Press Release
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Update regarding Prostatype Genomics' application to Medicare concerning reimbursement for Prostatype® in USA

Prostatype Genomics' application process for reimbursement in the USA with the largest insurer for diagnosed prostate cancer patients, Medicare, is proceeding smoothly. The company still expects approval during the second half of 2025, based on the ongoing progress in the process.

In September 2024, Prostatype Genomics initiated the application process to Medicare for reimbursement in the USA for diagnosed prostate cancer patients where the healthcare provider seeks complementary prognostic information to better determine whether a patient should undergo surgery, another radical treatment, or be put on active surveillance.

Medicare is the single largest insurer in the US for patients diagnosed with prostate cancer, corresponding to approximately 60% of the total market. The remaining 40% is covered by various private insurance companies. Prostatype Genomics recently communicated that invoicing to private insurance companies in the USA has begun. In the USA, more than 300,000 patients are diagnosed annually, and the market is experiencing strong growth, expected to double in size by 2040.

Prostatype Genomics has applied for reimbursement for Prostatype® with Medicare under an already existing reimbursement code and a known reimbursement level of USD 3,783 per completed test. This has facilitated communication with Medicare, as there are already three approved tests similar to Prostatype® on the US market that fall under the same reimbursement code.

Fredrik Rickman, CEO of Prostatype Genomics, comments:

"Medicare approval is the company's primary objective in the USA. The dialogue with Medicare is continuing smoothly. As previously communicated, we have already come so far in the commercial process with Prostatype® in the USA that we have started invoicing private insurance companies. Approval from Medicare has taken longer than we originally anticipated. The documentation for Prostatype® is extensive, and new data has recently been added with the published studies from Spain and Taiwan.

According to our partners in the USA, what we are experiencing is not unusual, although we had expected faster processing since both the Medicare code and reimbursement level were already in place at the time of the application. In regulatory processes, it is always difficult to predict how long the process will take to reach approval. In practice, Medicare asks us a number of questions, which we then answer. Medicare then returns with further questions that we continue to discuss with them. Even though the approval process takes time, the dialogue between the parties has consistently been conducted in a positive and professional manner, and based on the communication we have had with Medicare, the company assesses that approval will be achievable during the calendar year 2025."

"Thanks to previous investments, the company is ready and prepared for the launch of Prostatype® in the selected states we will initially focus on. We have the commercial plan in place, an established collaboration with a laboratory partner, agreements with a billing partner, and all the regulatory approvals required to operate in the US market. Collectively, these achievements represent a substantial and inherent value for the Company. We look forward with great anticipation and excitement to achieving our primary goal of obtaining reimbursement approval from Medicare, as it means that our commercial efforts in the US will truly accelerate."

Contacts

For further information about Prostatype Genomics, please contact:
Fredrik Rickman, CEO Prostatype Genomics AB
Telephone: +46 73 049 77 01.
e-mail: fredrik.rickman@prostatypegenomics.com

Certified Adviser

The Company's Certified Adviser is Tapper Partners AB.
Phone: +46 (0)70 44 010 98
E-mail: ca@tapperpartners.se

About Us

About Prostatype Genomics AB

Prostatype® is a genetic test that is available to patients and treating urologists as a supplementary decision support tool to answer the question of radical treatment or no radical treatment of prostate cancer. The test is developed by a research group at Karolinska Institutet and is provided by Prostatype Genomics AB.