An tOmbudsman Seirbhísí Airgeadais agus Pinsean
Financial Services and Pensions Ombudsman

Decision Ref:	2022-0095
Sector:	Insurance
Product / Service:	Private Health Insurance
Conduct(s) complained of:	Disagreement regarding Medical evidence submitted Delayed or inadequate communication Complaint handling (Consumer Protection Code) Rejection of claim
Outcome:	Rejected

LEGALLY BINDING DECISION OF THE FINANCIAL SERVICES AND PENSIONS OMBUDSMAN

The late Policyholder incepted a health insurance policy with the Provider on **10 October 2017**. The policy period in which this complaint falls, is from **October 2019** to **October 2020**, during which period, sadly, the late Policyholder died.

The Complainant is the Estate of the late Policyholder. This complaint concerns the Provider's refusal to approve the late Policyholder's **January 2020** application for cover for a high-cost cancer drug.

The Complainant's Case

In his letter to this Office dated **22 June 2020**, the Complainant set out the complaint, as follows:

> *"On the 17th January 2020,* [the Provider] *refused our request to pre-authorise cover for prescribed medications to treat my wife's reoccurrence of cancer. My wife…has successfully battled cancer on a number of occasions and we have been customers of* [the Provider] *for many years.*
>
> *To put matters into perspective, in mid-2018 we found out that my wife's oesophageal cancer had returned and surgery was required to remove her [surgery details redacted]. This operation was successful and after a period recuperating in*

hospital – [my wife] *made a good recovery. All of the health costs incurred at that time were paid by* [the Provider] *under the terms of our health insurance policy…*

In [date redacted], my wife's consultant advised us of another reoccurrence of cancer and in order to give [my wife] *the 'best chance' the paramount treatment option was for her to receive Pembrolizumab (immunotherapy drug) and Chemo-therapy medications together as a 'first-line' treatment of cancer.*

In December 2019, our consultant…submitted a pre-approval request for this blend of medication to [the Provider] – *this pre authorisation was refused by* [the Provider] *on 17 January 2020.*

We immediately replied to [the Provider] *and requested an urgent review and an appeal. This request seemed to be getting passed around from one department to another and we had difficulty initiating an appeal. We certainly felt* [the Provider] *were 'kicking the can down the road' and perhaps would have preferred us to 'just go away'. One of the options/choices given to us at the time was whether we wanted the matter treated as a complaint or an appeal? We found these ultimatums very distressing …*

Once we managed to action an appeal, we were requested to supply additional medical details from our consultant – we authorised the release of information from our medical team.

On 13th February 2020, [the Provider] *determined our appeal and reconfirmed* [its] *refusal of cover as 'the original decision stands' – without ever receiving the requested additional medical information from our consultant.*

We expected any appeal to be determined/reviewed by a higher tribunal with new eyes and believed that it could be approved in line with the approval process for a 'reasonably favourable prognosis' as described in our policy handbook – but the common understanding of an appeal process was not afforded to us by [the Provider] *and* [its] *'appeal decision' seems to have been made by the very same team who had refused us in the first instance. This is completely imbalanced and flies in the face of fairness – from our position, the* [Provider] *appeal process equates to something along the lines of a kangaroo court!*

We feel the way we have been treated by [the Provider] *is scandalous and it has resulted in us having to pay in the region of €22,000 for access to the drugs our consultant prescribed – This intervention was ultimately proven successful and eliminated the presence of tumours on* [my wife's] *medical scans in April 2020.*

Please be aware that the prescribed Pembrolizumab (aka Pembro/Keyrtuda) medication is covered by other Health Insurance providers in Ireland for the same condition – specifically [a named health insurance provider] *who have broken from their peer group and now cover their policyholders for the same condition (unlike* [the Provider]*).*

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We truly feel that [the Provider] *have treat*[ed] *us (and perhaps other policyholders) like pawns and with contempt when we had legitimate claims. It is our opinion that we have been sold an insurance policy that is not worth the paper it is written on…"*

In addition, in his letter to this Office dated **10 September 2021**, the Complainant submits, among other things, that:

"… [The Provider] *believes* [its] *actions were a 'genuine attempt to help' where in fact they were everything but. The case file shows a prolonged attempt to delay, divert and ultimately deny a reasonable claim – the result is a 'needlessly elongated process' that has gone on far longer than the two-week period suggested by the* [Provider] *…*

It should be noted that the Health insurance policy has been active for several years and has fully covered <u>all</u> medically necessary treatments and surgeries since its inception in 2017.

When the historic claims are analysed, it can be seen that the policy has covered in full several treatments that are not covered by NCPE [National Council for Pharmacoeconomics]*, NCCP* [National Cancer Control Programme]*, and HSE* [Health Service Executive] *guidelines …*

[Provider] *Letter Date:*	*04/02/2020*
Procedure Description:	*Oncotype Dx Test Code 50300*
<u>Approval Basis:</u>	*<u>Medical appropriateness</u>*

This proves – what is stated in the policy document – that [the Provider] *operates <u>two channels</u> for pre-approvals – one in line with NCPE, NCCP, and HSE definitions and the other when a treatment is determined to be medically needed (and not outlined in NCPE/NCCP/HSE definitions). The latter routing for an approval effectively draws a line through any exclusion conditions listed in the policy document in order to arrive at an approval.*

It is also important to point out that there was no 'warning' in any of the policy documentation that the policy cover for cancer treatment would ever result in cover being declined [or] *limited. (Note: There are limits mentioned for certain types of cardiac care). There is no indicator that* [Provider] *claims would be done outside of industry norms or that cover/approvals from* [the Provider] *would be any different from other insurance providers offering similar policies. The policy was always billed in the sales process to be 'equivalent' to others on the market and it was purchased in good faith on that basis …*

[The Provider] *states that all applications for High Cost drugs are submitted to the 'Medical Relations Team'.*

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The happenings in this complaint do not line up with this stated procedure – in fact it seems to have been handled mainly by '[the Provider] *Claims Support' up to 11:13 on 16/01/2020 when it was sent to Medical Relations . It was then forward to* [Ms S.] *at 14:14 who issued a 'No cover' instruction/reply at 16:33.*

This decision by a 3rd party is not listed in the approval guidelines described by [the Provider] *in this reply is questionable. It is also a single person decision of a high cost item with no oversight evident in order to avoid any bias etc. The decision is speedy and ultimately had a heavy impact on the claimant. It is unlikely this person could have possibly become familiar with the full patient file/history in the short time recorded (from 14:14 to 16:33). Why was this matter referred to a 3rd party for final decision and what determines which claims/decisions will be made outside of the published process.*

Note: In the follow up appeal/complaint [Provider] *internal correspondence dated 11/02/2020 13:42:02 a person called* [M.] *is referred to as 'Provider Affairs' – it goes on to confirm this to be the same person who dealt with the matter on 16/06/2020 – this person's role seems to exist to detect and decline claims for 'specific high cost oncology drugs'.*

