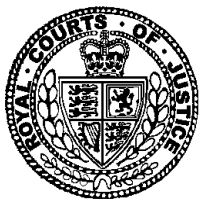

Neutral Citation Number: [2021] EWHC 3291 (Admin)

Case No: CO/3775/2021

IN THE HIGH COURT OF JUSTICE
QUEEN'S BENCH DIVISION
ADMINISTRATIVE COURT FOR WALES

Cardiff Civil Justice Centre

2 Park Street, Cardiff, CF10 1ET

Date: 03/12/21

Before :

THE HONOURABLE MRS JUSTICE STEYN DBE

- -

Between :

The Queen on the application of MARIA ROSE WALLPOTT **Cla**

- and -

WELSH HEALTH SPECIALISED SERVICES COMMITTEE

-and- **First Defe**

ANEURIN BEVAN UNIVERSITY HEALTH BOARD **Second Defe**

-and- **Interested**

NHS WALES

- -

- -

Vikram Sachdeva QC and Adam Boukraa (instructed by **Irwin Mitchell LLP**) for the **Claimant**

David Lock QC and Joel Semakula (instructed by **NHS Wales Shared Services Partnership**) for the **Defendants**

The **Interested Party** did not appear and was not represented

Hearing dates: 1 and 2 December 2021

- -

Approved Judgment

Mrs Justice Steyn :

A.

Introduction

1.
The claimant, Maria Wallpott, is suffering from a rare form of cancer. The doctors who are treating her have recommended that she undergo cytoreductive surgery with hyperthermic intraperitoneal chemotherapy ("CRS with HIPEC"), and the claimant fervently wishes to do so. As this treatment is not routinely available in Wales to those suffering with the type of cancer that the claimant has, her treating doctors made an individual patient funding request ("IPFR"). That request was refused by the first defendant, the Welsh Health Specialised Services Committee ("WHSSC"), acting on behalf of the second defendant, on 1 July 2021, and the decision to decline funding has been maintained on review.

2.
The WHSSC is a joint committee of the seven local health boards in Wales, which is hosted by Cwm Taf Morgannwg University Health Board. The second defendant, Aneurin Bevan University Health Board, is the local health board responsible for providing the claimant with NHS medical care. The decisions were made by the WHSSC on behalf of the second defendant.

3.
In this claim for judicial review, the claimant seeks to challenge the defendants' decision to refuse her funding request. She raises the following five grounds of challenge:

i)
In concluding that the "information provided did not demonstrate that the patient is likely to gain significantly more clinical benefit from the intervention than would normally be expected from patients with the same condition and the same stage of disease", the defendants failed to ask the right questions and/or reached an irrational conclusion.

ii)
The defendants unlawfully failed to give reasons for rejecting the evidence before them regarding the clinical benefit of the treatment for the claimant.

iii)
The defendants erred in their construction of the relevant guidance given by the National Institute for Health and Care Excellence ("NICE").

iv)
The defendants erred in taking into account the availability of alternative treatment in the form of the use of an EGFR inhibitor, in circumstances where such treatment was not in accordance with current practice in southeast Wales for patients with the claimant's condition.

v)
The defendants failed to ask the right questions in assessing the cost effectiveness of the treatment for which the claimant sought funding.

4.
This claim was filed on 2 November 2021, together with an application for urgent consideration seeking a substantive hearing by 3 December 2021. In accordance with the order of HHJ Lambert made on 5 November, the claim was listed for an expedited 'rolled up' hearing (that is, a hearing to determine both permission and the substantive claim).

5.
Mr Vikram Sachdeva QC and Mr Adam Boukraa appeared on behalf of the claimant. Mr David Lock QC and Mr Joel Semakula represented the defendants. I am grateful to them for the work they have

all evidently put into ensuring that this claim was ready to be heard urgently. As the claimant's medical situation is urgent, I have given judgment the day after the hearing ended. In view of the need for expedition, I have not sought to précis the parties' submissions in the way that I would have done if time had been less pressing. I have, nevertheless, given full consideration to those submissions, both written and oral.

B.
The claimant's medical condition

6.
The claimant is a 50 year old woman. On 28 April 2021 she was diagnosed with stage 4 metastatic appendiceal adenocarcinoma (more simply referred to as appendix cancer). The disease has spread to the claimant's omentum and peritoneum and has formed a large Krukenberg tumour. Appendix cancer is a type of colorectal cancer. As it has spread to the peritoneum, it is also a type of peritoneal carcinomatosis.

7.
Peritoneal carcinomatosis is an advanced form of cancer found in the peritoneal cavity; the fluid-filled gap between the walls of the abdomen and the organs in the abdomen. This type of cancer occurs when cancers spread from their origin in, for example, the appendix, bowel, rectum or ovaries. It is associated with short survival and poor quality of life, and may lead to bowel obstruction, accumulation of fluid in the peritoneal cavity and pain.

8.
The form of cancer from which the claimant suffers is described by Mr Gethin Williams, a consultant colorectal surgeon at Royal Gwent Hospital, in a letter to the claimant's GP dated 9 September 2021, as "exceedingly rare". The claimant has been advised that it affects about one to two out of every one million people.

9.
The claimant's case has been considered by multi-disciplinary teams (MDTs) in Gwent, Cardiff and Basingstoke. Her treating clinicians agree that despite being stage 4, her cancer is resectable and they have advised that she be offered CRS with HIPEC.

C.
Cytoreductive Surgery with Hyperthermic Intraperitoneal Chemotherapy

10.
CRS with HIPEC is described in the WHSSC's policies as follows:

"**Cytoreductive Surgery** involves removal of the maximum amount of the visible tumour through a number of surgical resections. The exact scope and extent of the surgery is dependent on the spread of the visible tumour assessed on an individual patient basis.

Hyperthermic Intraperitoneal Chemotherapy (HIPEC) involves flushing the abdominal cavity with a heated chemotherapy agent following surgical excision."

11.
The aim is to remove the macroscopic tumours using CRS and then, during the course of the operation, to treat any remaining microscopic traces of the cancer by distributing a heated

chemotherapeutic drug uniformly to all surfaces within the abdominal cavity, to increase drug penetration.

12.
There are two nationally designated centres in the UK where CRS with HIPEC can be provided, one of which is Basingstoke Hospital to which the claimant was referred by her treating clinicians in Gwent and Cardiff, and where it is proposed the surgery would be undertaken if funding can be obtained.

D.
The policies and guidance

The context: resource allocation in the NHS

13.
The context in which the policies in issue in this case have been adopted is explained by Professor Iolo Doull, the Medical Director of the WHSSC, in these terms:

"It is a feature of all national healthcare systems across the world, whether in the public or private sector, including the NHS, that demand for healthcare is rising and exceeds the ability of healthcare providers to meet all the healthcare demands of their local populations. This is a problem in both insurance and state-run healthcare systems across the globe. The only exception to this is for wealthy individuals who have unlimited resources to buy their own healthcare, but even then there can be limitations where the resource constraint is not money as, for example, with donated organs. However, for those of us without substantial personal wealth in the rest of the world, there is a gap between demand and the ability of a healthcare system to provide medical services to meet that demand."

14.
The combination of what he describes as "a massive rise in the demand for healthcare in the UK, as in all developed countries", the development of new, but expensive, effective treatments and drugs, including "new, highly expensive cancer drugs being developed and tested all the time, some of which have considerable benefits for patients suffering from life-threatening conditions", and the need to invest in health prevention means

"that the NHS has to make some very difficult decision about how to use its limited resources to best effect. We must always consider the opportunity costs of health investment, because money allocated to one type of health provision or prevention means, necessarily, that healthcare gain elsewhere will be foregone."

15.
There is, Professor Doull states, "enormous competition within the NHS for the allocation of budgets between different medical specialties". "Oncologists want more investment in oncology, those working in paediatrics want more investment in paediatrics and there is a strong demand to increase investment in public health so as to improve people's overall health by more effective preventative measures." And clinical teams working in other areas similarly, and rightly, seek more NHS investment to expand the range of treatments that they can offer to their patients.

16.
Professor Doull explains:

“For individual patients, the balance is between the potential benefits of a treatment and the potential risks. However, it is different for NHS decision makers. We have to make decisions about which treatments to fund so that we use our allocated budget to provide the most benefit to the greatest number of patients in our population. The issue for NHS decision makers is not just whether a treatment is clinically effective. In order to deliver on our obligations to the population as a whole, we need to be satisfied that the proposed treatment is cost effective. The principles of cost effectiveness have been developed by academics and are now a part of the working methods of NICE.”

