1 2	NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE
3	Guideline scope
4	Safe prescribing and withdrawal
5	management of prescribed drugs
6	associated with dependence or withdrawal
7	The Department of Health and Social Care in England has asked NICE to
8	develop a new clinical guideline on safe prescribing and withdrawal
9	management of prescribed drugs associated with dependence or withdrawal.
10	The guideline will be developed using the methods and processes outlined in
11	developing NICE guidelines: the manual.
12	This guideline will also be used to develop the NICE quality standard for safe
13	prescribing and withdrawal management of prescribed drugs associated with
14	dependence or withdrawal.
15	1 Why the guideline is needed
16	Key facts and figures
17	In the UK 11.5 million adults have a prescription for a medicine associated
18	with dependence or withdrawal symptoms. These include benzodiazepines, Z-
19	drugs such as zopiclone, opioids, gabapentin and pregabalin. Antidepressant
20	medicines, although not associated with dependence, can cause withdrawal
21	symptoms when they are stopped.
22	These medicines are usually used for conditions that are chronic, complex
23	and difficult to treat, including anxiety and insomnia, pain including

- 24 neuropathic and cancer pain, depression and generalised anxiety disorder.
- 25 Although they can provide long-term symptom management for a small
- 26 proportion of people taking them, they do not work for everyone and often
- 27 reduce rather than completely relieve symptoms. In addition, they have
- 28 adverse effects on the central nervous system that can outweigh their

1 benefits. However, they may continue to be prescribed when they are no

2 longer useful solely because stopping can cause unpleasant withdrawal

3 symptoms.

Dependence is characterised by tolerance (the need for increasing doses to maintain the same effect) and withdrawal symptoms if the dose is reduced or the medicine is stopped abruptly. Data from the National Drug Treatment Monitoring System suggest that 5% of people presenting to publicly funded addiction services in England describe their dependence as being partly or wholly on prescribed medicines.

10 Current practice

11 Prescriptions for antidepressants and gabapentinoids continue to increase.

12 Opioid prescribing began to fall during 2017 and 2018 after a sustained rise

13 between 2006 and 2016. Prescriptions for Z drugs have fallen modestly since

14 2014. Overall benzodiazepine prescribing decreased steadily between 2007

15 and 2017, although lorazepam prescribing increased.

16 There is wide geographic variation in the prescribing of medicines associated

17 with dependence or withdrawal symptoms. The highest number of

18 prescriptions occur in the north east of England, and the lowest in London.

19 Some clinical commissioning groups are identifying and supporting people

20 with a dependence on prescription medicines as part of medicines

21 optimisation.

22 People with a dependence on prescription medicines may be reluctant to

23 attend addiction services or seek help from their healthcare professionals

24 because of a perceived association with illegal drug use or alcohol

25 dependence.

26 Professional and policy bodies have issued guidelines on the clinical use of

- 27 medicines associated with dependence or withdrawal symptoms. However,
- there are few guidelines that focus on avoiding dependence and managing

29 withdrawal. This guideline aims to meet the need for evidence-based advice in

30 these areas.

1 **2** Who the guideline is for

- 2 This guideline is for:
- healthcare professionals who prescribe and administer medicines
- 4 associated with dependence or withdrawal symptoms, or who provide care
- 5 for people taking these medicines
- 6 commissioners of NHS and local authority services
- people using services, their families and carers and the public.
- 8 NICE guidelines cover health and care in England. Decisions on how they
- 9 apply in other UK countries are made by ministers in the Welsh Government,
- 10 <u>Scottish Government</u>, and <u>Northern Ireland Executive</u>.

11 Equality considerations

- 12 NICE has carried out <u>an equality impact assessment</u> during scoping. The
- 13 assessment lists equality issues identified, and how they have been
- 14 addressed.
- 15 The guideline will have particular relevance for people with cognitive
- 16 impairment, current or past history of substance misuse, current or past
- 17 mental health diagnoses and people in secure settings (prisons and
- 18 immigration removal centres).

3 What the guideline will cover

20 **3.1** Who is the focus?

21 Groups that will be covered

- Adults taking prescribed medicines that are associated with dependence or
 withdrawal symptoms (opioids, benzodiazepines, Z-drugs, gabapentinoids,
 or antidepressants).
- 25 No specific subgroups of people have been identified as needing specific
- consideration.

1 Groups that will not be covered

- 2 People taking opioids prescribed for end of life care.
- People having treatment for epilepsy.