[The Provider] *confirm in* [its] *reply they 'only relied on the guidance from three independent bodies' as their decision reason. It is proven that* [the Provider] *operate a dual channel pre-authorisation approval process – one for treatment based on NCPE/NCCP/HSE clinical indicators and one for reasonable favourable medical prognosis – this latter channel for determining a claim based on medical needs didn't even make a showing on the* [Provider] *radar at this point (16/10/2020) and there is certainly no documented effort on the part of* [the Provider] *to determine that it might (or might not) result in a reasonably favourable solution for the patient.*

It is our contention we have been discriminated against and denied the latter option listed on the Pre-Authorisation section of the member handbook stating "Approval is only given where the procedure or treatment meets specific clinical indicators ***or*** *we determine that it will result in a reasonable favourable medical prognosis" …*

[The Provider] *again returns to the NCPE/NCCP/HSE guidelines as the primary reason for claim denial and confirmation of same in the follow up appeal final decision. It seems that* [the Provider] *conveniently apply this rule for 'high cost drugs' to the detriment of some policyholders/claimants. The reply suggests that if the drugs had been lower in cost, the decision might have been different. This is clearly unfair and policyholders should not have to run the gauntlet of whether their prescribed drugs are high cost or not.*

[The Provider] *states that Pembrolizumab is still not recognised in Ireland for [type / location redacted] cancers by the NCCP. This is not true and this drug is fully approved in Ireland for this condition.*

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> *It appears that the drug was in the final stages of being rubber stamped by NCPE at the time of this claim. Clearly Consultants knew this and were happy to prescribe it knowing full well that approval was an imminent certainty. In fact health insurers seem to be aware of this as well and were fully covering the drug – even without the final rubber stamp (Ref:* [two named health insurance providers] *covering this drug…)"*.

In that regard, the Complainant refers to the National Centre for Pharmacoeconomics webpage, **Pembrolizumab (Keytruda®) for head and squamous cell carcinoma. HTA ID: 19051**, at https://www.ncpe.ie/drugs/pembrolizumab-keytruda-for-head-and-neck-squamous-cell-carcinoma-hta-id-19051/.

The Complainant further submits in his letter to this Office dated **10 September 2021** that:

> *"…* [the Provider] *provided no information whatsoever about the disputed immunotherapy drug to the consumer – they instead continually referred and redirected the Complainant to the Consultant for this information …*
>
> *Additionally,* [the Provider] *has failed in its obligations…in relation to 'the urgency of the situation' – there is clear evidence of timewasting and passing the matter to various agents and handlers, the frustration of the Complainant constantly having to summarise the case over and over again is well documented and clear to read/hear in the written/audio communications …*
>
> *The Provider's practice 'not' to communicate directly with a customer as to why their pre-approval application for a high cost drug was declined is evasive and equates to giving someone the run around – getting access to whatever details the consumer needed to action a resubmission or appeal near impossible…This process was exhausting …*
>
> [The Provider] *failed in its obligations to ensure clear instructions from the consumer were processed promptly…The consumer made continuous requests for an appeal to be elevated and this was on top of requests for urgency from the Consultant.* [The Provider] *agents and call handlers maintained a solid position and placed a near impermeable barrier between the consumer and the appeal process.* [The Provider] *agents continually towed the party-line with statements like 'an appeal has to be submitted by your Consultant' and caused the Complainant considerable stress and anguish.*
>
> [The Provider] *confirms that an appeal was logged on 23/01/2020, when an appeal was finally acknowledged* [on] *10/02/2020 and triggered – it appears to be a flawed process – the consumer was led to believe that something was ongoing where in reality decisions had been made internally and staff members were informed they were 'Not requesting anything further from the Consultant' …*

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[The Provider] *failed in its obligations to Consumer Protection principles on a grand scale* – [it] *never acted in the best interests of its customer – instead,* [it] *acted in* [its] *own interests by refusing claims that fell into some sort of 'high cost' category. Mechanisms were in place to route these claims to particular people who made the refusal – this proves the only interests* [the Provider] *had were self-serving to themselves …*

[The Provider] *admits to have made errors and effectively lied to the Complainant that they had requested additional information from the Consultant. Internal communications show wide knowledge of this untruth and there is no effort to inform the consumer that the information previously stated to them needed to be corrected. This implies a cover up of sorts was ongoing behind the scenes.*

[The Provider] *supplied a link to the NCCP Guidelines for [type redacted] Cancer and a review of the content at this link shows there is acceptance of "independent medical judgment in the context of individual clinical circumstances to determine any patient's care or treatment. The treatment regimen to be used should take into account factors such as histology, molecular pathology, age, performance status, co-morbidities and the patient's preference. Each treatment regimen has advantages and disadvantages, and there may be more than one good option. In addition, treatment choices can change over time as more evidence becomes available". We feel that our treating Consultant paid full attention to these guidelines and took…all of the latest evidence into account when deciding to prescribe a combination treatment to the patient/policyholder in this case …*

[The Provider's] *position is that they are not satisfied that the 'pembrolizumab' treatment was medically necessary. This stance ignores the manner in which events unfolded, the particular nature of the treatment that was ongoing, and the opinion of the recommending Consultant. Cancer treatment and rehabilitation by its very nature can be unpredictable and the* [Provider] *fails to recognise the very individual presentation of the patient requiring the treatment. It has to be noted that* [the Provider's] *own listed Consultant considered it necessary to prescribe this treatment. It also has to be noted that there was approval for a cancer treatment program. We do not accept that the additional medication in question should not be covered. We take the view that it is unreasonable, if not unconscionable to permit the* [Provider] *to refuse cover for the additional medication required".*

In its **Formal Response** to the complaint investigation by this Office dated **15 July 2021**, the Provider acknowledged that there were some references made by its Agents to the Complainant contacting the treating Consultant to submit further information as part of an appeal, and the Provider accepts that this created the impression that further information could have changed the outcome of the preapproval request, when it says that in all likelihood the declinature was based on factors outside of the treating Consultant's remit. For this reason, the Provider offered the Complainant a customer service payment of **€1,000.00 (one thousand Euro)**.

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In his letter to this Office dated **10 September 2021**, the Complainant declined this offer, as follows:

> *"We reject* [the Provider's] *settlement offer and believe the €1,000 customer service payment would go nowhere near making up for the amount of stress and inconvenience this case has, and continues to cause the Complainant and their family"*.

The Complainant says that the Provider's failure to preapprove the Complainant's request for cover for a high-cost cancer drug meant that they paid *"in the region of €22,000 for access to the drugs our consultant prescribed"* and in that regard, the Complainant seeks for the Provider to reimburse this cost.

The Provider's Case

The Provider says that the Complainant telephoned the Provider on **23 December 2019** to query cover for Pembrolizumab. The Agent advised the Complainant to call back with a procedure code.

On **2 January 2020**, the Complainant telephoned to query cover for Procedure Code 1619: intravenous infusion of cytotoxic chemotherapy and the Agent confirmed cover.

On **7 January 2020**, the Complainant emailed the Provider querying whether four different types of drugs were covered for first line treatment of [type redacted] cancers, namely, Fluorouracil (5FU), Cetuximab (Erbitux), Carboplatin and Pembrolizumab.

On **8 January 2020**, the Complainant telephoned the Provider to query if it had received his email.

