

**NATIONAL INSTITUTE FOR HEALTH AND CARE  
EXCELLENCE**

**Lyme disease**

**NICE quality standard**

**Draft for consultation**

February 2019

**This quality standard covers** assessing and managing Lyme disease in people of all ages. It describes high-quality care in priority areas for improvement.

**It is for** commissioners, service providers, health and public health practitioners and the public.

This is the draft quality standard for consultation (from 12 February to 12 March 2019). The final quality standard is expected to publish in July 2019.

## Quality statements

[Statement 1](#) People presenting with erythema migrans are diagnosed with Lyme disease by clinical assessment alone, without laboratory testing.

[Statement 2](#) People with an initial negative enzyme-linked immunosorbent assay (ELISA) test result for Lyme disease who were tested within 4 weeks of onset of symptoms, and who continue to have symptoms have a repeat ELISA test at 4 to 6 weeks after the first test.

[Statement 3](#) People with Lyme disease have antibiotic treatment, with the choice of antibiotic, dosage and duration determined by their symptoms and clinical presentation.

[Statement 4](#) Local authorities organise health promotion activities to raise public awareness about how to prevent Lyme disease.

NICE has developed guidance and a quality standard on patient experience in adult NHS services (see the NICE pathway on [patient experience in adult NHS services](#)), which should be considered alongside these quality statements.

Other quality standards that should be considered when commissioning or providing services for Lyme disease include:

- [Antimicrobial stewardship](#) (2016) NICE quality standard 121

A full list of NICE quality standards is available from the [quality standards topic library](#).

## Questions for consultation

### ***Questions about the quality standard***

**Question 1** Does this draft quality standard accurately reflect the key areas for quality improvement?

**Question 2** Are local systems and structures in place to collect data for the proposed quality measures? If not, how feasible would it be for these to be put in place?

**Question 3** Do you think each of the statements in this draft quality standard would be achievable by local services given the net resources needed to deliver them? Please describe any resource requirements that you think would be necessary for any statement. Please describe any potential cost savings or opportunities for disinvestment.

### ***Questions about the individual quality statements***

**Question 4** For draft statement 4: Should this statement be aimed at local authorities? If not, who should be organising health promotion activities to raise public awareness about how to prevent Lyme disease?

### ***Local practice case studies***

**Question 5** Do you have an example from practice of implementing the NICE guideline(s) that underpins this quality standard? If so, please submit your example to [NICE local practice case studies](#) on the NICE website. Examples of using NICE quality standards can also be submitted.

## Quality statement 1: Erythema migrans

### ***Quality statement***

People presenting with erythema migrans are diagnosed with Lyme disease by clinical assessment alone, without laboratory testing.

### ***Rationale***

Erythema migrans can be identified by clinical assessment. This skin rash is associated specifically with Lyme disease and so serological tests are not needed for diagnosis. Serological tests may not be helpful for diagnosis because they may be negative when the rash occurs. Prompt diagnosis and management of Lyme disease on the basis of erythema migrans helps reduce the risk of further symptoms developing.

### ***Quality measures***

#### **Structure**

a) Evidence of local arrangements to ensure that people presenting with erythema migrans are diagnosed with Lyme disease, without laboratory testing for Lyme disease.

**Data source:** Local data collection, for example, service specifications.

b) Evidence that healthcare professionals are trained to recognise symptoms of Lyme disease.

**Data source:** Local data collection, for example, audits of annual performance reviews and records of continuing professional development, such as completion of the [RCGP e-learning course](#).

#### **Process**

Proportion of people who present with erythema migrans who do not have laboratory testing for Lyme disease.

Numerator – the number in the denominator who do not have laboratory testing for Lyme disease.

Denominator – the number of people who present with erythema migrans.

**Data source:** Local data source, for example, an audit of patient records.

### **Outcome**

Proportion of people who are diagnosed with Lyme disease after presenting with erythema migrans.

Numerator – the number in the denominator with a diagnosis of Lyme disease.

Denominator – the number of people who present with erythema migrans.

**Data source:** Local data collection, for example, an audit of patient records.

### ***What the quality statement means for different audiences***

**Service providers** (such as general practice) have systems in place to ensure that people presenting with erythema migrans are diagnosed with Lyme disease, without having laboratory tests. They also ensure that GPs and other healthcare professionals are trained to recognise symptoms of Lyme disease, for example, through completion of the [RCGP e-learning course](#).

**Healthcare professionals** (such as GPs and practice nurses) diagnose people presenting with erythema migrans with Lyme disease, without ordering laboratory tests. They are trained to recognise symptoms of Lyme disease, which include erythema migrans, through, for example, completion of the [RCGP e-learning course](#).

