

## **Summary of the health technology assessment of FoundationOne CDx**

TLV has conducted a health technology assessment of FoundationOne CDx as a diagnostic tool. The health technology assessment includes an economic evaluation of FoundationOne CDx in comparison to techniques that are considered standard assays in the Swedish health care system today. The health technology assessment report presented by TLV provides a basis for decisions made by the Swedish Regions.

Molecular diagnostics is a collection of techniques used to analyse genetic variation and aberrations associated with a disease. DNA-sequencing is an example of one of these techniques. Modern DNA-sequencing techniques such as next generation sequencing (NGS) has radically changed medical research and drug development. NGS allows for rapid and efficient sequencing and diagnostics of disease associated genetic alterations and identifies genetic targets for which new therapies are developed, all important in the advancement and application of personalised medicine, also referred to as precision medicine.

FoundationOne CDx is a CE-marked *in vitro* medical diagnostic service that detects actionable DNA alterations in a broad range of cancers. The service includes extraction of genetic material from a patient's tumor, NGS-based genetic assessment, data analysis with bioinformatics and generation of a report that can help physicians make treatment decisions for patients with cancer. In TLV's health technology assessment FoundationOne CDx is evaluated as a molecular diagnostic test for patients with cancer.

FoundationOne CDx is approved for use in all solid tumors regardless of origin. However, TLV has limited its assessment of FoundationOne CDx to when it is used as a diagnostic test for the following types of tumors; non-small cell lung cancer, breast cancer, cancer of unknown origin, melanoma, colorectal cancer and ovarian cancer. In this health technology assessment FoundationOne CDx is evaluated as a diagnostic tool. The comparator is diagnostics with techniques, such as immunohistochemistry and hotspot NGS, that are standard diagnostic methods in the Swedish health care system today.

In the economic evaluation of FoundationOne CDx, the cost-comparison analysis of FoundationOne CDx versus standard diagnostic techniques is based on information that has been obtained from leading pathologists in Sweden. In TLV's health technology assessment the cost of FoundationOne CDx was higher than the cost of standard technologies in most cases. However, TLV recognizes that FoundationOne CDx has other advantages over standard techniques that are not included in the economic evaluation. These advantages include higher precision and sensitivity as well as a report that gives information about available targeted therapies.

There are uncertainties in the economic evaluation, predominantly regarding which techniques are included as standard diagnostic assays today and the cost of these. TLV has obtained information from the six health care regions in Sweden and notes that techniques as well as costs differ between the regions.