

Public Consultation

Aligning policies across Bedfordshire, Luton and Milton Keynes

Case for Change

Consultation runs from Tuesday 12 October to Tuesday 21 December 2021

1. Background - Who are we?

NHS Bedfordshire, Luton and Milton Keynes Clinical Commissioning Group (BLMK CCG) was formed on 1 April 2021 following the merger of Bedfordshire Clinical Commissioning Group (BCCG), Luton Clinical Commissioning Group (LCCG) and Milton Keynes Clinical Commissioning Group (MKCCG).

We are responsible for planning, organising and buying NHS-funded healthcare for the almost 1 million people living in BLMK. This includes hospital services, community health services, community pharmacies and mental health services.

BLMK CCG is run by GPs, nurses, hospital doctors and other clinicians - the people you see whenever you come into contact with the NHS. All 96 GP practices across Bedfordshire, Luton and Milton Keynes are members of the CCG.

We are committed to delivering local, high-quality healthcare services while making sure we achieve the best value for money and equity of access for our growing population.

2. What is this document about?

In 2021 the three former Clinical Commissioning Groups, Bedfordshire, Luton and Milton Keynes, merged to become BLMK CCG. As we came together, we reviewed the policies that each of the former CCG's held. For the most part there was considerable commonality across the policies, but three policies had marked differences. These policies relate to:

- Fertility Services
- Gluten-Free Food Prescribing
- Milton Keynes Pharmacy First Minor Ailment Scheme

In order to provide equal access to services across BLMK we need to move to a single policy for each service.

This document provides information so that you can understand and then respond to the following proposals:

Fertility Services - Make fertility services available to a broader group of residents (including those with specific protected characteristics to whom the service was not previously available) to ensure equal access to the service. This will include a review of the number of cycles of In-Vitro Fertilisation (IVF) available.

Bringing all the three former CCG areas in line regarding access to:

- **Pharmacy First Minor Ailment Scheme** (currently only available in Milton Keynes)
- **Gluten-Free Food Prescribing** (currently only access to bread and flour and only available in Luton)

On the next few pages you will find further detail on each of the service areas to help you help us make these important decisions.

3.Fertility Services

Fertility Services support people who have not been able to conceive naturally. These specialist fertility services are considered as level three services, or tertiary services and are accessible to people who have completed preliminary investigations and treatments in primary care and secondary care.

Treatments delivered by specialist fertility services include:

- In-vitro fertilisation (IVF) and Intra-cytoplasmic sperm injection (ICSI)
- Surgical sperm retrieval methods (SSR)
- Donor Insemination (DI)
- Intra Uterine Insemination (IUI) unstimulated
- Sperm, embryo and male gonadal tissue cryostorage and replacement techniques
- Egg donation where no other treatment is available
- Blood borne viruses (ICSI + sperm washing)

BLMK CCG currently has in place three policies covering specialist fertility services - one for each of the former CCG areas (Bedfordshire, Luton and Milton Keynes).

The eligibility criteria within the policies vary, some align through all three policies, some have small differences and some of them are vastly different. A detailed piece of work has been undertaken to map and understand the differences and work through how to bring the policies together as one. Clinical discussions have been held about what the criteria should look like moving forward.

A full list of the criteria, the differences and our proposals can be found at Appendix A. There is also variation between the number of IVF cycles that are currently available for patients; Bedfordshire and Milton Keynes offer one cycle of IVF treatment whilst Luton offers three.

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 - 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.

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.

The National Institute for Health and Care Excellence (NICE) develop guidelines for health and care services in England. Guidelines are provided for fertility services however these are recommendations only and need to be considered within a local context when commissioning services.

Access Criteria

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 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).

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 aligned to three 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. If the number of cycles were to be aligned to one across BLMK and the groups eligible to access services widened, we do not anticipate any significant change in current costs.

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 will be applied to all new referrals for treatment.

Options for Consultation (Fertility services)

As part of this consultation, we are seeking views on the following options for IVF Treatment:

Option 1:

To reduce the current offer of three cycles of IVF to residents in Luton to one cycle for all eligible patients, in line with the current offering in Bedfordshire and Milton Keynes and extend access to the service for same sex female couples, single females and any person with a uterus (including trans men and non-binary people), who are currently unable to access fertility services under existing policies.

