Scottish Medicines Consortium
Providing advice about the status of all newly licensed medicines
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secukinumab 150mg pre-filled syringe, 150mg pre-filled pen (Cosentyx®)
SMC No. (1159/16)

Novartis Pharmaceuticals

10 June 2016

The Scottish Medicines Consortium (SMC) has completed its assessment of the above product and advises NHS Boards and Area Drug and Therapeutic Committees (ADTCs) on its use in NHS Scotland. The advice is summarised as follows:

ADVICE: following a full submission

secukinumab (Cosentyx®) is accepted for use within NHS Scotland.

Indication under review: Treatment of active ankylosing spondylitis (AS) in adults who have responded inadequately to conventional therapy.

Secukinumab, compared with placebo, significantly improved symptoms of AS in adults with active disease inadequately controlled with non-steroidal anti-inflammatory drugs.

This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of secukinumab. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower.

Overleaf is the detailed advice on this product.

Chairman,
Scottish Medicines Consortium

Indication

Treatment of active ankylosing spondylitis (AS) in adults who have responded inadequately to conventional therapy.

Dosing Information

150mg by subcutaneous injection at weeks 0, 1, 2 and 3, then as a monthly maintenance dose starting at week 4.

Available data suggest that a clinical response is usually achieved within 16 weeks of treatment. Consideration should be given to discontinuing treatment in patients who have shown no response by 16 weeks of treatment. Some patients with an initial partial response may subsequently improve with continued treatment beyond 16 weeks.

Secukinumab should be used under the guidance and supervision of a physician experienced in the diagnosis and treatment of AS.

Product availability date

19 November 2015

Summary of evidence on comparative efficacy

Secukinumab is the first interleukin-17A (IL-17A) inhibitor licensed for treatment of ankylosing spondylitis (AS). It is an IgG1 monoclonal antibody that binds to and neutralises IL-17A, a pro-inflammatory cytokine. Inhibiting the effects of IL-17A on various cells reduces the release of pro-inflammatory cytokines, chemokines and mediators of tissue damage, and limits IL-17A-mediated contributions to autoimmune and inflammatory diseases.[1]

Two similar double-blind two- and five-year phase III studies (MEASURE 1 and 2) randomised 371 and 219 adults with moderate to severe AS defined by the Modified New York criteria for AS who had active disease characterised by a Bath ankylosing spondylitis disease activity index (BASDAI) score of at least four and spinal pain of at least four on a 10cm visual analogue scale (VAS). All patients had an inadequate response to a non-steroidal anti-inflammatory drug (NSAID) at the highest dose for at least three months or withdrawal from NSAID therapy due to intolerance, toxicity or contraindications. Patients were equally randomised, with stratification for prior use of tumour necrosis factor (TNF) inhibitor, to subcutaneous (SC) placebo, secukinumab 150mg or 75mg every four weeks starting at week 8 and at week 4 in the MEASURE 1 and 2 studies, respectively. Active treatment groups received a loading dose of secukinumab 10mg/kg intravenously (IV) at weeks 0, 2 and 4 in the MEASURE 1 study, and secukinumab (dose as per assigned group) SC at weeks 0, 1, 2 and 3 in the MEASURE 2 study, and placebo loading injections were administered in the placebo groups. At week 16, all placebo-treated patients in MEASURE 2 study and those within MEASURE 1 study who had not achieved an Assessment of Spondyloarthritis International Society 20 (ASAS20) response were re-randomised from placebo to secukinumab 150mg or 75mg SC, with the ASAS20 placebo-responders in MEASURE 1 study re-randomised in this way at week 24. Rescue therapy was not permitted before week 16. In both studies, the primary outcome was ASAS20 response at week 16 in the full analysis set, comprising all randomised patients who received at least one dose of study drug. This was compared between each secukinumab group and placebo using logistic regression, with

treatment and previous TNF inhibitor status as factors and weight as covariate.[2,3] Results for the licensed 150mg dose are presented below.[2,3]

