Reimbursement Perspectives on Precision Medicine

CADTH Symposium 2017

Ferg Mills, Dr. Natasha Leighl, Dr. David Shum, Olaf Koester
Perspectives

Natasha Leighl MD MMSc FRCPC
Professor of Medicine, University of Toronto
Thoracic Lead, Division of Medical Oncology
Princess Margaret Cancer Centre
OSI Pharmaceuticals Foundation Chair in Cancer New Drug Development
Co-chair, Canadian Cancer Trials Group Committee on Economic Analysis

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David Shum
Director, Market Access & Pricing at Roche Canada, responsible for the reimbursement, health economics, pricing, and private market for Roche products.

Olaf Koester
Director of pharmacy at the Central Manitoba Regional Health Authority;
Director of health outcomes at Procurity;
former director of the public drug plan of Manitoba Health.
"My policy on cake is pro having it and pro eating it."

- Boris Johnson
Agenda

• The Promise of Precision Medicine
• Best Practices, Challenges & Opportunities
• Recommendations for now and the future
• Q&A

• A note about slides...
Part 1: The promise
Accelerating Progress: FDA approvals in advanced lung cancer

**First-line (incl combination)**
- Docetaxel 2002
- Gefitinib† 2003
- Erlotinib 2004
- Pemetrexed‡ 2004
- Bevacizumab‡ 2006
- Pemetrexed‡ 2008
- Nivolumab 2015
- Pembrolizumab 2015++
- Crizotinib 2016+++*
- Atezolizumab 2016
- Pembrolizumab 1L 2016++

**Second-line and beyond**
- Carboplatin* 1989
- Vinorelbine 1994
- Paclitaxel 1998
- Gemcitabine 1996
- Docetaxel 1999
- Crizotinib§ 2011 (US)/2012 (EU)
- Erlotinib** 2013
- Pemetrexed‡ 2009
- Nab-Paclitaxel 2012
- Afatinib**,# 2013
- Ceritinib§ 2014
- Alectinib§ 2015
- Gefitinib** 2015
- Osimertinib 2015+

**Maintenance chemotherapy**
- Docetaxel 2002
- Gefitinib† 2003
- Erlotinib 2004
- Pemetrexed‡ 2004

**Molecularly targeted agents**
- Carboplatin* 1978
- Docetaxel 2002
- Gefitinib† 2003
- Erlotinib 2004
- Pemetrexed‡ 2004
- Bevacizumab‡ 2006
- Pemetrexed‡ 2008
- Nivolumab 2015
- Pembrolizumab 2015++
- Crizotinib 2016+++*
- Atezolizumab 2016
- Pembrolizumab 1L 2016++

Median OS, months
- First-line (incl combination)
- Docetaxel 2002
- Gefitinib† 2003
- Erlotinib 2004
- Pemetrexed‡ 2004
- Bevacizumab‡ 2006
- Pemetrexed‡ 2008
- Nivolumab 2015
- Pembrolizumab 2015++
- Crizotinib 2016+++*
- Atezolizumab 2016
- Pembrolizumab 1L 2016++

1970
- 1980
- 1990
- 2000
- 2010

- Carboplatin* 1989
- Vinorelbine 1994
- Paclitaxel 1998
- Gemcitabine 1996
- Docetaxel 1999

Median OS, months
- ~6
- ~8–10
- 12+
- 13+
- ~2–4

*Not approved in NSCLC, but commonly used; †Restricted to patients participating in a clinical trial or continuing to benefit from treatment already initiated; ‡Non-squamous NSCLC only; §ALK-positive NSCLC only; **EGFR exon 19 deletions or exon 21 (L858R) substitution mutations only; 
#Afatinib is approved for the treatment of patients with activating EGFR mutations but only PFS data have been published (May 2014).

Many patients have a targetable alteration (up to 70%) with the hope of better outcomes.


