>  |                  |
|                          |  | QTc interval   | The time interval between the start of the Q-wave and the end of the T-wave in the cardiac cycle as corrected with a nonspecified correction formula   | NCI Thesaurus Code: C100391 <sup>63</sup> |                  |
|                          |  | AV block   | An electrocardiographic finding of blocked cardiac electrical impulses along the fibers normally responsible for impulse conduction  | NCI Thesaurus Code: C26703 <sup>63</sup>  |                  |
|                          |  | ST-segment changes   | An electrocardiographic finding of ST-segment elevation or depression  | NCI Thesaurus Code: C26703 <sup>63</sup>  |                  |
| <b>Chest radiography</b> | Documented findings from the radiological examination of the chest (chest x-ray) | <ul style="list-style-type: none"> <li>■ Pulmonary infiltrates</li> <li>■ Pulmonary vascular redistribution</li> <li>■ Pulmonary congestion</li> <li>■ Pulmonary edema</li> <li>■ Cardiomegaly, chamber enlargement</li> <li>■ Pleural effusion(s)</li> <li>■ No abnormalities related to cardiovascular diseases</li> </ul> |  |   |                  |

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APPENDIX 7. CONTINUED

| Data Element    | Data Element Definition   | Permissible Values   | Permissible Value Definitions  | Mapping/Source of Definition              | Additional Notes |
|-----------------|---|--|--|---|------------------|
|                 |   | Pulmonary infiltrates  | Increased soft tissue density indicating the filling of airspaces with fluid, inflammatory exudate, or cells   |   |                  |
|                 |   | Pulmonary vascular redistribution  | Distension of the pulmonary veins, particularly in the upper lung fields during acute COVID-19   |   |                  |
|                 |   | Pulmonary congestion   | Imaging findings consistent with increased intravascular blood volume in the lungs   | NCI Thesaurus Code: C119217 <sup>63</sup> |                  |
|                 |   | Pulmonary edema  | Accumulation of fluid in the lung tissues, typically characterized by imaging findings such as pulmonary infiltrates, Kerley B lines, or peribronchial cuffing   | NCI Thesaurus Code: C26868 <sup>63</sup>  |                  |
|                 |   | Cardiomegaly, chamber enlargement  | Abnormal enlargement of the heart  | NCI Thesaurus Code: C61453 <sup>63</sup>  |                  |
|                 |   | Pleural effusion(s)  | Increased amounts of fluid within the pleural cavity. Symptoms include shortness of breath, cough, and chest pain. It is usually caused by lung infections, congestive HF, pleural and lung tumors, connective tissue disorders, and trauma. | NCI Thesaurus Code: C3331 <sup>63</sup>   |                  |
|                 |   | No abnormalities related to cardiovascular diseases  |  |   |                  |
| <b>Chest CT</b> | Documented findings from the CT examination of the chest, with or without angiography | <ul style="list-style-type: none"> <li>■ Pulmonary embolism</li> <li>■ Pulmonary infiltrates</li> <li>■ Pulmonary vascular redistribution</li> <li>■ Pulmonary congestion</li> <li>■ Pulmonary edema</li> <li>■ Cardiomegaly, chamber enlargement</li> <li>■ Pleural effusion(s)</li> <li>■ Thrombus</li> <li>■ Coronary artery aneurysm</li> <li>■ No abnormalities related to cardiovascular diseases</li> </ul> |  |   |                  |

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## APPENDIX 7. CONTINUED

| Data Element | Data Element Definition  | Permissible Values  | Permissible Value Definitions   | Mapping/Source of Definition   | Additional Notes |
|--------------|--|---|---|--|------------------|
|              |  | Pulmonary embolism  | The obstruction of the pulmonary artery or one of its branches by an embolus, sometimes associated with infarction of the lung, during acute COVID-19   | NCI Thesaurus Code: C50713 <sup>63</sup>   |                  |
|              |  | Pulmonary infiltrates   | Imaging-defined opacification and consolidation of lungs suggesting injury and substance denser than air, such as pus, blood, or protein, within the parenchyma of the lungs during acute COVID-19  |  |                  |
|              |  | Pulmonary vascular redistribution   | Distension of the pulmonary veins, particularly in the upper lung fields during acute COVID-19  |  |                  |
|              |  | Pulmonary congestion  | Imaging findings consistent with increased intravascular blood volume in the lungs during acute COVID-19  | NCI Thesaurus Code: C119217 <sup>63</sup>  |                  |
|              |  | Pulmonary edema   | Accumulation of fluid in the lung tissues   | NCI Thesaurus Code: C26868 <sup>63</sup>   |                  |
|              |  | Cardiomegaly, chamber enlargement   | Abnormal enlargement of the heart or heart chambers during acute COVID-19   | NCI Thesaurus Code: C61453 <sup>63</sup>   |                  |
|              |  | Pleural effusion(s)   | Increased amounts of fluid within the pleural cavity. Symptoms include shortness of breath, cough, and chest pain. It is usually caused by lung infections, congestive HF, pleural and lung tumors, connective tissue disorders, and trauma | NCI Thesaurus Code: C3331 <sup>63</sup>  |                  |
|              |  | Thrombus  | The formation of a blood clot in the lumen of a vessel or heart chamber   |  |                  |
|              |  | Coronary artery aneurysm  | Focal dilation of a coronary artery ( $\geq 1.5\times$ the adjacent normal segment)   | Boris JR, Béland MJ, Bergensen LJ, et al. 2017 AHA/ACC key data elements and definitions for ambulatory electronic health records in pediatric and congenital cardiology: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Data Standards. <i>J Am Coll Cardiol</i> . 2017;70:1029-1095. <sup>86</sup>                         |                  |
|              |  | No abnormalities related to cardiovascular diseases   |   |  |                  |
| CCTA         | CAD-RADS (Reporting and Data System) score specifically for CCTA, based on degree of maximal coronary stenosis | <ul style="list-style-type: none"> <li>■ 0</li> <li>■ 1</li> <li>■ 2</li> <li>■ 3</li> <li>■ 4</li> <li>■ 5</li> <li>■ Unknown</li> </ul> |   | Cury RC, Abbara S, Achenbach S, et al. CAD-RADS™ Coronary Artery Disease - Reporting and Data System. An expert consensus document of the Society of Cardiovascular Computed Tomography (SCCT), the American College of Radiology (ACR) and the North American Society for Cardiovascular Imaging (NASCI). <i>J Cardiovasc Comput Tomogr</i> . 2016;10:269-281. <sup>134</sup> |                  |

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APPENDIX 7. CONTINUED

| Data Element                        | Data Element Definition   | Permissible Values   | Permissible Value Definitions   | Mapping/Source of Definition   | Additional Notes   |
|-------------------------------------|---|--|---|--|--|
|                                     |   | 0  | 0%  |  |  |
|                                     |   | 1  | 1%-24%  |  |  |
|                                     |   | 2  | 25%-49%   |  |  |
|                                     |   | 3  | 50%-69%   |  |  |
|                                     |   | 4  | A. 70%-99% or B. Left main >50% or 3-vessel obstructive disease           |  |  |
|                                     |   | 5  | 100%  |  |  |
|                                     |   | Unknown  |   |  |  |
| <b>Lower extremity ultrasound</b>   | Documented findings from the ultrasound examination   | <ul style="list-style-type: none"> <li>■ DVT</li> <li>■ Arterial thrombosis</li> </ul> |   |  |  |
|                                     |   | DVT  | Thrombosis formation within deep veins during acute COVID-19              | NCI Thesaurus Code: C49343 <sup>63</sup>   |  |
|                                     |   | Arterial thrombosis  | Formation of a blood clot in the lumen of an artery during acute COVID-19 | NCI Thesaurus Code: C98826 <sup>63</sup>   |  |
| <b>Myocardial perfusion imaging</b> | An imaging procedure that quantifies blood flow throughout the heart muscle Refer to the 2020 AHA/ACC Key Data Elements and Definitions for Coronary Revascularization. |  |   | Dehmer GJ, Badhwar V, Bermudez EA, et al. 2020 AHA/ACC key data elements and definitions for coronary revascularization: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Data Standards (Writing Committee to Develop Clinical Data Standards for Coronary Revascularization). <i>J Am Coll Cardiol.</i> 2020;75:1975-2088. <sup>135</sup><br>NCI Thesaurus Code: C102676 <sup>63</sup> |  |
| <b>Coronary angiography</b>         | Documented findings from coronary angiography Refer to the 2020 AHA/ACC Key Data Elements and Definitions for Coronary Revascularization.                               |  |   | Dehmer GJ, Badhwar V, Bermudez EA, et al. 2020 AHA/ACC key data elements and definitions for coronary revascularization: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Data Standards (Writing Committee to Develop Clinical Data Standards for Coronary Revascularization). <i>J Am Coll Cardiol.</i> 2020;75:1975-2088. <sup>135</sup>  |  |
| <b>Left heart catheterization</b>   | Documented findings from left heart catheterization Refer to the 2020 AHA/ACC Key Data Elements and Definitions for Coronary Revascularization.                         |  |   | Dehmer GJ, Badhwar V, Bermudez EA, et al. 2020 AHA/ACC key data elements and definitions for coronary revascularization: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Data Standards (Writing Committee to Develop Clinical Data Standards for Coronary Revascularization). <i>J Am Coll Cardiol.</i> 2020;75:1975-2088. <sup>135</sup>  | Important variables for HF include left ventricular end-diastolic pressure (mm Hg) and left ventriculography EF. |
| <b>RA mean pressure</b>             | Mean right atrial pressure measured from pulmonary artery catheter  | <ul style="list-style-type: none"> <li>■ Numeric, mm Hg</li> </ul>                     |   |  |  |
| <b>PA mean pressure</b>             | Mean blood pressure in the pulmonary artery   | <ul style="list-style-type: none"> <li>■ Numeric, mm Hg</li> </ul>                     |   | NCI Thesaurus Code: C129958 <sup>63</sup>  |  |