17.
The approach to cost effectiveness taken by NICE is explained as follows:

“If possible, NICE considers value for money by calculating the incremental cost-effectiveness ratio (ICER). This is based on an assessment of the intervention’s costs and how much benefit it produces compared with the next best alternative. It is expressed as the ‘cost (in £) per quality-adjusted life year (QALY) gained’. This takes into account the ‘opportunity cost’ of recommending one intervention instead of another, highlighting that there would have been other potential uses of the resource. It includes the needs of other people using services now or in the future who are not known and not represented. The primary consideration underpinning our guidance and standards is the overall population need. This means that sometimes we do not recommend an intervention because it does not provide enough benefit to justify its cost. It also means that we cannot apply the ‘rule of rescue’, which refers to the desire to help an identifiable person whose life is in danger no matter how much it costs. Sometimes NICE uses other methods if they are more suitable for the evidence available, for example when looking at interventions in public health and social care.”

18.
Professor Doull states that there is “no absolute measure as to what is and what is not cost effective although the NHS in Wales follows NICE in using a rough measure of up to £30,000 per ICER as being the point where a treatment is said to be no longer cost effective.”

19.
This context is not disputed. On behalf of the claimant, Mr Sachdeva QC acknowledged that the funding decisions that NHS Wales and the defendants have to make are complex and difficult: there is not enough money to fund every treatment that would clinically benefit patients.

The WHSSC and NHS Wales policies

20.
In relation to the funding of CRS with HIPEC, WHSSC has adopted two policies. Policy Position: Cytoreductive Surgery with Hyperthermic Intraperitoneal Chemotherapy for Peritoneal Carcinomatosis (“PP90”) is directly applicable in the claimant’s case. Specialised Services Policy: CP02 Hyperthermic Intraperitoneal Chemotherapy (HIPEC) and Cytoreductive Surgery for treatment of Pseudomyxoma Peritonei (“CP02”) is directly applicable only in the case of patients with Pseudomyxoma Peritonei (“PMP”), which is not the type of cancer the claimant has, but CP02 is nevertheless of some relevance. In addition, a third policy, adopted by NHS Wales, is directly relevant: NHS Wales Policy: Making Decisions on Individual Patient Funding Requests (IPFR) (“the IPFR policy”).

21.
CP02 was issued in September 2015. The policy position adopted in CP02 is:

“Funding for treatment with Cytoreductive surgery and HIPEC for adult patients with confirmed Pseudomyxoma Peritonei is supported by the Welsh Health Specialised Services Committee.”

22.
CP02 states that clinical evidence indicates that CRS with HIPEC is

“effective in the treatment of patients with a low grade peritoneal mucinous tumour giving rise to Pseudomyxoma Peritonei, in which tumour cells appear low grade, are relatively scant and do not invade organs or lymph nodes and where the tumour will usually emanate from the appendix, but occasionally from the bowel or the gynaecological tract.

For this group of patients evidence indicates an 86% survival at 5 years, compared to 50% for patients with a more malignant pathology.”

23.
CPO2 states that it should be read in conjunction with the IPFR policy and PP90. In the “access criteria” section it states:

“**3.3 Exceptions**

Funding for peritoneal carcinomatosis is not supported.

If the referring clinician believes that there are exceptional grounds for treatment, an Individual Patient Funding Request (IPFR) can be made to the WHSSC under the [IPFR policy].”

24.
It is common ground that the statement that funding for peritoneal carcinomatosis is not supported should be read as “not routinely supported”. That is consistent with the reference to the IPFR policy under which an application for funding can be made for treatment that is not routinely commissioned and could not lawfully be rejected automatically. It is also consistent with paragraph 3.4 of CP02 which requires referrers and clinicians considering treatment to “inform the patient that this treatment is not routinely funded and consider alternative treatments” (emphasis added).

25.
PP90 was also issued in September 2015. It was due to be reviewed in March 2021, but the review date has been extended to July 2022. Professor Doull has explained that “as with so many areas of NHS policy, the demands of the COVID-19 pandemic have led to a delay in WHSSC being able to conduct a review”. PP90 is not challenged in these proceedings, and no point is taken with regard to the delayed review.PP90 expressly states that it “should be read in conjunction with” the IPFR policy and CP02.

26.
The policy position adopted in PP90 is:

“There is insufficient data on clinical and cost effectiveness to consider routine funding of HIPEC and CRS for the management of peritoneal carcinomatosis.”

27.
The basis for reaching this policy position is explained in PP90 in these terms:

“The WHSSC Prioritisation Group carried out an evidence evaluation in 2013 and made a recommendation not to fund HIPEC and CRS for colorectal cancer. In response to feedback obtained

via the consultation process a further evaluation was conducted in 2014. This updated evaluation was reconsidered by the Prioritisation Panel in Oct 2014.

Key findings were:

- The quality of evidence supporting the use of HIPEC outside the setting of Pseudomyxoma Peritonei with low grade disease is weak

- Many of the case series suggesting benefit in patients with metastatic colorectal cancer include Pseudomyxoma Peritonei patients within their mixed cohorts which may positively skew results.

- The morbidity arising from the usually very extensive surgery followed by intraperitoneal chemotherapy is significant with all patients requiring postoperative care in an ITU. Overall morbidity rates for grade 3 to 4 toxicity vary between 14.8 – 76% with mortality rates of 4.8 – 12%.

- There is only one randomised control trial (Verwaal et al, 2003) of 103 patients which suggests possible early benefit. At 21 months 30 patients were alive in the HIPEC group compared with 20 in the standard treatment group however importantly standard treatment used lower doses of chemotherapy than is now in conventional use. Procedure related mortality was 8% and there was no difference in overall long term survival (8 years). Any benefit for HIPEC was seen in patients with more limited stage disease and complete resection with no difference in advanced disease.

- There is no reliable data on cost effectiveness.

- Accepting the case study data the calculated number needed to treat for HIPEC and cytoreductive surgery vs. standard chemotherapy to avoid 1 additional death at 7 months is 11.

The conclusions of the Prioritisation Panel (31st October 2014) were that there was a lack of conclusive data for clinical and cost effectiveness and the significant harms associated with the procedure. The Prioritisation Panel ranked HIPEC and CRS for the management of peritoneal cancer as a low priority and therefore should not be routinely funded."

28.
The policy position adopted in Wales by WHSSC of not routinely funding CRS with HIPEC for patients with peritoneal carcinomatosis is different to the position adopted in England, Scotland and Northern Ireland where CRS with HIPEC is routinely available to such patients. The divergence with the policy position in England is addressed in PP90 in these terms:

"NB: This policy statement is in divergence with the current commissioning position in England. In 2013 NHS England Clinical Commissioning Board published Cytoreductive Surgery for Peritoneal Carcinomatosis and concluded that 'for colorectal cancer there is clear long term survival benefit for selected patients'. This was taken from the Bazian review (2012) which states 'with the provision [sic] it should only be provided by surgeons with the experience and expertise … it is effective and provides a significant benefit…'

Importantly this policy position does not take into account:

a) Consideration of the improvements in standard chemotherapy;

b) A critique of the quality of the evidence (low grade evidence);

c) A cost effectiveness evaluation;

and did not go through relative prioritisation process.”

29.
Under the heading “individual patient funding requests: implications of this policy statement”, PP90 states:

IPFR Decision making factors	**Decision making factors related to HIPEC**
Clinical exceptionality Is the clinical presentation of the patient unusual/ rare?	• Most patients present with abdominal pain, swelling or weight loss or on routine scans. • Evidence supporting the use in patients with limited disease is based on sub-group analysis and remains weak. • This is therefore unlikely to impact decision making
Evidence based considerations Does the treatment work? What is the evidence base for clinical and cost effectiveness?	• See above. The evidence base is weak and many of the case controlled studies predate newer Systemic Anti-Cancer Treatments which have been shown to prolong overall survival • The procedure costs £65,000 per patient. The very limited existing data assessing cost effectiveness is flawed • The WHSSC relative prioritisation process ranked this as low priority.
Ethical considerations How has the decision been reached? Is the decision a compromise based on a balance between the evidence-based input and a value judgement?	Long term follow up in the only randomised control trial suggests that for the vast majority of patients this is a palliative procedure with a significant mortality and morbidity.
Conclusion: **The lack of a sufficient evidence base, cost and palliative nature of the procedures means that this will not be commissioned via WHSSC**	

outside the setting of a randomised controlled trial.	

30.
Although on its face the “conclusion” quoted above would appear to indicate that WHSSC is not prepared to commission CRS with HIPEC in response to any individual request for funding, only being prepared to commission it in the context of a randomised controlled trial, it is common ground that such an interpretation would not accurately reflect WHSSC’s policy. The claimant submits such a policy would be unlawful and the court should strive to avoid an interpretation that would render the policy unlawful, which in this case would mean accepting the interpretation agreed by the parties. Mr Lock QC submits, and Professor Doull has given evidence, that properly understood WHSSC’s policy is that it will not routinely fund CRS with HIPEC for patients with peritoneal carcinomatosis but it will consider individual patient funding requests in accordance with the IPFR policy. I accept that is the proper interpretation of PP90.

