Platform CRM – TMC: a linked procedure for companion reimbursement

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impact of personalised medicine on the Belgian health care system
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“personalised medicines” reimbursed in BE

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October 25, 2016
reimbursement of medicines (CRM)

versus

reimbursements of acts/diagnostic tests (TMC)

- different commission
- different timelines
- different budget
- within NIHDI: different departments
Impact of personalised medicine on the Belgian health care system

**Medicines:**
- CRM
- Minister
- MD

6 months + suspensions

**Tests:**
- first: WG Clinical Biology, then:
  - TMC
  - Medico-mut
  - CBC
  - Ins Com

minimum 18 months

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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
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)

1. Novel testing technologies, e.g. NGS: convention

2. Validated molecular biology technologies, e.g. PCR: linked reimbursement procedure simultaneous reimbursement drug-test
Personalised medicine: linked reimbursement procedure

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
Personalised medicine: linked reimbursement procedure

• 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
Personalised medicine: linked reimbursement procedure

**Nomenclature: art. 33ter**

- **Code “A”**
  - Simple tests in view of treatment with personalised drug in chapter “VIII” that appears on list

- **Code “B”**
  - Moderately complex tests in view of ...

- **Code “C”**
  - ...

**Drugs: Chapter VIII**

- **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.**
  - ...

**Registration**

Attached list of markers, specifying:
- Marker
- Indication
- Code (complexity)

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