An tOmbudsman Seirbhísí Airgeadais agus Pinsean
Financial Services and Pensions Ombudsman

Decision Ref:	2021-0539
Sector:	Insurance
Product / Service:	Private Health Insurance
Conduct(s) complained of:	Rejection of claim - treatment abroad
Outcome:	Rejected

LEGALLY BINDING DECISION
OF THE FINANCIAL SERVICES AND PENSIONS OMBUDSMAN

The Complainant has a health insurance policy with a health insurance company (the "**Provider**"), against which this complaint is made.

The Complainant's Case

The Complainant has been a customer of the Provider since **22 January 1985**. The Complainant had cover under the Provider's Health Care Plan 1. On the **27 September 2018**, the Complainant underwent an MRI the report of which noted that "*left peripheral zone tumour is highly likely*" and subsequently the Complainant was informed by letter, dated **9 October 2018** and from his GP, that "*there is an abnormality in the left peripheral zone of the prostate.*" The Complainant submitted a **Prior Approval Application Form** on **14 February 2019** to request prior approval for planned treatment abroad for prostate cancer. According to the Complainant this treatment is not available in Ireland. The treatment is a non-invasive surgical procedure called High Intensity Focused Ultrasound ("**HIFU**"). The Complainant made an application for the cover of benefit for HIFU only and not any of the other existing procedures in Ireland.

The Complainant says that HIFU it is a new treatment and offers an alternative to the established surgical and radiation treatment for this condition. The Complainant asserts

that "*the facts point to HIFU, as now been established as an effective form of prostate focal therapy*."

The Complainant further argues that HIFU is safer with better patient outcomes and less side effects than alternative treatment options. The Complainant disputes that the treatment is not proven and in his submission of **November 2019** sets out where in his opinion, the Provider's criteria for covering the treatment have been met - the treatment was recommended to the Complainant by his doctors, the treatment is not currently available in Ireland but is approved in other Western countries and other health insurance companies list it as an approved form of treatment. The Complainant submits evidence of his brother's treatment with HIFU in the UK and of peer reviewed research studies to support his contention. The Complainant wants the Provider to pay a portion of his HIFU treatment costs.

The Complainant submits on **18 January 2021** that:

> "*both of the eminent urologist consultants I attended in Ireland and the UK advised that, Watchful Waiting, Chemotherapy and Radiation treatments were not considered or recommended to be appropriate alternative treatments in my case. My case was diagnosed as requiring direct treatment intervention either undergoing Prostatectomy in Ireland or HIFU in the UK. I was diagnosed with intermediate stage prostate cancer requiring early surgical treatment intervention. HIFU was recommended as the reasonable alternative treatment which I elected to undertake (for the reasons stated in my earlier submission) which is not available in Ireland.*"

The Complainant submits that:

> "*[the provider's correspondence to me wrongly concluded that the use of HIFU (High Intensity Focused Ultrasound) 'cannot' be accepted as a proven form of treatment for localised prostate cancer. This is contrary to the views of eminent Urologists in the UK and Ireland who have recommended this treatment for me*."

On **1 April 2019**, the Complainant submitted in written submissions:

> "*given the urgency to prevent any deterioration of my condition, I have elected to proceed with HIFU in the UK on the basis of the recommendations, and corroborative second opinion, from [UK Professor of Oncology] and [Irish Consultant Urological Surgeon] respectively, following mpMRI and Transperineal (template or targeted) biopsy diagnostic results in the UK which confirmed my diagnosis of intermediate localised prostate cancer*."

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The Complainant states that:

> "*[the Provider] is "not living up to its purported values and customer care in this case, it is behind the UK and most of the rest of EU countries in regard to recognising and providing benefit cover for HIFU.*"

The Complainant asserts that:

> "*I am appealing this decision in this case to the FSPO both on the grounds that 1; [the Provider] have not honoured their customer promise to ' provide timely access to quality healthcare and to the latest treatments, medicines and technologies in Ireland and abroad' and 2; that in making their decision, [the Provider] have unfairly and unreasonably determined that my HIFU treatment is not a safe and effective form of treatment, when considering the specific criteria by which its definition of 'a proven from of treatment' are to be met*."

The Complainant asserts that the Provider is unfairly refusing to approve his application for benefit abroad and is "*by default (if not intentionally) effectively evading making any benefit payment*." The Complainant submits by letter dated **11 May 2020** that "*due to [the Provider's] stance with me I naturally have had to finance this myself, which comes with its own personal cost.*" The Complainant states that he has incurred extensive expenses to date with regard to the HIFU treatment, which he asserts do not include travel and accommodation expenses and amount to €21,860.00. The Complainant contends that the Provider should offer him compensation against the costs that he has incurred in pursuing the HIFU treatment in the UK and he states "*at least up to the same benefit cost which [the Provider] would have paid out to [him] for preoperative diagnostic tests and Robotic Prostatectomy procedure and hospitalisation in Ireland plus the post treatment costs.*"

The Provider's Case

The Provider in its letter of **18 February 2019** asserts that it is unable to provide benefit for the HIFU treatment. The Provider sets out that the specified criteria for planned treatment abroad were not met in accordance with its Rule 6c in its **Rules, Terms and Conditions of Membership**. The Provider lists the specified criteria that it uses to determine a 'proven form of treatment', including that:

- studies have confirmed its safety and efficiency compared with standard treatments,

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- consensus amongst experts that further studies are not necessary to determine its safety or its effectiveness as compared with standard treatments, and

- evidence of randomised controlled trials with meaningful end points and follow-up over a five year period.

