An tOmbudsman Seirbhísí Airgeadais agus Pinsean
Financial Services and Pensions Ombudsman

Decision Ref:	2019-0358
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

Background

This complaint relates to a health insurance policy and the Provider's repudiation of the Complainant's claim.

The Complainant underwent a medical procedure in England to remove cancer from his prostate gland in **September 2016**. The Complainant states that he acted on medical advice received in Ireland that a procedure called *"High Intensity Focused Ultrasound"* was the most suitable treatment for his illness, or, at least, less invasive than removing his prostate completely which would have had a higher chance of serious side effects on the Complainant's quality of life thereafter. The Complainant asserts he received the full support of his Urologist in deciding to undergo the procedure, which was not available in Ireland. In the context of the procedure, the Complainant paid medical expenses in the sum of €15,000.00. The Complainant states that he could have opted for removal of his prostate in Ireland and this would likely have been covered under his policy. However, in considering medical advice, he submits that if he had chosen the latter treatment, it would have been less suitable and may have resulted in serious long term side effects, such as incontinence and impotence.

The Complainant sought prior approval from the Provider for his treatment. The Provider refused. The Complainant submitted further communications from his treating practitioners in support of his claim. The Provider reviewed his claim and it was again refused. In its Final Response Letter dated **25 September 2017**, the Provider states that,

> *"we will pay benefit for medically necessary surgical procedures that are currently listed in [the Provider's] schedule of benefits for Professional fees, Surgery and Procedures section"*.

In declining the claim the Provider goes on to state,

> *"we are unable to provide benefit towards to cost of 'High Intensity Focused Ultrasound' as this would be considered experimental and therefore does not meet [the Provider's] criteria for benefit"*.

The Complainant's Case

The Complaint is that the Provider wrongfully and unfairly refused to indemnify the Complainant under his health insurance policy for the medical costs he incurred abroad.

The Complainant wants the Provider to reimburse him for all or for a substantial portion of the costs he incurred for the medical procedure concerned.

The Provider's Case

The Provider contends that it has acted in accordance with the principles of fairness and natural justice at all times in respect of this claim.

The Provider states the particular treatment is excluded from benefit as it is not deemed a proven form of treatment and the Complainant was made aware of this exclusion, prior to proceeding to have the treatment carried out.

The Provider points out that the procedure in question (HIFU) is not listed as a covered procedure within the Schedule of Benefits of the Complainant's policy. There are however, a number of treatments such as surgery, chemotherapy and radiotherapy already listed in the Schedule of Benefits which, if undergone by the Complainant, would have entitled him to benefit payments under the policy in accordance with the rules.

Whilst the Provider has noted the Complainant's comments regarding the suitability of the preferred procedure available in the U.K. it points out that it has no role in determining the suitability of one treatment over another for any individual patient. The Provider's role is to determine whether or not the treatment undergone, or to be undergone, is covered for benefit in accordance with the Provider's rules. The Provider confirms that the procedure "*has been in use for many years, it is not a procedure that meets the criteria we use to be considered a proven form of treatment*". The Provider refers in that regard to the terms of its rules which confirm clearly that:-

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

/Cont'd…

The Provider also points out that in order for a particular treatment to be considered a proven form of treatment, the Provider assesses the treatment against a number of criteria which have been agreed with its Medical Advice Group. Those criteria are:-

> *"The procedure must be safe, effective (both from a clinical and cost perspective) and generally accepted by the medical community. In order to comply with this definition the following criteria must be satisfied:*
>
> *(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 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.*
>
> *(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*
>
> - *(a) the outcomes of a 1-year follow-up for procedures that have been the subject of at least one adequately powered randomised controlled trial or*
> - *(b) that it is not feasible to perform a randomised controlled trial for a 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."*

For those reasons, the treatment sought by the Complainant was not considered by the Provider to be a "*proven form of treatment*".

The Complaint for Adjudication

The complaint is that the Provider wrongfully refused the Complainant's claim for benefit under the policy.

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

/Cont'd…

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 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 16 September 2019, outlining the preliminary determination of this office 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, the final determination of this office is set out below.

The Complainant's application was first considered by the Provider's Panel on **13 September 2016** and was declined on **16 September 2016**. On **22 September 2016** the Provider received an e-mail from the Complainant's Consultant Urologist containing further information which was reviewed by the Provider's panel of medical advisors, however, the decision was not altered as the Provider stated that the treatment did not meet the Provider's criteria to be considered a proven form of treatment. The decision was subsequently appealed by the Complainant.

Further correspondence was sent from the Complainant's Consultant Urologist and the Professor of Interventional Oncology in charge of the Complainant's care in England in relation to the treatment, but the Provider's decision was not altered. The Provider contends that no evidence of long-term outcomes was available with respect to the treatment and this is one of the criteria required, in order to consider a treatment to be a proven form of treatment.

The Provider states in a letter dated **30 January 2017** that the Provider does not provide benefit for treatments that are considered unproven. The Complainant's Urologist stated in his letter dated **28 November 2017** that the therapy *"has been in play for ten years and indeed there is a randomised control trial to show its benefit over active surveillance".* It is clear that the medical opinion relied upon by the Complainant and the policy decision of the Provider regarding this particular treatment are very much at odds.

