

Pipeline Flex embolisation device with Shield Technology for the treatment of complex intracranial aneurysms

Medical technologies guidance

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1 Recommendations

- 1.1 The case for adopting the Pipeline Flex embolisation device with Shield Technology in the NHS is supported by the current evidence when it is used in patients with complex giant or large intracranial aneurysms which are unsuitable for surgery and being considered for stenting, and where large numbers of coils would be needed during stent-assisted coiling.
- 1.2 The Pipeline Flex embolisation device with Shield Technology is estimated to be cost saving when compared with stent-assisted coiling, in patients with complex giant or large intracranial aneurysms when the number of Pipeline embolisation devices inserted does not exceed 2, and when treatment would otherwise require the use of 34 or more coils combined with 1 stent for stent-assisted coiling. If 2 Pipeline embolisation devices are used the total procedure cost is estimated as £37,625 compared with £38,320 for the use of 34 coils for stent-assisted coiling (a saving of £695 using Pipeline embolisation device). **[2019]**
- 1.3 Clinicians should submit details of all patients being treated with the Pipeline Flex embolisation device with Shield Technology to the UK Neurointerventional Radiology Group audit database, to increase the evidence base and guide future use of this technology.

2 The technology

Description of the technology

- 2.1 The Pipeline Flex embolisation device with Shield Technology ('Pipeline'; Medtronic) is a self-expanding blood flow diverter that is placed across the neck of an intracranial aneurysm. While blood flow through the parent vessel is maintained via the device, flow within the aneurysm sac is disrupted, leading to stagnation and eventual thrombosis formation. Pipeline provides a scaffold for endothelial growth leading to the formation of a biological seal and exclusion of the aneurysm from the circulation. **[2019]**
- 2.2 Pipeline is a braided, cobalt chromium and platinum stent-like device which is loaded into and delivered via a microcatheter. It is manufactured in lengths of 10–35 mm and is available in different diameters from 2.5 to 5 mm (in 0.25 mm increments). Multiple devices can be used within each other and/or in sequence to increase the overall length of the construct or to increase the metal surface coverage within an aneurysm.
- 2.3 Pipeline is indicated for use in patients with unruptured, complex intracranial aneurysms, specifically large and giant, wide-necked and fusiform aneurysms. This is the group of patients covered by this guidance. Pipeline may also be used in patients whose aneurysms are unsuitable for standard coiling and/or stenting and for neurosurgical treatment; and in patients for whom previous coiling/clipping procedures have failed.
- 2.4 The cost of Pipeline stated in the sponsor's submission is £10,171. These costs have been updated in the latest revision of the cost model to £10,450. **[2019]**
- 2.5 The claimed benefits of Pipeline in the case for adoption presented by the sponsor are:

- A higher rate of complete, permanent occlusion of large/giant intracranial aneurysms compared with coiling and stent-assisted coiling, leading to reduced rates of retreatment and a decreased risk of haemorrhage.
- Increased access to treatment for patients with complex intracranial aneurysms. Pipeline offers a new option for treating patients with complex intracranial aneurysms which are not suitable for stent-assisted coiling or surgery, and patients for whom previous interventions have failed.
- Patients may experience a resolution of neurological symptoms as a result of relieving pressure on surrounding areas of the brain caused by the mass effect of aneurysms.
- Increased long-term vessel patency, preserving blood flow to distal tissues supplied by the aneurysmal artery.
- The high rate of complete, permanent occlusion of the target aneurysm with the possibility of reduced need for retreatment and an overall decrease in use of NHS resources.

Current management

- 2.6 Current options for managing complex intracranial aneurysms include coiling, often with concomitant use of stent placement (stent-assisted coiling), neurosurgical clipping requiring craniotomy (with or without bypass procedures), parent vessel occlusion (by open neurosurgery or by endovascular means) and conservative management.

