Country & Condition Card

Why this resource?

The availability of precision medicine (PM) is very different from country to country, making it hard to make a comparison, and to identify and share best practices between countries. Even within one country, the PM situation can be complex and hard to understand, and the environment is quickly changing.

Advocates who are working towards better access for PM in their country need to have facts depicted in a simple way at their disposal and these cards aim to fill that gap by giving a snapshot of the current situation of PM availability in a given country and for different conditions.

Information is presented in a comprehensive and visual way to make it easier for the advocate to take action, and to provide help to patients who need support.

How is this resource addressing the issue?

The Cards start with an overview of criteria that has been identified as the first information that advocates and patients typically look for. These include reimbursement of testing and treatment, as well as when testing is offered. For advocates who wish to have more information, each condition has a hyperlink to a more extensive chapter on the respective condition. These chapters have additional information for your research.

There are also links to the available Molecular Tumor Boards (MTBs) as well as Comprehensive Cancer Centers in your country, which have been identified as being an important factor in enabling patient access to PM. You will also find resources for more extensive information.

The information provided in this card depicts what should be happening in theory. However, many factors influence the actual delivery of PM to the patient and the reality on the ground may be different.

FIRST DRAFT

LAST UPDATED: OCT '21

Netherlands

How to navigate in this resource: clicking on the various elements will either take you to an external resource or to another section of the document with more information

Quick overview

Reimbursement of molecular testing

Lung Cancers: ALK, EGFR, PD-L1, ROS1, BRAF, MET, KRAS[2]

CUP: Whole Genome Sequencing (only for drug-diagnosis combination)[12]

Reimbursement of treatment

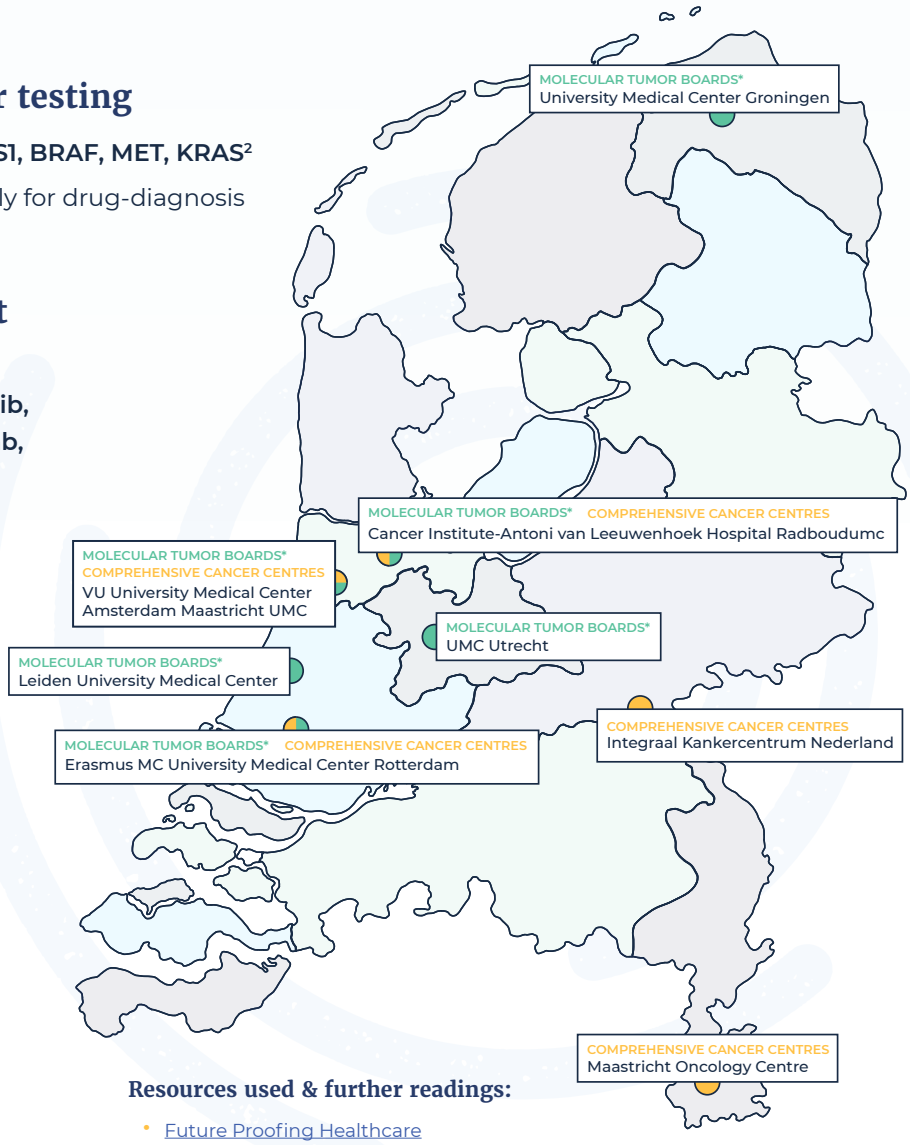
Lung Cancers: Afatinib, Osimertinib, Gefitinib, Crizotinib, Brigatinib, Ceritinib, Alectinib, Pembrolizumab, Durvalumab, Nivolumab, Atezolizumab[6]