Option 2:

To increase the number of cycles in Bedfordshire and Milton Keynes to three cycles for all patients aged 39 and under, and one cycle for all eligible patients aged 40-42, in line with the current Luton model and extend access to the service to same sex female couples, single females, and any person with a uterus (including trans men and non-binary people), who are currently unable to access fertility services under existing policies.

Our preferred option is Option 1:

To reduce the current offer of three cycles of IVF to residents in Luton to one cycle for all eligible patients, in line with the current offering in Bedfordshire and Milton Keynes and extend access to the service to same sex female couples, single females, and any person with a uterus (including trans men and non-binary people).

This takes into account our commitment to address unwarranted variation in access, both in BLMK and in the wider region, working within the constraints of the wider BLMK CCG health budget.

4. Gluten-free Foods

Gluten is a type of protein that is found in three types of cereal - wheat, barley and rye. A gluten-free diet is recommended for people who have been clinically diagnosed with coeliac disease. Gluten can cause symptoms that include bloating, diarrhoea, nausea, tiredness and headaches.

Certain foods are naturally gluten-free such as meat, vegetables, cheese, potatoes and rice. Gluten-free alternatives for those foods that do traditionally contain gluten, such as bread and pasta, are available to those who wish to continue to eat similar foods which contain the cereals described.

There is no cure for coeliac disease but switching to a gluten-free diet will help control symptoms.

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.

There is a lot of information available to patients via their GP, dietitian or available online about how to eat a healthy gluten-free diet.

When prescribing gluten-free foods the NHS pays both for the food plus the additional cost of processing the prescriptions. The cost of administering the service is estimated at £10 per patient, per month.

In 2018, a national consultation on gluten-free food prescribing was undertaken, the outcome of which was that the service would restrict gluten-free prescriptions to a staple list of gluten-free bread and mix products.

Under the new legislation, CCGs retained individual responsibility to be

able to restrict further by selecting bread only, mixes only or choose to end prescribing of all gluten-free foods if they feel this is appropriate for their population, whilst taking account of their legal duties to advance equality and have regard to reducing health inequalities.

Currently, Gluten-free food prescribing is only routinely available in the former Luton CCG area and only supplies bread and flour on prescription. Prescribing is available to any patient diagnosed with Coeliac disease or dermatitis herpetiformis and currently covers approximately 100 patients.

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 Milton Keynes, 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.

The following figures show a modelled full year impact, the total in the first column shows the current spend for gluten-free prescribing as \pounds 54,705. The total in the second column shows the predicted spend if gluten-free prescribing were to be extended to the Bedfordshire and Milton Keynes populations. This is an increase of \pounds 174,303 which would be an overall cost of \pounds 229,008.

Gluten-free prescribing modelling – roll out Luton approach		
	Current spend	Modelled at current population
MKCCG	£1,408	£66,622
LCCG	£52,899	£52,899
BCCG	£398	£109,487
Total	£54,705	£229,008
Increase from current spend		£174,303

Options for Consultation (Gluten-free foods prescribing)

As part of this consultation, we are seeking views on the following options for gluten-free food prescribing:

Option 1:

To withdraw the gluten-free bread and flour available on prescription in Luton whilst ensuring patients at risk of dietary neglect are still able to access when appropriate, in line with Bedfordshire and Milton Keynes.

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.

Our preferred option is Option 1:

To withdraw the gluten-free bread and flour available on prescription in Luton, whilst ensuring patients at risk of dietary neglect are still able to access when appropriate, in line with Bedfordshire and Milton Keynes. This takes into account our commitment to address inequality of access across BLMK whilst ensuring patients at risk of dietary neglect are still able to access gluten-free bread and flour on prescription if clinically appropriate. Option 1 would also create a small financial saving benefitting the wider BLMK CGG health budget.

5. Milton Keynes Pharmacy First Minor Ailment Scheme

Milton Keynes Pharmacy First Minor Ailment Scheme is a service provided in some pharmacies in Milton Keynes and only available to registered patients in the former Milton Keynes CCG area. It provides pharmacist advice on minor ailments and also supplies Over the Counter (OTC) medication free of charge to people who qualify for free prescriptions. The scheme was implemented to reduce demand for primary care and A&E. This scheme has never existed in Bedfordshire and Luton.