3 Clinical evidence

Summary of clinical evidence

- 3.1 Full details of all clinical outcomes considered by the committee are available in the [assessment report overview](#).
- 3.2 The key clinical outcomes for Pipeline presented in the decision problem are:
- successful device deployment
 - successful occlusion of the aneurysm, with or without preservation of flow through the parent vessel
 - size of the aneurysm and its contained thrombus mass
 - resolution of symptoms (including headache, diplopia, nystagmus or other neurological dysfunction), relief of pain and quality of life outcomes
 - resource use outcomes (for example, re-admission rates, repeat interventions and duration of hospital stay)
 - stroke related to device insertion (any cause, but particularly due to vessel occlusion or bleeding)
 - delayed parent vessel occlusion
 - subarachnoid haemorrhage and/or other major bleeding events needing admission to hospital
 - neurovascular death
 - device-related adverse events.
- 3.3 The sponsor identified 13 studies relevant to the scope, but because it judged the quality of many of these to be poor and because of duplication in patient reporting, the sponsor's submission presented detailed findings on a total of 139 patients from 2 studies, with a

maximum follow-up of 2 years. The studies were Pipeline for Intracranial Treatment of Aneurysms (PITA) and Pipeline for Uncoilable or Failed aneurysms (PUFS).

- 3.4 Nelson et al. (2011) reported outcomes up to 2 years for the PITA study: a prospective, multicentre single-arm feasibility study of 31 patients with 31 intracranial aneurysms that were small (<10 mm [20 patients]), large (10–25 mm [9 patients]) or giant (>25 mm [2 patients]). An aneurysm neck width ≥ 4 mm was recorded in 22 patients (71%). In 12 patients (39%), other interventions for the target aneurysm had failed.
- 3.5 A report to the FDA by the sponsor (FDA 2011) described the clinical evidence at 1 year from the PUFS study: an ongoing prospective, multicentre, single-arm study of 108 patients with 110 intracranial aneurysms that were small (<10 mm [1 patient]), large (10–25 mm [85 patients]) or giant (>25 mm [22 patients]). The mean aneurysm neck width was 8.8 mm. In 8 patients (7%), other interventions for the target aneurysm had failed.
- 3.6 In its literature search, the external assessment centre found 3 case reports and 1 conference abstract of 96 patients in addition to the 13 studies identified by the sponsor. It excluded 1 of the studies identified by the sponsor (Matouk et al. 2010) because it was outside the scope. The external assessment centre therefore included a total of 16 studies with 380 patients in its assessment report.
- 3.7 Across 13 studies with a total of 237 patients (239 complex intracranial aneurysms), successful device placement was reported in 50–100% of patients. In 8 of the 13 studies, successful device placement was reported in all patients (25 in total; Fiorella et al. 2008, 2009a, 2009b, 2010; Hartmann et al. 2010; Kilsch et al. 2011; Phillips et al. 2010; Sararols et al. 2011).
- 3.8 Nelson et al. (2011) reported clinical procedure success (defined as successful placement of the device without death or ipsilateral stroke) in 94% (29/31) of patients: the 2 failures were because of peri-procedural stroke. For patients in the PUFS study, the primary effectiveness end point was complete occlusion of the aneurysm and absence of parent

vessel stenosis greater than 50% at 180 days. The probability of exceeding the pre-determined 'success threshold' of 50% was statistically significant ($p < 0.0001$; FDA, 2011).

