1 2	NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE
3	Guideline scope
4 5	Heavy menstrual bleeding: assessment and management
6	Торіс
7 8 9	This guideline will update the NICE guideline on heavy menstrual bleeding: assessment and management (CG44) as set out in the <u>surveillance review</u> <u>decision</u> .
) 1	This guideline will also be used to develop the NICE quality standard for heavy menstrual bleeding.
2 3	The guideline will be developed using the methods and processes outlined in <u>Developing NICE guidelines: the manual</u> .
4 5	For more information about why this guideline is being developed, and how the guideline will fit into current practice, see the <u>context</u> section.
6	Who the guideline is for
7 8 9 0	 Women using services, families and carers and the public Healthcare professionals in gynaecology services Healthcare professionals in primary care Healthcare professionals in radiology services Commissioners of gynaecology services
2 3 4	NICE guidelines cover health and care in England. Decisions on how they apply in other UK countries are made by ministers in the <u>Welsh Government</u> , <u>Scottish Government</u> , and <u>Northern Ireland Executive</u> .

25 Equality considerations

- NICE has carried an <u>equality impact assessment</u> during scoping. The
 assessment:
- lists equality issues identified, and how they have been addressed
- explains why any groups are excluded from the scope.
- 30 The guideline will look at inequalities relating to women who are socially
- 31 disadvantaged, women with learning disabilities and women who have
- 32 difficulties with reading, understanding or speaking English.

33 **1** What the guideline is about

34 **1.1** Who is the focus?

35 Groups that will be covered

- Women with heavy menstrual bleeding, including:
- 37 women with suspected or confirmed fibroids
- 38 women with suspected or confirmed adenomyosis
- 39 women with no identifiable pathology.
- 40 The committee will give special consideration to women who wish to
- 41 preserve their fertility.

42 Groups that will not be covered

- Women without heavy menstrual bleeding who have other gynaecological
- 44 bleeding, for example,
- 45 intermenstrual bleeding
- 46 post-coital bleeding.
- Women with gynaecological conditions in which heavy menstrual bleeding
- 48 is not the main problem, such as endometriosis.

49 1.2 Settings

50 Settings that will be covered

• All NHS-funded healthcare settings

52 **1.3** Activities, services or aspects of care

- 53 We will look at evidence on the areas listed below when developing the 54 guideline, but it may not be possible to make recommendations on all the
- 55 areas.
- 56 Key areas that will be covered

57 Areas from the published guideline that will be updated

- 58 1 Diagnosis of cause of heavy menstrual bleeding
- 59 2 Management of heavy menstrual bleeding, including:
- 60 pharmacological treatment [note that guideline recommendations will
- 61 normally fall within licensed indications; exceptionally, and only if
- 62 clearly supported by evidence, use outside a licensed indication may
- 63 be recommended. The guideline will assume that prescribers will use
- a medicine's summary of product characteristics to inform decisions
- 65 made with individual patients]
- 66 surgical treatment.

67 Areas not in the published guideline that will be included in the update

- 1 Diagnosis and management of adenomyosis [this will include looking at
- 69 uterine artery embolisation for treating adenomyosis, subject to
- 70 discussion with NICE's Interventional Procedures Programme about the
- 71 relationship with NICE interventional procedures guidance 473 (<u>uterine</u>
- 72 <u>artery embolisation for treating adenomyosis)</u>].
- 73 Areas that will not be covered

74 Areas from the published guideline that will not be updated

- 75 1 Definition of heavy menstrual bleeding
- 76 2 Education and information provision
 - 3

- 77 3 Competencies:
- 78 training
- 79 maintenance
- 80 governance
- 4 The clinical and cost effectiveness of treatment with progesterone
 receptor modulators for fibroids of 3 cm or more in diameter (this topic
 was reviewed by the NICE standing committee, and an <u>addendum to</u>
- 84 <u>CG44</u> was published in August 2016)
- 85 Recommendations in areas that are not being updated may be edited to
- 86 ensure that they meet current editorial standards, and reflect the current policy
- 87 and practice context.

88 Areas not covered by the published guideline or the update

- 89 1 Management of endometriosis associated with heavy menstrual bleeding
- 90 [this will be covered in <u>NICE's guideline on endometriosis</u> that is
- 91 currently in development (publication expected September 2017)]

92 **1.4** *Economic aspects*

We will take economic aspects into account when making recommendations. We will develop an economic plan that states for each review question (or key area in the scope) whether economic considerations are relevant, and if so whether this is an area that should be prioritised for economic modelling and analysis. We will review the economic evidence and carry out economic analyses, using an NHS perspective, as appropriate.