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## APPENDIX 7. CONTINUED

| Data Element                                   | Data Element Definition   | Permissible Values                  | Permissible Value Definitions | Mapping/Source of Definition              | Additional Notes  |
|--|---|-------------------------------------|-------------------------------|---|---|
| <b>PA systolic pressure</b>                    | The blood pressure in the pulmonary artery during the contraction of the left ventricle of the heart  | ■ Numeric, mm Hg                    |                               | NCI Thesaurus Code: C120943 <sup>63</sup> |   |
| <b>PA diastolic pressure</b>                   | The blood pressure in the pulmonary artery during ventricular relaxation (diastole)   | ■ Numeric, mm Hg                    |                               | NCI Thesaurus Code: C120941 <sup>63</sup> |   |
| <b>PAPi</b>                                    | Pulse pressure across pulmonary artery divided by RA (calculated systolic pulmonary arterial pressure - diastolic pulmonary pressure)/right atrial pressure)  | ■ Numeric                           |                               |   |   |
| <b>Mean pulmonary capillary wedge pressure</b> | The pressure measured by wedging a pulmonary catheter with an inflated balloon into a small pulmonary arterial branch   | ■ Numeric, mm Hg                    |                               | NCI Thesaurus Code: C129955 <sup>63</sup> | May be recorded with or without V-wave.   |
| <b>Cardiac output</b>                          | The total volume of blood pumped by the heart over a set period of time, conventionally 1 min; it is calculated as heart rate times stroke volume and is additionally dependent on preload and afterload for functional output.                                       | ■ Numeric, L/min                    |                               | NCI Thesaurus Code: C119246 <sup>63</sup> |   |
| <b>Cardiac index</b>                           | The measure of an individual's cardiac output as divided by their body surface area). This calculation is a useful function to determine an individual's cardiac performance in relation to their body size, providing an overview of global cardiovascular function. | ■ Numeric, L/min/m <sup>2</sup>     |                               | NCI Thesaurus Code: C119245 <sup>63</sup> |   |
| <b>Transpulmonary gradient</b>                 | Difference between mean pulmonary artery pressure and mean pulmonary capillary wedge pressure   | ■ Numeric, mm Hg                    |                               |   |   |
| <b>Pulmonary vascular resistance</b>           | Pulmonary vascular resistance is calculated as (mean PA pressure minus mean pulmonary capillary wedge pressure) divided by cardiac output.  | ■ Numeric, Wood units or dynes/s/cm |                               | NCI Thesaurus Code: C119247 <sup>63</sup> | The resistance to blood flow generated by the pulmonary vasculature, which is normally one-sixth of systemic vascular resistance. The major determinant of pulmonary vascular resistance is pulmonary vessel constriction, most often caused by hypoxia. Prolonged elevated pulmonary vascular resistance can cause right HF. |
| <b>Systemic vascular resistance</b>            | Systemic vascular resistance is calculated as the systemic mean arterial blood pressure minus right arterial pressure divided by cardiac output.  | ■ Numeric, dynes/s/cm <sup>2</sup>  |                               | NCI Thesaurus Code: C119248 <sup>63</sup> | The resistance to blood flow generated by all systemic vasculature, excluding pulmonary vasculature. The major determinant of systemic vascular resistance is arteriolar tone, but blood viscosity and vascular capacitance are also contributing factors.  |

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APPENDIX 7. CONTINUED

| Data Element                                 | Data Element Definition   | Permissible Values   | Permissible Value Definitions   | Mapping/Source of Definition  | Additional Notes  |
|--|---|--|---|---|---|
| <b>Mixed venous O<sub>2</sub> saturation</b> | Saturation measured via a sample of blood from a pulmonary artery catheter measures the end result of O <sub>2</sub> consumption and delivery, used in the ICU as a measure of O <sub>2</sub> extraction by the body.   | <ul style="list-style-type: none"> <li>Numeric, %</li> </ul>   |   |   |   |
| <b>Cardiac MRI</b>                           | Medical imaging with MRI technology for noninvasive assessment of the function and structure of the cardiovascular system using ECG gating and high temporal resolution protocols with an intent to assess myocarditis, cardiac function, and structures during or after COVID-19 | <ul style="list-style-type: none"> <li>Myocardial edema by T2 mapping or T2-weighted imaging</li> <li>Myocardial injury by T1 mapping</li> <li>Myocardial injury by late gadolinium enhancement</li> <li>Myocarditis</li> <li>Pericardial changes</li> <li>Ventricular function abnormalities</li> <li>Other cardiac structural abnormalities</li> </ul> |   | <p>NCI Thesaurus Code: C16809<sup>53</sup><br/>                     Ferreira VM, Schulz-Menger J, Holmvang G, et al. Cardiovascular magnetic resonance in nonischemic myocardial inflammation: expert recommendations. <i>J Am Coll Cardiol.</i> 2018;72:3158-3176.<sup>56</sup><br/>                     Friedrich MG, Sechtem U, Schulz-Menger J, et al. Cardiovascular magnetic resonance in myocarditis: a JACC white paper. <i>J Am Coll Cardiol.</i> 2009;53:1475-1487.<sup>136</sup><br/>                     National Institute of Neurological Disorders and Stroke. Common data elements. Cardiac magnetic resonance imaging (MRI). Accessed March 4, 2022. <a href="https://www.commondataelements.ninds.nih.gov/cde_detailed_report/23564/Imaging%20Diagnostics/Assessments%20and%20Examinations/Stroke/Cardiac%20Magnetic%20Resonance%20Imaging%20%28MRI%29">https://www.commondataelements.ninds.nih.gov/cde_detailed_report/23564/Imaging%20Diagnostics/Assessments%20and%20Examinations/Stroke/Cardiac%20Magnetic%20Resonance%20Imaging%20%28MRI%29</a><sup>137</sup></p> | <p>Cardiac MRI criteria (Update to the Lake Louise Consensus Criteria for myocarditis)<sup>56</sup></p> <p>In the setting of clinically suspected myocarditis, cardiac MRI findings are consistent with myocardial inflammation, if both of the following criteria are present:</p> <ol style="list-style-type: none"> <li>T2-based imaging: regional high T2 signal intensity; or global T2 signal intensity ratio <math>\geq 2.0</math> in T2-weighted CMR images; or regional or global increase of myocardial T2 relaxation time</li> <li>T1-based imaging: regional or global increase of native myocardial T1 relaxation time or extracellular volume; or areas with high signal intensity in a nonischemic distribution pattern in late-gadolinium enhancement images</li> </ol> <p>The presence of LV dysfunction or pericardial effusion provides additional, supportive evidence for myocarditis.</p> |
|  |   | Myocardial edema by T2 mapping or T2-weighted imaging  | Regional or global myocardial SI increase in T2-weighted images suggestive of edema   |   |   |
|  |   | Myocardial injury by T1 mapping  | Regional or global myocardial injury by T1 mapping  |   |   |
|  |   | Myocardial injury by late gadolinium enhancement   | Increased global myocardial late gadolinium enhancement in gadolinium-enhanced T1-weighted images   |   |   |
|  |   | Myocarditis  | Acute viral myocarditis, usually lasting 1-3 d, is characterized by cardiomyocyte necrosis directly triggered by the viral infection. Humoral and cellular immunologic responses in the myocardium may persist for months and may result in a chronic postinfectious autoimmune myocarditis |   |   |
|  |   | Pericardial changes  | Pericardial effusion, thickening, increased signal intensity on late gadolinium enhancement   |   |   |
|  |   | Ventricular functional abnormalities   | LV systolic or diastolic dysfunction, RV systolic or diastolic dysfunction, functional valvular regurgitation   |   |   |
|  |   | Other cardiac structural abnormalities   | LV, RV, LA, RA chamber enlargement, wall motion abnormalities, valvular structural abnormalities, cardiac masses  |   |   |

Continued on the next page

## APPENDIX 7. CONTINUED

| Data Element                     | Data Element Definition                            | Permissible Values   | Permissible Value Definitions   | Mapping/Source of Definition  | Additional Notes  |  |
|----------------------------------|--|--|---------------------------------|---|---|--|
| <b>FDG-PET</b>                   | Documented findings from FDG-PET                   | <ul style="list-style-type: none"> <li>■ Myocarditis</li> <li>■ Pericarditis</li> <li>■ Other</li> </ul>   |                                 | NCI Thesaurus Code: C103400 <sup>63</sup>   | Focal/diffuse FDG uptake in the myocardium with/without perfusion mismatch can be helpful in the diagnosis of myocarditis, especially in patients who cannot undergo cardiac MRI. |  |
| <b>Brain CT without contrast</b> | Documented findings from brain CT without contrast | <ul style="list-style-type: none"> <li>■ Hemorrhagic stroke</li> <li>■ Acute ischemic stroke</li> <li>■ Hypoxic ischemic encephalopathy</li> </ul> |                                 |   |   |  |
|                                  |  |  | Hemorrhagic stroke              | Brain tissue necrosis due to an intracerebral bleed   | NCI Thesaurus Code: C95803 <sup>63</sup>  |  |
|                                  |  |  | Acute ischemic stroke           | Acute onset of neurological deficits resulting from a loss of blood supply to brain tissue in an area of arterial distribution. | NCI Thesaurus Code: C95802 <sup>63</sup>  |  |
|                                  |  |  | Hypoxic ischemic encephalopathy | Injury to the central nervous system that occurs when there is insufficient delivery of oxygen to all or part of the brain      | NCI Thesaurus Code: C35549 <sup>63</sup>  |  |
| <b>Brain MRI</b>                 | Documented findings from brain MRI                 | <ul style="list-style-type: none"> <li>■ Hemorrhagic stroke</li> <li>■ Acute ischemic stroke</li> <li>■ Hypoxic ischemic encephalopathy</li> </ul> |                                 |   |   |  |
|                                  |  |  | Hemorrhagic stroke              | Brain tissue necrosis due to an intracerebral bleed   | NCI Thesaurus Code: C95803 <sup>63</sup>  | Powers WJ, Rabinstein AA, Ackerson T, et al. Guidelines for the early management of patients with acute ischemic stroke: 2019 update to the 2018 guidelines for the early management of acute ischemic stroke: a guideline for healthcare professionals from the American Heart Association/American Stroke Association. <i>Stroke</i> . 2019;50:e344-418. <sup>138</sup><br>NCI Thesaurus Code: C137913 <sup>63</sup> |
|                                  |  |  | Acute ischemic stroke           | Acute onset of neurological deficits resulting from a loss of blood supply to brain tissue in an area of arterial distribution. | NCI Thesaurus Code: C95802 <sup>63</sup>  |  |
|                                  |  |  | Hypoxic ischemic encephalopathy | Injury to the central nervous system that occurs when there is insufficient delivery of oxygen to all or part of the brain      | NCI Thesaurus Code: C35549 <sup>63</sup>  |  |

AV indicates atrioventricular; BSA, body surface area; bpm, beats per minute; CAD-RADS, Coronary Artery Disease - Reporting and Data System; CCTA, coronary computed tomography angiography; CI, cardiac index; CO, cardiac output; COVID-19, coronavirus disease 2019; CT, computed tomography; DVT, deep vein thrombosis; ECG, electrocardiogram; EF, ejection fraction; FDG, fluorodeoxyglucose; HF, heart failure; HR, heart rate; ICU, intensive care unit; LA, left atrial; LBBB, left bundle branch block; LV, left ventricular; MRI, magnetic resonance imaging; PA, pulmonary artery; PAPI, pulmonary artery pulsatility index; PET, positron emission tomography; PVR, pulmonary vascular resistance; RA, right atrial; RBBB, right bundle branch block; RV, right ventricular; SV, stroke volume; and SVR, systemic vascular resistance.