31.
The IPFR policy was published by NHS Wales in June 2017. The purpose of the IPFR policy is explained in these terms:

“1.2.1 Continuing advances in technology, changing populations, better information and increasing public and professional expectations all mean that NHS Health Boards have to agree their service priorities for the application of their financial and human resources. Agreeing these priorities is a complex activity based on sound research evidence where available, sometimes coupled with value judgments. It is therefore important to be open and clear about the availability of healthcare treatments on the NHS and how decisions on what should be funded by the NHS are made.

1.2.2 A comprehensive range of NHS healthcare services are routinely provided locally by primary care services and hospitals across Wales. In addition, the Welsh Health Specialised Services Committee (WHSSC), working on behalf of all the Health Boards in Wales, commissions a number of more specialist services at a national level. The use of the term ‘Health Board’ throughout this policy includes WHSSC unless specified otherwise. However, each year, requests are received for healthcare that falls outside this agreed range of services. We refer to these as Individual Patient Funding Requests (IPFR)

1.2.3 Each Health Board in Wales has a separate Policy setting out a list of healthcare treatments that are not normally available on the NHS in Wales. This is because;

•
There is currently insufficient evidence of clinical and/or cost effectiveness; and/or

•
The intervention has not been reviewed by the National Institute for Health and Care Excellence (NICE) or the All Wales Medicines Strategy Group (AWMSG); and/or

•
The intervention is considered to be of relatively low priority for NHS resources.

1.2.4 The policy, called ‘Interventions Not Normally Undertaken’ (INNU) should be read together with this policy on making decisions.

1.2.5 The challenge for all Health Boards is to strike the right balance between providing services that meet the needs of the majority of the population in the geographical area for which it is then given responsibility, whilst having in place arrangements that enable it to accommodate people's individual needs. Key to this is having in place a comprehensive range of policies and schedule of services that the Health Board has decided to fund to meet local need within the resource available. To manage this aspect of the Health Board's responsibilities, there will always need to be in place a robust process for considering requests for individual patient funding within the overall priority setting framework. Demand for NHS services is always likely to exceed the resources available and, as a result, making decisions on IPFR are some of the most difficult a Health Board will have to make."

32.
If CRS with HIPEC for the treatment of peritoneal carcinomatosis were to be listed in the Interventions Not Normally Undertaken (INNU) policy, an "immediate review" of that policy would be triggered in circumstances where "NHS treatment would be provided in all (or almost all) other parts of the UK" (para 9.2 of the IPFR policy). However, that provision of the policy does not apply because it is not one of the listed treatments in the INNU policy.

33.
The IPFR policy provides:

"1.3.4 IPFR are defined as requests to a Health Board or WHSSC to fund NHS healthcare for individual patients who fall outside the range of services and treatments that a Health Board has arranged to routinely provide, or commission.

Such a request will normally be within one of the three following categories;

•
…

•
a patient and NHS clinician have agreed together that they would like a treatment that is provided by the Health Board in certain clinical circumstances but is not eligible in accordance with the clinical policy criteria for that treatment (for example, a request for treatment for varicose veins for cosmetic reasons alone);

•
…

1.3.5 The three categories of treatment will only potentially be funded in specific clinical circumstances. It is important to note that the NHS in Wales does not operate a blanket ban for any element of NHS healthcare. We will consider each IPFR on its individual merits and in accordance with the arrangements set out in this policy. We will determine if the patient should receive funding based on the significant clinical benefit expected from the treatment and whether the cost of the treatment is in balance with the expected clinical benefits.

1.3.6 In this policy, the words "significantly different to the general population of patients" means that the patient's condition does not have substantially the same characteristics as other members of that population. For a patient to be significantly different, their particular clinical presentation is unlikely to have been considered as being part of the population for which the policy was made." (emphasis added)

34.
At paragraph 4.3.2, the IPFR policy states:

“The purpose of taking an evidence-based approach is to ensure that the best possible care is available to provide interventions that are sufficiently clinically effective to justify their cost and to reduce inappropriate variation using evidence-based practices consistently and transparently. …”

35.
Paragraph 4.4.2 of the IPFR policy explains:

“Resources available for healthcare interventions are finite, so there is a limit to what LHB’s can routinely fund. That limitation is reasonable providing it is fair, and not arbitrary. It must be based on the evidence both about the effectiveness of those interventions and their cost. A cost effective intervention is one that confers a great enough benefit to justify its cost. That means policies must be based on research, but research is carried out in populations of patients, rather than individual patients. That leaves open the possibility that what is true for patients in general is not true about a specific individual patient. Fairness therefore also requires that there must be a mechanism for recognising when an individual patient will benefit from a particular intervention more than the general population of patients would. Identifying such patients is the purpose of the IPFR process.”

36.
Paragraph 5.3 of the IPFR policy sets out the criteria to be applied:

“The following guide will be used by all Health Board IPFR Panels when making IPFR decisions.

It is the responsibility of the requesting clinician to demonstrate the clinical case for the individual patient, and of the IPFR panel to consider the wider implications for the NHS, such that the criteria in **either (a) or (b)** below are satisfied:
(a) If guidelines (e.g. from NICE or AWMSG) recommend not to use the intervention/ drug; I. The clinician must demonstrate that the patient’s clinical circumstances are significantly different to the general population of patients for whom the recommendation is not to use the intervention, such that II. The clinician can demonstrate that the patient is likely to gain significantly more clinical benefit from the intervention than would normally be expected from patients for whom the recommendation is not to use the intervention, and III. The IPFR panel must be satisfied that the value for money of the intervention for that particular patient is likely to be reasonable.
(b) If the intervention has not been appraised (e.g. in the case of medicines, by AWMSG or NICE); I. The clinician can demonstrate that the patient is likely to gain significant clinical benefit, and II. The IPFR panel must be satisfied that the value for money of the intervention for that particular patient is likely to be reasonable.”

(emphasis added)

37.
It is common ground that the claimant's case fell to be considered by reference to the three criteria in (a), although it is notable that this is not a case where there are guidelines (from NICE, AWMSG or otherwise) that "recommend not to use the intervention". As explained below, the NICE guidelines recommend that CRS with HIPEC should only be used in the treatment of peritoneal carcinomatosis "with special arrangements", with patient selection undertaken by an experienced MDT, and in highly specialised centres. Nor does PP90 contain any recommendation not to use the intervention, albeit it will not be funded routinely (see paragraph 30 above).

38.
The IPFR policy then sets out a "decision making guide":

IPFR Panel **Decision-Making Factors**	**IPFR Panel** **Evidence for Consideration in Decision-Making**
SIGNIFICANT CLINICAL BENEFIT	
Is the clinical presentation of the patient's condition significantly different in characteristics to other members of that population? **and** Does this presentation mean that the patient will derive a greater clinical benefit from the treatment than other patients with the same condition at the same stage?	Consider the evidence supplied in the application that describes the specific clinical circumstances of the IPFR: • What is the clinical presentation of this patient? • Is evidence supplied to explain why the clinical presentation of this patient is significantly different to that expected for this disease and this stage of the disease? • Is evidence supplied to explain why the clinical presentation means that the patient will gain a significantly greater clinical benefit from the treatment than another patient with the same disease at the same stage?
EVIDENCE BASED CONSIDERATIONS	
Does the treatment work? What is the evidence base for clinical and cost effectiveness?	Consider the evidence supplied in the application, and supplementary evidence (where applicable) supplied by professional advisors to the Panel: • What does NICE recommend or advise? • What does the AWMSG recommend or advise? • What does the Scottish Medicines Consortium recommend or advise? • What does Public Health Wales advise?

	• Are there peer reviewed clinical journal publications available? • What information does the locally produced evidence summary provide? • Is there evidence from clinical practice or local clinical consensus? • Has the rarity of the disease been considered in terms of the ability for there to be a comprehensive evidence base available? • Does the decision indicate a need to consider policy or service change? If so, refer to service change processes.
ECONOMIC CONSIDERATIONS	
Is it a reasonable cost? What is the cost of the treatment and is the cost of the treatment likely to be reasonable? i.e. Is the cost of the treatment in balance with the expected clinical benefits?	Consider the evidence supplied in the application, and supplementary evidence (where applicable) supplied by professional advisors to the Panel: • What is the specific cost of the treatment for this patient? • What is the cost of this treatment when compared to the alternative treatment they will receive if the IPFR is declined? • Has the concept of proportionality been considered? (Striking a balance between the rights of the individual and the impact on the wider community), in line with Prudent Healthcare Principles. • Is the treatment reasonable value for money?
ETHICAL CONSIDERATIONS	
How has the decision been reached? Is the decision a compromise based on a balance between the evidence-based input and a value judgement?	Having considered the evidence base and the costs for the treatment requested are there ethical considerations that have not been raised in the discussions? • Is the evidence base sufficient to support a decision? • Is the evidence and analysis of the cost sufficient to support a decision? • Will the decision be made on the basis of limited evidence and a value judgement? If so,

	have you considered the values and principles and the ethical framework set out in the policy? • Have non-clinical factors been excluded from the decision? • Has a reasonable answer been reached based on the evidence and a value judgement after considering the values and principles that underpin NHS care?

