### NATIONAL INSTITUTE FOR HEALTH AND CARE 1 **EXCELLENCE** 2 **Guideline scope** 3 Gout: diagnosis and management 4 5 The Department of Health and Social Care in England and NHS England have 6 asked NICE to develop a guideline on the management of gout. 7 The guideline will be developed using the methods and processes outlined in 8 developing NICE guidelines: the manual. 9 This guideline will also be used to develop the NICE quality standard for gout. 1 Why the guideline is needed 10 11 Gout is a type of arthritis caused by monosodium urate crystals forming inside 12 and around joints, resulting in sudden flares of severe pain, heat and swelling. 13 Any joint can be affected but gout is most common in distal joints, such as the 14 big toes, knees and ankles, and finger joints. Key facts and figures 15 Between 2 and 3 in every 100 people in the UK have gout. It usually occurs in 16 men over 30 and women after menopause, and is more common in men than 17 women. Long-term complications of gout include joint damage and renal 18 stones. Almost 40% of people with gout have chronic kidney disease. 19 **Current practice** 20 Gout is most often managed in primary care without specialist rheumatological 21 input. Flares are usually treated with non-steroidal anti-inflammatory drugs 22 (NSAIDs), colchicine or steroids. However, most people go on to have further 23 flares. They can be prevented by a combination of lifestyle modification (losing 24 weight, changing diet) and medicines to reduce urate levels such as 25 allopurinol or febuxostat. However, only one-third of people with gout receive 26 these medicines and they are used effectively (lowering serum urate level to 27 the biochemical target) for only one-third of those who take them. People with 28 chronic kidney disease also often have contraindications to a number of

- agents used in the management of gout. Medications such as thiazide and
- 2 loop diuretics elevate serum uric acid levels and are commonly the first-line
- 3 treatments for chronic kidney disease.
- 4 Gout is a painful and debilitating condition with a high level of prevalence and
- 5 associated morbidity. There are a range of pharmacological and lifestyle
- 6 interventions available to manage gout, and this has led to variations in
- 7 management. Diagnosing gout, specifically differentiating gout from other
- 8 arthritis, is not always straightforward and the best method of diagnosis is
- 9 often unclear. This guideline aims to improve the diagnosis and management
- of gout and the quality of life for people affected by it.

# 2 Who the guideline is for

12 This guideline is for:

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- healthcare professionals providing NHS-commissioned services
- commissioners of health and social care services
- people using services, their families and carers, and the public.
- 17 It may also be relevant for:
- private healthcare providers, including physiotherapy and care homes.
- 19 NICE guidelines cover health and care in England. Decisions on how they
- apply in other UK countries are made by ministers in the Welsh Government,
- 21 <u>Scottish Government and Northern Ireland Executive.</u>

## 22 Equality considerations

- 23 NICE has carried out an equality impact assessment during scoping. The
- 24 assessment:
- lists equality issues identified, and how they have been addressed
- explains why any groups are excluded from the scope.

# 3 What the guideline will cover

#### 2 3.1 Who is the focus?

#### 3 Groups that will be covered

- Adults (18 years and older) with gout.
- 5 Specific consideration will be given to people with gout and chronic kidney
- 6 disease.

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### 7 Groups that will not be covered

- 8 People with calcium pyrophosphate crystal deposition, including
- 9 pseudogout.

## 10 3.2 Settings

## 11 Settings that will be covered

• All settings where NHS healthcare is provided or commissioned.

# 13 3.3 Activities, services or aspects of care

#### 14 Key areas that will be covered

- We will look at evidence in the areas below when developing the guideline,
- but it may not be possible to make recommendations in all the areas.
- 17 1 Information and support for people with gout and their families or carers
- 18 2 Diagnosis and assessment of gout
- 19 3 Management of gout flares
- 20 Pharmacological management
- 21 Non-pharmacological management
- 22 4 Long-term management of gout
- 23 Pharmacological management, including urate-lowering therapies
- 24 Non-pharmacological management, including diet and lifestyle
- 25 5 Ongoing care and monitoring
- 26 Treating to target
- 27 Monitoring disease activity and follow-up

- 1 6 Specialist services
- 2 Note that guideline recommendations for medicines will normally fall within
- 3 licensed indications; exceptionally, and only if clearly supported by evidence,
- 4 use outside a licensed indication may be recommended. The guideline will
- 5 assume that prescribers will use a medicine's summary of product
- 6 characteristics to inform decisions made with individual patients.

#### 7 Areas that will not be covered

8 1 Prevention of incident gout

## 9 Related NICE guidance

- Lesinurad for treating chronic hyperuricaemia in people with gout (2018)
- NICE technology appraisal guidance 506
- Canakinumab for treating gouty arthritis attacks and reducing the frequency
- of subsequent attacks (2013) NICE terminated appraisal 281
- Febuxostat for the management of hyperuricaemia in people with gout
- 15 (2008) NICE technology appraisal guidance 164

### 16 NICE guidance about the experience of people using NHS services

- 17 NICE has produced the following guidance on the experience of people using
- the NHS. This guideline will not include additional recommendations on these
- 19 topics unless there are specific issues related to the management and
- 20 diagnosis of gout.
- Medicines optimisation (2015) NICE guideline NG5
- Patient experience in adult NHS services (2012) NICE guideline CG138
- Medicines adherence (2009) NICE guideline CG76

## 24 3.4 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
- 29 analysis. We will review the economic evidence and carry out economic

- analyses, using an NHS and personal social services (PSS) perspective, as
- 2 appropriate.