All other CCGs in the East of England follow the national position of encouraging self-care advice and guidance and do not provide this service. The Minor Ailment Service was implemented following a pilot in 2006, this was followed by the Pharmacy First Scheme in April 2018, recent guidance from NHS England together with the National Community Pharmacy Consultation Scheme now places greater emphasis on the importance of self-care. Recently some Pharmacies in Milton Keynes have opted out of the Pharmacy First Scheme, in favour of the national scheme.

It should be emphasised that all patients of BLMK CCG have access to the nationally commissioned "Community Pharmacy Consultation Scheme" (CPCS), which allows referral direct from practice (typically the prescription clerk) for patients who require a consultation for minor illness, without having to go through the GP first. Through this scheme, community pharmacists provide advice and guidance to enable the patient to self-care and/or purchase OTC medication. Likewise, patients can attend community pharmacy for advice without an appointment and purchase OTC medication in line with NHS guidance.

The number of patients seen through the Pharmacy First Scheme in Milton Keynes over the last three years is as follows:

Year	Patients seen
2018/19	8986
2019/20	7373
2020/21	2838*
2021/22	572 (Q1) Modelled full year: 2288

*We saw a considerable drop in use with the pandemic being the contributing factor and only 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.

A full list of which self-care items are available through the Pharmacy First Minor Ailment Scheme can be seen on the consultation web page at www.blmkccg.nhs.uk/PolicyConsultation

The following figures show a modelled full year impact, the total in the first column shows the current spend for the Pharmacy First Minor Ailment scheme in Milton Keynes as £25,011. The total in the second column shows the predicted spend if the scheme were to be extended to the Bedfordshire and Luton populations. This would be an increase of $\pounds 60,962$ with a total cost of £85,973.

Roll out Pharmacy First - modelling		
	Current spend	Modelled at current population
MKCCG	£25,011	£25,011
LCCG	0	£19,859
BCCG	0	£41,103
Total	£25,011	£85,973
Increase from current spend		£60, 962

Options for Consultation (Pharmacy First Minor Ailment Scheme)

As part of this consultation, we are seeking views on the following options for the Pharmacy First Minor Ailment Scheme:

Option 1:

To withdraw the Pharmacy First Minor Ailment Scheme in Milton Keynes to align this service with the current offering in Bedfordshire and Luton.

Option 2:

To retain the Pharmacy First Minor Ailment Scheme in Milton Keynes and expand to include Bedfordshire and Luton.

Our preferred option is Option 1:

To withdraw the Pharmacy First Minor Ailment Scheme in Milton Keynes to align this service with the current offering in Bedfordshire and Luton.

This takes into account our commitment to address inequality of access across BLMK and encourages all residents to access the nationally commissioned "Community Pharmacy Consultation Scheme" (CPCS).

6.Policies

Full policy documents for each of the former CCG areas can be viewed on our website at:

www.blmkccg.nhs.uk/PolicyConsultation

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. 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.blmkccg.nhs.uk/your-health/individual-funding/

7. 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 Bedfordshire, Luton and Milton Keynes.

8. How can I give my views?

We would like to hear your views on the proposed options for the three policies.

Please complete the online questionnaire at: www.blmkccg.nhs.uk/PolicyConsultation This QR code takes you to our website



Further information about how you can share your views can be found online at: www.blmkccg.nhs.uk/PolicyConsultation

The formal consultation commences on Tuesday 12 October 2021 and ends on Tuesday 21 December 2021.

If you would like any of the supporting documents for the consultation in paper copy please call 01525 624264 or email blmkccg.communications@nhs.net.

The consultation feedback will be evaluated with a recommendation to Bedfordshire, Luton and Milton Keynes CCG Governing Body in February 2022.

Once complete, the results will be available on the BLMK CCG website.

Do you need this document in a different format?