APPENDIX 8. PHARMACOLOGICAL THERAPY

A. Therapies for Preexisting Cardiovascular Disease (Patient Taking Prior to Admission)

| Data Element   | Data Element Definition  | Permissible Values   | Permissible Value Definitions | Mapping/Source of Definition  | Additional Notes |
|--|--|--|-------------------------------|---|------------------|
| <b>Aldosterone inhibitor (mineralocorticoid receptor antagonist)</b> | Spironolactone or eplerenone, which antagonize the action of aldosterone at mineralocorticoid receptors  | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | Yancy CW, Jessup M, Bozkurt B, et al. 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. <i>J Am Coll Cardiol.</i> 2013;62:e147-e239. <sup>69</sup><br>NCI Thesaurus Code: C101255 <sup>63</sup>  |                  |
| <b>ACE inhibitor medication</b>                                      | A medication that inhibits ACE, an enzyme that catalyzes the conversion of angiotensin I to angiotensin II. Inhibition of ACE results in a reduction in angiotensin II and angiotensin II-induced aldosterone secretion, causing vasodilation and natriuresis.   | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | Whelton PK, Carey RM, Aronow WS, et al. 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA guideline for the prevention, detection, evaluation, and management of high blood pressure in adults: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. <i>J Am Coll Cardiol.</i> 2018;71:e127-e248. <sup>139</sup><br>NCI Thesaurus Code: C247 <sup>63</sup>   |                  |
| <b>ARB medication</b>  | An ARB medication, a class of agents that act by selectively inhibiting angiotensin II receptor activation in the renin-angiotensin-aldosterone system.<br>Angiotensin II receptor antagonists bind to and block the activation of angiotensin II type 1 (AT1) receptors, thereby reducing production and secretion of aldosterone, among other actions. The combined effects result in reduction of blood pressure. It is primarily used for the treatment of hypertension or HF. | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | Whelton PK, Carey RM, Aronow WS, et al. 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA guideline for the prevention, detection, evaluation, and management of high blood pressure in adults: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. <i>J Am Coll Cardiol.</i> 2018;71:e127-e248. <sup>139</sup><br>NCI Thesaurus Code: C66930 <sup>63</sup> |                  |
| <b>ARNi</b>  | Combination of an angiotensin receptor blocker (above) and a neprilysin inhibitor (eg, sacubitril). Additionally, inhibits neprilysin, a neutral endopeptidase that degrades vasoactive peptides, such as bradykinin, and natriuretic peptides.  | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | Yancy CW, Jessup M, Bozkurt B, et al. 2016 ACC/AHA/HFSA focused update on new pharmacological therapy for heart failure: an update of the 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Failure Society of America. <i>J Am Coll Cardiol.</i> 2016;68:1476-1488. <sup>140</sup> |                  |
| <b>Beta-adrenergic antagonist (beta blocker) medication</b>          | A beta-adrenergic receptor antagonist (beta blocker) medication. Includes bisoprolol, carvedilol, metoprolol succinate, metoprolol tartrate, atenolol.   | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | Yancy CW, Jessup M, Bozkurt B, et al. 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. <i>J Am Coll Cardiol.</i> 2013;62:e147-e239. <sup>69</sup><br>NCI Thesaurus Code: C29576 <sup>63</sup>   |                  |
| <b>Metformin</b>   | A specific agent belonging to the biguanide class of antihyperglycemic agents  | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | American Diabetes Association. 10. Cardiovascular disease and risk management: standards of medical care in diabetes-2020. <i>Diabetes Care.</i> 2020;43:S111-S134. <sup>141</sup><br>NCI Thesaurus Code: C61612 <sup>63</sup>  |                  |
| <b>SGLT2 inhibitor</b>   | SGLT2 inhibitors inhibit the sodium glucose cotransporter-2 in the kidney, and selected agents in this class have demonstrated benefit in HF, CKD, ASCVD, and diabetes.  | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | American Diabetes Association. 10. Cardiovascular disease and risk management: standards of medical care in diabetes-2020. <i>Diabetes Care.</i> 2020;43:S111-S134. <sup>141</sup><br>NCI Thesaurus Code: C98083 <sup>63</sup>  |                  |
| <b>GLP-1 receptor agonist</b>  | Select medications in this class have been shown to improve ASCVD outcomes, drive weight loss, and lower glucose.  | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | American Diabetes Association. 10. Cardiovascular disease and risk management: standards of medical care in diabetes-2020. <i>Diabetes Care.</i> 2020;43:S111-S134. <sup>141</sup>  |                  |

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APPENDIX 8. CONTINUED

A. Therapies for Preexisting Cardiovascular Disease (Patient Taking Prior to Admission) (Continued)

| Data Element           | Data Element Definition  | Permissible Values   | Permissible Value Definitions | Mapping/Source of Definition   | Additional Notes |
|------------------------|--|--|-------------------------------|--|------------------|
| <b>Statin</b>          | An HMG-CoA reductase inhibitor ("statin"). Lipid-lowering medications with proven ASCVD benefits.  | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | Grundy SM, Stone NJ, Bailey AL, et al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APha/ASPC/NLA/PCNA guideline on the management of blood cholesterol: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. <i>J Am Coll Cardiol.</i> 2019;73:e285-e350. <sup>142</sup>  |                  |
| <b>Ezetimibe</b>       | A cholesterol absorption inhibitor with lipid-lowering activity  | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | Grundy SM, Stone NJ, Bailey AL, et al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APha/ASPC/NLA/PCNA guideline on the management of blood cholesterol: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. <i>J Am Coll Cardiol.</i> 2019;73:e285-e350. <sup>142</sup><br>NCI Thesaurus Code: C47529 <sup>63</sup>  |                  |
| <b>PCSK9 inhibitor</b> | Inhibits an enzyme (PCSK9), resulting in a reduction in circulating LDL cholesterol  | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | Grundy SM, Stone NJ, Bailey AL, et al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APha/ASPC/NLA/PCNA guideline on the management of blood cholesterol: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. <i>J Am Coll Cardiol.</i> 2019;73:e285-e350. <sup>142</sup>  |                  |
| <b>Bempedoic acid</b>  | Bempedoic acid decreases LDL cholesterol by inhibiting ATP-citrate lyase.  | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | Grundy SM, Stone NJ, Bailey AL, et al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APha/ASPC/NLA/PCNA guideline on the management of blood cholesterol: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. <i>J Am Coll Cardiol.</i> 2019;73:e285-e350. <sup>142</sup>  |                  |
| <b>Aspirin</b>         | Acetylsalicylic acid decreases synthesis of prostaglandin, platelet aggregation, and inflammation. This agent exhibits analgesic, antipyretic, and anticoagulant properties. | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | Levine GN, Bates ER, Bittl JA, et al. 2016 ACC/AHA guideline focused update on duration of dual antiplatelet therapy in patients with coronary artery disease: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. <i>J Am Coll Cardiol.</i> 2016;68:1082-1115. <sup>143</sup><br>NCI Thesaurus Code: C287 <sup>63</sup>   |                  |
| <b>P2Y12 inhibitor</b> | A nonaspirin P2Y12 inhibitor such as clopidogrel, ticagrelor, prasugrel as an antiplatelet agent   | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | Levine GN, Bates ER, Bittl JA, et al. 2016 ACC/AHA guideline focused update on duration of dual antiplatelet therapy in patients with coronary artery disease: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. <i>J Am Coll Cardiol.</i> 2016;68:1082-1115. <sup>143</sup>   |                  |
| <b>Warfarin</b>        | A vitamin K antagonist anticoagulant   | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | January CT, Wann LS, Calkins H, et al. 2019 AHA/ACC/HRS focused update of the 2014 AHA/ACC/HRS guideline for the management of patients with atrial fibrillation: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. <i>J Am Coll Cardiol.</i> 2019;74:104-132. <sup>144</sup><br>NCI Thesaurus Code: C945 <sup>63</sup>   |                  |
| <b>DOAC</b>            | Oral anticoagulant that directly inhibits specific proteins within the coagulation cascade (rivaroxaban, apixaban, dabigatran, or edoxaban)                                  | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | January CT, Wann LS, Calkins H, et al. 2019 AHA/ACC/HRS focused update of the 2014 AHA/ACC/HRS guideline for the management of patients with atrial fibrillation: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. <i>J Am Coll Cardiol.</i> 2019;74:104-132. <sup>144</sup><br>Julia S, James U. Direct oral anticoagulants: a quick guide. <i>Eur Cardiol.</i> 2017;12:40-45. <sup>145</sup> |                  |

ACE indicates angiotensin-converting enzyme; ARB, angiotensin receptor antagonist blocker; ARNi, angiotensin receptor-neprilysin inhibitor; ASCVD, atherosclerotic cardiovascular disease; AT1, angiotensin II type 1; ATP, adenosine triphosphate; CKD, chronic kidney disease; DOAC, direct oral anticoagulant; GLP-1, glucagon-like peptide; HF, heart failure; HMG-CoA, β-Hydroxy β-methylglutaryl-CoA; LDL, low-density lipoprotein; PCSK9, proprotein convertase subtilisin kexin 9; and SGLT2, sodium-glucose cotransporter-2.

