

**Evidence Sources:  
Heavy Menstrual Bleeding  
Clinical Care Standard  
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The Australian Commission on Safety and Quality in Health Care has produced this Evidence Sources document to support the Heavy Menstrual Bleeding Clinical Care Standard. The clinical care standard supports the delivery of appropriate care for a defined condition and is based on the best evidence available at the time of development. Healthcare professionals are advised to use clinical discretion and consideration of the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian when applying information contained within the clinical care standard. Consumers should use the information in the clinical care standard as a guide to inform discussions with their healthcare professional about the applicability of the clinical care standard to their individual condition.

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# Evidence Sources: Heavy Menstrual Bleeding Clinical Care Standard

The quality statements for the Heavy Menstrual Bleeding Clinical Care Standard were developed in collaboration with the Heavy Menstrual Bleeding Clinical Care Standard Topic Working Group and are based on best available evidence.

Literature searches were conducted by Commission staff at different stages in the development of the clinical care standard. The initial search took place between May and November 2015. A draft evidence summary was prepared which was reviewed for completeness by the Heavy Menstrual Bleeding Clinical Care Standard Topic Working Group. A further search took place between November 2016 and February 2017 to identify any new evidence that might affect the relevance or validity of the final quality statements.

The initial search was aimed at reviewing the evidence-base for each potential quality statement. As set out below, several steps were involved. The first step was to identify national clinical practice guidelines; these would be the key sources of evidence if they were current, based on available evidence, developed using systematic methods and endorsed by key clinical organisations. The second step was to locate other Australian guidelines, standards, policies, protocols, and international guidelines and standards. The third step was to identify high-level evidence published after the release of clinical practice guidelines.

Australian clinical practice guidelines, standards and policies were identified by searching:

- The clinical practice guideline portal of the National Health and Medical Research Council
- Websites of professional colleges and organisations
- Websites of state and territory health departments and agencies
- The internet.

International clinical practice guidelines were identified by searching:

- Guideline clearing houses such as the Agency for Healthcare Research and Quality, and Guidelines International Network
- Websites of guideline developers, such as the UK's National Institute for Health and Care Excellence (NICE) and the Scottish Intercollegiate Guideline Network (SIGN).

Other high-level evidence was identified by searching:

- The Cochrane Collaboration for systematic reviews
- Medical literature databases (PubMed) for systematic reviews and meta-analyses.

A summary of evidence sources for each quality statement is provided in this document.

# Guidelines and evidence supporting the Heavy Menstrual Bleeding Clinical Care Standard

## Australian guidelines

Endocrinology Expert Group. Therapeutic Guidelines: Endocrinology Version 5, Revised February 2014, Therapeutic Guidelines Limited, Melbourne 2014

Note: No Australian clinical practice guideline was identified.

## International guidelines

National Institute for Health and Care Excellence. NICE guideline CG44: Heavy menstrual bleeding. London: Royal College of Obstetricians and Gynaecologists, 2007.

Full guideline (2007):

<https://www.nice.org.uk/guidance/cg44/evidence/full-guideline-195071293>

Partial update (2016):

<https://www.nice.org.uk/guidance/CG44/chapter/recommendations>

The Society of Obstetricians and Gynaecologists of Canada. Abnormal uterine bleeding in pre-menopausal women. Journal of Obstetrics and Gynaecology Canada 2013;35 (5 eSuppl):S1-S28.

The Society of Obstetricians and Gynaecologists of Canada. Endometrial ablation in the management of abnormal uterine bleeding. Journal of Obstetrics and Gynaecology Canada 2015; No. 322

## Quality standards: international

National Institute for Health and Clinical Excellence. Heavy menstrual bleeding Quality Standard 47. United Kingdom: NICE; 2013. Available from: [www.nice.org.uk/guidance/qs47](http://www.nice.org.uk/guidance/qs47)

Royal College of Obstetricians and Gynaecologists (Great Britain). Chapter 11: Heavy Menstrual Bleeding in: Standards for gynaecology: report of a working party: June 2008. London: RCOG Press; 2008. Available from: <https://www.rcog.org.uk/en/guidelines-research-services/guidelines/standards-for-gynaecology/>

## Position statements

Royal Australian and New Zealand College of Obstetricians and Gynaecologists. Uterine artery embolisation for the treatment of uterine fibroids. Melbourne: RANZCOG; 2014. Available from: <https://www.ranzcog.edu.au/college-statements-guidelines.html>.