**Commissioners** (NHS England) ensure that they commission services in which people presenting with erythema migrans are diagnosed with Lyme disease based on clinical assessment, without laboratory tests.

**People who go to their healthcare professional with a spreading red rash that is identified as ‘erythema migrans’** are diagnosed with Lyme disease from the rash alone and do not need to have blood tests.

## **Source guidance**

[Lyme disease](#) (2018) NICE guideline NG95, recommendation 1.2.11

## **Definition of terms used in this quality statement**

### **Erythema migrans**

Erythema migrans is a red rash, specific to Lyme disease, that increases in size and may sometimes have a central clearing. It is not usually itchy, hot or painful. It usually becomes visible from 1 to 4 weeks (but can appear from 3 days to 3 months) after a tick bite, and lasts for several weeks. It is usually at the site of a tick bite, and appears in around two-thirds of cases.

NICE has also produced a [resource](#) with images showing different presentations of erythema migrans.

[NICE's guideline on [Lyme disease](#), recommendation 1.2.1]

## **Equality and diversity considerations**

Healthcare professionals should be aware that it may be more difficult to identify erythema migrans in people from black, Asian and minority ethnic groups.

## Quality statement 2: Repeat ELISA tests

### ***Quality statement***

People with an initial negative enzyme-linked immunosorbent assay (ELISA) test result for Lyme disease who were tested within 4 weeks of onset of symptoms, and who continue to have symptoms have a repeat ELISA test at 4 to 6 weeks after the first test.

### ***Rationale***

The timing of the initial ELISA test is crucial in diagnosing Lyme disease if diagnosis is not based on clinical presentation. If the test is performed too early (within 4 weeks of symptom onset) people may not have developed antibodies to the bacteria that causes Lyme disease. People with a negative ELISA test result who continue to have symptoms may have had the test too early. Repeating the test at 4 to 6 weeks after the first test helps to ensure an accurate diagnosis.

### ***Quality measures***

#### **Structure**

Evidence of local arrangements to ensure that people who had an initial ELISA test within 4 weeks of their symptoms starting and have a negative result are retested at 4 to 6 weeks after the first test if they continue to have symptoms of Lyme disease.

**Data source:** Local data collection, for example, service specifications and written clinical protocols.

#### **Process**

Proportion of people with an initial negative ELISA test result for Lyme disease who were tested within 4 weeks of onset of symptoms, and who continue to have symptoms have a repeat ELISA at 4 to 6 weeks after the first test.

Numerator – the number in the denominator who have a repeat ELISA test at 4 to 6 weeks after the first test.

Denominator – the number of people with an initial negative ELISA test result for Lyme disease who were tested within 4 weeks of onset of symptoms, and who continue to have symptoms.

**Data source:** Local data collection, for example, an audit of patient records.

### ***What the quality statement means for different audiences***

**Service providers** (such as primary care and local microbiology laboratories) have local arrangements in place to ensure that people with an initial negative ELISA test result for Lyme disease who were tested within 4 weeks of onset of symptoms, and continue to have symptoms have the test repeated at 4 to 6 weeks after the first test if their symptoms continue. If there is no local diagnostic service, the sample is tested at the Rare and Imported Pathogens Laboratory (RIPL).

**Healthcare professionals** (such as GPs and clinicians in secondary care) repeat an ELISA test at 4-6 weeks after the first test for people with an initial negative ELISA test result for Lyme disease who were tested within 4 weeks of onset of symptoms, and continue to have symptoms. They are aware of local arrangements to support ordering the repeat test.

**Commissioners** (such as clinical commissioning groups and NHS England) commission local microbiology laboratory services to perform an ELISA test at 4-6 weeks after the first test for people with an initial negative ELISA test result for Lyme disease who were tested within 4 weeks of onset of symptoms, and continue to have symptoms. If there is no local diagnostic service, the sample is tested at the Rare and Imported Pathogens Laboratory (RIPL).

**People who had a negative blood test for Lyme disease in the 4 weeks after their symptoms began but continue to have symptoms** have another blood test 4 to 6 weeks after their first test when they return to their doctor. This helps to ensure that the person gets the correct diagnosis and treatment.

### ***Source guidance***

[Lyme disease](#) (2018) NICE guideline NG95, recommendation 1.2.17



## ***Definition of terms used in this quality statement***

### **Initial ELISA test for Lyme disease**

People without erythema migrans in whom Lyme disease is suspected have an ELISA test for Lyme disease. The timing of the initial ELISA test is important. If the test is carried out too early (within 4 weeks of symptoms starting) it may have been too soon for antibodies to have developed, resulting in a 'false negative' result. Repeating serological testing at a later point allows time for antibody response.