APPENDIX 8. CONTINUED

B. Therapies for COVID-19

| Data Element   | Data Element Definition   | Permissible Values   | Permissible Value Definitions | Mapping/Source of Definition   | Additional Notes |
|--|---|--|-------------------------------|--|------------------|
| <b>SARS-CoV-2 antiviral agents (remdesivir, molnupiravir)</b>  | A prodrug of an ATP analog, with potential antiviral activity against a variety of RNA viruses. Competes with ATP for incorporation into RNA and inhibits the action of viral RNA-dependent RNA polymerase.   | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | <p>Bhimraj A, Morgan RL, Shumaker AH, et al. Infectious Diseases Society of America guidelines on the treatment and management of patients with COVID-19. Accessed March 4, 2022. <a href="https://www.idsociety.org/practice-guideline/covid-19-guideline-treatment-and-management">https://www.idsociety.org/practice-guideline/covid-19-guideline-treatment-and-management</a><sup>2</sup></p> <p>COVID-19 Treatment Guidelines Panel. Coronavirus disease 2019 (COVID-19) treatment guidelines. National Institutes of Health. Accessed March 4, 2022. <a href="https://www.covid19treatmentguidelines.nih.gov">https://www.covid19treatmentguidelines.nih.gov</a><sup>3</sup></p> <p>Chiotos K, Hayes M, Kimberlin DW, et al. Multicenter initial guidance on use of antivirals for children with coronavirus disease 2019/severe acute respiratory syndrome coronavirus 2. <i>J Pediatric Infect Dis Soc.</i> 2020;9:701-715.<sup>33</sup><br/>                     NCI Thesaurus Code: C152185<sup>63</sup></p> |                  |
| <b>SARS-CoV-2 protease inhibitors (nirmatrelvir/ritonavir)</b> | Nirmatrelvir inhibits the SARS-CoV-2 main protease (M <sup>pro</sup> ), which results in inhibition of viral replication. Ritonavir has no direct activity against SARS-CoV-2 but is a pharmacokinetic boosting agent that results in higher plasma concentrations of nirmatrelvir. | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | <p>Bhimraj A, Morgan RL, Shumaker AH, et al. Infectious Diseases Society of America guidelines on the treatment and management of patients with COVID-19. Accessed March 4, 2022. <a href="https://www.idsociety.org/practice-guideline/covid-19-guideline-treatment-and-management">https://www.idsociety.org/practice-guideline/covid-19-guideline-treatment-and-management</a><sup>2</sup></p> <p>COVID-19 Treatment Guidelines Panel. Coronavirus disease 2019 (COVID-19) treatment guidelines. National Institutes of Health. Accessed March 4, 2022. <a href="https://www.covid19treatmentguidelines.nih.gov">https://www.covid19treatmentguidelines.nih.gov</a><sup>3</sup></p>   |                  |
| <b>Corticosteroids</b>   | Hormones synthesized in the cortex of the adrenal gland and consisting of 2 subclasses, glucocorticoids (carbohydrate regulation) and mineralocorticoids (electrolyte regulation)   | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | <p>Bhimraj A, Morgan RL, Shumaker AH, et al. Infectious Diseases Society of America guidelines on the treatment and management of patients with COVID-19. Accessed March 4, 2022. <a href="https://www.idsociety.org/practice-guideline/covid-19-guideline-treatment-and-management">https://www.idsociety.org/practice-guideline/covid-19-guideline-treatment-and-management</a><sup>2</sup></p> <p>COVID-19 Treatment Guidelines Panel. Coronavirus disease 2019 (COVID-19) treatment guidelines. National Institutes of Health. Accessed March 4, 2022. <a href="https://www.covid19treatmentguidelines.nih.gov">https://www.covid19treatmentguidelines.nih.gov</a><sup>3</sup></p> <p>Chiotos K, Hayes M, Kimberlin DW, et al. Multicenter initial guidance on use of antivirals for children with coronavirus disease 2019/severe acute respiratory syndrome coronavirus 2. <i>J Pediatric Infect Dis Soc.</i> 2020;9:701-715.<sup>33</sup><br/>                     NCI Thesaurus Code: C2322<sup>63</sup></p>   |                  |

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B. Therapies for COVID-19 (Continued)

| Data Element  | Data Element Definition   | Permissible Values   | Permissible Value Definitions | Mapping/Source of Definition  | Additional Notes   |
|---|---|--|-------------------------------|---|--|
| <b>IL-6 receptor monoclonal antibodies (tocilizumab, sarilumab)</b> | An antibody that recognizes and binds the IL-6 receptor   | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | <p>Bhimraj A, Morgan RL, Shumaker AH, et al. Infectious Diseases Society of America guidelines on the treatment and management of patients with COVID-19. Accessed March 4, 2022. <a href="https://www.idsociety.org/practice-guideline/covid-19-guideline-treatment-and-management">https://www.idsociety.org/practice-guideline/covid-19-guideline-treatment-and-management</a><sup>2</sup></p> <p>COVID-19 Treatment Guidelines Panel. Coronavirus disease 2019 (COVID-19) treatment guidelines. National Institutes of Health. Accessed March 4, 2022. <a href="https://www.covid19treatmentguidelines.nih.gov/">https://www.covid19treatmentguidelines.nih.gov/</a><sup>3</sup></p> <p>Dulek DE, Fuhlbrigge RC, Tribble AC, et al. Multidisciplinary guidance regarding the use of immunomodulatory therapies for acute coronavirus disease 2019 in pediatric patients. <i>J Pediatric Infect Dis Soc.</i> 2020;9:716-737.<sup>34</sup><br/>NCI Thesaurus Code: C124046<sup>63</sup></p> | Recommended by IDSA and NIH COVID-19 Treatment Guidelines Panel for patients with progressive severe or critical COVID-19 who have evidence of systemic inflammation   |
| <b>COVID-19 convalescent plasma</b>                                 | Plasma that has been collected from patients who have recovered from the novel coronavirus disease, COVID-19. This plasma contains antibodies developed against the SARS-CoV-2 virus and is being investigated for the treatment of COVID-19. | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | <p>Bhimraj A, Morgan RL, Shumaker AH, et al. Infectious Diseases Society of America guidelines on the treatment and management of patients with COVID-19. Accessed March 4, 2022. <a href="https://www.idsociety.org/practice-guideline/covid-19-guideline-treatment-and-management">https://www.idsociety.org/practice-guideline/covid-19-guideline-treatment-and-management</a><sup>2</sup></p> <p>COVID-19 Treatment Guidelines Panel. Coronavirus disease 2019 (COVID-19) treatment guidelines. National Institutes of Health. Accessed March 4, 2022. <a href="https://www.covid19treatmentguidelines.nih.gov/">https://www.covid19treatmentguidelines.nih.gov/</a><sup>3</sup></p> <p>Dulek DE, Fuhlbrigge RC, Tribble AC, et al. Multidisciplinary guidance regarding the use of immunomodulatory therapies for acute coronavirus disease 2019 in pediatric patients. <i>J Pediatric Infect Dis Soc.</i> 2020;9:716-737.<sup>34</sup><br/>NCI Thesaurus Code: C171633<sup>63</sup></p> | As of February 2022, both IDSA and the NIH COVID-19 Treatment Guidelines Panel recommend against its use in hospitalized patients. Among ambulatory patients with mild to moderate COVID-19 at high risk for progression to severe disease who have no other treatment options, the IDSA suggests FDA-qualified high-titer COVID-19 convalescent plasma within 8 d of symptom onset. |
| <b>JAK inhibitors (baricitinib, tofacitinib)</b>                    | A substance that inhibits the biological action of tyrosine-protein kinase JAK1, an enzyme that plays a key role in certain types of cancer and cytokine signaling  | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | <p>Bhimraj A, Morgan RL, Shumaker AH, et al. Infectious Diseases Society of America guidelines on the treatment and management of patients with COVID-19. Accessed March 4, 2022. <a href="https://www.idsociety.org/practice-guideline/covid-19-guideline-treatment-and-management">https://www.idsociety.org/practice-guideline/covid-19-guideline-treatment-and-management</a><sup>2</sup></p> <p>COVID-19 Treatment Guidelines Panel. Coronavirus disease 2019 (COVID-19) treatment guidelines. National Institutes of Health. Accessed March 4, 2022. <a href="https://www.covid19treatmentguidelines.nih.gov/">https://www.covid19treatmentguidelines.nih.gov/</a><sup>3</sup><br/>NCI Thesaurus Code: C129650<sup>63</sup></p>   | Recommended by IDSA and NIH COVID-19 Treatment Guidelines panel in patients with severe COVID-19 and evidence of systemic inflammation   |

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APPENDIX 8. CONTINUED

B. Therapies for COVID-19 (Continued)

| Data Element   | Data Element Definition   | Permissible Values  | Permissible Value Definitions   | Mapping/Source of Definition   | Additional Notes                    |
|--|---|---|---|--|-------------------------------------|
| <b>Monoclonal antibodies against SARS-CoV-2 (eg, bamlanivimab/etesevimab, casirivimab/imdevimab, sotrovimab, tixagevimab/cilgavimab, bebtelovimab)</b> | Any monoclonal antibody that is directed against the spike (S) protein of SARS-CoV-2                    | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul>  |   | <p>Bhimraj A, Morgan RL, Shumaker AH, et al. Infectious Diseases Society of America guidelines on the treatment and management of patients with COVID-19. Accessed March 4, 2022. <a href="https://www.idsociety.org/practice-guideline/covid-19-guideline-treatment-and-management">https://www.idsociety.org/practice-guideline/covid-19-guideline-treatment-and-management</a><sup>2</sup></p> <p>COVID-19 Treatment Guidelines Panel. Coronavirus disease 2019 (COVID-19) treatment guidelines. National Institutes of Health. Accessed March 4, 2022. <a href="https://www.covid19treatmentguidelines.nih.gov/">https://www.covid19treatmentguidelines.nih.gov/</a><sup>3</sup></p> <p>NCI Thesaurus Code: C173741<sup>63</sup></p> |                                     |
| <b>SARS-CoV-2 vaccine</b>  | Any vaccine that decreases the risk of acquiring SARS-CoV-2 infection and development of acute COVID-19 | <ul style="list-style-type: none"> <li>■ Fully vaccinated</li> <li>■ Partially vaccinated</li> <li>■ Unvaccinated</li> <li>■ Unknown</li> </ul>   |   | NCI Thesaurus Code: C173023 <sup>63</sup>  | Booster dose is covered separately. |
|  |   | Fully vaccinated  | >2 wk after completion of the relevant vaccination series (currently 2 doses for the mRNA vaccines) |  |                                     |
|  |   | Partially vaccinated  | >2 wk from the initial dose of a 2-dose series (currently applies only to the mRNA vaccines)        |  |                                     |
|  |   | Unvaccinated  | No vaccine, or <2 wk from first vaccine dose  |  |                                     |
|  |   | Unknown   |   |  |                                     |
| <b>SARS-CoV-2 vaccine type</b>   | Type of SARS-CoV-2 vaccine received   | <ul style="list-style-type: none"> <li>■ BNT162b2 (Pfizer-BioNTech)</li> <li>■ mRNA-1273 (Moderna)</li> <li>■ Ad26.COV2.S (Johnson &amp; Johnson/Janssen)</li> <li>■ Other, specify</li> <li>■ Unknown</li> </ul> |   | <p>COVID-19 Treatment Guidelines Panel. Coronavirus disease 2019 (COVID-19) treatment guidelines. National Institutes of Health. Accessed March 4, 2022. <a href="https://www.covid19treatmentguidelines.nih.gov/">https://www.covid19treatmentguidelines.nih.gov/</a><sup>3</sup></p> <p>Centers for Disease Control and Prevention. Different COVID-19 vaccines. Accessed March 4, 2022. <a href="https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines.html">https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines.html</a><sup>146</sup></p>   |                                     |

