Scottish Medicines Consortium
Providing advice about the status of all newly licensed medicines
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golimumab 50mg/0.5mL solution for injection in pre-filled pen or syringe and 100mg/mL solution for injection in pre-filled pen (Simponi®)

SMC No. (1124/16)

Merck Sharp & Dohme Limited

8 January 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

golimumab (Simponi®) is accepted for use within NHS Scotland.

Indication under review: treatment of adults with severe, active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) evidence, who have had an inadequate response to, or are intolerant to non-steroidal anti-inflammatory drugs (NSAIDs).

Golimumab, compared to placebo, significantly improved symptoms in adults with active non-radiographic axial spondyloarthritis.

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

Overleaf is the detailed advice on this product.

Chairman,
Scottish Medicines Consortium

Published 08 February 2016

Indication

Treatment of adults with severe, active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) evidence, who have had an inadequate response to, or are intolerant to non-steroidal anti-inflammatory drugs (NSAIDs).

Dosing Information

50mg subcutaneous injection once a month, on the same date each month.

Available data suggest that clinical response is usually achieved within 12 to 14 weeks of treatment (after 3 to 4 doses). Continued therapy should be reconsidered in patients who show no evidence of therapeutic benefit within this time period. In patients with body weight more than 100kg who do not achieve an adequate clinical response after 3 or 4 doses, increasing the dose to golimumab 100mg once a month may be considered, taking into account the increased risk of certain serious adverse drug reactions with the 100mg dose compared with the 50mg dose. Continued therapy should be reconsidered in patients who show no evidence of therapeutic benefit after receiving 3 to 4 additional doses of 100mg.

Treatment should be initiated and supervised by qualified physicians experienced in the diagnosis and treatment of non-radiographic axial spondyloarthritis. Patients should be given the Patient Alert Card.

After proper training in subcutaneous injection technique, patients may self-inject with golimumab if their physician determines that this is appropriate, with medical follow-up as necessary. Patients should be instructed to inject the full amount of golimumab according to the comprehensive instructions for administration provided in the package leaflet. If multiple injections are required, the injections should be administered at different sites on the body.

Product availability date

22 June 2015

Summary of evidence on comparative efficacy

Golimumab is a monoclonal antibody that binds to soluble and transmembrane tumour necrosis factor-α (TNF-α), thereby preventing binding to its receptors. It is the fourth TNF-α inhibitor licensed for treatment of patients with non-radiological axial spondyloarthritis (nr axial SpA), a subgroup of patients with axial SpA who do not have evidence of sacroiliitis on x-ray.

A two-part phase III study (GO-AHEAD) recruited 197 adults, aged 18 to 45 years, with active nr axial SpA for up to five years and chronic back pain for at least three months who had either active inflammation on magnetic resonance imaging (MRI) highly suggestive of sacroiliitis associated with spondyloarthropathy (by central review) plus one or more clinical characteristics, or were positive for the HLA-B27 gene and had a further two or more clinical characteristics in addition to this. Clinical characteristics included HLA-B27 gene positivity, inflammatory back pain, arthritis, enthesitis, dactylitis, psoriasis, inflammatory bowel disease

(IBD), uveitis, good response to non-steroidal anti-inflammatory drugs (NSAIDs), family history for SpA, or elevated C-reactive protein (CRP). Patients had active disease defined as a Bath ankylosing spondylitis disease activity index (BASDAI) score of at least four and spinal pain score of at least four on 10cm visual analogue scale (VAS) and had an inadequate response to or were not able to receive or tolerate 30 days maximally dosed NSAID. The proportion of the study population without evidence of sacroiliitis on MRI was limited to 50% and with normal CRP was limited to 60%. Randomisation was stratified by evidence or sacroiliitis on MRI (yes versus no) and CRP level (at or below the upper limit of normal (ULN) or above ULN [0.9mg/dL]). Patients were equally assigned to double-blind treatment with golimumab 50mg by subcutaneous (SC) injection or placebo at weeks 0, 4, 8 and 12 during the first part of the study. The primary outcome was the proportion of patients at week 16 achieving an Assessment in Ankylosing Spondylitis (ASAS) 20 response, defined as at least a 20% improvement from baseline and an absolute improvement of at least 10mm on three of the following: patient global assessment; pain (total back pain); Bath ankylosing spondylitis functional index (BASFI); inflammation (average of last 2 items of BASDAI relating to morning stiffness) and an absence of deterioration in the potential remaining domain. This was assessed in the full analysis population, comprising all randomised patients who received at least one dose of study drug. This was compared between the groups using the stratified Miettinen and Nurminen method with evidence of sacroiliitis on MRI at baseline and screening CRP as stratification factors.

