



Concordat and Moratorium on Genetics and Insurance

Preface

The Concordat and Moratorium on Genetics and Insurance has been updated to reflect the agreement's extension until 2019. The interim review that was due to take place in 2014 will now take place in 2016.

New Annex 2 has been added to clarify different types of genetic test.

The principles and purpose of the Concordat and Moratorium have not otherwise changed from the previous version.

Introduction

1. The Government and the Association of British Insurers (ABI) believe the relationship between medical data and insurance underwriting should be proportionate and based on sound evidence. They accept the commercial principle that, unless otherwise agreed, insurance companies should have access to all relevant information to enable them to assess and price risk fairly in the interest of all their customers.
2. The Government and the ABI:
 - a. agree to abide by a policy framework ('Concordat') for cooperation that provides that insurers' use of genetic information is transparent, fair and subject to regular reviews; and
 - b. remain committed to the voluntary Moratorium on insurers' use of predictive genetic test results until 1 November 2019, and a review of the Concordat in 2016.
3. The ABI will not seek to end the agreement outside of the review process or before the end of the Moratorium, and the Government sees no reason to introduce legislation on the use of genetic test results or family history during the term of the agreement.
4. This document provides a single high-level policy agreement ('the Concordat') between the Government and the ABI on the use of genetic test results in insurance underwriting practices. The Concordat includes the following elements that are all set out in this document.
 - The overall framework – the rules that apply to the use of predictive genetic test results and insurance.
 - The Moratorium – the provisions relating to the use of specific predictive genetic test results, the agreed circumstances and the applicable dates.
 - Reviews – the date and process for the next planned review of the Concordat.
 - Future applications – the process for any future applications for predictive genetic tests.
 - Monitoring – the procedures and requirements.
 - Complaints – the process for complaints about the use of predictive genetic tests.

Background

5. Genetic testing is used to diagnose, identify and predict genetic conditions. Genetic test results can confirm diagnoses of ill health and inform treatments and insurers can ask for this information. The Moratorium is concerned only with tests used to predict future illness. Few tests can predict with certainty when an illness might begin, or how severe it might be. However, there remain concerns that a minority of patients might be deterred from taking predictive genetic tests, if they are unaware that the Concordat protects their fair rights of access to insurance.
6. The Concordat and Moratorium preserves the principle that, unless otherwise agreed, insurance companies should have access to all relevant information to enable them to fairly assess the risk and price risk in the interest of all their customers. So, if a customer for life insurance knows (from medical information, family history or tests) of a specific risk to his or her health, it should in all normal circumstances be disclosed. If the risk is not disclosed, the insurance company may face ever more costly claims than it was able to assume in setting the price of its insurance policies. This could potentially affect the future pricing or availability of insurance cover to all.
7. The current approach works in practice because the number of policies affected by non-disclosure of predictive genetic test results appears to be low. This allows customers who have had adverse predictive genetic test results to obtain significant levels of cover, whilst protecting the customers of individual insurers from the consequences of extremely high claims, which have not been priced for.

Purpose

8. The Government and the ABI agree that the Concordat and Moratorium ensures fair rights of access.
 - To insurance for consumers – by allowing people to take out substantial amounts of cover without having to disclose the results of predictive genetic tests.
 - To relevant information for insurance companies – to enable fair assessment and risk pricing in the interests of all past, present and future customers.
9. The Concordat and Moratorium protects the interests of both customers and insurers, by preserving customers' access to insurance, and insurers' right of equal access to information about risks.
10. The Concordat creates a robust and flexible framework for cooperation between the Government and the ABI and its members. It is designed to balance the needs of consumers to have fair rights of access to insurance with the need for a commercially

viable, long term and fair insurance market. The Concordat sets out the policy on how predictive genetic tests may be used including:

- a. higher standards of evidence of increased risk than apply to other forms of medical information used by insurers;
- b. how the Government will obtain independent evidence and advice on the relevance of specific predictive genetic tests to insurance risk;
- c. a robust compliance process beyond the statutory and regulatory requirements; and
- d. an independent mechanism for handling any complaints.

Parties

11. The parties to this Concordat are the Government of the United Kingdom and Devolved Administrations ('the Government'), and the Association of British Insurers (ABI).
12. Adoption of the Concordat and Moratorium is a condition of membership of the ABI in which the ABI and its members commit to specific, agreed circumstances under which predictive genetic test information can be obtained and used.
13. The Concordat is a statement of intent and does not create legal obligations between the parties.
14. Nothing in this Concordat should be construed as conflicting with statutory requirements or with other professional duties and obligations.

