

Update from Prostatype Genomics Regarding the Medicare Reimbursement Process for Prostatype® in the United States

Prostatype Genomics has been actively engaged in the process regarding Medicare reimbursement for Prostatype® in the United States for some time. The process is currently in an intensive phase and continues in the same constructive and positive spirit that has characterized it since the beginning.

Prostatype Genomics has applied for reimbursement for Prostatype® under an already established regulatory framework (L38293/L38338) with Medicare in the U.S. market, where a reimbursement level has already been established (USD 3,783 per completed test). Prostatype® is designed to address the clinical question of whether a patient should undergo radical treatment or not (typically surgery or radiation therapy) in connection with a prostate cancer diagnosis. Despite the very low mortality rate among low- and intermediate-risk prostate cancer patients, many men are unnecessarily subjected to radical treatment, often resulting in significant lifelong side effects, primarily impotence and incontinence, leading to reduced quality of life.

With a precision medicine tool such as Prostatype®, greater confidence can be achieved in ensuring that the right patient receives the right treatment at the right time, while also identifying those patients who truly require radical treatment at an early stage.

In the United States, prognostic biomarkers similar to Prostatype® are widely used in prostate cancer care and, unlike in Europe and Asia, are also included in national clinical guidelines, making the U.S. the largest and most important market for Prostatype Genomics.

Fredrik Rickman, CEO of Prostatype Genomics, comments on the current situation:

“We understand and are fully aware that shareholders and other stakeholders are highly eager for the ongoing process to reach completion – naturally, so are we. The Company’s employees are working on these matters not only daily but also around the clock and will continue to do so until we are finished, even though our original expectation was that the approval would come sooner than it ultimately will.

At the same time, it is important to recognize that reimbursement evaluations for prognostic molecular diagnostics are typically extensive and involve several stages of review and dialogue. The inherent complexity makes it difficult to assess and provide clear timelines for when an approval will be in place, which is not unique to an organization such as Medicare. The absence of a rapid decision should not be interpreted negatively in processes such as the one the Company is currently engaged in,” says Fredrik Rickman.

“Our discussions with Medicare continue and the process is progressing constructively. Although we cannot provide a specific date for approval, we remain encouraged by the ongoing engagement and continued development in the review process. In light of the ongoing discussions taking place, including several in-person meetings with representatives from Medicare, we have every reason to view the current situation positively.

We remain fully focused on delivering an outcome that can create meaningful long-term value for patients, clinicians, and shareholders alike,” says Fredrik Rickman.

During 2024 and 2025, Prostatype Genomics has primarily invested in the U.S. market and achieved a number of regulatory and commercial milestones. The Company is prepared to accelerate commercialization immediately once Medicare reimbursement approval is received.

Fredrik Rickman further comments:

“Prostatype® has already been in use for some time at selected hospitals in the United States, providing us with a strong foundation ahead of a broader market launch. In order to market a product such as Prostatype® in the U.S., a number of regulatory and commercial approvals and permits are required, all of which Prostatype Genomics already has in place, including an established and validated laboratory partner as well as a billing partner.

As a result, the lead time for Prostatype Genomics to begin generating revenue in the U.S. is very short, particularly considering that we already have advanced discussions with the commercial team we intend to put in place as soon as approval is obtained.

The Company will inform the market without delay when further information becomes available,” concludes Fredrik Rickman.