N=6832 adenocarcinoma cases
5.4% multiple mutations
Benefits of newer agents v. chemotherapy

- Tablets versus intravenous administration (potential savings)
- Fewer side effects (potential savings)
- 3-fold ↑ response rate, 2-fold ↑ progression-free survival
- Rapid onset of benefit, prolonged benefit (>6 months)

**Baseline**  
**Day 21 on EGFR TKI**
The challenging complexity of cancer

The complexity of the disease

There are more than 200 tumour types which can have up to 1.2M mutations\(^1\)

Example: Lung cancer

Subsets of the same type of cancer can have a variety of mutations

\(^1\) More than 200 tumour types in ~30 tumour classes; Alexandrov et al Nature 2013
Precision Medicine

33% of global oncology drug sales have an associated biomarker.
The number of precision medicines has been steadily increasing

http://www.personalizedmedicinecoalition.org/
Evolution in Personalised Healthcare (PHC)

Pre-PHC: One drug fits all

PHC Today: One patient segment, one biomarker, one drug

PHC Future: Single patient, comprehensive profile, individualised treatment

Disruptive technologies prioritised as key drivers of evolution in PHC

Deeper understanding of disease biology
New therapeutic modalities
Comprehensive diagnostics
Big data & advanced analytics
Clinical Decision Support (CDS) tools
Part 2: Best Practices, Challenges, & Opportunities
French National Cancer Institute (INCa) + French Ministry of Health established national network of 28 molecular testing centres to ensure equal access to precision medicine

- Diagnostic, predictive, prognostic, monitoring, research (benefit >15% pts)
- Equipment purchase: €4.7M
- Annual funding: €4M
- Incremental funding as needed
  - € 2.5M KRAS colon cancer 2008
  - € 1.7M EGFR lung cancer 2009
  - € 3.5M 6 genes lung cancer 2010
  - € 2.8M BRAF, KIT melanoma 2011

Rapid implementation of testing
Post publication of evidence, EMEA drug approvals
INCa-Funded National Outcomes Database, Research Network (16 phase I centres)

• 17,664 consecutive lung cancer patients had molecular testing over 12 months

• ~50% had abnormalities detected; 1st-line treatment impacted in half (23.6%)

• Improved outcomes demonstrated with precision medicine at population level

• French investigators emerged as leaders in precision medicine drug development

Getting the right *treatment* to the right *person* using the right *test* at the right *time* for the right *price* – How?
A Canadian success story – ALK immunohistochemistry

- ALK inhibitors have dramatic impact in patients with ALK-rearrangement
- FDA drug approval crizotinib 2011, Health Canada 2012
- Low frequency event (~3% non-squamous lung cancer)
- FDA approved companion diagnostic test >$500 USD
- How can we incorporate into the Canadian system?
- Protein expression ~$40/test
- Established as alternative, FDA approved 2015
Drug costs (99%) outweigh costs of testing (1%) in test-and-treat model

An example - EGFR kinase inhibitors

- 1999
  - Initial reports of clinical efficacy
- 2001-3
  - Phase I, II studies published
- 2003
  - US FDA Drug conditional approval – gefitinib
- 2004
  - Phase III study (NCIC CTG BR.21) presented (all patients)
  - EGFR mutations discovered
- 2005
  - Health Canada drug approval gefitinib
  - US FDA, Health Canada drug approval erlotinib (all patients)
- 2009
  - Phase III study published: EGFR+ patients - TKI > chemo 1st line
- 2010
  - Manufacturer funded national testing/access program
- 2013
  - International guidelines for EGFR/ALK testing published
  - 1st line EGFR TKI funding (OPDP)
- 2014
  - EGFR testing funded (CCO) 1 year later
Do we know EGFR/ALK status in time?

- Canadian *EGFR* testing program (5 centres):
  - 2104 requests of estimated 5600 (38%) in 2010
  - 1998 samples received (95%), 1771 analysed (89%)
  - 17.1% EGFR mutation rate
  - Median turn-around-time 18 days (7 to retrieve sample, 11 to perform test; SD 9.7, range 15-26 days)
14.4% of >2500 unsuccessful:
• 5.4% test failure
• 9% insufficient tissue

Shiau et al. J Thorac Oncol 2014
Many delays along the path of lung cancer diagnosis and treatment...