On **9 January 2020**, the Complainant emailed the Provider requesting an urgent response to his email so that treatment could be scheduled. The Provider telephoned the Complainant to advise that preapproval was required for high-cost drugs and the request for preapproval must be made by the treating Consultant.

The Provider notes that the only high-cost drug listed in his email, and which therefore required preapproval, was Pembrolizumab, with the other three drugs not requiring preapproval. The Provider says the rationale for this is primarily that those three drugs, like many cytotoxic drugs used in chemotherapy, have been in use for many years, are out of patent and consequently are inexpensive.

On Friday **10 January 2020**, the Provider received a letter from the Policyholder's treating Consultant Oncologist dated Thursday **9 January 2020**, as follows:

> *"*[The Policyholder] *has recurrent [type and location redacted] cancer. As per international standard of care I plan to treat her with Pembrolizumab based chemotherapy pending your approval.*

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> [The Policyholder] *is currently an inpatient and unwell.*
>
> *Please prioritise this approval request and please note that this treatment is licenced in both Europe and the United States"*.

The Provider says this letter did not contain sufficient information for it to fully assess the request and it emailed the Consultant's Secretary asking for the attached **Request for Preauthorisation for Pembrolizumab Form** to be completed. The Provider also advised the Secretary that the Policyholder did not have cover for the private hospital and asked for confirmation of where the treatment would be taking place. The Provider says that this was to ensure as part of its preapproval assessment, that the Policyholder had appropriate hospital cover.

On Wednesday **15 January 2020**, the Provider received the **Request for Preauthorisation for Pembrolizumab Form** completed by the Consultant, who advised therein that the treatment was required *"for metastases of [type and location redacted] cancer"*.

On Thursday **16 January 2020**, the Provider emailed the Consultant's Secretary to advise that the Policyholder did not have cover for the private hospital and asked for confirmation of the name of the hospital where the treatment was planned.

The Provider says that all applications for high-cost drugs are submitted to its Medical Relations Team for assessment and that this is a written process between the Provider and the treating consultant.

On Friday **17 January 2020**, the Policyholder's preapproval request was assessed by the Medical Relations Team and was declined on the basis that the Provider did not cover the drug Pembrolizumab for the treatment of [type and location redacted] cancers. The Provider emailed the Consultant setting out the detailed reasons why payment was not approved, as follows:

> *"… Having reviewed the medical details submitted to us and on this occasion we're sorry to say that we are not in a position to cover the costs of this drug, as the referral does not fulfil the clinical criteria for this drug in line with our rules for payment.*
>
> *We only reimburse Pembrolizumab for the following indications:*
>
> - *As monotherapy for the treatment of adults with unresectable or advanced melanoma*
>
> - *For the treatment of ipilimumab-refractory patients with unresectable or advanced metastatic melanoma*

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- *First-line treatment of metastatic non-small cell lung carcinoma (NSCLC) in adults whose tumours express PD-L1 with a =50% tumour proportion score (TPS) with no EGFR or ALK positive tumour mutations*

- *As monotherapy for the treatment of adult patients with relapsed or refractory classical Hodgkin lymphoma (cHL) who are transplant-ineligible and have failed brentuximab vedotin".*

The Provider also wrote to the Policyholder on Friday **17 January 2020** to inform her that it was not able to cover the costs of Pembrolizumab, as follows:

> *"We have reviewed the medical details submitted to us and on this occasion we're sorry to say that we are not in a position to cover the costs of this drug, as the referral does not fulfil the clinical criteria for this drug in line with our rules for payment.*
>
> *Please contact* [your Consultant] *directly to discuss the above".*

The Provider says its process to assess coverage of a proposed treatment is informed by guidance from three independent bodies, namely the clinical guidelines set out by the National Cancer Control Programme, the drug reimbursement guidelines from the National Council for Pharmacoeconomics and the Health Service Executive.

The Provider refers to pg. 3 of the applicable **Membership Handbook**, as follows:

> *"**PRE-AUTHORISATION***
>
> *Certain procedures and treatments are not covered unless they are approved in advance by us. Approval is only given where the procedure or treatment meets specific clinical indicators or we determine that it will result in a reasonably favourable medical prognosis. If your treatment or procedure needs to be pre-authorised, this will be specified in the Schedule of Benefits/GP Booklet. To apply for pre-authorisation, your health care provider must submit a request in writing to* [the Provider] *in order for your claim to be considered. We will assess your request as soon as possible but in any case within 15 working days".*

The Provider also refers to Chapter 3, 'Exclusions From Your Cover', at pg. 23 of the **Membership Handbook**, as follows:

> *"We do not cover the following (subject to compliance with the Minimum Benefit Regulations): …*
>
> *The cost of a drug not recommended for cover by the National Centre for Pharmacoeconomics, National Cancer Control Programme or the Health Service Executive unless pre-approved by us prior to treatment…*

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> *The costs of drugs where they are used for a purpose which is different fro m that for which they were licenced by the Health Products Regulatory Authority …"*

The Provider says in this case, the proposed treatment did not meet these guidelines and that it does not endorse the use of a drug that is not recommended for the treatment of a policyholder's condition.

The Provider says it is guided by the regulatory bodies the National Cancer Control Programme, the National Council for Pharmacoeconomics and the Health Service Executive as to what is clinically appropriate for the medical conditions and the correct and appropriate drugs that are needed to treat them. The Provider says its health insurance policy is in line with the guidelines issued by these three regulatory bodies for the correct use of high-cost drugs.

In addition, the Provider refers to Chapter 3, 'Exclusions From Your Cover', at pg. 23 of the **Membership Handbook**, as follows:

> *"We do not cover the following (subject to compliance with the Minimum Benefit Regulations): …*
>
> *The costs of drugs where they are used for a purpose which is different from that for which they were licenced by the Health Products Regulatory Authority … "*

The Provider says that at the time of the Policyholder's request for the drug in **January 2020**, Pembrolizumab was not licenced for the treatment of [type redacted] cancers by the National Cancer Control Programme, who are the consensus experts and arbiters of treatment for cancer in Ireland, or the National Council for Pharmacoeconomics.

The Provider says there is also an obligation on the treating consultant to inform a policyholder from the outset, whether a drug is experimental or licenced for use correctly.

The Provider says it is not its practice to communicate directly with a policyholder as to why an application for a high-cost drug was declined. Instead, its practice for the assessment of preapproval high-cost drug claims, is to communicate any medical decisions directly to the policyholder's medical professional so that any sensitive medical information is discussed with the policyholder by a suitably qualified medical professional with whom they typically have a direct and regular relationship in terms of their medical history and who is best placed and best qualified to discuss such information with them in the appropriate environment of their medical practice.

The Provider says that on **20 January 2020**, the Complainant telephoned the Provider regarding the declinature and wished to appeal the decision. The Provider says the call was passed to a supervisor. The Complainant requested more clarity around the decision and a call-back was agreed.

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The Supervisor telephoned the Complainant later that same day to advise that the Policyholder would need to revert to her Consultant, to discuss the clinical criteria for the use of Pembrolizumab and the reasons for the declinature.

On **23 January 2020**, the Complainant emailed the Provider to appeal the declinature. The Provider sent an acknowledgement email on **24 January 2020**.

