第5回　ゲノム医療等実用化推進TF	藤原委員資料
平成28年2月18日	

国民皆保険制度下でのゲノム情報に基づく診療の実施

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国民皆保険制度下でゲノム情報に基づく診療の実施は可能か？

・米国内の検査所で検査を実施しており、検査品質管理・保証については米国国内法令で担保されている遺伝子検査/網羅的遺伝子検査に対して保険償還は可能なのか？
海外で検査は実施され、結果だけ日本に戻す場合に、保険償還を認めるのか？

・薬機法のプログラム医療機器として承認するというが、日本以外の欧米先進国で既に保険償還されて日常診療に用いられている遺伝子診断を、今から国内開発せよというのか？
日本の薬価が海外に比べて安い現状で、海外体外診断薬メーカーは薬事申請せず、自由診療での検査で検査キット・検査がされることを望むのではないか？　IVDの先発品と後発品に時間差が少ないことも企業の開発マインドにマイナス。
　　→　IVDラグ、コンパニオン診断薬ラグが発生している。

・がん患者における遺伝子診断の日常診療への導入の遅れ（D026）:
現行の保険制度では、がん患者とその家族に対する遺伝子カウンセリングは保険償還をみとめられていない。 ただし、がん患者やその家族に対応できる認定遺伝カウンセラーや臨床遺伝専門医、家族性腫瘍コーディネーターは未だ人材不足。

・薬機法承認と保険償還の齟齬の存在（D006－4、D004－2）:
平成28年春の診療報酬改定で保険償還の決まった、あるいは既に保険収載されている各種遺伝子検査/遺伝学的検査の多くについて、薬機法で承認された体外診断薬（IVD）が存在しない。一方で、公的な検査品質保証がなされていない各アカデミア独自に行っている検査（LDT）については保険償還されている実態:　希少疾患については良い仕組みだと思うが。

In Vitro Companion Diagnostic Devices

Guidance for Industry and Food and Drug Administration Staff

Document issued on: August 6, 2014

The draft of this document was issued on July 14, 2011.

For questions regarding this document that relate to CDRH contact Elizabeth Mansfield, at 301-796-4664, or elizabeth.mansfield@fda.hhs.gov; for questions for CBER contact Office of Communication, Outreach and Development (OCOD) at 240-402-7800 or 1-800-835-4709, or ocod@fda.hhs.gov. For questions for CDER, contact Christopher Leptak at 301-796-0017, or christopher.leptak@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research
Center for Drug Evaluation and Research

Contains Nonbinding Recommendations
Draft - Not for Implementation

Draft Guidance for Industry, Food and Drug Administration Staff, and Clinical Laboratories

Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.
Document issued on: October 3, 2014

You should submit comments and suggestions regarding this draft document within 120 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.regulations.gov. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this document, contact LDTframework@fda.hhs.gov. For questions regarding this document as applied to devices regulated by CBER, contact the Office of Communication, Outreach and Development in CBER at 1-800-835-4709 or 240-402-7800 or ocod@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Office of In Vitro Diagnostics and Radiological Health

Center for Biologics Evaluation and Research

IVD (in vitro diagnostic) devices
<u>LDT (laboratory developed test),</u> IVD used within a single laboratory
<u>IVD companion diagnostic device</u>, provide information that is essential for the safe and effective use of a corresponding therapeutic product.

Draft Guidance for Industry, Clinical Laboratories, and FDA Staff

In Vitro Diagnostic Multivariate Index Assays

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.
Document issued on: July 26, 2007

Comments and suggestions regarding this draft document should be submitted within 30 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit written comments to the Division of Dockets Management (HFA-305)

流動的な要素も

2009年のオバマ政権になってから
ゲノム医療関連のコンパニオン診断に関係する
FDAガイドラインは案のまま・・・

Center for Biologic Evaluation and Research

Preface

Gene expression profiling and expanded immunohistochemistry tests for guiding adjuvant chemotherapy decisions in early breast cancer management: MammaPrint, Oncotype DX, IHC4 and Mammostrat

Issued: September 2013

NICE diagnostics guidance 10

www.nice.org.uk/dg10

1 Recommendations

1.1 Oncotype DX is recommended as an option for guiding adjuvant chemotherapy decisions for people with oestrogen receptor positive (ER+), lymph node negative (LN−) and human epidermal growth factor receptor 2 negative (HER2−) early breast cancer if:

- the person is assessed as being at intermediate risk **and**
- information on the biological features of the cancer provided by Oncotype DX is likely to help in predicting the course of the disease and would therefore help when making the decision about prescribing chemotherapy **and**
- the manufacturer provides Oncotype DX to NHS organisations according to the confidential arrangement agreed with NICE.

1.2 NICE encourages further data collection on the use of Oncotype DX in the NHS (see section 7).

1.3 MammaPrint, IHC4 and Mammostrat are only recommended for use in research in people with ER+, LN− and HER2− early breast cancer, to collect evidence about potentially important clinical outcomes and to determine the ability of the tests to predict the benefit of chemotherapy (see section 7). The tests are not recommended for general use in these people because of uncertainty about their overall clinical benefit and consequently their cost effectiveness.

フランスでは2006年から国立がん研究所の傘下で、全国28か所に、大学等の検査部門で悪性腫瘍遺伝子診断センターを整備

（2016年までに全28医学検査部門に ISO15189 取得を義務づけ）

Table 3 | Molecular tests performed in France in 2011 by the 28 molecular genetics centres

Biomarker	Cancer	Clinical indication or ap
Predictive		
BCR–ABL translocation	Chronic myeloid or acute lymphoblastic leukaemia	Prescription of imatinib, da
ABL mutation	Chronic myeloid	
KIT and *PDGFRA* mutations	Gastrointes	
HER2 amplification	Breast can	
HER2 amplification	Gastric car	
KRAS mutations	Metastatic	
EGFR mutations	Lung cance	
Diagnostic		
JAK2 V617F mutation	Suspected	
Microsatellite instability	HNPCC spe	
Specific chromosomal abnormalities	Sarcomas	
Specific chromosomal abnormalities	Non-Hodgk	
Specific chromosomal abnormalities	Haemopath	
1p/19q co-deletion	Brain tumo	
B-cell or T-cell clonality	Non-Hodgk	
Prognostic		
MYCN amplification	Neuroblastom	
FLT3 and *NPM* mutations	Acute myeloid leukaemia	Contributes to treatment guidance
Specific chromosomal abnormalities	Haemopathies	Contributes to treatment guidance
BCR–ABL transcript level of expression	Chronic myeloid or acute lymphoblastic leukaemia	Monitoring of minimal residual disease

Abbreviation: HNPCC, hereditary nonpolyposis colorectal cancer.

わが国ではこのISO取得に、初年度　費用概算680万円以降、年間維持費100万～200万円（除く人件費）

Nat Rev Clin Oncol 9:479-486, 2012