- **Another 14 - 28 day delay if molecular testing not ordered**
- **Up to 6 weeks if repeat biopsy required**

<table>
<thead>
<tr>
<th>Event</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time from initial symptoms to first presentation to a doctor</td>
<td>21 days</td>
</tr>
<tr>
<td>Initial presentation to last date of diagnostic testing ordered by the family physician</td>
<td>22 days</td>
</tr>
<tr>
<td>Initial presentation to first appointment with a specialist</td>
<td>27 days</td>
</tr>
<tr>
<td>Time between initial appointment with the specialist and last date of additional diagnostic testing</td>
<td>22 days</td>
</tr>
<tr>
<td>Time from referral to cancer centre to initial consultation</td>
<td>12 days</td>
</tr>
<tr>
<td>Time from initial contact with treating physician to treatment start date</td>
<td>10 days</td>
</tr>
</tbody>
</table>

**Median time from onset of symptoms to start of therapy = 138 days (4.6 months)**

Adapted from Ellis et al. JTD, 2011
Biomarker testing and timeliness of results for non-squamous NSCLC (n=175)

72% of patients with non-squamous NSCLC had biomarker testing (more female, Asian, nonsmokers)

21% of patients with biomarker testing had results available at initial consultation
### Timeliness of treatment for non-squamous NSCLC with biomarker testing (n=126)

<table>
<thead>
<tr>
<th></th>
<th>Biomarker Result Available at Initial Consultation</th>
<th>Biomarker Result Not Available at Initial Consultation</th>
<th>Total</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time from first assessment to earliest biomarker result available (days)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N</td>
<td>21</td>
<td>105</td>
<td>126</td>
<td></td>
</tr>
<tr>
<td>Median (IQR)</td>
<td>-33 (-77, -6)</td>
<td>21 (13, 43)</td>
<td>18 (8, 35)</td>
<td></td>
</tr>
<tr>
<td>Time from first assessment to treatment decision (days)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N</td>
<td>14</td>
<td>76</td>
<td>90</td>
<td></td>
</tr>
<tr>
<td>Median (IQR)</td>
<td>0 (0, 27)</td>
<td>22 (14, 38)</td>
<td>21 (9, 35)</td>
<td>0.009</td>
</tr>
<tr>
<td>Time from first assessment to treatment start (days)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N</td>
<td>13</td>
<td>70</td>
<td>83</td>
<td></td>
</tr>
<tr>
<td>Median (IQR)</td>
<td>14 (0, 27)</td>
<td>29 (21, 51)</td>
<td>28 (19, 50)</td>
<td>0.006</td>
</tr>
</tbody>
</table>

*based on Mann-Whitney test*

13% required repeat biopsy
19% of EGFR/ALK+ patients started chemotherapy before results

*Lim et al. Ann Oncol 2015*
A targeted intervention to improve awareness to molecular testing in NSCLC

Assessment
- Surveyed physician attitudes and knowledge (pathologists, thoracic surgeons, respirology, interventional radiologists, radiation oncologists)

Knowledge Translation
- Developed key messages from literature, opinion leaders about how to improve diagnostic process
- Develop CME presentations for small groups, national specialty meetings

Evaluation
- Pre/Post-intervention surveys to measure change in awareness, understanding
- Assessment of barriers, with presentation to policy makers

- 255 specialists surveyed -
  - 30% unsure regarding tissue handling techniques
  - 19% chose incorrect fixation
  - Half unfamiliar with EGFR, ALK
  - 17% uncertain of whom to test

- After the intervention specialist knowledge increased regarding:
  - tissue handling techniques (OR=3.06, p<0.0001)
  - fixation (OR=3.38, p<0.0001)
  - Uncertainty decreased from 30% to 2% (OR=0.06, p<0.001)
  - Initiate reflex testing ASAP (OR=0.26, p<0.0001)

Zer et al ASCO 2014; Lim et al Curr Oncol in press
Funded by: Cancer Care Ontario Health Services Research Program
What did we learn?

