

Platform CRM – TMC: a linked procedure for companion reimbursement

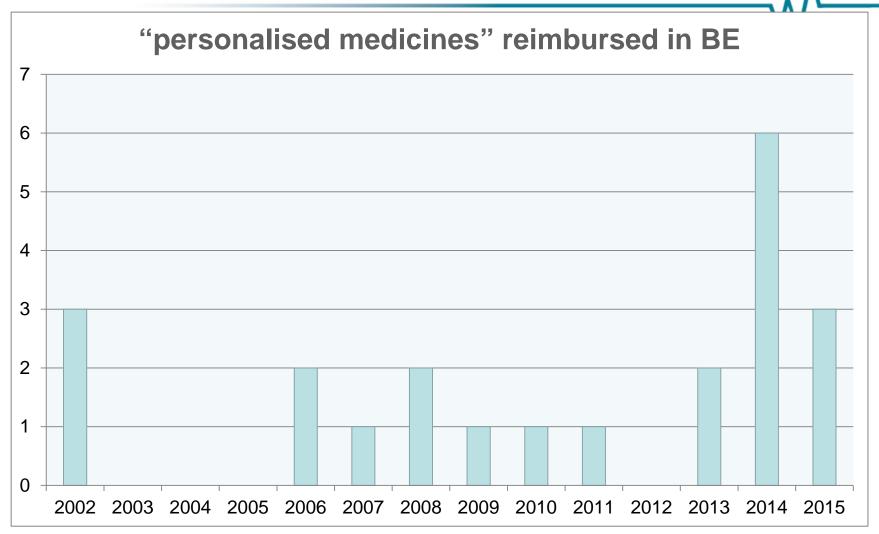
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reimbursement of medicines (CRM) versus

reimbursements of acts/diagnostic tests (TMC)

- different commission
- different timelines
- different budget
- within NIHDI: different departments



□ Medicines:

CRM Minister MD

6 months + suspensions

□ Tests:

first: WG Clinical Biology, then:

TMC Medicomut CBC Ins Com Minister RD

minimum 18 months



reimbursement of personalised medicine

access to personalized medicine

→ health care reimbursement procedures should be adapted to achieve a simultaneous reimbursement start for treatment and test

→ Challenge:

- 2 different technologies/processes/expertise
- keep up with quick technological evolution
- **□** flexibility



reimbursement of personalised medicine: permanent mixed working group CRM – TMC

Platform Companion Diagnostics

- launched 19/1/2016
- members:
 - representatives of TMC and CRM (Bureau)
 - laboratories, clinicians, insurers, WIV-ISP, KCE, NIHDI, ComPerMed
 - invitees (HealthData, Cancer Register,...)
 - conflict of interest, confidentiality
- secretariat:
 - Catherine Adriaens (pharmaceutical dept)
 - CDX@riziv.fgov.be



reimbursement of personalised medicine: permanent mixed working group CRM – TMC

- tasks:
 - advise to both CRM and TMC
 - new nomenclature
 - modifications of existing nomenclature (link drug)
 - ad hoc expertise dossiers (CRM-TMC)
 - e.g. Tagrisso (CRM)
- communication ComPerMed



reimbursement of personalised medicine

current projects for new nomenclature (art33bis)

- Novel testing technologies, e.g. NGS: convention
- 2. Validated molecular biology technologies, e.g. PCR: linked reimbursement procedure simultaneous reimbursement drug-test



package drug – test: single short HTA

 Proposal: the Commission for Reimbursement of Medicines (CRM) advises the Minister on the reimbursement of the drug and the "companion" tests

advise: platform CDx single Ministerial Decree

Nomenclature for tests: stays competence of TMC



Concept:

- article 33ter:
 - new "generic" nomenclature codes for tests linked to a drug
 - defined by TMC
 - published by royal decree
- chapter "VIII":
 - "personalised" drugs
 - + annex with "companion" tests

if the Minister decides to reimburse the drug, the marker will be added to the list by the same Ministerial Decree



Nomenclature: art. 33ter Drugs: Chapter VIII

Code "A" simple tests in view of treatment with personalised drug in chapter "VIII" that appears on list

Drug 1.

reimbursement if marker "x" is present/absent as detected by a test executed according to the conditions under article 33ter of the nomenclature Drug 2.

Code "B"

Moderately complex tests in view of ...

Registration

Code "C"

. . .

Attached list of markers, specifying:

- Marker
- Indication
- Code (complexity)



registration guidelines



