NHS
Cheshire and Merseyside

Clinical Commissioning Policy

CMICB_Clin078
Intrauterine devices: secondary care checking following insertion

Category 2 Intervention - Only routinely commissioned when specific criteria are met

Contents

Last Reviewed: March 2024

This policy statement will be reviewed 5 years from the date of the last review unless new evidence or technology is available sooner.

1. Policy statement

1.1 ***Note on terminology:*** *Intrauterine devices (IUDs) are effective methods of long-acting reversible contraception (LARC). Two types of IUD are available in the UK: copper IUDs and levonorgestrel-releasing IUDs (including the Mirena™ coil). Levonorgestrel-releasing IUDs are sometimes referred to as intrauterine systems (IUSs). This policy follows the Faculty of Sexual and Reproductive Healthcare (FSRH) in aligning terminology with international organisations and refers to levonorgestrel-releasing IUDs as IUDs.[1] Where the types of IUD need to be differentiated, the terms Cu-IUD (copper IDU) and LNG-IUD (levonorgestrel-releasing IUD) may be used.*

1.2 Secondary care checking of position following insertion of intrauterine devices (IUDs) is not routinely commissioned unless uterine perforation is suspected. Routine checks of position following IUD insertion are not recommended in primary or secondary care.

2. Exclusions

2.1 This policy relates to routine checking of position following insertion of an IUD. Subsequent management of non-visible threads and complications associated with an IUD are excluded from this policy.

2.2 Post-partum IUD insertion.

3. Core Eligibility Criteria

3.1 There are several circumstances where a patient may meet a 'core eligibility criterion' which means they are eligible to be referred for this procedure or treatment, regardless of whether they meet the policy statement criteria, or the procedure or treatment is not routinely commissioned.

3.2 These core clinical eligibility criteria are as follows:

- Any patient who needs 'urgent' treatment will always be treated.
- All NICE Technology Appraisals Guidance (TAG), for patients that meet all the eligible criteria listed in a NICE TAG will receive treatment.
- In cancer care (including but not limited to skin, head and neck, breast and sarcoma) any lesion that has features suspicious of malignancy, must be referred to an appropriate specialist for urgent assessment under the 2-week rule.
  NOTE: Funding for all solid and haematological cancers are now the responsibility of NHS England.
- Reconstructive surgery post cancer or trauma including burns.
- Congenital deformities: Operations on congenital anomalies of the face and skull are usually routinely commissioned by the NHS. Some conditions are considered highly specialised and are commissioned in the UK through the National Specialised Commissioning Advisory Group (NSCAG). As the incidence of some cranio-facial congenital anomalies is small and the treatment complex, specialised teams, working in designated centres and subject to national audit, should carry out such procedures.
- Tissue degenerative conditions requiring reconstruction and/or restoring function e.g. leg ulcers, dehisced surgical wounds, necrotising fasciitis.
- For patients expressing gender incongruence, further information can be also be found in the current ICB gender incongruence policy and within the NHS England gender services programme - https://www.england.nhs.uk/commissioning/spec-services/npc-crg/gender-dysphoria-clinical-programme/

4. Rationale behind the policy statement

4.1 The policy is consistent with previous Cheshire/Wirral policy, as well as with 2023 commissioning guidance from the Faculty of Sexual and Reproduction Healthcare[1].

5. Summary of evidence review and references

5.1 **Introduction**

LARC, which includes IUDs and subdermal implants, has a generally accepted role in reducing rates of abortion and unintended pregnancies.[2] One of the main advantages of LARC is that it doesn't depend on daily patient concordance in comparison to more traditional methods such as the oral contraceptive.[3] However, LNG-IUDs have a role in many other indications such as provision of endometrial protection in conjunction with oestrogen therapy (for up to 5 years), reduction in pain associated with primary dysmenorrhoea, endometriosis or adenomyosis and reducing menstrual blood loss.[1] Typically, many women report satisfaction with their decision to have an intrauterine device.[4]

5.2 **Effectiveness of IUS**

For the 52 mg LNG-IUD i.e. Mirena™, the reported failure rate during the first year of use is as low as 0.2%.[1] In addition, women using LNG-IUD for menstrual disorders reported decreased frequency and pain associated with their period and 73% of them would continue to use this method.[5] One study concluded that the cost of providing an LNG-IUD service in the community was 23% cheaper than providing combined oral contraception and that restriction of access because of the initial cost was a false economy.[6]