- 3.9 Major ipsilateral stroke or neurological death, as judged by the Clinical Events Committee, was reported in 6% (6/107) of patients at 180 days in the PUFS study (FDA 2011). Ipsilateral stroke was reported in 7% (2/31) of patients within 30 days in the PITA study (Nelson et al. 2011). Five other studies including a total of 58 patients (68 complex intracranial aneurysms) reported a stroke rate of 0% at follow-up ranging from 10 weeks to more than 52 weeks (Fiorella et al. 2009a, 2009b; Lylyk et al. 2009a; Klisch et al. 2011; Sararols et al. 2011).
- 3.10 In the PUFS study, 3 of the 6 patients who had a major ipsilateral stroke died (timing of events not reported). Nelson et al. (2011) reported no deaths in the PITA study.
- 3.11 Nelson et al. (2011) reported complete occlusion of the target aneurysm in 93% (28/30) of patients at 180 days (95% confidence interval [CI] 77.9 to 99.2); it was not possible to assess occlusion in 1 patient who had Pipeline surgically removed and the parent vessel ligated. All patients who had complete occlusion at 180 days also had complete occlusion at 2 years as assessed by either catheter angiography or MRI.
- 3.12 Complete occlusion without major stenosis was reported in 74% (78/106) of aneurysms at 180 days and 71% (75/106) of aneurysms at 1-year angiography (FDA 2011). Eight studies with a total of 131 patients all reported occlusion rates of 100% in patients assessed at follow-up ranging from 3 to 30 months (Fiorella et al. 2008, 2009a, 2009b, 2010; Klisch et al. 2011; Phillips et al. 2010; Sararols et al. 2011; Szikora et al. 2010b). Occlusion rates of 93%, 89% and 69% were reported by Lylyk et al. (2009a), Szikora et al. (2010a) and O'Kelly et al. (2011) respectively (absolute figures not reported).
- 3.13 Nelson et al. (2011) reported that 10% (3/31) of patients, 1 of whom had previously had a stroke, showed improvement in intracranial aneurysm-related symptoms at 30 days. There was no deterioration in neurological status at 30 days in the 28 patients free of stroke. The FDA report (2011)

described Rankin scoring (a general measure of neurological function) for 104 patients. The scores improved from baseline in 20% (21/104) of patients, remained unchanged in 67% (70/104) and deteriorated in 10% (10/104) at 180 days follow-up. There was an improvement in visual field sensitivity (not otherwise described) from baseline in 21% (19/89) of patients, no change in 73% (65/89) of patients and deterioration in eye function in 6% (5/89) of patients at follow-up of 180 days (FDA 2011). Three case reports described complete resolution of symptoms at follow-up ranging from 10 to 26 weeks (Fiorella et al. 2009a, 2009b; Sararols et al. 2011). Szikora et al. (2010b) reported resolution of symptoms in 61% of patients at a mean follow-up of 26 weeks.

- 3.14 Studies of 96, 18, 8 and 5 patients reported subarachnoid haemorrhage after surgery in 1%, 5%, 13% and 20% of patients respectively (absolute figures and follow-up not reported; Hampton et al. 2011; Hartmann et al. 2010; O'Kelly et al. 2011, Szikora et al. 2010b).

Committee considerations

- 3.15 The committee was advised by the experts that Pipeline is currently considered in some specialist units for patients who have symptoms caused by the mass effect of aneurysms, or a high risk of future bleeding, who are considered fit for general anaesthesia and who have an average life expectancy of at least 1 year.
- 3.16 The committee noted that Pipeline may be the only possible intervention for some patients who have symptoms caused by the mass effect of aneurysms, or a high risk of future bleeding, whose aneurysms are unsuitable for either stent-assisted coiling or surgical treatment and for whom parent vessel occlusion would result in stroke or death.
- 3.17 The committee considered that data from the studies described above provided evidence for the efficacy of Pipeline in most patients. In the context of the high risks posed to patients by untreated complex large or giant aneurysms the safety profile was judged to be acceptable.
- 3.18 The committee noted that the effect of the device on symptoms or on the risk of bleeding is subject to some delay.

- 3.19 The committee recognised that patient selection for treatment either by Pipeline or by comparator interventions is complex, and needs to be carried out by an experienced multidisciplinary team.
- 3.20 The committee noted that most of the clinical evidence came from the United States, where patient selection for different types of endovascular interventions may differ from the UK, in terms of the treatments selected for intracranial aneurysms based on their size and shape.
- 3.21 The committee noted that the clinical evidence comparing the efficacy of Pipeline with other interventions was very limited. This made evaluation difficult. The committee recognised the difficulties in conducting comparative studies, particularly randomised controlled trials, for large and giant complex intracranial aneurysms.
- 3.22 The committee noted that both new studies and an extension of the PUFS study are in progress.
- 3.23 The committee considered that data collection using a register would be an important practical way of developing evidence to guide future practice, in addition to the ongoing studies.