Royal Australian and New Zealand College of Obstetricians and Gynaecologists, Australasian CREI Consensus Expert Panel on Trial evidence (ACCEPT) group. Fibroids in infertility. Melbourne: RANZCOG; 2014. Available from: <https://www.ranzcog.edu.au/college-statements-guidelines.html>.

Cancer Australia. Abnormal vaginal bleeding in pre-and peri-menopausal women. A diagnostic guide for General Practitioners and Gynaecologists. Cancer Australia; 2011. Available from: <https://canceraustralia.gov.au/publications-and-resources/cancer-australia-publications/abnormal-vaginal-bleeding-pre-peri-and-post-menopausal-women-diagnostic-guide-general-practitioners>.

## Systematic reviews

Cooke I, Lethaby A, Farquhar C. Antifibrinolytics for heavy menstrual bleeding. Cochrane Database Syst Rev 2000:CD000249.

Fergusson RJ, Lethaby A, Shepperd S, Farquhar C. Endometrial resection and ablation versus hysterectomy for heavy menstrual bleeding. Cochrane Database Syst Rev 2013:CD000329.

Lethaby A, Duckitt K, Farquhar C. Non-steroidal anti-inflammatory drugs for heavy menstrual bleeding. Cochrane Database Syst Rev 2013:CD000400.

Lethaby A, Hickey M, Garry R, Penninx J. Endometrial resection / ablation techniques for heavy menstrual bleeding. Cochrane Database Syst Rev 2009:CD001501.

Lethaby A, Hussain M, Rishworth JR, Rees MC. Progesterone or progestogen-releasing intrauterine systems for heavy menstrual bleeding. Cochrane Database Syst Rev 2015;CD002126.

Lethaby A, Mukhopadhyay A, Naik R. Total versus subtotal hysterectomy for benign gynaecological conditions. Cochrane Database Syst Rev 2012:CD004993.

Marjoribanks J, Lethaby A, Farquhar C. Surgery versus medical therapy for heavy menstrual bleeding. Cochrane Database Syst Rev 2016:CD003855.

# Quality statement 1

## Assessment and diagnosis

The initial assessment of a woman presenting with heavy menstrual bleeding includes a detailed medical history, assessment of impact on quality of life, a physical examination, and exclusion of pregnancy, iron deficiency and anaemia. Further investigations are based on the initial assessment.

## Evidence sources

### Australian guidelines

Endocrinology Expert Group. Therapeutic Guidelines: Endocrinology Version 5, Revised February 2014, Therapeutic Guidelines Limited, Melbourne 2014

### International guidelines

National Institute for Health and Care Excellence. NICE guideline CG44: Heavy menstrual bleeding. London: Royal College of Obstetricians and Gynaecologists, 2007.

Full guideline (2007):

<https://www.nice.org.uk/guidance/cg44/evidence/full-guideline-195071293>

Partial update (2016):

<https://www.nice.org.uk/guidance/CG44/chapter/recommendations>

The Society of Obstetricians and Gynaecologists of Canada. Abnormal uterine bleeding in pre-menopausal women. Journal of Obstetrics and Gynaecology Canada 2013;35 (5 eSuppl):S1-S28.

### Additional sources

National Institute for Health and Clinical Excellence. Heavy menstrual bleeding Quality Standard 47. United Kingdom: NICE; 2013. Available from: [www.nice.org.uk/guidance/qs47](http://www.nice.org.uk/guidance/qs47)

## Quality statement 2

### Informed choice and shared decision making

A woman with heavy menstrual bleeding is provided with consumer-focused information about her treatment options and their potential benefits and risks. She is asked about her preferences in order to support shared decision making for her clinical situation.

#### Evidence sources

##### International guidelines

National Institute for Health and Care Excellence. NICE guideline CG44: Heavy menstrual bleeding. London: Royal College of Obstetricians and Gynaecologists, 2007.

Full guideline (2007):

<https://www.nice.org.uk/guidance/cg44/evidence/full-guideline-195071293>

Partial update (2016):

<https://www.nice.org.uk/guidance/CG44/chapter/recommendations>

##### Additional sources

Kennedy AD, Sculpher MJ, Coulter A, Dwyer N, Rees M, Abrams KR, et al. Effects of decision aids for menorrhagia on treatment choices, health outcomes, and costs: a randomized controlled trial. *JAMA* 2002;288:2701-8.

