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
certolizumab pegol (Cimzia®): is accepted for restricted use within NHS Scotland.

**Indication under review**: in combination with methotrexate, for the treatment of active psoriatic arthritis in adults when the response to previous disease-modifying antirheumatic drug (DMARD) therapy has been inadequate. Certolizumab pegol can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate.

**SMC restriction**: Use in patients whose disease has not responded to adequate trials of at least two standard DMARDs either individually or in combination.

In a phase III, randomised, placebo-controlled study in patients with active psoriatic arthritis, significantly more patients who received certolizumab pegol achieved at least 20% response on the American College of Rheumatology criteria (ACR 20) at 12 weeks compared with those who received placebo.

This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of certolizumab pegol. This SMC 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.

Co-Vice Chairman,
Scottish Medicines Consortium

Published 07 July 2014
**Indication**
Certolizumab pegol, in combination with methotrexate (MTX), is indicated for the treatment of active psoriatic arthritis in adults when the response to previous disease-modifying antirheumatic drug (DMARD) therapy has been inadequate.

Certolizumab pegol can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate.

**Dosing Information**

*Loading dose*
The recommended starting dose of certolizumab for adult patients is 400mg (given as two subcutaneous injections of 200mg each) at weeks 0, 2 and 4. For psoriatic arthritis, methotrexate should be continued with certolizumab pegol where appropriate.

*Maintenance dose*
After the starting dose, the recommended maintenance dose of certolizumab pegol for adult patients with psoriatic arthritis is 200mg every two weeks. Once clinical response is confirmed, an alternate maintenance dosing of 400mg every four weeks can be considered. Methotrexate should be continued during treatment with certolizumab pegol where appropriate.

Available data suggest that clinical response is usually achieved within 12 weeks of treatment. Continued therapy should be carefully reconsidered in patients who show no evidence of therapeutic benefit within the first 12 weeks of treatment.

Treatment should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of conditions for which certolizumab pegol is indicated. Patients should be given the special alert card.

**Product availability date**
25 November 2013

**Summary of evidence on comparative efficacy**
Psoriatic arthritis is an inflammatory arthritis associated with psoriasis, classified with the spondyloarthropathies. Certolizumab pegol is a humanised fragment antigen binding prime (Fab′) conjugated to polyethylene glycol (PEG) which neutralises human tumour necrosis factor (TNF)-α bioactivity and inhibits the production of inflammatory cytokines by monocytes. It has previously been accepted for use within NHS Scotland, in combination with methotrexate, for the treatment of moderate to severe active rheumatoid arthritis in adult patients when the response to disease modifying antirheumatic drugs (DMARDs), including methotrexate, has been inadequate; and also for the treatment of adult patients with severe active axial spondyloarthritis, comprising ankylosing spondyloarthritis (AS) and axial spondyloarthritis without radiographic evidence of AS (nr-axSpA).
A phase III, randomised, double-blind, placebo-controlled study (RAPID-PsA) evaluated the efficacy and safety of certolizumab pegol in 409 patients with adult onset active and progressive psoriatic arthritis (PsA). Patients were eligible if they were aged ≥18 years with a diagnosis of adult-onset PsA of at least 6 months’ duration as defined by the Classification Criteria for Psoriatic Arthritis (CASPAR) criteria. Patients had to have active psoriatic skin lesions or a history of psoriasis and active arthritis with ≥3 tender joints, ≥3 swollen joints and either erythrocyte sedimentation rate ≥28 mm/h (Westergren) or C-reactive protein > upper limit of normal (7.9mg/L); and had previously failed on at least one DMARD. Up to 40% of patients could have received a prior TNFα inhibitor, with a washout period of >3 months before the baseline visit (28 days in the case of etanercept). Patients who had prior failure on a previous TNFα inhibitor according to the investigator were excluded from the study. Patients were randomised equally, stratified by study site and prior exposure to a TNFα inhibitor, to receive subcutaneous placebo (0.9% sodium chloride, n=136) or certolizumab pegol 400mg at weeks 0, 2 and 4 as a loading dose; followed by either certolizumab pegol 200mg every two weeks (200mg Q2W, n=138), or certolizumab pegol 400mg every 4 weeks (400mg Q4W, n=135) for the 24-week double-blind, placebo-controlled treatment period. The cumulative monthly dose of certolizumab pegol was the same for all subjects randomised to certolizumab pegol. Concomitant methotrexate, sulphasalazine or leflunomide, maintained at a stable dose, was allowed if it had been initiated at least 28 days before the baseline visit. Oral corticosteroids at a stable dose equivalent to ≤10mg daily total prednisone were permitted. A total of 59 patients in the placebo group failed to achieve a 10% improvement from baseline in both swollen and tender joints at week 14 and 16 and underwent mandatory escape and were re-randomised to certolizumab pegol 200mg Q2W (n=30), or certolizumab pegol 400mg Q4W (n=29) at week 16.

