HGPI Health and Global Policy Institute

Policy Recommendations: Improving Patient Access to Genomic Cancer Medicine
Summary Report

August 2023

Health and Global Policy Institute

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Improving Patient Access to Genomic Cancer Medicine

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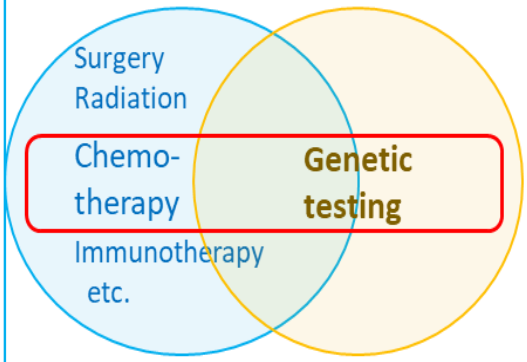
Genomic Cancer Medicine

Cancer medicine × Genomic medicine



(a) Test

Comprehensive Genomic Profiling (CGP)

(b) Examine

Expert Panel (EP) : Recommend treatment

(c) Prescribe

Molecularly-targeted drugs: Prescribe drugs that effectively target specific genetic mutations, etc.

Policy Issues

Issues on Patient Access

A: Medical human resources constraints

- EP workloads
- Too few Certified Genetic Counselors, etc.
- Reimbursements insufficient for workloads/ expenses

B: Genetic testing constraints

- Constraints on the timing of CGP
- Constraints on the frequency of CGP

C: Geographic/information constraints

- Few centers have the capacity for appropriate specimen collection
- Lack of real-time information on clinical trials
- Geographic constraints to clinical trial access

Delays in R&D/regulatory approval

Discrimination based on genetic information

No guidelines on handling genetic information

Insufficient patient/citizen literacy

Three Recommendations

I: Streamline operations and secure human resources

(1) Greatly refine scope of cases reviewed at EPs
(2) Implement online genetic counseling
(3) Review reimbursements

II: Review genetic testing practices

(1) Make CGP reimbursement rules more flexible
(2) Create testing algorithms for each type of cancer
(3) Disseminate genetic tests for which the number of genes tested has been narrowed down

III: Improve patient access to testing centers and clinical trials

(1) Expand testing opportunities (including liquid biopsies)
(2) Simplify access during preparatory stages of clinical trials
(3) Disseminate low-cost decentralized clinical trials (DCTs)

- Create basic plans based on "Genomic Medicine Promotion Act" (approved June 2023)
- Implement the Fourth-term Basic Plan to Promote Cancer Control Programs (March 2023), etc.

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RECOMMENDATION I: Streamline operations and secure human resources

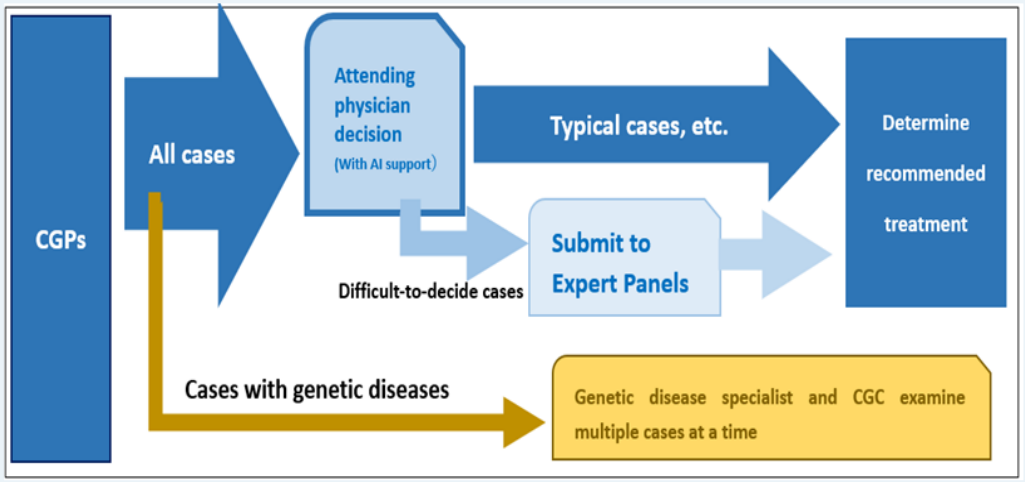
In view of the further spread of genomic cancer medicine, streamline operations thoroughly and adopt systems to secure human resources commensurate with workloads.

