NICE National Institute for Health and Care Excellence

Putting NICE guidance into practice

Resource impact report:
TNF alpha inhibitors for ankylosing spondylitis and non-radiographic axial spondyloarthritis (including a review of TA143 and TA233) (TA383)

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Summary

The guidance recommends adalimumab, certolizumab pegol, etanercept, golimumab and infliximab as options for treating severe active ankylosing spondylitis in adults and adalimumab, certolizumab pegol and etanercept as options for treating severe non-radiographic axial spondyloarthritis (nrAS) in adults. This is subject to conditions as set out in section 1.2.

No significant costs are expected for the ankylosing spondylitis patient group as a result of implementing the guidance. Significant costs are expected for the nrAS patient group.

It is estimated that 20,200 people with nrAS are eligible for treatment with TNF-alpha inhibitors. It is estimated that around 6,100 people with nrAS will have treatment with TNF-alpha inhibitors from year 7 onwards.

The estimated annual cost of implementing this guidance for the population of England based on the uptake in the resource impact assumptions is shown in table 1.

Table 1 Estimated annual cost of implementing the guidance

	2016/17	**2017/18**	**2018/19**	**2019/20**	**2020/21**	**2021/22**	**2022/23**
Population with nrAS having TNF-alpha inhibitor treatment each year	1,331	3,121	4,169	5,140	6,000	6,071	6,071
Cost impact each year for people with nrAS £(000s)	7,574	26,759	38,799	49,598	59,185	60,443	60,295

Merck Sharp & Dohme has agreed a patient access scheme with the Department of Health. This will make the 100 mg dose of golimumab available to the NHS at the same cost as the 50 mg dose. UCB Pharma has agreed a patient access scheme with the Department of Health. UCB Pharma will provide the first 12 weeks of certolizumab pegol free of charge, which is equivalent to 10 vials.

The technology appraisal includes 5 different biological medicines including inflimixab for which there is an originator biological medicine and 2 biosimilar products available in the NHS.

This report is supported by a resource impact template which may be used to calculate the resource impact of implementing the guidance by amending the variables.

This technology is commissioned by clinical commissioning groups. Providers are NHS hospital trusts.

Introduction

1.1 This report looks at the resource impact of implementing the NICE guidance on TNF alpha inhibitors for ankylosing spondylitis and non-radiographic axial spondyloarthritis (including a review of TA143 and TA233) in England.

1.2 The guidance states that:

> Adalimumab, certolizumab pegol, etanercept, golimumab and infliximab are recommended, within their marketing authorisations, as options for treating severe active ankylosing spondylitis in adults whose disease has responded inadequately to, or who cannot tolerate, non-steroidal anti-inflammatory drugs.
>
> Infliximab is recommended only if treatment is started with the least expensive infliximab product. People currently receiving infliximab should be able to continue treatment with the same infliximab product until they and their NHS clinician consider it appropriate to stop.
>
> Adalimumab, certolizumab pegol and etanercept are recommended, within their marketing authorisations, as options for treating severe non-radiographic axial spondyloarthritis in adults whose disease has responded inadequately to, or who cannot tolerate, non-steroidal anti-inflammatory drugs.
>
> The choice of treatment should be made after discussion between the clinician and the patient about the advantages and disadvantages of the treatments available. This may include considering associated conditions such as extra-articular manifestations. If more than 1 treatment is suitable, the least expensive (taking into account administration costs and patient access schemes) should be chosen.

The response to adalimumab, certolizumab pegol, etanercept, golimumab or infliximab treatment should be assessed 12 weeks after the start of treatment. Treatment should only be continued if there is clear evidence of response, defined as:

- a reduction in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score to 50% of the pre-treatment value or by 2 or more units and
- a reduction in the spinal pain visual analogue scale (VAS) by 2 cm or more.

Treatment with another tumour necrosis factor (TNF)-alpha inhibitor is recommended for people who cannot tolerate, or whose disease has not responded to, treatment with the first TNF alpha inhibitor, or whose disease has stopped responding after an initial response.

When using BASDAI and spinal pain VAS scores, healthcare professionals should take into account any physical, sensory or learning disabilities, or communication difficulties that could affect the responses to the questionnaires, and make any adjustments they consider appropriate.

