

The complaint

The estate of Mr F is unhappy that AXA PPP healthcare Limited declined a claim on Mr F's international healthcare insurance policy.

Although the estate of Mr F is being represented, for ease, I'll refer to all comments made by the estate's representative as being made on the estate's behalf.

What happened

Mr F was very sadly diagnosed with an aggressive type of cancer, with very poor prognosis. The estate of Mr F says medical treatment he received at the time didn't materially improve his condition. And a year later, he was considered an advanced and terminal patient on a high dose of chemotherapy with the consequential side effects with no chance of a cure.

The estate of Mr F says that Mr F was then due to receive immunotherapy in the European country he was receiving treatment in on a 'compassionate use' basis as it had been approved by that country's Medicine Agency and was within a phase II/phase III trial. However, because the biological production of the vaccine was unsuccessful it didn't go ahead.

Mr F was instead referred to a different European country to undergo a combination of treatment including biological therapy, vaccinations and immunotherapy. The estate of Mr F says Mr F's condition started to improve, the tumour stabilised, and his life was prolonged by the combination of treatment he received. And that before his death, Mr F's quality of life also improved.

AXA covered the initial biological therapy which it later said it covered in error but wouldn't seek reimbursement for.

After Mr F's death, a claim was submitted to AXA to cover the cost of the other treatment. These further costs were declined on the basis that the other treatment amounted to experimental treatment. AXA concluded that it hadn't been licensed by the European Medicines Agency (EMA) to treat the type of cancer Mr F had been diagnosed with. And it hadn't been established as an effective form of treatment for that cancer under the terms of the policy.

Unhappy, the estate of Mr F brought a complaint to the Financial Ombudsman. Our investigator looked into what happened and didn't uphold the estate of Mr F's complaint. Because the estate disagreed, this complaint was passed to me to consider everything afresh and decide.

I issued my provisional decision in June 2023 explaining in more detail why I wasn't intending to uphold the estate of Mr F's complaint. An extract of my provisional decision is set out below.

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At the outset I acknowledge that I've summarised this complaint in far less detail than the

estate of Mr F has, and in my own words. I'm not going to respond to every single point made. No discourtesy is intended by this. Instead, I've focussed on what I think are the key issues here. The rules that govern the Financial Ombudsman Service allow me to do this as it's an informal dispute resolution service. If there's something I've not mentioned, it isn't because I've overlooked it. I haven't. I'm satisfied I don't need to comment on every individual point to be able to reach an outcome in line with my statutory remit.

The relevant regulatory obligations and policy terms and conditions

The insurance industry regulator, the Financial Conduct Authority ('FCA'), has set out rules and guidance for insurers in the 'Insurance: Conduct of Business Sourcebook' ('ICOBS'). ICOBS says that insurers should act honestly, fairly and professionally in accordance with the best interests of their customers. It also says they shouldn't unreasonably reject an insurance claim.

The policy terms and conditions set out at section 8 entitled: your cover for cancer treatment, that cover is provided for:

drug treatment of cancer (such as chemotherapy drugs, hormone therapies and biological therapies) where the drug has been licensed for use by the European Medicines Agency if you are receiving treatment in Europe or the Food and Drug Administration if you are receiving treatment anywhere else in the world, and is used within the terms of that licence.

The same section also says:

there are some drug treatments for cancer that are typically given for prolonged periods of time. Such prolonged treatment normally falls outside benefit. However, in the case of treatment of cancer we make an exception (subject to the limits detailed below) for chemotherapy drugs and biological therapies such as...(Herceptin) and...(Avastin). These drug treatments will be covered when they are used within the terms of their licence, and up to the period of the drug licence.

Treatment is defined under the policy terms as:

Surgical or medical services (including diagnostic tests) that are needed to diagnose, relieve or cure a disease, illness or injury.

The terms of the policy also set out at section 6 things that AXA doesn't pay for. That includes:

- *The use of a drug which has not been established as being effective or which is experimental. This means they must be licensed by the European Medicines Agency if you are receiving treatment in Europe, or the US Food and Drug Administration (FDA) if you are receiving treatment anywhere else in the world, and be used within the terms of that licence.*
- *Treatment which has not been established as being effective or which is experimental. For established treatment, this means procedures and practices that have undergone appropriate clinical trial and assessment, sufficiently evidenced in published medical journals for specific purposes to be considered proven safe and effective therapies.*

Has AXA acted fairly and reasonably by declining the claim?

I know the estate of Mr F will be very disappointed but for the reasons set out below, I'm intending to find that AXA has fairly declined the claim for medical costs.