4 NHS considerations

System impact

- 4.1 No secondary treatments were required at 1-year follow-up among patients in the PUFS study (FDA 2011). Need for retreatment was not reported in the PITA study (Nelson et al. 2011). Need for retreatment was not reported in the other 14 studies included in the external assessment centre's assessment report.

Committee considerations

- 4.2 The committee noted that little evidence was available on the need for retreatment following treatment with Pipeline.
- 4.3 The committee recognised that there are a small number of patients for whom Pipeline offers the only possible means of treatment (an estimated 60 patients per year in the UK). For these patients the potential benefits offered by Pipeline are important, because they are at high risk of aneurysm rupture and because their intracranial aneurysms are unsuitable for other treatments.

5 Cost considerations

Cost evidence

- 5.1 The sponsor submitted a de novo cost analysis for Pipeline for the treatment of complex intracranial aneurysms. Full details of all cost evidence and modelling considered by the committee are available in the [assessment report overview](#).
- 5.2 The sponsor presented a decision tree (for the peri-procedural period) followed by a Markov model (for long-term outcomes) to estimate the costs and consequences associated with Pipeline against 5 comparator interventions: stent-assisted coiling, neurosurgical clipping, endovascular parent vessel occlusion, neurosurgical parent vessel occlusion and conservative management. The patient population included those with unruptured large or giant intracranial aneurysms as outlined in the scope, but did not include fusiform or wide-necked aneurysms.
- 5.3 The decision-tree structure separated patients who had survived initial treatment, based on a mortality rate for the procedure, into 1 of 3 occlusion categories (complete occlusion, residual neck and residual aneurysm). For each occlusion category, patients were tracked through 5 possible health states: 'no complications', 'new non-fatal rupture', 'post rupture', 'fatal rupture' and 'dead (all cause)'. It was assumed that transition probabilities for the health states would be constant over time. The time horizon of the base-case analysis was 10 years.
- 5.4 An NHS and personal social services perspective was used. The cost analysis included the costs associated with the duration of the procedure, staff time (surgeon, radiologist, nurse, anaesthetist), hospital costs (neurology operating or neurosurgical operating room, and recovery ward), imaging (angiography, fluoroscopy or MRI), consumables, drugs; and for conservative management only, long-term monitoring with annual MRI. The cost associated with stroke was assumed to be representative of the cost of rupture. Costs applied to each type of retreatment were assumed to be the same as the full cost if

that treatment had been used initially.

- 5.5 The costs and consequences associated with adverse events were not included in the base-case analysis because the sponsor considered there to be insufficient reliable data for each treatment group. However, the sponsor did include costs associated with mortality at 31 days, rupture and retreatment.
- 5.6 In the base case the number of Pipeline embolisation devices used was 1.46, based on data submitted to the sponsor from use of the device in UK hospitals up to August 2011. The number of coils used in the base case was 40 and was derived from an estimate in an editorial review by Wehman in 2006. It was assumed that 1 stent would be needed for each stent-assisted coiling intervention.
- 5.7 The base case presented the total procedure costs over the 10-year time horizon associated with Pipeline as £24,341. For the comparators, the total procedure costs were £37,451 for stent-assisted coiling, £11,658 for neurosurgical clipping, £16,893 for endovascular parent vessel occlusion, £11,654 for neurosurgical parent vessel occlusion and £10,352 for conservative management. The only intervention against which Pipeline was shown to be cost saving was stent-assisted coiling, with a cost saving of £13,110 per patient.
- 5.8 Two scenario analyses were presented. One included costs associated with the adverse events of subarachnoid haemorrhage related to the aneurysm, thromboembolic stroke and intracranial haemorrhagic stroke remote from the aneurysm using data from the PUFS study and data from Darsault et al. (2001) for the comparators. The other scenario analysis restricted the time horizon to 6 months (short-term). Conservative management was excluded from the short-term scenario because it does not have a 'peri-procedural' mortality rate.
- 5.9 In both scenario analyses Pipeline was shown to be cost saving only when compared with stent-assisted coiling. When costs associated with adverse events were included in the model, Pipeline remained a cost-saving intervention compared with stent-assisted coiling, with an associated saving of £13,327. When outcomes were restricted to the

short term (6 months), Pipeline remained cost saving compared with stent-assisted coiling (£10,316).