The primary outcome, proportion of patients achieving an ASAS20 response at week 16, was significantly greater with golimumab compared to placebo as detailed in Table 1. There were also significant improvements with golimumab for the key secondary outcomes, ASAS40, ASAS partial remission, 50% improvement in BASDAI (BASDAI50) response and mean change from baseline in Spondyloarthritis Research Consortium of Canada (SPARCC) MRI sacroiliac (SI) joint score. Significant improvements with golimumab were also observed for mean change from baseline in additional secondary outcomes including BASFI, which assesses function, and Bath ankylosing spondylitis metrology index (BASMI), which assesses hip and spine mobility. The quality of life outcomes, short-form 36 (SF-36) physical component summary (PCS) and mental component summary (MCS), Euro-Qol-5D (EQ-5D) health questionnaire and the ankylosing spondylitis quality of life questionnaire (ASQol) were significantly improved with golimumab relative to placebo, as detailed in Table 1.

Table 1: Primary and secondary outcomes in full analysis set of GO-AHEAD study.[2]

Response Outcome	**Responders at week 16**		**Difference (95% CI)**
	Golimumab	**Placebo**	
ASAS20	71% (69/97)	40% (40/100)	31% (18% to 44%)
ASAS40	57% (55/97)	23% (23/100)	34% (20% to 46%)
BASDAI50	58% (56/97)	30% (30/100)	28% (14% to 41%)
ASAS partial remission	33% (32/97)	18% (18/100)	15% (3.2% to 27%)
Outcome (units)	**Mean change baseline to wk 16**		**Difference (95% CI)**
	Golimumab	**Placebo**	
SPARCC MRI SI joint score	-5.3	-0.9	-4.3
BASFI (cm)	-2.63	-0.90	-1.73 (-2.33 to -1.12)
BASMI (cm)	-0.48	-0.08	-0.39 (-0.58 to -0.20)
SF-36 PCS	10.3	3.7	6.6 (4.3 to 8.8)
SF-36 MCS	5.8	1.6	4.2 (1.4 to 7.1)
EuroQol-5D	2.1	0.6	1.5 (0.9 to 2.1)
ASQol	-5.2	-1.8	-3.5 (-4.7 to -2.2)

ASAS = assessment in ankylosing spondylitis; BASDAI50 = 50% improvement in Bath ankylosing spondylitis disease activity index; SPARCC = Spondyloarthritis Research Consortium of Canada; MRI = magnetic resonance imaging; SI = sacroiliac; BASFI = Bath ankylosing spondylitis functional index; BASMI = Bath ankylosing spondylitis metrology index; SF-36 = short-form 36; PCS = physical component summary; MCS = mental component summary; ASQoL = ankylosing spondylitis quality of life questionnaire; CI = confidence interval.

The pre-specified subgroup of patients who had objective signs of inflammation (OSI), defined as CRP greater than ULN and/or sacroiliitis on MRI, is representative of the indication under review and comprised 80% (158/179) of the study population. In the OSI subgroup, golimumab, compared to placebo, significantly increased the proportion of patients at week 16 achieving responses for ASAS20, ASAS40, ASAS partial remission and BASDAI50, as detailed in Table 2. Results in the OSI subgroup were numerically similar to or greater than results observed in the overall study population.[2]

Table 2: Primary and secondary outcomes in OSI subgroup of GO-AHEAD study.[2]

Response Outcome	Responders at week 16		Difference (95% CI)
	Golimumab	Placebo	
ASAS20	77% (60/78)	38% (30/80)	40% (25% to 53%)
ASAS40	60% (47/78)	22% (18/80)	38% (23% to 51%)
BASDAI50	59% (46/78)	29% (23/80)	30% (15% to 44%)
ASAS partial remission	35% (27/78)	19% (15/80)	16% (2.5% to 30%)

OSI = objective signs of inflammation; ASAS = assessment in ankylosing spondylitis; BASDAI50 = 50% improvement in Bath ankylosing spondylitis disease activity index; CI = confidence interval

Patients who successfully completed part one of the study were eligible to enter part two, where all patients received open-label golimumab 50mg SC at week 16 then every four weeks up to week 48. Data are currently available from analyses of ASAS20, ASAS40, BASDAI50 and ASAS partial remission at 24 weeks in the full analysis set. In the group that received golimumab in parts one and two, the majority of patients (>91%) who achieved responses at week 16 maintained these at week 24 and many patients who were non-responders at week 16 achieved a response by week 24, resulting in an overall increase in response rates at week 24: 84% (78/93), 73% (68/93), 75% (70/93) and 42% (39/93) for the respective outcomes. A similar pattern was observed in the group that received placebo in part one and golimumab in part two, with response rates for the respective outcomes at week 24 of 71% (68/96), 52% (50/96), 57% (55/96) and 43% (41/96).[2]