39.
Paragraph 7.5 describes the process where requests are referred to the panel for consideration. It states:

“The panel will consider each IPFR on its own merits, using the decision making criteria set out in this policy. The IPFR Co-ordinator or Senior Officer will complete a record of the panel’s discussion on each IPFR, including the decision and a detailed explanation for the reason for that decision. Where possible, they should set out their assessment of the likely incremental clinical benefit and their broad estimate of the likely incremental cost so that their judgements on value for money are clear and transparent.

A standard decision letter should be prepared to communicate the decision to the requesting clinician. …”

40.
Paragraph 8 of the IPFR policy provides a right to request a review hearing. Such a review “does not constitute a review of the merits of the original decision. It has the restricted role of hearing review requests that fall into one or more of three strictly limited grounds”, namely, failure to act fairly and in accordance with the IPFR policy, irrationality and failure to exercise powers correctly.

41.
Paragraph 8.10 provides, in respect of review panel hearings:

“The IPFR Senior Officer will complete a record of the review panel’s discussion including the decision and a detailed explanation for the reason for the decision. They will also prepare a standard decision letter to communicate the decisions of the panel to the patient and referring/supporting clinician. ”

The NICE guidance

42.
NICE (in its original form as the National Institute for Clinical Excellence) was first established in 1999 as a special health authority, serving England and Wales. Its legal relationship with England and Wales now differs. In relation to England, the general duties of NICE are set out in section 233 of the Health and Social Care Act 20122012 Act. By section 237, the Secretary of State for Health may issue regulations authorising NICE to give “advice or guidance”. The resulting regulations are theNational Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013 (SI 2013/259). By regulation 7, NICE may publish a “technology appraisal recommendation” for the use of a particular medicine or treatment. By regulation 7(6), “a relevant health body must comply with a technology appraisal recommendation”.

In relation to Wales, the obligation to follow a technology appraisal ("TA") appears to stem from a funding direction issued by the Welsh Government.

43.
NICE has not published a TA in respect of the use of CRS with HIPEC for the treatment of peritoneal carcinomatosis. NICE has published "interventional procedures guidance" ("IPG"). Unlike a TA, which (the parties agreed) the defendants would be bound to apply, an IPG does not provide binding guidance. It is, nonetheless, common ground that the WHSSC was bound to have regard to the IPG issued by NICE in determining the claimant's IPFR. The purpose of an IPG is to assess the safety and efficacy of the procedure that is the subject of the IPG.

44.
NICE published Cytoreduction surgery with hyperthermic intraoperative peritoneal chemotherapy for peritoneal carcinomatosis ("IPG 688") on 3 March 2021. IPG 688 provides:

"This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. …

1 Recommendations

1.1 Evidence on the safety of cytoreduction surgery with hyperthermic intraoperative peritoneal chemotherapy for peritoneal carcinomatosis shows frequent and serious but well-recognised complications. Evidence on its efficacy is limited in quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research. Find out what special arrangements mean on the NICE website."

45.
Paragraphs 1.2 and 1.3 set out certain steps that clinicians wishing to perform CRS with HIPEC for peritoneal carcinomatosis should take, and that should be taken by healthcare organisations. IPG 668 continues:

"1.4 Patient selection should be done by an experienced multidisciplinary team.

1.5 The procedure should only be done in highly specialised centres by clinicians with specialist expertise and specific training in cytoreduction surgery and hyperthermic intraoperative peritoneal chemotherapy."

46.
Under the heading "Committee considerations", IPG 668 provides:

"**The evidence**

3.1 NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 10 sources, which was discussed by the committee. The evidence included 6 meta-analyses, 3 systematic

reviews and 1 randomised controlled trial. It is presented in the summary of key evidence section in the interventional procedures overview. Other relevant literature is in the appendix of the overview.

3.2 The professional experts and the committee considered the key efficacy outcomes to be: progression-free survival, disease-free survival, recurrence-free survival, overall survival and improvement in quality of life (physical and emotional).

3.3 The professional experts and the committee considered the key safety outcomes to be: postoperative haemorrhage, perioperative mortality, anastomotic leaks, sepsis, pain, stoma rate, readmission to an intensive care unit and the need for further surgery.

3.4 Two commentaries from patients who have had this procedure were discussed by the committee.

Committee comments

3.5 This procedure is unlikely to be curative and may be offered to patients for whom cure is not the intention. Therefore, it is important that patients are clearly informed that the procedure is associated with significant periprocedural morbidity including prolonged treatment in an intensive care unit and long-term postoperative recovery.

3.6 The resectability of the tumours is important in determining the outcome, but criteria for this have not been clearly established.

3.7 Hyperthermic intraoperative peritoneal chemotherapy has no standardised protocol, and protocols are continuing to evolve. Variations in the drug regimens include temperature, dose, duration of infusion time, and whether a drug is used on its own or in combination with other drugs.

3.8 There have been large improvements in survival and quality of life for patients with metastatic cancer in recent years because of advances in systemic chemotherapy. This made it difficult to assess the benefits of hyperthermic intraoperative peritoneal chemotherapy.

3.9 The outcomes are different depending on the type of tumour being treated.” (emphasis added)

47.
The five page guidance from which the quotations above are drawn is accompanied by a 94 page overview. The efficacy summary in respect of colorectal cancer states:

“A systematic review and meta-analysis of 1,036 patients (in 76 studies including 15 controlled and 16 non-controlled studies) who had treatments for peritoneal carcinomatosis from colorectal cancer reported that the mean overall survival for CRS plus HIPEC was 29.2 (±11.3) months. Meta-analysis of 15 controlled studies (including 3,179 patients) reported that the mean overall survival for the CRS plus HIPEC treatment group was 34.3 (±14.8) months and the traditional therapy group was 18.8 (±8.8) months. The summarised hazard ratio for overall survival was 2.67 (95% CI 2.21 to 3.23, I^2=0%, p<0.00001).

…

5-year survival

The systematic review and meta-analysis of 10,036 patients who had treatments for peritoneal carcinomatosis from colorectal cancer reported that the 5-year survival rate was 27.5% (±14.1). Meta-analysis of 15 controlled studies (with 3,179 patients) reported that 5-year survival for the CRS plus HIPEC group 40% (±11.5) compared with 18% (±14.1) for the traditional therapy group.

…

Summary of findings from the evidence review for this policy

Clinical effectiveness

- When delivered by a surgeon and units with the experience and expertise in achieving high rates of complete cytoreduction provides a significant survival benefit in peritoneal carcinomatosis secondary to colorectal and ovarian carcinoma.

…

The evidence suggests that the completeness of cytoreduction is an important determinant of effectiveness, and therefore this parameter should be monitored where the procedure is done.

…

Issues for consideration by IPAC

- …
- NICE Colorectal cancer guideline published in January 2020 supports the use of CRS and HIPEC for people with metastatic colorectal cancer in the peritoneum … 'Although evidence on the effectiveness was mixed, the committee decided that it was important to recommend referral to a nationally commissioned specialist centre after discussion within a multidisciplinary team for consideration of CRS and HIPEC so that more patients can have potentially curative treatment. This advice is in line with NICE IPG 331." (emphasis added)

48.
IPG 668 replaced IPG 331 which was published on 1 February 2010. IPG 331 provided, as does IPG 668, that CRS with HIPEC should only be used with special arrangements for clinical governance, consent and audit or research, and patient selection should be carried out in the context of a MDT, including oncologists and surgeons with experience in this operation. Paragraph 1.1 of IPG 331 stated:

"Current evidence on the efficacy of cytoreduction surgery (CRS) followed by hyperthermic intraoperative peritoneal chemotherapy (HIPEC) for peritoneal carcinomatosis shows some improvement in survival for selected patients with colorectal metastases, but evidence is limited for other types of cancer. The evidence on safety shows significant risks of morbidity and mortality which need to be balanced against the perceived benefit for each patient. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research."

The Cedar review

49.
Professor Doull states in his witness statement:

"In 2018 WHSSC commissioned Cedar (a combined NHS-academic healthcare technology research centre, part of both Cardiff and Vale University Health Board and Cardiff University) to carry out a

rapid evidence review of ‘Cytoreductive Surgery with Hyperthermic Intraperitoneal Chemotherapy for Peritoneal Carcinomatosis’. The final version was submitted to WHSSC in July 2018.

Subsequently CRS with HIPEC was presented to the WHSSC Prioritisation Panel on 16 October 2018, and the Cedar review was considered in the supporting evidence. The procedure was assessed and prioritised against ten other topics by the prioritisation panel, using agreed WHSSC methodology.

The WHSSC Prioritisation Panel concluded that there was a “lack of conclusive data for clinical and cost effectiveness and significant harms associated with the procedure.” The Prioritisation Panel ranked CRS with HIPEC as a low priority and consequently the WHSSC policy (PP90) and its recommendations remained unchanged.”