CUP: Patients could receive targeted treatment or immunotherapy via the DRUP protocol (only for last line patients)[11]

When testing is offered to the patient

Lung Cancers: CGP tests performed on need and/or recommendation[2]

CUP: CGP tests performed on need and/or recommendation by oncologist



Resources used & further readings:

- Future Proofing Healthcare
- Integraal Kankercentrum Nederland
- EAPM - Factsheet Lung Cancer
- Lung Cancer Europe Position Paper
- Unlocking the potential of PM in EU
- Zorginstitut Nederland

* Molecular tumor boards (MTBs), unlike tumor boards, discuss patients with all types of cancer whose tumors have been analyzed with advanced genomic diagnostic tests, in order to make recommendations for individual patient treatments. MTBs typically include cancer genomicists and bioinformatics experts as well as medical oncologists, surgeons, radiation therapists, researchers and pathologists.[14]

Lung Cancer

Average diagnoses per year: **14,000**
Deaths (2019): **10,233**[1]

Patient organisation(s):
Longkanker Nederland, NFK

Testing	
Country-specific guidelines for biomarker testing of advanced or recurrent NSCLC	EGFR, ALK, ROS1, BRAF, NTRK, KRAS, MET, RET, NRG1, PD-L1, ERBB2/ HER2*
Access to molecular testing (offered when)	CGP tests performed on need and/or recommendation[2]
Testing types	Reflex testing, on-demand testing, tissue & liquid biopsy, NGS[8]

Financial Access	
Reimbursement of molecular testing (mostly for small panel)	ALK, EGFR, PD-L1, ROS1, BRAF, MET, KRAS[2]
Reimbursement of lung cancer drugs**	**Targeted therapy:** Afatinib, Osimertinib, Gefitinib, Crizotinib, Brigatinib, Ceritinib, Alectinib **Immunotherapy:** Pembrolizumab, Durvalumab, Nivolumab, Atezolizumak[6] Temporary reimbursement for NTRK Fusions

Treatment	
Availability of clinical trials	150 CTs for lung cancer (as of 2021)[3]
Expertises centres for rare lung cancer (ALK, ROS-1 and BRAF)	UMCG, MUMC, AVL, Amsterdam UMC, Erasmus MC & Radboud MC

Other
According to guidelines, it is obligatory to discuss all newly diagnosed lung cancer patients in multidisciplinary tumor boards for staging treatment recommendations[7]
Lung cancer screening: NL is taking part in the 4-IN THE LUNG RUN project aiming to evaluate when it is safe to increase risk-based screening intervals after a negative baseline CT.