General principles

15. The parties to this Concordat agree the following principles.
 - Insurers should not treat customers who have an adverse predictive genetic test result less favourably than others without justification.
 - Customers should receive clear explanations of their rights. They should have access to a free, independent service for resolving complaints.
 - Insurers and customers should have equal access to information such as health status that is material and relevant for underwriting the type of cover applied for, except as provided for by the Concordat and the Moratorium.

Predictive genetic tests

16. This agreement applies to predictive genetic tests, which examine the structure of chromosomes (cytogenetic tests) or detect abnormal patterns in the DNA of specific genes (molecular tests). It does not apply to diagnostic genetic tests, nor does it apply to non-genetic medical tests, for example, blood or urine tests for cholesterol, liver function or diabetes (see Annex 2).
17. Applications to approve the use of predictive genetic test results by insurers will only be for conditions that are:
 - a. monogenic (single gene disorders that are inherited in a simple fashion);
 - b. late-onset (symptoms are delayed until adult ages); and of
 - c. high penetrance (a high probability that those with the gene will develop the disorder).
18. It is the case, however, that an applicant may disclose a positive result from a predictive genetic test if they wish the result to be considered in the underwriting decision.

Policy on the use of predictive and diagnostic genetic test results

19. Insurers agree the following measures to reassure customers so that they are not deterred from taking a predictive genetic test by fear of potential insurance consequences. The measures cover:
 - a. the nature and detail of information sought from customers;
 - b. how insurers will handle information provided voluntarily by customers; and
 - c. the use made of that information.

20. The Government and the ABI will work with patient interest groups and industry representatives to:
- a. close the information gap and help consumers make an informed decision on whether or not to take a predictive genetic test through, for example, this Concordat and Moratorium containing all relevant provisions in a single document and the ABI making a consumer information leaflet available to constituent groups; and
 - b. examine methods of improving access to insurance through, for example, identifying a common evidence base to underpin underwriting decisions.

Information sought from customers

21. Insurers agree to the following:
- a. customers will not be asked, nor will they be put under pressure, to take a predictive genetic test to obtain insurance cover;
 - b. customers who have taken a predictive test before the date of this Concordat will be treated in the same way as customers taking tests under the terms of the Concordat;
 - c. customers will not be required to disclose any of the following:
 - i. a predictive genetic test result from a test taken after the insurance cover has started, for as long as that cover is in force;
 - ii. the predictive test result of another person, such as a blood relative; or
 - iii. a predictive or diagnostic test result acquired as part of clinical research (for example, the 100,000 Genomes Project) To avoid doubt, customers may be asked to disclose details of any symptoms, diagnosis or treatment received outside of the clinical research programme, even if those relate to a condition they found out about through the research programme.
 - d. customers making relevant insurance applications will be required to disclose a predictive genetic test result only if all of the following apply:
 - i. the customer is seeking insurance cover above the financial limits set out in the Moratorium;
 - ii. the test has been assessed by a panel of experts and approved by Government. To date, the only test that people are required to disclose under the agreement is for Huntington's Disease for life insurance where

the insured sum is over £500,000. Any change to the list of approved tests would be notified on the ABI and Department of Health¹ websites

- iii. the insurer asks the customer to disclose the information.
- e. they will make available information to customers, before an application for insurance cover is completed, about what customers will and will not have to disclose about their genetic tests in line with this Concordat and Moratorium;
- f. they are permitted to seek, with the person's consent, access to appropriate family medical history, diagnostic genetic test results, and to reports from GPs to accurately price the risk from any health information an applicant discloses;
- g. they will maintain stringent procedures for seeking access to relevant medical information held by a GP or other clinician, agreed between the ABI and the British Medical Association;
- h. they will protect personal medical information in accordance with the ABI Confidentiality Policy; and
- i. they will destroy medical evidence when it is no longer relevant to them.

Handling of information provided voluntarily

- 22. Insurers agree that customers may choose to disclose predictive genetic test results that are in their favour to provide context for family history information. Individual insurance companies will publish information about the way they will, or will not, use such test results to inform their underwriting decisions.
- 23. Most insurance companies will take into account the result of such a voluntarily disclosed genetic test result, even if it has not been approved, provided that the result is from a reputable source.