The Provider says that on **27 January 2020**, it emailed the Complainant, as follows:

> *"Please be advised that there are specific guidelines for the use of this drug. Our claims team have explained the reason for declining the claim to* [the Policyholder's] *consultant and she will need to contact her consultant directly to discuss this.*
>
> [The Policyholder] *should be able to discuss this with her consultant over the phone, her consultant is aware of the rules that surround the use of this drug and he can explain this in full to her.*
>
> *Once* [the Policyholder] *has discussed this with her consultant, they can then submit an appeal in writing regarding this which includes the medical reasons for appealing the same"*.

On **28 January 2020**, the Complainant emailed the Provider asking for the specific guidelines for the use of the drug.

The Provider says that on **31 January 2020**, the Provider emailed the Complainant explaining the clinical criteria for the drug, setting out the four indications for which it will reimburse for the use of Pembrolizumab, as previously provided to the Policyholder's Consultant by email on **17 January 2020**. The Provider also advised that:

> *"In order to set up an appeal for the decision to decline* [the Policyholder's] *pre approval we would require a letter from* [her] *consultant stating this appeal. Once we receive this I can forward this appeal onto the relevant team to review".*

The Complainant emailed the Provider later that same day to express his dissatisfaction and to note that he had understood that he had made an appeal by email on 23rd January. The Provider emailed the Complainant to apologise for any inconvenience caused and advised that the relevant team would be in contact directly with the Policyholder's Consultant's Secretary. An email was then sent to the Secretary, as follows:

> *"The member has been in touch with us in relation to the decline below. Can you please confirm if you have discussed the medical reasons for the decline with the member?*
>
> *If you have additional medical information we will happily review but based on the current information received the request has been declined for the reasons noted…"*

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The Provider says that on **3 February 2020**, the Complainant emailed expressing his dissatisfaction again and requesting that his appeal be elevated to a complaint.

On **5 February 2020**, the Provider emailed the Complainant advising that it had been in contact directly with the Policyholder's Consultant on 31st January for additional information regarding the treatment and the pre-approval claim.

The Provider says this was a misstatement, in that it had not asked the Consultant in its email of 31st January for any specific information. The Provider also advised that:

> *"If you would like to continue with the setting up* [of] *a complaint I will arrange this for you, however I would just…like to make you aware that whilst the communication between* [the Provider] *and yourself will be investigated for this complaint I cannot guarantee that this will change the outcome of this claim".*

The Provider says that on **7 February 2020**, the Complainant emailed to advise that the Consultant may be away at a medical conference and there may be a delay in providing information. The Complainant also provided additional research into Pembrolizumab and confirmed that he wanted the Provider to process his appeal and his complaint jointly. The Provider emailed the Complainant to confirm that it had set up a complaint.

On **10 February 2020**, the Complaint Handler telephoned the Complainant to explain that the drug Pembrolizumab that was submitted for preapproval was not covered under the National Cancer Control Programme guidelines for the Policyholder's type of cancer and the decision was not overturned. The Complainant asked for a further escalation of the case. The Complaint Handler emailed the Complainant with her contact details.

The Provider says that on **11 February 2020**, the Complaint Handler emailed the Complainant to advise that after referring the matter again to management and the medical team, the original decision still stood.

On **12 February 2020**, the Complainant emailed the Complaint Handler seeking clarification on two further items, as follows:

> *"Please can you answer the following points for my additional understanding?*
>
> 1. *When, the previously requested information was received by you from* [the Policyholder's treating Consultant].
>
> 2. *If the approval guidelines for a 'reasonably favourable prognosis' were applied in determining your final decision".*

On **13 February 2020**, the Provider issued the Complainant with its **Final Response**, as follows:

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"… I understand you are unhappy your request on [the Policyholder's] *behalf for pre-approval for the use of the drug Pembrolizumab to treat* [her] *[type redacted] cancer has been declined.*

Thank you for taking my call on Monday 10th February 2020 and allowing me to explain to you why we are not in a position to approve this treatment for [the Policyholder]*.*

As discussed during our telephone conversation as part of the investigation of your complaint we referred this case to our Medical Director. I asked that they review this case as a priority and take into consideration the points you raised regarding the consultant's view on this treatment and also the section regarding "Pre-Authorisation" you made reference to the Membership Handbook Section 1 Your Contract Page 3.

From the review and as we discussed, we are unable to authorise the approval. Our process to assess coverage of a proposed treatment is informed by guidance from independent bodies – the clinical guidelines set out by the National Cancer Control Programme and the drug reimbursement guidelines from the National Council for Pharmacoeconomics.

In this case, the proposed treatment does not meet those guidelines and [the Provider] *does not endorse the use of a drug that is not licensed for treatment of this condition. We are very supportive of the difficult job the NCPE and the NCCP have to do, and that is why it is our policy to rely on their guidance to ensure that a thorough and rigorous process is applied to the assessment process.*

In relation to the questions posed in your email dated 12th February 2020:

- *When, the previously requested information was received by you from* [the Policyholder's treating Consultant]*?*
  We have not received any further information from [the Consultant]*. Our Claims Specialist Team emailed* [the Consultant's] *secretary on 31st January 2020 to explain the decline reason and ask she discuss this directly with* [the Policyholder].

- *If the approval guidelines for a 'reasonably favourable prognosis' were applied in determining your final decision?*
  We reviewed the request under specific clinical indicators for the condition, in line with NCPE and NCCP guidance".

The Provider says it notes the Complainant's comments that the Provider operates *"a dual channel pre-authorisation approval process – one for treatment based on NCPE/NCCP/HSE clinical indicators and one for reasonable favourable medical prognosis"* and his contention that the Policyholder was *"denied the latter option"*.

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By way of example, the Complainant refers to the Provider's approval on **4 February 2020** of the Oncotype Dx Test for the Policyholder based on medical appropriateness, even though he says this test was not approved by the National Council for Pharmacoeconomics, the National Cancer Control Programme and the Health Service Executive.

The Provider says that this is an inaccurate comparison as the Oncotype Dx Test is a test used in a diagnostic setting as a genomic expression profiling assay and not a High-Cost Drug and in any event, the Oncotype Dx Test is approved by all three entities, hence its approval of the test for the Policyholder following International Best Practice Guidelines and the recommendations from the National Council for Pharmacoeconomics, the National Cancer Control Programme and the Health Service Executive, as per its processes.

In relation to the Complainant's comment that its preapproval process for high-cost drug claims is *"a single person decision"*, the Provider says that all its high-cost drugs are subject to what its Medical Relations Team refers to as, a triple lock approval approach, in that the high-cost drugs must have approval from the National Council for Pharmacoeconomics, the National Cancer Control Programme (from a clinical efficacy and effectiveness perspective) and the Health Service Executive before cover is extended to the drug. The Provider says its Medical Relations Team reviewed the Policyholder's request for Pembrolizumab using these clinical guidelines and cover was declined. In that regard, the Provider says its decisions are not single person based but guided by the clinical governance of the National Cancer Control Programme and the National Council for Pharmacoeconomics.

The Provider confirms that it took the Policyholder's request for Pembrolizumab and its preapproval process very seriously.