In both studies, secukinumab 150mg, compared with placebo, significantly increased proportions of patients achieving ASAS20 at week 16: 61% (76/125) versus 29% (35/122) in MEASURE 1; and 61% (44/72) versus 28% (21/74) in MEASURE 2, with odds ratios relative to placebo of 3.89 (95% confidence interval [CI]: 2.28 to 6.65) and 4.38 (95% CI: 2.14 to 8.96), respectively.[2,3] There were improvements for secondary outcomes assessing disease activity (including ASAS40, ASAS-5/6 response, ASAS partial remission and BASDAI), function (Bath ankylosing spondylitis functional index [BASFI]), spinal mobility (Bath ankylosing spondylitis metrology index [BASMI]) and quality of life (short-form 36 physical component summary score [SF-36 PCS] and AS Quality of Life [ASQoL] questionnaire). Many of these were statistically significant as detailed in table 1.[2,3]

Table 1: Primary and secondary outcomes in MEASURE 1 and 2 Studies[2-4]

	MEASURE 1		**MEASURE 2**	
	Responders (%)		**Responders (%)**	
	Secukinumab N=125	**Placebo N=122**	**Secukinumab N=72**	**Placebo N=74**
ASAS20	76 (61%)*	35 (29%)	44 (61%)*	21 (28%)
ASAS40	52 (42%)*	16 (13%)	26 (36%)*	8 (11%)
ASAS-5/6	61 (49%)*	16 (13%)	31 (43%)*	6 (8.1%)
ASAS partial remission	19 (15%)#	4 (3.3%)	10 (14%)	3 (4.0%)
BASDAI50			22 (31%)*	8 (11%)
Least squares mean change from baseline to week 16				
BASDAI (range 0 to 10)	-2.32*	-0.59	-2.19#	-0.85
SF-36 PCS (range 0 to 100)	5.57*	0.96	6.06*	1.92
ASQoL (range 0 to 18)	-3.58*	-1.04	-4.00#	-1.37
BASFI (range 0 to 10)	-1.84*	-0.37	-2.15*	-0.68
BASMI (range 0 to 10)	-0.40+	-0.12	-0.51	-0.22

ASAS20 = at least 20% and one unit (on 10 unit scale) improvement in three of the four main domains of the Assessment of Spondyloarthritis International Society (ASAS) response criteria, with no worsening greater than 20% in the four domain. ASAS40 = at least 40% and two units improvement in three of the four main domains of the ASAS response criteria, with no worsening in the fourth domain. ASAS-5/6 = at least 20% improvement in five of the six domains of the ASAS response criteria; ASAS partial remission = score of 2 units or less on each of the four main domains of the ASAS response criteria. BASDAI50 = at least 50% improvement in Bath Ankylosing Spondylitis Disease Activity Index (BASDAI). SF-36 PCS = short-form 36 physical component summary score. ASQoL = Ankylosing Spondylitis Quality of Life Questionnaire. BASFI = Bath Ankylosing Spondylitis Functional Index. BASMI = Bath Ankylosing Spondylitis Metrology Index. * $p<0.001$ versus placebo; # $p<0.01$ versus placebo; + $p<0.05$.

Analyses after all patients had completed 52 weeks' treatment indicated that improvements with secukinumab at week 16 were sustained through to week 52 for ASAS20, ASAS40 and other secondary outcomes.[2,3]

In the MEASURE 1 study, magnetic resonance imaging (MRI) of the spine and sacroiliac joints was performed in a subgroup who were TNF inhibitor-naive and treated at selected centres, comprising 38, 34 and 33 patients from secukinumab 150mg, secukinumab 75mg and placebo groups, respectively. Least square mean reduction from baseline to week 16 was significantly greater with secukinumab 150mg compared with placebo for Berlin sacroiliac joint total oedema score, -1.30 versus -0.17, but not Berlin spine score, -1.08 versus -0.55, or total ASspi-MRI-a score, -1.13 versus -0.66.[2]