Use of information

- 24. Insurers agree that:
 - a. they will not use information from predictive genetic test results to underwrite travel insurance, private medical insurance, or any other one-off or annual policy, or long term care insurance policies;
 - b. the broad classes of insurance for which genetic test results may be relevant are confined to the following products:

¹ <https://www.gov.uk/government/publications/agreement-extended-on-predictive-genetic-tests-and-insurance>

- i. life;
 - ii. critical illness; and
 - iii. income protection.
- c. where they make use of the results of approved tests to impose special terms or conditions, they will not impose unjustified exclusions from cover, or other special terms or conditions, which have the effect of preventing a policyholder from making a claim for a condition that is not related to the genetic condition identified by an approved test; and
- d. unless it is to the applicant's advantage, if a predictive genetic test result is disclosed where it was not required to have been, insurers will not take it into account either:
 - i. in deciding whether or not to offer cover; or
 - ii. as a risk factor in setting terms.

The Moratorium

25. The Moratorium on insurers' use of predictive tests makes an exception to the principle of disclosure. It allows customers who have taken a predictive genetic test to obtain significant levels of cover without disclosing the results of that test. Insurers are only prepared to bear the risks and costs of this non-disclosure, which are spread across the broad pool of policyholders, whilst the number of policies affected by non-disclosure of predictive genetic tests appears to be low. On this basis, the Government and the ABI have agreed that the Moratorium should remain in place.
26. The terms of the Moratorium are as follows.
- I. Customers will not be required to disclose the results of predictive genetic tests for policies up to £500,000 of life insurance, or £300,000 for critical illness insurance, or paying annual benefits of £30,000 for income protection insurance (the 'financial limits').
 - II. When the cumulative value of insurance exceeds the financial limits, insurers may seek information about, and customers must disclose, tests approved with the Government for use for a particular insurance product, subject to the restrictions in the Concordat.
 - III. The Government will announce and the ABI will publish on its website the date of the next review which will be three years before the expiry date of the current Moratorium.

Compliance

27. Where an ABI member firm transacts applicable classes of insurance business, at each review the CEO will confirm to ABI that the firm will comply with the Concordat and Moratorium for its full duration, that it will follow the agreed complaints procedure, and report all complaints it receives to ABI. ABI will publish a list of firms that have confirmed compliance on its website.
28. Each year, the ABI will report to the Government the number of complaints received about the operation of the Concordat and Moratorium within the context of the number of relevant policies taken out.
29. Before each review, the ABI will prepare a report on all complaints received by its members (if any) about the operation of the Concordat and Moratorium since the last review. Patient groups and other relevant stakeholders are, at any time, invited to submit evidence on the on-going operation of the Concordat. All available evidence will be used to inform the next review in 2016.
30. Data on tests used to predict future illness may be gathered and analysed to provide objective evidence on the prevalence of predictive genetic tests and anti-selective behaviour, and the impact these have on cross-subsidies and the sustainability of the Concordat and Moratorium.
31. ABI member firms that transact relevant classes of new business will do the following:
 - a. comply with the terms of the Concordat and Moratorium as a condition of membership of the ABI;
 - b. log all complaints about genetics, respond to them in accordance with the Concordat and Moratorium, and report them to the ABI;
 - c. support research initiatives where practicable (and lawful);
 - d. inform consumers what information they do, and do not, need to disclose;
 - e. have at least one nominated genetics underwriter (NGU), and a deputy NGU, who is responsible for all matters relating to genetic information and the operation of the Concordat and Moratorium, as set out in the ABI Duties and Responsibilities of the Nominated Genetics Underwriter document;
 - f. the number of NGUs should be aligned to the scale of the business; and
 - g. staff will be appropriately trained in dealing with genetic information, depending on their role and responsibilities.

Resolution of disputes and complaints

32. Customers have the right to ask an insurer to provide information on whether, and if so, how, a predictive test result has contributed to an underwriting decision. They have the right of appeal against an underwriting decision and a right to have a complaint dealt with fairly.
33. If, at the end of the complaints process, the insurer does not uphold the complaint, the insurer will write to the complainant setting out the firm's final decision and the reasons for it. This communication must tell the complainant about further action they can take, with relevant details, if they remain dissatisfied.
34. Depending on the circumstances of the case, the further action open to complainants may include the following.
 - The complainant has the right to have any complaint about the operation of the Concordat and Moratorium considered by the (free to complainants) independent Arbitration Service administered by the Chartered Institute of Arbitrators.
 - In cases where the complaint concerns a contract that has been concluded, the complainant has the right to have the complaint considered by the (free to customers) Financial Ombudsman Service if the complainant believes they have suffered, or may suffer, a financial loss, material distress or material inconvenience as a result of the insurer's wrongful act or omission.
 - The complainant may take legal action against the insurer.