For alternative formats please call **01525 624264** or email **blmkccg.communications@nhs.net**

Bedfordshire, Luton and Milton Keynes Clinical Commissioning Group (BLMK CCG) Email: blmkccg.communications@nhs.net Website: www.blmkccg.nhs.uk

Reference: 327/BLMK/POLICY/Oct2021 Large print

Appendix A – List of Criteria for Fertility Services Policy:

No change to criteria in the existing 3 policies:

Criteria	Explanation of existing policies	BLMK proposed alignment
Previous sterilisation	Current policies align on previous sterilisation and include criteria that treatment is not offered to couples if previous sterilisation has taken place, even if reversed.	BLMK CCG is proposing to keep the current criteria around previous sterilisation.
Medical Conditions	Current policies align on the medical conditions criteria which stipulates that "Treatment may be denied on other medical grounds not explicitly covered in this document."	BLMK CCG is proposing to keep the current criteria around medical conditions.
Donor eggs and donor sperm	Current policies cover use of donors eggs and donor sperm under specific criteria.	BLMK CCG is not proposing to change this element of the policies.
Surrogacy	The 3 policies are similar and state that surrogacy is not covered under the policy.	For the purposes of this policy, surrogacy is a female external to the couple being used to carry a pregnancy on behalf of the couple where there are medical reasons where the female is unable to carry.
		The CCG does not fund surrogacy; this includes part funding during a surrogacy cycle. Individuals may be eligible for appropriate investigation where there is evidence of subfertility.

Where BLMK propose to align to NICE guidelines:

Criteria	Explanation of existing policies	BLMK proposed alignment
Ovarian Reserve Testing, use FSH		BLMK CCG is proposing to align to NICE guidelines for this criteria i.e. the patient should have a follicle- stimulating hormone (FSH) of less than 8.9.
	Current policies vary on the number of cycles offered. BCCG and MKCCG offer 1 full cycle but LCCG offer 3 cycles for women under the age of 40. BCCG do not offer any cycles to women aged 40-42 whereas LCCG and MKCCG offer 1 cycle to women aged 40-42.	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).

Criteria	Explanation of existing policies	BLMK proposed alignment
Chronic Viral Infections	Managing the risk of transmission of chronic viral infections is described in the LCCG and BCCG policies, but not in the MKCCG policy.	BLMK CCG is proposing to provide the following clarification: This may not be a fertility treatment, but should be considered as a risk reduction measure for a couple or individual who wish to have a child, but do not want to risk the transmission of a serious pre-existing viral condition to their partner and therefore potentially the unborn baby. As there is a need to prevent the transmission from partner to partner of chronic viral infections, during conception, such as HIV, Hep C etc. any decision about fertility
	management should be the result of discussions between the couple, a fertility specialist and an HIV specialist where appropriate. (Ref: NICE Guideline cg156 (2013) 1.3.9 and 1.3.10.)	

BLMK proposed alignment of remaining criteria:

Criteria	Explanation of existing policies	BLMK proposed alignment
Known Parental Status	Current policies align on known parental status and include the criteria that treatment is not offered to couples if there are any living children from the current or any previous relationships, regardless of whether the child resides with them. This includes any adopted child within their current or previous relationships.	BLMK CCG is proposing to alter the criteria to: 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.

Criteria	Explanation of existing policies	BLMK proposed alignment
Embryo transfers	Current policies vary on the number of embryo transfers between maximum of 2 in MKCCG and BCCG, up to 6 in LCCG.	Beint 000 is proposing to implement the
Paternal Age	The only existing policy to include a paternal age limit is BCCG which stipulates that "treatment must be commenced before the male is 55 years of age".	BLMK CCG is proposing that no paternal age limit would be included in the future policy.
Minimum / Maximum BMI	Current policies vary slightly on the minimum Body Mass Index (BMI) for females. In LCCG and BCCG the minimum requirement is 19 for females, however in MKCCG there is no minimum. All three policies are aligned on the maximum BMI (30) for females. In LCCG and BCCG male BMI is required to be less than 35. No maximum is stated for males in the MKCCG policy.	BLMK CCG are proposing that BMI should be between at least 19 and up to 30 for female and less than 35 for males.

