Response Document for Inflectra in Rheumatoid Arthritis

Multiple Technology Appraisal (MTA): Adalimumab, etanercept, infliximab, certolizumab pegol, golimumab, tocilizumab and abatacept for rheumatoid arthritis not previously treated with DMARDs or after conventional DMARDs only have failed [ID537]

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Hospira UK Limited
Horizon
Honey Lane
Hurley
Maidenhead, SL6 6RJ
UK
Telephone [redacted]
www.hospira.com
Registered in England No. 1923357

Hospira Response:

The biological disease-modifying anti-rheumatic drugs (DMARDs) adalimumab, etanercept, infliximab, certolizumab pegol, golimumab, tocilizumab and abatacept, each in combination with methotrexate, are recommended as options for treating rheumatoid arthritis for severe disease that has not responded to intensive therapy with a combination of conventional DMARDs (NICE draft guidance [ID537], 2015). Conventional DMARDs include methotrexate, leflunomide and sulfasalazine. NICE technology appraisal draft guidance (NICE draft guidance [ID537], 2015) recommends the use of the above biological DMARDs in patients with rheumatoid arthritis who have a disease activity severity (DAS28) score greater than 5.1. The draft guidance does not recommend the use of biological DMARDs in previously untreated disease. It further states that the cheapest option should be used, taking into account administration costs, required dose, and product price per dose.

The annual costs of treatment with each of the biological DMARDs under consideration are summarised in Table 1.

Table 1 Annual costs of treatment of severe rheumatoid arthritis with biological DMARDs

DMARD	Mode of administration	Annual cost (£)*
Adalimumab	SC	9,155.64
Etanercept	SC	9,295.00
Remicade (originator infliximab)	IV	7,049.62 (first year); 5,727.81 (subsequent years)
Inflectra (infliximab biosimilar)	IV	6,344.69 (first year); 5,155.06 (subsequent years)
Certolizumab pegol†	SC	10,367.50 (first year); 9,295 (subsequent years)
Golimumab	SC	9,155.64
Abatacept[ζ]	IV or SC	IV:12,700.80 (first year); 11,793.60 (subsequent years) SC: £907.20 (first year); £15,724.80 (subsequent years)
Tocilizumab[ζ]	IV[#]	9,318.40

* Using list prices from the British National Formulary, April 2015. † The list price is provided here; through the patient access scheme, the first 12 weeks of therapy with certolizumab pegol are free of charge. ζ Available at a discount via a patient access scheme; the level of discount is commercial in confidence. # Tocilizumab may be administered subcutaneously; however, the subject of this appraisal is the IV formulation of tocilizumab for rheumatoid arthritis that has been previously treated with methotrexate. SC, subcutaneous; IV, intravenous

Inflectra (biosimilar infliximab) has demonstrated comparable clinical efficacy to Remicade (originator infliximab) (EMA [Inflectra], 2015). The contraindications, adverse reactions and administration schedule for Inflectra are the same as for Remicade (NICE draft guidance [ID537], 2015). The Appraisal Committee's preliminary recommendations acknowledge that the costs of Inflectra may vary in different settings because of negotiated procurement discounts. However, the Appraisal Committee considered the list price of Inflectra, which is 10% less than that of the originator product. The resulting small reduction in the incremental cost-effectiveness ratio (ICER) led to the conclusion that the availability of biosimilar treatments is not a key driver of cost effectiveness (NICE draft guidance [ID537], 2015).

It is understood that this appraisal will make a recommendation for the use of Inflectra in the indication of rheumatoid arthritis for severe disease that has not responded to intensive therapy with a combination of conventional DMARDs, as it has been included in the scope of this appraisal (NICE draft guidance [ID537], 2015). However, from recent correspondence with NICE, Hospira understands that Inflectra has not been included in the Assessment Group's economic model. Due to the late inclusion of Inflectra in the scope of this appraisal, the timelines have not allowed for Hospira to develop an economic model.

Hospira is concerned that the assertion that Inflectra is not a more cost effective treatment option compared with Remicade (NICE draft guidance [ID537], 2015; section 4.3.10), is not justified, based on its exclusion from the Assessment Group's model.

Furthermore, using the tender prices would lead to an even lower ICER compared with Remicade than when the Inflectra list price is used, rendering the treatment even more cost effective. This could have a considerable effect on treatment costs over the lifetime treatment of patients. Thus using Inflectra in preference to Remicade could provide cost savings to the National Health Service (NHS).

Hospira requests that the Appraisal Committee take into consideration that Inflectra is offered across a range of in-market tender (contract) prices based on the size of the regional market. The tendering process for Inflectra is complete and the tender prices are now available. The lowest Inflectra in-market tender price of (£[redacted]) is at [redacted]% discount of the Remicade list price; the highest Inflectra in-market price (£[redacted]) is at [redacted]% discount of the Remicade list price. Hospira suggests that the Assessment Group consider in-market tender prices for Inflectra in the appraisal as they represent the actual cost to the NHS in clinical practice.

Although Remicade is offered at around a 15% discount to the list price through the tender frameworks, there is the stipulation that at lower volumes (agreed individually with each trust or clinical commissioning group), the price of Remicade would increase. Therefore it would be appropriate to model the cost-effectiveness based on the list price of Remicade.

Finally, Hospira would like the Committee to consider that precedent was set in the approach of using in-market tender prices with the NICE technology appraisal of erythropoiesis-stimulating agents (ESAs) [TA323]; (NICE final guidance [TA323], 2014). In a scenario analysis, the Assessment Group applied the best contract prices (those reflecting the highest discounts from list price) 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 final guidance [TA323], 2014).

References

National Institute for Health and Care Excellence (NICE); 2015. Rheumatoid arthritis - adalimumab, etanercept, infliximab, certolizumab pegol, golimumab, abatacept and tocilizumab - review [ID537]: appraisal consultation document, June 2015.

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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.