The Provider asserts that HIFU is not consistent with the Providers' definition of a 'proven form of treatment' insofar as it doesn't meet the above criteria. By letter dated **19 February 2019**, the Provider wrote to the Complainant and said as follows:

> "*Your application for treatment abroad has been reviewed by our panel of medical advisors. Regrettably, we are unable to provide benefit for your proposed treatment, in accordance with Rule 6 (c) of [the Provider's]* ***Rules - Terms and Conditions****, as the specified criteria for planned treatment abroad are not fully satisfied (please see attached rule).*
>
> *The specified criteria are as follows:*
>
> - *Prior Approval has been sought.*
> - *The referral is by a Consultant recognised by [the Provider].*
> - *There is an urgent medical necessity for treatment of the condition from which the member is suffering.*
> - *The treatment or a reasonable alternative is not available in this country.*
> - *The treatment abroad is considered by [the Provider's] Medical Director to be generally accepted as a proven form of treatment.*
> - *There is a reasonable medical prognosis.*
> - *The treatment abroad is provided in an institution or hospital which would be an equivalent to those recognised in Ireland by [the Provider].*
> - *The treatment is provided by a consultant who would otherwise also be eligible for recognition by [the Provider] if practising in Ireland.*
>
> *To determine whether a particular treatment is a proven form of treatment [the Provider] Healthcare assesses the treatment against a number of criteria. The procedure must be safe, effective (both from a clinical and cost perspective) and generally accepted by the medical community*."

By letter, addressed to the Complainant and dated **19 February 2019**, the Provider submits that:

> "*With regard to your proposed treatment, there are no randomised controlled trials with meaningful end points and follow-up over a five year period.*

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Furthermore, there is no evidence suggesting consensus amongst experts regarding the procedure and that might consider further studies or clinical trials as not necessary to determine its safety or its effectiveness as compared with standard treatments. Therefore, the treatment is not consistent with [the Provider's] definition of a proven form of treatment and no benefit is payable in accordance with rule 6c."

By letter dated **11 February 2021**, the Provider further submits that:

"*While our criteria indicates that it is in the opinion of the Medical Director that HIFU is not generally accepted as a proven form of treatment, it should be noted that the Medical Director's view is based on evaluation of the available medical literature and recommendations and guidelines from medical professional recognised bodies as detailed in our previous decisions. While [the Provider] continue to provide access to members to quality healthcare and to the latest treatments, medicines and technologies in Ireland and abroad it is a requirement that those treatments, medicines and technologies have to meet [the Provider's] criteria to be considered proven forms of treatments… As per our previous decision, based on the review of the medical literature and the recommendations from respected and professional bodies, HIFU to treat prostate cancer does not meet [the Provider's] criteria to be considered a proven form of treatment. Therefore the question is not what alternative treatments are available to the member but rather does HIFU meet the criteria to be considered a proven form of treatment for prostate cancer and, based on our reviews, as detailed previously it is not. If the consultant indicates that the member requires a prostatectomy then benefit may be payable for that in Ireland subject to normal underwriting as the procedure is generally accepted as a proven form of treatment. [The Provider] have a number of codes for prostatectomy depending on exactly the type of surgery to be performed. However, [the Provider] do not provide the equivalent benefit of a procedure available in this country for an alternative procedure abroad unless that alternative treatment abroad is also a proven form of treatment*."

The Provider submits there is a specific criteria that must be met before and treatment is considered as covered by the health insurance policy and the Provider notes that:

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> *"Where a procedure is not listed In the Schedule of Benefits, [the Provider] only provide benefit for treatment abroad where the treatment is considered a proven form of treatment….*
>
> *I note the further information received from the member relating to the request for treatment abroad with High Intensity Focused Ultrasound (HIFU} to treat his prostate cancer. Having reviewed the use of HIFU in prostate cancer, [the Provider's] view Is that the procedure does not meet our criteria, as detailed above, to be considered a proven form of treatment. It Is a requirement that all the criteria are met. In the case of HIFU while there has been research performed into its use, overall there is insufficient evidence to support the procedure meeting [the Provider's] criteria to be considered a proven form of treatment."*

The Provider submits that the Complainant has failed to meet its criteria for a proven form of treatment such that it might cover the treatment. The Provider's Medical Director finds that "*the procedure does not meet [the Provider's] criteria to be considered a proven form of medical treatment"* and the Provider has declined cover on this basis. The Provider also notes that the Complainant proceeded with treatment prior to an assessment or prior approval by the Provider.

The Complaint for Adjudication

The complaint is that the Provider wrongfully declined the Complainant's application for benefit payment for his planned treatment abroad.

Decision

During the investigation of this complaint by this Office, the Provider was requested to supply its written response to the complaint and to supply all relevant documents and information. The Provider responded in writing to the complaint and supplied a number of items in evidence. The Complainant was given the opportunity to see the Provider's response and the evidence supplied by the Provider. A full exchange of documentation and evidence took place between the parties.

In arriving at my Legally Binding Decision, I have carefully considered the evidence and submissions put forward by the parties to the complaint.

Having reviewed and considered the submissions made by the parties to this complaint, I am satisfied that the submissions and evidence furnished did not disclose a conflict of fact such as would require the holding of an Oral Hearing to resolve any such conflict. I am also

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satisfied that the submissions and evidence furnished were sufficient to enable a Legally Binding Decision to be made in this complaint without the necessity for holding an Oral Hearing.

A Preliminary Decision was issued to the parties on 26 November 2021, outlining my preliminary determination in relation to the complaint. The parties were advised on that date, that certain limited submissions could then be made within a period of 15 working days, and in the absence of such submissions from either or both of the parties, within that period, a Legally Binding Decision would be issued to the parties, on the same terms as the Preliminary Decision, in order to conclude the matter.

In the absence of additional submissions from the parties, within the period permitted, I set out below my final determination.

The Provider relies on Rule 6, Section (c) of the **Rules, Terms and Conditions of Membership** contained in the Provider's **Schedule of Benefits for Professional Fees, Surgery and Procedures**.

Rule 1 (a) of the the Provider's **Schedule of Benefits for Professional Fees, Surgery and Procedures** states: The terms of your policy with us are in the following documents (iv) The Schedules.

Rule 6 (c) 21 **Rules, Terms and Conditions of Membership** says as follows:

> "*If you wish to apply for benefit for a planned treatment abroad, we require a fully completed Prior Approval Application from by your Irish based referring consultant*."

In addition Rule 6 (c) 26) (v) states:

> "*Benefit is not payable for new, not proven forms of surgical procedures*."

The Provider notes that "*for treatment abroad that is not outlined in the Schedule of Benefits for Professional Fees, we will cover up to the plan maximum (€100,000 in [the Complainants] case) once the proposed treatment meets our criteria*."