- 5.10 Sensitivity analyses carried out by the sponsor showed that the main factors influencing the cost analysis were the number and cost of consumables, in particular the numbers of Pipeline embolisation devices and endovascular coils. The sponsor carried out sensitivity analysis for the use of 1–3 Pipeline embolisation devices and separately for 5–100 coils.
- 5.11 The number of Pipeline embolisation devices used in the base case was 1.46 per patient. On receipt of more data from UK hospitals, the sponsor submitted a revised number of 1.658 in October 2011. The external assessment centre reviewed the data and concluded that when 1.658 Pipeline embolisation devices were used, Pipeline was more costly compared with stent-assisted coiling if 22 coils were used (an estimated cost increase of £19), but cost saving when 23 coils were used. The cost saving when using 1.658 Pipeline embolisation devices compared with stent-assisted coiling with 23 coils was estimated to be £588 (total procedure costs of £26,546 and £27,134 respectively). When 2 Pipeline embolisation devices were used, Pipeline was more costly by an estimated £185 than stent-assisted coiling using 28 coils, but was less costly than stent-assisted coiling when 29 coils were used. The cost saving when using 2 Pipeline embolisation devices compared with stent-assisted coiling with 29 coils was estimated to be £421 (total procedure costs of £30,354 and £30,775 respectively).
- 5.12 During consultation, expert advisers expressed doubts about 5 parameters in the cost model: the cost of microcatheters; the use of a balloon in stent-assisted coiling; drug costs; the procedure duration; and the cost of additional endovascular equipment. Additional exploratory analyses were carried out by the external assessment centre to examine the impact of changing these parameters, in ways which the expert advisers suggested were more appropriate.
- 5.13 In the sponsor's economic model, the cost of microcatheters used in stent-assisted coiling was comparable to the cost of a Marksman catheter (£1,030) used to insert Pipeline. However, the expert advisers

stated that cheaper microcatheters (average cost £460.50) would be used for stent-assisted coiling than for Pipeline in UK practice. The external assessment centre's exploratory analyses demonstrated that reducing the cost of 2 microcatheters for stent-assisted coiling from £1,030 to £460.50 reduced the total procedure cost for stent-assisted coiling from £37,451 to £36,137.

- 5.14 The sponsor's economic modelling also assumed that a balloon is used in 50% of stent-assisted coiling procedures and is not used to insert Pipeline. However, the expert advisers stated that use of a balloon is relatively uncommon in the UK for stent-assisted coiling procedures. In the exploratory analyses carried out by the external assessment centre, removing the cost of a balloon reduced the total procedure cost for stent-assisted coiling from £36,137 to £35,725, while the total procedure cost for Pipeline (with 2 devices) remained at £30,354.
- 5.15 The sponsor's economic model assumed different drug use for patients having stent-assisted coiling and those having Pipeline (18,000 mg aspirin and 6,750 mg clopidogrel compared with 25,000 mg aspirin and 13,500 mg clopidogrel respectively). The expert advisers stated that in clinical practice drug use in the 2 groups is likely to be equal. The external assessment centre noted that in the sponsor's economic model drug use was calculated from 2 non-comparative studies, but that few published data are available on clinical use. The external assessment centre stated that the low cost of these drugs means that relatively small differences in drug use are unlikely to have a significant impact on the overall procedure costs for stent-assisted coiling and Pipeline. In the absence of a systematic review the external assessment centre stated that the drug costs used in the model were appropriate.
- 5.16 In its exploratory analysis the external assessment centre identified 2 calculation errors in the sponsor's economic model, both relating to the number of days of drug therapy. The external assessment centre stated that correcting these calculation errors made only a very small difference in the total procedure costs for both Pipeline and stent-assisted coiling, reducing them from £30,354 to £30,346 and £35,725 to £35,724 respectively.