Summary of evidence on comparative safety

The adverse event profile of golimumab is well characterised and consistent with that of TNF-α inhibitors in general. Across the safety database for golimumab in its indications, the most commonly reported adverse event is upper respiratory tract infection, and the most serious adverse events include serious infections (sepsis, pneumonia, tuberculosis, invasive fungal and opportunistic infections), demyelinating disorders, lymphoma, hepatitis B virus reactivation, congestive heart failure, autoimmune processes (lupus-like syndrome) and haematologic reactions.[2]

In the full study population of the GO-AHEAD study at week 16 within the golimumab and placebo group, respectively, there were similar rates of adverse events (41% and 46%), serious adverse events (1.0% and 2.0%) and discontinuations due to adverse events (2.1% and 1.0%).

The most common adverse events were infections (25% and 23%) and disorders of the gastro-intestinal tract (8.2% and 15%), nervous system (10% and 11%), skin and subcutaneous tissues (9.3% and 6.0%) and respiratory system (8.2% and 8.0%). Injection site reactions were reported by zero and three patients in the respective groups. There were no serious opportunistic infections, active tuberculosis, malignancies or serious systemic hypersensitivity. There were no serious infections noted at week 16, but two were reported at the latest cut-off within golimumab-treated patients.[2]

Summary of clinical effectiveness issues

Golimumab is the fourth TNF-α inhibitor licensed for nr axial SpA and the second (after certolizumab pegol) that can be administered monthly. The others are etanercept, certolizumab pegol and adalimumab.[6-8] For this indication, adalimumab and certolizumab pegol have been accepted by SMC for use in NHS Scotland. Etanercept, certolizumab pegol and adalimumab are currently being reviewed for this indication by the National Institute of Health and Care Excellence (NICE) in a multiple technology assessment.[9]

The primary outcome in the pivotal GO-AHEAD study, ASAS20, is recognised by the European Medicines Agency (EMA) as an acceptable measure of clinical response, although ASAS40 is considered a more appropriate measure of major clinical response.[10] Golimumab, compared to placebo, demonstrated a significant improvement in the proportions of patients achieving both ASAS20 and ASAS40 and other measures of disease activity, physical function, hip and spine mobility, and quality of life.[2,3]

The pre-defined subgroup (n=158) with OSI is representative of the indication. The treatment effect of golimumab compared to placebo was equivalent to or greater than that observed in the total study population. Significant effects were observed for proportion of patients achieving responses of ASAS20, ASAS40, BASDAI50, and ASAS partial remission. In contrast, within the subgroup (n=39) who had CRP in the normal range and no evidence of sacroiliitis on MRI, golimumab, compared to placebo, did not significantly improve ASAS20 or ASAS40 response rates. These patients are not included in the licensed indication.[2,3]

In the pivotal study, golimumab was administered every four weeks, corresponding to 13 doses per annum.[2,3] However, the summary of product characteristics[1] indicates that golimumab should be administered once a month on the same date each month, which corresponds to 12 doses per annum. The impact of this on clinical effectiveness is unclear.

The pivotal study only included patients who were naive to TNF-α inhibitor treatment.[2,3] This may limit the application of results to patients previously treated with these medicines.

Pre-specified subgroup analysis indicated potential differences between males and females and between patients aged ≤30 years and >30 years for treatment effect of golimumab relative to placebo for ASAS20 and ASAS40 response rates and there were imbalances between treatment groups at baseline in age and gender. However, additional analysis provided during the European regulatory review indicated that the age and gender imbalances had minimal impact on the overall treatment effect of golimumab.[2,3]

As there are no direct comparative data for golimumab versus other TNF-α inhibitors in this indication, results of an indirect comparison were presented. A Bayesian network meta-

analysis (NMA) compared golimumab to adalimumab, etanercept and certolizumab pegol in adults with nr axial SpA for the outcomes of ASAS20, ASAS40, ASAS partial remission, BASDAI50; mean change in BASDAI and BASFI from baseline; and incidence of adverse events, serious adverse events and infections. It was presented as an analysis of six studies, however, one of the studies was duplicated. Data were input from the pivotal regulatory studies of each TNF-α inhibitor and a small pilot study of adalimumab. Results suggest that golimumab was generally comparable to the other TNF-α inhibitors. However, the analyses were weakened by duplication of data input and by heterogeneity across the studies in terms of concomitant use of DMARDs, disease duration and severity. Input data were from the whole study populations rather than subgroups with OSI, which are representative of the indication. Also, the quality of data input for some TNF-α inhibitors may have been compromised by issues arising from classification of patient populations based on local versus central reading of x-rays.