4 **3.2** Settings

5 Settings that will be covered

- 6 All settings within which NHS or local authority commissioned care is
- 7 provided.

8 3.3 Activities, services or aspects of care

9 Key areas that will be covered

- 10 We will look at evidence in the areas below when developing the guideline,
- 11 but it may not be possible to make recommendations in all the areas.
- 12 1 Safe prescribing of medicines associated with dependence.
- 13 Risk factors for dependence on prescribed medicines.
- 14 Optimum prescribing strategies to limit the risk of dependence.
- 15 2 Monitoring to identify and minimise the risk of dependence and
- 16 recognise symptoms of withdrawal.
- 17 3 Methods for safe withdrawal of prescribed medicines associated with
- 18 dependence or withdrawal symptoms.
- 19 4 Information for people taking medicines associated with dependence or20 withdrawal symptoms.

21 Areas that will not be covered

- Managing dependence on and withdrawal from drugs that have not been
 prescribed.
- 24 2 Therapeutic efficacy and adverse events (other than dependence and
- 25 withdrawal symptoms) of the included medicines when used to treat
- 26 specific conditions. For guidance on these topics see 'Related NICE
- 27 guidance'.

1 Related NICE guidance

2 **Published**

- 3 Drug misuse prevention: targeted interventions (2017) NICE guideline
- 4 NG64
- 5 <u>Controlled drugs: safe use and management</u> (2016) NICE guideline NG46
- 6 <u>Neuropathic pain in adults</u> (2013) NICE guideline 173
- 7 <u>Headaches in over 12s: diagnosis and management</u> (2012, updated 2015)
- 8 NICE guideline CG150
- 9 Coexisting severe mental illness (psychosis) and substance misuse:
- 10 <u>assessment and management in healthcare settings</u> (2011) NICE guideline
- 11 CG120
- 12 Generalised anxiety disorder and panic disorder in adults: management
- 13 (2011, updated 2019) NICE guideline CG113
- 14 Depression in adults with a chronic physical health problem: recognition
- 15 and management (2009) NICE guideline CG91
- Depression in adults: recognition and management (2009) NICE guideline
 CG90
- 18 Drug misuse in over 16s: opioid detoxification (2007) NICE guideline CG52
- 19 Naltrexone for the management of opioid dependence (2007) NICE
- 20 technology appraisal guidance TA115
- 21 <u>Methadone and buprenorphine for the management of opioid dependence</u>
- 22 (2007) NICE technology appraisal guidance TA114
- 23 Obsessive-compulsive disorder and body dysmorphic disorder: treatment
- 24 (2005) NICE clinical guideline CG31
- 25 Guidance on the use of zaleplon, zolpidem and zopiclone for the short-term
- 26 <u>management of insomnia</u> (2004) NICE technology appraisal guidance
- 27 **TA77**
- 28 In development
- 29 <u>Depression in adults: treatment and management</u>. NICE guideline.
- 30 Publication expected February 2020
- 31 <u>Chronic pain: assessment and management</u>. NICE guideline. Publication
- 32 expected August 2020

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1 NICE guidance about the experience of people using NHS services

- 2 NICE has produced the following guidance on the experience of people using
- 3 the NHS. This guideline will not include additional recommendations on these
- 4 topics unless there are specific issues related to safe prescribing and
- 5 withdrawal management of prescribed drugs associated with dependence or
- 6 withdrawal.
- 7 Medicines optimisation (2015) NICE guideline NG5
- 8 Patient experience in adult NHS services (2012) NICE guideline CG138
- 9 <u>Service user experience in adult mental health</u> (2011) NICE guideline
- 10 CG136
- 11 <u>Medicines adherence</u> (2009) NICE guideline CG76

12 **3.4** *Economic aspects*

We will take economics 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 the area should be prioritised for economic modelling and analysis. We will review the economic evidence and carry out economic analyses, using an NHS and personal social services (PSS) perspective. In sensitivity analyses, we will seek to include broader public sector costs, if applicable.

