



November 2, 2020

The Honorable Seema Verma, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, D.C. 20201

RE: Comment on CMS-3372-P (Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of “Reasonable and Necessary”)

Dear Administrator Verma,

The National Organization for Rare Disorders (NORD) thanks the Centers for Medicare and Medicaid Services (CMS) for the opportunity to provide comments regarding the “Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of “Reasonable and Necessary”” proposed rule.

NORD is a unique federation of voluntary health organizations dedicated to helping the 25 to 30 million Americans living with a rare disease, many of whom depend on the Medicare program to cover their health care needs. While we appreciate CMS’s ongoing commitment to streamlining and standardizing the Medicare coverage determination process, we are concerned that the proposal to codify a new definition of “reasonable and necessary” may adversely impact access to care for the patients that we represent. Accordingly, we encourage CMS to withdraw this section of the proposed rule.

Defining “Reasonable and Necessary”

Medicare coverage is limited to items and services that are “reasonable and necessary” for the diagnosis or treatment of an illness or injury. The proposed rule seeks to codify the meaning of “reasonable and necessary” in statute, and would add a requirement that Medicare cover an item or service if it is provided by one or more commercial plans, unless evidence supports that there is a difference between commercial patients and Medicare patients. It is unclear whether the proposed definition would apply only to devices, or whether it would apply all to Medicare items and services. NORD is concerned about the potential impact to patients under either interpretation, but is especially troubled by a broader application, as it would likely lead to access constraints for rare disease patients.

The ability of Medicare Administrative Contractors (MACs) to make individual, case-by-case, determinations of medical necessity are especially important to patients with rare conditions. By definition, rare disease patients often have unique medical needs, and what is considered “reasonable and necessary” for one patient may not be “reasonable and necessary” for most other Medicare beneficiaries. Codifying the requirement that a therapy be “appropriate for Medicare patients” means that coverage decisions are not made within the context of a specific condition but at a population level. This may cause the needs of patients with rare conditions to be overlooked.

NORD is also concerned by CMS’s proposal to use commercial insurance as a criterion for determining coverage through Medicare. First, it is unclear how commercial coverage and commercial insurance

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policies will be used in CMS's determinations. For example, the proposed rule does not indicate the weight that CMS will place on commercial coverage compared to other criteria, or how the agency would handle coverage differences among commercial insurers. The proposal states that MACs would be responsible for reviewing commercial offerings to inform Local Coverage Decisions (LCDs) and may also be allowed to develop coverage policies that mirror the limitations regularly used in the commercial market. When misused, protocols such as step therapy and prior authorization can delay the start or continuation of necessary medical treatment. Medicare has historically offered greater levels of coverage than the commercial market, reflecting the needs of Medicare beneficiaries. For example, more than 22 percent of patients with Medicare are living with five or more chronic conditions, 15 percent are living with a disability, and 3 percent, or two million people, are living in a long-term care facility.ⁱ In addition, having a serious or chronic health condition and being over age 65 are both associated with significantly higher utilization of health care services.ⁱⁱ NORD is opposed to policies that could create new barriers to access for these patients. Finally, this proposed rule could create an opportunity for insurers, who participate in both the commercial market and Medicare, to make decisions for their commercial plans with the goal of influencing Medicare coverage requirements. NORD requests that this section of the proposed rule be withdrawn, and that CMS engage with patient organizations and other appropriate stakeholders to craft a process that does not endanger the quality of coverage for rare disease patients.

Conclusion

NORD is a unique federation of health organizations dedicated to helping people with rare "orphan" diseases and assisting the organizations that serve them. NORD is committed to the identification, treatment, and cure of rare disorders through programs of education, advocacy, research, and patient services. NORD aims to ensure that the perspective of the patient is considered each time a decision by the federal government can impact access to care.

We once again thank CMS for the opportunity to comment on this proposed rule. We look forward to continuing to work with the agency to ensure that rare disease patients have timely access to transformative therapies. For questions regarding NORD or the above comments please contact Corinne Alberts at calberts@raredisease.org.

Sincerely,



Rachel Sher
Vice President, Policy and Regulatory Affairs

ⁱ The Kaiser Family Foundation. (2019) An Overview of Medicaid. Retrieved at <https://www.kff.org/medicare/issue-brief/an-overview-of-medicare/>

ⁱⁱ Sawyer, B. Claxton, G. (2019) How do health expenditures vary across the population? *Peterson-KFF Healthy System Tracker*. Retrieved at https://www.healthsystemtracker.org/chart-collection/health-expenditures-vary-across-population/#item-while-health-spending-increases-throughout-adulthood-for-both-men-and-women-spending-varies-by-age_2016