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Dr Patrick Mann
Novitas Solutions
2020 Technology Pkwy Suite 100
Mechanicsburg, PA 17050
Sent via email

RE: Summary of Comments on DL39365

Dear Dr Mann and Novitas Team,

Thank you for the opportunity to provide comments on DL39365. This letter supports, augments and summarizes the feedback to Novitas concerning DL39365 "Genetic Testing for Oncology".

Pacific Edge is significantly (and adversely) impacted by the changes Novitas proposes to introduce, both in the general sense of relying on certain third party databases to make coverage decisions – of which only NCCN is applicable to MAAA tests like Cxbladder – and in the specific sense regarding the conclusions Novitas reached after conducting an evidentiary review resulting in a non-coverage determination for all of the Cxbladder products.

Since July 2020 Pacific Edge has relied on the unambiguous documented conclusion from Novitas on A58529 "the CxBladder test is now covered utilizing the reasonable and necessary guidelines". Novitas made this decision following a review of the available evidence for the assay and documented this decision in a public comment/response article that remains available on the CMS website, and via e-mail correspondence to Pacific Edge officials in response to questions. For more than two years this sufficed for appropriately guiding coverage and Novitas supported Pacific Edge for positive coverage determinations for Medicare Advantage appeals on this basis. When A58529 was retired, Novitas advised Pacific Edge by email that:

> "*The Review and Comment documents should not be used to determine coverage. The Medicare Advantage plan should be using LCDs and/or LCA for coverage determinations.* ***Since 0012M and 0013M is listed in A58917; Billing and Coding: Molecular Pathology and Genetic Testing, that is the article that should be referenced in determining coverage.***"

A58917 continues to appropriately guide coverage of Cxbladder tests, such that for more than three years, Medicare patients have benefitted from the improvements that Cxbladder offers to the standard of care in urology. In particular, Medicare patients that present to the physician with blood in the urine were offered non-invasive Cxbladder testing to determine whether or not cystoscopy and imaging (that have associated comorbidities) are necessary as part of further evaluation. However, if finalized, the non-coverage determination in DL39365 would eliminate Cxbladder and all non-invasive alternatives to cystoscopy for physicians to order for their Medicare patients with hematuria – a dramatic removal of benefits that may result in more patients receiving unnecessary invasive procedures such as cystoscopies and imaging that have known patient morbidities, thus causing unnecessary harm to Medicare patients.

Simultaneously over the last three years Pacific Edge has continued to generate evidence that supports the adoption of Cxbladder, and continues to a) confirm the performance characteristics of existing tests while b) continuing to develop new tests, thus further

highlighting our commitment to clinical evidence generation and the urology community we serve. This new evidence further supports the performance of the assays, and none of it supports a decision to remove longstanding coverage. We are not aware of any new evidence or adverse reporting event that Novitas can rely on to reverse the established, evidence-based position it established in July 2020.

While Pacific Edge is concerned with the proposed LCD's reliance on 3rd party databases, which have been largely communicated by industry associations, e.g. ACLA and The Coalition for 21st Century Medicine, we are most concerned by the content of the evidentiary review undertaken for our Cxbladder products. Some of the Novitas criticisms indeed have merit – before standardizing our commercial approach, there were occasions where Pacific Edge was ambiguous about which product was the target of the study and some patient cohorts were used to establish the AV and CV on multiple related products. However, this has been clarified through more recent publications (see Appendix in our Medical Rebuttal) and with respect to each product, the necessary requirements for analytical validation and clinical validation have been either peer-reviewed or were submitted to other clinical certification bodies including CLIA and New York State, and the appropriate patient population and use of our tests is articulated in our Test Request Form, while the correct interpretation of results is clearly outlined on our Test Results. These points are all noted in detail in our medical rebuttal.

In the Novitas review there are substantial misunderstandings regarding the appropriate use of our tests, the appropriate patient population in which to use them and the applicable standard of care. The misunderstandings appear to have driven Novitas to the conclusion that our tests do not add value and have been described as 'not medically reasonable and necessary'. In response, our Medical Affairs Team prepared a detailed rebuttal in which we explain in detail why Novitas should reconsider its position, as the reframing of our peer-reviewed publications in the context of the standard of care provide a consistent message that Cxbladder is analytically valid, clinically valid and clinically useful for urologists.

The physicians that use our tests in clinical practice have echoed these sentiments; indeed, more than 20 plan to provide feedback in support of the Cxbladder tests, because they also believe the evidence supporting the tests is sufficient to support continued patient access. All of the largest associations in urology – AUA, LUGPA and AACU – have submitted comments separately regarding this LCD to you, and more than a dozen key opinion leaders have independently co-authored an opinion piece, expected to be published in an appropriate journal at the conclusion of this process.

Regarding the appropriateness of relying solely on NCCN to make Medicare coverage decisions for molecular algorithmic tests, Pacific Edge notes two points. The first is that pre-emptive non-coverage for tests not supported with at least a 2a rating in the NCCN guidelines (or higher) appears to be a re-definition of 'medically reasonable and necessary'. NCCN guidelines aim to develop a consensus of the standard of care – a definition that far supersedes that of 'medically reasonable and necessary'. The current reliance on NCCN substitutes a higher standard, i.e. 'consensus standard of care' for the requirements of the Social Securities Act defined as 'medically reasonable and necessary'. The second point is that this leaves tests with 2b recommendations non-covered, even if such assays have 50-85% support from the guidelines committee. We urge Novitas to reconsider whether NCCN 2b recommendations should at a minimum not be automatically non-covered, allowing Medicare beneficiaries continued access to the tests. This point is significant, as Cxbladder Monitor peer-reviewed evidence was used in the determination of an NCCN 2b recommendation for urinary biomarkers and consequently carries an NCCN 2b recommendation by name.

As a diagnostic testing provider, Pacific Edge is both patient-centric and value-based in its approach to addressing unmet clinical needs. As the average age of patients presenting with

hematuria is ~73 years old (American Urological Association), hematuria patients are majority Medicare patients, and a primary consideration in everything that we do. Consequently, a small number of patients have connected with us as we prepared our written comments and have also sent those comments to you. Pacific Edge also understands that BCAN – a patient advocacy organization well known for keeping out of medical policy discussion – has also submitted comments. They too recognize the impact of the test on Medicare beneficiaries. While separate from clinical evidence considerations, value-based considerations are important for the healthcare system as a whole. The Medicare allowable for Cxbladder tests is $760/test and a recently developed budget impact model (abstract accepted at the WSAUA conference on 10/1-5, 2023) highlights a saving of >$500 per patient for a Cxbladder Detect clinical pathway when compared to the standard of care pathway. The combination of clinical utility and economic utility provides an excellent example of value-based care regarding how new technologies can benefit patients, physicians and payers alike.

Pacific Edge remains committed to contextualizing the clinical value of Cxbladder for Novitas, CMS or any other payor, and providing the peer-reviewed evidence to support our claims. I am personally available to discuss at any time, have members of my team engage with the Medical Affairs Team at Novitas or assist with assembling independent urology experts from among our customer base.

Respectfully,

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