• Required molecular testing needs to be funded with treatment
• Reflex testing most efficient approach for results in time
• Incorporation into diagnostic algorithm required (guidelines, quality indicator)

• Need protocols at all levels
  – Real-time feedback on sample sufficiency for interventional radiology, respirology, thoracic surgery (e.g. onsite pathology)
  – Respirology diagnostic approach to lung cancer
  – Better clinical data, prompts on sample requisitions
  – Reflex testing and tissue sparing protocols, pathology technician education

• How to meet rising costs, demands of molecular testing?
  – More targets
  – Changing targets over time
  – More early stage cancers with screening
What are the challenges?

1. List of actionable targets growing rapidly!
2. Different types of alterations: mutations, rearrangements, copy number variations, protein expression
3. Available Tissue – 50 ng DNA, 20 x 4 μm slides
4. Repeat versus archival
5. Time (most > 2 weeks)
6. Cost
Molecular Profile Changes upon Progression (at 9 to 12 months)

**EGFR TKI acquired resistance**

- **Unknown**: 18%
- **HER2**: 8%
- **HER2 + T790M**: 4%
- **T790M**: 60%
- **MET amplification**: 3%
- **small cell + MET**: 1%
- **small cell**: 1%
- **small cell + T790M**: 2%
- **MET + T790M**: 3%

**ALK TKI acquired resistance**

- **Unknown**: 24%
- **ALK amp**: 11%
- **ALK mut**: 8%
- **No ALK amp or mut**: 34%
- **Bypass tracks**
  - **KIT, MET, EGFR**: 22%
  - **L1196M**: 7%
  - **G1269A**: 2%
  - **S1206Y**: 2%
  - **G1202R**: 2%
  - **T1151Tins**: 2%
  - **L1152R**: 2%
  - **C1156Y**: 2%
# Repeat Biopsy vs. Archival Tissue Requirements

<table>
<thead>
<tr>
<th></th>
<th>6 Trials - mandatory repeat biopsy [87 Consents]</th>
<th>31 Trials - repeat biopsy not required [360 Consents]</th>
<th>Total</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Proportion of patients proceeding to study treatment</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>33 (38%)</td>
<td>211 (59%)</td>
<td>244 (55%)</td>
<td>0.0007</td>
</tr>
<tr>
<td>No</td>
<td>54 (62%)</td>
<td>149 (41%)</td>
<td>203 (45%)</td>
<td></td>
</tr>
<tr>
<td><strong>Time from consent to repeat biopsy</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N</td>
<td>68</td>
<td>59</td>
<td>127</td>
<td>0.02</td>
</tr>
<tr>
<td>Median (IQR)</td>
<td>21 days (12-29)</td>
<td>16 days (8-23)</td>
<td>18 days (11-27)</td>
<td></td>
</tr>
<tr>
<td><strong>Time from consent to study treatment</strong></td>
<td></td>
<td></td>
<td></td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>N</td>
<td>33</td>
<td>211</td>
<td>244</td>
<td></td>
</tr>
<tr>
<td>Median (IQR)</td>
<td>54 days (46-69)</td>
<td>14 days (6-25)</td>
<td>16 days (7-33)</td>
<td></td>
</tr>
</tbody>
</table>

~25% deteriorated or died, did not start therapy
Half of these had the target biomarker

*Lim et al. J Thorac Oncol 2015*
Repeat Biopsies – is there a better way?

Quantitative PCR
Sanger sequencing
Pyrosequencing
ARMS
TAM-Seq
PNA clamp
Emulsion PCR (dd)
BEAMing
NGS

Blood sample
Serum/Plasma
Buffy coat

Circulating Free Plasma DNA

Panel of biomarkers

Nucleic acid
ECM
Lipids
PBMC
Endothelial cells
Stem cells
CTC
Resistant T790M cfDNA plasma-genotyping: an alternative to tissue testing in TKI-resistant NSCLC

- Preliminary Assessment of Clinical Response Rates to AZD9291 as a Function of the EGFR T790M Mutation
- Similar RR in either tissue or plasma

<table>
<thead>
<tr>
<th>Tissue</th>
<th>Plasma</th>
</tr>
</thead>
<tbody>
<tr>
<td>T790M+</td>
<td>T790M-</td>
</tr>
<tr>
<td>RR</td>
<td>62% (26/42)</td>
</tr>
<tr>
<td>DCR</td>
<td>95% (40/42)</td>
</tr>
</tbody>
</table>

