

Date	Organisation / Role	Current wording / content	Comments Received	Page No. / Location in document	Change Made (Yes/No)	If Yes - Changed to	If No - Reason	Notes
17/08/2021	Quality & System Performance NHS South, Central and West	Egg Donation - Current policies allow for egg donation under specific criteria.	Assume means the use of donor eggs, this and the use of donor sperm could be in one section perhaps	Appendix A - Table 1	Yes	Donor eggs and donor sperm - Current policies cover use of donors eggs and donor sperm under specific criteria.		
		BLMK CCG is proposing to implement the number of cycles as per the outcome of this consultation. BLMK CCG is proposing to apply NICE guidelines in relation to age criteria for service users (e.g.: patients up to the age of 42 will be eligible)	is the current BCCG and LCCG minimum age criteria 23 years to be removed? This would be in line with NICE CG. Beneficial point in view of improving access conversations.	Appendix A - Table 2	Yes	BLMK CCG is proposing to implement the number of cycles as per the outcome of this consultation. BLMK CCG is proposing to apply NICE guidelines in relation to age criteria for service users (e.g.: patients up to the age of 42 will be eligible and the existing minimum age of 23 years stated in the existing BCCG and LCCG policies should be removed)		
		Donor Insemination	Assume this is just a section to refer to the use of donor sperm and donor oocytes as in the previous section i.e. funded. 'Donor insemination' may be confusing terminology it just is AI using donor perm, sorry may be a bit pedantic here...	Appendix A - Table 2	Yes	This row in the table has been removed on the rationale that it could be confusing and other sections clarify the use of donor eggs/sperm and IUI/AI. Also could be confusing to say not proposing to change because some aspects of access to IUI are expected to change.		
		Donor Insemination - BLMK CCG is not proposing to change this element of the policies but will add clarity by aligning the wording to NICE guidelines.	Agree that there needs to be a clear section on the requirements what is expected of same sex couples and women not in a partnership and people who are unable to, or would find it difficult, to have vaginal intercourse to establish their fertility status before seeking NHS funded services. This is discussed later in the page 10 section.	Appendix A - Table 2	Yes	as above this row of the table has been removed.		
		Minimum / Maximum BMI - BLMK CCG are proposing that BMI should be between at least 19 and up to 30 for female and less than 35 for male.	NICE CG notes that: 'Men who have a BMI of 30 or over should be informed that they are likely to have reduced fertility'.	Appendix A - Table 3	No			
		Duration of sub-fertility - Couples with unexplained infertility or mild male factor infertility/subfertility must have infertility of at least 3 years of ovulatory cycles, despite regular unprotected vaginal sexual intercourse.	Clinical evidence from NICE notes that 84% of women would conceive within one year of regular unprotected sexual intercourse, 92% after two years and only a one per cent increase to 93% after three years. NICE made this change in 2013 from 3 to 2 years due to the small increase as noted above. This could be a positive point for improving access to services conversation, coupled with the fact that that female fertility declines with age and therefore waiting longer for referral for specialist services potentially drives down success rates. Reducing the time period of expectant management from three years to two years in instances of unexplained infertility would impact on cost and activity in the first year of implementation, before a 'steady state' is achieved.	Appendix A - Table 3	Yes	Following discussion at the 'clinical panel' on Wed 15th Sept agreed to change the duration of sub-fertility from 3 years to 2 years based on the clinical evidence from NICE.		
		IUI (Unstimulated)	Just for clarity maybe it would be good to discuss this under a title of 'patients who have who have social, cultural or religious objections to IVF - the use of 'replacement cycle' would avoid confusion with the other AI discussion. Have we reviewed the equivalence of the one IUI to one IVF. I believe LCCG policy states 6 IUI as replacement cycles for one IVF if I have the right 2019 version.	Appendix A - Table 3	Yes	Patients who have who have social, cultural or religious objections to IVF - BLMK CCG is proposing to implement the number of IUI cycles in line with the number of IVF cycles agreed as per the outcome of this consultation, e.g. 1 cycle of IVF offered = 1 3 cycles of IUI offered. 3 cycles of IVF offered = 3 9 cycles of IUI offered. This would still be applicable under exceptional circumstances and an IFR/ITP application for funding has been made.		