20 **3.5** *Key issues and draft questions*

21 While writing this scope, we have identified the following key issues and draft 22 questions related to them:

- 23 1 Safe prescribing of medicines associated with dependence
- 24 1.1 What are the risk factors (both patient and prescribing factors) for
- dependence on prescribed opioids, benzodiazepines, Z-drugs andgabapentinoids?
- 1.2 What are the optimum prescribing strategies to limit the risk ofdependence?
- 29 2 Monitoring to identify and minimise the risk of dependence and
- 30 recognise symptoms of withdrawal

1	2.1 What is the optimal frequency of review of prescribed medicines	
2	associated with dependence or withdrawal symptoms?	
3	2.2 What should be included in a review of prescribed medicines	
4	associated with dependence or withdrawal symptoms?	
5	2.3 What are the common symptoms associated with withdrawal of	
6	these medicines?	
7	3 Methods for safe withdrawal of prescribed medicines associated with	
8	dependence or withdrawal symptoms	
9	3.1 What are the most clinically and cost effective pharmacological and	I
10	non-pharmacological strategies, for example tapered withdrawal, for the	е
11	safe withdrawal of prescribed medicines associated with dependence of	r
12	withdrawal symptoms?	
13	4 Information for people taking prescribed medicines associated with	
14	dependence or withdrawal symptoms	
15	4.1 What information is needed by people who may develop	
16	dependence, or who have developed dependence or withdrawal	
17	symptoms (for example information about the possible risk of	
18	dependence or withdrawal symptoms) related to prescribed medicines?	?
19		
20	The key issues and draft questions will be used to develop more detailed	
21	review questions, which guide the systematic review of the literature.	
22	3.6 Main outcomes	
23	The main outcomes that may be considered when searching for and	
24	assessing the evidence are:	
25	health-related quality of life	
26	 cessation or reduction of prescriptions for medicines associated with 	
27	dependence or withdrawal symptoms	
28	 patient satisfaction 	
29	mortality	
•		

- 30 healthcare resource use
- dependence.

4 NICE quality standards and NICE Pathways

2 4.1 NICE quality standards

3 NICE quality standards that will use this guideline as an evidence source

4 when they are being developed

- 5 Safe prescribing and withdrawal management of prescribed drugs
- 6 associated with dependence and withdrawal. NICE quality standard.
- 7 Publication date to be confirmed.

8 4.2 NICE Pathways

- 9 <u>NICE Pathways</u> bring together everything we have said on a topic in an
- 10 interactive flowchart. When this guideline is published, the recommendations
- 11 will be included in the NICE Pathway on safe prescribing and withdrawal
- 12 management of prescribed drugs associated with dependence or withdrawal
- 13 (in development).
- 14 Other relevant guidance will also be added or linked to, including:

15 **Published**

- 16
- 17 Controlled drugs: safe use and management (2016) NICE guideline NG46
- 18 <u>Neuropathic pain in adults</u> (2013) NICE guideline 173
- 19 <u>Headaches in over 12s: diagnosis and management</u> (2012, updated 2015)
- 20 NICE guideline CG150
- 21 Coexisting severe mental illness (psychosis) and substance misuse:
- 22 <u>assessment and management in healthcare settings</u> (2011) NICE guideline
- 23 CG120
- 24 Generalised anxiety disorder and panic disorder in adults: management
- 25 (2011, updated 2019) NICE guideline CG113
- 26 Depression in adults with a chronic physical health problem: recognition
- 27 and management (2009) NICE guideline CG91
- 28 Depression in adults: recognition and management (2009) NICE guideline
- 29 CG90

- 1 Obsessive-compulsive disorder and body dysmorphic disorder: treatment
- 2 (2005) NICE clinical guideline CG31
- 3 Guidance on the use of zaleplon, zolpidem and zopiclone for the short-term
- 4 <u>management of insomnia</u> (2004) NICE technology appraisal guidance
 5 TA77
- 6 <u>Medicines optimisation</u> (2015) NICE guideline NG5
- 7 Patient experience in adult NHS services (2012) NICE guideline CG138
- 8 <u>Service user experience in adult mental health</u> (2011) NICE guideline
- 9 CG136
- 10 Medicines adherence (2009) NICE guideline CG76
- 11 In development
- 12 <u>Depression in adults: treatment and management</u>. NICE guideline.
- 13 Publication expected February 2020
- 14 Chronic pain: assessment and management. NICE guideline. Publication
- 15 expected August 2020
- 16
- 17 An outline based on this scope is included below. It will be adapted and more
- 18 detail added as the recommendations are written during guideline
- 19 development.



1

2 **5** Further information

This is the draft scope for consultation with registered stakeholders. The consultation dates are 29 August to 26 September 2019.

The guideline is expected to be published in November 2021.

You can follow progress of the guideline.

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

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