In relation to the Complainant's comments about the *"urgency of the situation"* and his contention that *"there is clear evidence of timewasting"*, the Provider notes the turnaround time for the preapproval of any drug or procedure is 15 days, as set out in the policy terms and conditions, and that this allows it adequate time to make a full assessment of what is being asked of it. The Provider says in some cases it endeavours to turn preapprovals around in 72-96 hours and in this case, taking into consideration the urgency of the situation, a decision was made on the Policyholder's request for Pembrolizumab within 24 hours of receiving the full paperwork from her Consultant.

The Provider says it is important to clarify that it is the Provider's role to pay for treatments that are clinically appropriate and are covered by the relevant health insurance policy. In that regard, the Provider once again reiterates that at the time of the Policyholder's request for the drug in **January 2020**, Pembrolizumab was not approved for the treatment of [type and location redacted] cancers by either the National Cancer Control Programme or the National Council for Pharmacoeconomics.

The Provider notes that in **January 2020**, a rapid assessment was undertaken by the National Centre for Pharmacoeconomics to see if there was a cost-effective merit in approving Pembrolizumab for other specific cancers including [type and location redacted]

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cancers. It was then decided at that time that a full pharmacoeconomic assessment should be undertaken. A pre-submission was entered on **24 February 2020**, which then led to a yearlong assessment. In **May 2021**, this assessment was completed, and it was decided that this drug should be considered for reimbursement.

However, the Provider says that this is only the first step on the ladder, in that Pembrolizumab is still (at the time of writing on **27 September 2021**) not approved by the Health Service Executive or the National Cancer Control Programme for [type and location redacted] cancers. Once a National Centre for Pharmacoeconomics assessment is completed and deemed cost effective, the Provider notes it can take anywhere from 6-12 months to have a regimen devised and made available to patients.

In relation to the Complainant's comment in his letter to this Office of **10 September 2021** that two named health insurance providers, including the Policyholder's previous health insurance provider, *"were fully covering the drug – even without the final rubber stamp"*, the Provider says that in **August 2016**, in order to form its company, the Provider acquired the health insurance provider that the Complainant says was the Policyholder's previous insurer and which he says covered Pembrolizumab on its policy.

The Provider notes that all the policies that transferred at that point to the Provider retained the same terms and conditions that applied prior to the transfer of business in **August 2016** and in that regard, the Provider confirms that the clinical rules which currently apply to the use of Pembrolizumab (in that it is not covered for the treatment of [type and location redacted] cancers at the time of writing on **27 September 2021**) still applied to those policies prior to the Provider's acquisition, and therefore moving to a different policy with the Provider made no difference to these clinical rules.

In any event, the Provider says its records indicate that the Policyholder, immediately prior to her incepting her policy with the Provider in **October 2017**, did not hold health insurance with either of the two health insurance providers the Complainant specifically refers to, but instead was insured with a different third insurer from 2014 to 2017.

In addition, the Provider acknowledges that on **15 July 2021**, when it submitted a copy of its Complaint Communications Logs with its **Formal Response** to the complaint investigation by this Office, that this had been incorrectly manually formatted. The Provider explains that this occurred when the Communications Logs were exported from the mainframe system to an excel page. Due to the volume of notation in some of the cells, the Provider says the data in the cells did not fit the column and the data wrapping function did not adjust automatically before the PDF version was saved. The Provider says this was a genuine mistake and that it in no way intended to withhold information and it does not consider that the omissions withheld any material additional information in respect of this complaint. The Provider exported its Complaint Communication Logs again, this time formatted correctly, and submitted this evidence again to this Office on **27 September 2021**.

In relation to the Complainant's comment that he *"had difficulty initiating an appeal … seemed to be getting passed around from one department to another"*, the Provider says

/Cont'd…

the declinature letter to the Policyholder on **17 January 2020** set out the appeals process that was available. The Provider notes the Complainant made an appeal by email on **23 January 2020** and later a complaint on **3 February 2020**.

The Provider says that it is satisfied that the timeline of events it set out above, confirms that it dealt with the preapproval application, the appeal and the resultant complaint in accordance with its obligations under the Central Bank of Ireland's ***Consumer Protection Code 2012 (as amended)***.

The Provider says that between **28 January 2020** and **13 February 2020**, the Complainant had several discussions with the Provider regarding appealing the declinature of the Policyholder's preapproval request for Pembrolizumab. As the Provider has an appeal process in place and as required under Provision 7.20 of the ***Consumer Protection Code 2012 (as amended),*** this was offered to the Complainant. At his instruction, an appeal was logged, and the outcome was communicated to the Complainant.

Having reviewed the file, the Provider acknowledges there were some references made by its Agents in respect of the Complainant contacting the Consultant to submit further information. The Provider believes that this was a genuine attempt to assist the Policyholder and the Complainant, to ensure that the Provider had the full medical facts of the case to inform its decision. However, having reviewed the communications again, the Provider accepts that these attempts may have created the impression that further information could or would have resulted in a change to the outcome of the preapproval request when in all likelihood the declinature was based on factors outside of the Consultant's control.

The Provider appreciates that this acknowledgement comes at a late stage in the adjudication process, and it says it can see now that this may have needlessly elongated the process for the Complainant, by just over two weeks. In recognition of this, the Provider, in its **Formal Response** to the complaint investigation by this Office dated **15 July 2021**, offered the Complainant a customer service payment of **€1,000.00 (one thousand Euro)** in recognition of any stress and inconvenience caused.

The Complaint for Adjudication

The complaint is that the Provider incorrectly and unfairly declined the late Policyholder's application for the pre-approval of cover for a high-cost cancer drug in **January 2020** and her subsequent appeal; and proffered poor customer service in relation to the appeal of its decision to refuse cover.

/Cont'd…

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. Since the preliminary decision of this Office was issued on **11 February 2022,** the Complainant has submitted that because of the conflict between the parties, an oral hearing is required, in the interests of fairness. The Complainant maintains in that regard that the complexity and sophistication of the issues arising in the complaint, are such that an oral hearing is warranted.

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. In my opinion this conflict between the parties does not require the parties' oral evidence, and in my opinion, the written 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 **11 February 2022**, 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. Following the consideration of additional submissions from the parties, the final determination of this office is set out below.

The evidence shows that the Policyholder sought for the Provider to preapprove cover for the use of the high-cost cancer drug Pembrolizumab by way of the Complainant's email to the Provider on Tuesday **7 January 2020**, as follows:

> *"My wife* [the Policyholder]*, is currently being scheduled for cancer treatment and her oncologist needs to know if the following medications are covered by* [the Provider] *for First Line treatments of [type redacted] cancers.*
>
> 1. *Fluorouracil (5FU)*
> 2. *Cetuximab (Erbitux)*
> 3. *Carboplatin*
> 4. *Pembrolizumab"*.

/Cont'd…

The Provider advised the Complainant by telephone on **9 January 2020** that a preapproval request for a high-cost drug such as Pembrolizumab must be made by the treating Consultant.

