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MOH Circular No. 100/2021

29 July 2021

All Registered Medical Practitioners

All Private Hospitals and Medical Clinics Act (PHMCA) Licensed Clinical Laboratories

All Research Institutions Notified under the Human Biomedical Research Act (HBRA)

### MORATORIUM ON GENETIC TESTING AND INSURANCE

The Ministry of Health (MOH) and the Life Insurance Association (LIA) have developed a 'Moratorium on Genetic Testing and Insurance' to support Precision Medicine (PM) in Singapore. The Moratorium aims to prevent individuals from being deterred to undergo clinical genetic tests for any medical indications and/or participating in PM research due to concerns about insurability. Under Phase 1 of the Moratorium, it bans the use of all genetic test results from biomedical research<sup>1</sup> in insurance underwriting, which has been rolled out since 27 January 2021.

2 Under Phase 2 of the Moratorium, MOH will further introduce controls on the use of predictive genetic test<sup>2</sup> results from clinical care in insurance underwriting, with effect from **27 October 2021**. This circular provides details on this phase of the Moratorium, which should be read in conjunction with MOH Circular No. 08/2021, 'Moratorium on Genetic Testing and Insurance: Ban on the Use of Genetic Test Results from Biomedical Research in Insurance Underwriting' (**Annex A**).

# Controls on the use of predictive genetic test results from clinical care in insurance underwriting

The use of predictive genetic test results from clinical care in insurance underwriting will be subject to a 'double key' model. The 'double key' refers to the following two conditions specified in the Moratorium: (a) the sum assured/pay-out is above the financial limits; and (b) the applicant has taken a predictive genetic test for an approved genetic disease. This means that insurers are restricted to only request the disclosure of and/or use predictive genetic test results with strong scientific evidence to underwrite five financial products for high value insurance contracts (see paragraph 4(d) for more details). This will protect

<sup>&</sup>lt;sup>2</sup> Predictive genetic tests predict a future risk of disease in individuals without symptoms or signs of a genetic disorder (i.e. testing in asymptomatic individuals).











<sup>&</sup>lt;sup>1</sup> In the Moratorium, biomedical research refers to any systematic investigation with the intention of developing or contributing to generalisable knowledge.

consumers in Singapore from genetic discrimination in insurance, while allowing insurers to manage the financial sustainability of the insurance market. The use of **diagnostic** genetic test<sup>3</sup> results in clinical care is left to the discretion of individual insurers, similar to other diagnostic test results, such as a mammogram and biopsy diagnosing breast cancer.

- 4 The key protections of the Moratorium are detailed as follows:
  - (a) Insurers are **not** allowed to require applicants to undertake a genetic test (whether diagnostic or predictive) to obtain insurance coverage.
  - (b) Insurers are **not** allowed to request the disclosure of and/or use the result of any genetic test for the purpose of underwriting any insurance, if the genetic test was conducted in the context of biomedical research, regardless of where or when the research was conducted or the nature of the research (see **Annex A** for details).
  - (c) Insurers are **not** allowed to request the disclosure of and/or use predictive genetic test results from any individuals or medical providers for the purpose of underwriting:
    - (i) Health insurance<sup>4</sup>, Integrated Shield Plan<sup>5</sup>, general insurance, group insurance and any other insurance not covered by the Moratorium:
    - (ii) If the genetic test was a Direct-to-Consumer (DTC) genetic test<sup>6</sup>;
    - (iii) If the genetic test result is from another person such as a blood relative of the applicant; and
    - (iv) If the genetic test was taken after the insurance coverage has started (unless the applicant consented to take the test before the coverage started).
  - (d) Insurers are only allowed to request the disclosure of and/or use predictive genetic test results to underwrite financial products: (a) life, (b) total permanent disability, (c) long-term care, (d) critical illness and

<sup>&</sup>lt;sup>6</sup> DTC genetic test refers to a genetic test that is provided directly to consumers by the manufacturer or supplier of the test.











