Policy Recommendations: Furthering the Development of Precision Cancer Medicine

—Proposals for Effective Policy Changes Based on Key Characteristics of Precision Medicine in Cancer Treatment—

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Policy Issues in Various Areas

A. Healthcare Provision System
- Disparities in Medical Care Access
- Human Resource Shortages
- Expert Panel Shortages

B: Scope of Health Insurance Coverage
- Companion Diagnostics (Number of Tests)
- Cancer Gene Panel Tests (Timing of Testing)
- Cancer Genome Medicine (Timing of Treatment)

C :Research & Developments
- Lack of Coordination in R&Ds
- Delay in:
  - Database Building
  - Feedback to Patients and Public

D:Regulatory Approval
- Rigid Operation of:
  - Evidence Accreditation
  - Pharmaceutical Approvals

E: Ethical, Legal and Social Issues (ELSI)
- Social Discrimination
- Psychological Burden on Patients

F :Patient and Public Involvement (PPI)
- Difficulty in Managing Patient Groups
- Delay in Patient Involvement

Key Characteristics of Precision Cancer Medicine

(a)Limited Medical Indications
- Shortages of Specialists/Facilities
- Limited Number of Clinical Trials
- Difficulties in:
  - Evidence Accreditation
  - Managing Patient Groups

(b)Use of Genetic Information
- Delay in Database Building
- Risk of Social Discrimination

(c) High Cost In Testing/Treatment
- Rigid Operation of:
  - Regulatory Approvals
  - Pharmaceutical Approvals

Policy Issues Shared Among Cancer Medicine
- Disparities in Medical Care Access
- Psychological Burden on Patients
- Delay in Patient Involvement

Three Recommendations

Recommendation I : Aggregate Medical/Human Resources
- (1)Develop “Hub-and-spokes” Network Across All Areas
- (2) Utilize Information and Communication Technology (ICT) , including the use of online services

Recommendation II : Properly Manage Genetic Information
- (1) Maintain Data on Genetic Information
- (2) Legislate a Genetic Nondiscrimination Act and Raise Public Awareness

Recommendation III : Review from Economic/Scientific Perspective
- (1) Relax Insurance Coverage Conditions (ex. Diagnostic Pharmaceutical, Genetic Counseling)
- (2) Review Pharmaceutical Approvals (ex. Prior Approval of Therapeutics)

Manage within the Context of Cancer Medicine as a Whole

- Improve Access to Medical Care Delivery
- Reduce Psychological Burden on Patients
- Promote Patient Involvement in Guideline Development etc.

Definition

Precision Cancer Medicine (Commonly used in clinical settings of lung/breast cancer)	Test conducted to detect mutations in one or multiple genes (Companion diagnostic testing)	→ Treatment tailored to mutated sections of genes of individuals (Molecularly targeted drugs)
Genomic Cancer Medicine (Part of Precision Cancer Medicine)	Test conducted to detect mutations in many genes (Genomic Cancer Testing or Profiling)	→ Advanced treatments/Clinical Trials (No standard cancer treatment) (Certain tests covered by insurance)

《Key Points of Three Recommendations》

Recommendation I：Aggregate Medical/Human Resources

Develop "Hub-and Spokes" Network	To effectively utilize human resources of specialists, and to close the access gap, (a) aggregate the clinical knowledge and skills to central/core cancer hospitals for genomic cancer treatment ("Hub"), and (b) work with other partnering hospitals ("Spokes") to provide quality-assured care to patients living in rural areas, while utilizing the use of online services.
Eliminate Expert Panel Shortages	In the case that an expert panel is required, consider relaxing requirements (e.g. introducing AI or other software algorithms).
Improve Access to Clinical Trials	Promote DCT (Decentralized Clinical Trial) so that even patients living in rural areas can participate in clinical trials conducted only at the center/core hospitals, while continuing treatment at other partnering hospitals.

Recommendation II：Properly Manage Genetic Information

Establish Databases	Establish database system and laws for data management that can be easily utilized by industry, academia, and government, such as (a) by building a "whole genome sequence database" and (b) by integrating multiple registry data owned by academic societies.
Return Research Results	Establish a feedback system for the return and dissemination of research results to patients and the public.
Correct Social Discrimination	Legislate a genetic nondiscrimination act, and raise public awareness for a wide range of generations, including in school education.