99 **1.5** Key issues and questions

While writing this scope, we have identified the following key issues, and key
questions related to them. The recommendations will be tailored to the groups
covered by the guideline (see section 1.1).

- 103 1 Diagnosis of cause of heavy menstrual bleeding
- 104 1.1 What is the most clinically and cost-effective diagnostic strategy for
- 105 investigations in women presenting with heavy menstrual bleeding?

- 106 1.2 What is the most clinically and cost effective imaging strategy for
- 107 diagnosing adenomyosis in women with heavy menstrual bleeding?

108

- Management of heavy menstrual bleeding 109 2 110 2.1 What is the most clinically and cost-effective pharmacological treatment for heavy menstrual bleeding in women with: 111 - suspected or confirmed fibroids 112 113 suspected or confirmed adenomyosis - no identifiable pathology? 114 2.2 What is the most clinically and cost-effective surgical treatment for 115 116 heavy menstrual bleeding in women with: 117 - Suspected or confirmed fibroids - Suspected or confirmed adenomyosis 118 - no identifiable pathology? 119 120 NB The surgical options for treating women with heavy menstrual 121 bleeding and adenomyosis will include uterine artery embolisation. 122 2.3 What is the most clinically and cost-effective treatment for heavy 123 menstrual bleeding among pharmacological and surgical treatments? The key questions may be used to develop more detailed review questions, 124 which guide the systematic review of the literature. 125 1.6 Main outcomes 126
- 127 The main outcomes that will be considered when searching for and assessing128 the evidence are:
- 129 1 clinical outcomes and effectiveness:
- 130 diagnostic accuracy of investigations
- 131 reduction in menstrual blood loss
- 132 adverse events
- 133 patient satisfaction

134 2 health-related quality of life.

Links with other NICE guidance, NICE quality standards, and NICE Pathways

- 137 2.1 NICE guidance
- 138 NICE guidance that will be updated by this guideline
- 139 Heavy menstrual bleeding: assessment and management (NICE guideline
- 140 CG44)
- 141 NICE guidance about the experience of people using NHS services
- 142 NICE has produced the following guidance on the experience of people using
- 143 the NHS. This guideline will not include additional recommendations on these
- 144 topics unless there are specific issues related to heavy menstrual bleeding:
- 145 Patient experience in adult NHS services (2012) NICE guideline CG138
- 146 Medicines adherence (2009) NICE guideline CG76
- 147 NICE guidance that is closely related to this guideline
- 148 **Published**
- 149 NICE has published the following guidance that is closely related to this150 guideline:
- 151 Uterine artery embolisation for treating adenomyosis (2013) NICE
- 152 interventional procedure guidance 473
- 153 Hysteroscopic morcellation of uterine leiomyomas (fibroids) (2015) NICE
- 154 interventional procedure guidance 522
- 155 Magnetic resonance image-guided transcutaneous focused ultrasound for
- 156 <u>uterine fibroids</u> (2011) NICE interventional procedure guidance 413
- 157 <u>Uterine artery embolisation for fibroids</u> (2010) NICE interventional
- 158 procedure guidance 367
- 159 Laparoscopic techniques for hysterectomy (2007) NICE interventional
- 160 procedure guidance 239

- 161 Endometrial cryotherapy for menorrhagia (2006) NICE interventional
- 162 procedure guidance 157
- 163 Fluid-filled thermal balloon and microwave endometrial ablation techniques
- 164 <u>for heavy menstrual bleeding</u> (2004) NICE technology appraisal guidance
 165 78
- Photodynamic endometrial ablation (2004) NICE interventional procedure
 guidance 47
- 168 Magnetic resonance (MR) image-guided percutaneous laser ablation of
- 169 <u>uterine fibroids</u> (2003) NICE interventional procedure guidance 30
- Laparoscopic laser myomectomy (2003) NICE interventional procedure
 guidance 23
- 172 In development
- 173 NICE is currently developing the following guidance that is closely related to
- 174 this guideline:
- 175 Endometriosis: diagnosis and management. NICE guideline. Publication
- expected September 2017.