I note the contents of the **Prior Approval for Treatment Abroad Form** which notes that HIFU "*is widely used in the UK*" and its effectiveness or success has "*favourable reports in the literature*" and that "*it is being used in an increasing number of patients with prostate cancer*" and this **Prior Approval for Treatment Abroad Form** is signed by the Complainant's Irish Consultant Urological Surgeon on **17 January 2019**.

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I note the contents of the Provider's **Assistant Medical Officer Decision** which lays out the Provider's criteria for proven form of treatment and finds that HIFU for treatment of prostate cancer "*is not a procedure that meets [the Provider's] criteria to be considered a proven form of treatment."* The **Assistant Medical Officer Decision** is dated **15 February 2019** and signed by the Assistant Medical Officer.

By letter dated **20 December 2020**, the Provider notes that "*the referral was by Prof [Irish Consultant Urological Surgeon] who is a Consultant recognised by [the Provider]…. Yes, the treatment was provided in an institution or hospital which would be equivalent to those recognised in Ireland by [the Provider]….Yes, the treatment was provided by a consultant who would be eligible for recognition by [the Provider] if practising in Ireland*. "

By letter dated **20 December 2020**, The Provider notes that "*there was an urgent medical necessity for treatment as outlined by [Irish Consultant Urological Surgeon] in Question three of the Prior Approval Application form*." By letter dated **26 March 2021**, the Provider states that:

> "*In [the Provider] Rules Terms & Conditions, in relation to treatment abroad it is stated 'All treatment must be pre-authorised by [the Provider] and satisfy a list of specific criteria set out by [the Provider]. You must receive written approval from [the Provider] before you travel'. Therefore, while: the exact criteria were not detailed in this document the fact that a list of specific criteria had to be met was. When we received the request for treatment abroad the criteria required to consider a procedure a proven form of treatment were detailed in the response."*

By letter dated **11 February 2021**, the Provider asserts that:

> "*3 a) and b) We wish to advise that in accordance with rule 6) C) 21- 24) the following criteria is noted in the Rules, Terms and Conditions of Membership and also referenced on the prior approval application form*
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> .
>
> - *If you wish to apply for benefit for a planned treatment abroad, we require a fully completed Prior Approval Application from by your Irish based referring consultant.*
> - *We must receive the completed application 20 business days prior to commencement of your treatment.*
> - *We require a copy of the referral letter from your Irish consultant to your treating consultant abroad and this must detail the medical urgency of your treatment.*

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- *All treatment must be pre-authorised by [the Provider's] Insurance and satisfy a list of specific criteria set out by [the Provider's] Insurance. You must receive written approval from [the Provider's] Insurance before you travel.*

This prior approval application form was issued to [the Complainant] on the 13 November 2018 with a cover email noting that specific criteria must be satisfied and that this criteria was on the last page of the questionnaire…. Upon receiving this application form it was reviewed by our panel of medical advisors and a response issued to [the Complainant] on the 18 February 2019 declining benefit as not a proven form of treatment.

However, we did not receive the completed application form from [the Complainant until the 14 February 2019 and we were not aware at that time that [the Complainant] had the proposed procedure 6 days earlier on the 8 February 2019."

Recordings of a telephone call and a webchat chat session (dated **15 May 2019**) have been furnished in evidence and have been reviewed. I have considered the content of the telephone call dated **15 December 2020.** During the telephone call Provider Agent 1 said as follows to the Complainant:

> Provider Agent 1: "*needs to send in a prior approval request…so the medical officers on that team they will assess that medical information once it is received based on the normal terms and conditions of the policy and the medical information, generally that is done within 10 working days….obviously it needs to be approved before you go abroad to have the treatment done hence 'for approval.'*"

I note that Provider Agent 1 supplies detailed information on how the Complainant can send in the form. I accept that on the basis of the call, the Complainant was aware of the procedure for prior approval. I also accept more generally that the Complainant was informed of the criteria under which his claim would be assessed and that the prior approval was required.

I note the content of the letter from the Complainant's UK Professor of Oncology dated **18 December 2018** and addressed to the Complainant's GP which says that "*he is certainly eligible for a focal treatment directed to the left base of the prostate which could be done using high intensity focused ultrasound*." I also note the content of the letter from the UK Professor of Oncology dated **22 January 2019** and addressed to the Complaint which says that "*[Irish Consultant Urological Surgeon] seems very supportive for the HIFU treatment, which I am happy to proceed with*." I note the content of the letter from the UK Professor of Oncology dated **7 March 2019** and addressed to the Complaint which says as follows:

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"*all insurance companies in the UK to my knowledge cover HIFU as they accept that it is an established treatment (10 years in use) with published long term outcomes and considerably safer, in addition to the considerably lower toxicity profile. …*

I think there is still uncertainty in relation to the optimal treatment but the same can be said to surgery, radiotherapy and active surveillance as the long term outcomes of each. according to the most recent trials are the same. … there are published 5 year follow up studies in well defined population groups. There are no randomised controlled trials and to my knowledge there are no randomised controlled trials that are planned, given the difficulty in recruiting men to a treatment of such low toxicity compared to surgery and radiotherapy. Indeed pilots that have attempted to recruit a randomised trial have failed in this area."

I note that the Complainant's Irish Consultant Urological Surgeon wrote to him, on **1 April 2019** and said "*I do however, consider that high intensity focus ultrasound (HIFU) is a very legitimate alternative to the other treatments and this is the treatment that you expressed an interest in*." I note that the Complainant's Irish Consultant Urological Surgeon wrote to him, on **16 June 2020** and said "*HIFU is a perfectly legitimate treatment for men with early stage prostate cancer. Unfortunately, it is not available in this country, hence the reason you had it done London. It may be introduced in Ireland sometime in the future but currently there are no specific plans.*" I am satisfied on a close review of this correspondence that HIFU was recommended as an appropriate treatment by the Complainant's Irish and UK based doctors/consultants.

By letter dated **20 December 2020**, the Provider sets out its criteria for assessing whether a medical procedure is a *proven form of treatment* as follows:

"*For a procedure to be considered a proven form of treatment we require that:*

(i) There is reliable evidence that the procedure has been the subject of well-controlled studies with clinically meaningful endpoints, which have determined its safety and efficacy compared with standard treatments.