*Other data were also assessed but remain commercially confidential.**

Summary of evidence on comparative safety

The adverse event profile of secukinumab has been characterised within its existing indication for use in plaque psoriasis. In the placebo-controlled phase of the AS studies and over the whole study periods, the adverse event profile was similar to that observed with secukinumab in the psoriasis studies. There were no new safety issues identified from the AS studies.[2]

Over the placebo-controlled phase of MEASURE 1 and 2 studies, pooled data for the 150mg and 75mg secukinumab groups versus placebo in each study indicated that the rates of adverse events were 68% (170/249) versus 56% (68/122) in MEASURE 1, and 61% (89/145) versus 64% (47/74) in MEASURE 2. The most common adverse events were nasopharyngitis (12% versus 7.4% in MEASURE 1, and 10% versus 4.0% in MEASURE 2); dyslipidaemia (10% versus 4.9% and 1.4% versus 1.4%), and headache (8.0% versus 5.7% and 4.1% versus 8.1%). Infection or infestations were reported as adverse events for more patients in the secukinumab groups, compared with placebo, 30% (75/249) versus 12% (15/122) in MEASURE 1, and 32% (46/145) versus 27% (20/74) in MEASURE 2.[3] It was noted that the increased incidence of infection was mainly due to increased rates of mild to moderate upper respiratory tract infection.[2] In the secukinumab and placebo groups there were low rates of serious adverse events, 2.0% versus 4.1% in MEASURE 1 and 5.5% versus 4.0% in MEASURE 2, and discontinuation due to adverse events, 1.2% versus 4.1% in MEASURE 1 and 4.8% versus 5.4% in MEASURE 2.[3]

In relation to adverse events of special interest, it was noted that there were no new findings of Crohn´s disease or major adverse cardiovascular events (MACE) and no new concerns about malignancies. Hypersensitivity and immunological reactions remained rare and the immunogenic potential of secukinumab appeared very low.[2]

Summary of clinical effectiveness issues

Secukinumab is the first IL-17A inhibitor for treatment of AS. However, it is the sixth biologic therapy licensed for active AS in patients with an inadequate response to conventional (NSAID) therapy, after the TNF inhibitors, infliximab, etanercept, adalimumab, certolizumab pegol and golimumab.[1,5-9] In February 2016, Healthcare Improvement Scotland (HIS) issued advice in relation to the National Institute for Health and Care Excellence (NICE) technology assessment (TA 383: TNF-alpha inhibitors for AS and non-radiographic axial spondyloarthritis) that the recommendations are as valid for Scotland as for England and Wales. NICE recommended adalimumab, certolizumab pegol, etanercept, golimumab and infliximab, within their marketing authorisations, as options for treating severe active AS in adults whose disease has responded inadequately to, or who cannot tolerate, NSAIDs.[10,11] There are limited treatment options for patients who do not respond to TNF inhibitors.

Clinical experts consulted by SMC considered that there is an unmet need in this therapeutic area, namely treatments for patients with disease that has not responded to NSAIDs or TNF inhibitors.

In the pivotal MEASURE 1 and 2 studies the primary outcome of ASAS20 is recognised by the European Medicines Agency (EMA) as an acceptable measure of clinical response, though ASAS40 is considered a more appropriate measure of major clinical response.[12] Secukinumab 150mg, compared with placebo, significantly increased the proportions of patients achieving both ASAS20 and ASAS40. It also improved other measures of disease activity (ASAS-5/6, ASAS partial remission, BASDAI), physical functioning (BASFI) and quality of life (SF-36 PCS and ASQoL). Spinal mobility was not a key secondary outcome, but BASMI was assessed as an exploratory outcome and there were

improvements, which were significant in MEASURE 1. There were also improvements in MRI-assessed sacroiliac joint oedema within a subgroup of TNF inhibitor-naive patients in MEASURE 1.[1-3]