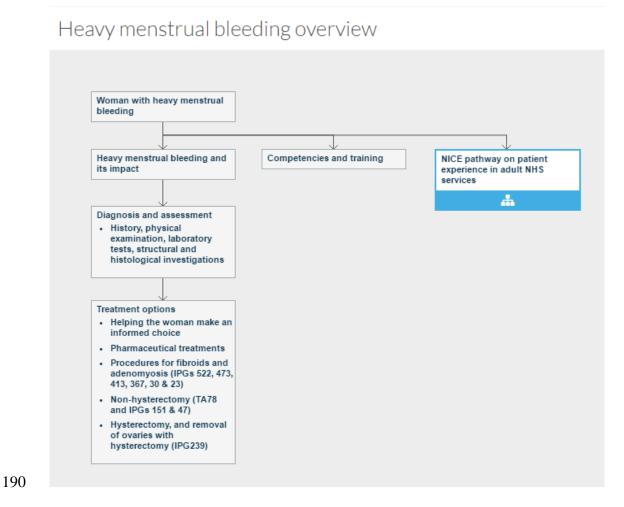
177 2.2 NICE quality standards

- 178 NICE quality standards that may need to be revised or updated when this
- 179 guideline is published
- 180 Heavy menstrual bleeding (2013) NICE quality standard 47

181 **2.3** *NICE Pathways*

- 182 NICE Pathways bring together all related NICE guidance and associated
- 183 products on a topic in an interactive topic-based flow chart.
- 184 There is a live pathway for heavy menstrual bleeding:
- 185 <u>http://pathways.nice.org.uk/pathways/heavy-menstrual-bleeding</u>
- 186 When the revised guideline is published, the recommendations will be
- 187 incorporated into a revised pathway. An outline, based on the scope, is

- 188 included below. It will be adapted and more detail added as the
- 189 recommendations are written during guideline development



191 **3 Context**

192**3.1**Key facts and figures

Heavy menstrual bleeding is one of the most common reasons for 193 gynaecological consultations in both primary and secondary care. The NICE 194 clinical knowledge summary on menorrhagia states that about 1 in 20 women 195 aged 30-49 years consult their GP each year because of heavy periods and 196 197 menstrual problems, and that menstrual disorders comprise 12% of all 198 referrals to gynaecology services. Heavy periods affect women's quality of life 199 and can restrict participation in the workplace and socially. (See the context section of the current guideline CG44 for further details.) 200

201 **3.2** *Current practice*

For diagnosis of heavy menstrual bleeding, the current guideline (CG44) recommends ultrasound as the first investigation, followed by hysteroscopy when results are inconclusive. Since CG44 was first published in 2007, transvaginal ultrasound equipment and software have improved, and outpatient hysteroscopy has become more widely available. Therefore the relative clinical and cost effectiveness of diagnostic strategies may have changed.

- 209 For treating heavy menstrual bleeding, outpatient management comprising
- 210 insertion of a levonorgestrel-releasing intrauterine system (LNG-IUS) has
- 211 increased in popularity, and there has been a reduction in surgical

212 procedures. The technique of microwave endometrial ablation is no longer

- available in the UK.
- 214 Improvements in diagnostic imaging in recent years have resulted in an
- 215 increase in the reported prevalence of adenomyosis, which is commonly
- associated with heavy menstrual bleeding. This condition was not included in
- 217 CG44. The technique of uterine artery embolisation, which is covered in NICE
- 218 interventional procedure guidance 473, will be reviewed in this context.

219 **3.3** *Policy, legislation, regulation and commissioning*

- 220 Legislation, regulation and guidance
- 221 Professional bodies have produced the following relevant guidance:
- <u>Clinical recommendations on the use of uterine artery embolisation (UAE)</u>
- in the management of fibroids (2013) Report of RCOG/RCR joint working
 party, third edition
- Best practice in outpatient hysteroscopy (2011) RCOG/BSGE GTG59
- 226 **Commissioning**
- 227 Gynaecology services for heavy menstrual bleeding are locally commissioned.
- Since CG44 was first published in 2007 there has been a trend away from

- secondary care towards community-based diagnostic and treatment services
- 230 using a variety of providers.

4 Further information

This is the final scope, incorporating comments from registered stakeholders during consultation

The guideline is expected to be published in July 2017.

You can follow progress of the guideline.

Our website has information about how <u>NICE guidelines</u> are developed.

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