There were two co-primary endpoints. The clinical co-primary endpoint was American College of Rheumatology 20% (ACR20) response at week 12, assessed using the Health Assessment Questionnaire Disability Index (HAQ-DI) and C-reactive protein (CRP) levels. The radiographic co-primary endpoint was change from baseline in modified Total Sharp Score (mTSS) at week 24, a methodology that quantifies the extent of bone erosions and joint space narrowing in distal interphalangeal, proximal interphalangeal, metacarpophalangeal, metatarsophalangeal and wrist joints.

Significantly more patients in the certolizumab pegol groups than the placebo group achieved an ACR20 response at week 12: 24% for placebo compared with 58% for certolizumab pegol 200mg Q2W and 52% for certolizumab pegol 400mg Q4W. The primary outcome was also met in the subgroups of patients who had received prior treatment with a TNFα inhibitor and in patients taking concomitant DMARDs (predominantly methotrexate). See table below.

### Table 1. Results of the primary clinical outcome from RAPID-PsA.

<table>
<thead>
<tr>
<th>Proportion of patients achieving ARC20 response at week 12</th>
<th>Placebo</th>
<th>Certolizumab pegol 200mg Q2W</th>
<th>Certolizumab pegol 400mg Q4W</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall study population (n=409)</td>
<td>24%</td>
<td>58%</td>
<td>52%</td>
</tr>
<tr>
<td>Prior TNFα inhibitor (n=80)</td>
<td>15% (4/26)</td>
<td>45%* (14/31)</td>
<td>65%* (15/23)</td>
</tr>
<tr>
<td>Concomitant DMARD (n=287)</td>
<td>28% (25/88)</td>
<td>59% (58/99)</td>
<td>55% (55/100)</td>
</tr>
</tbody>
</table>

*p<0.001; **p=0.012
The prespecified analysis of the change from baseline in mTSS score showed no statistically significant difference between certolizumab pegol and placebo. This was thought to be due to the method used for imputation of scores in patients with <2 usable mTSS scores at baseline, which inappropriately overestimated radiographic progression in all treatment groups. In a post hoc analysis using conventional imputation methods that have been used in other studies in PsA, there was a significant difference in the least squares mean (LSM) change from baseline in mTSS in favour of certolizumab pegol (LSM change from baseline of 0.28 for placebo versus 0.06 for the combined certolizumab pegol groups).

A number of secondary outcomes were analysed: ACR20 at week 24 was achieved in 24%, 64% and 56% of patients in the placebo, certolizumab pegol 200mg Q2W and certolizumab pegol 400mg Q4W groups, respectively (p<0.001 for comparisons of certolizumab pegol versus placebo). There was also a significant difference in favour of certolizumab pegol in the proportions of patients achieving ACR50 and ACR70 responses at week 24.

In patients with at least 3% body surface area of psoriatic skin involvement at baseline, the proportion of patients who achieved a 75% reduction in the Psoriasis Area and Severity Index (PASI75) at week 24 was 15%, 62% and 61% respectively (p<0.01).

