NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Guideline scope

Lyme disease: diagnosis and management

Topic

NHS England has asked NICE to develop guidance on the diagnosis and management of Lyme disease.

The guideline will be developed using the methods and processes outlined in Developing NICE guidelines: the manual.

For more information about why this guideline is being developed, and how the guideline will fit into current practice, see the context section.

Who the guideline is for

- People using services, families and carers and the public.
- Healthcare professionals in primary care.
- Healthcare professionals in secondary care, including physicians, microbiologists and infection specialists.

It may also be relevant for:

- Public health specialists.
- Local authorities.

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, Scottish Government, and Northern Ireland Executive.

Equality considerations

NICE will carry out an equality impact assessment during scoping. The assessment will:

- list equality issues identified, and how they have been addressed
- explain why any groups are excluded from the scope.

1 What the guideline is about

1.1 Who is the focus?

Groups that will be covered

- Adults, young people and children with suspected or confirmed Lyme disease.

1.2 Settings

Settings that will be covered

- All settings where NHS care is provided or commissioned.

1.3 Activities, services or aspects of care

Key areas that will be covered

1 Assessment (history and examination).

2 Diagnosis (first line investigations and confirmatory tests).

3 Management (e.g. treatment using antibiotics for early and late Lyme disease).

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

4 Information needs of people with suspected or confirmed Lyme disease.

Areas that will not be covered

5 Managing other tick-borne infections.

6 Managing chronic fatigue syndrome. This is covered by the NICE guideline: Chronic fatigue syndrome/myalgic encephalomyelitis (or encephalopathy) (CG53).

7 Transmission of the disease between people.

8 Preventing Lyme disease.

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 and personal social services (PSS) perspective, as appropriate.

1.5 Key issues and questions

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

1 In whom should Lyme disease be suspected?

2 Which symptoms or clinical signs should lead to:

- 2.1 Diagnostic testing to confirm or rule out Lyme disease?
- 2.2 Starting treatment?

3 What is the most clinically- and cost-effective test or combination of tests for diagnosing Lyme disease in different clinical scenarios or presentations? For example:

- 3.1 Early disease (less than 6 months from a tick bite or start of symptoms) with symptoms or signs.
- 3.2 Late disease (more than 6 months from a tick bite or start of symptoms) with or without symptoms or signs in people who have not had any previous treatment.
- 3.3 Early or late disease where a full course of definitive treatment has been completed but symptoms or signs have recurred.
- 3.4 Early or late disease where symptoms and signs have not resolved despite a full course of definitive treatment.

4 What is the best way to manage Lyme disease (e.g. with antibiotics) in different clinical scenarios and presentations? For example:

4.1 Early (less than 6 months from tick bite or start of symptoms) Lyme disease with symptoms or signs.

4.2 Late (more than 6 months from tick bite or start of symptoms) Lyme disease with or without symptoms in people who have not had any previous treatment.

4.3 Early or late disease where a full course of definitive treatment has been completed but symptoms or signs have recurred.

4.4 Early or late disease where symptoms and signs have not resolved despite a full course of definitive treatment.

4.5 Definite tick bite without symptoms or signs.

5 What information do people with suspected or confirmed Lyme disease need?

These review questions will be developed in more detail to guide the systematic review of the literature.

1.6 Main outcomes

The main outcomes that will be considered when searching for and assessing the evidence are:

1 Quality of life
2 Cure (resolution of symptoms).
3 Reduction of clinical symptoms
4 Symptom relapse
5 Adverse events
6 Resource use
7 Diagnostic test accuracy

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

2.1 NICE guidance

NICE guidance about the experience of people using NHS services

NICE has produced the following guidance on the experience of people using the NHS. This guideline will not include additional recommendations on these topics unless there are specific issues related to Lyme disease:

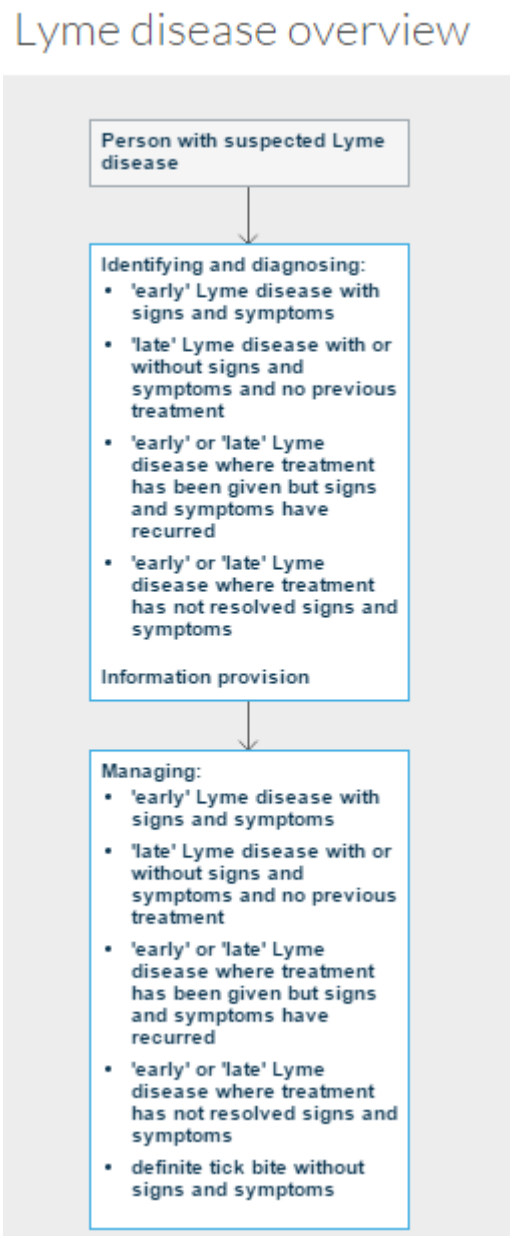
- Patient experience in adult NHS services (2012) NICE guideline CG138
- Service user experience in adult mental health (2011) NICE guideline CG136
- Medicines adherence (2009) NICE guideline CG76

2.2 NICE Pathways

NICE Pathways bring together all related NICE guidance and associated products on a topic in an interactive topic-based flow chart.

When this guideline is published, the recommendations will be incorporated into a new pathway on Lyme disease.

An outline of the new pathway, based on the scope, is included below. It will be adapted and more detail added as the recommendations are written during guideline development.



3 Context

3.1 Key facts and figures

Lyme disease (Lyme borreliosis) is a tick-borne infectious disease. It is caused by a specific group of *Borrelia burgdorferi* bacteria, which can be transmitted to humans through a bite from an infected tick.

Lyme disease can be asymptomatic. People may not notice or remember being bitten. There is a variable incubation period from a few days to 1 month and in approximately two-thirds of people this is followed by a circular, target-

like rash centred on the bite, known as erythema migrans. In the absence of this rash, diagnosis is often difficult because the early symptoms are similar to those for flu. These symptoms include aching, fever, headache, fatigue, sweating, joint pain, light and sound sensitivity, abnormal skin sensations and stiff neck. Lyme disease is frequently self-limiting and resolves spontaneously.

Early treatment reduces the risk of later symptoms developing, however, in some cases, symptoms persist after treatment (post-infectious Lyme disease). If Lyme disease does not resolve spontaneously, later symptoms of the infection can include joint pain and swelling, neurological problems and heart problems. Relapse has also been documented. There is controversy over the existence of 'chronic Lyme disease' or 'post Lyme disease' syndrome. Although early treatment is almost always successful, the best treatment in late-diagnosed cases is unknown and some people do not recover completely after the recommended course of antibiotics.

The true incidence of Lyme disease remains unknown. Public Health England estimates that between 2,000 and 3,000 people develop it each year in the UK, and a large proportion are not diagnosed.

Geographical location is an important risk factor. The distribution of confirmed cases varies by region, with over 50% diagnosed in the South East and South West of England. Ticks live in areas of overgrown vegetation and feed on wildlife. People who work or spend a lot of time outdoors in these areas are at increased risk of tick exposure. Infection is more likely if the tick remains attached to the skin for more than 24 hours.

3.2 Current practice

Diagnosis and assessment of Lyme disease is currently guided by Public Health England's suggested referral pathway for patients with symptoms related to Lyme disease. People presenting with an erythema migrans rash are assumed to have Lyme disease and treated with antibiotics. Those without a rash, but with symptoms suggestive of Lyme disease and at risk of tick exposure, have blood tests.

People with positive tests are treated. If the test is negative but symptoms persist, repeat samples are sent 3–4 weeks later.

If symptoms persist after treatment, the blood test is repeated to test for relapse and other causes are considered. Neurologists or infectious disease physicians are involved if there are significant neurological symptoms. Practitioners can liaise with the Rare and Imported Pathogens Laboratory staff for advice.

In England and Wales cases of laboratory-confirmed Lyme disease have increased significantly. This is thought to be as a result of better reporting, increased diagnostic testing, and increased awareness by the public and healthcare professionals, but care still needs to be improved. There is still limited understanding of the epidemiology, diagnostic tests and treatment options. Experience of typical cases is limited. In 2012, The James Lind Alliance published its top 10 research priorities (Lyme Disease). These included a focus on diagnosis, treatment options and the long-term consequences of the disease.

4 Further information

This is the draft scope for consultation with registered stakeholders. The consultation dates are 17 March to 14 April 2016.

The guideline is expected to be published in July 2018.

You can follow progress of the guideline.

Our website has information about how NICE guidelines are developed.