MOLECULAR HEALTH
MH GUIDE

From NGS data to individual therapy recommendations

MH Guide: Billing of molecular tumor diagnostics

The 2016 EBM amendment re-defined the compensation regime for molecular-pathological tumor analyses and enabled the use of modern procedures such as next-generation sequencing (NGS).[1] MH Guide helps pathologists identify clinically-relevant gene variants from complex NGS data, and supports treating physicians in making therapeutic decisions. The following pages provide an overview of how to apply and bill NGS and the MH Guide analysis.

MH Guide: The software identifies clinically-relevant gene variants and supports therapeutic decision-making

MH Guide is a CE-certified in-vitro diagnostics (IVD) software that analyzes tumor genetic data from sequencing and compares it with biomedical knowledge. MH Guide thus identifies patient-specific, clinically-relevant gene variants and provides a comprehensive assessment of individual therapeutic options and of recruiting clinical studies. Therapeutic options are clearly listed in a report and can be implemented directly in practice. MH Guide supports treating physicians in making clinical decisions based on the patient's genetic tumor profile.[2,3]

Commissioning an MH Guide analysis in seven easy steps[2,3]

1: GIVE INDICATION
The oncologist provides the indication for molecular pathological diagnostic tests.

2: REQUEST MOLECULAR DIAGNOSTICS
The oncologist sends sample material (tumor biopsy or tumor sample) with a referral letter and the medical report to the pathologist on site, requesting evidence of tumor-relevant mutations.

3: PERFORM NGS ANALYSIS
Apart from examining the tumor, the pathologist
(a) carries out the NGS analysis directly or
(b) commissions a molecular pathology laboratory to do so

4: UPLOAD NGS INTO MH GUIDE
The commissioned laboratory performs the NGS tests and uploads the data onto the web portal for MH Guide assessment.

5: ANALYZE NGS DATA
MH Guide analyzes NGS data, comparing it with information provided by the Dataome knowledge database and supporting the creation of a customized report.

6: ISSUE REPORT
The commissioned laboratory processes the MH Guide report, approves and signs it, and sends it to the respective pathologist. The latter issues the findings report with all pathological test results and the MH Guide report.

7: SELECT THERAPEUTIC OPTIONS
The oncologist receives the report from the pathologist in question, including individual therapy information and possible studies.

The NGS analysis and evaluation with MH Guide are reimbursable

The costs for an NGS analysis and subsequent data analysis, e.g. with MH Guide, are reimbursed as standard care for certain indications.[4] The following options are available:

- Billing based on the uniform evaluation standard (*Einheitlicher Bewertungsmassstab*, EBM) Chapter 19.4 "In-vitro diagnostics of tumor genetic changes", e.g. according to fee schedule item (*Gebuehrenordnungsposition*, GOP) 19424, or according to 19425 with more than 20 kilobases (kb) as a single application subject to approval (cf. Fig. 1)[4,5]
- Billing based on EBM chapter 11.4 "In-vitro diagnostics of constitutional genetic changes" for hereditary tumor syndromes, such as breast, ovarian, or intestinal cancer[4,5]
- Invoicing in the hospital as outpatient service as "Outpatient specialist medical care pursuant to §116 SGB (*Sozialgesetzbuch* [Social Code]) V" (e.g. gastrointestinal tumors or lung tumors)[6]
- Billing in the hospital via selective contracts with certain health insurance companies for ovarian, peritoneal, and fallopian tube carcinomas, as well as for rare pediatric and adolescent tumors[4]

In addition, there is the possibility of billing an NGS analysis and assessment with MH Guide as a private service, i.e. the private health insurance company assumes the costs.[4]

New billing of molecular tumor analyses in registered physicians' practices thanks to EBM amendment

The EBM extension of chapter 19.4 "In-vitro diagnostics for tumor genetic changes" in July 2016 brought significant changes for molecular tumor analysis and for the use of NGS to search for mutations. Since then, the following two service components are remunerated extra-budgetarily:[1,7]

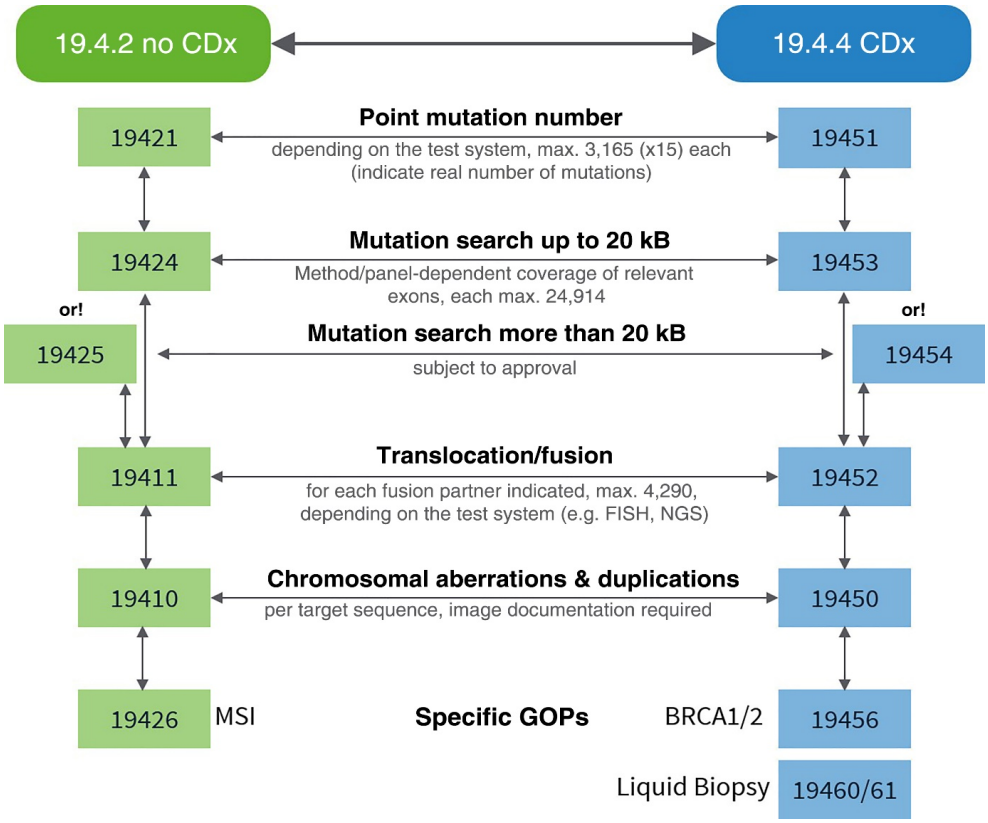
- General oncological molecular pathology – Section 19.4.2 "In-vitro diagnostics for tumor genetic changes"
- Companion Diagnostics (CDx) – Section 19.4.4 "In-vitro diagnostics for tumor genetic changes for the indication of pharmacological therapy"

In addition, these service contents have been described pathogenetically since the amendment.[1,7] For instance, GOP 19424 (mutation search to detect or exclude a disease-relevant somatic mutation up to 20 kb) describes the following requirements as mandatory service content:[5]

- A detection limit ≤10% for the detection of a mutation
- Bioinformatic assessment of sequence data collected

The assessment method is not specified.[1,7] This also enables new procedures such as NGS to be used for mutation detection.[1]

Overview of the most important GOPs



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