Patients in the certolizumab pegol groups had significant improvements in physical function, assessed by Health Assessment Questionnaire Disability Index (HAQ-DI), compared with placebo. The mean change from baseline in HAQ-DI at week 24 was -0.50 for the combined certolizumab pegol groups versus -0.19 for placebo; p<0.01.

Results from RAPID-PsA up to 48 weeks have been published in abstract form. Clinical efficacy of certolizumab pegol was maintained over 48 weeks, including patients with and without prior TNFα inhibitor.

There were significant improvements in quality of life for patients who received certolizumab pegol compared with placebo in both disease-specific measures (Psoriatic Arthritis Quality of Life [PsAQOL] and Dermatology Life Quality Index [DLQI]) and general health-related measures (Short Form Health Survey-36 Item [SF-36] and Health Status).

Other data were also assessed but remain commercially confidential.*

Summary of evidence on comparative safety

No comparative safety data, except versus placebo, are available. Refer to the summary of product characteristics for full details of adverse events (AE).

In the RAPID-PsA study, all randomised patients who received at least one dose of study medication were included in the safety analysis. Similar proportions of patients in the certolizumab pegol and placebo groups experienced any adverse event (62% versus 68% respectively) and adverse events related to study treatment (26% versus 27%) during the 24-week double-blind placebo-controlled period. Serious adverse events were reported in 6.6% (n=22) of certolizumab pegol patients and 4.4% (n=6) of placebo patients.

The most common adverse events that occurred in a greater proportion of patients in the certolizumab pegol groups than the placebo groups (difference of ≥2%) were upper respiratory tract infection (7.8% versus 5.1%), alanine aminotransferase increased (3.6% versus 1.5%), headache (3.6% versus 1.5%), aspartate aminotransferase increased (3.0% versus 0.7%) and sinusitis (2.7% versus 0.7%).
Two deaths were reported during the 24-week, double-blind phase of RAPID-PsA; one due to myocardial infarction in the certolizumab pegol 200mg Q2W group and one sudden death of unknown cause in the certolizumab pegol 400mg Q4W group. Neither was considered related to study medication by the investigator.\(^2\)

The safety profile for certolizumab pegol in psoriatic arthritis was consistent with the safety profile in rheumatoid arthritis and previous experience with certolizumab pegol.\(^5\)

### Summary of clinical effectiveness issues

Treatment of psoriatic arthritis is with NSAIDs and DMARDs; current guidelines recommend biologics for the treatment of active psoriatic arthritis in patients who have failed to respond to, are intolerant of, or have had contraindications to at least two DMARDs.\(^8,9\) Certolizumab pegol offers another treatment option for patients with active psoriatic arthritis who are candidates for treatment with a TNF\(\alpha\) inhibitor.

In the RAPID-PsA study, certolizumab pegol demonstrated a significant benefit over placebo in the proportion of patients who achieved an ACR20 response. This is a validated outcome for studies in psoriatic arthritis, however, patients who have an ACR20 response may still have significant disease. ACR50 and ACR70 responses were assessed as secondary outcomes and these were also significantly improved with certolizumab pegol compared with placebo. There were significant improvements in quality of life measures in patients who received certolizumab pegol compared with placebo.

The licensed indication for certolizumab pegol is in combination with methotrexate, however, only 64% of study patients in RAPID-PsA were taking concurrent methotrexate. Sub-group analysis in patients who were taking concomitant DMARD, which was predominantly methotrexate, showed that the primary outcome was met in these patients. Although study randomisation was not stratified by DMARD use at baseline, the patient characteristics were similar between groups for patients with and without DMARDs.\(^7\) The European Public Assessment Report (EPAR) noted that, although certolizumab pegol was effective compared with placebo with or without concomitant methotrexate, the results favoured combination treatment.\(^7\)

The RAPID-PsA study included patients who had previously received treatment with a TNF\(\alpha\) inhibitor, but not primary failures, as well as patients who were TNF\(\alpha\) inhibitor-naive. Overall, 20% of patients had received a prior TNF\(\alpha\) inhibitor and certolizumab pegol demonstrated a significant benefit over placebo in this population.

