**NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE**

**Health Technology Evaluation**

# Ianalumab for treating active Sjogren's syndrome ID6634

**Draft scope**

## Draft remit/evaluation objective

To appraise the clinical and cost effectiveness of ianalumab within its anticipated marketing authorisation for treating active Sjogren's syndrome.

## Background

Sjogren's syndrome is a chronic inflammatory and autoimmune disorder characterised by dry eyes (keratoconjunctivitis sicca) and dry mouth (xerostomia) due to lymphocytic infiltration of the tear and salivary glands. Symptoms can also include dryness of the skin, nose, throat, vagina; joint and muscle pain; peripheral neuropathies; pulmonary, thyroid, and renal disorders; fatigue, low mood; and impaired concentration.[1,2] Sjogren's syndrome can occur alone (primary) or in association with other autoimmune conditions (secondary), such as lupus, rheumatoid arthritis, and systemic sclerosis.[1]

Sjogren's syndrome is the second most common autoimmune rheumatic condition in the UK. It affects approximately 0.6% of adults, of whom 90% are women, with a mean age of 50 years.[2]

The reported incidence and prevalence of Sjogren's syndrome vary depending on the classification criteria, study design, location, and population studied. A global systematic review and meta-analysis estimated the incidence of primary Sjogren's syndrome to be 5 to 7 per 100,000 person-years. Prevalence estimates from the same analysis vary, with pooled estimates from population-based studies reporting around 40 per 100,000 people, although higher estimates have been reported in other study designs. Secondary Sjogren's syndrome occurs in a proportion of people with other autoimmune conditions, with pooled prevalence estimates from a global systematic review and meta-analysis of approximately 19.5% (95% CI 11.2 to 27.8) in rheumatoid arthritis, and around 14% (95% CI 8.88 to 19.04) in systemic lupus erythematosus, and is also more common in women. There is reported overlap with systemic sclerosis.[1]

Although common, Sjogren's syndrome is often underdiagnosed, and frequently untreated. Systemic complications include arthritis; Raynaud's syndrome; pulmonary, renal, or neurological issues; and mucosa-associated lymphoid tissue (MALT) lymphoma.[1]

Current treatment is largely focused on managing glandular symptoms and systemic manifestations. Lifestyle changes may help with some symptoms such as fatigue and gastrointestinal reflux. Dry eye can be treated with artificial tear substitutes, ciclosporin eye drops, intermittent corticosteroid eye drops, and cholinergic drugs to stimulate tear secretion, with adjunctive measures including spectacle eye shields, punctal plugs, or permanent punctal occlusion. Dry mouth is managed mainly with supportive measures, such as saliva substitutes, oral lubricants, and cholinergic agents, including cevimeline and pilocarpine.[1]

Systemic treatment for extraglandular manifestations is individualised. Musculoskeletal symptoms may be initially managed with simple analgesics. Hydroxychloroquine is used as a first-line disease-modifying anti-rheumatic drug (DMARD) for inflammatory musculoskeletal pain, with methotrexate or other DMARDs (including azathioprine, leflunomide, sulfasalazine, or ciclosporin) and oral corticosteroids may be considered. There are no specific treatments for fatigue, but hydroxychloroquine may be considered if needed. Vasculitis is typically treated with corticosteroids, with intravenous immunoglobulin or rituximab considered in more severe or refractory cases. Less common complications include renal tubular acidosis and peripheral neuropathy.[1]

Sjogren's syndrome affects each person differently, and there are currently no medications that conclusively slow the progression of Sjogren's syndrome or treat all aspects of the condition.[3]

Deucravacitinib for treating active Sjogren's syndrome is currently under NICE evaluation.

**The technology**

Ianalumab (brand name unknown, Novartis) does not currently have a marketing authorisation in the UK for active Sjogren's syndrome. It has been studied in clinical trials compared with placebo in adults with active Sjogren's syndrome.

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| **Intervention(s)** | Ianalumab |
| **Population(s)** | Adults with active Sjogren's syndrome |
| **Comparators** | • Deucravacitinib (subject to NICE evaluation)<br>• Best supportive care |
| **Outcomes** | The outcome measures to be considered include:<br>• disease activity<br>• patient-reported symptoms<br>• glandular function<br>• fatigue<br>• adverse effects of treatment<br>• health-related quality of life. |

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| **Economic analysis** | The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year.<br><br>The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared.<br><br>Costs will be considered from an NHS and Personal Social Services perspective.<br><br>The availability of any commercial arrangements for the intervention, comparator and subsequent treatment technologies will be taken into account.<br><br>The cost effectiveness analysis should include consideration of the benefit in the best and worst seeing eye. |
| **Other considerations** | Guidance will only be issued in accordance with the marketing authorisation. Where the wording of the therapeutic indication does not include specific treatment combinations, guidance will be issued only in the context of the evidence that has underpinned the marketing authorisation granted by the regulator. |
| **Related NICE recommendations** | None.<br><br>**Related technology appraisals in development:**<br><br>Deucravacitinib for treating active Sjogren's syndrome. NICE technology appraisal guidance [ID6715] Publication date to be confirmed. |

**Questions for consultation**

What interventions and components of care should be considered as part of best supportive care for Sjogren's syndrome in NHS clinical practice?

Are there any additional comparators that should be considered relevant to NHS clinical practice?

Where do you consider ianalumab will fit into the existing care pathway for active Sjogren's syndrome?

Please select from the following, will ianalumab be:
A. Prescribed in primary care with routine follow-up in primary care
B. Prescribed in secondary care with routine follow-up in primary care
C. Prescribed in secondary care with routine follow-up in secondary care
D. Other (please give details):

For comparators and subsequent treatments, please detail if the setting for prescribing and routine follow-up differs from the intervention.

Would ianalumab be a candidate for managed access?

Do you consider that the use of ianalumab can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation?

Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits.

Please indicate if any of the treatments in the scope are used in NHS practice differently than advised in their Summary of Product Characteristics. For example, if the dose or dosing schedule for a treatment is different in clinical practice. If so, please indicate the reasons for different usage of the treatment(s) in NHS practice. If stakeholders consider this a relevant issue, please provide references for data on the efficacy of any treatments in the pathway used differently than advised in the Summary of Product Characteristics.

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the proposed remit and scope may need changing in order to meet these aims. In particular, please tell us if the proposed remit and scope:

- could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which ianalumab will be licensed;
- could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology;
- could have any adverse impact on people with a particular disability or disabilities.

Please tell us what evidence should be obtained to enable the committee to identify and consider such impacts.

NICE intends to evaluate this technology through its Single Technology Appraisal process. (Information on NICE's health technology evaluation processes is available at https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/changes-to-health-technology-evaluation).

**References**

1. BMJ Best Practice (2025) Sjogren syndrome (accessed November 2025)
2. Sjögren's UK (2025) Sjögren's (SHOW-grins) (accessed November 2025)
3. Sjögren's Foundation (2025) Treatment (accessed November 2025)