		Same Sex Couples	Think this section should include; women in same-sex couples, single women and couples not able to have vaginal intercourse	Appendix A - Table 3	Yes	Women in same-sex couples, single women and couples not able to have vaginal intercourse		
		Same sex couples - female: Same sex female couples are entitled to 6 cycles of NHS funded donor AI or IUI.	Important to be specific that it should be IUI (not just AI as that can be both intra uterine or intra cervical) This section needs to clarify what is expected in terms of establishing fertility status before seeking NHS funding. LCCG position is referring to this i.e self-funded AI. For women in same-sex / or not in relationships or unable to have intercourse, there should be some period of unsuccessful AI before they would be considered to be at risk of having an underlying problem and be eligible to be referred for assessment and possible treatment in the NHS. NICE notes that: 'In women aged under 40 years who have not conceived after 2 years of regular unprotected intercourse or 12 cycles of artificial insemination (where 6 or more are by intrauterine insemination), offer 3 full cycles of IVF... 'For women under 40 who are using artificial insemination rather than sexual intercourse to conceive, more than half of women will get pregnant within 6 cycles of intrauterine insemination. Within 12 cycles, more than 3 out of 4 women will become pregnant'.	Appendix A - Table 3	Yes	Same sex couples - female: Same sex female couples are entitled to 6 cycles of NHS funded donor IUI.		
		Same sex couples - male: Same sex male couples will not be able to access fertility treatment within their relationship but will be eligible for appropriate investigation where there is evidence of subfertility.	Agree, the scope of NICE guideline makes it clear that it is intended for people who have a possible pathological problem (physical or psychological) to explain their infertility. However, if we promise to investigate, we would need to define when and that would need to be that same as for same sex female couples etc. If we are clear as per earlier point that that surrogacy is not funded by the CCG but all individuals can have access to sub fertility investigations as necessary not sure we need to make the point again for male same sex couples. The surrogacy point also covers other trans couples where the is not womb.		Yes	Section removed as surrogacy sections already covers these points.		
		Option 2b Trans or non-binary couples or individuals who meet all criteria in this policy must have had unexplained fertility for a period of 3 years. Or have received 6 cycles NHS funded donor AI or IUI. Or have a diagnosed cause of absolute infertility to be eligible to receive NHS funded fertility treatment.	If we discuss the patient groups in terms of couples trying to conceive and concerned about sub fertility i.e. couples unable to have intercourse, same sex couples, single women and trans or non-binary couples I think we have identified what the policy addresses and if we introduce the definition early in the policy, we do not need to single them out. What is expected in terms of 'evidence' for sub fertility and what is offered should be consistent for all. Thus not sure all these options are necessary and again using the exceptions process would single out different process for different patient groups.		Yes	Women in same-sex couples, single women and couples not able to have vaginal intercourse are entitled to NHS funded IVF treatment on the NHS following 6 cycles of NHS funded donor AI or IUI. BMI eligibility criteria above apply only to the female partner undergoing fertility treatment. The partner of a prospective person who has undertaken NHS funded fertility treatment, whether successful or not, will be deemed to have received their entitlement to NHS funded fertility treatment upon completion their treatment, in line with the criteria for heterosexual couples and will not be eligible for additional cycles with their partner or any future partners. Couples will be required to fit all other criteria within a policy in line with heterosexual couples.		
31-Aug-21	Pateint and Public Engagement Committee		How many pateints are affected by the policies in each area - make this clear in the Case for Change Document		Yes	Gluten Free numbers - see page 4 MK Pharmacy First Data - see page 5 During 2019/2020 480 people across Bedfordshire, Luton and Milton Keynes accessed IVF treatment, this is approximately 0.05% of the BLMK population.		Gluten free data already included (100 patients) JB added table to Pharmacy first which shows usage data
03-Sep-21	Fertility Network UK		What definition of a cycle is going to be used as currently all 3 CCG's are using different definitions and only MK use the NICE definition of a cycle?		Yes	The definition of a cycle and abandond cycle have been added to the glossary in the appendix detailing the criteria changes.		