- 5.17 In the sponsor's economic model, the average duration of the procedure (in hours) and therefore the use of additional endovascular equipment were different for stent-assisted coiling and insertion of Pipeline. The expert advisers stated that the procedures are likely to take the same amount of time in clinical practice. The external assessment centre noted that the time taken for stent-assisted coiling was derived from 1 non-comparative study and the time for inserting Pipeline from another. However the external assessment centre was not able to judge which study was the best source for duration of procedure and no systematic review was carried out. The external assessment centre stated that because both studies were appropriately and accurately used in the model no changes were justified with regard to procedure time for stent-assisted coiling or Pipeline. The external assessment centre also noted that the sponsor included the use of additional endovascular equipment in the model based on the duration of procedure, but provided no justification for why it was included only for stent-assisted coiling and not for Pipeline or the other comparators. Furthermore, there was no justification for why the cost of additional equipment was only included in calculating the retreatment cost but not the cost of the initial procedure. The exploratory analyses demonstrated that removing the costs of additional endovascular equipment from the model reduced the total procedure cost of stent-assisted coiling from £35,724 to £35,693 while the total procedure cost for Pipeline remained at £30,346.

Committee considerations

- 5.18 The committee considered the cost consequences of using Pipeline against 5 comparators – stent-assisted coiling, neurosurgical clipping, endovascular parent vessel occlusion, neurosurgical parent vessel occlusion and conservative management.
- 5.19 The committee noted that in UK clinical practice, patients who might currently be considered for Pipeline would be those for whom surgery would not be possible and for whom stent-assisted coiling would be the only other potential intervention. It therefore considered that comparison of costs with those for stent-assisted coiling was of particular relevance. The committee noted that for this cost comparison, the main drivers of cost were the numbers of Pipeline embolisation devices used and the

numbers of coils used during stent-assisted coiling. The committee was given advice from the experts about whether 1 or 2 Pipeline embolisation devices should be used as the most typical number on which to base its judgements about cost. It therefore considered the cost modelling for a range of scenarios – with different numbers of Pipeline embolisation devices. During its discussions the committee was informed both by expert advisers and by data from the sponsor that 2 Pipeline embolisation devices were likely to be needed for most patients treated in the UK for complex giant or large aneurysms.

- 5.20 There was considerable uncertainty about the number of coils likely to be used during stent-assisted coiling. The committee was advised that 40 coils was probably an overestimate of the number needed for most complex aneurysms and there were suggestions that about 25–30 coils might be more typical of the number needed for aneurysms being considered for treatment using Pipeline. The committee recognised that it is not possible to estimate accurately the number of coils which will be required to treat an aneurysm during stent-assisted coiling, but it was advised by experts that the number can usually be predicted with an accuracy of plus or minus 6 coils.
- 5.21 The committee discussed a number of parameters in the sponsor's economic model based on comments received during public consultation. As described in sections 5.12 to 5.17, these included: the cost of microcatheters used for stent-assisted coiling; balloon use in UK practice during stent-assisted coiling; drug costs for patients having Pipeline and those having stent-assisted coiling; the duration of the procedure and the use of additional endovascular equipment in stent-assisted coiling. These parameters were examined in additional analyses by the external assessment centre.
- 5.22 The committee considered that the costs for microcatheters used for stent-assisted coiling in the sponsor's base-case analysis were overestimated. It agreed with the views of the expert advisers that it was reasonable to use the average cost of the microcatheters most commonly used in UK clinical practice. This reduced the total procedure cost for stent-assisted coiling from £37,451 to £36,137.