In the MEASURE 1 and 2 studies, 27% (66/247) and 39% (57/146) patients had failed previous treatment with a TNF inhibitor, with most having received only one previous TNF inhibitor. Subgroup analysis by previous response to TNF-inhibitors within each study indicated that the ASAS20 response at week 16 with secukinumab 150mg was significantly greater than with placebo in patients who were TNF inhibitor-naive, 68% (30/44) versus 31% (14/45), and in patients who had failed previous treatment with a TNF inhibitor, 50% (14/28) versus 24% (7/29) in the MEASURE 2 study,[1,13] and, in the MEASURE 1 study, response rates were 66% (61/92) versus 33% (29/89) in TNF inhibitor-naive patients and 46% (15/33) versus 18% (6/33) in patients who had failed previous treatment with a TNF inhibitor.[4] This provides reassurance with respect to the use of secukinumab in practice for patients who have failed previous treatment with TNF inhibitors, although the response rates in these patients tended to be lower than in treatment-naive patients. Similarly, the NICE TA assessment report noted that studies based on registry data demonstrated that sequential treatment with TNF inhibitors can be worthwhile in patients with AS. However, the drug survival, response rates, and benefits were reduced with second and third TNF inhibitors.[14]

Pooled analyses were performed using data from secukinumab groups in MEASURE 1 and 2 that had shown efficacy in these studies (i.e. 75mg and 150mg groups in MEASURE 1 and 150mg group in MEASURE 2). Within these, a pre-specified subgroup analysis by body weight included 175, 243 and 98 patients weighing <70kg, 70-90kg and >90kg, respectively, who had ASAS20 response rates at week 16 with secukinumab of 65%, 59% and 55% in the respective subgroups (versus 20%, 34% and 28% with placebo).[2]

Secukinumab has not been directly compared to the standard treatment of TNF inhibitors in patients with active AS and an inadequate response to NSAIDs. Therefore, Bayesian network meta-analyses (NMA) that included data from ten studies were performed comparing secukinumab with adalimumab, certolizumab pegol, etanercept, golimumab and infliximab in patients with active AS for the main outcomes of ASAS20, ASAS40, BASDAI50, and mean change from baseline in BASDAI and BASFI. This supported an assumption of equivalent efficacy that underpins an economic cost-minimisation analysis. The validity of this conclusion may be limited by some weaknesses. The number of studies included in the NMA was not as extensive as those in similar indirect comparisons of TNF inhibitors for treatment of AS performed by the Cochrane collaboration and NICE, although similar conclusions were drawn from all analyses.[14,15] There was some heterogeneity across the included studies in disease duration and severity, including previous use of TNF inhibitors. Finally, there was no comparison of outcomes assessing spinal mobility or safety.

Clinical experts consulted by SMC considered that secukinumab for AS is a therapeutic advancement due to its novel mechanism of action, clinical benefits and because it provides a new treatment option for patients who have not responded to NSAIDs or TNF inhibitors. They considered that it is likely to be used after failure of TNF inhibitors.

Summary of comparative health economic evidence

The submitting company presented a cost-minimisation analysis which compared secukinumab against a range of comparators in adult patients with active AS who had responded inadequately to conventional therapy. The comparators included adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and infliximab biosimilars.

The time horizon for the analysis was 5 years and thus captured costs associated with loading doses of treatment in year one and subsequent years of maintenance treatment from year one onwards.

The data used to support the comparable efficacy of secukinumab and the comparators were derived from an NMA. The results of the analysis reported that secukinumab was of comparable efficacy to the comparators.

The cost-minimisation analysis focused on medicine and administration costs. In terms of administration, a one-off training cost of £41 to enable patients to self-inject was applied to all therapies with the exception of infliximab. For the infliximab comparators, an administration cost of £326 was applied per dose because of the intravenous formulation of the medicine.