E.
The IPFR application, decision and review

50.
Following the diagnosis on 28 April 2021 (see paragraph 6 above), on 24 May 2021, the Royal Gwent Hospital Colorectal Cancer MDT considered the claimant’s case. She was referred by Mr Gethin Williams to Mr Brendan Moran, a consultant general and colorectal surgeon at the Peritoneal Malignancy Centre at Basingstoke Hospital, where her case was initially discussed on 1 June 2021, and to Lt Col Leigh Davies, a consultant colorectal surgeon at the University Hospital of Wales. The claimant’s case was considered by the Cardiff MDT on 16 June 2021 and discussed with Mr Moran.

51.
On 17 June 2021 Lt Col Davies submitted an IPFR. He asked for the application to be considered urgently (within 24-28 hours), noting:

“The patient has cancer and needs a rapid decision to facilitate urgent and early treatment. There has been delay previously. Patient and relatives highly anxious”.

52.
The reference to previous delay is to the fact the claimant had a CT scan following trauma in June 2020. That scan has since been described by Mr Moran as showing some evidence of an abnormality near the caecum at that point in time at the site of the appendix. That scan was initially reported as being unable to exclude malignancy of the caecum but it appears that nothing was done to investigate the position. Lt Col Davies has described that as a missed opportunity to prevent advanced disease.

53.
This is not a clinical negligence claim. The defendants take no position in these proceedings on whether there was negligence on the part of the treating physician in June 2020. Professor Doull has explained in his evidence that when considering the IPFR the panel considered that the possibility that the claimant had been treated negligently earlier in the process was not a relevant consideration. He explains:

“Patients in the NHS in Wales do not get additional priority because of errors made earlier in a treatment process. We allocate funding based on a patient’s presenting medical condition alone, not on the circumstances which led to that presenting condition. Hence, to use an example, two drivers in a road traffic crash get the same level of treatment regardless as to which driver caused the crash. A victim of violence gets the same treatment regardless as to whether he was a wholly innocent victim of an assault or whether he had been the perpetrator of a fight in which he came off worse. I can understand why Mr Davies thought that this was a key feature of the case, but the NHS does not

differentiate between the treatments available as NHS funded care for patients with identical presenting conditions depending on what led to the patient being in that condition."

The claimant does not take issue with this aspect of the defendants' approach.

54.
In the IPFR application form, Lt Col Davies stated that the diagnosis was peritoneal malignancy secondary to appendix carcinoma. It was stage 4. He described Ms Wallpott as "otherwise fit and well". He stated:

"The patient has already been discussed in Basingstoke MDT and has been assessed as resectable. This is confirmed with the opinion of the Cardiff Colorectal MDT in the presence of the Lead Malignancy Clinician.

…

This is a NICE approved therapy and is potentially lifesaving. Current survival rates in patients who undergo CRS and HIPEC are up to 40% over 5 years the equivalent of liver resection for metastatic disease."

55.
I note that the figures cited by Lt Col Davies reflect the 5 year survival rate referred to by NICE in the IPG 668 overview (see paragraph 47 above).

56.
The IPFR application continued:

Has the patient been through all NICE / AWMSG approved regimes?	Yes – The proposed treatment is NICE approved.
What is the usual treatment pathway and why is the patient not following the usual treatment pathway?	Peritoneal disease has limited potential for successful treatment with systemic chemotherapy with the vast majority succumbing to disease progression within a year on chemotherapy alone with little effect on median survival on this modality The only reasonable life-saving option is the proposed treatment. The usual treatment pathway if this patient was resident in the rest of the UK would be for them to undergo CRS & HIPEC as per NICE guidance.
What is the alternative treatment intervention?	Systemic chemotherapy – poor success rate in peritoneal malignancy due to poor peritoneal penetration. Recent advances in life expectancy from systemic chemotherapy with other sites of metastatic disease have not been demonstrated in peritoneal disease. Median life expectancy with peritoneal disease and systemic chemotherapy remains poor at approximately 9 months.
	They are largely unhelpful in improving survival quality of life nor life expectancy.

What are the reasons for not using an alternative intervention strategy?	

(emphasis added)

57.
In the section of the form headed “evidence of clinical effectiveness”, in response to the request for details of key studies supporting the use of this intervention for this condition, Lt Col Davies referred to two Dutch trials (one a randomised controlled trial), a review article written by the Basingstoke team in association with Paul Sugarbaker, who he described as the world’s leading authority on CRS and HIPEC, and the NICE guidance which he attached. He provided a full reference list of 19 articles.

58.
In the economic assessment section, Lt Col Davies stated the cost of CRS with HIPEC as £65,000 compared to the cost of chemotherapy of £16,285. He put the net cost of the procedure as “£65,000-£16,000 = £49,000”, stating:

“If this intervention is approved then there is a lesser requirement for full ongoing chemotherapy as above”.

59.
In the section of the application form headed “statement in support of application”, Lt Col Davies stated:

“This patient has been assessed by multiple MDTs including a specific Peritoneal Malignancy MDT in Basingstoke and the conclusions of these MDTs is that this patient has resectable disease with the intent of cure.

She is a young patient with a missed opportunity to treat her disease at an earlier stage of only 1 year previously but the lesion was not identified on her scan at that time. As such there is considerable anxiety surrounding this patient’s ongoing management from both the patient and her Sister

The treatment has been appraised by NICE and is an approved treatment for the management of peritoneal malignancy secondary to appendix metastases. Appendix disease has a better outcome for colorectal metastases as it often behave[s] biologically more like PMP.

This is an increasing frequent finding at the colorectal MDT. The patient is an exceptional [case] because although the patient’s disease is advanced by standard criteria it remains at this time resectable by the surgical techniques described above. Given the potential gains to the patient, I feel that this intervention should be undertaken in this case.

The benefits in this otherwise fit patient would greatly outweigh the potential benefits that this intervention would offer a typical cancer patient in a similar position.

This application is submitted as this patient will not be helped by systemic chemotherapy which is almost universally unhelpful in these patients – systemic treatment is no better than best supportive care and they will have a median survival of between 8 and 12 months. They have been assessed as potentially resectable by a number of clinicians with experience in cytoreductive surgery and HIPEC and deemed suitable for surgery. With CRS and HIPEC they have a good chance of long term (>5 years) survival and similar outcomes to Liver and lung resection for colorectal metastases.

…” (emphasis added)

60.
On 1 July 2021, the WHSSC panel considered the IPFR and decided not to approve the request for funding. The decision letter, addressed to Lt Col Davies, dated 6 July 2021 states:

“**Reason for Decision:**

The information provided did not demonstrate that the patient is likely to gain significantly more clinical benefit from the intervention than would normally be expected from patients with the same condition and the same stage of disease.

Discussion was held around the efficacy of CRS with HIPEC, and the NICE published efficacy summary was referenced. The Panel also acknowledged that the proposed procedure is radical with significant risk of morbidity and mortality.

NICE IPG688 states that:

“Evidence on the safety of cytoreduction surgery with hyperthermic intraoperative peritoneal chemotherapy for peritoneal carcinomatosis shows frequent and serious but well-recognised complications. Evidence on its efficacy is limited in quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research”.

It was also questioned by the Panel if Genetic testing had been carried out on the tumour, as no information had been provided on this. It was suggested that all future requests for this intervention includes results of genetic testing of the tumour and referring clinicians need to clarify whether or not they have undertaken high microsatellite instability (MSI-H)/DNA mismatch repair (dMMR) assessments.”

61.
The Panel Record Sheet of the meeting on 1 July 2021 records:

Evidence of Significant Clinical Benefit (…)	The extant WHSSC policy for CRS and HIPEC states that this treatment should not be routinely available. The panel noted that the IPFR form suggests that the proposed treatment is NICE approved for this indication and quotes that Peritoneal carcinomatosis secondary to appendix carcinoma is a current indication for periotonectomy and HIPEC treatment should the disease be assessed as resectable (NICE IPG688 – 2021). The form also quotes NICE IPG331 but the Panel clarified that the quoted guidance has now been replaced with NICE IPG688 (March 2021) which states that: [The same quotation as is included in the letter was set out.] The information provided did not demonstrate any clinical features which would suggest that the patient is likely to gain significantly more clinical benefit from the intervention than would normally be expected from patients with the same condition and the same stage of disease.