<sup>&</sup>lt;sup>3</sup> Diagnostic genetic tests confirm or rule out a diagnosis based on existing symptoms, signs or abnormal non-genetic test results which indicate that the condition in question may be present (i.e. testing in symptomatic individuals).

<sup>&</sup>lt;sup>4</sup> Health insurance provides benefits for daily cash limits or for medical costs resulting from accidents or illness. It is also known as medical expense insurance, hospital and surgical insurance, or hospital income plan.

<sup>&</sup>lt;sup>5</sup> Integrated shield plan provides higher coverage than MediShield Life and comprises two parts, namely, the basic MediShield Life and an additional private insurance portion run by private insurers.

- **(e) disability income insurances** (detailed in Table 1, **Annex B**) if **both** the following conditions<sup>7</sup> are met:
- (i) The sum assured/pay-out exceeds the financial limits specified in the Moratorium; and
- (ii) The applicant has taken a predictive genetic test from the list of approved predictive genetic tests specified in the Moratorium for medical conditions such as Huntington's disease and breast cancer (see Table 1, **Annex B**).
- (e) Insurers are allowed to use the result of any diagnostic genetic test, similar to other diagnostic test results, to inform their decision about an insurance application.
- As Phase 2 of the Moratorium will be rolled out from **27 October 2021**, medical practitioners, clinical laboratories, and research institutions are strongly encouraged to make any necessary changes to their current processes (such as including information on the controls of the Moratorium within the relevant consent forms, where appropriate) during this three-month sunrise period.
- We seek your cooperation in ensuring that the information in this circular is only shared with relevant individuals who need to be involved to support its implementation.
- 7 Should you require further clarification, please email us at <a href="mailto:eLIS@moh.gov.sg">eLIS@moh.gov.sg</a>.

Thank you.

Yours faithfully,

A/PROF KENNETH MAK
DIRECTOR OF MEDICAL SERVICES
MINISTRY OF HEALTH

<sup>&</sup>lt;sup>7</sup> The 'double key' model is only applicable to Singapore residents. For non-residents, the use of predictive genetic test results in insurance underwriting for the aforementioned five products is left to the insurer's discretion.











### Annex A

MOH Circular No. 08/2021, 'Moratorium on Genetic Testing and Insurance: Ban on the Use of Genetic Test Results from Biomedical Research in Insurance Underwriting', dated 27 January 2021













<u>Table 1: 'Double key' model: Financial Limits and List of Approved Predictive</u> <u>Genetic Tests – for Singapore residents<sup>1</sup> only<sup>2</sup></u>

Financial product	Description	Key #1: Financial limits	Key #2: Approved predictive genetic tests <sup>3</sup> (medical condition/gene)
Life Insurance	Provides financial protection against the financial loss that can happen due to the insured's <b>death</b> .	S\$2,000,000 sum assured	
Total Permanent Disability Insurance	Provides financial protection against the financial loss of the insured when he or she is found to be permanently disabled.	S\$2,000,000 sum assured	Huntington's
Long-Term Care Insurance (Policies that pay out if individual is unable to perform 2 Activities of Daily Living (ADLs) <sup>4</sup> and above for 6 months)	Helps to meet some or all of the costs of daily living of the insured who, as a result of an accident or illness, is unable to perform a specified number of ADLs.	S\$3,000 per month	disease (HTT)

<sup>&</sup>lt;sup>1</sup> This includes Singapore citizens, Singapore permanent residents, Singapore residents with a Singapore work pass or permit (totalling 183 days or more in the 12 months before the insurance application date) and Singapore residents with a Singapore pass or permit (totalling 90 days or more in the 12 months before the insurance application date).

<sup>&</sup>lt;sup>4</sup> ADLs refer to a set of activities such as bathing or washing, dressing, feeding, transferring, mobility and toileting.











<sup>&</sup>lt;sup>2</sup> The 'double key' model is only applicable to Singapore residents. For non-residents, the use of predictive genetic test results in insurance underwriting for the aforementioned five products is left to the insurer's discretion.