1.3 NICE has previously appraised TNF-alpha inhibitor treatments for ankylosing spondylitis (TA143 and TA233). Certolizumab pegol and infliximab are additional alternative options for this patient group. There are no significant costs anticipated for this patient group because there are no changes in the anticipated uptake from this group. The resource impact report considers the resource impact for treating nrAS.

1.4 Merck Sharp & Dohme has agreed a patient access scheme with the Department of Health. This will make the 100 mg dose of golimumab available to the NHS at the same cost as the 50 mg dose. UCB Pharma has agreed a patient access scheme with the Department of Health. UCB Pharma will provide the first 12 weeks

of certolizumab pegol free of charge, which is equivalent to 10 vials.

1.5 This report is supported by a resource impact template. The template aims to help organisations in England, Wales and Northern Ireland plan for the financial implications of implementing the NICE guidance by amending the variables.

1.6 This technology is commissioned by clinical commissioning groups. Providers are NHS hospital trusts.

2 Background and epidemiology of Ankylosing spondylitis and non-radiographic axial spondyloarthritis

2.1 Ankylosing spondylitis and non-radiographic axial spondyloarthritis are part of a group of clinically heterogeneous inflammatory rheumatologic diseases known as spondyloarthritis. Spondyloarthritis can be categorised as having either predominantly axial (sacroiliac joints or spine) or peripheral involvement. In people with axial spondyloarthritis, the predominant symptom is back pain with inflammation of the sacroiliac joints (sacroiliitis) or the spine, or both. The onset of symptoms typically occurs in the third decade of life. Damage is progressive and irreversible and there is increased risk of spinal fracture later in life. There may also be peripheral joint involvement or extra-articular manifestations such as uveitis, inflammatory bowel disease and psoriasis.

2.2 Disease is classified as ankylosing spondylitis if changes to the sacroiliac joints or the spine, or both, can be seen on X-ray. These include erosions, sclerosis (thickening of the bone), and partial or total ankylosis (fusion of joints). The prevalence of ankylosing

spondylitis is thought to range from 0.05% to 0.23% and it is about 3 times more common in men than in women.

2.3 Not everyone with symptoms of axial spondyloarthritis will have changes that can be seen on X-ray. Disease is then classified as axial spondyloarthritis without radiographic evidence of ankylosing spondylitis (non-radiographic axial spondyloarthritis). Sacroiliitis or inflammation of the spine may be visible on MRI. Limited epidemiological data are available for non-radiographic axial spondyloarthritis, but it affects about equal numbers of men and women.

2.4 Conventional therapy for ankylosing spondylitis and non-radiographic axial spondyloarthritis includes non-steroidal anti-inflammatory drugs and physiotherapy. Tumour necrosis factor (TNF) alpha inhibitors (adalimumab, certolizumab pegol, etanercept, golimumab and infliximab) are typically used when the disease has not responded adequately to conventional therapy.

2.5 Table 2 sets out the population with nrAS in England eligible for treatment with TNF-alpha inhibitors.

Table 2 Number of people with nrAS eligible for treatment in England

Population	Proportion	Number of people
Total adult population in England		41,766,418
Prevalence of nrAS	0.15%	62,650
Of these, people meeting BSR guidelines for TNF-alpha inhibitors treatment	38.00%	23,807
Those not contraindicated for TNF-alpha inhibitors treatment	85.00%	20,236
Of these, people who are likely to continue using TNF-alpha inhibitors	30.00%	6,071
Total number of people estimated to have TNF-alpha inhibitor treatment each year from year 7		6,071

2.6 Therefore it is estimated that approximately 20,200 people are eligible for treatment with TNF-alpha inhibitors each year.

2.7 From year 7 it is estimated that 6,100 people will have treatment with TNF-alpha inhibitors each year once uptake has reached 30%. This would be equivalent to 11 people per 100,000 population.

3 Assumptions made

3.1 The resource impact template makes the following assumptions:

- It is assumed that when the guidance is fully implemented, all of the people in the group likely to continue using TNF-alpha inhibitors would switch TNF-alpha inhibitor if one did not work for them.
- It is assumed that there around 10% of people with nrAS likely to continue using TNF-alpha inhibitors are already receiving this treatment.

- Current and future uptake assumptions are based on clinical expert opinion.
- Clinical expert opinion estimates that around 30% of the population eligible for treatment with TNF-alpha inhibitors would receive the treatment.