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## APPENDIX 8. CONTINUED

## B. Therapies for COVID-19 (Continued)

| Data Element                                       | Data Element Definition  | Permissible Values   | Permissible Value Definitions | Mapping/Source of Definition   | Additional Notes   |
|--|--|--|-------------------------------|--|--|
| <b>Date of SARS-CoV-2 immunization</b>             | Date that SARS-CoV-2 immunization was completed. This would be the date of the second dose for a 2-dose series vaccine (currently the mRNA vaccines). Do not use date of booster dose. | <ul style="list-style-type: none"> <li>■ Date, mm/dd/yyyy</li> </ul>   |                               |  |  |
| <b>Manufacturer of SARS-CoV-2 vaccine received</b> | The manufacturer of the vaccine received   | <ul style="list-style-type: none"> <li>■ Pfizer/BioNTech</li> <li>■ Moderna</li> <li>■ Johnson &amp; Johnson</li> <li>■ AstraZeneca</li> <li>■ Mixed (received doses from &gt;1 manufacturer)</li> <li>■ Other</li> <li>■ Unknown</li> </ul> |                               |  |  |
| <b>Booster dose of SARS-CoV-2 vaccine received</b> | Receipt of additional SARS-CoV-2 vaccine dose after completion of a full vaccination series  | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul>   |                               |  |  |
| <b>Date of SARS-CoV-2 booster dose</b>             | Date that SARS-CoV-2 booster was given   | <ul style="list-style-type: none"> <li>■ Date, mm/dd/yyyy</li> </ul>   |                               |  |  |
| <b>IVIG</b>  | Blood product derived from pooled Ig antibodies extracted from donor plasma delivered intravenously  | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul>   |                               | COVID-19 Treatment Guidelines Panel. Coronavirus disease 2019 (COVID-19) treatment guidelines. National Institutes of Health. Accessed March 4, 2022. <a href="https://www.covid19treatmentguidelines.nih.gov/">https://www.covid19treatmentguidelines.nih.gov/</a> <sup>63</sup><br>NCI Thesaurus Code: C121331 <sup>63</sup> | The NIH COVID-19 Treatment Guidelines Panel recommends against the use of non-SARS-CoV-2-specific IVIG for the treatment of COVID-19. IVIG is often used as first-line treatment for MIS-C, although the optimal choice for immunomodulatory therapy in MIS-C has not been entirely established. |

ATP indicates adenosine triphosphate; COVID-19, coronavirus disease-2019; IDSA, Infectious Diseases Society of America; IgG, immunoglobulin G; IL-6, interleukin-6; IVIG, intravenous immunoglobulin; JAK, Janus kinase; MIS-C, multisystem inflammatory syndrome in children; mRNA, messenger ribonucleic acid; NIH, National Institutes of Health; RNA, ribonucleic acid; and SARS-CoV-2, severe acute respiratory syndrome-coronavirus-2.

APPENDIX 8. CONTINUED

C. Cardiovascular Mortality During Acute COVID-19 Infection

| Data Element       | Data Element Definition   | Permissible Values   | Permissible Value Definitions   | Mapping/Source of Definition  | Additional Notes |
|--------------------|---|--|---|---|------------------|
| IV vasopressors    | IV vasopressor agents are a group of medicines that augment blood pressure predominantly through an increase in vascular tone.  | <ul style="list-style-type: none"> <li>■ Norepinephrine</li> <li>■ Epinephrine</li> <li>■ Dopamine</li> <li>■ Vasopressin</li> <li>■ Phenylephrine</li> <li>■ Other</li> <li>■ None</li> </ul> |   | Bozkurt B, Hershberger RE, Butler J, et al. 2021 ACC/AHA key data elements and definitions for heart failure: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Data Standards (Writing Committee to Develop Clinical Data Standards for Heart Failure). <i>J Am Coll Cardiol.</i> 2021;77:2053-2150. <sup>67</sup><br>NCDR Auxiliary Data Collection CathPCI Registry Data Dictionary v1.0 (data element #14617) <sup>98</sup>  |                  |
|                    |   | Norepinephrine   | Norepinephrine is a sympathomimetic drug that increases blood pressure and enhances ventricular contractility.  |   |                  |
|                    |   | Epinephrine  | Epinephrine is a sympathomimetic drug that increases blood pressure and enhances ventricular contractility.   |   |                  |
|                    |   | Dopamine   | Dopamine is a sympathomimetic drug that increases blood pressure and enhances ventricular contractility.  |   |                  |
|                    |   | Vasopressin  | Vasopressin is a vasoactive hormone used synergistically with another sympathomimetic drug (typically norepinephrine) to increase and maintain peripheral vascular tone in patients with distributive shock.                |   |                  |
|                    |   | Phenylephrine  | Phenylephrine is a sympathomimetic drug whose primary activity results from stimulation of the alpha receptors of the vasculature, resulting in vasoconstriction while producing comparatively mild direct cardiac effects. |   |                  |
|                    |   | Other  |   |   |                  |
| IV inotropic agent | IV positive inotropic agents are a group of medicines that stimulate and increase the force of contraction of the heart muscle. | <ul style="list-style-type: none"> <li>■ Milrinone</li> <li>■ Dobutamine</li> <li>■ Other</li> <li>■ None</li> </ul>   |   | Bozkurt B, Hershberger RE, Butler J, et al. 2021 ACC/AHA key data elements and definitions for heart failure: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Data Standards (Writing Committee to Develop Clinical Data Standards for Heart Failure). <i>J Am Coll Cardiol.</i> 2021;77:2053-2150. <sup>67</sup><br>NCDR Auxiliary Data Collection CathPCI Registry Data Dictionary v1.0 (data element # 14617) <sup>98</sup> |                  |
|                    |   | None   |   |   |                  |

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C. Therapies for Supportive Care During COVID-19 Infection (Continued)

| Data Element  | Data Element Definition  | Permissible Values  | Permissible Value Definitions  | Mapping/Source of Definition  | Additional Notes   |
|---|--|---|--|---|--|
|   |  | Milrinone   | Milrinone is a phosphodiesterase 3 inhibitor that works to increase the heart's contractility, decrease pulmonary vascular resistance, and as a systemic vasodilator.  |   |  |
|   |  | Dobutamine  | Dobutamine is a direct-acting inotropic agent whose primary activity results from stimulation of the $\beta$ receptors of the heart while producing comparatively mild chronotropic, hypertensive, arrhythmogenic, and vasodilative effects. |   |  |
|   |  | Other   |  |   |  |
|   |  | None  |  |   |  |
| <b>COVID-19-specific intermediate- or full-dose anticoagulation (heparin, low-molecular-weight heparin, DOAC, warfarin)</b> | Intermediate- or full-dose anticoagulation used to prevent VTE complications attributable to SARS-CoV-2 specifically and not because of documented VTE or another noninfectious indication. Note that this excludes the low-dose prophylactic anticoagulation often given to inpatients for VTE prophylaxis (see below). | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul>  |  | Piazza G, Morrow DA. Diagnosis, management, and pathophysiology of arterial and venous thrombosis in COVID-19. <i>JAMA</i> . 2020;324:2548-2549. <sup>147</sup> COVID-19 Treatment Guidelines Panel. Coronavirus disease 2019 (COVID-19) treatment guidelines. Accessed March 4, 2022. <a href="https://www.covid19treatmentguidelines.nih.gov/">https://www.covid19treatmentguidelines.nih.gov/</a> <sup>3</sup> | Therapeutic anticoagulation in the absence of documented VTE or another non-COVID-19 indication is not routinely recommended for hospitalized patients with COVID-19 outside of the context of a clinical trial. |
| <b>COVID-19-specific anticoagulation dosing strategy</b>  | For patients receiving intermediate- or full-dose anticoagulation because of SARS-CoV-2 specifically and not because of documented VTE or another noninfectious indication.  | <ul style="list-style-type: none"> <li>■ Full dose</li> <li>■ Intermediate dose</li> <li>■ Unknown</li> </ul>   |  |   | Note that "low-dose" anticoagulation is specifically excluded from this element (see below).   |
|   |  | Full dose   | Standard treatment dose  |   |  |
|   |  | Intermediate dose   | Intermediate dose is defined here as a dosing strategy targeting levels of anticoagulation less than standard treatment doses but greater than standard VTE prophylaxis doses.   |   |  |
|   |  | Unknown   | A proper value is applicable but not known.  |   |  |
| <b>Anticoagulation for VTE prophylaxis</b>  | Administration of a prophylactic dose (not therapeutic dose) of anticoagulant to prevent VTE during hospitalization for COVID-19   | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul>  |  | NCI Thesaurus Code: C116684 <sup>63</sup>   |  |
| <b>Anticoagulant medication administered for VTE prophylaxis</b>  | Name of the anticoagulant medication administered to prevent VTE during hospitalization for COVID-19   | <ul style="list-style-type: none"> <li>■ Unfractionated heparin</li> <li>■ Low-molecular-weight heparin</li> <li>■ Fondaparinux</li> <li>■ Bivalirudin</li> <li>■ Other</li> <li>■ Unknown</li> </ul> |  | COVID-19 Treatment Guidelines Panel. Coronavirus disease 2019 (COVID-19) treatment guidelines. National Institutes of Health. Accessed March 4, 2022. <a href="https://www.covid19treatmentguidelines.nih.gov/">https://www.covid19treatmentguidelines.nih.gov/</a> <sup>3</sup>  |  |