<sup>&</sup>lt;sup>3</sup> The list of approved predictive genetic tests, drawn up in consultation with MOH's Genetic Testing Advisory Committee, ensures that only tests with strong scientific evidence can be used for insurance underwriting. The list may be revised as more scientific evidence becomes available.

Financial product	Description	Key #1: Financial limits	Key #2: Approved predictive genetic tests <sup>3</sup> (medical condition/gene)
Long-Term Care Insurance (Policies that pay out if individual is unable to perform 1 ADL)	Helps to meet some or all of the costs of daily living of the insured who, as a result of an accident or illness, is unable to perform a specified number of ADLs.	S\$3,000 per month	
Critical Illness Insurance	Pays out a benefit when the insured is diagnosed with one or more specified diseases or has undergone one or more specified medical procedures.	S\$500,000 sum assured	Huntington's disease (HTT) Breast cancer (BRCA1) Breast cancer (BRCA2)
Disability Income Insurance	Pays a fixed amount each month to replace part of the income the insured would lose if the insured is not able to work as a result of an accident or illness.	S\$10,000 per month	











# MINISTRY OF HEALTH (MOH) – LIFE INSURANCE ASSOCIATION (LIA) MORATORIUM ON GENETIC TESTING AND INSURANCE - FREQUENTLY ASKED QUESTIONS (FAQs)

The FAQs should be read in conjunction with the earlier Phase 1 FAQs disseminated with MOH Circular No. 08/2021 titled 'Moratorium on Genetic Testing and Insurance: Ban on the Use of Genetic Test Results from Biomedical Research in Insurance Underwriting', dated 27 January 2021 (see <u>Annex A</u>).

### Phase 2

**Background** 

Q1:	Can a clinical genetic test be a diagnostic genetic test and a predictive genetic test?		
A:	<b>Yes</b> , a clinical genetic test can be either a diagnostic or predictive genetic test, depending on whether the individual tested has any signs or symptoms of the genetic condition at the point of taking the genetic test.		
	Using clinical genetic testing for Huntington's disease (i.e. HTT genetic test) as an example:		
	<ul> <li>Diagnostic genetic test: The individual has the relevant signs and symptoms (e.g. involuntary jerking or writhing movements) or abnormal non-genetic test results (e.g. MRI changes) which indicate that the condition in question may be present. The HTT genetic test confirms the diagnosis of Huntington's disease.</li> </ul>		
	<ul> <li>Predictive genetic test: The individual has no sign or symptom of Huntington's Disease. There are no abnormal non-genetic test results which indicate that this condition is present. If the HTT genetic test result is abnormal, it predicts that this individual will develop the disease in the future.</li> </ul>		
Scope	Scope of the Moratorium		
Q2:	What is the scope of the Moratorium? What does it cover?		
A:	The Moratorium controls the use of research, direct-to-consumer (DTC) and predictive genetic test results in insurance underwriting, with a distinction made between the predictive and diagnostic genetic tests.		
	In Phase 1, the Moratorium imposes a ban on the use of <u>all</u> genetic test results from human <u>biomedical research</u> in insurance underwriting.		
	In Phase 2, in addition to upholding the above-mentioned Phase 1's ban, the Moratorium introduces additional controls on the use of <u>predictive</u> genetic test results from <u>clinical care</u> in insurance underwriting. The Moratorium categorises insurance policies into seven financial products: (a) life, (b) total permanent		