Patients receiving golimumab should be given the Patient Alert Card. After proper training in SC injection technique, patients may self-inject with golimumab if their physician determines that this is appropriate.

Clinical experts consulted by SMC considered that it may be an alternative to other TNF-α inhibitors, particularly in patients who would benefit from a monthly dosing schedule.

Summary of comparative health economic evidence

The company presented a cost-utility analysis which compared golimumab, conventional therapy, adalimumab, certolizumab pegol and etanercept in the licensed population. SMC clinical expert responses have confirmed that the comparators are appropriate.

The company used a short-term decision tree followed by a long-term Markov model to assess the cost-effectiveness of golimumab versus the comparators. In the short-term model, patients who were initiated to a TNF-α inhibitor were assessed at 12 weeks. Patients who responded to treatment remained on treatment, while patients who did not respond at 12 weeks were switched to conventional therapy and remained on conventional therapy for the duration of the analysis. Patients who were initiated to conventional therapy remained on conventional therapy throughout the model irrespective of response at week 12. The Markov model included 5 health states: TNF-α inhibitor treatment, just discontinued, discontinued, discontinued treatment and death. Patients entered the model following the decision tree and patients who entered treated with a TNF-α inhibitor could remain on treatment or discontinue. The 'just discontinued' and 'discontinued' health states were tunnel states which patients were assumed to pass through within 24 weeks. Patients in the discontinued treatment health state were assumed to receive conventional therapy and patients could also die throughout the model.

The sources of the clinical data included a NMA which provided information regarding treatment efficacy at week 12 and adverse events. The GO-AHEAD study informed baseline characteristics, disease progression and treatment discontinuation. Data from the published literature, previous health technology assessments, and the GO-RAISE[11] study were also used in the economic model.

Utility estimates were derived from EQ-5D data which were collected in the GO-AHEAD study. The analysis also included a utility decrement for adverse events.

Medicines costs were included in the analysis as were costs associated with administration, initiation and monitoring, long-term disease management and adverse events.

A PAS was submitted by the company and was assessed by the Patient Access Scheme Assessment Group (PASAG) as acceptable for implementation in NHS Scotland. The PAS was a discount applied to the 100mg presentation of the medicine. With the PAS, the results indicated that the incremental cost-effectiveness ratio (ICER) for golimumab versus conventional therapy was £19,280. This result was based on an incremental cost of £39,770 and an incremental quality adjusted life year (QALY) gain of 2.06. The company also presented the ICERs for the other comparators versus conventional therapy which were as follows: adalimumab (£19,737), certolizumab pegol (£17,569) and etanercept (£20,089). 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.

The analysis was most sensitive to reducing the time horizon to 1 year (£37,556), and taking 70% of the utility decrement per 1 unit change in BASFI/BASDAI (£27,543).

The company also presented a cost-minimisation analysis (CMA) which compared golimumab against adalimumab, certolizumab pegol and etanercept. The analysis assumed there were no meaningful differences in efficacy or in administration costs between the medicines and focused on medicines costs only. With the PAS, golimumab was a cost-effective treatment option against adalimumab and etanercept but not against certolizumab pegol when an estimate of the PAS price for certolizumab pegol was included in the analysis.

The main weaknesses were as follows

- The base case analysis presented by the company was a cost-utility analysis which included conventional therapy as a comparator and used non-significant differences from the NMA versus adalimumab, certolizumab pegol, etanercept and conventional therapy. However the NMA indicated that golimumab was generally comparable to the other TNF-α inhibitors and, therefore, the CMA presented by the company in the initial submission may have been more appropriate. In addition, the certolizumab pegol submission (960/14) highlighted that conventional therapy was considered less relevant to Scottish practice, which also supports the relevance of the CMA presented by the company. Following discussions at NDC and consideration of SMC expert responses, the TNF-α inhibitors were identified as the primary comparators and the CMA as the appropriate analysis for consideration.
- The CMA focused on medicines costs only and the company suggested that no administration costs were included as there are no meaningful differences between the treatments included in the evaluation. SMC expert responses have confirmed that this assumption is appropriate.

Despite these issues, the economic case has been demonstrated.

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

Summary of patient and public involvement

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

A submission was received from the National Ankylosing Spondylitis Society (NASS), which is a registered charity.

