PROMEDICA | Your Health. Our Mission.
PHYSICIANS

April 12, 2021

Re: MCIT / Medicare Coverage and Analysis Group (CAG)

To Whom It May Concern:

Recently, I became aware of a delay in implementation of the MCIT rule. This is particularly problematic in clinical cardiac electrophysiology, as this is clearly an area where new technology is impacting outcomes and mortality in patients on a regular basis. While I certainly do not pretend to know intimate details regarding the MCIT and its potential delay, I certainly do not favor any delay in its approval and usage. Only then will cardiac electrophysiologists, and obviously other physicians in other dynamic areas of medicine, be able to offer their patients devices and treatments which could clearly impact their mortality and morbidity.

Certainly, the Impulse Dynamics CCM device meets these criteria. This is designed to improve heart failure and we anticipate mortality in an extremely difficult patient population, many of whom do not qualify for existing technologies such as cardiac resynchronization therapy, or have failed that. We literally have hundreds, if not thousands, of these patients in our practice. The data that has been collected so far and published in numerous peer-reviewed formats is impressive, and while we certainly need to continue to follow outcomes in these patients (hence the excellent designed of several trials by the company), there should be no further delay in granting our patients access to this technology.

Recently, some articles have questioned the merits of the MCIT rule. The authors of such articles are right to raise issues like applicability to the Medicare population and safety. However, it should be duly noted that practicing physicians like myself do not take the decision to offer a patient a surgical procedure lightly. The joint decision to move forward in this regard is always made after a careful and thorough discussion of risks benefits and alternatives; the problem here is that alternatives are often not available or have been exhausted to no avail. Likewise, while implantation of the CCM device is technically invasive, it is truly minimally so, and device implantation carries a very low though non-zero risk.

Thank you for your careful and strong consideration of my opinion and those of other implanting physicians. The ability to offer treatment to patients with recalcitrant heart failure, and who either do not qualify for or will have failed other therapy, is critically important. The decision to withhold such therapy should be made only when there are concerns regarding the relative risk benefit ratio of the technology, and not be impacted by unnecessary administrative red tape.

Sincerely,

Mark Richards, PhD, MD, FACC, FHRS
Director of Arrhythmia Services and The Heart Rhythm Center
ProMedica Heart Institute

CARDIOLOGY

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