- The estate of Mr F accepts in response to our investigator's view that the vaccine hasn't received EMA approval. However, it says it isn't a 'drug' in the common sense, rather the vaccine which formed part of the treatment is individualised for the specific patient and uses the patient's own blood and tissue. So, by its nature, they say it's unlikely to be considered a 'drug' for which EMA approval would ever be offered.
- AXA says the vaccine is a drug as it's a substance or combination of substances that is intended to treat, prevent or diagnose a disease, or to restore, correct or modify physiological functions by exerting a pharmacological, immunological or metabolic action.
- Drug isn't defined by the policy. But one of the examples of 'drug treatment' given at section 8 of the policy terms (referred to above) includes biological therapies which the National Cancer Institute says is a type of treatment that uses substances made from living organisms to treat disease – and says includes cancer treatment vaccines.
- But the policy only covers drug treatment of cancer (such as biological therapies) where the drug has been licensed for use by the EMA (if receiving treatment in Europe) which Mr F was. But the vaccine hadn't received EMA approval to treat Mr F's type of cancer. So, I don't think it was covered by the policy terms.
- In the absence of a definition of 'drugs', I think it would be fair and reasonable to conclude that 'drugs' as referred to in section 6 of the policy terms – and referred to above – also includes biological therapies as it's expressly provided as an example of drug treatment in section 8 of the policy terms. That's relevant in the context of Mr F's claim as it relates to cancer cover. So, I think AXA has fairly concluded that the vaccine isn't covered under the policy on the basis that it hasn't been established as being effective or is experimental for the type of cancer Mr F had been diagnosed with. That's because, again, although it might've been licensed by the EMA, it wasn't being used within the terms of that licence.
- Further and in the alternative, I don't think AXA has unfairly concluded that the treatment for which the costs are being claimed is experimental or hadn't been established as being effective for the type of cancer Mr F had been diagnosed with. The exclusion in section 6 says "for established treatment, this means procedures and practices that have undergone appropriate clinical trial and assessment, sufficiently evidenced in published medical journals for specific purposes to be considered proven safe and effective therapies".
- I've considered all the medical literature the estate of Mr F has provided in relation to the costs of the treatment being claimed for under the policy including the report dated February 2023, attached to the estate of Mr F's response to our investigator's opinion on the complaint. This report reflects the type of cancer Mr F had "is rapidly fatal even with maximum conventional treatment options. Therefore, from a medical point of view, in this case it is also necessary to consider novel forms of therapy". And "at the time of receiving the immunotherapy, no therapy option existed that corresponded to the medical standard. All conventional options had been fully exhausted". The report explains that the treatment Mr F received had been in clinical use for many years and details some encouraging results.

- But importantly I think in this case, the estate of Mr F accepts in its response to the investigator's view that although phase III trials of the treatment Mr F were ongoing prior to Mr F's treatment, the results were only published in November 2022. That's around three years after Mr F's death and over a year after AXA issued its final response letter to the complaint. So, at the time he was undergoing the treatment, I don't think AXA has unfairly concluded the treatment being claimed for hadn't undergone appropriate clinical trials and assessment for the type of cancer he'd been diagnosed with.
- A leading cancer charity website describes phase III trials as comparing the new treatment with the standard treatment to see which treatment works better for a particular type of cancer and usually involves many more patients. So, until those trials are concluded – which they hadn't been for the combination of treatment Mr F was receiving at the time he was receiving it – I don't think AXA has unfairly concluded that this treatment hadn't been established as being effective. So, I don't think AXA has also unfairly relied on the other exclusion in section 6 to decline the claim.
- The combination of the vaccine and immunotherapy may have been better for Mr F compared with more conventional treatment that's been discussed in the medical literature and it was supported by his treating medical team at the time. Mr F also responded well to it. However, I don't think that means AXA has unfairly relied on the terms of the policy to decline the claim. Clinical trials and experimental treatment can sometimes lead to encouraging individual results. But I don't think it can fairly be said that such individual results means that it's established as being effective more widely through advanced clinical trials, the results of which aren't clear at the time the individual is having the treatment.

I've taken into account the list of insurers which the estate of Mr F says do provide cover for vaccine treatments and immunotherapy for cancer. Even if that's the case, different insurers will provide different insurance coverage based on the risks they're prepared to insure and how they define certain terms in their insurance policies, including experimental treatment. I've considered the estate of Mr F's claim against the policy terms Mr F had the benefit of at the time and I think AXA has fairly declined cover for the costs claimed.

I've also taken into account that AXA covered the costs of a certain biological therapy, and what the estate of Mr F describes as an anti-angiogenic selective monoclonal antibody drug ('the antibody drug'), in the region of £15,000. I understand that the antibody drug formed part of the overall treatment Mr F had and worked together with the vaccine and immunotherapy Mr F also had. When first administered in the country Mr F ended up having treatment, the estate of Mr F says the antibody drug was administered under a compassionate use protocol whereby the manufacturer reimburses the cost to the hospital if it doesn't display an effect in the individual patient. But as it worked well for Mr F, the manufacturer didn't reimburse the costs and so it was covered by AXA.