disability, (c) long-term care, (d) critical illness, (e) disability income, (f) health and integrated shield plans, and (g) general and other insurance products not covered in the Moratorium (e.g. motor vehicle and personal accident insurance). Only products (a) to (e) are covered by a 'double key' model. This means that the insurer can only request the disclosure of and/or use predictive genetic test results to underwrite these five products if two conditions are met: (i) the sum assured/pay-out exceeds the financial limits specified in the Moratorium; and (ii) the applicant has taken a predictive genetic test from the list of approved predictive genetic tests specified in the Moratorium. For the avoidance of doubt, if only one condition is met, the 'double key' model is not fulfilled, and the insurer cannot request the disclosure of and/or use predictive genetic test results to underwrite the product. Insurers cannot request the disclosure of and/or use predictive genetic test results for the purpose of underwriting products (f) and (g). Under the Moratorium, <u>DTC</u> genetic test results (whether predictive or diagnostic) cannot be used in insurance underwriting. The use of diagnostic genetic test results done while under clinical care is left to the discretion of individual insurers, similar to other diagnostic test results. Does the Moratorium apply to genetic tests provided directly to consumers by the manufacturer or supplier of the tests (i.e. DTC genetic tests)? Yes, when Phase 2 of the Moratorium is implemented from 27 October 2021, insurers cannot request the disclosure of or use DTC genetic test results in insurance underwriting. Does the Moratorium apply to prenatal and newborn screening genetic test results? **No**, prenatal and newborn screening genetic tests (e.g. for metabolic disorders) do not fall within the scope of the Moratorium. The use of prenatal and newborn screening test results done while under clinical care is left to the discretion of individual insurers, similar to other diagnostic test results. Does the Moratorium apply to pharmacogenetic tests (i.e. tests that predict the individual's response to drugs)? Yes, as pharmacogenetic tests are mainly used to predict an individual's response to drugs, these tests are considered as predictive genetic tests, which are thus subject to the 'double key' model. 'Double key' model, financial limits and list of approved predictive genetic tests









For the aforementioned five financial products covered by the 'double key' model, can the insurer use an individual's predictive genetic test results in



Q3.

A:

Q4:

A:

Q5:

A:

Q6:

	insurance underwriting if only one of the 'double key' conditions is fulfilled?		
A:	<b>No</b> , the insurer can <u>only</u> request the disclosure of and/or use predictive genetic test results to underwrite the five products if <u>both</u> (i) the sum assured/pay-out exceeds the financial limits specified in the Moratorium; <u>and</u> (ii) the applicant has taken a predictive genetic test from the list of approved predictive genetic tests specified in the Moratorium.		
Q7:	How were the financial limits and the list of approved predictive genetic tests in the Moratorium determined?		
A:	The <b>financial limits</b> were pegged to the amount of pay-out for the 99th percentile of insurance policies/policyholders such that 99% of insurance policies/policyholders will fall below the financial limits, and predictive genetic test results cannot be used in these insurance underwriting.		
	The <b>list of approved predictive genetic tests</b> , drawn up in consultation with the Genetic Testing Advisory Committee and through negotiations with LIA, ensures that only tests that are clinically and scientifically validated can be used for underwriting. The list may be revised to include more tests when more scientific evidence becomes available.		
	mentation of the Moratorium and its application (Q9-Q19 are set in the context e Moratorium has been implemented)		
Q8:	When will the Moratorium take effect?		
A:	Phase 1 of the Moratorium commenced on 27 January 2021.		
	Phase 2 of the Moratorium will take effect from 27 October 2021.		
	All relevant LIA members will comply with the terms stated in the Moratorium.		
Q9:	Can the insurer request for the individual to undergo genetic testing as part of insurance application?		
A:	<b>No</b> , the insurer cannot require or pressure (directly or indirectly) the individual to undertake a genetic test (diagnostic or predictive) for the purpose of insurance application, even if the individual has a family history of a genetic condition(s).		
Q10:	If an individual has taken a:		
	(i) genetic test done as part of biomedical research;		
	(ii) predictive genetic test; or		
	(iii) diagnostic genetic test,		
	can the insurer request the disclosure of or use his/her results in insurance underwriting if the test was taken before the Moratorium is implemented?		











A: For (i): **No**, the insurer cannot request the disclosure of or use the genetic test results from biomedical research in insurance underwriting, regardless of when the test was done.