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APPENDIX 8. CONTINUED

C. Therapies for Supportive Care During COVID-19 Infection (Continued)

| Data Element                     | Data Element Definition  | Permissible Values   | Permissible Value Definitions   | Mapping/Source of Definition   | Additional Notes |
|----------------------------------|--|--|---|--|------------------|
|                                  |  | Unfractionated heparin   | Heparin is an indirect thrombin inhibitor composed of a mixture of heterogeneous mucopolysaccharides with a molecular weight of 5-30 kDa.                                     |  |                  |
|                                  |  | Low-molecular-weight heparin   | Low-molecular-weight heparin compounds are fractions of heparin that primarily act by inhibiting the activated clotting factor X. Examples include enoxaparin and dalteparin. |  |                  |
|                                  |  | Fondaparinux   | Fondaparinux is a synthetic anticoagulant based on the pentasaccharide sequence that makes up the minimal antithrombin-binding region of heparin.                             |  |                  |
|                                  |  | Bivalirudin  | Bivalirudin is a semisynthetic derivative of hirudin and is a highly specific inhibitor of thrombin.  |  |                  |
|                                  |  | Other  |   |  |                  |
|                                  |  | Unknown  | A proper value is applicable but not known.   |  |                  |
| <b>Renal replacement therapy</b> | Use of renal replacement therapy during hospitalization for COVID-19 in a patient without end-stage renal disease prior to such hospitalization. These therapies may include CRRT, prolonged intermittent renal replacement therapy, IHD, or other forms of renal replacement therapy. | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |   | COVID-19 Treatment Guidelines Panel. Coronavirus disease 2019 (COVID-19) treatment guidelines. National Institutes of Health. Accessed March 4, 2022. <a href="https://www.covid19treatmentguidelines.nih.gov/">https://www.covid19treatmentguidelines.nih.gov/</a> <sup>3</sup> |                  |

COVID-19 indicates coronavirus disease-2019; CRRT, continuous renal replacement therapy; DOAC, direct oral anticoagulant; IHD, intermittent hemodialysis; IV, intravenous; SARS-CoV-2, severe acute respiratory syndrome-coronavirus-2; and VTE, venous thromboembolism.

## APPENDIX 9. THERAPEUTIC AND SUPPORTIVE PROCEDURES FOR COVID-19

### A. Mechanical Support

| Data Element  | Data Element Definition   | Permissible Values   | Permissible Value Definitions  | Mapping/Source of Definition  | Additional Notes |
|---|---|--|--|---|------------------|
| <b>MCS</b>  | MCS required. MCS is circulatory support using implanted devices most commonly used to supplement vasopressors and inotropes in the management of patients with low cardiac output and cardiogenic shock. | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul>   |  | NCDR CathPCI Registry Coder's Data Dictionary v5.0 (data element #7422) <sup>84</sup> |                  |
| <b>Implantation of temporary MCS device</b>                     | MCS device used. MCS devices are the implanted devices used to supplement vasopressors and inotropes in the management of patients with low cardiac output and cardiogenic shock.                         | <ul style="list-style-type: none"> <li>■ IABP</li> <li>■ Impella</li> <li>■ TandemHeart</li> <li>■ VA ECMO</li> <li>■ VV ECMO</li> <li>■ Other</li> <li>■ Unknown</li> </ul> |  | NCDR CathPCI Registry Coder's Data Dictionary v5.0 (data element #7423) <sup>84</sup> |                  |
| <b>Implantation of a long-term durable MCS device performed</b> | Mechanical pump to help pump blood from the ventricle(s) to the body, used in the management of patients with low cardiac output and cardiogenic shock  | <ul style="list-style-type: none"> <li>■ LVAD</li> <li>■ RVAD</li> <li>■ BiVAD</li> <li>■ Total artificial heart</li> <li>■ None</li> </ul>                                  |  |   |                  |
| <b>Date of MCS</b>  | Date that MCS was used  | <ul style="list-style-type: none"> <li>■ Date, mm/dd/yyyy</li> </ul>   |  |   |                  |
| <b>MCS time</b>   | Time that MCS was used  | <ul style="list-style-type: none"> <li>■ Time, hh:mm (using 24-h clock)</li> </ul>   |  |   |                  |
| <b>Noninvasive mechanical ventilatory support</b>               | A type of mechanical ventilation procedure that uses a noninvasive means, such as a face mask or nasal mask, to deliver oxygenated air into the lungs   | <ul style="list-style-type: none"> <li>■ CPAP</li> <li>■ BiPAP</li> <li>■ None</li> <li>■ Unknown</li> </ul>   |  | NCI Thesaurus Code: C171457 <sup>63</sup>   |                  |
|   |   | CPAP   | A form of noninvasive mechanical pressure support ventilation that uses a CPAP level to support spontaneous breathing activity | NCI Thesaurus Code: C124040 <sup>63</sup>   |                  |
|   |   | BiPAP  | A type of noninvasive mechanical ventilation procedure that that uses BiPAP to support spontaneous breathing activity          | NCI Thesaurus Code: C171500 <sup>63</sup>   |                  |
|   |   | None   |  |   |                  |
|   |   | Unknown  | A proper value is applicable but not known.  |   |                  |

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APPENDIX 9. CONTINUED

A. Mechanical Support (Continued)

| Data Element   | Data Element Definition   | Permissible Values   | Permissible Value Definitions  | Mapping/Source of Definition   | Additional Notes   |
|--|---|--|--|--|--|
| <b>Invasive mechanical ventilatory support</b>               | Artificial ventilation to assist or replace spontaneous breathing through tracheostomy or endotracheal tubes  | <ul style="list-style-type: none"> <li>■ Mechanical ventilation</li> <li>■ Adaptive servo-ventilation</li> <li>■ None</li> </ul> |  |  |  |
|  |   | Mechanical ventilation   | Mechanical ventilation technique is a life-sustaining technique through which gas is moved toward and from the lungs through an external device connected directly to the patient. |  |  |
|  |   | Adaptive servo-ventilation   | Positive airway pressure therapy in which air pressure target is adjusted according to the patient's breathing patterns  |  | In patients with NYHA class II-IV HF/rEF and central sleep apnea, adaptive servo-ventilation causes harm. <sup>148</sup> |
|  |   | None   |  |  |  |
| <b>Oxygen therapy</b>  | The administration of oxygen to an individual, usually to aid in respiration  | <ul style="list-style-type: none"> <li>■ Yes (if yes, specify L/min)</li> <li>■ No</li> <li>■ Unknown</li> </ul>                 |  | NCI Thesaurus Code: C94624 <sup>63</sup>   |  |
| <b>Maximum fraction of inspired oxygen (Fio<sub>2</sub>)</b> | Maximum molar fraction of oxygen in an inhaled gas  | <ul style="list-style-type: none"> <li>■ Numeric</li> </ul>  |  | NCI Thesaurus Code: C38082 <sup>63</sup>   |  |
| <b>PEEP</b>  | The maximum end-expiratory alveolar pressure above atmospheric pressure supplied to patients on invasive or noninvasive ventilation   | <ul style="list-style-type: none"> <li>■ Numeric, cm H<sub>2</sub>O</li> </ul>   |  | COVID-19 Treatment Guidelines Panel. Coronavirus disease 2019 (COVID-19) treatment guidelines. National Institutes of Health. Accessed March 4, 2022. <a href="https://www.covid19treatmentguidelines.nih.gov/">https://www.covid19treatmentguidelines.nih.gov/</a> <sup>3</sup> |  |
| <b>Fio<sub>2</sub>/PEEP ratio</b>                            | Ratio of Fio <sub>2</sub> to PEEP used to achieve desired arterial oxygenation  | <ul style="list-style-type: none"> <li>■ Numeric</li> </ul>  |  |  |  |
| <b>VA ECMO</b>   | ECMO, in which a venous cannula is usually placed in the right or left common femoral vein for extraction, and an arterial cannula is usually placed into the right or left femoral artery for infusion, with an oxygenator between the extraction and infusion cannulae. Used to provide circulatory support and to facilitate gas exchange. | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul>   |  | NCI Thesaurus Code: C171507 <sup>63</sup>  |  |
| <b>VV ECMO</b>   | ECMO to provide adequate gas exchange, usually in respiratory failure/ARDS. The access cannula is usually placed in the inferior vena cava via the femoral vein. The tip of the return cannula should sit close to the right atrium, and it may be placed via the femoral or internal jugular vein.   | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul>   |  | NCI Thesaurus Code: C171507 <sup>63</sup>  |  |

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## APPENDIX 9. CONTINUED

## A. Mechanical Support (Continued)

| Data Element                                   | Data Element Definition  | Permissible Values   | Permissible Value Definitions | Mapping/Source of Definition   | Additional Notes |
|--|--|--|-------------------------------|--|------------------|
| <b>Prone positioning in ventilated patient</b> | Positioning of a mechanically ventilated patient so that their anterior chest is dependent, which allows for improved oxygenation by ameliorating the ventral-dorsal transpulmonary pressure difference, reducing dorsal lung compression, and improving lung perfusion. | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | COVID-19 Treatment Guidelines Panel. Coronavirus disease 2019 (COVID-19) treatment guidelines. National Institutes of Health. Accessed March 4, 2022. <a href="https://www.covid19treatmentguidelines.nih.gov/">https://www.covid19treatmentguidelines.nih.gov/</a> <sup>63</sup><br>NCI Thesaurus Code: C173751 <sup>63</sup> |                  |
| <b>Cardiac arrest requiring CPR</b>            | Cardiac arrest that is treated by CPR or defibrillation, regardless of outcome   | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | NCI Thesaurus Code: C141268 <sup>63</sup>  |                  |
| <b>Date of CPR for cardiac arrest</b>          | Date that CPR for cardiac arrest was performed   | <ul style="list-style-type: none"> <li>■ Date, mm/dd/yyyy</li> </ul>                     |                               |  |                  |
| <b>Time of CPR for cardiac arrest</b>          | Time that CPR for cardiac arrest was performed   | <ul style="list-style-type: none"> <li>■ Time, hh:mm (using 24-h clock)</li> </ul>       |                               |  |                  |

ARDS indicates acute respiratory distress syndrome; BiPAP, bilevel positive airway pressure; BiVAD, biventricular assist device; CPAP, continuous positive airway pressure; COVID-19, coronavirus disease-2019; CPR, cardiopulmonary resuscitation; FiO<sub>2</sub>, fraction of inspired oxygen; HFrEF, HF with reduced ejection fraction; IABP, intra-aortic balloon pump; LVAD, left ventricular assist device; MCS, mechanical circulatory support; PEEP, positive end expiratory pressure; RVAD, right ventricular assist device; VA ECMO, venoarterial extracorporeal membrane oxygenation; and VV-ECMO, venovenous extracorporeal membrane oxygenation.