(ii) There is reliable evidence that the consensus amongst experts regarding the procedure is that further studies or clinical trials are not necessary to determine its safety or its effectiveness as compared with standard treatments.

(iii) Long term outcomes are available, defined as 5-year follow-up, unless there are exceptional extenuating circumstances related to specific well-defined population groups for whom there is no other reasonable alternative form of treatment otherwise available, when we may either accept

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a) the outcomes of one year follow-up for procedures that been the subject of at least one actively powered randomised control trial or
b) that It is not feasible to perform a randomised controlled trial for treatment and there is otherwise good evidence in the medical literature that the treatment is effective and generally accepted by the medical profession as appropriate with regard to good standards of medical practice."

Discussing how the above test is quantified, the Provider submits by letter dated **20 December 2020,** that:

"[re. (i) above] this is measured by doing an online literature search to find details of any well controlled studies and also taking into account any articles that may be presented by the member or his/her treating consultants either in Ireland or abroad….[re. (ii) above]. This is measured by looking at recent published works on the procedure to see if the. authors recommend further trials. We also look at registries of current trails to establish whether the procedure is currently the subject of a trial into its safety or effectiveness compared with standard treatments. We also examine reports from professional bodies or other expert groups to see if they consider the evidence sufficient to consider a procedure as being a proven form of treatment…[re. (iii) above]…this is again measured by looking a published research and reports from professional bodies or other expert groups."

By letter dated **20 December 2020**, The Provider states that:

"*HIFU, this is not a treatment that is available for prostate cancer in Ireland nor have we received any requests to include it for benefit in the Schedule of Benefits for Professional Fees. With regard to reasonable alternative treatment, there are a number of recognised treatments for the stage of prostate cancer that [Complainant] has been diagnosed with available in this country. These include the following – 'watchful waiting,' chemotherapy, surgery and radiotherapy· and, where these have been determined as proven forms of treatment and it is medically necessary for them to be delivered in a hospital setting, they are listed in the Schedule of Benefits and members are entitled to benefit in accordance with our Rules, Terms and Conditions of Membership. Note: this particular criterion should not be read out of context. If the treatment for which benefit is being requested abroad is a proven form of treatment and is not available in Ireland but a reasonable alternative proven form of treatment is available, then benefit will be provided for the equivalent treatment. However, if the treatment abroad request is*

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for an unproven form of treatment we do not provide benefit for alternative proven forms of treatment that are available here."

The Complainant submits on **18 January 2021** that:

"*I consider my application has in fact met with all additionally listed criteria stated on the prior approval application form, apart from one which states the need for [the Provider's] Chief Medical Officer to be satisfied 'that the treatment abroad to be generally accepted as a proven form of treatment'. I submit that – having virtually met all the myriad of other criteria listed - that this one, which was vaguely stated and 'based on opinion', was onerously applied by the Provider in order to deny me benefit*."

On **1 April 2019**, the Complainant submitted written submissions and argued as follows:

"*High intensity focused ultrasound (HIFU) is a treatment that uses high-energy sound waves to heat and destroy cancer tumour cells. It can be used to treat different types of cancer, including bladder, kidney, liver and pancreatic cancers as well as for localised prostate cancer. Although not as yet available in Ireland the HIFU technology has been used for more than a decade in the UK and in other European countries as well as Canada, and more recently in the USA where, after rigorous evaluation of the more recent research and consensus among experts about the safety and proven potential benefits of the procedure, the Food and Drug Administration (FDA) finally approved (in October 2017) the HIFU procedure for general ablation of prostatic tissue which is now being used to treat localised prostate cancer (Pea)...*

… the HIFU procedure in particular, is shown to be an effective and relatively more safe (in terms of resulting complications and patient quality of life outcomes e.g. incontinency and impotency) procedure for treating intermediate localised prostate cancer than the 'standard' therapy procedures such as Radical Prostatectomy, and forms of Radio Therapy.

…

I would contend the first clause in the above rule can be regarded as being the case. There is indeed reliable evidence from peer reviewed published 5 year long term outcome studies showing comparable efficacy, in addition to the considerably lower toxicity profile, than the 'standard' radical treatments…

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While it is true that the HIFU procedure is subject to ongoing research and that it has only recently been approved for extensive clinical trials in a significant number but not all NHS centres in the UK, It is increasingly being accepted as an effective from of treatment by both leading medical consultants and the insurance establishment in the UK on the basis that there is already clear and reliable evidence, from the recently published peer reviewed research, including five year follow up studies cited above (as well as in much of the various research studies listed in Appendix A), which show the relative efficacy of HIFU to be the same when compared to other 'Standard Treatments.'

As far as relative safety is concerned, HIFU is also shown in the relevant studies to be substantially better in terms of risk of e.g. post-operative infection, incontinence and impotency as well as other post-surgical complications and side-effects of the comparative 'standard' treatments referred to above… As mentioned above the NHS in the UK has approved and provides HIFU treatment as an alternative to the established radical surgery and radiation treatment to patients with my diagnosis although, as yet, due to scarcity of mpMRI and HIFU equipment and the trained personnel in all its treatment centres it is only available in a limited (but growing) number of treatment centres as part of ongoing clinical trials programme with a view to being rolled out over time to be offered as a standard procedure…..

There are indeed a number of published peer reviewed studies including five year follow-up studies, (and even some 10 year and fourteen year follow up studies) indicating that Focal Therapy, predominantly with HIFU treatment, to be 'at least as effective in treating localised intermediate PCa' in well-defined populations as other standard treatments. In particular, the study published in The Journal of European Urology 'Multicentre Study of 5-year Outcomes Following Focal Therapy in Treating Clinically Significant Nonmetastatic Prostate Cancer" referenced above…

As far as the necessity or otherwise for further clinical trials for the HIFU procedure is concerned, the same can be said for the efficacy of standard treatments of surgery, radio therapy and active surveillance, as the medium and long-term outcome (5 year plus follow up) for each are the same (as are for HIFU) according to the most recent trials….

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While it is true that there are, as yet, no "properly randomised" comparative trial studies specifically in regard to HIFU, this is shown to be for good reason i.e. the difficulty in recruiting sufficient cohorts of men to a treatment of such low toxicity and morbidity compared with surgery or radio therapy….