[NICE's guideline on [Lyme disease](#), recommendation 1.2.17, [Lyme disease](#) (full guideline), evidence reviews for diagnostic tests, and expert opinion].

## Quality statement 3: Antibiotic treatment

### ***Quality statement***

People with Lyme disease have antibiotic treatment, with the choice of antibiotic, dosage and duration determined by their symptoms and clinical presentation.

### ***Rationale***

Prompt treatment of Lyme disease with an antibiotic at adequate dosage and duration, chosen according to the person's symptoms and clinical presentation, will stop or reduce the symptoms of Lyme disease and may also prevent the relapse of symptoms. Prompt and standardised antibiotic treatment, determined by the person's symptoms and clinical presentation, also offers reassurance to people who have ongoing symptoms.

### ***Quality measures***

#### **Structure**

Evidence that local formularies align with NICE's recommendations on antibiotic treatment for Lyme disease so that healthcare professionals in primary and secondary care prescribe an antibiotic to people with Lyme disease according to their symptoms.

**Data source:** Local data collection, for example, local formularies.

#### **Process**

Proportion of people diagnosed with Lyme disease who are given the correct antibiotic for their symptoms and clinical presentation.

Numerator – the number in the denominator who are given the correct antibiotic for their symptoms and clinical presentation.

Denominator – the number of people diagnosed with Lyme disease.

**Data source:** Local data collection, for example, a case note review of patient records.

b) Proportion of people diagnosed with Lyme disease who are given the correct antibiotic for their symptoms and clinical presentation at the recommended dosage.

Numerator – the number in the denominator who are given the correct antibiotic for their symptoms and clinical presentation at the recommended dosage.

Denominator – the number of people diagnosed with Lyme disease.

**Data source:** Local data collection, for example, a case note review of patient records.

c) Proportion of people diagnosed with Lyme disease who are given the correct antibiotic for their symptoms and clinical presentation for the recommended duration.

Numerator – the number in the denominator who are given the correct antibiotic for their symptoms and clinical presentation for the recommended duration.

Denominator – the number of people diagnosed with Lyme disease.

**Data source:** Local data collection, for example, a case note review of patient records.

### **Outcome**

Proportion of people with Lyme disease treated with antibiotics whose symptoms have resolved or improved.

Numerator – the number in the denominator whose symptoms have resolved or improved.

Denominator – the number of people diagnosed with Lyme disease who have had a course of antibiotics.

**Data source:** Local data collection, for example, a case note review of patient records.

### ***What the quality statement means for different audiences***

**Service providers** (primary care and NHS hospital trusts) ensure they develop or have access to a local antibiotic formulary that is aligned with NICE's

recommendations on antibiotic treatment according to symptoms and clinical presentation for Lyme disease.

**Healthcare professionals** (such as GPs, prescribers in A&E departments, and specialists in secondary and tertiary care) treat diagnosed Lyme disease with antibiotics. They use the person's symptoms and clinical presentation to determine the antibiotic, dosage and duration.

**Commissioners** (such as NHS England and clinical commissioning groups) ensure that service specifications require antibiotic treatment according to symptoms and clinical presentation for people diagnosed with Lyme disease.

**People diagnosed with Lyme disease** have antibiotic treatment that is chosen according to their symptoms. This is to make sure that they are given the correct antibiotics at the right dose and for long enough to treat their symptoms.

### ***Source guidance***

[Lyme disease](#) (2018) NICE guideline NG95, recommendations 1.3.4, 1.3.5 and 1.3.11.

### ***Definition of terms used in this quality statement***

#### **Antibiotic treatment according to their symptoms**

Recommended antibiotics, dosages and duration of initial treatment of Lyme disease, according to the person's symptoms and clinical presentation, are given in [tables 1 and 2](#) of NICE's guideline on Lyme disease. [NICE's guideline on [Lyme disease](#), recommendations 1.3.4 and 1.3.5]

## Quality statement 4: Awareness of Lyme disease

### ***Quality statement***

Local authorities organise health promotion activities to raise public awareness about how to prevent Lyme disease.

### ***Rationale***

Increasing public knowledge of Lyme disease and how to reduce the risk of infection will help to prevent Lyme disease. This includes raising awareness of tick habitats, which is important because infected ticks can be found throughout the UK, including urban parks. Other information to support prevention includes recommended methods of tick removal, checking the skin for ticks, wearing clothes that do not expose the skin, and using tick repellents.