Evidence-Based Considerations (…)	The Panel noted that the IPFR form stated that CRS with HIPEC is a NICE approved therapy. It was clarified that NICE has only published an IPG not a Technology Appraisal supporting its use. The IPFR states that "This is a NICE approved therapy and is potentially lifesaving". The NICE IPG however states "This procedure is unlikely to be curative and may be offered to patients for whom cure is not the intention. Therefore, it is important that patients are clearly informed that the procedure is associated with significant periprocedural morbidity including prolonged treatment in an intensive care unit and long-term postoperative recovery". Discussion was held around the efficacy of CRS with HIPEC, and the NICE published efficacy summary was referenced. The Panel also acknowledged that the proposed procedure is radical with a significant risk of morbidity and mortality. The panel discussed other improvements in cancer care including the benefit of genetic testing and new drugs and that HIPEC had not be [sic] compared with current treatment options.
Economic Considerations (…)	£73,000 approx for package of treatment …The Panel were not satisfied that the value for money of the intervention for this particular patient is likely to be reasonable. There is lack of information to demonstrate that the treatment is cost-effective in comparison to the expected clinical benefits.
Ethical Considerations (…)	The information provided did not demonstrate that the patient is likely to gain significantly more clinical benefit from the intervention than would normally be expected from patients with the same condition and the same stage of disease. Current clinical evidence does not suggest the treatment is curative. Current clinical evidence does not support the use of CRS with HIPEC as being clinically effective. It was also questioned by the Panel if Genetic testing has been carried out on the tumour, as no information had been provided on this. It was suggested that all future requests for this intervention includes results of future genetic testing of the tumour and referring clinicians need to clarify whether or not they have… undertaken high microsatellite (MSI-H)/DNA mismatch repair (dMMR) assessments."
Rationale for Decision	[This was set out in the same terms as appear in the letter quoted above.]

(emphasis added)

62.

A review of the decision of 1 July 2021 was sought on 14 July 2021. Lt Col Davies stated:

“The panel of non-experts in CRS and HIPEC have reviewed the IPFR application and decided that this patient is not resectable despite her being considered for the same by 3 separate MDTs of specialists in colorectal malignancy and 2 of these are specialist MDTs in CRS and HIPEC.”

He stated that the claimant’s disease was exceptional because it was resectable.

63.
A second panel considered the IPFR on 5 August 2021 and decided that the decision not to approve funding should stand. The decision letter sent to Lt Col Davies on 9 August 2021 states:

“The additional information provided did not demonstrate that the patient is likely to gain significantly more clinical benefit from the intervention than would normally be expected from patients with the same condition and the same stage of disease.

The Panel noted the additional information submitted highlighting the MSI status of the patient confirmed that the patient has other forms of treatment available to them i.e. Monoclonal Antibody therapy/chemotherapy which can be less toxic and improve the patient[’]s quality of life.

There was no new or additional information provided to the Panel to justify changing the initial funding decision.”

64.
On 17 September 2021 a further review application was submitted by Dr Hilary Williams. The grounds were, first, that there was no clear definition of exceptionality or why the claimant had not been found to be exceptional, secondly, that the policy was outdated and failed to distinguish between appendix and colorectal cancer, thirdly, the finding that alternative treatment was available was wrong as current practice in southeast Wales is not to use EGFR inhibitors in right sided tumours (including appendiceal cancer) in view of the compelling evidence that right and left sided cancers have different responses to chemotherapy and biological therapies, and the inefficacy of such alternative treatment.

65.
The further review request was rejected on 30 September 2021 on the basis that grounds for review had not been clearly stated in line with the policy.

F.
Ground 1: Tameside/Irrationality

66.
There are two aspects to ground 1. First, the claimant submits that the panel failed to ask the right questions to ascertain clinical benefit, in breach of the Tameside duty. In particular, the claimant contends that the panel was required to ask the following two questions as set out in the decision making guide (see paragraph 38 above):

i)
“Is the clinical presentation of the patient’s condition significantly different in characteristics to other members of that population?” and

ii)
“Does this presentation mean that the patient will derive a greater clinical benefit from the treatment than other patients with the same condition at the same stage?”

67.
I consider that the claimant's Tameside point essentially boils down to the question whether the WHSSC's interpretation of the comparator to be adopted in applying criterion II of the IPFR policy was erroneous. Professor Doull has given evidence that the panels (at the initial and review stages) interpreted the IPFR policy as involving "a comparison between Ms Wallpott and other patients with advanced cancer who would be recommended for the treatment but were not offered it because of the policy which said it would not be routinely funded". There was no hint of this reasoning in the contemporaneous decision letters or panel records.

68.
In support of the defendants' interpretation, Mr Lock QC relies on R (Condliff) v North Staffordshire Primary Care NHS Trust [2011] EWCA Civ 910, [2012] PTSR 460, in which Toulson LJ referred at [19] et seq to a paper entitled Priority Setting: Managing Individual Funding Requests, published in 2008 by the NHS Confederation. At [21] Toulson LJ notes:

"Under the heading 'What approach should PCTs take to individual funding requests?' the author suggests:

"Exceptionality is essentially an equity issue that is best expressed by the question: 'On what grounds can the PCT justify funding this patient when others from the same group are not being funded?'"

69.
Mr Lock QC submits that it is only an equity issue if the comparator is the pool of patients who, but for the decision not to fund the treatment for them, would receive the treatment. If their clinician would not recommend it for them, they would be unaffected by the policy and so no lack of equity arises.

70.
It is well established and common ground that interpretation of policy is a matter for the court. In my judgement, the defendants' interpretation is inconsistent with the terms of the policy. First, paragraph 1.3.6 states that in the IPFR policy, the words "significantly different to the general population of patients" mean that the patient's condition does not have substantially the same characteristics as other members of that population i.e. the general population of patients. There is nothing in paragraphs 1.3.5 or 1.3.6 to support the defendants' interpretation. Paragraph 1.3.6 refers to the "population for which the policy was made". In this case, PP90 was made for the whole population of patients with peritoneal carcinomatosis: it applies to all such patients.

71.
Secondly, the decision making guide in the IPFR policy expressly specifies (see paragraph 38 above) that the comparison is with the clinical presentation "expected for this disease and this stage of the disease". Panels are not directed in the decision making guide to further reduce the comparator population of patients to those with the same condition, at the same stage and for whom the treating clinician has recommended the treatment. On the contrary, each of the questions decision-makers are directed to answer in the box headed "significant clinical benefit" directs them to compare the patient to "other patients with the same condition at the same stage".

72.
Thirdly, Criterion II in paragraph 5.3 of the IPFR policy compares the patient's position with that of "patients for whom the recommendation is not to use the intervention" (emphasis added). It is clear from the opening sentence at (a) - "If guidelines (e.g. from NICE or AWMSG) recommend not to use

the intervention/drug" - that the "recommendation" referred to is one contained in guidelines, such as from NICE. In circumstances where there are guidelines recommending that an intervention should not be used, the purpose of the comparison is to consider what (if anything) distinguishes the individual patient, whose treating clinician is seeking funding for the intervention, from others with the same condition at the same stage to whom that recommendation applies, so as to justify a departure from the recommendation not to use the intervention in the individual patient's case.

73.
IPG 668 does not make a recommendation not to use CRS with HIPEC for patients with peritoneal carcinomatosis. It is, as Mr Lock QC submitted, permissive.It requires the procedure to be used with special arrangements, and for the procedure to be done in highly specialised centres, following patient selection by experienced MDTs. Insofar as it could be said that there are any patients with peritoneal carcinomatosis for whom the NICE recommendation is not to use CRS with HIPEC, it is those who are not selected by an experienced MDT for the procedure to be done by a highly specialised centre. (Nor is PP90 a recommendation not to use the intervention (see paragraphs 30 and 37 above); and, in any event, if it could be construed in such a way, any such recommendation in PP90 would apply to all patients with peritoneal carcinomatosis.)

74.
This is flatly inconsistent with the defendants' submission that the comparator population excludes those whose clinicians do not recommend the treatment for them. The IPFR policy expressly posits comparison with those patients who will not be recommended for the treatment by their clinicians because it would be contrary to guidance.

75.
In my judgement, Condliff does not assist on this point. The court was not interpreting the policy that is before me, and the IPFR policy does not direct panels to address equity by asking the question posed in the paper to which Toulson LJ referred.

76.
I also accept the claimant's contention that the defendants' interpretation would appear to introduce a test of uniqueness: cfR (Ross) v West Sussex Primary Care Trust [2008] EWHC 2252 (Admin). Mr Lock QC referred in his submissions (on instructions, albeit the matter is not in evidence) to one case in which funding has been granted for CRS with HIPEC for treatment of peritoneal carcinomatosis, but the basis for that decision appears to have been that the clinical presentation was so close to PMP that the patient should be treated, in effect, as if they fell within CP02.

77.
The claimant's alternative submission under this ground is that the panel was required to come to a decision which was rational on the evidence, that is within the range of reasonable decisions taken by a panel: Basma v Manchester University Hospitals NHS Foundation Trust [2021] EWCA Civ 278 at [73]-[83].

78.
I consider that it is unnecessary and would be inappropriate to address this alternative submission. The WHSSC has not reached a conclusion as to whether the criterion that the claimant would be likely to gain significantly more clinical benefit than the general population of patients with stage 4 peritoneal carcinomatosis is met because of the misinterpretation of the policy to which I have referred.

79.
Accordingly, I find that this ground succeeds on the basis that in making the decision the defendants misinterpreted the IPFR policy.