5.3 **Adverse effects**

Adverse effects include acne, breast tenderness/pain with the risk of expulsion of around 1 in 20 which is most common in the 1st year of use, particularly within the first 3 months of insertion. Although ovarian cysts may occur, these are mostly asymptomatic and resolve spontaneously. Return of fertility following discontinuation is similar to other methods. Perhaps the greatest concern is the rate of uterine perforation during insertion and this has been reported to occur between 1 to 2 in 1,000 insertions.[1] Guidance from the medicines and healthcare products regulatory agency (MHRA) suggest that women should be warned of the likely symptoms including severe pelvic pain after insertion, pain or heavy bleeding which continues for more than a few weeks, pain during sex, or not being able to feel the threads. The practitioner should also explain how to check the threads and for the woman to return for a check-up if these cannot be felt. Overall, the MHRA still recommend that the benefits of intrauterine contraception outweigh the risks for most women.[7]

5.4 **Access to services and commissioning arrangements**

A study, published in 2011, of GPs' views on the use of LNG–IUDs in nulligravid women aged under 25 years discovered that uptake was low and there were misconceptions related to pelvic inflammatory disease (PID), and perceived difficulty of insertion. The authors concluded that the LNG – IUD is an excellent method of contraception and should be offered more widely to this age group.[8] Further, a qualitative survey of 35 women with experience of hospital/community maternity services in Lothian concluded that women should be able to access intrauterine contraception treatment immediately after delivery and there should be robust clinical pathways in place to provide support post insertion.[4]

From the early 2000s, GPs have been commissioned to provide LARC which includes IUDs. In 2015, a survey was conducted to evaluate the consistency, quality and efficiency of commissioning of intrauterine contraception in London. The results showed variation in clinical governance of these services and the authors therefore recommended that

commissioners should make explicit references to quality and safety criteria as poor-quality specifications could give rise to serious untoward incidents and/or litigation.[2]

This 2015 survey has to be taken into context of NICE guidance (2005) on LARC, published 10 years previously, which specified that intrauterine devices should be inserted/removed only by trained professionals who can demonstrate their continuing experience of inserting at least one intrauterine device per month.[3] Further, the Faculty of sexual and reproductive healthcare (FSRH) in their 2023 guideline on intrauterine contraception, specify that health professionals should hold the appropriate "FSRH Letter of Competence in Uterine Techniques" and can evidence their recertification/reaccreditation. More specifically, professionals must be able to show evidence of at least 2 continuing professional development (CPD) credits, completion of designated distance learning courses, basic life support and anaphylaxis update, and a minimum of 12 insertions with at least 2 different types of intrauterine method in conscious women undertaken during a 12 month period within 24 months of recertification.[1,9]

5.5 **Need for secondary care provision**

The 2023 FSRH guidance states that "with the exception of PPIUC, routine post-insertion check-ups are not required"[1]. This recommendation is in keeping with current clinical practice.

5.6 **Conclusions**

Intrauterine devices are one of the most effective contraceptive methods available and are useful in a number of other situations. For most women, there are few adverse effects and the main concerns, which occur in a minority of women, are around the initial insertion, uterine perforation and unintended expulsion.

In the main, routine management of IUDs can be performed in primary care. This assumes that the attending clinicians have been adequately trained, hold the appropriate certification, perform the minimum number of procedures per annum and comply with continuing professional development requirements.

Secondary care checking following insertion of an IUD is not routinely required, but may be necessary if:

- Uterine perforation is suspected.
- Following post-partum insertion.

REFERENCES

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6. Advice and Guidance

6.1 Aim and Objectives

- This policy aims to ensure a common set of criteria for treatments and procedures across the region. This is intended to reduce variation of access to NHS services in different areas and allow fair and equitable treatment for all patients.

- This policy relates to the commissioning of interventions which optimise clinical effectiveness and represent value for money.

- This document is part of a suite of policies which the Integrated Care Board (ICB) uses to drive its commissioning of healthcare. Each policy is a separate public document in its own right but should be considered alongside all the other policies in the suite as well as the core principles outlined.

- At the time of publication, the evidence presented per procedure/treatment was the most current available.

- The main objective for having healthcare commissioning policies is to ensure that:
  - Patients receive appropriate health treatments
  - Treatments with no or a very limited evidence base are not used; and
  - Treatments with minimal health gain are restricted.

- Owing to the nature of clinical commissioning policies, it is necessary to refer to the biological sex of patients on occasion. When the terms ‘men’ and ‘women’ are used in this document (unless otherwise specified), this refers to biological sex. It is acknowledged that this may not necessarily be the gender to which individual patients identify.

6.2 Core Principles

- Commissioning decisions by ICB Commissioners are made in accordance with the commissioning principles set out as follows:

  - Commissioners require clear evidence of clinical effectiveness before NHS resources are invested in the treatment.
  - Commissioners require clear evidence of cost effectiveness before NHS resources are invested in the treatment.
  - Commissioners will consider the extent to which the individual or patient group will gain a benefit from the treatment.