The Complainant formally appealed the original decision of the Provider on **1 August 2017.** A letter from the Professor in charge of the treatment in England was furnished. This appeal

/Cont'd…

was formally denied by way of final response letter dated **25 September 2017** after a review of the information by the Provider's medical advisors, who advised that the treatment could not be deemed to be a proven form of treatment. On **11 April 2018** the Provider's panel of medical advisors and the Provider's Medical Officer reviewed the case again, however, the original decision was maintained.

I note that in September 2016, after the Complainant was recommended by his Urologist, to undergo *"High Intensity Focused Ultrasound"*, the Complainant contacted the Provider and spoke to an agent; a recording of this telephone conversation has been furnished in evidence to this office. During the phone call, the Complainant informed the agent that he had a scheduled appointment for the Ultrasound in the coming weeks in England and understood he had to apply for prior approval.

The Complainant, understandably, was reluctant to vacate his scheduled appointment for the purpose of allowing the approval process to take place, as he had prostate cancer and wanted to deal with it as expeditiously as possible. The agent informed the Complainant that he had spoken with a colleague and he informed the Complainant that even if the Complainant's medical procedure was deemed suitable and would be covered, he would require the prior approval from the Provider.

A letter from the Complainant's Consultant was sent to the Provider outlining that the only available treatments in Ireland for the Complainant's condition would carry a risk of impotence and incontinence. The Consultant Urologist disputes the suggestion by the Provider that the treatment is unproven. Correspondence from the Professor whose care the Complainant was under in England was also made available. The Professor outlined how several of the major insurance carriers in the U.K. covered the treatment, along with a governing body in the U.S.A.

I note that in responding to the formal investigation of this complaint, by way of letter dated 4 January 2019, the Provider sought to rely upon the **April 2018** conclusions of the European Network for Health Technology Assessment, which had reviewed the procedure which is the subject of the complaint (known as HIFU) and made certain conclusions. I am conscious however, that at the time when the Provider declined the Complainant's request for prior approval, those conclusions were not available to the Provider and could not have informed its decision. Likewise, the guidelines issued by the European Association of Urology in **2018** regarding the treatment and investigation of prostate cancer which references the procedure which is the subject of this complaint, under "*Investigational Therapies*", was likewise not available to the Provider at the time when it made its decision to decline the Complainant's claim. I have however, considered the details which were made clear to the Complainant by way of the Provider's Final Response Letter dated 25 September 2017, which explained to the Complainant that for the Provider's Medical Director to regard the procedure which is the subject of this complaint as one which is a "*generally accepted proven form of treatment*" a number of conditions had to be met:

/Cont'd…

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

(ii) *There is reliable evidence that the consensus amongst experts 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, to find as 5-year follow-up."*

The Provider explained to the Complainant that the treating consultant had confirmed that there had been no randomised controlled trials of HIFU in localised prostate cancer, and also that there was no long-term data available at that time. It also pointed out that the National Institute for Health and Care Excellence (NICE) in the U.K. had guidelines at that time, for the diagnosis and management of prostate cancer which specifically stated that:-

> *"Do not offer high-intensity focused ultrasound and cryotherapy to men with localised prostate cancer, other than in the context of controlled clinical trials comparing their use with established interventions*."

In addition, the Provider referred the Complainant to the information available from the European Association of Urology at that time, regarding HIFU which stated:-

> *"1. The available short-term data requiring cryosurgery and high-intensity focused ultrasound (HIFU) does not prove equivalence to standard interventions.*
>
> *2. 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.*
>
> *3. Focal therapy of any sort appears promising but remains investigational, with uncertainties surrounding outcome definitions, follow-up and re-treatment criteria."*

The Provider noted that the European Association of Urology recommended cryotherapy and HIFU only within a clinical trial setting and, in Ireland, the National Clinical Effectiveness Committee published guidelines (on a date which was not confirmed) which stated:-

> "*Presently, high-intensity focused ultrasound (HIFU) and cryotherapy should be considered experimental, pending the results of future trials*".

I note that in those circumstances, the Provider declined to provide benefit towards the cost of the HIFU treatment, sought by the Complainant as the Provider considered the treatment to be experimental and not to meet the Provider's criteria for benefit as outlined within the policy rules.

It is of course understandable that in the Complainant's particular situation he may well have wished to embark on the treatment discussed with his Consultant, notwithstanding the absence of any evidence of long-term outcomes, but he did so in the knowledge that

/Cont'd…

the policy of health insurance held with the Provider did not offer benefit for treatment of that nature, and that this was a cost which the Provider would not meet.

I am satisfied on the basis of the evidence made available that he made an informed decision to proceed in that manner. I am also satisfied however, that the Provider was entitled to decline the Complainant's claim for benefits for the reasons outlined above, and accordingly, as there is no evidence before me of any wrongdoing on the part of the Provider, it is not appropriate to uphold this complaint.

This complaint is rejected.

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.

MARYROSE MCGOVERN
DIRECTOR OF INVESTIGATION, ADJUDICATION AND LEGAL SERVICES

15 October 2019

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.