* Blood assessment BEAMing (Sysmex)

- ORR to Rociletinib for 188 Evaluable Patients With Both Central T790M Tissue Test Result and Plasma T790M
- Similar ORR observed when detecting T790M in either tissue or plasma (ORR 53%)
- Not all patients with progression on first-line TKI are candidates for tissue re-biopsy

CCT790M (peripheral blood circulating DNA for EGFR T790M)

Participating Laboratory Centres (n=4)

- Vancouver: BCCA
- Edmonton: CCI
- Toronto: UHN
- Montreal: McGill

Adapted from Dr. MS Tsao
Between the evidence, the drug approval and provincial funding...

- Clinical trials (including phase IV)
- Expanded access, compassionate programs
  - Patient assistance programs
  - Self pay
Trials in Selected Genomic Subgroups

clinicaltrials.gov, accessed Feb 10, 2017
Precision Medicine – Drug Approvals no longer based on large phase III trials

<table>
<thead>
<tr>
<th>RCTs</th>
<th>EGFR mt IPASS 1L</th>
<th>EGFR T790M AURA3 2L</th>
<th>ALK+ 1014 1L</th>
<th>PDL-1≥50% KN024 1L</th>
<th>ROS1+ phase I (EUROS1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>RR (%)</td>
<td>71% v 47%</td>
<td>65% v 34%</td>
<td>74% v 45%</td>
<td>45% v 28%</td>
<td>72% (80%)</td>
</tr>
<tr>
<td>Median PFS (m)</td>
<td>9 months</td>
<td>10.1 months</td>
<td>10.9 months</td>
<td>10.3 months</td>
<td>19.2 months (9.1 mos)</td>
</tr>
<tr>
<td>HR PFS</td>
<td>0.48 P&lt;0.01</td>
<td>0.30 P&lt;0.01</td>
<td>0.48 P&lt;0.01</td>
<td>0.50 P&lt;0.01</td>
<td></td>
</tr>
<tr>
<td>QoL, toxicity</td>
<td>Better QoL Less toxic</td>
<td>Less toxic</td>
<td>Better QoL Less toxic</td>
<td>Less toxic</td>
<td></td>
</tr>
<tr>
<td>HR OS</td>
<td>NS (&gt;60% crossover)</td>
<td>N/A</td>
<td>NS (&gt;70% crossover)</td>
<td>0.60 P&lt;0.01</td>
<td></td>
</tr>
</tbody>
</table>

Mok et al NEJM 2008; Mok et al NEJM 2016; Solomon et al NEJM 2014; Reck et al 2016; Shaw et al NEJM 2013
Dabrafenib (BRAF Inh) And Trametinib (MEK Inh) In BRAFV600E-mutant Advanced NSCLC: BRF113928

Stage IV NSCLC
BRAF V600E
ECOG 0-2
Second line

Cohort A (D monotherapy)
\( n = 60 \)

- ORR 32%, DCR 56%
- Median DoR 9.6 mo.

Cohort B (combination D+T)
\( n = 40/59 \)

- ORR 63%, DCR 88%
- Responses lasting > 6 mo. observed

* Cohort C with D + T in previously untreated V600E NSCLC

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* Planchard et al. Lancet Oncol 2016; ASCO 2015 (abstr 8006)
Part 3: Recommendations
National Network

• System funding of:
  – Molecular testing
  – Outcomes databases
  – Support for trials (e.g. Canadian Cancer Trials Group)

• Ensure testing funded at time of treatment funding

• Develop a comprehensive approach to testing, rather than gene by gene or site limited focus
Q&A
# Molecular Testing – Beyond EGFR and ALK

NCCN now recommends testing for **BRAF, HER2, MET amplification, ROS1, RET rearrangements, MET exon 14 skipping mutations, PDL-1 (22C3)**