- 5.23 Based on expert advice, the committee accepted that the inclusion of balloon use during stent-assisted coiling in the sponsor's base-case analysis was inappropriate and that it was reasonable to adjust this cost to zero. This reduced the total procedure cost for stent-assisted coiling from £36,137 to £35,725, while the total procedure cost for Pipeline remained at £30,354.
- 5.24 The committee considered the drug costs presented in the sponsor's base-case analysis. It noted the external assessment centre's view that few published data are available on clinical use and that the low cost of these drugs and the difference in drug use would not be likely to have any significant impact on the overall procedure costs for either stent-assisted coiling or Pipeline. The committee agreed that the drug cost in the sponsor's base-case analysis was appropriate
- 5.25 The committee considered the average duration of the procedure presented in the sponsor's base-case analysis. It noted the external assessment centre's view that both studies were appropriately and accurately used in the model and that therefore no changes were justified for the average duration of the procedure for stent-assisted coiling or inserting Pipeline. The committee agreed that the average duration of the procedure presented in the sponsor's base-case analysis was appropriate.
- 5.26 The committee was advised by the experts that it was not appropriate to include the cost for additional endovascular equipment for stent-assisted coiling only. This was because the cost of endovascular equipment was likely to be the same for Pipeline compared with stent-assisted coiling. The committee accepted the views of the expert advisers that removing this cost from the model for stent-assisted coiling was appropriate. This reduced the total procedure cost for stent-assisted coiling from £35,724 (this cost takes account of the drug cost calculation errors referred to in section 5.16) to £35,693 while the total procedure cost for Pipeline remained at £30,346.
- 5.27 With these issues in mind, the committee considered a graph showing the costs of Pipeline and of stent-assisted coiling using different numbers of Pipeline embolisation devices and coils. This indicated that

the total cost of treatment using 2 Pipeline embolisation devices is greater than that of stent-assisted coiling (using 1 stent) if 31 coils or fewer are used, but Pipeline is less costly if 32 or more coils are needed. The cost saving associated with Pipeline compared with stent-assisted coiling with 32 coils was estimated to be £492 (total costs of £30,346 and £30,838 respectively).

- 5.28 The committee noted that using 2 Pipeline embolisation devices would incur a higher total treatment cost than neurosurgical clipping, endovascular parent vessel occlusion, neurosurgical parent vessel occlusion or conservative management for patients in whom those other options were feasible.
- 5.29 For the guidance review, the external assessment centre revised the model to reflect updated costs. The main parameter changes were costs associated with staff, hospital imaging equipment, drugs, rupture and adverse event costs. Further details of the revised model are in the revised model summary. **[2019]**

6 Conclusions

- 6.1 The committee concluded that current evidence supports the case for adoption of Pipeline when it is used in highly selected patients with complex giant or large intracranial aneurysms which are unsuitable for surgery and being considered for stenting, when the number of Pipeline embolisation devices does not exceed 2 and when 32 or more coils and 1 stent would be needed during stent-assisted coiling. For these patients use of Pipeline appears efficacious and is less costly than stent-assisted coiling.
- 6.2 The committee noted that standard management of intracranial aneurysms varies according to the size and type of aneurysm and the symptoms the patient experiences. This may include conservative management, for example, in patients whose complex giant or large intracranial aneurysms are unsuitable in size or shape for stent-assisted coiling or surgery, and for whom parent vessel occlusion would result in stroke or death. The recommendations in section 1 of the guidance are based on circumstances in which Pipeline releases resources, and were not framed on the basis of treating patients for whom there is no other viable option apart from conservative management. The committee saw little evidence in this patient group and this area of unmet clinical need would benefit from further research.

7 Committee members and NICE lead team

Medical Technologies Advisory Committee members

The Medical Technologies Advisory Committee is a standing advisory committee of NICE. A list of the Committee members who took part in the discussions for this guidance appears below.

Committee members are asked to declare any interests in the technology to be evaluated. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The minutes of each Medical Technologies Advisory Committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

Professor Bruce Campbell (Chair)

Consultant Vascular Surgeon, Exeter

Dr Peter Groves (Vice Chair)

Consultant Cardiologist, Cardiff and Vale NHS Trust

Dr Dilly Anumba

Senior Clinical Lecturer/Honorary Consultant Obstetrician and Gynaecologist, University of Sheffield

Ms Susan Bennett

Lay member

Professor Bipin Bhakta

Charterhouse Professor in Rehabilitation Medicine and NHS Consultant Physician, University of Leeds