03-Sep-21	Fertility Network UK	BLMK CCG has finite resources to fund a whole range of health services and treatments. Specialist fertility services are expensive treatments which can often prove unsuccessful. There is a real need to balance funding for this treatment with all other treatments/services across the NHS in Bedfordshire, Luton and Milton Keynes.	What modelling of data and costs have been used, it says it is expensive, but where does that come from - need to include rationale.		2 Yes	There is a real need to balance funding for this treatment with all other treatments and services across the NHS in Bedfordshire, Luton and Milton Keynes. The CCG's current annual spend on fertility services is £895,264 with an average cost per patient of £1,865. During 2019/2020, 480 people across BLMK accessed IVF treatment, this is approximately 0.05% of the BLMK population.		
03-Sep-21	Fertility Network UK		Need to look at how many people would move onto the second and how many would go onto a third and be eligible. What work has been done in this area to arrive at the options in the consultation?		No		As per above the modelling has been reviewed and assumptions about number of people who move onto second and third cycles is based on historical local data. The case for change explains the clinical discussion about criteria and how the criteria should look moving forward.	
03-Sep-21	Fertility Network UK	The Luton policy of routinely offering up to three cycles is at odds with the majority of the surrounding CCG Areas. Within the East of England health region, only Thurrock and the former Luton CCG offer more than one cycle. All others offer one, except for Cambridgeshire and Peterborough who do not currently fund any cycles (though they have recently proposed implementing a single cycle). In the wider geography, Oxfordshire, Buckinghamshire and Berkshire CCGs all offer only one cycle.	Cambridgeshire and Peterborough - check language used to explain their decision to re-instate (1 fresh and 1 frozen - not full cycle as per NICE) Projections - Figures in the document suggest that there would be an almost doubling in spending which is at odds with the Camden findings which show that very few people move onto a third cycle. Also don't understand how the two options were reached - would be beneficial to think more holistically about what might be the right thing to do. Need to show rationale for the options.		2 Yes	The Luton policy of routinely offering up to three cycles is at odds with the majority of the surrounding CCG Areas. Within the East of England health region, only Thurrock and the former Luton CCG offer more than one cycle. All others offer one cycle and in the wider geography, Oxfordshire, Buckinghamshire and Berkshire CCGs all offer one cycle.		
03-Sep-21	Fertility Network UK		The consultation documents need to show the detail behind the suggested changes in policy so that the public can have a full understanding of the changes and what they would cost.		No		We have used data collected through our Luton service, which is closer to demography than using the Camden data or national data.	
06-Sep-21	Healthwatch				Yes	Detail added including numbers accessing services and costs for each option		

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06-Sep-21	Healthwatch Luton	What is the cost of fertility services to BLMK CCG? The CCG's current annual spend on fertility services is £895,264. If the number of cycles was increased to 3 across BLMK this would increase to at least £1,670,149, an increase of £774,845. As the CCG has a finite financial resource, this would require consideration of where resources could be saved in other service areas. This may mean we would have to stop some other services so the money was available for this.	The language around having to reduce other services if these services are all levelled up can be seen as a threat to services	Pg 3	Yes	What is the cost of fertility services to BLMK CCG? The CCG's current annual spend on fertility services is £895,264. If the number of cycles was increased to 3 across BLMK this would increase to at least £1,670,149, an increase of £774,845. As the CCG has a finite financial resource, this would require a review of budget allocation.		
06-Sep-21	Healthwatch Luton	A decision was taken over 30 years ago to include gluten-free foods on prescription, when there was limited availability of gluten-free foods to buy. Today the availability of gluten-free foods has increased dramatically and they are found in almost all major supermarkets.	Documents state that there is an 'Abundance' of gluten free foods available, the language of abundance is not quite right.	Pg 3	Yes	A decision was taken over 30 years ago to include gluten-free foods on prescription, when there was limited availability of gluten-free foods to buy. Today the availability of gluten-free foods has significantly increased and they are found in almost all major supermarkets.		