- NASS has received funding from pharmaceutical companies in the past two years, including from the submitting company.

- Since most people with non-radiographic axial spondyloarthritis (nr-axSpA) are neither deformed, nor have peripheral joint abnormalities, much of the burden of living with the disease is invisible. The key symptom is inflammatory back pain which is especially severe at night and following immobility. Many people with nr-axSpA suffer with issues including depression, fatigue and poor sleep. Work is a major issue, with more than 50% of people who are affected suffering work instability. All of these problems exert a profound influence on patients' quality of life.

- There are other anti-TNFs available for axial spondyloarthritis, These are making huge differences to the lives of patients. However, golimumab would increase the options available to physicians and patients. Patients are aware of the side effects but most feel "the benefits far outweigh the downsides".

- Golimumab would give patients another anti-TNF treatment option. As the treatment options for nr-axSpA are currently so limited, it is very important for patients to have the widest possible choice.

Additional information: guidelines and protocols

ASAS and the European League Against Rheumatism (EULAR) developed recommendations for management of ankylosing spondylitis, including axial spondyloarthritis. These recommend that for patients with persistently high disease activity despite conventional treatments, an anti-TNF agent should be given and noted that there is no evidence of a difference in efficacy of the various TNF inhibitors on axial spondyloarthritis.[12]

ASAS published a 2010 update of the international ASAS recommendations for the use of anti-TNF agents in patients with axial spondyloarthritis in 2011. All patients should have tried a minimum of two NSAIDs at maximum recommended dose for a minimum of four weeks in total, unless contraindicated. Pre-treatment with a DMARD is not required in patients with predominately axial manifestations. All patients with axial SpA should be considered for the use of an anti-TNF agent as the burden of disease is similar in patients with radiographic and non-radiographic SpA and the efficacy of anti-TNF drugs was considered similar. Anti-TNF therapy should be continued for at least 12 weeks to assess for response.[13]

Additional information: comparators

Other TNF-α inhibitors licensed for this indication are etanercept, adalimumab and certolizumab pegol.

Cost of relevant comparators

Drug	Dose Regimen	Cost per year (£)
Golimumab	**50mg* SC once every month**	**9,156**
Certolizumab pegol	400mg SC at weeks 0, 2 and 4, then 200mg every two weeks or 400mg every four weeks	9,295 (10,725 in year 1)
Etanercept	25mg SC twice a week or 50mg SC once each week	9,295
Adalimumab	40mg SC every other week	9,156

Doses are for general comparison and do not imply therapeutic equivalence. Costs are from eVadis on 03 October 2015, except golimumab, which is from MIMS on 15 October 2015. The costs do not take any patient access schemes into consideration. SC = subcutaneous injection. * 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.

Additional information: budget impact

The company estimated that 4,107 patients would be eligible for treatment in year 1 rising to 4,805 in year 5. The market share was estimated as 3% in year 1, rising to 16% in year 5. Once market share was taken into account, the company estimated that 117 patients would be treated in year 1, rising to 730 patients in year 5.

Without PAS the gross budget impact was estimated as £1.1m in year 1, rising to £7m in year 5. As medicines were assumed to be displaced, the net medicines budget impact was estimated as £45k in year 1, rising to £283k in year 5.

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

2. European Medicines Agency. European public assessment report for golimumab. Committee for Medicinal Products for Human Use (CHMP) assessment report EMA/CHMP/422136/2015, 21 June 2015.

3. Sieper J, van der Heijde D, Dougados M, et al. A randomized, double-blind, placebo-controlled, sixteen-week study of subcutaneous golimumab in patients with active nonradiographic axial spondyloarthritis. Arthritis Rheumatol 2015; 67: 2702-12.

4. Clinicatrials.gov. Record for NCT01453725.

5. *Commercial In Confidence*

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. National Institute of Health and Care Excellence (NICE). Multiple technology assessment in development, ID694: TNF-alpha inhibitors for ankylosing spondylitis and non-radiographic axial spondyloarthritis (including a review of TA143 and TA233).

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

11. Deodhar A, Braun J, Inman RD, et al. Golimumab administered subcutaneously every 4 weeks in anklyosing spondylitis: 5-year results of the GO-RAISE study. Ann Rheum Dis 2015; 74: 757-61.

12. 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.

13. van der Heijde D, Sieper J, Maksymowych WP, et al. 2010 Update of the international ASAS recommendations for the use of anti-TNF agents in patients with axial spondyloarthritis. Ann Rheum Dis. 2011; 70: 905-908.

This assessment is based on data submitted by the applicant company up to and including 4 January, 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.