



August 28, 2023

The Honorable Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244

RE: Medicare Program; Transitional Coverage for Emerging Technologies [CMS-3421-NC]

Dear Administrator Brooks-LaSure,

Heart Valve Voice US (“HVV”) is a non-profit patient-led organization with the mission of improving healthcare for people living with heart valve disease. Specifically, HVV works with stakeholders, including patients and clinicians, to address access barriers to optimal care.

Valvular heart disease is a leading cause of cardiovascular morbidity and mortality worldwide with the resultant disease burden projected to increase in the future. If not treated, heart valve disease can cause heart failure or other life-threatening conditions. In the United States, Diseases of the aortic valve account for 61% of all valvular heart disease deaths and have a well-established association with advanced age and chronic cardiovascular disease.<sup>1</sup> While mortality rates have slowly decreased in developed countries with the advent of new interventions, no therapies are currently available to prevent the disease. Physicians may recommend heart valve repair or replacement given new symptoms of heart valve disease or disease progression.

On behalf of the heart valve disease patient community HVV is appreciative of the opportunity to provide CMS with its unique perspective on the proposed establishment of a new Transitional Coverage of Emerging Technologies (TCET) pathway for certain eligible devices designated as “breakthrough” by the US Food and Drug Administration (FDA). HVV generally supports a transitional coverage pathway that will ensure patients have access to breakthrough lifesaving and life-enhancing therapies that are not currently available so long as they do not create additional burdens for patients.

**CMS has an opportunity to enhance access to breakthrough technologies for heart valve patients.**

For patients living with heart valve disease, having additional treatment options is paramount to management of their condition. A pathway whereby FDA provides transitional coverage of breakthrough

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<sup>1</sup> Percentages of deaths due to valvular heart disease, by valve, 2017—data obtained from CDC, Atlanta, GA, USA. Available online: [https://www.cdc.gov/heartdisease/valvular\\_disease.htm](https://www.cdc.gov/heartdisease/valvular_disease.htm) (Accessed on Aug. 23, 2023)

designated medical devices will allow patients greater access to innovative treatments while additional evidence is gathered in real world applications.

**Evidence development for breakthrough technologies should be patient centered.**

CMS should prioritize reducing the burden on clinicians and patients by prioritizing evidence gathering methodologies that can be utilized with minimal effort for practices and patients by utilizing existing electronic health records data, claims data, and other available information.

**Transitional Coverage for Emerging Technologies should be voluntary, timely, and predictable.**

HVV agrees with CMS that an NCD that requires CED as a condition of coverage should not last indefinitely to ensure that there are not additional burdens placed on beneficiaries. The lack of clarity in the coverage timeline outlined in the TCET proposal also underscores a concern that CMS may lack adequate resources to meet current demands and therefore transitional coverage may put more burden on an already stressed system.

**Conclusion**

Heart valve patients understand that time is of the essence to address the gaps that breakthrough technologies often face between FDA approval and CMS coverage. Further delays may prevent Medicare patients living with heart valve disease from gaining access to breakthrough medical innovations. The implementation of a voluntary, timely, and predictable coverage process will allow CMS to achieve its goal of providing Medicare coverage for innovative technologies.

HVV appreciates the opportunity to comment on the proposed Transitional Coverage for Emerging Technologies pathway and looks forward to the implementation of policy that safely provides expedited access to new and innovative medical technologies for patients living with heart valve disease. If you have questions or would like to discuss this further, please contact Lindsay Videnieks, Executive Director, Heart Valve Voice at [Lindsay@WoodberryAssociates.com](mailto:Lindsay@WoodberryAssociates.com).

Sincerely,



Lindsay A. Videnieks  
Executive Director