Statement of John M. Clymer to
Centers for Medicare and Medicaid Services
on Medicare Drug Price Negotiation
Patient-Focused Listening Session for Entresto
November 1, 2023

Good afternoon. My name is John Clymer. I am executive director of the National Forum for Heart Disease & Stroke Prevention, a non-profit, non-partisan organization dedicated to health equity and optimizing cardiovascular health and well-being throughout the lifespan. Through our Value & Access Collaboration, patient, provider, payer, purchaser, public health, and pharma organizations collaborate to enhance health and well-being by supporting people's access to evidence-based care that is appropriate for them.

The National Forum appreciates the opportunity to provide input on the Medicare Drug Price Negotiation Program, as it will have rippling effects on population health in the short and long term.

- Heart failure, the condition sacubitril/valsartin treats, makes everyday activities such as walking, climbing stairs, and carrying groceries difficult.
- People with heart failure that is not well-managed often are swept into the revolving door of hospital readmissions[i], harming their well-being while raising costs to Medicare and the taxpayers who fund it.
- We urge CMS to make sure its drug price negotiation program ensures beneficiary access to appropriate evidence-based care, that is, the right treatment for the right patient at the right time. Given that over 70 percent of all patients hospitalized with heart failure are Medicare beneficiaries,[ii] it is essential that this policy improves and not reduces access to sacubitril/valsartan.
- It is imperative that this program not worsen access challenges for disadvantaged populations. The prevalence of heart failure among Medicare Fee-For-Service beneficiaries is highest among Black and American Indian/Alaska Natives. We recommend CMS work with the Office of Minority Health to achieve this requisite.
- We urge CMS to guard against potential unintended consequences. Price ceilings intended to benefit consumers could result in *reduced* access if pharmacy benefit managers drop medications from formularies or move them to higher out-of-pocket cost tiers because higher-priced drugs offer PBMs bigger rebates. Heart failure therapies are not interchangeable. In multiple clinical trials, treatment with sacubitril/valsartan achieved a relative risk reduction for hospitalization or death of 20 percent or more

compared to alternative therapies.[iiiiv] The magnitude of benefit was consistent in Black and White patients.[v] [vi]

- We support the implementation of evidence-based care that aligns incentives for patients, providers, pharma innovators, and purchasers.

In summary, the National Forum urges CMS to ensure the Medicare Drug Price Negotiation Program:

- supports evidence-based strategies for appropriate care, and protects beneficiary access;
- guards against potential unintended consequences, such as utilization management that could result in reduced access to appropriate treatment; and
- aligns incentives for all stakeholders.

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[i] Oktay AA, Rich JD and Shah SJ (2013). The emerging epidemic of heart failure with preserved ejection fraction. Curr Heart Fail Rep. https://pubmed.ncbi.nlm.nih.gov/24078336/

[ii] [ii] Fang J et al. (2008). Heart failure-related hospitalization in the U.S., 1979 to 2004. JACC. https://www.sciencedirect.com/science/article/pii/S0735109708017907?via%3Dihub

[iii] Effects of Sacubitril/Valsartan in the PARADIGM-HF Trial (Prospective Comparison of ARNI with ACEI to Determine Impact on Global Mortality and Morbidity in Heart Failure) According to Background Therapy | Circulation: Heart Failure (ahajournals.org)

[iv] Paradigm-HF: a Paradigm Shift in Heart Failure Treatment? - PMC (nih.gov)

[v] Racial Differences, Outcomes and Response to Sacubitril/Valsartan in Heart Failure with Reduced Ejection Fraction: PARADIGM-HF. Eldrin F. Lewis1, Brian Claggett1, Scott D. Solomon1, John J.V. McMurray1, Karl Swedberg1, Akshay S. Desai1, Jean L. Rouleau1, Michael Zile1, Victor C. Shi2, Martin P. Lefkowitz2, Milton Packer3; 1Brigham and Women's Hospital, Boston, MA; 2Novartis, East Hanover, NJ; 3Baylor Heart and Vascular Institute, Dallas, TX, in Journal of Cardiac Failure Vol. 22 No. 8S August 2016

vi Berardi C, Braunwald E, Morrow DA, Mulder HS, Duffy CI, O'Brien TX, Ambrosy AP, Chakraborty H, Velazquez EJ, DeVore AD; PIONEER-HF Investigators. Angiotensin-Neprilysin Inhibition in Black Americans: Data From the PIONEER-HF Trial. JACC Heart Fail. 2020 Oct;8(10):859-866. doi: 10.1016/j.jchf.2020.06.019. Epub 2020 Sep 9. PMID: 32919915.