The base case results indicated that after five years the total cost associated with secukinumab was £36,651. The total cost of adalimumab, etanercept, golimumab, infliximab, and infliximab biosimilars were £42,826, £43,477, £42,826, £75,612, and £69,152 respectively. As a result, secukinumab generated savings of £6,175, £6,826, £6,175, £38,961, £32,501 versus each comparator respectively. A PAS is in place for certolizumab pegol and this was included in the analysis by using an estimate of the relevant price of certolizumab pegol but, owing to commercial in confidence issues, the result versus certolizumab pegol cannot be presented.

A Patient Access Scheme (PAS) was submitted by the company and was assessed by the Patient Access Scheme Assessment Group (PASAG) as acceptable for implementation in NHS Scotland. Under the PAS a simple discount was given on the price of the medicine.

With the PAS, the savings associated with secukinumab increased against all comparators. SMC would wish to present the with-PAS cost-effectiveness estimates that informed the SMC decision. However, owing to the commercial in confidence concerns regarding the PAS, SMC is unable to publish these results. As such, only the without-PAS figures can be presented.

The company provided a scenario analysis which modelled the impact of using an alternative administration cost of £1,453 for infliximab. This cost reflected a weighted average of administration delivered in an outpatient setting (8.33%) and a day case setting (91.67%). As a result, secukinumab generated savings of £76,955 and £70,494 (both without PAS) versus infliximab and infliximab biosimilars respectively.

The main weaknesses were

- The appropriateness of selecting a cost-minimisation analysis as the relevant format of the economic analysis is dependent on demonstrating the comparable efficacy and safety of the treatments under review. There were a number of weaknesses with the NMA such as the limited number of studies included in the NMA, heterogeneity across the included studies, and no comparison of outcomes assessing spinal mobility or safety. However, following discussions at the New Drugs Committee (NDC), the NMA was considered sufficiently robust to support a cost-minimisation analysis.

- The time horizon for the analysis was five years and the analysis did not assume any treatment discontinuation. Therefore, the base case results were not conservative as savings between the medicines were calculated over an extended time period. The company provided sensitivity analyses which reduced the time horizon to 1 and 2 years respectively and with PAS secukinumab remained the cost-minimising treatment option.
- The company did not present subgroup analyses such as focussing on patients who were TNF inhibitor naive, or had failed treatment on a previous TNF inhibitor. However, following discussions at the NDC, the analysis provided by the company which reflected the licensed population was considered appropriate.

Despite the above uncertainties, the economic case has been demonstrated.

Summary of patient and public involvement

The following information reflects the views of the specified Patient Group.

- A submission was received from National Ankylosing Spondylitis Society, which is a registered charity.

- The patient group has received 9% pharmaceutical company funding in the past two years, but none from the submitting company.

- Ankylosing Spondylitis (AS) is a chronic progressive inflammatory disease of the spine which often produces pain, stiffness, deformity and disability throughout adult life, with symptoms usually begin in adolescence. Associated disorders including uveitis, psoriasis, and inflammatory bowel disease are also common. Work disability is a major problem. Many patients also suffer with mental health issues including depression.

- Current treatment of AS is limited to anti-inflammatory medication and anti-tumour necrosis factor (TNF) therapy. Anti-TNF therapy can be effective for the majority of people with AS and benefits include: reduced pain and stiffness, improved mobility, reduction in attacks of uveitis and reduced levels of fatigue. However, there are currently no effective alternative treatments for those who cannot be managed by anti-inflammatory medication and who do not respond to anti-TNF therapy.

- Patients raised some concerns regarding potential short and long-term side effects of secukinumab treatment. The route of administration (self administered SC injection) was also perceived as a drawback.