- Commissioners will balance the needs of an individual patient against the benefit which could be gained by alternative investment possibilities to meet the needs of the community.
- Commissioners will consider all relevant national standards and consider all proper and authoritative guidance.
- Where a treatment is approved Commissioners will respect patient choice as to where a treatment is delivered, in accordance with the 'NHS Choice' framework.
- Commissioning decisions will give 'due regard' to promote equality and uphold human rights. Decision making will follow robust procedures to ensure that decisions are fair and are made within legislative frameworks.

6.3 Individual Funding Requests (Clinical Exceptionality Funding)

- If any patients are excluded from this policy, for whatever reason, the clinician has the option to make an application for clinical exceptionality. However, the clinician must make a robust case to the Panel to confirm their patient is distinct from all the other patients who might be excluded from the designated policy.

- The ICB will consider clinical exceptions to this policy in accordance with the Individual Funding Request (IFR) Governance Framework consisting of: IFR Decision Making Policy; and IFR Management Policy available on the C&M ICB website: https://www.cheshireandmerseyside.nhs.uk/your-health/individual-funding-requests-ifr/

6.4 Cosmetic Surgery

- Cosmetic surgery is often carried out to change a person's appearance to achieve what a person perceives to be a more desirable look.

- Cosmetic surgery/treatments are regarded as procedures of low clinical priority and therefore not routinely commissioned by the ICB Commissioner.

- A summary of Cosmetic Surgery is provided by NHS Choices. Weblink: http://www.nhs.uk/conditions/Cosmetic-surgery/Pages/Introduction.aspx and http://www.nhs.uk/Conditions/Cosmetic-surgery/Pages/Procedures.aspx

6.5 Diagnostic Procedures

- Diagnostic procedures to be performed with the sole purpose of determining whether or not a restricted procedure is feasible should not be carried out unless the eligibility criteria are met, or approval has been given by the ICB or GP (as set out in the approval process of the patients responsible ICB) or as agreed by the IFR Panel as a clinically exceptional case.

- Where a General Practitioner/Optometrist/Dentist requests only an opinion the patient should not be placed on a waiting list or treated, but the opinion given and the patient returned to the care of the General Practitioner/Optometrist/Dentist, in order for them to make a decision on future treatment.

6.6 Clinical Trials

- The ICB will not fund continuation of treatment commenced as part of a clinical trial. This is in line with the Medicines for Human Use (Clinical Trials) Regulations 2004 and the Declaration of Helsinki which stipulates that the responsibility for ensuring a clear exit strategy from a trial, and that those benefiting from treatment will have ongoing access to it, lies with those conducting the trial. This responsibility lies with the trial initiators indefinitely.

7. Monitoring and Review

7.1 This policy remains in force until it is superseded by a revised policy or by mandatory NICE guidance or other national directive relating to this intervention, or to alternative treatments for the same condition.

7.2 This policy can only be considered valid when viewed via the ICB website or ICB staff intranet. If this document is printed into hard copy or saved to another location, you must check that the version number on your copy matches that of the one published.

7.3 This policy may be subject to continued monitoring using a mix of the following approaches:
- Prior approval process
- Post activity monitoring through routine data
- Post activity monitoring through case note audits

7.4 This policy will be kept under regular review, to ensure that it reflects developments in the evidence base regarding effectiveness and value.

8. Quality and Equality Analysis

8.1 Quality and Equality Impact Analyses have been undertaken for this policy at the time of its review.

9. Clinical Coding

9.1 **Office of Population Censuses and Surveys (OPCS)**

Q12.1 Introduction of intrauterine contraceptive device
Q12.2 Replacement of intrauterine contraceptive device
Q12.3 Removal of displaced intrauterine contraceptive device NEC
Q12.4 Removal of intrauterine contraceptive device NEC
Q12.8 Other specified
Q12.9 Unspecified

9.2 **International classification of diseases (ICD-10)**

Document Control

Ref:	CMICB_Clin078 – Intrauterine devices: secondary care checking following insertion
Version:	2
Supersedes:	Previous Clinical Commissioning Group (CCG) Policies
Author (inc Job Title):	Consultant in Public Health, NHS Midlands and Lancashire
Ratified by: **(Name of responsible Committee)**	ICB Board
Cross reference to other Policies/Guidance	N/A
Date Ratified:	March 2024
Date Published and where (Intranet or Website):	March 2024 - (Website)
Review date:	March 2029
Target audience:	All Cheshire & Merseyside ICB staff and provider organisations

Version History
Version 1 – March 2024 – Policy ratified by NHS Cheshire & Merseyside ICB
Version 2 – March 2024 – Policy wording clarified to emphasize that the policy relates to routine checks following insertion – Paragraphs 1.2 and 2.1.