In fact, some of these other 'standard treatments' (prostate brachytherapy, radiation and robotic prostatectomy), have been approved for clinical use (including their eligibility for benefit by [Provider] and other insurance companies) without or before the completion of randomised comparative studies."

The Complainant contends, on **1 March 2021,** that:

"I have provided such evidence; including statements form my doctors as well as key studies, confirming that this is the case for the HIFU treatment I have undergone. In fact, (as would be expected from this non- invasive surgical procedure) the safety profile and risk of collateral pathological side effects is lower than the other standard treatments offered for my condition. The efficacy of HIFU in these studies in terms of meaningful outcomes i.e. comparative mortality and recurrence rates is shown to be at least equal to that of standard treatments….. Leading Urologists both in Ireland and the UK have recommended HIFU as a safe and effective treatment in my case. Although, [the Provider] have pointed out that there have been calls from some experts for longer term (more than 5 years) follow up studies - see below) to further substantiate HIFU as a proven comparatively effective treatment, I contend that [the Provider] , in this case, has unfairly and unreasonably applied a 'change of goal post' on this criteria … in determining HIFU as 'unproven' and, consequently, to deny me benefit for my Treatment Abroad…The studies I have submitted satisfy [the Provider's] definition of what they consider to be long-term outcomes,(defined as 5-year follow-up) and all strongly evidence safety and efficacy of HIFU with comparable outcomes to standard treatments, including the more recent study I have cited above as evidence under (I) which studied outcomes over 8 years. NB: Studies requiring randomised controlled trials are not a stated prerequisite under this criterion - providing long term trials 'defined as 5 year follow up' are available.*"

By letter dated **18 January 2021**, the Complainant submits that:

"I have provided qualifying evidence meeting [the Provider's] specifically listed sub-criterion that requires 5 year studies showing relative effectiveness of HIFU treatment, compared with alternative standard forms of treatments, as proof of its effectiveness as a treatment. [The Provider's] medical officer's assessment that it would be a requisite of proof that longer term studies in randomised trials are

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carried out (which, by the way, were never a "proven" requisite for the standard forms of treatment such as prostatectomy - which they already cover for benefit in Ireland), is a burden of proof unreasonably applied in my case and which I contend "moves the goalposts" beyond [the Provider's] own specified criteria forming the unfairly applied basis in their assessment for their decision to deny me benefit. The HIFU treatment I received is not some form of fringe, unproven, ineffective quack doctor treatment which I would concede [the Provider's] might legitimately refuse to provide benefit cover in honouring its stated purpose and promise to its customers. I respectfully suggest for consideration that it was reasonable for me to follow the eminent specialists' advice both here in Ireland (ref [Irish Consultant Urological Surgeon's] recommendations and statements as to the efficacy and safety of the procedure on my application for approval of treatment abroad) as well as in the UK (ref. [UK Professor of Oncology]), as being 'in the best interests of my health and wellbeing'. I would also contend that it was, under these circumstances, which I have petitioned and evidenced, a reasonable expectation from my policy that [the Provider's] would and should in this case, pay benefit towards my treatment abroad."

By letter dated **20 December 2020**, the Provider submits that "*based on the medical information submitted, our comprehensive review of the literature on HIFU and in accordance with [the provider's] definition of 'Proven form of Treatment' HIFU to treat prostate cancer is not generally accepted as a proven form of treatment and this is the opinion of [the Provider's] Medical Director*."

By letter dated **26 March 2021**, the Provider states that:

"*In relation to HIFU for prostate cancer, [the Provider] have recently sought the opinion of a consultant urologist who is a member of the medical advice group on the current state of evidence for this procedure. When considering whether a procedure could be considered a proven form of treatment [the Provider] sometimes use a Grid system where we lay out the relevant evidence. While not definitive, the more ticks in the left hand column 'approved' the more likely the procedure is to meet [the Provider's criteria to be considered a proven form of treatment. Following discussions with the consultant urologist, [the Provider's] medical director is of the opinion that in relation to the use of HIFU for prostate cancer the grid would look as follows*:

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	Approved	Further Follow-up Required	Not Approved/ No Reference	No Documents
Literature on safety and efficacy		✓		
5-year follow-up available (or 1 year if exceptional)		✓		
Appropriate use guidelines			✓	
NICE			✓	
FDA			✓	
Aetna			✓	
CPT	✓*			

*Specific Code only added to CPT (Current Procedural Terminology) in 2021 i.e. after the member's treatment.

The Provider asserts by letter dated **20 December 2020,** that:

> "*on the HSE website, they say that HIFU treatment is still going through clinical trials for prostate cancer*."
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> …
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> "*All of these reviews would have looked at the available evidence. The European Association of Urology for example noted that in updating the guidelines on prostate cancer for 2020 they included 223 additional references that were not included in the 2019 version. Therefore, while there may be research papers in support of HIFU for localised prostate cancer, the consensus opinion of experts, in Ireland, United Kingdom and around Europe, as detailed above, is that at this point the procedure requires further research*."
>
> …
>
> "*as previously confirmed by the consultant abroad, [UK Professor of Oncology], there are no randomised trials available in relation to HIFU for this member's condition. Therefore, whilst there have been many published papers in relation to HIFU for prostate cancer there is not reliable evidence that the procedure has been the subject of well-controlled studies with clinically meaningful endpoints, which have determined its safety and efficacy compared with standard treatments…..the procedure and the overall evidence has been looked at by a number of expert groups who have concluded that further research is required*."