National Institute for Health and Clinical Excellence. Heavy menstrual bleeding Quality Standard 47. United Kingdom: NICE; 2013. Available from: [www.nice.org.uk/guidance/gs47](http://www.nice.org.uk/guidance/gs47)

Royal College of Obstetricians and Gynaecologists (Great Britain). Chapter 11: Heavy Menstrual Bleeding in: Standards for gynaecology: report of a working party: June 2008. London: RCOG Press; 2008. Available from: <https://www.rcog.org.uk/en/guidelines-research-services/guidelines/standards-for-gynaecology/>

# Quality statement 3

## Initial treatment is pharmaceutical

A woman with heavy menstrual bleeding is offered pharmaceutical treatment, taking into account evidence-based guidelines, her individual needs and any associated symptoms. Initial treatment is provided to a woman undergoing further investigations to exclude malignancy and significant pathology.

### Evidence sources

#### Australian guidelines

Endocrinology Expert Group. Therapeutic Guidelines: Endocrinology Version 5, Revised February 2014, Therapeutic Guidelines Limited, Melbourne 2014

#### International guidelines

National Institute for Health and Care Excellence. NICE guideline CG44: Heavy menstrual bleeding. London: Royal College of Obstetricians and Gynaecologists, 2007.

Full guideline (2007):

<https://www.nice.org.uk/guidance/cg44/evidence/full-guideline-195071293>

Partial update (2016):

<https://www.nice.org.uk/guidance/CG44/chapter/recommendations>

The Society of Obstetricians and Gynaecologists of Canada. Abnormal uterine bleeding in pre-menopausal women. Journal of Obstetrics and Gynaecology Canada 2013;35 (5 eSuppl):S1-S28.

#### Additional sources

Australian Medicines Handbook. Adelaide: Australian Medicines Handbook Pty Ltd 2017.

National Institute for Health and Clinical Excellence. Heavy menstrual bleeding Quality Standard 47. United Kingdom: NICE; 2013. Available from: [www.nice.org.uk/guidance/qs47](http://www.nice.org.uk/guidance/qs47)



# Quality statement 4

## Quality ultrasound

A woman having an ultrasound to investigate the cause of her heavy menstrual bleeding has a pelvic (preferably transvaginal) ultrasound, which assesses endometrial thickness and uterine morphology in days 5–10 of her menstrual cycle.

### Evidence sources

#### International guidelines

National Institute for Health and Care Excellence. NICE guideline CG44: Heavy menstrual bleeding. London: Royal College of Obstetricians and Gynaecologists, 2007.

Full guideline (2007):

<https://www.nice.org.uk/guidance/cg44/evidence/full-guideline-195071293>

Partial update (2016):

<https://www.nice.org.uk/guidance/CG44/chapter/recommendations>

The Society of Obstetricians and Gynaecologists of Canada. Abnormal uterine bleeding in pre-menopausal women. *Journal of Obstetrics and Gynaecology Canada* 2013;35 (5 eSuppl):S1-S28.

#### Additional sources

Australasian Society for Ultrasound in Medicine. Statement on the performance of a gynaecological scan. Sydney: ASUM, 2014.

Bennett GL, Andreotti RF, Lee SI, Dejesus Allison SO, Brown DL, Dubinsky T, et al. ACR appropriateness criteria on abnormal vaginal bleeding. *J Am Coll Radiol* 2011;8:460-8.

National Institute for Health and Clinical Excellence. Heavy menstrual bleeding Quality Standard 47. United Kingdom: NICE; 2013. Available from: [www.nice.org.uk/guidance/qs47](http://www.nice.org.uk/guidance/qs47)  
World Health Organization. Manual of diagnostic ultrasound, Volume 2. Second ed. Geneva: WHO, 2013.

The Royal Australian and New Zealand College of Radiologists. Standards of Practice for Diagnostic and Interventional Radiology, Version 10.1. Sydney: RANZCR, 2016.

# Quality statement 5

## Intra-uterine hormonal devices

When pharmaceutical treatment is being considered, a woman is offered the levonorgestrel intra-uterine system if clinically appropriate, as it is the most effective medical option for managing heavy menstrual bleeding.