B. Electrophysiological Procedures

| Data Element  | Data Element Definition  | Permissible Values   | Permissible Value Definitions   | Mapping/Source of Definition  | Additional Notes   |
|---|--|--|---|---|--|
| <b>Insertion of a temporary transvenous pacing wire</b>       | Temporary transvenous pacing wire was inserted. Indications for temporary transvenous pacing are similar to indications for permanent pacing. Typically, temporary transvenous pacing is performed via a pacing wire placed in the RV from a central venous access site. | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul>                   |   | Kusumoto FM, Schoenfeld MH, Barrett C, et al. 2018 ACC/AHA/HRS guideline on the evaluation and management of patients with bradycardia and cardiac conduction delay: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. <i>J Am Coll Cardiol.</i> 2019;74:e51-156. <sup>149</sup>   |  |
| <b>Date of temporary transvenous pacing wire insertion</b>    | Date temporary transvenous pacing wire was inserted  | <ul style="list-style-type: none"> <li>■ Date, mm/dd/yyyy</li> </ul>                                       |   |   |  |
| <b>Implantation of a cardioverter-defibrillator performed</b> | A battery-powered electrical impulse generator implanted in patients at risk of sudden cardiac death to detect cardiac arrhythmia and correct it by delivering a jolt of electricity, implanted during current encounter   | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul>                   |   | Cannon CP, Brindis RG, Chaitman BR, et al. 2013 ACCF/AHA key data elements and definitions for measuring the clinical management and outcomes of patients with acute coronary syndromes and coronary artery disease: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Clinical Data Standards (Writing Committee to Develop Acute Coronary Syndromes and Coronary Artery Disease Clinical Data Standards). <i>J Am Coll Cardiol.</i> 2013;61:992-1025. <sup>150</sup> | Information about the type of device (pacemaker, BiV/resynchronization/CRT, ICD, combination), cardiac chamber(s) involved, and year of implantation may be helpful. |
|   |  | Yes  | ICD: a battery-powered electrical impulse generator implanted in patients at risk of sudden cardiac death to detect cardiac arrhythmia and correct it by delivering a jolt of electricity. This would include BiV-ICDs. |   |  |
|   |  | No   | No ICD history  |   |  |
|   |  | Unknown  | A proper value is applicable but not known.   |   |  |
| <b>Type of permanent cardioverter-defibrillator implanted</b> | A battery-powered electrical impulse generator implanted in patients at risk of sudden cardiac death to detect cardiac arrhythmia and correct it by delivering a jolt of electricity, implanted during current encounter   | <ul style="list-style-type: none"> <li>■ Transvenous</li> <li>■ Subcutaneous</li> <li>■ Unknown</li> </ul> |   |   |  |
| <b>Date of ICD implantation</b>                               | Date that ICD was implanted  | <ul style="list-style-type: none"> <li>■ Date, mm/dd/yyyy</li> </ul>                                       |   |   |  |
| <b>Insertion of a permanent pacemaker</b>                     | A cardiac pacemaker where the generator is implanted inside the body   | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul>                   | This would include a BiV pacemaker without an ICD function  | NCI Thesaurus Code: C99552 <sup>63</sup>  |  |

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**APPENDIX 9. CONTINUED**

**B. Electrophysiological Procedures (Continued)**

| <b>Data Element</b>                            | <b>Data Element Definition</b>  | <b>Permissible Values</b>  | <b>Permissible Value Definitions</b> | <b>Mapping/Source of Definition</b>      | <b>Additional Notes</b> |
|--|---|--|--------------------------------------|--|-------------------------|
| <b>Electric cardioversion</b>                  | The administration of electric current to correct abnormal heart rhythm   | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                                      | NCI Thesaurus Code: C99948 <sup>63</sup> |                         |
| <b>Date of electric cardioversion</b>          | Date that DC cardioversion was performed  | <ul style="list-style-type: none"> <li>■ Date, mm/dd/yyyy</li> </ul>                     |                                      |  |                         |
| <b>Cardiac arrest requiring defibrillation</b> | The sudden cessation of cardiac activity in an individual who becomes unresponsive, without normal breathing and no signs of circulation. Certain forms of cardiac arrest (eg, ventricular fibrillation) may be reversed by defibrillation. | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                                      | NCI Thesaurus Code: C50479 <sup>63</sup> |                         |
| <b>Date of defibrillation</b>                  | Date that defibrillation was performed  | <ul style="list-style-type: none"> <li>■ Date, mm/dd/yyyy</li> </ul>                     |                                      |  |                         |

BiV indicates biventricular; CRT, cardiac resynchronization therapy; DC, direct current; ICD, implantable cardioverter-defibrillator; and RV, right ventricle.

C. Invasive Coronary/Vascular/Neurovascular Revascularization Treatment

| Data Element | Data Element Definition  | Permissible Values   | Permissible Value Definitions   | Mapping/Source of Definition  | Additional Notes  |
|--------------|--|--|---|---|---|
| PCI          | Refer to the 2020 AHA/ACC Key Data Elements and Definitions for Coronary Revascularization.        | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul>                               |   | Dehmer GJ, Badhwar V, Bermudez EA, et al. 2020 AHA/ACC key data elements and definitions for coronary revascularization: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Data Standards (Writing Committee to Develop Clinical Data Standards for Coronary Revascularization). <i>J Am Coll Cardiol.</i> 2020;75:1975-2088. <sup>135</sup>   | Any attempt (successful or unsuccessful) to treat a stenosis by any technique, or even failed attempts to cross the stenosis with a wire or device, should be counted as PCI at any time point. |
| Date of PCI  | Date that PCI was performed  | <ul style="list-style-type: none"> <li>■ Date, mm/dd/yyyy</li> </ul>   |   | NCDR CathPCI Registry Coder's Data Dictionary v5.0 (data element #7000) <sup>84</sup>   |   |
| Time of PCI  | Time that PCI was performed  | <ul style="list-style-type: none"> <li>■ Time, hh:mm (using 24-h clock)</li> </ul>                                     |   | NCDR CathPCI Registry Coder's Data Dictionary v5.0 (data element #7000) <sup>84</sup>   |   |
| PCI status   | Classification of the urgency of PCI procedure at the time the operator decides to perform the PCI | <ul style="list-style-type: none"> <li>■ Elective</li> <li>■ Urgent</li> <li>■ Emergency</li> <li>■ Salvage</li> </ul> |   | Hicks KA, Tcheng JE, Bozkurt B, et al. 2014 ACC/AHA key data elements and definitions for cardiovascular endpoint events in clinical trials: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Data Standards (Writing Committee to Develop Cardiovascular Endpoints Data Standards). <i>J Am Coll Cardiol.</i> 2015;66:403-469. <sup>151</sup><br>NCDR CathPCI Registry Coder's Data Dictionary v5.0 (data element #7800) <sup>84</sup> |   |
|              |  | Elective   | The procedure can be performed on an outpatient basis or during a subsequent hospitalization without significant risk of infarction or death. For stable inpatients, the procedure is being performed during this hospitalization for convenience and ease of scheduling and NOT because the patient's clinical situation demands the procedure before discharge. If the diagnostic catheterization was elective and there were no complications, the PCI would also be elective. |   |   |
|              |  | Urgent   | The procedure is performed on an inpatient basis and before discharge because of significant concerns that there is risk of ischemia, infarction, or death. Patients who are outpatients or in the emergency department at the time that the cardiac catheterization is requested would warrant an admission based on their clinical presentation.  |   |   |
|              |  | Emergency  | The procedure is performed as soon as possible because of substantial concerns that ongoing ischemia or infarction could lead to death. "As soon as possible" refers to a case of sufficient acuity that a scheduled case would be cancelled to perform this procedure immediately in the next available room during business hours, or the on-call team would be activated if this were to occur during off-hours.   |   |   |

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C. Invasive Coronary/Vascular/Neurovascular Revascularization Treatment (Continued)

| Data Element | Data Element Definition  | Permissible Values   | Permissible Value Definitions   | Mapping/Source of Definition  | Additional Notes |
|--------------|--|--|---|---|------------------|
|              |  | Salvage  | The procedure is a last resort in a patient with cardiogenic shock when the PCI begins (ie, at the time of introduction into a coronary artery or bypass graft of the first guidewire or intracoronary device for the purpose of mechanical revascularization). Within the last 10 min before the start of the case or during the diagnostic portion of the case, the patient may have received chest compressions for a total of at least 60 s or have been on unanticipated extracorporeal circulatory support (eg, extracorporeal mechanical oxygenation, or cardiopulmonary support). |   |                  |
| Stent used   | A small stainless steel expandable mesh tube, inserted within the lumen of tubular body structures, to help keep it open | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> </ul>  |   | NCI Thesaurus Code: C17168 <sup>63</sup>  |                  |
| Stent type   | Type of stent used to treat lesion   | <ul style="list-style-type: none"> <li>■ Bare-metal</li> <li>■ Drug-eluting</li> <li>■ Drug-eluting with bioabsorbable polymer</li> <li>■ Bioresorbable</li> <li>■ Covered</li> <li>■ Multiple types</li> <li>■ Other</li> </ul> |   | Dehmer GJ, Badhwar V, Bermudez EA, et al. 2020 AHA/ACC key data elements and definitions for coronary revascularization: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Data Standards (Writing Committee to Develop Clinical Data Standards for Coronary Revascularization). <i>J Am Coll Cardiol.</i> 2020;75:1975-2088. <sup>135</sup> |                  |
|              |  | Bare-metal   | Metallic coronary stent without a polymer or antiproliferative drug coating   |   |                  |
|              |  | Drug-eluting   | Metallic coronary stent with or without a polymer but with an antiproliferative drug coating  |   |                  |
|              |  | Drug-eluting with bioabsorbable polymer  | Metallic coronary stent with a bioabsorbable polymer with an antiproliferative drug coating   |   |                  |
|              |  | Bioabsorbable  | Stent struts composed of bioabsorbable materials also containing an antiproliferative drug  |   |                  |
|              |  | Covered  | Metallic coronary stent scaffold incorporating fabric or graft material, such as PTFE or polyurethane as a membrane component   |   |                  |
|              |  | Multiple types   | Treatment of several arteries using different stent types   |   |                  |
|              |  | Other  | A proper value is applicable but not known.   |   |                  |