## 3 3.5 Key issues and draft questions

- 4 While writing this scope, we have identified the following key issues and draft
- 5 questions related to them:
- 6 1 Information and support for people with gout and their families or carers
- 7 1.1 What information and support is needed by people with gout and
- their families or carers in relation to gout, and when should this be
- 9 provided?
- 10 2 Diagnosis and assessment of gout
- 2.1 What signs and symptoms indicate gout as a possible diagnosis?
- 12 2.2 What are the most accurate and cost effective approaches to
- diagnosing gout, in particular serum urate level compared to joint
- 14 aspiration?
- 15 3 Management of gout flares
- 3.1 In people with gout (including people with gout and chronic kidney
- 17 disease), what is the clinical and cost effectiveness of pharmacological
- interventions, including NSAIDs, colchicine, corticosteroids and IL-1
- inhibitors, for managing gout flares?
- 20 3.2 What is the clinical and cost effectiveness of non-pharmacological
- interventions, including rest, elevation and topical ice, for managing gout
- 22 flares?
- 23 4 Long-term management of gout
- 4.1 Which people with gout should be offered urate-lowering therapy
- 25 (ULT) such as a xanthine oxidase inhibitor, a uricosuric or a uricase, and
- when should urate-lowering therapy be started?
- 4.2 In people with gout (including people with gout and chronic kidney
- disease), which urate-lowering therapies (either alone or in combination
- with each other) are the most clinically and cost effective for first-line
- 30 treatment?

1		4.3 In gout that is inadequately controlled by first-line treatment, which
2		urate-lowering therapies (either alone or in combination) are the most
3		clinically and cost effective?
4		4.4 If first-line treatment for gout is not tolerated, which urate-lowering
5		therapies (either alone or in combination with each other) are the most
6		clinically and cost effective?
7		4.5 In people with gout (including people with gout and chronic kidney
8		disease), what is the clinical and cost effectiveness of colchicine,
9		NSAIDs and corticosteroids in the prevention of gout flares during the
10		initiation or titration of urate-lowering therapy?
11		4.6 What is the clinical and cost effectiveness of diet and lifestyle
12		modifications for gout?
13	5	Ongoing care and monitoring
14		5.1 What is the clinical and cost effectiveness of a 'treat-to-target'
15		management strategy compared with usual care for gout?
16		5.2 What is the best serum urate level target to use when monitoring
17		disease activity in gout?
18		5.3 What is the optimum frequency of disease activity monitoring using
19		serum urate level measurement in gout?
20		5.4 What follow-up should be offered to people after a gout flare?
21	6	Specialist services
22		6.1 What are the indications for referring people with gout to specialist
23		services?
24		6.2 What is the clinical and cost effectiveness of surgical excision of
25		tophi (deposits of monosodium urate crystals)?
26		
27	The	key issues and draft questions will be used to develop more detailed
28	revi	ew questions, which guide the systematic review of the literature.
29	3.6	Main outcomes
30	The main outcomes that may be considered when searching for and	
31	assessing the evidence are:	

quality of life

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- 1 2 pain
- 2 3 joint swelling
- 3 4 joint tenderness
- 4 5 joint inflammation
- 5 6 serum urate levels
- 6 7 frequency of flares
- 7 8 tophus number and size
- 8 9 adverse events and complications of gout
- 9 radiographic joint damage
- 10 renal stones
- 11 10 adverse events and complications of intervention.

# 12 4 NICE quality standards and NICE Pathways

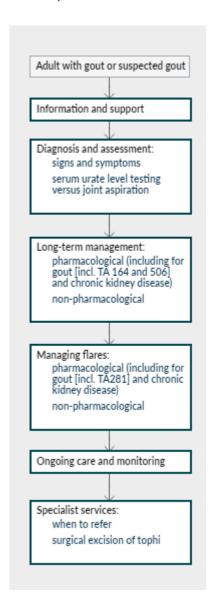
## 13 **4.1 NICE quality standards**

- 14 NICE quality standards that will use this guideline as an evidence source
- when they are being developed
- Gout. NICE quality standard. Publication date to be confirmed

## 17 **4.2 NICE Pathways**

- 18 NICE Pathways bring together everything we have said on a topic in an
- interactive flowchart. When this guideline is published, the recommendations
- will be included in the NICE Pathway on gout (in development).
- 21 Other relevant guidance will also be added, including:
- Lesinurad for treating chronic hyperuricaemia in people with gout (2018) NICE
- 23 technology appraisal guidance 506
- 24 Febuxostat for the management of hyperuricaemia in people with gout (2008)
- 25 NICE technology appraisal guidance 164
- 26 Canakinumab for treating gouty arthritis attacks and reducing the frequency of
- 27 subsequent attacks (2013) NICE technology appraisal 281 (terminated
- 28 appraisal)

- 1 An outline based on this scope is included below. It will be adapted, and more
- 2 detail added as the recommendations are written during guideline
- 3 development.



**Further information** 5 5

> This is the draft scope for consultation with registered stakeholders. The consultation dates are 19 December 2019 to 21 January 2020.

The guideline is expected to be published in March 2022.

You can follow progress of the guideline.

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Our website has information about how NICE guidelines are developed.

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