Additional information: guidelines and protocols

In February 2016 NICE published technology assessment number 383: TNF-alpha inhibitors for AS and non-radiographic axial spondyloarthritis. Adalimumab, certolizumab pegol, etanercept, golimumab and infliximab are recommended, within their marketing authorisations, as options for treating severe active AS in adults whose disease has responded inadequately to, or who cannot tolerate, NSAIDs. Infliximab is recommended only if treatment is started with the least expensive infliximab product. The choice of treatment should be made after discussion between the clinician and the patient about advantages and disadvantages of the treatments available. This may include considering associated conditions such as extra-articular manifestations. If more than one 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: reduction in BASDAI score to 50% of pre-treatment value or by 2 or more units and reduction in spinal pain VAS by 2 cm or more. Treatment with another 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.

On 24 February 2016 HIS advised that the recommendations in NICE TA 383 were as valid for Scotland as for England and Wales.[10]

In 2010 the Assessment of Spondyloarthritis International Society (ASAS) and European League Against Rheumatism (EULAR) updated their recommendations for the management of AS. TNF-alpha inhibitors were recommended for use in patients who continue to have highly active disease despite the use of conventional treatments such as NSAIDs. The different TNF-alpha inhibitors are considered to be equally efficacious. Switching to a second TNF-alpha inhibitor is recommended in patients who experience a loss of response.[16]

The BSR published guidelines on AS are under review with an expected publication date in the first quarter of 2016.[17]

Additional information: comparators

TNF-inhibitors, adalimumab, certolizumab pegol, golimumab, etanercept or infliximab.

Cost of relevant comparators

Drug	Dose Regimen	Cost per year (£)
Secukinumab	**150mg SC at weeks 0, 1, 2, 3 and 4 then every four weeks**	**7,922[A]**
Certolizumab pegol	400mg SC at weeks 0, 2 and 4, then 200mg every two weeks or 400mg every four weeks	9,295[B]
Etanercept (Enbrel®)	25mg SC twice a week or 50mg SC once each week	9,295
Adalimumab	40mg SC every other week	9,156
Golimumab	50mg* SC once every month	9,156
Infliximab (Remsima®, Inflectra®)	5mg/kg IV at weeks 0, 2 and 6 then every six to eight weeks	9,065 to 12,083[C]
Infliximab (Remicade®)	5mg/kg IV at weeks 0, 2 and 6 then every six to eight weeks	10,071 to 13,428[D]

Doses are for general comparison and do not imply therapeutic equivalence. Costs are from eVadis on 03 March 2016 and MIMS. Costs do not take any patient access schemes into consideration. SC = subcutaneous injection; IV = intravenous infusion. * for patients weighing >100kg not achieving adequate clinical response after 3 or 4 doses, increasing the dose of golimumab to 100mg may be considered, taking account of increased risk of certain serious adverse drug reactions. [A] cost of secukinumab in the first year is £9,750; [B] cost of certolizumab pegol in first year is £10,368; [C] cost of infliximab (Inflectra® or Remsima®) in first year is £12,083 to £15,106; [D] cost of infliximab (Remicade®) in first year is £13,428 to £16,785.

Additional information: budget impact

The submitting company estimated there would be would be 1,179 patients eligible for treatment with secukinumab in year 1 and 1,391 patients in year 5, to which confidential estimates of treatment uptake were applied.

SMC is unable to publish the with PAS budget impact due to commercial in confidence issues. A budget impact template is provided in confidence to NHS health boards to enable them to estimate the predicted budget with the PAS.

*Other data were also assessed but remain commercially confidential.**

References

The undernoted references were supplied with the submission. Those shaded in grey are additional to those supplied with the submission.

1. Novartis. Summary of product characteristics or Cosentyx, last updated 20 November 2015.

2. European Medicines Agency. European public assessment report for secukinumab.

3. Baeten D, Sieper J, Braun J, et al. Secukinumab, an interleukin-17A inhibitor, in ankylosing spondylitis. N Engl J Med 2015; 373: 2534-48.