### ***Quality measures***

#### **Structure**

Evidence of local arrangements to promote awareness of how to prevent Lyme disease.

**Data source:** Local data collection, for example, displaying or providing copies of Public Health England's [toolkit and resources for local authorities](#) to raise awareness of the potential risks caused by ticks and tick-borne disease in England.

#### **Outcome**

Incidence of Lyme disease.

**Data source:** Local data collection, for example, an audit of patient records. Public Health England publishes statistics on Lyme disease confirmed through laboratory testing. The number of cases is reported by region each quarter: [Common animal-associated infections quarterly reports](#).

### ***What the quality statement means for different audiences***

**Public health practitioners** ensure that they implement local authority awareness-raising activities about the potential risks of tick bites and tick-borne disease, and

how to reduce the risk. Activities could include providing up-to-date leaflets, posters for display in local GP practices, online information (including social media) and organising outreach events tailored to local needs. Activities are timed to coincide with periods associated with a higher risk of tick exposure, and with other relevant local public health events.

**Commissioners** (local authorities) ensure that they provide up-to-date, consistent and coordinated information about Lyme disease, such as Public Health England's [toolkit and resources for local authorities](#), to raise awareness of the potential risks of tick bites and tick-borne disease, and how to reduce the risk. They support and monitor local activities.

### ***Source guidance***

[Lyme disease](#) (2018) NICE guideline NG95, recommendation 1.1.3

### ***Equality and diversity considerations***

Information should be in a format that suits people's needs and preferences. It should be accessible to people who do not speak or read English, and it should be culturally appropriate and age appropriate.

For people with additional needs related to a disability, impairment or sensory loss, information should be provided as set out in NHS England's [Accessible Information Standard](#).

### ***Question for consultation***

Should this statement be aimed at local authorities? If not, who should be organising health promotion activities to raise public awareness about how to prevent Lyme disease?

## About this quality standard

NICE quality standards describe high-priority areas for quality improvement in a defined care or service area. Each standard consists of a prioritised set of specific, concise and measurable statements. NICE quality standards draw on existing NICE or NICE-accredited guidance that provides an underpinning, comprehensive set of recommendations, and are designed to support the measurement of improvement.

Expected levels of achievement for quality measures are not specified. Quality standards are intended to drive up the quality of care, and so achievement levels of 100% should be aspired to (or 0% if the quality statement states that something should not be done). However, this may not always be appropriate in practice. Taking account of safety, shared decision-making, choice and professional judgement, desired levels of achievement should be defined locally.

Information about [how NICE quality standards are developed](#) is available from the NICE website.

See [quality standard advisory committees](#) on the website for details of standing committee 1 members who advised on this quality standard. Information about the topic experts invited to join the standing members is available on the [quality standard's webpage](#).

This quality standard has been included in the NICE Pathway on [Lyme disease](#), which brings together everything we have said on a topic in an interactive flowchart.

NICE has produced a [quality standard service improvement template](#) to help providers make an initial assessment of their service compared with a selection of quality statements. This tool is updated monthly to include new quality standards.

NICE produces guidance, standards and information on commissioning and providing high-quality healthcare, social care, and public health services. We have agreements to provide certain NICE services to Wales, Scotland and Northern Ireland. Decisions on how NICE guidance and other products apply in those countries are made by ministers in the Welsh government, Scottish government, and Northern Ireland Executive. NICE guidance or other products may include references

to organisations or people responsible for commissioning or providing care that may be relevant only to England.

### ***Improving outcomes***

This quality standard is expected to contribute to improvements in the following outcomes:

- quality of life of people with Lyme disease
- public awareness of Lyme disease
- patient experience of people with Lyme disease in primary, secondary and tertiary care services

It is also expected to support delivery of the Department of Health and Social Care outcome frameworks:

- [NHS outcomes framework](#)
- [Public health outcomes framework for England](#).

### ***Resource impact***

NICE quality standards should be achievable by local services. The potential resource impact is considered by the quality standards advisory committee, drawing on resource impact work for the source guidance. Organisations are encouraged to use the [resource impact statement](#) for the source guidance to help estimate local costs.

### ***Diversity, equality and language***

During the development of this quality standard, equality issues were considered and [equality assessments](#) are available. Any specific issues identified during development of the quality statements are highlighted in each statement.

Commissioners and providers should aim to achieve the quality standard in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity and foster good relations. Nothing in this quality standard should be interpreted in a way that would be inconsistent with compliance with those duties.



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