Criteria	Explanation of existing policies
	Duration of sub-fertility varies between the three existing policies and between age groups. LCCG and BCCG stipulate 3 years or more of regular intercourse or an equivalent 12 self- funded cycles of Intra-Uterine Insemination (IUI) over a period of 3 years for unexplained infertility, and 2 years for MKCCG.

BLMK proposed alignment

BLMK CCG are proposing the following:

Where a female or any person with a uterus is of reproductive age and having regular unprotected vaginal intercourse two to three times per week, failure to conceive within 12 months should be taken as an indication for further investigation.

If the female or any person with a uterus is aged 36 or over then such investigation should be considered after 6 months of unprotected regular vaginal intercourse since their chances of successful conception are lower and the window of opportunity for intervention is less.

Couples with unexplained infertility or mild male factor infertility/subfertility must have infertility of at least 2 years of ovulatory cycles, despite regular unprotected vaginal sexual intercourse.

Females aged 40 to 42 years, who have not conceived after 2 years of regular unprotected vaginal intercourse, will be eligible for treatment as long as other criteria in this policy are met.

Couples with a diagnosed cause of absolute infertility which precludes any possibility of natural conception, including same sex female couples and single females, or any person with a uterus (including trans men and non-binary people) and who meet other eligibility criteria will have immediate access to NHS funded assisted reproduction services.

Where mild male factor infertility has been diagnosed evidence should be provided to demonstrate that any underlying treatable cause has been investigated and ruled out.

Criteria	Explanation of existing policies	BLMK proposed alignment
Smoking Status	Current policies vary on the length of time which constitutes non-smoking status, however all apply non-smoking as a criteria for treatment.	BLMK CCG are proposing to keep non-smoking status as a criteria for treatment and align the measure of non-smoking.
Residential Status	Current policies vary on residential status. Under LCCG policy couples should be registered with a LCCG GP for 12+ months. Under BCCG policy couples should be either registered with BCCG GP for 12+ months or registered with a GP within the East of England Consortium Fertility Service Clinical Group for 12+ months. MKCCG does not state any residential status.	BLMK CCG is proposing to stipulate that those accessing the service should be registered with a GP in BLMK CCG for 12+ months and currently reside within the BLMK area.
Rubella Status	Current policies vary on the requirement for service users to be rubella immune. BCCG and LCCG require woman to be rubella immune however MKCCG does not state.	Rubella is very serious if a pregnant person catches it in the early stages of pregnancy, because it can profoundly damage the unborn child.
		BLMK CCG are proposing that rubella immunity testing will be carried out at primary care investigation stage.

Criteria	Explanation of existing policies	BLMK proposed alignment
Patients who have social, cultural or religious objections to IVF	Intra-Uterine Insemination (IUI) is stated in the current policies as a replacement for IVF/ICSI and without donor sperm under exceptional circumstances and an IFR/ITP application for funding has been made. As with IVF cycles this varies across the three policies with BCCG and MKCCG offering 1 cycle but LCCG offering 3 cycles for women under the age of 40. BCCG do not offer any cycles to women aged >40, whereas LCCG and MKCCG offer 1 cycle to women aged >40.	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 = 3 cycles of IUI offered. 3 cycles of IVF offered = 9 cycles of IUI offered. This would still be applicable under exceptional circumstances and an IFR application for funding has been made.
Women in same- sex couples, single women and couples not able to have vaginal intercourse	Current policies vary for same sex couples. LCCG offer IVF treatment following 6 cycles of self-funded IUI. MKCCG offer IVF treatment to same sex couples who meet other eligibility criteria. BCCG does not mention same sex couples.	Women in same-sex couples (where one of the couple has a uterus), single women and couples not able to have vaginal intercourse are entitled to NHS funded IVF treatment following 6 cycles of NHS funded donor IUI. BMI eligibility criteria above apply only to the female partner or person with a uterus undergoing the fertility treatment.

Criteria	Explanation of existing policies	BLMK proposed alignment
Women in same- sex couples, single women and couples not able to have vaginal intercourse		The partner of a 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 of 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.

Glossary:

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."

Abandoned / cancelled cycle of IVF - "An abandoned fresh cycle is one where ovarian stimulation begins but does not culminate in an embryo transfer. An abandoned frozen cycle is one where hormone treatment is started but does not culminate in an embryo transfer."