I note that this is in accordance with Section 1, 'Your Contract', at pg. 3 of the applicable **Membership Handbook (June 2019)**, as follows:

> *"**PRE-AUTHORISATION***
>
> *Certain procedures and treatments are not covered unless they are approved in advance by us. Approval is only given where the procedure or treatment meets specific clinical indicators or we determine that it will result in a reasonably favourable medical prognosis. If your treatment or procedure needs to be pre-authorised, this will be specified in the Schedule of Benefits/GP Booklet. To apply for pre-authorisation, your health care provider must submit a request in writing to* [the Provider] *in order for your claim to be considered. We will assess your request as soon as possible but in any case within 15 working days".*
>
> [My underlining added for emphasis]

As a result, the Policyholder's treating Consultant Oncologist wrote to the Provider on **9 January 2020**, as follows:

> *"*[The Policyholder] *has recurrent [type redacted] cancer. As per international standard of care I plan to treat her with Pembrolizumab based chemotherapy pending your approval.*
>
> [The Policyholder] *is currently an inpatient and unwell.*
>
> *Please prioritise this approval request and please note that this treatment is licenced in both Europe and the United States"*.

I note that the Provider emailed the Consultant's Secretary the following day on Friday **10 January 2020** asking for the attached **Request for Preauthorisation for Pembrolizumab Form** to be completed and returned.

The Secretary emailed the completed **Request for Preauthorisation for Pembrolizumab Form** to the Provider on Wednesday **15 January 2020**. This **Form** set out four different indications for the use of the drug, as follows:

> *"First line monotherapy for the treatment of advanced (unresectable or metastatic) melanoma in adults*
>
> *For the treatment of ipilimumab-refractory patients with unresectable or advanced metastatic melanoma*

/Cont'd…

First-line treatment of metastatic non-small cell lung carcinoma (NSCLC) in adults whose tumours express PD-L1 with a ≥50% tumour proportion score (TPS) with no EGFR mutations or ALK translocations

As monotherapy for the treatment of adult patients with relapsed or refractory classical Hodgkin lymphoma (cHL) who are transplant-ineligible and have failed brentuximab vedotin".

I note the Consultant did not tick *"YES"* to any of the four indications for use. Instead, he inserted the handwritten annotation:

"For metastases of [type redacted] cancer".

This request for the drug Pembrolizumab was assessed by the Provider's Medical Relations Team and declined on Friday **17 January 2020** on the basis that the Provider did not cover the drug for the treatment of [type redacted] cancers.

It should be noted that the Policyholder's health insurance policy with the Provider, like all insurance policies, did not provide cover for every eventuality. Rather the policy cover was subject to the terms, conditions, endorsements and exclusions set out in the policy documentation.

I note that **Section 3**, '**Exclusions From Your Cover'**, of this **Membership Handbook** provides at pg. 23 that:

"We do not cover the following (subject to compliance with the Minimum Benefit Regulations): …

- *The cost of a drug not recommended for cover by the National Centre for Pharmacoeconomics, National Cancer Control Programme or the Health Service Executive unless pre-approved by us prior to treatment;*

- *The costs of drugs where they are used for a purpose which is different from that for which they were licenced by the Health Products Regulatory Authority".*

The Provider says it declined the Policyholder's request for the drug in **January 2020** because at that time, Pembrolizumab was not approved for the treatment of[type redacted] cancers by either the National Cancer Control Programme (the consensus experts and arbiters of treatment for cancer in Ireland) or the drug reimbursement guidelines from the National Council for Pharmacoeconomics or by the Health Service Executive.

In his letter to this Office dated **10 September 2021,** the Complainant submits that:

"[The Provider] *states that Pembrolizumab is still not recognised in Ireland for [type redacted] cancers by the* [National Cancer Control Programme]. *This is not true and this drug is fully approved in Ireland for this condition.*

/Cont'd…

It appears that the drug was in the final stages of being rubber stamped by [the National Council for Pharmacoeconomics] *at the time of this claim. Clearly Consultants knew this and were happy to prescribe it knowing full well that approval was an imminent certainty".*

In that regard, I note that the Complainant refers to the National Centre for Pharmacoeconomics webpage, **Pembrolizumab (Keytruda®) for head and squamous cell carcinoma. HTA ID: 19051**, at https://www.ncpe.ie/drugs/pembrolizumab-keytruda-for-head-and-neck-squamous-cell-carcinoma-hta-id-19051/, which provides, as follows:

"Pembrolizumab (Keytruda®) for head and squamous cell carcinoma. HTA ID: 19051

Pembrolizumab (Keytruda®) is indicated as monotherapy or in combination with platinum and 5-flourouracil, for the first-line treatment of metastatic or unreasonable recurrent [type redacted] squamous cell carcinoma (HNSCC) in adults whose tumours express PD-L1 with a combined positive score.

NCPE Assessment Process	***Complete***
Rapid review commissioned	*25/11/2019*
Rapid review completed	*02/01/2020*
Rapid Review outcome	*A full HTA is recommended to assess the clinical effectiveness and cost effectiveness of pembrolizumab compared with the current standard of care*
Full pharmacoeconomic assessment commissioned by the HSE	*07/01/2020*
Pre-submission consultation with Applicant	*24/02/2020*
Full submission received from Applicant	*28/08/2020*
Preliminary review sent to Applicant	*16/02/2021*
NCPE assessment re-commenced	*18/03/2021*
Factual accuracy check sent to Applicant	*30/04/2021*
NCPE assessment re-commenced	*10/05/2021*
NCPE assessment completed	*18/05/2021*

/Cont'd…

NCPE assessment outcome	*The NCPE recommends that pembrolizumab be considered for reimbursement if cost effectiveness can be improved relative to existing treatments*".*

These details indicate that the outcome of the National Centre for Pharmacoeconomics' assessment into the use of Pembrolizumab for the treatment of [type redacted] cancers was not completed until **18 May 2021**, some 16 months after the Policyholder's request in **January 2020**.

The Complainant has repeatedly asserted in submissions to both the Provider and this Office that other health insurance providers in Ireland were providing cover for the use of Pembrolizumab for the treatment of [type redacted] cancers at the time of the Policyholder's request for the drug, in **January 2020**.

Even if this was correct, I am conscious that in **January 2020,** the Policyholder was insured with the Provider, not with one of the other providers of health insurance. The health insurance policy that the Policyholder had entered into with the Provider is a contract like any other, it is based on the legal principles of offer, acceptance, and consideration.

The Provider may offer terms, and these terms can be accepted by those seeking insurance, who then elect to pay the premium in consideration of the contract. It is a matter for the Provider to decide the cover it is willing to offer and in paying the premium, the customer chooses to accept the extent and the limits of this cover.

