

Novartis statement about Entresto® (sacubitril/valsartan) selection for Medicare Drug Price Negotiation Program

Aug 29, 2023

Novartis believes the unconstitutional price-setting provisions in the Inflation Reduction Act (IRA) will limit the pharmaceutical industry's ability to discover and develop new life-saving and meaningful medicines for the people who need them most.

Novartis is particularly concerned that the IRA disincentivizes innovation and post-approval research, particularly for small molecule medicines including, among others, those that treat cancer, heart disease, and mental illness – diseases that affect millions of Americans.

More comprehensive changes are required to ensure the IRA's drug price-setting provisions do not result in worse access for patients; that the law is implemented in the most transparent and patient-centric manner possible; that the process allows for meaningful stakeholder input; and that ongoing innovation is valued equally for small molecules and biologics.

The Centers for Medicare and Medicaid Services (CMS) has selected Entresto® (sacubitril/valsartan) as one of the first 10 medicines in the Medicare Drug Price Negotiation Program for 2026. Entresto is an angiotensin receptor-neprilysin inhibitor (ARNi) approved for the treatment of heart failure in the US that helps patients stay alive longer and out of the hospital. It is the first and only ARNi currently FDA approved for use in the US and has no therapeutic alternative. Entresto is a life-saving medicine that has helped more than 1.7 million US heart failure patients. Within Medicare, the latest data shows that 587,000 beneficiaries take Entresto annually.¹

Since the initial FDA approval in 2015 for heart failure with reduced ejection fraction, Novartis has continued to prove the efficacy of Entresto in clinical trials, resulting in an expansion of the FDA approved label in 2021 to include all chronic heart failure patients with left ventricular ejection fraction below normal – in addition to the pediatric heart failure population. Under the IRA, which discourages the research and development of additional indications for small molecule medicines by implementing price controls nine years after the first FDA approval, we may not have been able to invest in researching and developing Entresto in these additional indications, depriving patients of a meaningful treatment advance.

Through negotiations with Medicare Part D plans, Novartis has worked extensively to ensure coverage for people with heart failure – an especially vulnerable population – who need Entresto.² On average, Medicare beneficiaries pay less than \$50 per month for Entresto.

For more information on Entresto, please visit www.entresto.com.

We strongly urge CMS to recognize the significant value Entresto brings to patients and the healthcare system.

List of links present in page

1. <https://uat2.arctic.novartis.com/news/novartis-statement-about-entresto-sacubitrilvalsartan-selection-medicare-drug-price-negotiation-program>
2. <https://www.entresto.com>