G.
Ground 2: Reasons

80.
It is not disputed that there was a duty to give reasons. The policy expressly required a “detailed explanation” to be given of the reasons for the decision. Even if that were not the case, fairness required reasons to be given in this case. That is so, first, because of the vital importance of the decision to the claimant. In the IPFR application submitted in June 2021, the claimant’s treating clinician described the “median survival” (i.e. her life expectancy) with the only other available treatment, systemic chemotherapy, as between 8 and 12 months. Whereas the treatment for which he sought funding gave a “good chance of long term (>5 years) survival”, that “good chance” being expressed elsewhere in the form as “up to 40%”. He also described the proposed treatment as “potentially lifesaving”, albeit IPG688 advised that the procedure is “unlikely to be curative”. In this context, fairness necessarily imposed a requirement to give proper reasons for any decision to refuse to fund the treatment. Secondly, the claimant had a right to seek review of the decision on limited grounds, in accordance with the terms of the policy. If the claimant was not provided with an adequate explanation of the reasons for refusal of the request, she would be unable to exercise that review right effectively.

81.
Both parties rely on the opinion of Lord Brown, with which all members of the Judicial Committee of the House of Lords agreed, given in South Bucks District Council v Porter (No2) [2004] 1 WLR 1953 at [35]-[36], addressing the extent of the duty to give reasons in the context of a planning inspector’s decision. In particular, Lord Brown observed at [36]:

“The reasons for a decision must be intelligible and they must be adequate. They must enable the reader to understand why the matter was decided as it was and what conclusions were reached on the “principal important controversial issues”, disclosing how any issue of law or fact was resolved. Reasons can be briefly stated, the degree of particularity required depending entirely on the nature of the issues falling for decision. The reasoning must not give rise to a substantial doubt as to whether the decision-maker erred in law, for example by misunderstanding some relevant policy or some other important matter or by failing to reach a rational decision on relevant grounds. But such adverse inference will not readily be drawn. The reasons need refer only to the main issues in the dispute, not to every material consideration. They should enable disappointed developers to assess their prospects of obtaining some alternative development permission, or, as the case may be, their unsuccessful opponents to understand how the policy or approach underlying the grant of permission may impact upon future such applications. Decision letters must be read in a straightforward manner, recognising that they are addressed to parties well aware of the issues involved and the arguments advanced. A reasons challenge will only succeed if the party aggrieved can satisfy the court that he has genuinely been substantially prejudiced by the failure to provide an adequately reasoned decision.”

82.
As Chamberlain J observed in Inclusion Housing Community Interest Company v Regulator of Social Housing[2020] EWHC 346 (Admin) at [77], that passage has been applied generally in public law cases, both in and outside the planning and environmental field.

83.
The contentious issue is whether the reasons given satisfied the requirements described by Lord Brown. In making that assessment, a further question arises as to whether, insofar as Professor Doull gives evidence as to the panel's reasons (endorsed in the statement given by Professor Vivienne Harpwood, the Chair of the WHSSC IPFR Panel), his evidence is inadmissible in accordance with the Ermakov line of authority (drawn from R v Westminster City Council, ex p Ermakov [1996] 2 All ER 302).

84.
Professor Doull gives evidence regarding the panel's deliberations at paragraphs 54 to 78 of his statement. At paragraph 60 he refers to the alleged negligence at an earlier stage of the claimant's treatment (see paragraph 53 above). There is no live issue between the parties and so I consider that evidence is admissible background evidence. Paragraphs 54-59 of Professor Doull's statement address the interpretation of the NICE guidance, the admissibility of which I address in the context of ground 3. Paragraphs 74 to 77 address the issue of alternative treatments that I consider when addressing ground 4. Paragraphs 71 to 72 address the issue of cost effectiveness, the admissibility of which I have considered in the context of ground 5 below.

85.
At paragraph 61, Professor Doull refers to the fact that the procedure is routinely commissioned by NHS England and asserts that if that is correct it was not a relevant matter for the panel to consider. The claimant acknowledges that it was open to the defendants to adopt a different policy to each of the other countries of the UK and, as I have said, she does not challenge PP90. Although Mr Sachdeva referred in his oral submissions to paragraph 9.2 of the IPFR as showing that the approach taken to NHS treatment across the rest of the UK is a mandatory consideration in certain circumstances, there is no pleaded claim alleging a failure to take into account the approach in the rest of the UK when determining this IPFR. Accordingly, this paragraph does not go to a live issue and I consider it admissible background evidence.

86.
In paragraphs 62 to 70 of his statement, Professor Doull addresses in detail the panel's approach to the question of clinical benefit and in particular the comparison to be drawn in addressing the second criterion. It is unnecessary to address the Ermakov principles in detail in this judgment. In short, as Chamberlain J put it in the Inclusion case at [78]:

"So far as ex post facto reasons are concerned, the authorities draw a distinction between evidence elucidating those originally given and evidence contradicting the reasons originally given or providing wholly new reasons: Ermakov, pp. 325-6. Evidence of the former kind may be admissible; evidence of the latter kind is generally not. Furthermore, reasons proffered after the commencement of proceedings must be treated especially carefully, because there is a natural tendency to seek to defend and bolster a decision that is under challenge: Nash, [34(e)]."

87.
In my view, it is plain that Professor Doull's evidence in paragraphs 62 to 70 goes well beyond elucidating the reasons given contemporaneously. His witness statement provides new reasons and it does so after the commencement of proceedings. Insofar as he has explained the interpretation of the IPFR policy adopted by the panel, I have taken this part of his evidence into account on the basis that the interpretation error to which I have referred is identified. Save to that extent, I consider that this section of Professor Doull's evidence is clearly inadmissible ex post facto reasoning.

88.
In considering the reasons given contemporaneously by the WHSSC for each decision, as Mr Sachdeva QC accepts, it is necessary to look at both the decision letters and the records of the panel meetings. The primary reason given in both decision letters is that the information provided did not show that criterion II of paragraph 5.3(a) of the IPFR policy (see paragraph 36 above) was met. This was no more than an incantation of the criterion and a bare statement that it was not met.

89.
Mr Lock QC submits that all that was required was a very brief statement because that reflected the treating clinician's failure to put forward evidence that this criterion was met. He contends that the information put forward amounted to no more than bare assertions.

90.
Lt Col Davies had put forward the following factors in support of his contention that criterion II was met:

i)
The claimant's cancer was assessed by the MDTs as resectable. This was exceptional for a patient with her condition at stage 4. It was a potentially vital factor because most patients with the same condition, at the same stage, would not be resectable. (And for patients with the same condition who were resectable, but at an earlier stage of the disease, and so potentially having a greater life expectancy and quality of life than the claimant, the overall assessment of benefit – having regard to the risks - would potentially differ.)

ii)
Appendix cancer often behaves biologically more like PMP (for which CRS with HIPEC is routinely funded by NHS Wales) and has a better outcome than other colorectal cancers. This was an increasingly frequent finding made at the colorectal MDT. This information that appendix cancer has a better outcome than other colorectal cancers fell to be considered in the context of the NICE guidance which referred to "a significant survival benefit" in peritoneal carcinomatosis where it was secondary to two types of carcinoma, namely, colorectal and ovarian (see paragraph 47 above).

iii)
Compared to the cohort of patients with this disease, and at this stage of the disease, the claimant is young and otherwise fit and well, with a WHO performance status of zero (i.e. the best level).

iv)
The only alternative treatment available was systemic chemotherapy which was "largely"/"almost universally" unhelpful in treating peritoneal disease due to poor penetration of the peritoneum. So the "large improvements in survival and quality of life … because of advances in systemic chemotherapy" - which made it difficult for NICE to assess the benefits of HIPEC - referred to in IPG688 (see paragraph 46 above), were said to be inapplicable in this case.

91.
Neither the decision letters nor the panel records addressed any of these reasons. It is evident that Lt Col Davies understood the first decision to mean that the panel had rejected the assessment made by the MDTs that the claimant's cancer is resectable and so he took that reasoning to be the target of his application for review. While I accept the defendants' witness evidence that the assessment that the claimant's cancer was resectable, and that it was possible (albeit unlikely) that the procedure would be curative for the claimant, was accepted by the WHSSC, given the WHSSC's failure to address any

of those four key factors, it is unsurprising that Lt Col Davies misunderstood the basis for the refusal of funding. It is equally unsurprising that Dr Heather Williams was still asking in her second review request why the panel considered the claimant did not fit what she referred to as the exceptionality criterion. The reasoning was also insufficient to enable the claimant to identify during the review process any error made by the WHSSC in interpreting the IPFR policy (see ground 1 above).

92.
In my judgement, it is clear that the reasons given in this case failed to address the principal controversial important issues and they were insufficient to enable the claimant to have a fair opportunity to exercise the right to review.

H.
Ground 3: Construction of the NICE guidance

93.
The first decision states that, “Current clinical evidence does not support the use of CRS with HIPEC as being clinically effective”. The claimant submits that this finding shows that the panel has erroneously construed IPG668 as meaning that the treatment is not clinically effective at all, and there are no patient sub-groups in whom it is clinically effective. That is, the claimant submits, a plain misreading of the NICE guidance.