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The Provider further submits by letter dated **20 December 2020,** that: "*the EUA guideline indicates that the general view of European experts in this area is that further research is required and the procedure should only be offered as part of a trial.*"

…

"[the Provider] carries outs its own assessment of procedures for compliance with all of the criteria that have been agreed with our Medical Advice Group as being necessary to establish a treatment as a proven form of treatment. We review available literature as detailed above and [Provider] have consulted guidance documents from bodies in Ireland (National Clinical Effectiveness Committee), the UK (NICE, NHS) and Europe (EAU, European Network for Health Technology Assessment). [the Provider] does not specifically liaise with other insurers. Where other insurers have published their clinical guidance documents online, we will review these. For example, Aetna and Cigna in the United States have a wide range of such documents published In the case of HIFU, Aetna considers high intensity focused ultrasound (HIFU) medically necessary only for radio-recurrent prostate cancer in the absence of metastatic disease and this is the only medical indication listed for cover. Cigna considers it medically necessary in the following clinical situation only – as a local treatment for recurrent prostate cancer following radiation therapy when BOTH of the following criteria are met:

- *Positive, recent (i.e., repeat), transrectal ultrasound guided biopsy completed due to suspicion of local recurrent of prostate cancer*

- *Candidate for local therapy alone as evidence by ALL of the following:*

    - *Original clinical stage T1-T2, NX or NO*
    - *Recent PSA < 10 ng/ml*
    - *Absence of distant metastases.*

The above medical circumstances are different to those that pertain in the Complainant's case."

…

/Cont'd…

"In his submission, however [the Complainant] indicates, "the European Urology Association accepts this treatment procedure for cases such as mine". However, in their 2020 guideline on prostate cancer the EUA say in relation to High Intensity Focused Ultrasound that 'the lack of any long-term prospective comparative data on oncology outcomes prevents whole gland HIFU from being considered as a reasonable alternative to the established curative treatment options'.

In addition, in relation to focal therapy; while they note a number of studies are available including 'three studies on focal HIFU' and also 37 studies which compared a number of different modalities for providing focal treatment including HIFU they concluded that "given the lack of robust comparative data on medium to long-term oncological outcomes for focal therapy against curative interventions significant uncertainties remain in regard to focal therapy as a proven alternative to either active surveillance or radical therapy."

The Provider also submits that:

"The evidence for HIFU has also been looked at by the European Association of Urology (EUA), European Society for Radiotherapy and Oncology and the International Society of Geriatric Oncology as part of their joint guideline on prostate cancer. In relation to the evidence supporting HIFU the guidelines detail a summary of the evidence around HIFU and state:

I. The available short-term data regarding cryosurgery and high-intensity focused ultrasound (HIFU) does not prove equivalence to standard Interventions.

II. There is no reliable long term comparative data to Indicate that cryosurgery or HIFU leads to equivalent oncological outcomes compared with radical prostatectomy or external beam radiation therapy.

Ill. Focal therapy of any sort appears promising but remains investigational, with uncertainties surrounding outcome definitions, follow-up and re-treatment criteria.

They then recommend:

i. Only offer cryotherapy end high—intensity focused ultrasound within a clinical trial setting.

ii. Only offer focal therapy within a clinical trial setting."

/Cont'd…

By letter dated **11 February 2021**, the Provider submits that:

> *"NICE also updated the guideline "focal therapy using high-intensity focused ultrasound for localised prostate cancer" in April 2012.*
>
> *However, NICE is only one of a number of bodies who do not support the use of HIFU outside a research setting. The others include:*
>
> *• The European Association of Urology, as recently as 2020 says that HIFU "should only be offered within a clinical trial or well-designed cohort study".*
> *• The National Clinical Effectiveness Committee in Ireland still says high intensity focused ultrasound should be considered experimental pending the results of future trials.*
> *• The European Network for Health Technology Assessment who stated that there is insufficient evidence to determine whether HIFU is more effective than (or at least as effective as) and/or has a better (or at least similar) safety profile than Active surveillance, Watchful Waiting, salvage radical prostatectomy or salvage radiotherapy for the treatment of prostate cancer*.

The Provider also submits that "*The National Institute for Health and Care Excellence (NICE) in the UK has guidelines for the diagnosis and management of prostate cancer. These guidelines specifically state 'do not offer high intensity focused ultrasound and cryotherapy to men with localised prostate cancer other thon in the context of controlled clinical trials comparing their use with established Interventions.'*"

The Complainant states, on **18 January 2021,** that:

> "*The specific quotes which [The Provider] have selectively plucked from the NICE guidelines recommending HIFU to be prescribed as a treatment only in a clinical trial situation, are actually from over twelve years ago, 2008 - and is, confusingly, cited from a NICE webpage where only some of the other guidelines were updated in May 2020. HIFU, as attested above, is no longer a treatment requiring clinical trial approval and is an accepted procedure by the NHS in the UK. This in fact corroborates that NHS UK (who operate under NICE guidelines) now also perform HIFU outside a clinical trial setting as an accepted and approved reasonable alternative from of treatment to standard treatments for PCa conditions such as mine, and although not as yet available across the whole of the NHS, has become a routine treatment in an increasing number of its hospital centres. HIFU is no longer therefore a treatment confined to clinical trial programmes…*

/Cont'd…

> *"I would postulate that there is also a 'chicken and egg scenario' at play here - as to why the HIFU procedure is not as yet available in Ireland as a treatment..."*

The Complainant further submits that:

> "*Although [the Provider] has sought in its submission to dismiss this evidence as insufficiently reliable or credible, the clinical trials carried out by a number of eminent institutions "including Imperial College London and University College London, found that after five years (the follow up period required for studies stipulated in their own criteria) the cancer survival rate from HIFU was 100 per cent. The cancer survival rate from standard surgery and radiotherapy is also 100 per cent at five years in comparative studies*."

The Provider submits that in Ireland, "*the National Clinical Effectiveness Committee published guidelines for the diagnosis, staging and treatment of patients with prostate cancer and in this they state: Presently, high-intensity focused ultrasound (HIFU) and cryotherapy should be considered experimental, pending the results of future trials.*"

The Provider further submits the NHS website in relation to HIFU states that, "*HIFU treatment is still going through clinical trials for prostate cancer. In some cases, doctors can carry out HIFU treatment outside of clinical trials. HIFU is not widely available and its long-term effectiveness has not yet been conclusively proven*". The Provider also submits by letter dated **11 February 2021** that "*the website for the clinic that [the Complainant] attended states that within the NHS focal therapy is 'only available on a limited basis.'*"

The Provider contends, by letter dated **26 March 2021**, that:

> "*the availability of this procedure in the NHS would not alter [the Provider's] view that the procedure does not meet our criteria to be considered a proven form of treatment*."

