November 7, 2022

Center for Medicare and Medicaid Services (CMS) Representatives,

Thank you for the opportunity to comment on the MEDCAC's efforts to improve the coverage with evidence development (CED) program to expedite earlier Medicare beneficiary access to innovative technology. As background, Inflammatix is a California-based molecular diagnostics company developing the TriVerity™ acute infection and sepsis test to aid physicians in the diagnosis of acute infections and sepsis. The test works by quantifying the expression levels of 29 immune mRNAs and combining them using advanced algorithms to inform on the likelihood of a bacterial infection, the likelihood of a viral infection, and the patient's severity. TriVerity is a catridge-based test that will run on our novel proprietary Myrna™ instrument platform (also in development) and is expected to be used in the hospital Emergency Departments and other healthcare settings where patients suspected of acute infection and sepsis are seen.

Novel diagnostic technologies have suffered from underinvestment largely due to concerns over the 'valley of death' between FDA clearance and reimbursement. A novel diagnostic ultimately proven to be of no benefit can and should be eventually withdrawn from market. But a greater risk than fiscal loss due to ineffective products is stagnation due to lack of support during the critical post-clearance phase when a technology is undergoing utility studies. As the COVID-19 pandemic has shown, American health security relies on a nimble diagnostics industry, which in turn relies on a reliable path to payment for novel products.

We commend CMS' dedication to develop a program that will allow Medicare beneficiaries to access impactful medical innovations several years sooner than they do currently. The agency's continued dialogue, starting with Medical Coverage of Innovative Technology (MCIT), followed by Transitional Coverage for Emerging Technology (TCET) and now CED, indicates that a proposed rule is imminent. In looking to streamline access for Medicare beneficiaries to life-changing and life-saving technology, we would ask that CMS pay special attention to how promising molecular diagnostics, especially Multianalyte Assay with Algorithmic Analysis (MAAA) tests, are to be assessed.

Over the last few decades, MAAA tests have helped improve care in cancer, transplant and other conditions affecting Medicare beneficiaries. Advances in laboratory, genomic and data sciences promise that novel MAAA tests will continue to be brought forth to address significant unmet needs.

Since MAAA tests have required unique expertise (i.e. laboratory science, genomics, bioinformatics) to review, analyze and approve, CMS appropriately assigned the MolDx program within Palmetto GBA's organization to assess MAAA tests' evidence for coverage determination. **As CMS contemplates CED and/or TCET, we recommend that CMS delegate the ability to recommend CED/TCET for MAAA tests to the existing MolDx program (which currently is not an option).**

In addition, Inflammatix respectfully requests CMS to provide more details on the criteria and process for which technologies are to be considered for CED/TCET. Early on, FDA Breakthrough designation was considered as the

singular criteria for such eligibility. Since this singular approach was removed, no definitive alternative criteria have been put forth by CMS and we would like to better understand the agency's policy for approval.

For those technologies selected for CED/TCET, corresponding data collection objectives, study endpoints and duration of data collection associated should be clearly defined. We also support the establishment of efficient communication channels that allow for meaningful dialogue between CMS staff, test manufacturer representatives and other relevant stakeholders (i.e. clinicians, patients). Finally, since MAAA test developers are usually early-stage small companies with limited resources, establishing processes that are simple and not administratively burdensome would be greatly appreciated.

While not directly relevant to the MEDCAC's assessment of CED, our team looks forward to CMS informing on how coding and payment will be determined for MAAA eligible tests. Effective coding and payment-defining mechanisms are also fundamental to bringing innovative products to patients. Considering the unique nature of MAAA tests, determining whether crosswalk or gapfill method for payment determination may be a factor. Accordingly, given that such determination takes place annually (typically each June), calendar realities may arbitrarily delay such decisions which could materially impact patient access to the novel test. In the case that gapfill is determined as the appropriate method, final pricing may not be set for an additional year**. We suggest that either an accelerated crosswalk or gapfill process be considered.** Alternatively, a temporary price that is recommended by the manufacturer and accepted by CMS could be set that governs the temporary coverage period before reverting to the traditional crosswalk/gapfill method when such temporary coverage status is to be transitioned to permanent.

We look forward to engaging with the agency and other stakeholders to finalize the rules that will enable Medicate beneficiaries to access important novel medical innovations, including advanced molecular diagnostic tests like our TriVerity acute infection and sepsis test.

Sincerely,

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