TNF-alpha inhibitors for ankylosing spondylitis and non-radiographic axial spondyloarthritis (including a review of TA143 and TA233) – MTA Economic Value Document for Inflectra™ (infliximab)

19/06/2015

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1. Ankylosing spondylitis

1.1. Introduction

Adalimumab, etanercept, golimumab and infliximab (Remicade and Inflectra) have marketing authorisations in the UK for the treatment of adults with severe active ankylosing spondylitis that has responded inadequately to conventional therapy. Certolizumab pegol has a marketing authorisation in the UK for the treatment of 'adults with severe active ankylosing spondylitis who have had an inadequate response to, or are intolerant to, nonsteroidal anti-inflammatory drugs'.

It is anticipated that implementing the draft positive recommendations (detailed in the ACD, May 2015) for the ongoing appraisal [ID694] (NICE, 2015), may lead to increased treatment costs due to the increased number of patients with ankylosing spondylitis receiving TNF-α inhibitors. The average lifetime treatment costs for adults, taking into account drug costs, administration costs and monitoring costs per 12-week cycle, are presented for conventional therapy and TNF-α inhibitors (**Table 1**).

The incremental cost for treatment with proprietary infliximab (Remicade) compared with conventional therapy is £40,267. Costs for treatment with infliximab may change if biosimilars become available as a result of lower drug costs:

i. The list price of the biosimilar infliximab Inflectra, is lower than that of the proprietary infliximab (Remicade).

ii. There is also potential for additional cost savings associated with Inflectra versus all comparators, due to the provision of Inflectra on NHS tender frameworks at prices lower than the NHS list price.

There are differences in price between tender regions as the prices are based on the current market size for infliximab. The lowest Inflectra in-market tender price of ([redacted]) is at [redacted] discount off the proprietary infliximab (Remicade) list price; the highest Inflectra in-market price [redacted] is at [redacted] discount off the proprietary infliximab (Remicade) list price.

The NHS tendering process is complete and the in-market prices are nationally available within the range of [redacted] and [redacted] discount off the proprietary infliximab (Remicade) list price.

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Each NHS tender region applies different timeframes to the tender frameworks. In this case the shortest framework is 10 months and the longest 24 months. The Commercial Medicines Unit issues re tender information towards the end of each framework period.

Differences in cost between Inflectra and proprietary infliximab (Remicade) are due to drug costs alone, not due to dosing, as the treatment schedule is the same for both drugs, as stated below:

- 5 mg/kg given as an intravenous infusion followed by additional 5 mg/kg infusion doses at 2 and 6 weeks after the first infusion, then every 6 to 8 weeks.
- If a patient does not respond by 6 weeks (i.e. after 2 doses), no additional treatment with infliximab should be given.

This document presents the results of cost-effectiveness analyses conducted using both the list and tender prices of Inflectra within the Assessment Group's model, in order to provide a representation of the actual cost to the NHS of using Inflectra in clinical practice for the treatment of severe active ankylosing spondylitis.

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1.2. Economic considerations

Cost-effectiveness analyses conducted using the assessment group model indicated that among TNF-α inhibitors, proprietary infliximab (Remicade) has the highest treatment costs resulting in the highest incremental cost effectiveness ratio (ICER) compared with conventional therapy. In **Table 1**, the cost shown for Inflectra is the NHS list price, which is lower than the list price for proprietary infliximab (Remicade).

Cost-effectiveness analyses conducted using a price for Inflectra that incorporates a 40% discount to discount to the list price of proprietary infliximab results in treatment costs that are comparable to the to the other TNF-α inhibitors. The resulting ICER for Inflectra is comparable to that of the other TNF-α TNF-α inhibitors, and is lower than the ICER for proprietary infliximab (**Table 2**). These outcomes are also obtained when the price used for Inflectra is the lowest tendered price (

Table 2: Inflectra at 40% discount to Remicade price

Treatment	Mean QALYs	Inc QALYs	Mean Costs	Inc Costs	ICER
Conventional Therapy	7.231		106,486		
Certolizumab Pegol PAS	7.835	0.605	126,987	20,500	33,900
Golimumab	7.835	0.605	128,669	22,183	36,681
Adalimumab	7.835	0.605	128,754	22,267	36,821
Etanercept	7.835	0.605	129,132	22,645	37,447
Certolizumab Pegol	7.835	0.605	130,560	24,074	39,809
Infliximab – biosimilar (Inflectra)	7.835	0.605	[redacted]	[redacted]	[redacted]
Infliximab – proprietary (Remicade)	7.835	0.605	146,754	40,267	66,586

Note: All costs shown are based on the dose for an adult of 73 kg. QALY, Quality-adjusted Life Year; ICER, Incremental Cost Effectiveness Ratio, PAS, patient access scheme

Table 3), the highest tendered price (**Table 4**), or the average tendered price in the UK (**Table 5**).

Table 1: Inflectra List Price

Treatment	Mean QALYs	Inc QALYs	Mean Costs	Inc Costs	ICER
Conventional Therapy	7.231		106,486		
Certolizumab Pegol PAS	7.835	0.605	126,987	20,500	33,900
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Table 3: Inflectra at lowest tendered price

Treatment	Mean QALYs	Inc QALYs	Mean Costs	Inc Costs	ICER
Conventional Therapy	7.231		106,486		
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Infliximab – biosimilar (Inflectra)	7.835	0.605	[redacted]	[redacted]	[redacted]
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Table 4: Inflectra at highest tendered price

Treatment	Mean QALYs	Inc QALYs	Mean Costs	Inc Costs	ICER
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Table 5: Inflectra at average tendered price

Treatment	Mean QALYs	Inc QALYs	Mean Costs	Inc Costs	ICER
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1.3 Conclusions

At the NHS list price for Inflectra, treatment costs remain lower than for proprietary infliximab (Remicade) (**Table 1**).

We suggest that the Assessment Group consider Inflectra in-market tender prices in the appraisal as they represent the actual cost to the NHS in clinical practice. This approach was taken in the NICE technology appraisal of erythropoiesis‑stimulating agents (ESAs) [TA323]; (NICE, 2014). In a scenario analysis, the Assessment Group applied the best contract prices available for the ESAs to its base-case analysis, rather than the prices listed on the British National Formulary. The Committee concluded that the contract prices of the ESAs were the most relevant prices as they reflected the actual prices paid by the NHS for ESAs based on a 'price‑volume' agreement with the companies (NICE, 2014).

Using the conservative approach of the lowest discounted tender price available across the UK, UK, Inflectra is cost saving versus proprietary infliximab (Remicade) (**Table 4**). Using the highest discounted tender price, Inflectra represents even greater value for money to the NHS; Inflectra is associated with a lower ICER compared to conventional therapy than for golimumab, adalimumab, etanercept, certolizumab pegol and proprietary infliximab (Remicade) (

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Table 3). Using the average discounted tender price for Inflectra results in an ICER that is lower than for proprietary infliximab (Remicade) and comparable to the other TNF-α inhibitors (**Table 5**).

For the treatment of severe active ankylosing spondylitis, the use of Inflectra compared with proprietary infliximab (Remicade) provides cost savings to the NHS.

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National Institute for Health and Care Excellence (NICE); 2014. Erythropoiesis-stimulating agents (epoetin and darbepoetin) for treating anaemia in people with cancer having chemotherapy (including review of TA142). NICE technology appraisal guidance [TA323], November 2014.

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