4 Resource impact

4.1 The annual cost associated with implementing the guidance for the population of England is shown in table 3 below. The cost from year 7 once steady state reached is equivalent to £60.3 million.

Table 3 Resource impact of implementing the guidance for the population of England using NICE assumptions

	2016/ 17	2017/ 18	2018/ 19	2019/ 20	2020/ 21	2021/ 22	2022/ 23
Population with nrAS having TNF-alpha inhibitor treatment each year	1,331	3,121	4,169	5,140	6,000	6,071	6,071
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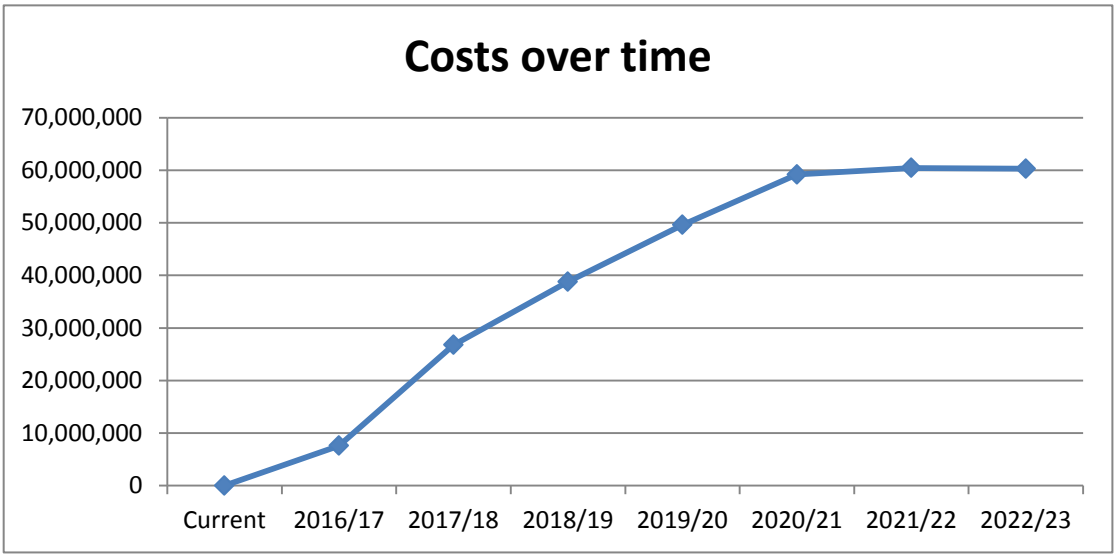

5 Savings and benefits

5.1 There are benefits to people receiving the treatments. Patient experts reported that use of TNF-alpha inhibitors to treat nrAS had completely changed some people's lives by restoring mobility and reducing pain, and allowing people to continue working and fulfil parental and carer duties.

5.2 People with nrAS may need fewer hospital admissions, for flares of extra articular manifestations and complications of NSAIDS, as a result of treatment with TNF-alpha inhibitors.

5.3 People with nrAS can need help with social care needs. This need is met by both unpaid carers, such as relatives, and paid carers. When people with nrAS are treated with TNF-alpha inhibitors this need may be reduced. As the nature of the care needed and the source of care are variable, it is not possible to provide a national cost for this.

6 Implications for commissioners

6.1 Ankylosing spondylitis and non-radiographic axial spondyloarthritis fall within the programme budgeting category 15X Problems of the Musculo skeletal system.

6.2 Adalimumab, certolizumab pegol, etanercept are high cost drugs and as such are excluded from PBR tariff.

About this resource impact report

This resource impact report accompanies the NICE technology appraisal guidance on Ankylosing spondylitis and axial spondyloarthritis (non-radiographic) - adalimumab, etanercept infliximab and golimumab (inc rev TA143 and TA233) and should be read in conjunction with it. See terms and conditions on the NICE website.

This report is written in the following context

This report represents the view of NICE, which was arrived at after careful consideration of the available data and through consulting healthcare professionals. The report is an implementation tool and focuses on the recommendations that were considered to have a significant impact on national resource use.

Assumptions used in the report are based on assessment of the national average. Local practice may be different from this, and the impact should be estimated locally.

Implementation of the guidance is the responsibility of local commissioners and providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, 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 costing tool should be interpreted in a way that would be inconsistent with compliance with those duties.