U.S. FOOD & DRUG ADMINISTRATION

Proposed Changes to ICD-10-CM Diagnosis Coding for COVID-19 Related Pneumonia

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Introduction

- The FDA's Center for Biologics Evaluation and Research (CBER's) mission is to ensure the safety and efficacy of biological products, including blood and blood products, and thus to protect and improve public health;

- Under the Food and Drug Administration Amendments Act (FDAAA) of 2007, CBER is responsible for conducting the U.S. population-based active surveillance of blood and blood product safety;

- CBER uses large private and public (e.g., CMS) medical databases to:
  - Conduct active safety and utilization surveillance of blood components and products;
  - Evaluate the spread of transfusion-transmissible infections.

Background

- On March 11, 2020, WHO classified coronavirus disease 2019 (COVID-19) as a global pandemic;
- An outbreak of COVID-19 caused by the 2019 novel coronavirus (SARS-CoV-2) started in China with a cluster of pneumonia cases reported in December 2019;
- COVID-19 is generally a respiratory disease, with symptoms including: cough, fever, myalgia, fatigue, shortness of breath, and dyspnea;
- Although infected persons may not develop symptoms immediately due to an incubation period of up to two weeks, COVID-19 is a serious disease that frequently results in pneumonia;
- The elderly, immunocompromised and those with chronic comorbidities (e.g., hypertension, diabetes) have been identified to be at a highest risk for severe COVID-19 infections resulting in pneumonia, hospitalization, and death;
- COVID-19 cases have been confirmed worldwide, including United States, and the number of reported cases continues to rise.

Background cont.

- As of August 2020, the coronavirus infections have been reported in over 180 countries, with more than 23 million cases and over 800,000 deaths: https://coronavirus.jhu.edu/map.html;
- As of August 2020, U.S. had over 5.7 million cases (1.7%) and over 170,000 deaths, reported by 50 states, District of Columbia, and territories. U.S. COVID-19 Distribution Maps are available from: https://www.cdc.gov/covid-data-tracker/index.html#cases;
- It is expected that cumulatively the number of COVID-19 cases will continue to rise and that the infection may become seasonal due to efficient human-to-human transmission and potential persistence on inanimate surfaces;
- Also, there is a hypothesized potential risk of COVID-19 to blood supply given that donors may be asymptomatic;
- In summary, COVID-19 and related complications (e.g., pneumonia, mortality) will continue to pose a public safety concern in the United States and around the world, and therefore require continuous surveillance.

• COVID-19 Related Pneumonia Coding Proposal

- **The objective of the FDA/CBER's proposal is to generate a specific code for COVID-19 Related Pneumonia, and thus to improve coding specificity for pneumonia due to COVID-19;**
- **Although the interim coding guidelines advise the use of two diagnosis codes, one for COVID-19 and one for 'other viral pneumonia', CMS data suggest that using two codes may underrecord pneumonia due to COVID-19, with <50% of COVID-19 cases having had 'other viral pneumonia' recorded;**
- **Also, CDC COVID-19 mortality data shows that <50% of COVID-related deaths had pneumonia diagnosis code(s) recorded, suggesting a potentially substantial underrecording of pneumonia due to COVID-19 when using two diagnosis codes.**

COVID-19 Related Pneumonia Coding Proposal

- **If introduced, a specific code for COVID-19 Related Pneumonia will:**
  - Improve coding precision for capturing COVID-related pneumonia, using large databases, by distinguishing the Pneumonia due to COVID-19 from the SARS-associated pneumonia code and from other viral and unspecified pneumonia codes;
  - Allow a more accurate surveillance using real-world evidence to assess and characterize COVID-related pneumonia cases in all settings, including geographic distribution and severity;
  - Enable Public Health Organizations and researchers to ascertain effectiveness of therapies by monitoring serious complications of COVID-19;
  - Assist in the development of prevention strategies of serious COVID-related complications, including pneumonia and mortality;
- **Overall, specific code for Pneumonia due to COVID-19 will improve coding precision and thus lead to better diagnosis, treatment and prevention strategies, and will further assure public safety.**

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