06-Sep-21	Healthwatch Milton Keynes	Individual Funding Request (IFR) Process For all of the above proposals it should be noted that the Individual Funding Request (IFR) process is still available for patients who believe that they have exceptional circumstances. Any application needs to be made on behalf of the patient by a clinician, and the key point to remember is the need to demonstrate the exceptional nature of the case – i.e. why the patient should receive treatment which is outside BLMK CCG's current funding arrangements. Further information can be found on BLMK CCG's website: https://www.blmccg.nhs.uk/your-health/individual-funding/	IFR – Need to review the wording regarding IFR to make it clear that this is a challenging process and is only successful in specific circumstances	Pg 5	Yes	For all of the above proposals it should be noted that the Individual Funding Request (IFR) process is still available for patients. Funding requests are reviewed and decided upon by a panel but applications will only be taken forward if there are exceptional clinical circumstances. IFR applications need to be made on behalf of the patient by a clinician. Further information can be found on BLMK CCG's website: https://www.blmccg.nhs.uk/your-health/individual-funding/		
06-Sep-21	Healthwatch		Preferred options – Need more rationale to show why they are the preferred options		Yes	Have included a paragraph ahead of each preferred option with outline of rationale.		
06-Sep-21	Healthwatch Milton Keynes		MK Pharmacy First – What is the rationale for the preferred option, to remove the service. Did that service actually save money? Has it costs money? Has it actually met the aims and objectives?				The number of patients seen through this service in Milton Keynes over the last three years is as follows: YearPatients seen 2018/19 8986 2019/20 7373 2020/21 2838* 2021/22 572 (Q1) Modelled full year: 2288 *Big drop in use with the pandemic being the contributing factor and a slight increase in GP prescriptions for items such as paracetamol. These numbers show a year on year decline on the use of this service, even prior to the Covid emergency, but clearly Covid has had a significant impact. The reduction in the numbers of patients using the service suggests that patients have been able to make alternative arrangements to obtain advice and medication, or that time-limited self-care has been possible with alternatively sourced over the counter medicine or without medication. Whether this has had an impact on ongoing health is not known, though it is worth noting that, by definition, the service is for minor ailments which are likely to resolve over a short period.	
06-Sep-21	Healthwatch Central Bedfordshire		Add a paragraph to the case for change to explain the governance process, that the Gov Body will make the final decision taking into account the views of the public collected during the consultation	Pg 5	Yes	Pg 5 How will a decision be made? When the public consultation closes, a report will be written which brings together all of the feedback received during the consultation and the analysis of the public survey. This report will be shared with the BLMK CCG Governing Body who at the public meeting in February 2022 will take into account the views of the public when they make their decision on which options will be taken forward and become policy for BLMK CCG.		
06-Sep-21	Healthwatch Central Bedfordshire		Make clear in the document that the consultation is not as a result of the Covid pandemic	Pg 2	No		The introduction articulates that the reason for the consultation is a need to align policies across BLMK	
06-Sep-21	Healthwatch Bedford Borough	What happens to those currently receiving fertility treatment? All patients accessing fertility treatment, or those who start fertility treatment under the current three policies, will continue to be entitled to the eligibility criteria within each policy for the area in which they reside. Once this consultation is complete and the new policy is agreed; the new criteria would be applied to all new requests for treatment.	Need to make sure the document is clear for people who have already been referred for Fertility Services that they will receive treatment under the current policies	Pg3	No	What happens to those currently receiving fertility treatment? All patients accessing fertility treatment, or those who start fertility treatment under the current three policies, will continue to be entitled to the eligibility criteria within each policy for the area in which they reside. Once this consultation is complete and the new policy is agreed; the new criteria would be applied to all new referrals for treatment.	There is already a paragraph that explains that patients will continue to receive treatment under current policies if they are already under a referral.	
13-Sep-21	Bedford Borough OSC		When talking about Gluten Free foods, commitment was made to look at the wording around the clinical decision and prescriptions for vulnerable patients.	pg4	No		No change required as document includes the following explanation of how those at risk of dietary neglect are provided with access to gluten-free prescriptions. 'The former Bedfordshire and Luton CCG areas have a process for those on universal credit (i.e. those most at risk from the loss of gluten-free food prescribing) to enable them to continue to access gluten-free food via community pharmacists. Within MK, the former CCG had an exceptional cases appeals process for those at risk of dietary neglect, which also allows patients at risk to continue to access these foods. It is not envisaged that this clinical decision will change for any area. Through an alignment of these processes those patients could still access these foods.'	
20-Sep-21	Internal Review	Option 2: To provide gluten-free bread and flour on prescription in Bedfordshire, Luton and Milton Keynes, to the value of £174,303 and seek to recover these costs by identifying cost savings in other service areas.	This is the only one of the options that uses that cost within the option text and appears to try to sway the reader	Pg4	For discussion	Option 2: To retain gluten-free bread and flour on prescription in Luton and provide the same access to gluten-free bread and flour in Bedfordshire and Milton Keynes.		