<u>For (ii)</u>: **No**, the insurer cannot request the disclosure of or use the predictive genetic test results in insurance underwriting <u>unless</u> the 'double key' conditions are fulfilled for financial products covered by the 'double key' model.

<u>For (iii)</u>: The Moratorium does not control the use of the applicant's diagnostic genetic test results in insurance underwriting. Its use is left to the discretion of individual insurers, similar to other diagnostic test results.

# Q11: If a family member (i.e. blood relative) takes a:

- (i) genetic test done as part of biomedical research;
- (ii) predictive genetic test; or
- (iii) diagnostic genetic test,

is the individual applying for insurance required to declare the family member's results?

A: For (i) and (ii): **No**, the insurer cannot request the disclosure of or use these types of genetic test results of any family members in insurance underwriting.

<u>For (iii)</u>: The Moratorium does not control the use of the diagnostic genetic test results of the applicant's family members in insurance underwriting. Insurers may request the applicant to declare his/her family member's results and use them to inform decision about an insurance application, similar to other diagnostic test results.

# Q12: What are the implications if a family member (i.e. blood relative) refuses to provide his/her results of a:

- (i) genetic test done as part of biomedical research;
- (ii) predictive genetic test; or
- (iii) diagnostic genetic test

to the applicant during insurance application?

A: For (i) and (ii): The insurer cannot request the disclosure of or use these types of genetic test results of any family members in insurance underwriting.

<u>For (iii)</u>: Insurers may request for information on family history, including whether the applicant has family member(s) with a diagnosed genetic condition to inform their decision on the insurance application. Insurers may request for the family member's test results. The inability to provide the requested family test results (for whatever reason) may affect the insurer's decision on outcome of the insurance application, policy terms and/or claims process.











Q13:	For insurance policies that were already in effect <u>before</u> the roll-out of the Moratorium, can the insurer now request and use the results of a:	
	(i)	genetic test done as part of biomedical research;
	(ii)	predictive genetic test; or
	(iii)	diagnostic genetic test
	in insurance underwriting?	
A:	For (i) and (ii): <b>No</b> . As the policy is already in effect, the claims process and outcome of such insurance policies continue to be subject to the terms of the insurance contract as they were agreed by the insured and insurer before the Moratorium is implemented.	
	For (iii): The Moratorium does not control the use of the applicant's diagnostic genetic test results in insurance underwriting. Its use is left to the discretion of individual insurers, similar to other diagnostic test results.	
Q14:	If an indi	vidual has taken a:
	(i)	genetic test done as part of biomedical research;
	(ii)	predictive genetic test; or
	(iii)	diagnostic genetic test,
		nsurer use the results in insurance underwriting if the individual ally/voluntarily disclosed the results?
A:	For (i): <b>No</b> . Even in the event of accidental/voluntary disclosure of one's genetic test results from biomedical research, the insurer cannot use these results in insurance underwriting.	
	For (ii): <b>Possible</b> . The insurer may take into account the test results if they are favourable/beneficial to the individual. However, if the results are unfavourable to the individual, the insurer should not use them <b>unless</b> the 'double key' conditions are fulfilled.	
	For (iii): The Moratorium does not control the use of the applicant's diagnostic genetic test results in insurance underwriting. In the event of accidental/voluntary disclosure, the use of such results is left to the discretion of individual insurers, similar to other diagnostic test results.	
Q15:	If an individual voluntarily discloses his/her predictive genetic test result which has ruled out a risk otherwise suggested by family history, can the insurer use the test result in insurance underwriting?	
A:	Yes, the insurer may take into account the predictive genetic test result to inform their decision on the insurance application.	
Q16:	If an individual was asymptomatic when he/she took a predictive genetic test, but subsequently developed that genetic condition with signs and	