In that regard, **Section 3, 'Exclusions From Your Cover'**, of the **Membership Handbook** provides at pg. 23 that:

> *"We do not cover …*
>
> - *The cost of a drug not recommended for cover by the National Centre for Pharmacoeconomics, National Cancer Control Programme or the Health Service Executive unless pre-approved by us prior to treatment".*

The Complainant notes that Section 1, 'Your Contract', at pg. 3 of the **Membership Handbook** provides that:

> *"**PRE-AUTHORISATION***
>
> *… Approval is only given where the procedure or treatment meets specific clinical indicators or we determine that it will result in a reasonably favourable medical prognosis … "*
>
> [Underlining added for emphasis]

/Cont'd…

In his letter to this Office dated **10 September 2021,** the Complainant refers to this as:

> *" … a dual channel pre-authorisation approval process – one for treatment based on NCPE/NCCP/HSE clinical indicators and one for reasonable favourable medical prognosis…".*

In that regard, the Complainant continues that:

> *" … there is certainly no documented effort on the part of* [the Provider] *to determine that* [the use of Pembrolizumab for the treatment of the Policyholder's cancer] *might (or might not) result in a reasonably favourable solution for the patient.*
>
> *It is our contention we have been discriminated against and denied the latter option listed on the Pre-Authorisation section of the member handbook stating "Approval is only given where the procedure or treatment meets specific clinical indicators* ***or*** *we determine that it will result in a reasonable favourable medical prognosis" … "*

I note that Section 3, 'Exclusions From Your Cover', at pg. 23 of the **Membership Handbook** excludes cover for:

> *"The cost of a drug not recommended for cover by the National Centre for Pharmacoeconomics, National Cancer Control Programme or the Health Service Executive unless pre-approved by us prior to treatment".*

I am of the opinion that this policy exclusion was clear and that it allowed for the Provider to refuse cover for any drug that was not recommended for cover by one of the three regulatory bodies listed, regardless of the treating consultant having recommended or proposed using the drug for treating the Policyholder. In my opinion, as this was a policy exclusion from cover, the Provider had no obligation to firstly determine whether the use of the drug in a particular case, would result in a reasonably favourable medical prognosis.

Based on the evidence before me, I am satisfied that the Provider was entitled to decline the late Policyholder's application for the pre-approval of cover for the use of the high-cost cancer drug Pembrolizumab in strict accordance with the terms and conditions of her health insurance policy.

The evidence shows that the Provider emailed the Policyholder's Consultant on **17 January 2020** setting out the reasons why it had refused preapproval, as follows:

> *" … Having reviewed the medical details submitted to us and on this occasion we're sorry to say that we are not in a position to cover the costs of this drug, as the referral does not fulfil the clinical criteria for this drug in line with our rules for payment.*
>
> *We only reimburse Pembrolizumab for the following indications:*

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- *As monotherapy for the treatment of adults with unresectable or advanced melanoma*

- *For the treatment of ipilimumab-refractory patients with unresectable or advanced metastatic melanoma*

- *First-line treatment of metastatic non-small cell lung carcinoma (NSCLC) in adults whose tumours express PD-L1 with a =50% tumour proportion score (TPS) with no EGFR or ALK positive tumour mutations*

- *As monotherapy for the treatment of adult patients with relapsed or refractory classical Hodgkin lymphoma (cHL) who are transplant-ineligible and have failed brentuximab vedotin.*

If you have any queries or wish to appeal this decision please call us on [number redacted] *or email us at* [email redacted] …"

It was thus open to the Consultant to respond to this decision, by way of an appeal, if he was of the opinion that the Policyholder did in fact satisfy one of the stated indications for the use of the Pembrolizumab.

I note that the Provider also wrote to the Policyholder on **17 January 2020** to inform her that it was not able to cover the costs of Pembrolizumab, as follows:

"We have reviewed the medical details submitted to us and on this occasion we're sorry to say that we are not in a position to cover the costs of this drug, as the referral does not fulfil the clinical criteria for this drug in line with our rules for payment.

Please contact [your Consultant] *directly to discuss the above …*

If you have any queries or wish to appeal the decision made please call us on [number redacted] *or email us at* [email redacted] …"

Recordings of telephone calls have been furnished in evidence and I am satisfied that the different Agents who dealt with the Complainant throughout were at all times professional and courteous and each endeavoured to assist him.

I note that during the telephone call between the Complainant and the Provider on **20 January 2020**, that the Complainant expressed his dissatisfaction at the Provider having sent what he refers to as a *"one line cold and heartless response"* to the Policyholder on **17 January 2020** which simply advised that it was not in a position to cover the cost of the drug.

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I accept that it is standard practice in the health insurance industry for insurers to send the specific medical reasons for declining cover to the treating medical professional, for it is widely accepted that this is the person who is best placed to explain these reasons in detail to the policyholder, in the appropriate environment of a consultation. In any event, as the preapproval request was made by the treating Consultant, I take the view that it was appropriate that the Provider issue the Consultant with the specific medical reasons for the refusal of cover.

I note that the Provider advised the Policyholder in its declinature letter of **17 January 2020** that she should contact her Consultant directly to discuss the contents of the letter and the Supervisor also advised the Complainant of this approach during the telephone call on **20 January 2020**.

During this telephone call he was advised that based on the information furnished by the Consultant, the pre-approval application was declined because the request did not meet the clinical indicators. The Complainant suggested that it was for the Provider to contact the Consultant to obtain the information it required to approve the use of the drug, but as the Supervisor then attempted to explain to the Complainant, the Consultant had already answered the questions the Provider needed answered, by way of completing the **Request for Preauthorisation for Pembrolizumab Form**, and it was based on those answers that the Provider would not allow the appplication. As a result, there was no additional information for the Provider to seek.

The Complainant informed the Provider by email on **23 January 2020** that he wanted to appeal its decision and by email on **3 February 2020** that he wanted to make a complaint. He further advised the Provider by email on **7 February 2020** that he wanted it to process his appeal and his complaint jointly, as follows:

> *"In reply to whether we wish to proceed as a complaint or an appeal? – As time is of the essence and we do not know the inner workings of your corporate processes, we would prefer not to opt for a 50/50 choice and instead ask that you process our concerns jointly"*.

The Complaint Handler telephoned the Complainant on **10 February 2020** to explain that the Provider was standing over its decision, because the drug Pembrolizumab was not covered under the National Cancer Control Programme guidelines for the Policyholder's type of cancer.

The Complainant asked for a further escalation of the case and on **11 February 2020**, the Complaint Handler emailed to advise him that after referring the matter again to management and the medical team, the original decision still stood.

The Complainant questions why the Provider presented him with the option to appeal its decision when it appears that no further information from the Policyholder's Consultant could have changed the outcome of the decision.

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In addition, the Complainant says the Provider had advised him by email on **5 February 2020** that it had been in contact directly with the Consultant on **31 January 2020** seeking additional information regarding the treatment and the pre-approval application but that he then learnt that this was not the case and that no further information had been sought or obtained from the Consultant prior to the Provider concluding its appeal and complaint review and its **Final Response Letter** of **13 February 2020**.

In that regard, the Complainant's position is that once the Consultant had completed the **Request for Preauthorisation for Pembrolizumab Form** to the Provider indicating that the Policyholder did not satisfy one of the four indications for the use of the drug Pembrolizumab, then no further information from the Consultant, such as his rationale for recommending the use of the drug for treating the Policyholder's cancer, could have changed the outcome of the Provider's decision.

I take the view that this is correct. Either the Policyholder satisfied one of the four indications for the use of the drug Pembrolizumab, or she did not.