The co-primary radiographic outcome (mTSS) did not show a significant difference between certolizumab pegol and placebo in the prespecified analysis, however, a post hoc analysis using conventional methods for imputation of missing baseline data did show a significant improvement in mTSS for certolizumab pegol over placebo. This is a potential limitation of the study.

There are no clinical studies versus an active comparator. The company submitted a mixed treatment comparison (MTC) with alternative TNF\(\alpha\) inhibitors licensed for psoriatic arthritis. The MTC primarily evaluated data from 10 studies in patients with no prior exposure to TNF\(\alpha\) inhibitors. Outcomes included ACR response rates, Psoriatic Arthritis Response Criteria (PsARC), Psoriasis Area and Severity Index (PASI), physical functioning (HAQ-DI) and quality of life measures (SF-36). The company concluded that, while there were differences in the point estimates of the outcomes among the TNF\(\alpha\) inhibitors, generally there were no significant differences between the therapies, and certolizumab pegol showed similar efficacy to adalimumab, etanercept, infliximab and golimumab at...
12 to 16 weeks and 24 weeks. There was a statistically significant result for change in SF-36 (physical component score) in favour of adalimumab and etanercept compared with certolizumab pegol. However, the company stated that the results for SF-36 should be interpreted with caution due to a limited number of studies (n=5) in this network. There were no significant differences for the comparison of certolizumab pegol with any other TNFα inhibitor for any other outcome.

The MTC was generally well conducted, but was limited by heterogeneity in the baseline characteristics among the studies in terms of the duration and severity of psoriatic arthritis, and in the time-points used for the primary analyses. In addition, not all outcomes of interest were assessed for every study. The MTC was limited to patients who were naïve to treatment with TNFα inhibitors.

Certolizumab pegol should be administered by subcutaneous injection every two weeks, but there is an option for 4-weekly dosing once clinical response is confirmed.5

<table>
<thead>
<tr>
<th>Summary of comparative health economic evidence</th>
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</table>

The company submitted a cost-utility analysis comparing certolizumab pegol with other TNFα inhibitors already accepted by SMC for patients with active PsA, namely etanercept, infliximab, adalimumab and golimumab. The analysis included only patients who have no prior experience with TNFα inhibitor therapy and have failed one or more conventional DMARDs. A cost-minimisation analysis was also submitted which evaluated the costs of each treatment assuming no difference in efficacy.

A lifetime Markov cohort model was used which followed patients as they moved through health states based on PsARC. The model had a short term phase (trial period) where the initial response to treatment was evaluated at 6 months. Response to treatment was measured by PsARC for joints and PASI75 for psoriasis and then changes in quality of life based on HAQ-DI scores were assigned to responders (defined by PsARC response) as well as non-responders. Non-responders moved to standard care which was assumed to consist of continuing use of conventional DMARDs. The short term model was followed by a long term follow-up period where responders remained on treatment until loss of efficacy or withdrawal due to other reasons. The source of the clinical data in the model was the MTC of alternative TNFα inhibitors described above, where numerical differences in outcomes were included.

The utility values in the model were derived by mapping HAQ-DI and PASI scores to EQ-5D data collected in the pivotal RAPID-PsA study using a regression analysis. A utility mapping algorithm was estimated which resulted in different utility decrements according to patients’ HAQ-DI and PASI scores. No adverse event disutilities or costs were included. As the treatments appear to have broadly similar safety profiles, this seems reasonable.

Drug acquisition and administration costs were included for the TNFα inhibitors and standard care. Monitoring costs were included in the model and these involved a range of procedures and lab tests to monitor disease and/or treatment-related complications. Disease management costs related to loss of functionality were included. These costs were linked to patients’ HAQ-DI scores and included GP, outpatient, hospital and other healthcare contacts. PASI-related costs were considered in the sensitivity analysis only.