Use of predictive genetic test results

35. The Government will seek the advice of independent experts on the approval of any application to use the results of predictive genetic tests for insurance. The ABI will give sufficient notice of any application to ensure that expert and lay individuals can be invited to review the application. The application will be made in accordance with the process agreed with the Government. The outcome of the application will be published.
36. Predictive genetic tests ordered directly by consumers from commercial providers commonly known as direct-to-consumer genetic tests, are covered by this agreement.

Duration and review

37. The Concordat came into effect on 14 March 2005. The Moratorium came into effect on 1 November 2001. The Concordat and Moratorium will continue to be updated in

the light of experience, research findings and developments in genetic technology, and clinical practice.

38. The review that was scheduled for 2014 is in effect being deferred by two years to 2016 with a corresponding extension of the moratorium to 2019. Future reviews will always be at least three years before any extended end date of the Moratorium.

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ANNEX 1 - RELEVANT PUBLICATIONS

Genetic Tests and Insurance: What you need to know

This consumer guide is for people who are thinking about taking a genetic test and want to know how this could affect their insurance. The consumer guide is available at:

<https://www.abi.org.uk/Insurance-and-savings/Topics-and-issues/Genetics>

Insurance and genetic conditions

Genetic Alliance UK have a page on their website that explains what information you must disclose to insurance companies, what you do not need to disclose, and what information your GP can give to them with your permission

<http://www.geneticalliance.org.uk/insurancenew.htm>

GP report insurance package

The BMA has worked with the ABI to compile a pack including: a standard covering letter for insurers to send to GPs, together with an overview of the types of information that are relevant to different types of insurance policy; a standard GPR form; and a standard consent declaration for patients

<http://bma.org.uk/practical-support-at-work/ethics/confidentiality-and-health-records>

House of Lords Science and Technology Committee Inquiry into Genomic Medicine

The House of Lords Select Committee on Science and Technology launched an inquiry into genomic medicine in February 2008. The inquiry provided an assessment of genome technologies and their actual and potential impact on clinical practice in the post-genome era. The Committee's Genomic Medicine report was published in July 2009. The report can be found at:

<http://www.publications.parliament.uk/pa/ld200809/ldselect/ldsctech/107/107i.pdf>

Government Response to the House of Lords Science and Technology Committee Inquiry into Genomic Medicine

The Government response to the House of Lords report on Genomic medicine was published in December 2009. The response reinforces the Government's commitment to genetics research, health research, development and innovation. It sets out how the Government intends to continue to ensure the NHS is ready for future developments and that new technologies are properly developed and translated into clinical practice. The response can be found at:

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/238500/7757.pdf

ANNEX 2 - EXPLANATORY NOTES

EXPLANATORY NOTES

The Concordat and Moratorium applies to predictive genetic tests which examine the structure of chromosomes (cytogenetic tests) or detect abnormal patterns in the DNA of specific genes (molecular tests). It does not apply to non-genetic medical tests, for example: urine tests for diabetes and blood tests for cholesterol, prostate cancer, liver function or diabetes.

GENETIC TESTS OF THE INDIVIDUAL

Where this document refers to the use of genetics tests, it is always relating to the examination of **an individual's inherited** chromosomes or DNA. It does not include genetic testing of medical conditions themselves the individual might be suffering from such as the genetic make-up of a cancer or an infectious disease.

TYPES OF GENETIC TEST RESULT

A genetic test result can be predictive or diagnostic:

- a predictive genetic test is taken prior to the appearance of any symptoms, signs or abnormal non-genetic tests results which indicate that the condition in question is present.
- a diagnostic genetic test is taken to confirm a diagnosis based on existing symptoms, signs or abnormal non-genetic tests.

Predictive genetic tests

Predictive tests are used to detect faulty gene patterns associated with conditions that appear after birth, often later in life. These tests can be helpful to people who have a family member with a genetic condition, but who have no symptoms, signs or abnormal non-genetic tests consistent with the condition at the time of testing. Predictive testing can identify faulty gene patterns that increase a person's chances of developing conditions with a genetic basis. In the UK it is rare that this type of genetic testing will take place other than where there is a relevant family history.

Diagnostic genetic tests

Diagnostic testing is used to diagnose or rule out a specific genetic or chromosomal condition. In many cases, genetic testing is used to confirm a diagnosis when a particular condition is suspected because of symptoms, signs, or abnormal non-genetic tests including unusual findings on a routine blood or other test.

This document is available from:

<https://www.gov.uk/government/publications/agreement-extended-on-predictive-genetic-tests-and-insurance>

www.abi.org.uk