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C. Invasive Coronary/Vascular/Neurovascular Revascularization Treatment (Continued)

| Data Element                        | Data Element Definition   | Permissible Values   | Permissible Value Definitions   | Mapping/Source of Definition  | Additional Notes |
|-------------------------------------|---|--|---|---|------------------|
| <b>TIMI flow prior to PCI</b>       | Indicate if the previously treated and stented lesion is being treated for in-stent restenosis. | <ul style="list-style-type: none"> <li>■ TIMI 0</li> <li>■ TIMI 1</li> <li>■ TIMI 2</li> <li>■ TIMI 3</li> <li>■ Unknown</li> </ul>  |   | NCDR CathPCI Registry Coder's Data Dictionary v5.0 (data element #8007) <sup>84</sup> |                  |
|                                     |   | TIMI 0   | No flow/no perfusion  |   |                  |
|                                     |   | TIMI 1   | Slow penetration without perfusion  |   |                  |
|                                     |   | TIMI 2   | Partial flow/partial perfusion (>TIMI 1 but <TIMI 3)  |   |                  |
|                                     |   | TIMI 3   | Complete and brisk flow/complete perfusion  |   |                  |
|                                     |   | Unknown  | A proper value is applicable but not known.   |   |                  |
| <b>TIMI flow after PCI</b>          | Indicate the postintervention TIMI flow.  | <ul style="list-style-type: none"> <li>■ TIMI 0</li> <li>■ TIMI 1</li> <li>■ TIMI 2</li> <li>■ TIMI 3</li> <li>■ Unknown</li> </ul>  |   | NCDR CathPCI Registry Coder's Data Dictionary v5.0 (data element #8026) <sup>84</sup> |                  |
|                                     |   | TIMI 0   | No flow/no perfusion  |   |                  |
|                                     |   | TIMI 1   | Slow penetration without perfusion  |   |                  |
|                                     |   | TIMI 2   | Partial flow/partial perfusion (>TIMI 1 but <TIMI 3)  |   |                  |
|                                     |   | TIMI 3   | Complete and brisk flow/complete perfusion  |   |                  |
|                                     |   | Unknown  | A proper value is applicable but not known.   |   |                  |
| <b>% stenosis prior to PCI</b>      | Percent diameter stenosis immediately before the treatment of this lesion                       | <ul style="list-style-type: none"> <li>■ Numeric, %</li> </ul>   | Percentage diameter reduction, ranging from 0 to 100, associated with the identified vessels. Percent stenosis at its maximal point is estimated to be the amount of reduction in the diameter of the "normal" reference vessel proximal to the lesion. In instances where multiple lesions are present, enter the single highest percent stenosis noted. | NCDR CathPCI Registry Coder's Data Dictionary v5.0 (data element #8004) <sup>84</sup> |                  |
| <b>% stenosis after PCI</b>         | Percent diameter stenosis after treatment of this lesion  | <ul style="list-style-type: none"> <li>■ Numeric, %</li> </ul>   | Percentage diameter reduction, ranging from 0 to 100, associated with the identified vessels. Percent stenosis at its maximal point is estimated to be the amount of reduction in the diameter of the "normal" reference vessel proximal to the lesion. In instances where multiple lesions are present, enter the single highest percent stenosis noted. | NCDR CathPCI Registry Coder's Data Dictionary v5.0 (data element #8025) <sup>84</sup> |                  |
| <b>Percutaneous arterial access</b> | Arterial access site(s)   | <p>(Multi-select)</p> <ul style="list-style-type: none"> <li>■ Femoral artery</li> <li>■ Brachial artery</li> <li>■ Radial artery</li> <li>■ Other</li> <li>■ Unknown</li> </ul> |   | NCDR CathPCI Registry Coder's Data Dictionary v5.0 (data element #7320) <sup>84</sup> |                  |

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**APPENDIX 9. CONTINUED**

**C. Invasive Coronary/Vascular/Neurovascular Revascularization Treatment (Continued)**

| <b>Data Element</b>                                  | <b>Data Element Definition</b>   | <b>Permissible Values</b>  | <b>Permissible Value Definitions</b> | <b>Mapping/Source of Definition</b> | <b>Additional Notes</b> |
|--|--|--|--------------------------------------|-------------------------------------|-------------------------|
| <b>Thrombectomy for pulmonary embolism</b>           | Interventional procedure to remove a blood clot from a pulmonary artery in a patient with acute pulmonary embolism | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                                      |                                     |                         |
| <b>Thrombectomy for stroke</b>                       | Interventional procedure to remove a blood clot from an artery in a patient with acute ischemic stroke             | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                                      |                                     |                         |
| <b>Thrombectomy for peripheral arterial thrombus</b> | Interventional procedure to remove a blood clot from a peripheral artery, excluding acute ischemic stroke          | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                                      |                                     |                         |
| <b>Thrombolysis for pulmonary embolism</b>           | Treatment to remove a blood clot from a pulmonary artery in a patient with acute ischemic stroke                   | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                                      |                                     |                         |
| <b>Thrombolysis for stroke</b>                       | Treatment to remove a blood clot from an artery in a patient with acute ischemic stroke                            | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                                      |                                     |                         |

PCI indicates percutaneous coronary intervention; PTFE, polytetrafluoroethylene; and TIMI, Thrombolysis in Myocardial Infarction.

**APPENDIX 10. END-OF-LIFE MANAGEMENT**

| Data Element                                       | Data Element Definition  | Permissible Values   | Permissible Value Definitions | Mapping/Source of Definition  | Additional Notes  |
|--|--|--|-------------------------------|---|---|
| <b>Limitation of resuscitation</b>                 | Any documented order or decision regarding patient request to limit a component of emergency therapy to restore circulation or ventilation (eg, no intubation, no shocking, no chest compressions) | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | Bozkurt B, Hershberger RE, Butler J, et al. 2021 ACC/AHA key data elements and definitions for heart failure: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Data Standards (Writing Committee to Develop Clinical Data Standards for Heart Failure). <i>J Am Coll Cardiol.</i> 2021;77:2053-2150. <sup>67</sup>  |   |
| <b>DNR</b>   | Explicit documentation by health care provider or patient indicating that no resuscitative efforts are to be performed in the event of circulatory or respiratory arrest                           | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | Bozkurt B, Hershberger RE, Butler J, et al. 2021 ACC/AHA key data elements and definitions for heart failure: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Data Standards (Writing Committee to Develop Clinical Data Standards for Heart Failure). <i>J Am Coll Cardiol.</i> 2021;77:2053-2150. <sup>67</sup>  |   |
| <b>Inactivation of ICD defibrillation mode</b>     | Inactivation of ICD defibrillation mode without plans to reactivate (excludes inactivation for specific surgical procedures)   | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | Bozkurt B, Hershberger RE, Butler J, et al. 2021 ACC/AHA key data elements and definitions for heart failure: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Data Standards (Writing Committee to Develop Clinical Data Standards for Heart Failure). <i>J Am Coll Cardiol.</i> 2021;77:2053-2150. <sup>67</sup>  |   |
| <b>Advance care planning</b>                       | The process of clarifying goals of care, communicating wishes and goals for medical care in the event of an emergency, and documenting those wishes or plan in an advance directive                | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | Bozkurt B, Hershberger RE, Butler J, et al. 2021 ACC/AHA key data elements and definitions for heart failure: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Data Standards (Writing Committee to Develop Clinical Data Standards for Heart Failure). <i>J Am Coll Cardiol.</i> 2021;77:2053-2150. <sup>67</sup><br>Fried TR, Redding CA, Robbins ML, et al. Stages of change for the component behaviors of advance care planning. <i>J Am Geriatr Soc.</i> 2010;58:2329-2336. <sup>152</sup><br>Sudore RL, Lum HD, You JJ, et al. Defining advance care planning for adults: a consensus definition from a multidisciplinary Delphi panel. <i>J Pain Symptom Manage.</i> 2017;53:821-832.e1. <sup>153</sup> | Advance directive is defined as documentation in the medical record that the patient has an advance directive.<br>An advance directive is instructions given by individuals specifying what actions should be taken for their health in the event that they are no longer able to make decisions due to illness or incapacity and therefore appoints a person to make such decisions on their behalf. |
| <b>Medical order for life-sustaining treatment</b> | A written medical order by a physician, advanced practice registered nurse, or physician assistant that records a patient's treatment preferences as to life-sustaining treatment                  | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               | Bozkurt B, Hershberger RE, Butler J, et al. 2021 ACC/AHA key data elements and definitions for heart failure: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Data Standards (Writing Committee to Develop Clinical Data Standards for Heart Failure). <i>J Am Coll Cardiol.</i> 2021;77:2053-2150. <sup>67</sup>  |   |
| <b>Discharge to hospice</b>                        | Discharge to either home hospice or to a facility with hospice care  | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               |   |   |
| <b>Palliative care consultation</b>                | Consultation with a palliative care provider   | <ul style="list-style-type: none"> <li>■ Yes</li> <li>■ No</li> <li>■ Unknown</li> </ul> |                               |   | Note that "palliative care provider" does not require that person has formal training in palliative care, but rather, anyone acting in that role.   |

DNR indicates do not resuscitate, and ICD, implantable cardioverter-defibrillator.