### Evidence sources

#### Australian guidelines

Endocrinology Expert Group. Therapeutic Guidelines: Endocrinology Version 5, Revised February 2014, Therapeutic Guidelines Limited, Melbourne 2014

#### International guidelines

National Institute for Health and Care Excellence. NICE guideline CG44: Heavy menstrual bleeding. London: Royal College of Obstetricians and Gynaecologists, 2007.

Full guideline (2007):

<https://www.nice.org.uk/guidance/cg44/evidence/full-guideline-195071293>

Partial update (2016):

<https://www.nice.org.uk/guidance/CG44/chapter/recommendations>

The Society of Obstetricians and Gynaecologists of Canada. Abnormal uterine bleeding in pre-menopausal women. Journal of Obstetrics and Gynaecology Canada 2013;35 (5 eSuppl):S1-S28.

#### Additional sources

Kai J, Middleton L, J D, H P, Tryposkiadis K, Gupta J. Usual medical treatments or levonorgestrel-IUS for women with heavy menstrual bleeding. Br J Gen Pract 2016.

Lethaby A, Hussain M, Rishworth JR, Rees MC. Progesterone or progestogen-releasing intrauterine systems for heavy menstrual bleeding. Cochrane Database Syst Rev 2015;CD002126.

Marjoribanks J, Lethaby A, Farquhar C. Surgery versus medical therapy for heavy menstrual bleeding. Cochrane Database Syst Rev 2016:CD003855

National Institute for Health and Clinical Excellence. Heavy menstrual bleeding Quality Standard 47. United Kingdom: NICE; 2013. Available from: [www.nice.org.uk/guidance/qs47](http://www.nice.org.uk/guidance/qs47)

# Quality statement 6

## Specialist referral

A woman with heavy menstrual bleeding is referred for early specialist review when there is a suspicion of malignancy or other significant pathology based on clinical assessment or ultrasound. Referral is also arranged for a woman who has not responded after six months of medical treatment.

### Evidence sources

#### Australian guidelines

Endocrinology Expert Group. Therapeutic Guidelines: Endocrinology Version 5, Revised February 2014, Therapeutic Guidelines Limited, Melbourne 2014

#### International guidelines

National Institute for Health and Care Excellence. NICE guideline CG44: Heavy menstrual bleeding. London: Royal College of Obstetricians and Gynaecologists, 2007.

Full guideline (2007):

<https://www.nice.org.uk/guidance/cg44/evidence/full-guideline-195071293>

Partial update (2016):

<https://www.nice.org.uk/guidance/CG44/chapter/recommendations>

The Society of Obstetricians and Gynaecologists of Canada. Abnormal uterine bleeding in pre-menopausal women. Journal of Obstetrics and Gynaecology Canada 2013;35 (5 eSuppl):S1-S28.

#### Additional sources

Cancer Australia. Abnormal vaginal bleeding in pre-and peri-menopausal women. A diagnostic guide for General Practitioners and Gynaecologists. Cancer Australia; 2011. Available from: <https://canceraustralia.gov.au/publications-and-resources/cancer-australia-publications/abnormal-vaginal-bleeding-pre-peri-and-post-menopausal-women-diagnostic-guide-general-practitioners>

National Institute for Health and Clinical Excellence. Heavy menstrual bleeding Quality Standard 47. United Kingdom: NICE; 2013. Available from: [www.nice.org.uk/guidance/gs47](http://www.nice.org.uk/guidance/gs47)

Pennant ME, Mehta R, Moody P, Hackett G, Prentice A, Sharp SJ, et al. Premenopausal abnormal uterine bleeding and risk of endometrial cancer. BJOG 2017;124:404-11.

Royal College of Obstetricians and Gynaecologists. Advice for heavy menstrual bleeding services and commissioners. London: RCOG, 2014.

# Quality statement 7

## Uterine-preserving alternatives to hysterectomy

A woman who has heavy menstrual bleeding of benign causes and who is considering surgical management is offered a uterine-preserving procedure, if clinically appropriate. The woman receives information about procedures that may be suitable (such as endometrial ablation or removal of local pathology) and is referred appropriately.