<table>
<thead>
<tr>
<th>Province</th>
<th>A few more genomic targets</th>
</tr>
</thead>
<tbody>
<tr>
<td>BC</td>
<td>✗ 25 gene panel</td>
</tr>
<tr>
<td>Alberta</td>
<td>25 gene panel</td>
</tr>
<tr>
<td>Quebec</td>
<td>✗ BRAF, KRAS</td>
</tr>
<tr>
<td>New Brunswick</td>
<td>✗ HER2, BRAF, MET, KRAS, NGS</td>
</tr>
<tr>
<td>NFLD</td>
<td></td>
</tr>
<tr>
<td>PEI</td>
<td></td>
</tr>
<tr>
<td>Nova Scotia</td>
<td>✗ HER2, BRAF, MET, KRAS, NGS</td>
</tr>
</tbody>
</table>

Sources: Drs. J. Agulnik (JGH), A. Robinson (KGH), Z. Xu (QE2), A. Karsan (BCCA), G. Bebb (TBCC), J.C. Cutz (McMaster), V. Chong (Merck)
<table>
<thead>
<tr>
<th>DRUG Generic name (brand name)</th>
<th>INDICATION</th>
<th>FDA APPROVAL DATE</th>
<th>ADDITIONAL DAYS UNTIL HEALTH CANADA APPROVAL DATE</th>
</tr>
</thead>
<tbody>
<tr>
<td>afatinib (Giotrif)</td>
<td>First-line, EGFR+, ECOG 0-1</td>
<td>July 12, 2013(^{35})</td>
<td>112(^{36})</td>
</tr>
<tr>
<td>crizotinib (Xalkori)</td>
<td>Second-line, ALK+, ECOG 0-2, with one prior chemotherapy treatment</td>
<td>August 26, 2011(^{37})</td>
<td>243(^{38})</td>
</tr>
<tr>
<td>crizotinib (Xalkori)</td>
<td>First-line, ALK+, ECOG 0-2</td>
<td>August 26, 2011(^{39})</td>
<td>243(^{40})</td>
</tr>
<tr>
<td>ceritinib (Zykadia)</td>
<td>ALK+, progressed on or intolerant to crizotinib</td>
<td>April 29, 2014(^{41})</td>
<td>332(^{42})</td>
</tr>
<tr>
<td>nivolumab (Opdivo)</td>
<td>Disease progression on or after cytotoxic chemotherapy and good performance status</td>
<td>March 4, 2015(^{43})</td>
<td>359(^{44})</td>
</tr>
<tr>
<td>osimertinib (Tagrisso)</td>
<td>EGFR T790M mutation +, who have progressed on or after EGFR TKI therapy</td>
<td>November 13, 2015(^{45})</td>
<td>235(^{46})</td>
</tr>
<tr>
<td>pemetrexed (Alimta)</td>
<td>Maintenance following first-line pemetrexed and cisplatin</td>
<td>July 2, 2009(^{47})</td>
<td>313</td>
</tr>
<tr>
<td>pembrolizumab (Keytruda)</td>
<td>Tumours express PD-L1, had disease progression on or after platinum-containing chemotherapy</td>
<td>October, 2015</td>
<td>~300</td>
</tr>
</tbody>
</table>

Osimertinib  
\textbf{EGFR T790M+ post initial TKI failure}  
Nov 13, 2015  
\~240

Alectinib  
\textbf{ALK+ post crizotinib failure}  
Dec 11, 2015  
290

Crizotinib  
\textbf{ROS1+}  
March, 2016  
Pending

- Canada slower than US in targeted therapy approvals (median 13 v 6.7 months)

\textit{Ezeife et al Cancer 2015; adapted from Lung Cancer Canada 2016}
Ref: Gagan and Van Allen Genome Medicine (2015) 7:80
Ongoing Genomics Research

- POG study (WGS, 5000 patients, funding for 500)
- OncoPanel/HemePanel
- Roche-supported

- National pilot involving 1500 patients (28 gene panel)
- Partnership with NCIC
- Industry-supported (AZ, Pfizer, Sanofi)

- GAPP recipient ($6M)
- national initiative
- “Cloud-based genome analysis infrastructure and shared interfaces”

- COMPACT/IMPACT studies
- 500+ gene panel

- Personalize My Treatment (40 gene panel)
- Industry-supported (Roche, Bayer, Merck, Novartis, Pfizer)

* Not licensed for sale in Canada.