The results of the cost-utility analysis showed certolizumab was dominant when compared with infliximab, but was not cost-effective when compared with the other TNFα inhibitors. For the comparisons with adalimumab and golimumab the incremental cost-effectiveness ratios (ICERs) were £44k and £188k per quality-adjusted life-year (QALY) respectively. When compared with etanercept,
certolizumab pegol was estimated to be less costly but also less effective. The ICER versus standard care was estimated to be £24,468 per QALY.

A Patient Access Scheme (PAS) was submitted by the company and assessed by the Patient Access Scheme Assessment Group (PASAG) as acceptable for implementation in NHS Scotland. Under the PAS a simple discount was offered which reduced the list price of certolizumab pegol. The results of the cost-utility analysis with the PAS showed certolizumab pegol dominated adalimumab, golimunab and infliximab. When compared with etanercept, certolizumab pegol was less costly but also less effective. The ICER versus standard care was estimated to be £22,228 per QALY. The results of the cost-minimisation analysis with the PAS showed certolizumab pegol was cost-saving.

One-way sensitivity analysis showed the results were most sensitive to changes in the time horizon, the method for calculating utility values and the change in HAQ upon treatment discontinuation. The company also provided the ICERs for each TNFα inhibitors versus standard care which showed the majority of the treatments had similar incremental costs and QALY gains over standard care, with the exception being infliximab which was associated with a relatively higher incremental cost.

The key weakness is the base case cost-utility analysis included non-significant differences in PsA related outcome measures and as such the cost-minimisation analysis could be considered more appropriate. While the MTC showed no significant difference between the active treatments in terms of the key clinical outcome measures, for the quality of life SF-36 measure there was a statistically significant result for change in SF-36 (physical component score) in favour of adalimumab and etanercept compared with certolizumab pegol. However, the disease-specific quality of life measure (HAQ-DI) did not show a significant difference between the treatments and the submitting company argued using HAQ-DI and PASI scores to derive utility values was a well established approach in this area. As noted above, the submitting company also argued that the results of the SF-36 analysis are uncertain due to the small number of studies included in this network. The SMC statistical advisor considered the number of studies included was not sufficient reason to reject the results of this analysis.

The results of the cost-minimisation analysis with the PAS indicate certolizumab pegol has comparable efficacy to, and is less costly than, infliximab, golimunab, adalimumab and etanercept. The MTC indicated there may be some evidence of improved quality of life for patients receiving adalimumab and etanercept based on SF-36 scores, but this difference was not apparent with other recognised quality of life measures. Therefore, the economic case has been demonstrated.

It is SMC policy to include the estimated QALY gain in the detailed advice document for all submissions. The PAS for certolizumab pegol includes a discount to the NHS that is commercial in confidence and the submitting company has advised that publication of the QALY gain, when considered with other cost-effectiveness data in the public domain, could reveal the level of discount. For this reason SMC has agreed not to publish the estimated QALY gain.

*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 Information Group.

- Submissions were received by the Psoriasis and Psoriatic Arthritis Alliance (PAPAA) and the Psoriasis Association (PA), which are both U.K. registered charities.
• PAPAA has not received any funding from pharmaceutical companies in the past two years. PA has received funding from several pharmaceutical companies in the past two years.

• Psoriatic Arthritis is a destructive form of arthritis which requires timely treatment to prevent irreversible damage to the joints. Persistent pain, swollen joints and fatigue are very common symptoms. Hands and feet are common sites affected and walking, manual dexterity and self-care can be problematic. Psoriatic arthritis affects younger people with the onset peaking at 30-40 years.

• Severe psoriatic arthritis can lead to permanent disability. Employment can be affected and patients worry about caring for young children. The psychological impact of living with psoriatic arthritis should not be underestimated.

• Many patients do not respond to current treatments. Certolizumab would provide an alternative choice for patients. It is administered as an injection rather than infusion.

• Concerns were highlighted including a lack of long-term safety data, a lack of comparison with current treatments and cost.