The Complainant submits, by letter dated **11 May 2020,** the following:

> "*When discussing my treatment options with [Irish Consultant Urological Surgeon], I did ask why the option of HIFU was not currently available in Ireland -- his response was that it had being seriously discussed within the Irish Urologist circle and while they agree that it is a safe and recommended option to treat 'Localised - prostate cancer'- the demographics here in Ireland would not make it a viable option at this point in time*."

/Cont'd…

The Provider submits by letter dated **20 December 2020,** that: "*we are unaware of the basis for saying the treatment is not available in Ireland due to demographic reasons*."

On **1 April 2019**, the Complainant submitted written submissions and argued as follows:

> *"Contrary to [the Provider's] assertions in their final response to my appeal for benefit, there is indeed proof that other leading health insurance companies in the UK e.g. [Insurance Company X], [Insurance Company Y] and [Insurance Company Z] cover HIFU treatment for Intermediate Localised Prostate Cancer (Pea) and consider HIFU an approved form of treatment in specific circumstances (such as mine). See attached statement from [Complainant's brother] and [Insurance Company X] healthcare proof of invoice settlement for HIFU treatment. While Insurance companies do not publish their internal criteria for approving the medical treatments they will cover (for reasons of commercial confidentiality) it is self-evident and safe to assume that they would not have considered providing benefits for HIFU treatment for diagnosed conditions such as mine unless they were satisfied it was an accepted proven and safe form of treatment…"*

The Provider further submits that, by letter dated **20 December 2020,** that:

> "*1. We note the member 's submission to your office and he mentions that the procedure is performed in a number of centres and that the insurance company [Insurance Company X] provide benefit. While the procedure is available in some centres in the UK, it has only limited availability. Prostate cancer is the most common cancer in men in the UK with almost 50,000 new cases diagnosed every year, the lack of centres providing HIFU would indicate a lack of acceptance by the profession rather than support for the procedure*."

The Provider submits by letter dated **20 December 2020,** that "*in the interest of patient safety we must ensure that all proposed treatment is a proven form of treatment*."

The Complainant submits, on **1 March 2021,** that:

> "*In response, [the Provider] have cited the specific criteria on which its definition of a "proven form of treatment" is determined by its chief medical officer, which are applied as caveats for the stated purpose of "protecting health and safety of their customers" - which would justifiably deny benefit to patients who have chosen to undergo unsafe or ineffective medical interventions - but which I contend were not reasonably applied or determined, given the circumstances, in my case*."

/Cont'd…

The Complainant submits, by letter dated **18 January 2021,** that "*see the link to the Urologists clinic in the UK website publicly listing the companies which provide insurance cover benefit for HIFU. HIFU Focal Therapy and Private Healthcare Insurance - UK Prostate Cancer Treatment (thefocaltherapyclinic.co.uk)*."

The Provider submits by letter dated **20 December 2020,** that it

> "*cannot comment on the cover provided by or criteria used by other health insurers in deciding to allow benefit or not for a procedure. We are unaware of any insurers in Ireland who cover this procedure however some international insurers may."*

The Provider submits in its **Final Response Letter** dated **6 June 2019** and addressed to the Complainant, the following:

> "*[the Provider] does not know the criteria used by UK Insurers to determine whether a treatment Is covered for insurances purposes or not and we do not know whether or not the above statement Is correct. An internet search with regard to cover for HIFU has not readily answered this question but has identified that [UK Health Insurer] website provides information on HIFU by an expert reviewed… Consultant Urological Surgeon. The article states that not all NHS Trusts offer this treatment yet because it is still part of ongoing research, although its becoming more widely used. In addition the article also states that HIFU is becoming more widely available for prostate cancer but only is part of clinical trials. This is because the data on the effectiveness of this treatment is still being collected and monitored*."

The Provider submits in its **Final Response Letter** of **6 June 2019** that:

> "*In our previous decision we had quoted the guidelines published by the European Association of Urology and we had noted that the guidelines mention that HIFU should be offered within a clinical trial setting. Indeed these 2019 revised guidelines on prostate cancer make reference to the study you mention above. The guidelines acknowledge the study's limitations (prospective uncontrolled, single arm case series) and further state that focal therapy should remain investigational for the time being; robust prospective trials reporting standardised outcomes are needed before recommendations in support of focal therapy for routine clinical practice can be made.*

/Cont'd…

Furthermore we reinforce our last decision in which we concluded that there were no well controlled studies to assess this procedure (the study you have presented is a prospective uncontrolled study) which have determined its safety and efficacy compared with standard treatments, nor is there consensus amongst experts that this procedure should be offered in cases of intermediate risk localised prostate cancer (apart from in clinical trials) as shown by the 2019 recommendations of the European Urology Association on Prostate Cancer (amongst others…).”

The Provider submits, by letter dated **26 March 2021**, the following:

“*We note the further information received from [the Complainant] and the reference to a recently published article (Focal therapy compared to radical prostatectomy for non-metastatic prostate cancer: a propensity score-matched study) which concludes ‘In patients with non metastatic low-intermediate prostate cancer, oncological outcomes over 8 years were similar between focal therapy and radical prostatectomy’. As detailed previously, while there is evidence to support the use of HIFU for prostate cancer, the overall body of evidence does not support the procedure meeting [the Provider’s] criteria to be considered a proven form of treatment*."

The Provider by letter dated **11 February 2021** notes:

“[*The Complainant] has provided a copy of an article ‘High-intensity focused ultrasound focal therapy for prostate cancer’. While I note he has referred to it as a ‘recent study carried out in this regard the article itself is not in fact a study in that it is not written based on particular research carried out by the authors. It is a review article where the authors describe HIFU for prostate cancer and discuss previous studies. As [The Complainant] himself has noted, the article calls for more research. The authors note ‘randomised controlled trials are currently recruiting to provide more solid data, and earlier cohorts of patients will continue to be studied so that long-term outcomes can be better understood'. While I note [The Complainant] mentions that ‘such a caveat is the academic norm for nearly all scientific research papers’, this is not actually the case and authors only say it when they actually believe further research is required. The article however confirms that randomised clinical trials are still ongoing which confirms [the Provider’s] assertion that there is not ‘reliable evidence that the consensus among experts regarding the procedure is that further studies or clinical trials are not necessary to determine its safety or its effectiveness as compared with standard treatments*.’”