*ERBB2/HER2 to be included in next guideline revision
** All 19 available lung cancer drugs are reimbursed in NL, this list pertains only to targeted therapy/immunotherapy

From Testing to Targeted Treatments

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Cancer of Unknown Primary

Diagnoses (2018): **1,300**
Deaths: [4]

Patient organisation(s):
Missie Tumor Onbekend

Testing	
Country-specific guidelines for biomarker testing	
Access to molecular testing (offered when)	CGP tests performed on need and/or recommendation by oncologist- national care pathway and guidelines are being prepared and updated by oncologists and pathologists professional bodies
Testing types	Reflex testing, on-demand testing, tissue & liquid biopsy, NGS, WGS

Financial Access	
Reimbursement of molecular testing	Via "facultatieve prestatie" (only for drug-diagnosis combination)[12]
Reimbursement of treatment	Nothing specifically for CUP, but patients could receive targeted treatment or immunotherapy via the DRUP protocol

Treatment	
Approved treatment by regulatory authorities	None
Availability of clinical Trials	1: CUPISCO
Centres of excellence	NKI/AvL, Erasmus MC, UMCG, MUMC

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Other parameters:	
Turnaround times	Single and multi biomarker testing turnaround time less than 2 weeks[9]
Innovative clinical trials	• DRUP (Drug Rediscovery Protocol): This is an innovative pan-cancer clinical trial that seeks to expand the use of EMA and/or FDA-approved targeted therapies beyond their approved indications)[11] • DAP (Drug Access Protocol)[13]
Reimbursement time of innovative oncology treatments after EU market authorization	Average 234 days[10]
Length of hospital stays for cancer patients	3-4 days for PM patients vs 7 days for patients treated with chemotherapy[9]

Methodology

This resource is a co-created effort from a multi-stakeholder working group within the "From Testing to Targeted Treatments" Program. This group includes patient organization representatives and advocates as well as representatives from the pharma and diagnostics companies, enabling a more nuanced and comprehensive view on the content and the needs of potential advocates.

This version of the cards is the result of multiple rounds of discussion, brainstorming, literature review and feedback. Initially, 75 parameters were identified and in subsequent rounds prioritized to include these final criteria, having been assessed as being the most important by the group. The content pulls together various publications, reports and other sources identified by working group contributors, and aims to display facts and information in a simple way with references to further readings.

Standards

All resources used for the cards should be from reliable and credible sources. Any information must be referenced to a publicly available resource, e.g

- Resources should be up-to-date and not published more than five years ago;
- Taken from websites belonging to educational and governmental institutions;
- Published in academic databases; from medical societies

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References

[1] https://iknl.nl/kankersoorten/longkanker/registratie/incidentie

[2] https://www.euapm.eu/pdf/EAPM_revolutionising_lung_cancer_care_all_together_netherlands_feb_2021.pdf

[3] Clinical Trial.gov

[4] https://iknl.nl/getmedia/ea952e4d-9af7-4d59-9f03-865c858bc0cd/Rapport_PrimaireTumorOnbekend_IKNL_2020.pdf

[5] https://iknl.nl/en/ncr/ncr-data-figures

[6] https://www.lungcancereurope.eu/wp-content/uploads/2020/02/LuCE-POSITION-PAPER-English.pdf

[7] https://richtlijnendatabase.nl/richtlijn/niet_kleincellig_longcarcinoom/diagnostiek/ngs_versus_pcr_bij_testen_op_mutaties.html

[8] https://www.lungcancerjournal.info/action/showPdf?pii=S0169-5002%2821%2900086-6

[9] https://ecpc.org/wp-content/uploads/2021/03/unlocking-the-potential-of-precision-medicine-in-europe-23022021.pdf

[10] https://www.efpia.eu/publications/downloads/efpia/every-day-counts-improving-time-to-patient-access-to-innovative-oncology-therapies-in-europe/

[11] https://www.researchgate.net/publication/340222163_The_Drug_Rediscovery_Protocol_DRUP_trial_A_Dutch_National_Study_on_behalf_of_the_Center_for_Personalized_Cancer_Treatment_CPCT_to_Facilitate_Patient_Access_to_Commercially_Available_Targeted_Anti-canc

[12] https://puc.overheid.nl/nza/doc/PUC_638877_22/1/[WM1]

[13] https://www.nvmo.org/2021/01/drug-access-protocol-gestart/

[14] https://health.ucsd.edu/specialties/cancer/programs/personalized-therapy/pages/tumor-board.aspx