AXA says that the antibody drug isn't licensed by the EMA for the treatment of the cancer Mr F had been diagnosed with and wasn't being used within the terms of its licence. And that it was covered in error. AXA hasn't sought reimbursement of this cost from the estate of Mr F.

I don't think it's fair and reasonable for AXA to cover the other costs claimed by the estate of Mr F because it covered the cost of the antibody drug by mistake – particularly as AXA hadn't approved the vaccine and immunotherapy. And I don't think this means that it has discretion about whether to approve and accept claims for treatment/drugs which it would otherwise consider to be experimental under the policy terms.

AXA has said that those who assessed the claim for the antibody drug may have wrongly concluded that it was being used outside of Europe and so applied the FDA licensing rather than the EMA marketing authorisation rules. And because the antibody drug is licensed by the EMA for other indications it's possible that these were misread. But whatever the reason, I don't think Mr F was disadvantaged by this and AXA paid the costs for part of his medical treatment plan which it says shouldn't have been covered.

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I invited both parties to provide any information in response to my provisional decision. AXA didn't reply. The estate of Mr F replied disagreeing with my provisional decision. In summary it said:

- I hadn't addressed all points raised by the estate of Mr F, which isn't fair and reasonable given the complex factual matrix surrounding the claim and its value.
- My provisional decision doesn't properly take into account that the vaccine had initially been approved by the Medicines Agency of the European country Mr F first received treatment in and AXA had initially been prepared to cover the costs of the vaccine.
- My provisional decision doesn't examine the progression of the treatment Mr F had and others like it. There have been developments over recent years. Numerous other health insurers do provide cover for similar treatment and AXA is behind the curve in relation to insurance for vaccine treatments and immunotherapy for cancer. Cover is far below the industry standard and is not what's expected from a comprehensive global international health plan.
- My provisional decision is silent on the issue of the estate of Mr F having to fund the cost of transferring Mr F by air ambulance when he first became ill. A separate complaint about this had been upheld by AXA. But it's not clear the basis on which AXA upheld that complaint and paid the claim for the cost of air ambulance but didn't uphold this claim (treatment costs).

What I've decided – and why

I've considered all the available evidence and arguments to decide what's fair and reasonable in the circumstances of this complaint.

I explained in my provisional decision that this included the further points raised by the estate of Mr F, together with attachments, sent to our investigator at the end of March 2023. I've also carefully considered the further submissions dated July 2023 in response to my provisional decision. However, the further submissions don't change my mind and I don't uphold this complaint. I'll explain why.

As I set out in my provisional decision, although I've considered everything, I'm satisfied I don't need to comment on every individual point to be able to reach an outcome in line with my statutory remit. I've focussed on what I think are the key issues. The rules that govern the Financial Ombudsman Service allow me to do this as it's an informal dispute resolution service.

I also want to assure the parties that I've taken into account the full chronology of events which led to Mr F eventually receiving treatment the estate says should be covered under the policy in a different European country. However, for the reasons set out in my provisional decision, I don't think AXA has acted unfairly by relying on the terms of the policy to decline the treatment costs claimed for.

I've also taken into account the list of insurers which the estate of Mr F says provide cover for vaccine treatments and immunotherapy for cancer. Even if that's the case, as explained in my provisional decision, different insurers will provide different insurance coverage based on the risks they're prepared to insure and how they define certain terms in their insurance policies, including experimental treatment. I'm not satisfied this means AXA has acted unfairly in this case. And although there have been great strides in the development of the type of treatment Mr F had for cancer over more recent years, I don't think AXA has unfairly relied on the terms of the policy when concluding that treatment wasn't covered in this case.

The estate of Mr F has also referred to an earlier complaint made to AXA about having to self-fund the air ambulance for Mr F to initially transfer him to a different European country to the one he was in when he became very unwell. The estate said the costs should've been covered under the policy. I understand AXA did ultimately cover the costs and offered a goodwill gesture of £500 for delays. However, in July 2022, our investigator asked the estate of Mr F to clarify the extent of the complaint they wanted investigated by the Financial Ombudsman Service. And the estate confirmed that the complaint they wanted investigated related to AXA's final decision dated 15 July 2021.

Having considered this final response letter, I'm satisfied that it related to the complaint about not covering treatment costs for cancer as opposed to any issues around the claim for the cost of the air ambulance. So, it was right for the investigation and my decision to focus on the complaint made about the treatment costs. Although AXA ended up paying the claim for the costs of the air ambulance, for the reasons set out above and in my provisional decision (an extract of which is set out above and forms part of my final decision), I don't think AXA has unfairly declined the claim for the costs of the cancer treatment. So, I don't uphold this complaint.

My final decision

I don't uphold this complaint.

Under the rules of the Financial Ombudsman Service, I'm required to ask the estate of Mr F to accept or reject my decision before 22 September 2023.

David Curtis-Johnson
Ombudsman