Dr Keith Blanshard

Consultant Radiologist, Leicester Royal Infirmary

Dr Martyn Bracewell

Senior Lecturer in Neurology and Neuroscience, Bangor University

Dr Daniel Clark

Head of Clinical Engineering, Nottingham University Hospitals NHS Trust

Professor Karl Claxton

Professor of Economics, University of York

Mrs Gail Coster

Radiography Manager, Strategy, Planning and Governance, Yorkshire NHS Trust

Dr Craig Dobson

General Practitioner and Senior Lecturer in Medical Education and General Practice, Hull York Medical School

Dr Alex Faulkner

Senior Research Fellow, Centre for Biomedicine & Society, King's College London

Professor Tony Freemont

Professor of Osteoarticular Pathology, University of Manchester

Professor Peter Gaines

Consultant Interventional Radiologist, Sheffield, Vascular Institute and Sheffield Hallam University

Mr Harry Golby

Head of Commissioning, Acute, Access and Diagnostics, Salford NHS

Mr Matthew Hill

Lay member

Dr Paul Knox

Reader in Vision Science, University of Liverpool

Ms Catherine Leonard

Reimbursement Manager, Medtronic UK

Dr Susanne Ludgate

Clinical Director, Devices Medicines and Healthcare Products Regulatory Agency

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Professor of Health Economics, Institute of Health Sciences, University of Leeds

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Professor Sharon Peacock

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Professor Brian Pollard

Professor of Anaesthesia, Manchester University

Dr Allan Swift

Director of Quality and Regulatory Affairs, Gen-Probe Life Sciences

Dr Allan Wailoo

Reader in Health Economics, School of Health and Related Research, University of Sheffield

Professor Stephen Westaby

Consultant Cardiac Surgeon, John Radcliffe Hospital, Oxford

Dr Janelle York

Lecturer and Researcher in Nursing, University of Salford

NICE lead team

Each medical technology assessment is assigned a lead team of a NICE technical analyst and technical adviser, an expert adviser, a technical expert, a patient expert, a non-expert member of the Medical Technologies Advisory Committee and a representative of the external assessment centre.

Suzi Peden

Technical Analyst

Lizzy Latimer

Technical Adviser

Dr Tony Goddard

Lead Expert Adviser

Dr Philip White

Lead Expert Adviser

Dr Dilly Anumba

Non-expert MTAC member

Grace Carolan-Rees and Kathleen Withers

External assessment centre representatives

8 Sources of evidence considered by the committee

The external assessment centre report for this assessment was prepared by Cedar (Clinical evaluation device assessment reporting):

- Withers K, Carolan-Rees D, Dale M et al. External Assessment Centre report: Pipeline embolisation device for the treatment of complex intracranial aneurysms. September 2011.

Submissions from the following sponsor:

- Covidien

The following individuals gave their expert personal view on Pipeline by providing their expert comments on the draft scope and assessment report.

- Dr Tony Goddard, Consultant Diagnostic and Interventional Neuroradiologist, British Society of Neuroradiologists
- Dr Robert Lenthall, Consultant Neuroradiologist, British Society of Neuroradiologists
- Dr Andrew Molyneux, Consultant Neuroradiologist, British Society of Neuroradiologists
- Dr Philip White, Consultant Neuroradiologist, British Society of Neuroradiologists

The following individuals gave their expert personal view on Pipeline in writing by completing a patient questionnaire or expert adviser questionnaire provided to the committee.

- Dr Tony Goddard, Consultant Diagnostic and Interventional Neuroradiologist, British Society of Neuroradiologists
- Dr Robert Lenthall, Consultant Neuroradiologist, British Society of Neuroradiologists
- Dr Andrew Molyneux, Consultant Neuroradiologist, British Society of Neuroradiologists
- Dr Philip White, Consultant Neuroradiologist, British Society of Neuroradiologists

Update information

January 2019: This guidance has been updated to include a review of the cost model using more recent values. The device name has also been updated. Updated costs identified during the guidance review are denoted as **[2019]**.

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Accreditation