4. *Commercial in Confidence**

5. Janssen Biologics. Summary of product characteristics for golimumab, last revision of text on 22 June 2015.

6. AbbVie Ltd. Summary of product characteristics for adalimumab, last updated 3 August 2015.

7. UCB Pharma Ltd. Summary of product characteristics for certolizumab pegol, last updated 23 June 2105.

8. Pfizer Ltd. Summary of product characteristics for etanercept, last updated 23 April 2015.

9. Merck, Sharpe and Dohme Ltd. Summary of product characteristics for infliximab, last updated 30 October 2015.

10. Healthcare Improvement Scotland (HIS). Advice on National Institute of Health and Care Excellence (NICE) technology assessment 383, 24 February 2016.

11. National Institute of Health and Care Excellence (NICE) technology assessment 383; TNF-alpha inhibitors for AS and non-radiographic axial spondyloarthritis, guidance.

12. European Medicines Agency. CHMP guideline on clinical investigation of medicinal products for the treatment of ankylosing spondylitis, CPMP/EWP/4891/03, 23 April 2009.

13. Sieper J, Braun J, Baralaikos X, et al. Secukinumab efficacy in anti-TNF-naive subjects and subjects previously exposed to anti-TNF therapy: results of a randomised, double-blind, placeco-controlled phase 3 study (MEASURE 2) in ankylosing spondylitis. Poster presented at EULAR 2015.

14. National Institute of Health and Care Excellence (NICE) technology assessment 383; TNF-alpha inhibitors for AS and non-radiographic axial spondyloarthritis, assessment report.

15. Maxwell LJ, Zochling J, Boonen A, et al. TNF-alpha inhibitors for ankylosing spondylitis. Cochrane Database of Systematic Reviews 2015, Issue 4. Art. No.: CD005468. DOI: 10.1002/14651858.CD005468.pub2.

16. Braun J, van den Berg R, Baraliakos X, et al. 2010 update of ASAS/EULAR recommendations for the management of ankylosing spondylitis. Ann Rheum Dis 2011; 70: 896-904.

17. British Society for Rheumatology (BSR). New guidelines in development: ankylosing spondylitis / spondyloarthropathies and biologics. www.rheumatology.org

This assessment is based on data submitted by the applicant company up to and including 12 May 2016.

*Agreement between the Association of the British Pharmaceutical Industry (ABPI) and the SMC on guidelines for the release of company data into the public domain during a health technology appraisal: http://www.scottishmedicines.org.uk/About_SMC/Policy_statements/Policy_Statements

Drug prices are those available at the time the papers were issued to SMC for consideration. SMC is aware that for some hospital-only products national or local contracts may be in place for comparator products that can significantly reduce the acquisition cost to Health Boards. These contract prices are commercial in confidence and cannot be put in the public domain, including via the SMC Detailed Advice Document. Area Drug and Therapeutics Committees and NHS Boards are therefore asked to consider contract pricing when reviewing advice on medicines accepted by SMC.

Patient access schemes: A patient access scheme is a scheme proposed by a pharmaceutical company in order to improve the cost-effectiveness of a drug and enable patients to receive access to cost-effective innovative medicines. A Patient Access Scheme Assessment Group (PASAG, established under the auspices of NHS National Services Scotland reviews and advises NHS Scotland on the feasibility of proposed schemes for implementation. The PASAG operates separately from SMC in order to maintain the integrity and independence of the assessment process of the SMC. When SMC accepts a medicine for use in NHS Scotland on the basis of a patient access scheme that has been considered feasible by PASAG, a set of guidance notes on the operation of the scheme will be circulated to Area Drug and Therapeutics Committees and NHS Boards prior to publication of SMC advice.

Advice context:

No part of this advice may be used without the whole of the advice being quoted in full.

This advice represents the view of the Scottish Medicines Consortium and was arrived at after careful consideration and evaluation of the available evidence. It is provided to inform the considerations of Area Drug & Therapeutics Committees and NHS Boards in Scotland in determining medicines for local use or local formulary inclusion. This advice does not override the individual responsibility of health professionals to make decisions in the exercise of their clinical judgement in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.