### Evidence sources

#### Australian guidelines

Endocrinology Expert Group. Therapeutic Guidelines: Endocrinology Version 5, Revised February 2014, Therapeutic Guidelines Limited, Melbourne 2014

#### International guidelines

National Institute for Health and Care Excellence. NICE guideline CG44: Heavy menstrual bleeding. London: Royal College of Obstetricians and Gynaecologists, 2007.

Full guideline (2007):

<https://www.nice.org.uk/guidance/cg44/evidence/full-guideline-195071293>

Partial update (2016):

<https://www.nice.org.uk/guidance/CG44/chapter/recommendations>

The Society of Obstetricians and Gynaecologists of Canada. Abnormal uterine bleeding in pre-menopausal women. Journal of Obstetrics and Gynaecology Canada 2013;35 (5 eSuppl):S1-S28.

The Society of Obstetricians and Gynaecologists of Canada. Endometrial ablation in the management of abnormal uterine bleeding. Journal of Obstetrics and Gynaecology Canada 2015; No. 322.

#### Additional sources

Chen S, Pitre E, Kaunelis D, Singh S. Uterine-preserving interventions for the management of symptomatic uterine fibroids: a systematic review of clinical and cost-effectiveness. Ottawa (ON) 2016. <http://www.ncbi.nlm.nih.gov/pubmed/26985555>

Fergusson RJ, Lethaby A, Shepperd S, Farquhar C. Endometrial resection and ablation versus hysterectomy for heavy menstrual bleeding. Cochrane Database Syst Rev 2013:CD000329.

Lethaby A, Hickey M, Garry R, Penninx J. Endometrial resection / ablation techniques for heavy menstrual bleeding. Cochrane Database Syst Rev 2009:CD001501.

National Institute for Health and Clinical Excellence. Heavy menstrual bleeding Quality Standard 47. United Kingdom: NICE; 2013. Available from: [www.nice.org.uk/guidance/qs47](http://www.nice.org.uk/guidance/qs47)

Royal Australian and New Zealand College of Obstetricians and Gynaecologists. Uterine artery embolisation for the treatment of uterine fibroids. Melbourne: RANZCOG; 2014. Available from: <https://www.ranzcoq.edu.au/college-statements-guidelines.html>.

Royal Australian and New Zealand College of Obstetricians and Gynaecologists, Australasian CREI Consensus Expert Panel on Trial evidence (ACCEPT) group. Fibroids in infertility. Melbourne: RANZCOG; 2014. Available from: <https://www.ranzcoq.edu.au/college-statements-guidelines.html>.

Royal College of Obstetricians and Gynaecologists (Great Britain). Chapter 11: Heavy Menstrual Bleeding in: Standards for gynaecology: report of a working party: June 2008. London: RCOG Press; 2008. Available from: <https://www.rcog.org.uk/en/guidelines-research-services/guidelines/standards-for-gynaecology/>

# Quality statement 8

## Hysterectomy

Hysterectomy for management of heavy menstrual bleeding is discussed when other treatment options are ineffective or are unsuitable, or at the woman's request. A woman considering a hysterectomy is given balanced information about the risks and benefits of the procedure before making a decision.

### Evidence sources

#### International guidelines

National Institute for Health and Care Excellence. NICE guideline CG44: Heavy menstrual bleeding. London: Royal College of Obstetricians and Gynaecologists, 2007.

Full guideline (2007):

<https://www.nice.org.uk/guidance/cg44/evidence/full-guideline-195071293>

Partial update (2016):

<https://www.nice.org.uk/guidance/CG44/chapter/recommendations>

The Society of Obstetricians and Gynaecologists of Canada. Abnormal uterine bleeding in pre-menopausal women. Journal of Obstetrics and Gynaecology Canada 2013;35 (5 eSuppl):S1-S28.

#### Additional sources

National Institute for Health and Clinical Excellence. Heavy menstrual bleeding Quality Standard 47. United Kingdom: NICE; 2013. Available from: [www.nice.org.uk/guidance/qs47](http://www.nice.org.uk/guidance/qs47)

Royal College of Obstetricians and Gynaecologists (Great Britain). Chapter 11: Heavy Menstrual Bleeding in: Standards for gynaecology: report of a working party: June 2008. London: RCOG Press; 2008. Available from: <https://www.rcog.org.uk/en/guidelines-research-services/guidelines/standards-for-gynaecology/>

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