symptoms at the point of insurance application, can the insurer request the disclosure of or use the individual's previous predictive genetic test results in insurance underwriting? A: **No**, the insurer is not allowed to request the disclosure of or use the results of the test taken by the individual when he/she was asymptomatic, for underwriting, as these are the results of a predictive genetic test (defined based on when the test was done), even though the individual subsequently develops the condition. However, as the patient is symptomatic at the point of insurance application, the individual should declare the symptoms and declare if any diagnosis of a medical condition was made. If a diagnostic genetic test was done, it should also be declared (as with any other diagnostic medical test results), and insurers can use the diagnostic genetic test result in insurance underwriting. The individual will also need to follow the process of standard insurance application (including detailed health examination/answering questionnaire). Q17: How will the insurance company request for the applicant's predictive genetic test results if the 'double key' conditions are fulfilled? A: The insurance company may ask an applicant to disclose in the application form if he/she has undergone HTT and/or BRCA1/2 predictive genetic testing (as appropriate) and if so, to disclose the result only if (a) it is to be used for the same type of insurance policy; and (b) the total coverage he/she has with all insurance companies, including the one he/she is currently applying for, exceeds the financial limits specified in the Moratorium. Q18: If an individual has previously taken a: genetic test done as part of biomedical research; (i) (ii) predictive genetic test; or diagnostic genetic test, can the individual submit the results to the insurer and request for the policy's premiums be reduced? A: For (i): The Moratorium does not apply retrospectively. Therefore, for policies already in effect before the ban on the use of all genetic test results from human biomedical research in insurance underwriting, i.e. before 27 January 2021, the claims process and outcome of the policy will remain subject to the terms of the insurance contract as agreed between the insured and insurer at the point of signing the contract. From 27 January 2021 onwards, i.e. after the ban on the use of all genetic test results from human biomedical research in insurance underwriting, research results cannot be used for policies that had not been signed before that date. For (ii): The Moratorium does not apply retrospectively. Therefore, for policies already in effect before the controls of the Moratorium came into effect, the









claims process and outcome of the policy will remain subject to the terms of the



insurance contract as agreed between the insured and insurer at the point of signing the contract, including the use of any such genetic test results as well as the premiums.

For policies that are not signed before 27 October 2021, when the controls are implemented from this date, the request of disclosure and/or use of any such predictive genetic test results will be subject to the terms of the Moratorium, i.e. the predictive genetic test results cannot be used unless the 'double key' conditions are fulfilled.

For (iii): The Moratorium does not control the use of the applicant's diagnostic genetic test results in insurance underwriting. Its use is left to the discretion of individual insurers, similar to other diagnostic test results.

#### Q19: Does the Moratorium have an expiry date and will it be amended in future? What will happen to the policies after the Moratorium is amended? Will the amendments be applied retrospectively?

A: The Moratorium is open-ended with no expiry date. It will be reviewed regularly and updated where necessary to keep up with the rapidly evolving developments in genetic testing.

Policies that were already in effect before the roll-out of the Moratorium will remain subject to the terms and conditions of the insurance contract as agreed between the insured and insurer at the point of signing the contract. The amendments will not be applied retrospectively.

Only new policies that are signed after the implementation of the amended Moratorium will be subject to the new terms and conditions of the amended Moratorium.

## **Others**

### Q20: Whom should I contact if I have further queries on the Moratorium?

A: You may write in to eLIS@moh.gov.sq.

#### Q21: Whom should an individual contact if he/she has concerns/disputes with his/her insurance company?

A: For all disputes/concerns: Consumers can approach their insurers directly to resolve the issue. Insurers will maintain a log of complaints and how they were handled.

For complaints on insurance claims: Consumers can approach the Financial Industry Disputes Resolution Centre (FIDReC) as the first port of call for mediation, or as an independent arbitrator or adjudicator.

Where there is no existing relationship with the insurer, consumers can approach the Singapore Mediation Centre (SMC) for mediation.

(Please refer to MAS's Dispute Resolution Guide (2005) for further details. The











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guide can be accessed at <a href="https://www.moneysense.gov.sg/-/media/moneysense/guides-publication/disputeresolutionguide.pdf">https://www.moneysense.gov.sg/-/media/moneysense/guides-publication/disputeresolutionguide.pdf</a>).