(1) Refine the scope of cases reviewed at Expert Panels

[Issue] Requiring EPs to review all cases results in massive workloads

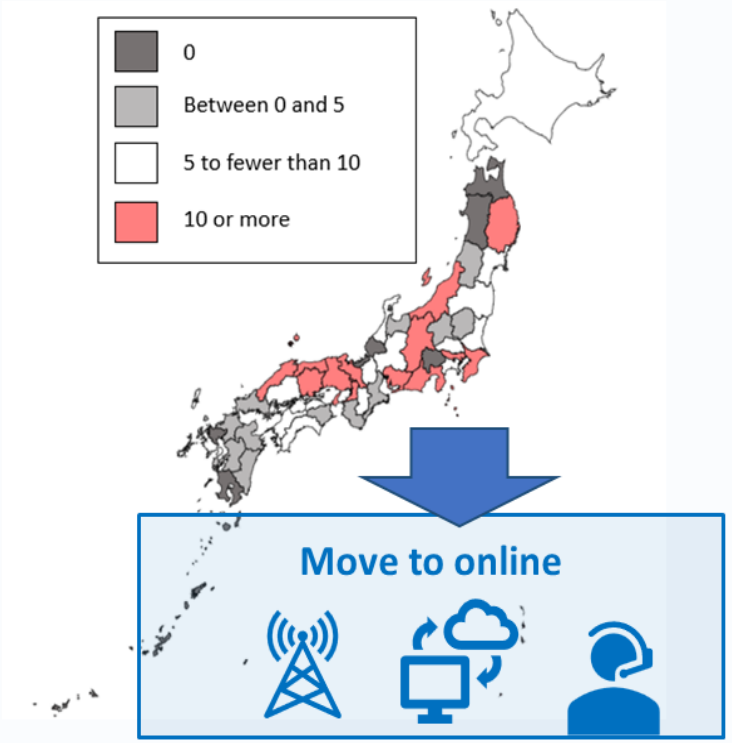
Narrow down cases reviewed

1) As a general rule, attending physicians determine treatment strategies
2) Difficult-to-decide cases should then be referred to EPs
3) Genetic diseases should be reviewed in batches by specialists



(2) Implement online genetic counseling

[Issue] Lack of Certified Genetic Counselors (CGCs) and their uneven distribution



(3) Review reimbursements

Service fees sufficient for workloads

Recommendation II: Review genetic testing practices including how tests are performed

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RECOMMENDATION II: Review genetic testing practices including how tests are performed

Based on the accumulated clinical experiences, revise the genetic tests and related practices to meet the needs of those serving in clinical settings, and to suit the characteristics of each type of cancer.

(1) Make CGP reimbursement rules more flexible

1) Take cancer types and patients' conditions into consideration
2) Review rules from medical, clinical, and health economics perspectives

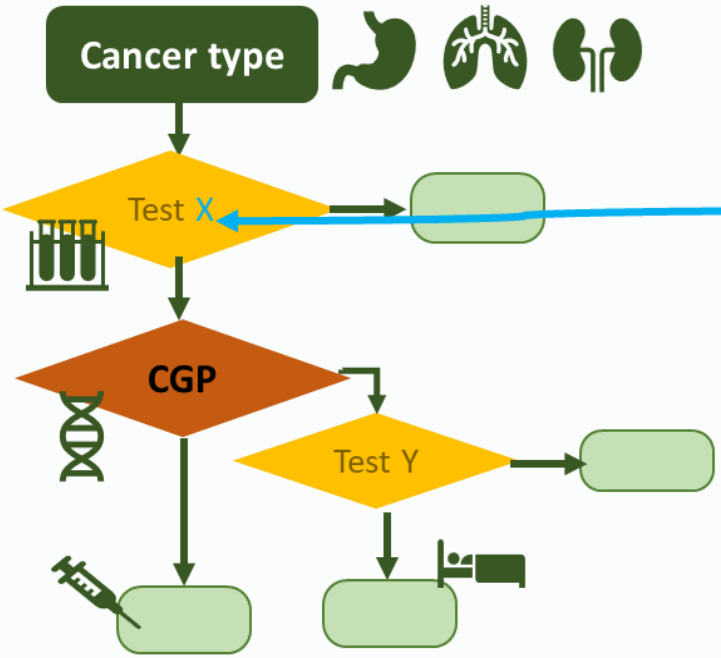
a) Timing of CGP
General rule: "After standard treatments have been completed"
=> make it more flexible

b) Frequency of CGP
"One CGP per lifetime"
=> allow multiple tests

c) CGP testing methods
Liquid biopsies
=>utilize them more actively

(2) Create testing algorithms for each type of cancer

1) With the initiative from each academic society
2) Review algorithms from medical, clinical, and health economics perspectives



(3) Disseminate genetic tests for which the number of genes tested has been narrowed down (as compared to CGP)

Diagnostics that can test for multiple driver gene mutations* (multi-CDx) are also recommended.**

* Genes mutations, etc. that drive cancer progression

**Companion diagnostics (CDx) are tests using diagnostics that are paired with one or more molecular-targeted drugs

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RECOMMENDATION III: Improve patient access to testing centers and clinical trials

Make drastic improvements to patient access to testing centers and clinical trials, while paying attention to the constraints and disparities related to geographic factors/information.

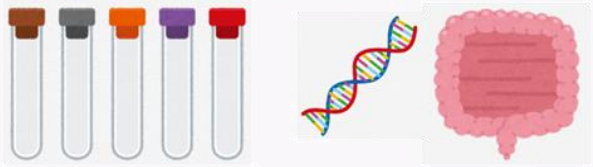
(1) Expand testing opportunities (including liquid biopsies)

[Issue] Too few sites that can conduct appropriate specimen collection

1) Expand sites for CGP specimen collection

- Include core hospitals for coordinated cancer care, etc.

2) Make proactive use of liquid biopsies (for gastrointestinal cancers, etc.)



(2) Simplify access during the preparatory stages of clinical trials

[Issues] Lack of real-time clinical trial information
Patient burdens associated with clinical trial screening

1) Revise C-CAT reports

- Make information closer to real-time
- Include clinical trial contact information for inquires

2) Expand sites where screenings are performed

- Include satellite facilities (family doctor facilities)

(3) Disseminate low-cost decentralized clinical trials (DCTs)

[Issue] Geographic constraints to clinical trial access

Disseminate DCTs that can be conducted with simple systems and small budgets