I am also of the view, however, that an appeal process is not simply a process whereby previously unsubmitted information can be provided for consideration; it also allows for any mistakes to be identified and corrected. In that regard, in advising both the Consultant and the Policyholder in writing on **17 January 2020** of the option to appeal, the Provider was affording the Consultant the opportunity to respond to the declinature, by way of an appeal, if he had made an error in completing the **Request for Preauthorisation for Pembrolizumab Form** and if perhaps the Policyholder did in fact, in some way, satisfy one of the stated indications for the use of the drug.

In addition, I take the view that if it had not offered the option to appeal, the Provider would in that regard have been in breach of its obligations under the Central Bank of Ireland's ***Consumer Protection Code 2012 (as amended)***.

I note the Provider emailed the Complainant on **5 February 2020** to advise, among other things, that:

> *"… we were in contact with* [the Policyholder's] *consultant on the 31/01/2020 for additional information regarding the treatment and this claim …"*

The Provider accepts in its **Formal Response** to the complaint investigation by this Office dated **15 July 2021** that this was a misstatement, in that its email to the Consultant's Secretary on **31 January 2020** read, as follows:

> *"The member has been in touch with us in relation to the decline below. Can you please confirm if you have discussed the medical reasons for the decline with the member?*
>
> *If you have additional medical information we will happily review but based on the current information received the request has been declined for the reasons noted* [in our email of **17 January 2020**]*".*

/Cont'd…

I also note in its **Formal Response** that the Provider acknowledged that there were some references made by its Agents to the Complainant making contact with the Consultant to submit further information as part of an appeal, and that the Provider accepted that this created the impression that further information could have changed the outcome of the preapproval request when the Provider says that in all likelihood, the declinature was based on factors outside of the treating Consultant's remit. For this reason, I note the Provider offered the Complainant a customer service payment of **€1,000.00 (one thousand Euro)**.

In his letter to this Office dated **10 September 2021**, I note the Complainant declined this offer, as follows:

> *"We reject* [the Provider's] *settlement offer and believe the €1,000 customer service payment would go nowhere near making up for the amount of stress and inconvenience this case has, and continues to cause the Complainant and their family"*.

Having regard to all of the above, I am of the opinion that the evidence does not support the complaint that the Provider incorrectly and unfairly declined the late Policyholder's application for the preapproval of cover for a high-cost cancer drug in **January 2020** (and her subsequent appeal) and proffered poor customer service in relation to the appeal of its decision to refuse cover.

I am conscious that this was a very difficult situation for the Policyholder and her family, as they were continually faced with her ongoing medical challenges; sadly the Policyholder lost her battle against cancer in June 2020. The cover available to her under her health insurance policy, was however governed by the terms and conditions which are outlined above. In my opinion, there is no evidence of the Provider wrongfully declining the pre-approval application that she wished to make, to be covered for the cost of the drug Pembrolizumab.

Since the preliminary decision of this Office was issued, I note that the Complainant has sought to rely on an earlier decision of this Office, **2018-0169**, published in the FSPO Database of Decisions at https://www.fspo.ie/decisions/

The Complainant says that:

> *"In relation to the main component of this complaint, we believe not enough consideration has been given to the nature of treatment that is 'Medically Necessary'. The Provider's stance is outlined on page 6, paragraph 3, of the Preliminary Decision but does not appear to have been analysed to the extent that we feel is necessary to determine a fair and reasonable decision."*

I note that in fact the contents of page 6 paragraph 3 of the preliminary decision, comprised part of the submissions offered by the Complainant, rather than by the Provider.

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I am conscious that page 3 of the policyholder's Membership Handbook contains a note to advise that

> **GROUND RULES**
>
> ***We*** will only cover the costs of ***medical care*** which our ***medical advisers*** believe is an ***established treatment*** which is ***medically necessary***. In addition ***we*** only cover ***reasonable and customary costs***.

I am also conscious that the provider did not decline the Complainant's application for pre-approval for cover for Pembrolizumab, by reference to the policy meaning of "*medically necessary*". Instead, the application for pre-approval was declined by the Provider because at the relevant time, Pembrolizumab was not approved for the treatment of [type redacted] cancers by either the National Cancer Control Programme (the consensus experts and arbiters of treatment for cancer in Ireland) or the drug reimbursement guidelines from the National Council for Pharmacoeconomics or by the Health Service Executive. For the reasons outlined above, I am satisfied that the Provider was entitled to take that position, in declining the application for pre-approval of cover.

Insofar as the Provider's error is concerned regarding its communications with the Consultant and the impression created that additional medical information had been sought from the Consultant, I am satisfied that the Provider's offer to the Complainant of the sum of €1,000 was an appropriate and reasonable figure for the nature of the error which occurred and if the Complainant wishes to accept that compensatory measure, it will be a matter for him to communicate directly with the Provider in that regard.

Although the Complainant has recently urged this Office to make a direction to the Provider to make that payment, I do not consider this necessary or appropriate in circumstances where the provider has made clear that this compensatory payment for this error, remains available to the Complainant, if he wishes to accept it. I would suggest in that regard that the Complainant communicate with the Provider to make the necessary arrangement for the transfer of payment, unless he wishes to decline that gesture, in which case he is not required to arrange for payment from the Provider.

Finally, I note that in its letter to this Office dated **27 September 2021**, the Provider also acknowledged that when it first submitted a copy of its Complaint Communications Logs with its **Formal Response** on **15 July 2021**, that this had been incorrectly manually formatted.

The Provider explains that this occurred when the Complaint Communications Logs were exported from the mainframe system to an excel page, in that the data in the cells did not fit the column due to the volume of notation in some of the cells and the data wrapping function did not adjust automatically before the PDF version was saved.

/Cont'd…

The Provider says this was a genuine mistake and that it in no way intended to withhold information and it does not consider that the omissions withheld any material additional information in respect of this complaint.

The Provider exported its Complaint Communications Logs again, this time formatted correctly, and submitted it to this Office on **27 September 2021**.

In his letter to this Office dated **29 September 2021**, I note the Complainant says that:

> *"… This 'mistake' was nothing to do with formatting and is a clear withholding/deletion of key information that would inform the investigation …*
>
> *We do not accept this as a 'mistake' – it is more likely a targeted deletion occurred within the complaint logs and parking this matter now under the 'genuine mistake' umbrella would not likely convince 'the man on the Clapham omnibus' and it certainly does not convince us"*.

I have examined the incomplete copy of the Complaint Communications Logs that the Provider first submitted to this Office on **15 July 2021** and the corrected copy of the Complaint Communications Log that it furnished to this Office on **27 September 2021** and having done so, I accept the Provider's explanation for the error.

Administrative errors of this nature are unsatisfactory, but I accept the Provider's position that the omissions did not result in any material additional information in respect of this complaint, being withheld.

The circumstances of this complaint are tragic, but on the basis of the evidence before me, and for the reasons outlined above, I am not satisfied that this complaint can reasonably be upheld.

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
Financial Services and Pensions Ombudsman (Acting)

15 March 2022

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PUBLICATION

Complaints about the conduct of financial service providers

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.

Complaints about the conduct of pension providers

Pursuant to *Section 62* of the *Financial Services and Pensions Ombudsman Act 2017*, the Financial Services and Pensions Ombudsman will **publish case studies** in relation to complaints concerning pension 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.