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**Additional information: guidelines and protocols**

The Scottish Intercollegiate Guidelines Network (SIGN) published clinical guideline 121 “Diagnosis and management of psoriasis and psoriatic arthritis in adults” in 2010. It recommends the use of adalimumab, etanercept or infliximab for the treatment of active psoriatic arthritis in patients who have failed to respond to, are intolerant of, or have had contraindications to, at least two disease-modifying therapies.\(^7\)

NICE published MTA 199 “Etanercept, infliximab and adalimumab for the treatment of psoriatic arthritis” in 2010.\(^8\) It states that etanercept, infliximab and adalimumab are recommended for the treatment of adults with active and progressive psoriatic arthritis when the following criteria are met.

- The person has peripheral arthritis with three or more tender joints and three or more swollen joints, and
- The psoriatic arthritis has not responded to adequate trials of at least two standard DMARDs, administered either individually or in combination.

Etanercept, adalimumab or infliximab treatment should be discontinued in people whose psoriatic arthritis has not shown an adequate response using the Psoriatic Arthritis Response Criteria (PsARC) at 12 weeks.\(^8\)

The British Society for Rheumatology published “Guidelines for the treatment of psoriatic arthritis with biologics” in 2012. It includes a treatment algorithm in which patients with predominantly peripheral psoriatic arthritis would receive the following lines of treatment as required: NSAIDs and/or intra-articular steroids, then first and second DMARDs, then first and second anti-TNF drugs.\(^9\)

These guidelines all predate the licensing of certolizumab pegol for psoriatic arthritis.
**Additional information: comparators**

Other TNFα inhibitors licensed for this indication: adalimumab, etanercept, golimumab, infliximab; ustekinumab (an interleukin inhibitor).

### Cost of relevant comparators

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dose Regimen</th>
<th>Cost per year (£)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Certolizumab pegol</td>
<td><strong>Loading dose:</strong> 400mg subcutaneously weeks 0, 2 &amp; 4. <strong>Maintenance dose:</strong> 200mg subcutaneously every two weeks</td>
<td>First year: 10,368; subsequent years: 9,295</td>
</tr>
<tr>
<td>Infliximab</td>
<td>Initially 5mg/kg by intravenous infusion followed by 5mg/kg two and six weeks after the first infusion, then every eight weeks</td>
<td>First year: 13,428; subsequent years: 10,071 to 11,749</td>
</tr>
<tr>
<td>Ustekinumab*</td>
<td>Initially 45mg subcutaneously, followed by 45mg four weeks later and then every 12 weeks. Alternatively, 90mg may be used if body weight &gt;100kg</td>
<td>First year: 10,735; subsequent years: 8,588 to 10,735</td>
</tr>
<tr>
<td>Etanercept</td>
<td>25mg subcutaneously twice weekly or 50mg once weekly</td>
<td>9,295</td>
</tr>
<tr>
<td>Adalimumab</td>
<td>40mg subcutaneously every second week</td>
<td>9,156</td>
</tr>
<tr>
<td>Golimumab</td>
<td>50mg subcutaneously once a calendar month</td>
<td>9,156</td>
</tr>
</tbody>
</table>

Doses are for general comparison and do not imply therapeutic equivalence. Costs for adalimumab and etanercept from eVadis on 24 March 2014; costs for all other drugs from MIMS online on 28 March 2014. Cost for infliximab assumes a body weight of 70kg.

*Ustekinumab was not a comparator in the company submission – it was only recently accepted by SMC and was included in this list for completeness.*

**Additional information: budget impact**

Without the PAS, the submitting company estimated the gross drug budget impact to be £445k in year 1 and £2.02m in year 5. As other drugs were assumed to be displaced the net drug budget impact was estimated to be £49k in year 1 and £54k in year 5.

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

The undernoted references were supplied with the submission. The reference shaded in grey is additional to those supplied with the submission.


5. UCB Pharma Limited, Summary of Product Characteristics, certolizumab pegol, Cimzia®, 200mg solution for injection; last updated 04/12/13.


This assessment is based on data submitted by the applicant company up to and including 16 May 2014.

*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.