/Cont’d…

The Complainant submits on **18 January 2021** that:

> "*I would respectfully suggest that using a criterion for exclusion in forming an opinion whether any medical treatment is 'unproven' because the scientific research papers into its safety and efficacy calls for further research is in itself unsound, as citing such a caveat is the academic norm for nearly all scientific research papers.*"

I accept that the Provider was contractually entitled to determine, pursuant to Rule 6 (c) 21 of its **Rules, Terms and Conditions of Membership** and on an assessment of *a fully completed Prior Approval Application form,* whether *benefit was payable - benefit is not payable for new, not proven forms of surgical procedures*. I note from the Complainant's Health Care Plan 1's **Table of Benefits** (dated **1 March 2018)** that under section 7 "Elective Treatment Abroad (subject to prior approval) is covered up to €100,000.00 for *surgical procedures available in Ireland (as per level of cover in Ireland)* or where the *treatment is not available in Ireland*. I accept that, as set out in its letter of **19 February 2019**, the Provider was entitled to establish a criteria including that the treatment abroad must be *considered by [the Provider's] Medical Director to be generally accepted as a proven form of treatment.* I accept that the Complainant was informed at any early stage of the nature of this criteria. The Complainant and the Provider submitted a considerable amount of evidence as to whether HIFU this fell under a *proven form* of procedure.

I note that the Complainant's Irish Consultant Urological Surgeon wrote to him, on **16 June 2020** and said "*HIFU is a perfectly legitimate treatment for men with early stage prostate cancer. Unfortunately, it is not available in this country, hence the reason you had it done London. It may be introduced in Ireland sometime in the future but currently there are no specific plans.* I am satisfied that the HIFU was recommended as an appropriate treatment by the Complainant's Irish and UK based doctors. I note the Provider's submission that the HSE website says that *"HIFU treatment is still going through clinical trials for prostate cancer*." I note the Complainant's submission that *there are, as yet, no 'properly randomised' comparative trial studies specifically in regard to HIFU*."

I am satisfied that the balance of the evidence favours the Provider's position in this matter. In particular I note that the procedure is not available in Ireland, it is not an established reasonable alternative to existing treatment options, there is no reliable long term comparative data to indicate its effectiveness against existing treatments and that medical experts have found that HIFU should be considered experimental pending the results of future trials. I note the Provider's submission that it has a "*duty of care towards our members."*

/Cont'd…

I accept that the Provider has important obligations in respect of patient safety and recommending efficient and proven treatments in the face of serious disease progression.

I note contents of the email from [Location] clinic in Ireland quoting an estimate of €15,000.00 to the Complainant on **20 March 2019**. I note the contents of the quote from the London Urology organisation of GBP£11,710.00 for *hospital stay, anaesthetist and surgeon's fees*. I note contents of the **Statements of Invoices and Receipt of Payment** document submitted and that the total (less travel or accommodation expenses) is €21,860.00.

The Provider submits that, by letter dated **20 December 2020,** that "[*the Provider] did not receive a copy of these medical expenses from [the Complainant]. However, as part of [the Complainant's] correspondence dated 2nd April 2019 quotations for the treatment were submitted from the [UK based Urology Company]. We have not received any travel or accommodation expenses*."

The Complainant submits that:

> "*HIFU is a one-off day care procedure, which is non-invasive treatment by comparison to a minimum three-day overnight hospitalisation and longer recovery period for the surgical Prostectomy procedure in Ireland. The costs for treatment, which I would be entitled under my policy with [Provider] Insurance, if I had elected for the prostatectomy in an approved private clinic in Ireland is comparable to the cost of HIFU treatment available to me in the UK (Approx. EUR 15,000 minimum including hospital and surgeon and anaesthetist fees (see enclosed estimate from [Location] Clinic and [Health Insurer X] - ppp settlement statement of HIFU hospitalisation package cost)…. Considering all the above, and that [the Provider] would be otherwise benefiting from my decision to proceed with HIFU procedure in the UK by not paying for Prostatectomy treatment in Ireland*,"

By letter dated **26 March 2021**, the Provider responded by saying:

> "*Irrespective of what benefit we may have paid or will pay in the future for surgical prostatectomy or other treatment for [the Complainant] that potential benefit cannot be used to offset the costs of treatment that in itself is not eligible for benefit*."

By letter dated **20 December 2020**, The Provider states that "*we have not received any claim form regarding the HIFU treatment [the Complainant] received in the UK*."

/Cont'd…

I also accept that the Complainant was informed of the criteria under which his claim would be assessed and that the approval was *prior* approval. I note the expenses that were involved on the Complainant's part but I accept that in circumstances where prior approval was not sought or received in advance of the treatment and where it was not in keeping with the Provider's criteria, the Provider was entitled to refuse cover. I also note that no claim form has been submitted to the Provider and that the Provider is under no obligation to offset payments for unproven treatments on the basis that it didn't have to pay out for theoretical, comparative or future treatments.

While I understand the Complainant's motivation to get, what he considered to be the best treatment available for his condition as quickly as possible, I cannot ignore the Provider's entitlement to set out its own commercial and medical terms and conditions and rules.

I accept that the Provider acted in accordance with its **Rules, Terms and Conditions of Membership** when it declined to cover the Complainant's HIFU treatment.

For this reason, I do not uphold this complaint.

Conclusion

My Decision pursuant to ***Section 60(1)*** of the ***Financial Services and Pensions Ombudsman Act 2017***, is that this complaint is rejected.

The above Decision is legally binding on the parties, subject only to an appeal to the High Court not later than 35 days after the date of notification of this Decision.

GER DEERING
FINANCIAL SERVICES AND PENSIONS OMBUDSMAN

20 December 2021

/Cont'd…

Pursuant to *Section 62* of the *Financial Services and Pensions Ombudsman Act 2017*, the Financial Services and Pensions Ombudsman will publish legally binding decisions in relation to complaints concerning financial service providers in such a manner that—

(a) ensures that—

(i) a complainant shall not be identified by name, address or otherwise,

(ii) a provider shall not be identified by name or address, and

(b) ensures compliance with the Data Protection Regulation and the Data Protection Act 2018.