29-Sep-21	BLMK CCG Governing Body		Governing Body suggested that we should be clear in our consultation plan about how we will ensure fairness and range of responses			Consultation plan has been reviewed to ensure we are using all available channels to ensure BLMK residents are aware of the consultation.		
02-Oct-21	BLMK CCG Governing Body	As an organisation committed to principles of equality, diversity and inclusion we want to ensure equity of access. Following review by the BLMK Equality Diversity and Inclusion Group it is recommended that the fertility services policy entry point should be broadened to fund artificial insemination for same sex females, single females and transmen with uterus to ensure equity of access.	I have no issue with the numbers around fertility - it's the language	Pg 3	Yes	Following review by the BLMK Equality Diversity and Inclusion Group it is recommended that the fertility services policy entry point be broadened to provide access to specialist fertility services for same sex female couples, single females and any person with a uterus (including trans men and non-binary people).	Changes made subsequent to the paper submission deadline for Governing Body.	
06-Oct-21	BLMK CCG Governing Body		Just to say that the national pharmacy contract has changed to incorporate the pharmacy first type schemes we perhaps should bring that out more	Pg 5	Yes	Content added on the National Pharmacy Scheme to the document		

General / all policies
 Gluten Free / Pharmacy
 Fertility

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17/08/2021	Quality & System Performance NHS South, Central and West	For specialist fertility the former MK and Bedfordshire areas offer one cycle,	We should be clear on what we mean with cycles, helpful approach could be perhaps to talk about fresh cycle and frozen cycle. It also looks better in the options if you offer just one fresh cycle that you can still have a frozen cycle i.e. two embryo transfers.		Yes	The definition of a full cycle has been added to the case for change appendix.		
		The access criteria have been reviewed by the BLMK Equality Diversity and Inclusion Group who have recommended that the IVF policy entry point should be amended to fund artificial insemination for same sex females, single females and transmen with uterus . This would see an increase in current spend (based on the current number of cycles per locality).	Perhaps we could avoid singling out any specific patient groups in here, as relationships may be complex. For example, trans female, in a gay relationship may have stored sperm and now they potentially have eggs and a womb just need to have AI and possibly need IVF. The paper uses the wording of 'trans or non-binary couples later on, maybe that would be broader approach. We could also be possibly looking to extend the access to people unable to have intercourse as per NICE CG suggestion: 'Consider unstimulated intrauterine insemination as a treatment option in the following groups as an alternative to vaginal sexual intercourse: •People who are unable to, or would find it very difficult to, have vaginal intercourse •Because of a clinically diagnosed physical disability or psychosexual problem who are •Being partner or donor sperm •People with conditions that require specific consideration in relation to methods of conception (for example, after sperm washing where the man is HIV positive) •People in same-sex relationships. [new 2013] For people in the above recommendation who have not conceived after 6 cycles of donor or partner insemination, despite evidence of normal ovulation, tubal patency and semenalysis, offer a further 6 cycles of unstimulated intrauterine insemination before IVF is considered. [new 2013]' Possible alternative wording for the groups covered in the policy (for improved access) same-sex couples, single women and trans or non-binary couples.		Yes	The appendix document has been updated to reflect these comments.		
		Equity of access will be increased, to reduce inequalities Number of cycles would be in line with geographical peers reducing "postcode lottery"	Unwarranted variation in access to care may be better term.		Yes	The appendix document has been updated to reflect these comments.		
		Equity of access will be increased, to reduce inequalities Number of cycles made available are in line with NICE Guidance	Just may need to add fresh cycles, otherwise this is not quite true for our options of one frozen transfer per fresh cycle. NICE definition of cycle is a fresh transfer and transfer of any resultant frozen embryos, so could be more than one frozen after the fresh cycle. NICE CG: What is a full cycle of IVF? A full cycle of IVF is one in which 1 or 2 embryos produced from eggs collected after ovarian stimulation are replaced into the womb as fresh embryos (where possible), with any remaining good quality embryos frozen for use later (see freezing embryos after IVF). When these frozen embryos are used later, this is still considered to be part of the same cycle.		Yes	The appendix document has been updated to reflect these comments.		