94.
In their detailed grounds of resistance, the defendants asserted that the panel “never came to a finding that the treatment was not clinically effective at all”. Mr Lock QC submits that IPP668 is permissive. Paragraphs 54-59 of Professor Doull’s statement address the interpretation of the NICE guidance. That is evidence that goes far beyond elucidation of the reasons given in the contemporaneous reasons and I do not consider it admissible.

95.
In my judgement, it is unclear how the panel in their decisions construed the NICE guidance. I would accept that Mr Lock’s description of IPG668 as permissive is apt. It is not prescriptive, save to the extent of imposing requirements in relation to matters such as who can select patients and undertake the procedure. But it is clear that it is permissive because NICE has assessed that it is a clinically effective treatment for some patients with peritoneal carcinomatosis, albeit careful selection is required and treatment at specialised centres.

96.
The statement that “Current clinical evidence does not support the use of CRS with HIPEC as being clinically effective” is concerning. It appears to reflect the interpretation of PP90 that the defendants acknowledge cannot be correct i.e. that this treatment should only be funded in randomised controlled trials. The defendants have acknowledged that PP90 should not be interpreted in that way. Funding for it can be sought pursuant to the IPFR policy. That must be on the basis that it is acknowledged to be clinically effective for some patients with peritoneal carcinomatosis, otherwise every IPFR application for this treatment would be automatically rejected. That would be unlawful.

97.
While I am not persuaded that this has been made out as a separate ground, the lack of clarity as to how the NICE guidance was interpreted provides further support for the conclusion that the reasons given were inadequate. And the concern to which I have referred in the paragraph above is a matter

to be taken into account in considering whether this is an appropriate case for the application of s. 31(2A) of the Senior Courts Act 1981.

I.

Ground 4: Mistake of fact/Irrelevant Consideration re alternative treatment

98.
In the review decision the WHSSC expressly took into account its view that the claimant "has other forms of treatment available to them", referring specifically to EGFR inhibitors. There was no evidence before the panel to suggest that such treatment was available to the claimant and as soon as this point was made in the decision letter the claimant's treating clinician clarified that, in fact, this treatment is not available to the claimant because her cancer is on the right side of the abdomen and it is not current practice in southeast Wales to use EGFR inhibitors in right-sided tumours.

99.
The defendants' initial position, reflected in the evidence of Professor Doull, was that this treatment was "available", that term being a statement of NHS commissioning policy, even though it was not treatment that her clinician would make use of in her case. However, in his oral submissions, Mr Lock QC acknowledged that whether treatment is available has to be determined by whether it is available to the patient.

100.
That is plainly right. The decision letter referred to alternative treatment "available to them" (i.e. to the claimant). That reflects the IPFR policy: the decision making guide refers to "alternative treatment they will receive if the IPFR is declined" (emphasis added). The use of EGFR inhibitors was not recommended by the claimant's clinicians as an appropriate treatment for her. The conclusion that it was a treatment that was available to her was a factual error.

101.
The leading case on mistake of fact as a ground of challenge in judicial review proceedings is E v Secretary of State for the Home Department [2004] QB 1044 at [66]. To establish unfairness stemming from a mistake of fact it is generally necessary to meet the following requirements:

"First, there must have been a mistake as to an existing fact, including a mistake as to the availability of evidence on a particular matter. Secondly, the fact or evidence must have been "established", in the sense that it was uncontentious and objectively verifiable. Thirdly, the appellant (or his advisers) must not have been responsible for the mistake. Fourthly, the mistake must have played a material (not necessarily decisive) part in the tribunal's reasoning."

102.
In my judgement, these requirements are met. The fact that the use of EGFR inhibitors was not a treatment available to the claimant was an existing fact at the time of the challenged decision. It is uncontentious. The claimant and her advisers cannot be held responsible for the mistake. Her treating clinicians addressed the question as to what alternative treatment was available and made no suggestion that use of EGFR inhibitors was a possible treatment available to the claimant. Nor were they asked if it was an available treatment.

103.
The only criterion that Mr Lock QC submits is not met is the fourth: materiality. He contends that the IPFR was refused essentially on the grounds that evidence to demonstrate that the claimant was likely

to gain significantly more clinical benefit from the intervention than would normally be expected for patients in the relevant population was lacking. The reference to alternative treatment was, he submits, no more than an ancillary point. The decision would have been the same even if the error had not been made.

104.
I do not accept that the error was immaterial. A significant aspect of the assessment of clinical benefit for the claimant of CRS with HIPEC involved assessing the degree of benefit of that treatment compared to any alternative treatments available to her. So for example, the net benefit of CRS with HIPEC would be reduced if, as the panel suggested in the context of their first decision, there were (relevant) “improvements in cancer care including the benefit of genetic testing and new drugs”. Whereas there could be no such reduction of the assessed benefit by reference to a treatment (EGFR inhibitors) that was unavailable to the claimant. The removal of this suggested alternative from the equation was material because it had the effect that the only alternative treatment available (systemic chemotherapy) was one which the panel were informed was almost universally unhelpful to patients in the claimant’s position.

J.
Ground 5: Economic considerations

105.
The panel found that the cost of the treatment was £73,000. Although Lt Col Davies had stated the figure for the treatment was £65,000, the claimant does not suggest that difference gives rise to any public law error. The aspect of the decision that the claimant takes issue with is the failure to deduct the sum of £16,000 (or thereabouts) in respect of chemotherapy. Lt Col Davies addressed the question in the application whether there were any offset costs. He stated that there were because in the intervention was approved there would be a lesser requirement for full ongoing chemotherapy. He stated that £16,000 should be offset from the cost of CRS with HIPEC.

106.
In the decision, the WHSSC recorded that the cost was £73,000 and they did not offset any cost in respect of the lesser requirement for chemotherapy. Nor did they give any explanation for not doing so.

107.
Mr Lock QC submitted that as CRS with HIPEC was unlikely to be curative, it was likely that the need for systemic chemotherapy would only be postponed and so there would be not offset. The difficulties with this submission are, first, that there is nothing in the contemporaneous records of the decisions, or even in the evidence produced during the course of these proceedings, to support the submission that that is the view the WHSSC took. There is no evidence to support the submission that treatment with systemic chemotherapy would be used after CRS with HIPEC; a submission which is contrary to the information provided by the consultant colorectal surgeon. And if his view that there would be a lesser requirement for chemotherapy if the funding was approved was rejected, no reason for doing so was given.

108.
Mr Lock QC submits that cost effectiveness was not a major part of the decision because the panel had concluded the request should be refused applying earlier criteria. I accept that is the case, but it is nevertheless apparent on the face of the decision that some consideration was given to economic considerations and so the question whether the panel reached an unlawful conclusion does arise.

109.
Mr Lock QC also submitted that even if there should have been an offset, it is immaterial because there was no way this treatment was ever going to be found to be cost effective. In this regard he relied on PP90 itself and the statement that there is “no reliable data on cost effectiveness”. In my judgement, if the defendants were to take the approach of concluding in response to an IPFR in respect of CRS with HIPEC that it automatically fails the cost effectiveness test because of the findings in PP90, that would amount to fettering their discretion and failing to apply the IPFR policy on the individual merits of each case. I do not suggest that is what they have done here, but that would be the effect if the line taken by Mr Lock QC in his submissions was taken.

110.
For the reasons I have given, I consider that the panel failed to have regard to a material consideration in failing to offset the chemotherapy cost or, if they rejected Lt Col Davies statement that it fell to be offset, then they failed to state their conclusion or give any reasons for it.

111.
Professor Doull has provided evidence at paragraphs 71 to 72 of his statement regarding cost effectiveness. In my judgement, that part of his evidence clearly falls foul of the Ermakov principles. It is true that the reasons given are not contradictory of the contemporaneous reasons, but that will often be the case where contemporaneous reasons do little more than recite the test and assert it is not met. In this case, the extensive reasons for the decisions given in evidence do not provide mere clarification or elucidation. They constitute new reasons given for the first time after the commencement of proceedings; and in addition the reasons are given by one panel member supported by one other, in the context of decisions taken by panels with many more members. Such evidence is not admissible. Accordingly, I also reject the contention that the error was immaterial.

K.
Section 31(2A) of the Senior Courts Act 1981

112.
The defendants submit that this is a case in which I should apply s.31(2A) of the Senior Courts Act 1981 and refuse relief on the grounds that it is highly likely that the outcome for the applicant would not have been substantially different but for the errors that I have identified.

113.
In my judgement, this is very far indeed from an appropriate case in which to refuse relief under that section. It is not for me to put myself in the shoes of the decision-makers. It is plain that the “highly likely” threshold is nowhere close to being met in this case given, in particular, the misinterpretation of the policy and the failure to give any adequate reasons for rejecting the factors the claimant’s treating clinician relied on as demonstrating the criteria were met in her case.

L.
Conclusion

114.
Accordingly, I grant permission and allow this application for judicial review. I will hear the parties on the precise form of the order.