Recommendation III：Review from Economic/Scientific Perspective

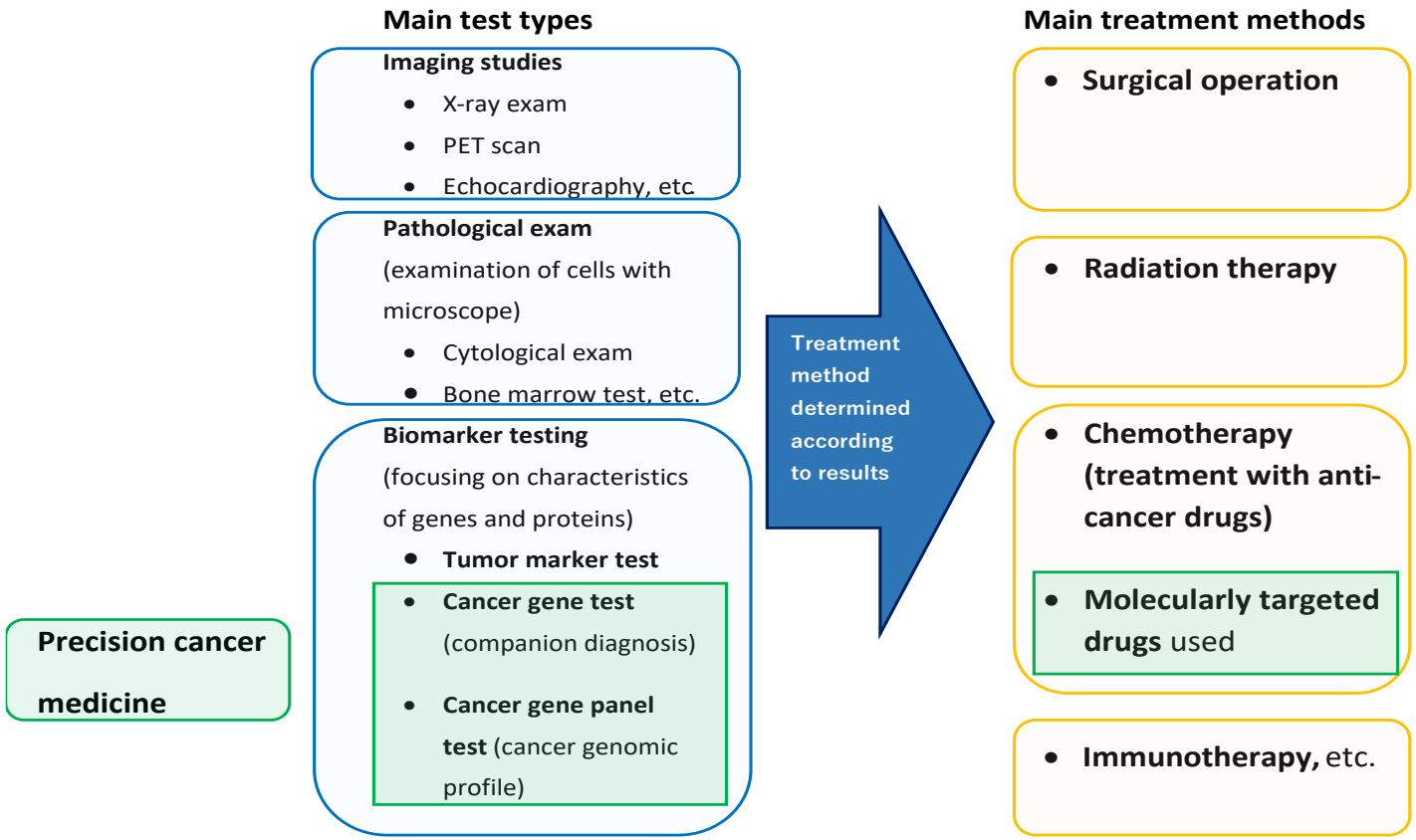
Number of Tests	Review the limitations of insurance coverage as to the number of tests using companion diagnostics and liquid biopsies, etc.
Timing of Tests/Treatment	Review the restrictions on insurance coverage of cancer gene panel tests and cancer genome therapies so that they can be performed even before completion of standard cancer treatment.
Genetic Counseling	Make genetic counseling, which should be provided in combination with genetic testing, covered by insurance, including online medical care
Diagnostic Pharmaceutical	Operate the approval processes in a more flexible manner, e.g. allow prior approval under the temporary provision of alternate tests for CDx (e.g. tests in clinical trials).

Appendix: Defining Precision Cancer Medicine

While the definition of precision cancer medicine can vary depending on the source, in this document, we use it to refer to all tests and treatments that focus on the mutated sections of genes to provide the optimal drugs for those mutations.

In practice, definitive cancer diagnoses are usually reached by using a combination of multiple testing methods, such as those listed in the right table. For example, imaging studies may be combined with pathological examinations.

There are cases in which cancer gene tests or other such tests are conducted but molecularly targeted drugs or similar treatments are not selected. We include such cases within the scope of "precision cancer medicine," since the testing phase focuses on genetic mutations.



(Note 1) Cancer gene testing (companion diagnostic testing)
To determine if a certain drug (namely, a molecularly targeted drug) will be effective for the cancer of the patient in question, a single test is conducted to detect mutations in one or multiple genes. As a general rule, these tests involve the use of diagnostic agents called companion diagnostics, or CDx.

(Note 2) Gene panel testing (genomic cancer testing or profiling)
These procedures use a single test to detect the presence or absence of mutations in many genes, usually over 100. In general, there is no standard treatment for the results based on this test, and the therapeutic agents and policies are determined by the judgment of specialists.