03-Sep-21	Operations Manager, Fertility Network UK	Known parental status	would a couple where one partner had an adult child living independently be seen in the same way as a couple with a young child living with them?		Yes	Couples are ineligible for treatment if there are any living children from the current or any previous relationships who they have contact with. This includes any adopted child within their current or previous relationships; this will apply to adoptions either in or out of the current or previous relationships.		
		Child Welfare	carrying out a welfare of the child assessment is mandatory under section 13(5) of the Human Fertilisation and Embryology Act so it seems odd to include it in the criteria you are proposing to keep.		Yes	This has been removed from the criteria in the appendix document		
		Medical Conditions	what are the type of medical conditions that would lead you to deny treatment? I haven't come across this before.		No		E.g. cancer	
		Ovarian Reserve Testing, use FSH	you say here you are going to align to NICE guidance. NICE has no guidance on using ovarian reserve testing to determine who should have access to treatment. The guidelines on ovarian reserve are about response to ovarian stimulation. If you want to set guidance, you should be clear about where this comes from. Also, it would be good to see the evidence-base for recommending FSH rather than AMH and AFC.		Yes	This has been removed from the criteria in the appendix document		
		Maternal age and number of cycles	NICE guidance is quite specific about which women aged 40-42 should be eligible and it isn't clear here whether you will apply the general criteria used for access to treatment or the specific criteria for women in this age group?		Yes	The appendix document has been updated to reflect these comments.		
		Donor Insemination	wasn't quite clear what you were proposing here when aligning to NICE?		Yes	The appendix document has been updated to reflect these comments.		
		Chronic Viral Infections	it is important to be clear that needing any intervention for HIV patients is unusual. The vast majority of HIV patients have an undetectable viral load.		Yes	The appendix document has been updated to reflect these comments.		
		Embryo transfers	One cycle should not be two embryo transfers, but one cycle and the transfer of all remaining embryos.		Yes	The definition of a full cycle has been added to the case for change appendix.		
		Minimum / Maximum BMI	would be useful to have the evidence base for this.		No		The evidence used for this is NICE guidance.	
		Duration of sub-fertility	evidence base for 3 years for unexplained infertility? Wasn't sure here whether you going to offer treatment to all same sex female couples and single females regardless of fertility status and whether these figures had been modelled?		Yes	The appendix document has been updated to reflect these comments.		
03-Sep-21	Fertility Network UK		We get a lot of feedback on the previous child criteria, as there is a big difference between having a young child living with you to having a 25 yr old estranged child that lives abroad, so it is worth putting more detail in this criteria to help clarity.		Yes	Couples are ineligible for treatment if there are any living children from the current or any previous relationships who they have contact with. This includes any adopted child within their current or previous relationships; this will apply to adoptions either in or out of the current or previous relationships.		

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03-Sep-21	Fertility Network UK		You say that human rights are not relevant in the impact assessment, however there is a 1969 UN declaration on social progress and development which says that you should aim at the elimination of involuntary sterility so that all couples may be able to reach their desired number of children, so there is a Human rights element to it. WHO defines infertility as a disease and as a national health service we have a duty of care for any illness.		Yes	The QIAEADPIA has been updated to include: "Consideration of: The 1969 United Nations declaration on social progress and development which states "Ensure that family planning, medical and related social services aim not only at the prevention of unwanted pregnancies but also at the elimination of involuntary sterility and subfecundity in order that all couples may be permitted to achieve their desired number of children, and that child adoption may be facilitated". https://www.un.org/en/development/desa/population/theme/rights/index.asp The World Health Organisation defines infertility as a disease and as a national health service there is a duty of care for any illness. "Infertility is a disease of the male or female reproductive system defined by the failure to achieve a pregnancy after 12 months or more of regular unprotected sexual intercourse." https://www.who.int/news-room/fact-sheets/detail/infertility#:~:text=Infertility%20is%20a%20disease%20of,on%20the%20of%20families%20and%20communities. "		
01-Oct-21	BLMK CCG Governing Body		I agree with the point re inequality of access for financially disadvantaged people and I think it could come out more strongly in section 2.11 of the equality analysis.			Pharmacy First QIAEADPIA to be reviewed to take comment into account		

General / all policies
 Gluten Free / Pharmacy
 Fertility